

# Quell<sup>®</sup> 2.0

Wearable Pain Relief  
Technology™



## User Manual

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## Chapter 1

# Pain Relief with Quell® 2.0

## Introduction

Quell Wearable Pain Relief Technology™ is patented, non-invasive nerve stimulation system that provides relief from chronic pain. It consists of a device and an electrode that attaches to the device.

Quell provides pain relief by comfortably stimulating sensory nerves in your calf. The nerves carry neural pulses to the brain that trigger a natural response to block pain signals in your body.

Pain relief is initiated by using the app on your smartphone. Regular therapy sessions are 60 minutes. After your first session, therapy will automatically restart every other hour. You have complete control and can start or end therapy anytime.

The more you use Quell, the better the chance of experiencing relief. For best results, use Quell daily. We recommend that new users wear Quell for a minimum of 3 therapy sessions per day (up to 24/7) at a strong, but comfortable intensity for at least the first 30 days.

If you have any questions about how to use Quell, please call Quell Customer Care at 1-800-204-6577 or email us at [CustomerCare@quellrelief.com](mailto:CustomerCare@quellrelief.com).



## What's Included

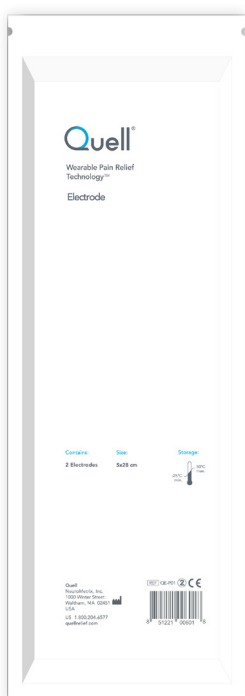
Upon receiving your Quell<sup>2.0</sup> Starter Kit, you should inspect its contents to make sure all of the following are included:



Quell<sup>2.0</sup> Device



Quell Band



Quell Electrode Pack\*  
(packaging may vary)



USB Cable



AC Adapter



Quick Start Guide

\* Only use electrodes manufactured by NeuroMetrix, Inc.

## Chapter 2

# Getting Started & Device Basics

## Getting Started

1. Fully charge your Quell device before first use. Once plugged into an outlet, a blinking white light indicates your device is charging. Once the light turns solid, your device is fully charged.
2. Download the free Quell Relief app to your smartphone or tablet from the App Store or Google Play.
3. Follow the step-by-step setup instructions in the app to pair your device and setup your Quell Health Cloud account while your device is charging.
4. Once your device is fully charged, follow the instructions to calibrate your device and begin therapy.

**For additional details on each step, follow instructions below.**

## Charging the Battery

A fully charged battery can provide up to 25 hours of therapy for most users.

### To charge the battery:

- 1 Plug the USB cable into the micro-USB port on the side of the device.
- 2 Plug the other end of the cable into the AC Adapter.

The AC Adapter should then be **plugged into a standard electrical outlet**. We do not recommend using a computer USB port for charging Quell. The white indicator lights on the device will show that the device is charging.

When the battery is fully charged, the white indicator light will remain solid. It will take approximately 3 hours to charge an empty battery. When the battery is fully charged, unplug the cable from the device.

If the orange light blinks while device is connected to the outlet, charging has failed. Call 800-204-6577.

When recharging your device, if the battery is too low to start a therapy session (<10%), you can charge the device for approximately 20 minutes to provide enough battery life for one therapy session.

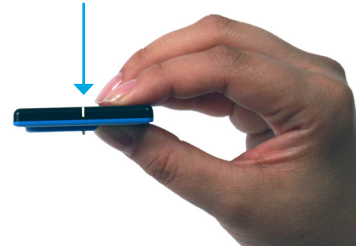
**Do not use your device with the USB cable connected as this creates a safety hazard.**

## Checking the Battery

To check battery level, pick up and hold the device in your hand. The indicator light will blink white if the battery has sufficient charge to run at least one therapy session. If no indicator light flashes, the battery needs to be recharged following the steps above.



Indicator Light



## Downloading the Quell Relief App

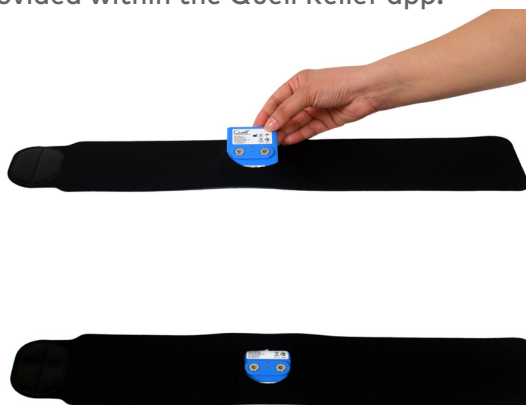
Using your smartphone, open the App Store or Google Play. Search "Quell Relief" and download the app to your device. Ensure that your smartphone's Bluetooth is turned on and that your device is running iOS 10 or later, or Android 4.4 or later. Launch the Quell Relief app and follow the step by step instruction within the app to pair and setup a Quell Health Cloud account while charging your device. Once your device is fully charged, you can finish setup and complete calibration.

By signing up for a Quell Health Cloud account, not only do you unlock unique features and back up your data so it's never lost, you have an opportunity to be part of something bigger. When you participate, your de-identified data helps fuel scientific research on chronic pain. For more details, review Chapter 8, Using the Mobile App.

**The instructions below expand upon the setup instructions provided within the Quell Relief app.**

## Inserting the Device

Place the Quell band with the blue accents face down so that you are looking at the back of the band. Insert the device into the opening on the back of the band with the indicator light facing up. The indicator light should align with the viewing window on the front of the band, and the snap connectors should be visible through the opening on the back of the band.

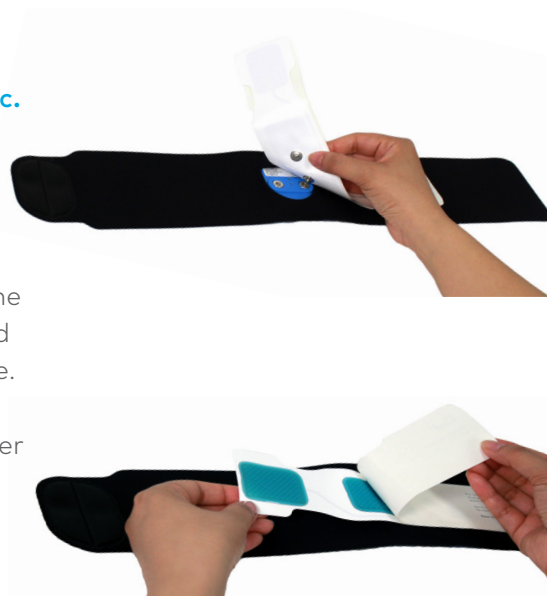


## Attaching the Electrode

You will need to attach a new electrode prior to first use of the device and replace the electrode on average every 2 weeks thereafter. You should reseal the package if it contains an electrode. **Improper storage of the electrode will reduce its life.**

**Only use Quell electrodes manufactured by NeuroMetrix, Inc.**

1. Align the snaps on the electrode to the snap connections on the back of the device. Insert snaps until they are securely fastened to the device.
2. Remove the liner covering the electrode prior to placing the device on your leg. Remember to save the liner as it should be re-applied to protect the electrode when it is not in use. When re-applying the liner to the electrode for storage, ensure graphics on the liner are facing up so that the paper side doesn't stick to the gel.
3. The electrode should be replaced approximately 2 weeks from the date of its first use. You can set a tracking reminder within the app.





## Device Placement

Place your Quell band on your upper calf about 1-2 inches below the knee. You may place on either leg. Be sure the electrode is only covering healthy skin that is not irritated and does not have cuts or other wounds. Position the device so that it is comfortable. **You may position the device on the inside, outside, or back of the leg.** You should avoid placing the device directly over your shinbone.

If the device cannot be placed in the standard location as shown, refer to APPENDIX D for alternate site options.

Wrap the band around your leg and adhere the Velcro® end. The band should fit securely and comfortably around your leg. The electrode should make smooth contact with the skin. If there is buckling of the electrode, smooth the electrode and re-secure the band. **It is important that all four electrode pads are in contact with the skin.** If the pads are only partially on the skin, then the stimulation may feel uncomfortable or your device may not start therapy.

The band was designed to stretch and fit most legs. If the band does not fit your leg, contact Customer Care at 1-800-204-6577 or visit [www.QuellRelief.com](http://www.QuellRelief.com) for information on how to get an Extra Small or Extra Large Quell band.



### Recommended Positioning On Leg

Outside of Calf



Back of Calf



Inside of Calf



### Avoid Positioning

Front of Shin



## Chapter 3

# Calibration

The calibration process must be completed when using the device for the first time. Watch the Calibration video on the app or on [quellrelief.com/quell-user](http://quellrelief.com/quell-user) before you use Quell for the first time.

Calibration allows your Quell to learn your nerve sensitivity (sensation threshold). Based on your sensation threshold, your Quell device will deliver a customized stimulation level for pain relief therapy that is stronger than the sensation threshold. During the calibration process, Quell will slowly increase stimulation to determine your sensation threshold. Once you have completed the calibration process, you will be ready to begin your first therapy session.

Read through all the steps below or within the app before you begin to calibrate your device.



### Step 1:

Sit in a quiet place where you can focus, with your feet flat on the floor. The device should be securely wrapped around your leg as described in Chapter 2, Getting Started & Device Basics.

### Step 2:

Begin calibration with the app. The indicator light on your device will begin to blink white as calibration begins.

### Step 3:

Wait until you feel the slightest tingle under the band, then immediately tap the button within the app. It may take 20-30 seconds to feel the sensation the first time and the sensation may feel very light. **Do not wait until the sensation feels very strong to tap the button.** You will feel subsequent stimulation slightly faster.

### Step 4:

Repeat Step 3 until the app indicates that you have successfully completed calibration. People typically tap the button 3-6 times during calibration. If at any time you feel like you have made a mistake, stop calibration and restart the process.

**You are now ready to begin therapy.**

You do not need to stay seated or remain still during therapy. You may move around and be as active as you can be while wearing Quell.



## Chapter 4

# Pain Relief Therapy

Chronic pain is different for everyone. Please be patient. It may take several weeks of consistently using Quell before you start to experience pain relief. **The more you use Quell, the better the chance of pain relief. For best results, use Quell daily.** We recommend using Quell for a minimum of 3 therapy sessions every day, but Quell can be used up to 24 hours per day.

During a therapy session, the device will comfortably stimulate the nerves in your leg to provide pain relief. Regular therapy sessions last 60 minutes, and a new session will automatically restart every other hour. If you prefer to not have automatic restart turned on, you can change your Therapy Dose under Settings within the app.

**To optimize pain relief, you should feel a strong but comfortable sensation during therapy.** The intensity that you will require is estimated based on your sensation threshold determined during calibration. However, because of differences among people, this estimated intensity may be too low and feel weak, or too high and feel uncomfortable. In either case, you should adjust the intensity within the app. **The greatest pain relief will be obtained when you set the intensity to the highest level that is also comfortable.** The device will remember changes made to the intensity within the first 10 minutes of therapy if the therapy session is successfully completed, and you should not need to adjust often. Please follow the steps below for initiating a therapy session.

## Preparing for Therapy Session

Before starting a therapy session make sure you have an electrode attached to the device. You should also check the battery to ensure it has an adequate charge. If the indicator light blinks

white, you have sufficient charge to run a therapy session. Place the device on your leg as described in Chapter 2, Getting Started & Device Basics.

## Starting a Therapy Session

To start a therapy session, tap the start button on the Dashboard screen in the app. The indicator light will blink white for the duration of the therapy session.

You can also set therapy to start automatically after attaching the device to your leg. Within the Settings menu of the app, select Therapy Automation and turn on Automatic Start. Once enabled, therapy will begin automatically within one minute of placing the device on your leg. You will no longer need to start therapy within the app. You can always stop therapy by tapping the STOP button within the app, or by double tapping the device firmly with your fingers.

## What Therapy Feels Like

**The intensity will gradually increase during the first 2 minutes to an intensity that is strong but comfortable.** This strong but comfortable intensity is based on results of the calibration process. You may feel a strong sensation at first but it will typically fade to a comfortable level after a couple of minutes. If the sensation is uncomfortable or painful, you should decrease the intensity within the app. Therapy will continue for 60 minutes in Regular dose (see Chapter 8 for personalization options).

Once you have placed the device on your leg, you may cover the device with your clothing. You should be careful not to dislodge the device and electrode when covering with clothing. You may

go about your normal activities during a therapy session. **Do not shower, bathe or swim with the device on your leg.**

## Adjusting Intensity During a Therapy Session

Frequent adjustments should not be necessary; however, if the sensation feels uncomfortable or is not strong enough, you may make adjustments. To adjust therapy intensity or to stop therapy, tap the buttons on the Dashboard screen in the smartphone app.

You may adjust intensity as needed at any time during a therapy session using the smartphone app. **Optimal pain relief will be obtained at the highest intensity that is also comfortable.**

If you find you are frequently adjusting intensity, try recalibrating your device.

## Ending a Therapy Session

Regular therapy sessions will run automatically 60 minutes on, then 60 minutes off, unless you turn off therapy during a session or recalibrate between therapy sessions.

To stop an active therapy session before it ends, tap the STOP button on the Dashboard screen in the app. **If the app is not readily accessible, you can manually stop therapy during a session by double tapping the device firmly with your fingers.** Your leg should be still. **You should not remove the device while it is stimulating,** so make sure that the white indicator light is not blinking before removing the device and electrode from your leg. Otherwise you may experience an uncomfortable sensation while removing the device.

After ending a therapy session, you may either leave the device on your leg or remove it. If you remove the device, be careful to not damage the electrode and remember to reapply the liner (see page 11 for instructions on

removing electrode).

If you leave the device on your leg for long periods of time, you should check your skin regularly to make sure that it does not get irritated. We recommend airing out your skin for 15-30 minutes after 5 hours or after wearing your device overnight. You may also switch legs to give your skin a break. Chapter 7 provides information on skin care.

If a problem arises during a therapy session, stimulation will stop and the indicator light will blink orange for 2 minutes. Refer to APPENDIX B for troubleshooting assistance.

**Air-out skin after wearing for 5 hours or when you wake up from wearing Quell overnight. After 5 hours of wear during the daytime, the device will pulse on and off for 1 minute as a reminder.**

## Personalizing Therapy

Therapy can be personalized to meet your needs within the app. Within the Settings menu, you can choose from a variety of Therapy Dose, Stimulation, and Therapy Automation options. If you decide to update any of these settings, the new selection will take effect at the start of your next therapy session.

To learn about the different therapy personalization settings, please review Chapter 8, Using the Mobile App.



## Chapter 5

# Overnight Therapy

You may use Quell at bedtime and throughout the night to relieve pain while you sleep.

Before going to sleep, make sure the device is placed securely and comfortably around your leg. Start a therapy session within the app. The default sleep setting is "Gentle Overnight." In this setting, the first therapy session will stimulate at your regular intensity level. Subsequent therapy sessions will start automatically every other hour throughout the night. If you are asleep during these sessions, the device will automatically lower the intensity.

Within the Settings menu of the app, you will find multiple sleep mode options that you can choose from. If you decide to change Sleep Modes, the new selection will take effect at the start of your next nighttime therapy session.

To learn about the different sleep settings, please review Chapter 8, Using the Mobile App.

## Chapter 6

# Electrodes

Quell electrodes may look unassuming, but they are key to enabling the Quell device to deliver clinical strength therapy for drug-free pain relief. The electrodes are designed to operate consistently for up to 2 weeks. With repeated use, the electrode gel may peel and/or dry out thereby losing some of its adhesion, but the electrode is still usable.

## Electrode Removal

You should be careful to not damage the electrode when you remove it from your upper calf area. Slowly peel the electrode from your skin, while making sure that each of the gel pads does not separate from the electrode. Avoid touching the gel with your fingers as that can damage the gel and decrease the life of the electrode. After removal of the electrode, you should cover it with the liner.



If you have difficulty removing the electrode, refer to Chapter 7 for tips on skin care to ease electrode removal.

## Electrode Storage

Electrodes should always be stored with the liner covering the gel pads. Place the liner with graphic side up so the paper does not stick to the gel. Electrodes should be stored in a sealed bag at room temperature out of direct sunlight. You may also snap the electrode into the device for convenient storage.

## Electrode Replacement

The gel pads on the electrodes are primarily water, so you may observe signs of wear during the course of normal use, which can include irregular edges on the gel pads, gel spreading, color fading,

or some of the underlying silver traces becoming exposed. **Your Quell electrode does not need to be replaced until stimulation during therapy feels uncomfortable and/or you see the orange error light on the Quell device blink when you attempt to start therapy.**

The electrode should be replaced prior to 2 weeks if stimulation becomes painful despite positioning the device so that the entire electrode is making smooth contact with the skin. You can order electrodes at [www.quellrelief.com/replace](http://www.quellrelief.com/replace) or from the location where you purchased your device. It is recommended that electrode is replaced at 2 week interval to maximize therapy comfort and efficacy. If stimulation during therapy is still comfortable and there are no signs of damage to the electrode after 2 weeks of use, you may continue to use the electrode.

## Electrode Options

Quell Standard Electrodes are included in most Quell Starter Kits. They are designed to deliver comfortable, effective pain relief year round. The Standard electrode gel is optimized to provide consistent, comfortable nerve stimulation in most conditions and is ideal for daily use. Each individual Quell Electrode is designed to last for approximately 2 weeks of typical use.

Quell Sport Electrodes are a second type of electrode designed to work with your Quell. The Sport Electrode has a unique gel developed to better hold up in situations with high levels of humidity and perspiration. The Sport Electrode has a sweat-resistant gel that absorbs less moisture, but is otherwise comparable to the Standard Electrode included in the Starter Kit.

You can order replacement Electrodes at [www.quellrelief.com/replace](http://www.quellrelief.com/replace).

## Chapter 7

# Skin Care

Quell works by electrically stimulating the sensory nerves in the upper calf through your skin. Some people have dry or sensitive skin, and it is important to regularly monitor your skin where it contacts the electrode to ensure that skin irritation does not occur. If your skin becomes irritated, using the device may be uncomfortable. There are some simple things you can do to take care of your skin while using Quell.

**Ensure your skin is clean and dry. Never use the device on open wounds or rashes or over swollen, red, infected, irritated, or inflamed skin.**

## Prevent Skin Irritation

### Air-out Skin

Air-out skin for 15-30 minutes after 5 consecutive hours of wear during the day, or after overnight use. You may also switch the device to the other leg every 5 hours, or when you wake up. After 5 hours of use during the day, the device will pulse on and off for 1 minute as a reminder to air out your skin.

**If you have sensitive skin, you may also want to start slowly.** Limit the time the device is on your skin during the first week. If you do not experience irritation you may increase use while closely monitoring your skin.

## Check for Skin Irritation

Signs of skin irritation can include the following:

- Skin itches while device is on the skin or after removal
- Skin is red where it contacted electrode
- Raised or reddened hair follicles

**If skin irritation develops you should not place the device over the irritated area until it completely heals.** You may apply a topical steroid cream to help accelerate healing and reduce irritation. You may also place the device on the other leg or use different locations as shown in APPENDIX D.

If you experience skin irritation, then you should limit device use for a week to make sure that further irritation does not occur.

## Chapter 8

# Using the Mobile App

From your mobile device or tablet, search for "Quell Relief" by NeuroMetrix, Inc. and download the app. Before proceeding, make sure that Bluetooth® is enabled on your mobile device or tablet.

iOS and Android devices must have Bluetooth Low Energy (LE, also called Bluetooth Smart) compatibility. The Quell Relief app also requires iOS 9 or later, or Android 4.4 or later.

**For more insights on the data tracked with the app**, visit [www.quellrelief.com/how-quell-works/app/](http://www.quellrelief.com/how-quell-works/app/) and select Sleep, Therapy, Activity, or Pain.



## Creating a Health Cloud Account

By signing up for a Quell Health Cloud account, not only do you unlock unique features and back up your data so it's never lost, you have an opportunity to be part of something bigger. Thanks to people like you, the Quell Health Cloud is already one of the largest pain databases in the world, with over 15 million hours of data. This data is fueling scientific research and Quell product improvements.

Only de-identified data are used in scientific research and product improvement. This means your registration information (i.e., name, email or contact address) is disconnected from your personal usage, sleep, activity and pain data so you cannot be identified. Our research is performed using aggregated data. This means researchers combine your de-identified data with millions of other data points and look at the data set as a whole.

The tables below and on the next page describe app features and how they may help you optimize your

Feature	Why is it important?
<b>Sleep Position Tracking</b>	Enables device to track sleep metrics including time slept on back or on sides, and the number of times position changed while sleeping. Sleep Position Tracking must be initiated everytime you go to bed in order to track sleep position.
<b>Lights Out</b>	Use if Quell overestimates your 'Time Asleep.' To indicate when you are ready for sleep, press 'Lights Out.' To indicate when you are awake in the morning despite remaining in bed, press 'Awake.'
Sleep Onset Detection	The default setting detects when you actually went to sleep. Disable 'Sleep Onset Detection' if Quell underestimates your time asleep. You should then indicate when going to sleep using 'Lights Out.' This feature can be found under "Lights Out" section of the Settings menu on the app.
<b>Sleep Mode</b>	This setting may only be used when Therapy Dose is set to Low, Regular, or High.
Bedtime only	Therapy is only delivered while falling asleep.
Gentle overnight	Overnight therapy is delivered at reduced intensity. (Default setting)
Full power	Overnight therapy is delivered at daytime intensity.
As needed	Therapy is only delivered when Quell detects poor sleep quality.



<b>Stimulation</b>	Select the type of stimulation Quell will provide during therapy based on what is most comfortable for you. Standard is the default stimulation and will feel like a constant vibration. Intense provides a more intensive stimulation option for those that desire it. Sensitive should only be used if you find Standard and Intense are uncomfortable. Your selection will take effect with the next therapy session.
Standard	Feels like a constant vibration. (Default Setting)
Intense	Feels like a more intensive vibration.
Sensitive	Feels like a low vibration.
<b>Therapy Dose</b>	You can select the duration and timing of your therapy sessions.
Manual	Therapy is 60 minutes and does not restart automatically.
Low	Therapy is 30 minutes and restarts every 60 minutes.
Regular	Therapy is 60 minutes and restarts every 60 minutes. (Default Setting)
High	Therapy is 60 minutes and restarts every 30 minutes.
<b>Therapy Automation</b>	
Time of Day Adjustment	Enable if stimulation feels particularly strong at a certain time of day. Once enabled, indicate the time of day when stimulation feels strongest. The device will automatically compensate so the stimulation feels consistent to you at the time you selected.
Body Postion Adjustment	Enable if stimulation is too strong when you lie down. Therapy intensity will automatically compensate so stimulation feels consistent when you are lying down.
Automatic Start	Enables device to begin therapy automatically within one minute of placing the device on your leg. When enabled, you do not need the app to start therapy.
Weather	When enabled, you will receive an alert when weather conditions may worsen your pain if your profile indicates weather sensitivity.
<b>Calibration</b>	Used to determine the optimal therapy stimulation level the first time you use Quell.
<b>Electrode</b>	Keep track of how many days have passed since you replaced your electrodes.
<b>Notifications</b>	
Push Notifications	When enabled, you will get notifications with customized insights to exhanche your Quell experience and to keep you updated on new features and special deals.
Electrode Replacement	When enabled, you will get a notification that it is time to replace your electrodes.
Rate Pain	When enabled, you will get a notification to remind you to rate your pain every few days. Tracking your pain helps uncover patterns and triggers.
<b>Intensity Display</b>	When enabled, the stimulation intensity will be displayed on the Dashboard during therapy sessions.
<b>Pairing</b>	Shows the serial number of the device to which it is paired. To pair with a different device, tap Un-Pair.
<b>Account</b>	Create a Health Cloud account to backup your data and contribute de-identified data to fuel scientific research on chronic pain. If you already created an account, it shows the email you used to create the account. You may change email associated with your Health Cloud account or the password for the account.

## Chapter 9

# Maintenance, Safety, and Service

## Maintenance

Contact Quell Customer Care at 1-800-204-6577 if the device requires service.

## Cleaning Device

Use a damp cloth to clean the exterior of the device. Do not use any other cleaning solutions since they may damage the case. Never immerse the device in water or other liquids.

## Cleaning Band

Remove device before washing the band. Handwash band with a gentle detergent and let it air dry. If band material is becoming stretched, it may be put through a gentle dryer cycle; ensure Velcro is adhered to band before drying. Replacement bands are available at [www.store.quellrelief.com](http://www.store.quellrelief.com).

## Device Storage

When device is not in use, store it in a dry location away from direct sunlight.

## Disposal

Used electrodes can be disposed of in normal trash receptacles. Dispose of the device according to national, state, and local regulations as the device contains a Lithium-Ion battery.

## Limited Warranty

NeuroMetrix, Inc. manufactures its hardware products in accordance with industry standard practices. NeuroMetrix warrants the Quell device to be free from defects in materials and workmanship at the time of shipment. The warranty term is two years beginning on the date of sale to the original purchaser, as further described in the following text.

This warranty does not cover damage due to external causes, including accident, abuse, misuse, problems with electrical power, usage not in accordance with product instructions, failure to perform required maintenance, and problems caused by use of parts or components not supplied by NeuroMetrix. This warranty does not apply to any product repaired or altered by anyone other than NeuroMetrix or an authorized NeuroMetrix representative. Quell products purchased from unauthorized resellers are not covered by this warranty.

NeuroMetrix will repair or replace products that are shown to be other than as warranted above and covered under this limited warranty that are returned to NeuroMetrix under a NeuroMetrix issued Return Material Authorization (RMA) Number. To initiate a return, contact Customer Care at 1-800-204-6577.

All parts removed from repaired products will become the property of NeuroMetrix. If NeuroMetrix repairs or replaces a product, the original warranty is not extended.

NEUROMETRIX MAKES NO EXPRESS OR IMPLIED WARRANTIES OR REPRESENTATIONS BEYOND THOSE STATED IN THIS WARRANTY STATEMENT. NEUROMETRIX DISCLAIMS ALL OTHER WARRANTIES AND REPRESENTATIONS, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

NEUROMETRIX'S OBLIGATIONS FOR ANY FAILURE OF A PRODUCT TO BE AS WARRANTED ARE LIMITED TO, AT NEUROMETRIX OPTION, REPAIR OR REPLACEMENT OF THE PRODUCTS SET FORTH IN THIS WARRANTY STATEMENT.

UNDER NO CIRCUMSTANCES WILL NEUROMETRIX BE LIABLE FOR ACTUAL OR CLAIMED DEFECTS IN ANY PRODUCT BEYOND THE REMEDIES SET FORTH IN THIS WARRANTY STATEMENT. IN NO EVENT SHALL NEUROMETRIX BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT REGARDLESS OF THE LEGAL THEORY UPON WHICH SUCH CLAIM IS BASED AND EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY THEREOF.

## APPENDIX A

# Indicator Light

### Device on Skin

Device State	Indicator Light Status	Explanation
Standby	No Light Illuminated	Device in standby, no therapy or calibration in progress
Calibration	Double Blinking White Light	Calibration in progress
Therapy	Double Blinking White Light	Therapy session in progress
Stimulation halted earlier than expected	Orange Light Blinking Once Per Second	Therapy or Calibration has halted due to an error condition; see Appendix B for possible causes.

### Device off Skin

Device State	Indicator Light Status	Explanation
Battery Check	Single Blinking White Light Once Every 3 Seconds	Battery has adequate charge to run therapy
	No Light Illuminated	Battery needs to be charged.

### Charging

Device State	Indicator Light Status	Explanation
Charging	Blinking White Light	Device is charging
	Solid White Light	Device is fully charged
	Orange Light Blinking	Charging issue, call Quell Customer Care at 1-800-204-6577.

## APPENDIX B

# Troubleshooting

## Calibration

### **I cannot start the calibration procedure.**

Within the app, the Calibration option can be found under the Settings menu. To start calibration, tap "Start Calibration."

You should be sitting down or standing still with your foot flat on the floor. Make sure the electrode is snapped onto the device, the liner has been removed, and your Quell is properly placed on your leg (on the upper calf, 1-2" below your knee). All 4 gel pads on the electrode must be making complete contact with the skin.

### **I am trying to calibrate but I don't feel anything.**

Confirm electrode liner has been removed and that the light is blinking. The purpose of the calibration process is to measure your sensation threshold, meaning that when you feel even the slightest sensation, you should click the button. Do not wait until the sensation feels very strong to click the button. It may take 20-30 seconds to feel the sensation the first time and the sensation may feel very light. You will feel subsequent stimulation slightly faster. If you go through the calibration process and never feel stimulation, the therapeutic intensity will be set at the maximum possible intensity.

## Calibration Tips

- It is a good idea to wait about 5 minutes after putting the electrode on for the skin-gel interface to stabilize, before you start calibrating.
- If your leg is cold (for example, if you come in from the outside during winter), you should wait 30-60 minutes so that your leg warms up to room temperature before calibrating.

This is because cold will artificially elevate the sensation threshold (the same reason cold makes you feel numb).

- Do not calibrate right after a therapy session because the sensation threshold will be artificially elevated. You should wait at least 1 hour and preferably 2 hours after a therapy session.

## Therapy

Make sure you initiate therapy only after the device and electrode are properly placed on the calf.

**I am trying to start therapy with the app and getting a short (2-second) blink of an orange light.**

Recharge battery.

**I start therapy and a white light blinks once and stops.**

Your device has not been calibrated. You need to calibrate device at least once before therapy.

**I am not getting pain relief.**

We recommend that you **use your Quell for at least 3 therapy sessions per day for the first month.** Make sure you feel a **strong but comfortable** sensation during therapy sessions (indicated by single white blinking light). If not, you can try calibrating the device again or increasing the therapeutic intensity by using the app or pressing and holding the button.

**The therapy stopped and the light is blinking orange continuously.**

A blinking orange light typically indicates poor contact between the electrode and the skin. This may occur because the device is not securely placed on the leg or because the electrode is dry. Check that the electrode is snapped in, the electrode gel pads are in complete contact with the skin, and the band is attached snugly (but not too tightly) on the leg. Start therapy again. If the problem recurs, remove the device and inspect the electrode. Place the device back on the leg and restart the therapy session. If the problem persists, then replace the electrode.

**The light is blinking white but I do not feel anything.**

The intensity may be too low. Use the app to increase the intensity until you feel a **strong but comfortable** sensation. Alternatively, calibrate the device again.

**The device isn't automatically restarting.**

Go to Settings and Therapy Dose. If "Manual" is selected, you need to manually restart therapy. With any other selection (Regular, Low, or High Dose), therapy will automatically restart as long as the device is attached to your leg and all 4 gel pads on the electrode are making complete contact with your skin.

**The therapy stings or feels uncomfortable.**

Turn off the device by using the app or by firmly double tapping the device with your fingers. Remove the device and inspect the electrode, make sure all four electrode gel pads are in good condition. If your skin is dry then consider using skin moisturizer, but wait 20-30 minutes for the moisturizer to absorb into your skin before attaching your Quell to your leg. Place the device and electrode back on your leg, making sure that there is complete contact between the electrode and the skin. Sometimes it is helpful to smooth the electrode onto the skin first and then secure the sports band. If the discomfort persists, then you should replace the electrode.

If replacing the electrode doesn't help, you may need to recalibrate. One way to check calibration level is to see how long it takes to feel any sensation during therapy session. If it is felt within the first five seconds, it is a good indication that calibration is too high.

**I have leg cramps/muscle contraction during therapy, or muscle soreness after use.**

Confirm that the intensity is appropriate – strong but comfortable. You can recalibrate. You may also want to decrease the intensity, as long as it remains strong.

Try the other leg. One leg may be more prone to cramping or soreness than the other leg.

Reposition the device to minimize the amount of electrode on the back of the calf. This usually means positioning the device on the inside or outside rotated towards the front (but not right on top of the tibia bone).

If you mostly have cramping/soreness when lying down, make sure that the device is not positioned such that it is compressed between the bed and your leg. Compressing the device forces the electrodes closer to the muscle, making it more likely to activate it. If this is happening, position the device so that it will not be compressed between the bed and your leg in your preferred sleep position to minimize any discomfort.

There is no risk associated with soreness. If you are getting a lot of pain relief from Quell, you may decide it is worth it to keep wearing it, even if you have some soreness as a consequence.

**The device increased intensity on its own.**

If the increase was noted toward the latter half of the therapy session, the habituation ramp is too steep for you. The device is designed to increase intensity throughout a therapy session to compensate for nerve habituation. For some people, this ramp is too steep, in which case the therapy intensity should be decreased during the therapy session. If you allow therapy to run the full 60 minutes, the device will remember the adjustment for future therapy sessions.

**My device is pulsing at the end of therapy.**

Pulsing serves as a reminder that you have been wearing the device on the same place for at least 5 hours. You should consider removing the device to allow the covered skin to breathe. You may also move the device to the other leg if more therapies are desired. A "long term wear" alert will pulse for one minute at the conclusion of the 3rd therapy session (at least 5 hours of wear).

If you don't remove the device, it will pulse again at the conclusion of each subsequent session until the device is removed. Sessions will still continue to run automatically. The device will not pulse after five hours of overnight wear while you are sleeping, but will alert you when you get out of bed.

## Sleep

**Do I need to do anything to the device on wake up?**

No, you do not need to do anything special. Once you are up and moving about for more than a few minutes, the device will automatically revert to normal daytime therapeutic intensity the next time it restarts therapy. We do recommend you remove your device or switch legs after waking up to prevent skin irritation. When you put your Quell back on and start therapy, the device will restart at normal intensity.

**The device is waking me up when therapy restarts overnight.**

Check sleep settings on smartphone app. You may have inadvertently changed sleep mode setting or may need to change the settings to "Gentle Overnight", "Bedtime Only", or "As Needed" mode.

**My device doesn't "wake up"/restart in the morning.**

Make sure your electrodes are securely attached and that the orange light isn't blinking. You should also wait 60 minutes to see if device will restart on its own.

Use the app to check Sleep Mode. If Sleep Mode was set to "Bedtime Only", the first session in the morning will need to be manually started.



## Electrodes

### **The gel sticks to my skin when I am removing the electrode.**

Be sure to peel the electrode from the skin very carefully. If, despite this, the gel is coming off the electrode, then try applying a light lotion on the skin area where electrodes will make contact at least thirty minutes to an hour prior to placing your Quell on your leg, giving enough time for the lotion to fully absorb into the skin.

### **The gel is dry and losing its stickiness.**

Even when the electrode seems to be losing its adhesion to the skin, it should still be usable; the band will help to keep contact with the skin.

The electrodes should last approximately 2 weeks with typical use. Be sure to store electrodes properly between uses as described in Chapter 6.

### **The gel on my electrode is coming off and/or spreading.**

The electrode should still function and can be used safely as long as the stimulation feels comfortable and the device does not repeatedly blink orange during therapy sessions. Gel spread is more likely to occur in hot, humid weather since the hydrogel may absorb additional moisture to cause it to expand. You may want to try the Quell Sport Electrode.

### **How can I minimize gel spread?**

Ensure that the band isn't wrapped too tightly around the leg, as that will contribute to gel spread. The electrode shouldn't leave an imprint on the leg after it is removed. If it does, you need to loosen the band slightly.

Remove your Quell when not in use to allow the gel to cool.

Minimize outdoor use during hot, humid weather, when possible.

Be mindful about where the device and electrode are stored in hot and humid weather, i.e., a hot car.

In some cases, it may also help to alternate between two electrodes (if you switch the device at the 5-hour or "long-term wear" alert, for example) to minimize the amount of gel migration that may result from extended sessions.

Issues with gel spread are less frequent during cooler, drier months.

### **What do I do if I have lost the electrode liner?**

Use a piece of wax paper (plain paper will stick to the hydrogel).

Another option is to place the electrode in a plastic zipper bag laid flat or loosely folded (if a larger bag is unavailable) with the gel facing out.

Gel will stick to itself if pads are allowed to touch.

## Skin Care

### **My skin is irritated (redness or rash) or itches where the device was worn.**

Skin irritation may occur. The skin should be aired out after wearing for 5 hours and after overnight use by removing the device and electrode from the leg or switching legs. If at any time the skin begins to feel irritated (itchy) while the device is on, device should be removed and the skin allowed to breathe.

Consider using light skin moisturizer 20-30 minutes before placing your Quell on your leg if your skin is dry.

Ensure that the strap is not being placed too tightly; this can cause the strap/electrode to create indents in the skin and lead to irritation.

Alternate leg on which Quell is worn, if possible.

Reorient the device so the electrode is covering another part of the leg, i.e., button faces in toward the other leg or the back of the leg or the outside of the leg.

If skin is irritated, do not place device or electrode over the irritated area until it has fully healed. See Chapter 7 for ways to reduce your risk of skin irritation.

## Charging

### **My device isn't charging.**

Confirm the charging adapter is plugged into a functioning wall outlet that is on. USB outlets on a computer may not have sufficient power to charge the device, so it is not recommended. Using a charger other than the one provided with Quell, i.e., a cell phone charger, isn't advisable.

### **What if there is no flashing light?**

If the battery has been drained completely and all lights are off, allow at least 20 minutes for the white light to begin flashing after connecting the device to the charging adaptor plugged into a wall outlet.

### **What if there is a flashing orange light?**

If the orange light continues to blink after the device has been plugged in, there is a charging issue. Please call Customer Care at 1-800-204-6577.

## APPENDIX C

# Frequently Asked Questions

### What should therapy feel like?

You should feel a strong, but comfortable vibrating or light pressure sensation. You may reduce the intensity if it feels uncomfortable and increase intensity for your ideal stimulation.

### How often should I use Quell?

You may run therapy as often (even 24 hours a day) or as little as needed for pain relief. Some users only wear the device in the evenings and while sleeping. Others wear it during the day and at night. **We recommend that you use your Quell for at least 3 therapy sessions per day for the first month.**

### When do I need to calibrate my device?

You must calibrate the device before first use. You may repeat calibration if pain relief has diminished, or if therapy sensation becomes uncomfortable/too strong.

### Do I need to calibrate the device before each therapy session?

No. Once your device is calibrated you do not need to calibrate it again unless pain relief has diminished.

### Do I need to recalibrate when I switch legs?

No.

### If I have foot pain, should I position the device closer to my foot?

No, you should position the device on your upper calf 1-2 inches below the knee as described in Chapter 3.

### Can I place the device on my arms or lower back?

No. Quell is designed to be worn on the upper calf.

### How long will it take to experience relief?

We recommend using your Quell for at least 3 therapy sessions per day at a strong, but comfortable intensity for the first 30 days. Please be patient because it may take several weeks to experience optimal relief.

### Will pain relief continue beyond the end of the therapy session?

Pain relief may last up to an hour after the session ends.

### How often do I need to change the electrode?

Every 2 weeks.

### Can I use my device while showering or bathing?

No.

### Are there side effects?

No. You may experience some mild skin irritation under the electrodes with prolonged use.

### Can I use it with pain medications?

Speak to your doctor about your pain medication use in conjunction with Quell.

### Can multiple people share the device?

No. The device is calibrated for one person and should not be shared.

### Can I use Quell while sleeping?

Yes.

### What does Quell do while I am sleeping?

It starts 60 minute therapy sessions every other hour throughout the night or as needed to help control your pain.

### Do I need to set up Quell differently for sleep use?

No, but you may choose from 4 sleep setting options.

**What if I only want a single 60 minute therapy session when going to sleep?**

Set the sleep mode to Bedtime Only using the smartphone app.

**What should I do before going to sleep?**

Make sure the device is securely and comfortably placed around your leg. Start the first therapy session by clicking the button.

**Will wearing Quell overnight irritate my skin?**

Skin irritation may occur in some cases (see APPENDIX B, Troubleshooting, Skin Care).

**Can I use Quell every night?**

Yes.

**Can I use a different manufacturer's electrode?**

No. The Quell electrode is the only electrode cleared by the FDA for use with the Quell device. The Quell electrode was designed to ensure optimal performance and the highest level of safety.

**How long does it take to recharge the battery?**

Fully recharging the battery will take 2-3 hours when connecting to a charging adaptor plugged into a wall outlet.

**How long should the battery last?**

Battery life is heavily dependent on your particular therapy intensity and frequency of use but a fully charged battery can last **up to 25 therapy hours**.

Like most rechargeable batteries, the charging capacity will start to taper off over the course of years, so there is not a specific time when it will completely stop working.

The battery in Quell was designed for years of problem-free use and is covered by our 2 year warranty.

## APPENDIX D

# Alternate Placement Sites

If you cannot place your Quell device at the recommended location just below the knee, due to situations such as a wound or skin irritation, then you may position it at one of the following alternate sites:



At mid-calf



Above the knee on the lower thigh

You should calibrate the device at the new site before initiating therapy.

## APPENDIX E

# Technical Specifications

Output	
Waveform	Biphasic with alternating leading phase, asymmetrical, rectangular
Regulated Current or Voltage	Current
Net Charge per Pulse	Nominally 8 $\mu\text{C}$ @ 500 per pulse; nominally 0 $\mu\text{C}$ per sequential pair of pulses; zero net current
Maximum Output Voltage ( $\pm 10\%$ )	121 V
Maximum Output Current (<1K $\Omega$ load) ( $\pm 10\%$ )	100 mA
Pulse Duration ( $\pm 4\%$ )	280 $\mu\text{sec}$
Pulse Frequency ( $\pm 4\%$ )	120-200 Hz, randomly varying, 60-100 Hz, randomly varying, or 30-50 Hz, randomly varying. Alternate pattern has uniform frequency distribution of 4 pulse sequences at 15-25 Hz; each pulse sequence lasts 8.6 msec with pulses evenly spaced; mean frequency is 20 Hz.
Pulse Pattern	Continuous or burst (4 pulse bursts, randomly 15-25 Hz with mean 20 Hz)
Maximum Phase Charge	18 $\mu\text{C}$
Maximum Current Density	0.85 mA/cm <sup>2</sup> into 500 $\Omega$ load
Maximum Average Current	5.6 mA into 500 $\Omega$ load
Maximum Average Power Density	10 mW/cm <sup>2</sup> into 500 $\Omega$ load
Maximum Pulse Energy (pulse duration <0.1s)	3.4 mJ per pulse
Output Trips	
No Load	Device not connected to patient
Insufficient Charge	Delivered charge below target
Over Load	Delivered charge above target
Electrode Peeling	Electrode dislodging from skin
Therapy Session	
Timer	30 minutes or 60 minutes
Start Therapy	Via app
Stop Therapy	Firmly double tap device or via app
Manual Intensity Increase/Decrease	0.5-2 mA / sec
Habituation Compensation	Adaptive stepwise increase in intensity during session



Electrode	
Type	Cutaneous electrode, disposable, single-patient use
Materials	Conductive hydrogel, PET, silver
Number of Electrodes	2, outer electrode area 28 cm <sup>2</sup> , inner electrode area 33 cm <sup>2</sup>
Connector	Male snap
Dimensions	0.2 cm x 5.3 cm x 28.3 cm (exterior)
Power	
Source	Permanent rechargeable battery
Battery Type	Rechargeable 3.7V Lithium-Ion battery
Battery Life	400 Charge Cycles
Charging Source	AC line adapter
Line Current Isolation	Patient disconnected when charging
Patient Leakage Current, DC	< 10 µA
Patient Leakage Current, Enclosure	< 100 µA
Physical	
Dimensions	9.4 mm x 51.4 mm x 77.4 mm
Weight (without straps)	30 g
Environmental	
IP Classification	IP22
Operating Temperature Range	5° C to 35° C*
Atmospheric Pressure Range	70 kPa to 106 kPa
Relative Humidity Range	15% to 93%
Transport and Storage Temperature Range	-25° C to 70° C
Atmospheric Pressure Range	70 kPa to 106 kPa
Relative Humidity Range	10% to 93%
Standards	
IEC	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-1-11, IEC 60601-2-10, IEC 62304

\*Note: May be operated at temperatures up to 40° C, however electrode pads may feel warm.

## APPENDIX F

# Precautions and Warnings

## Indications

Quell is intended for use as a transcutaneous electrical nerve stimulation device for the symptomatic relief and management of chronic intractable pain.

The device may be used during sleep. The device is only labeled for use and compatible with NeuroMetrix Quell brand electrodes.

## Contraindications

Do not use this device if you have a cardiac pacemaker, implanted defibrillator, or other implanted electronic device unless specialist medical opinion has first been obtained.

## Precautions

- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- Use this device only with electrodes and accessories recommended by the manufacturer.

## Adverse Reactions

- You may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.

## Warnings

- Do not place the stimulation electrodes across or through the head, directly on the eyes, covering the mouth, on the front of the neck, on the chest or upper back, or crossing the heart.

- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- Do not apply stimulation when in the bath or shower.
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.
- Apply stimulation only to normal, intact, clean, healthy skin.
- No modification of this device is allowed.
- Do not use the device on children under the age of 18.
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Operation in close proximity (e.g. 1 m) to shortwave or microwave therapy medical equipment may produce instability in the stimulator output.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Do not remove the device from the leg before therapy has stopped. Check that the light is not illuminated on device, otherwise you may experience an uncomfortable sensation when you remove the device.

## APPENDIX G

# Symbols



User Manual/device labeling



Type BF Applied Part



WEEE (Waste Electronic and Electrical Equipment) symbol in accordance with council directive 2002/96/EC

**MN:**

Abbreviation for model number



Keep dry



Manufacturer

## APPENDIX H

# Electromagnetic Compatibility Declaration


Quell is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions; CISPR 11	Group 1	Quell uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions; CISPR 11	Class B	Quell is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonics Current Emissions IEC 61000-3-2	Class A	
Fluctuations and Flicker IEC 61000-3-3	Complies	
Electrostatic Discharge Immunity (ESD); IEC 61000-4-2	+/- 15kV air; +/- 8kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the humidity should be at least 30%
Radiated RF; IEC 61000-4-3	10 V/m; 80 MHz to 2.7 GHz	10 V/m compliance level
Electric Fast Transient Burst Immunity IEC 61000-4-4	±2kV power leads	Mains power quality should be that of a typical domestic establishment.
Fast Surge Immunity IEC 61000-4-5	±2kV Line to ground	
Radio Frequency Common Mode Immunity IEC 61000-4-6	3 VRMS (80% AM at 1 kHz); 150 kHz to 80 MHz	
Power Frequency Magnetic Field Immunity IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	
Voltage Dip and Interrupt Immunity IEC 61000-4-11	Complies	Mains power quality should be that of a typical domestic establishment.

Table 1

Manufacturer's declaration - electromagnetic immunity

Quell is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

Immunity test	IEC 60601 Test Level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Quell Device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended separation distance</b>
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz
			where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).
			Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>
			Interference may occur in the vicinity of equipment marked with the following symbol:
			

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

<sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Quell Device is used exceeds the applicable RF compliance level above, the Quell Device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Quell Device.

<sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

**Table 2**

**Recommended separation distances between portable and mobile RF communications equipment and the Quell Device**

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

Rated maximum output power of transmitter $W$	Separation distance according to frequency of transmitter $m$		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.



## APPENDIX I

# FCC

This device complies with Part 15 of the FCC Rules. Operation is subject to the following 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.

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

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.
- Consult the dealer or an experienced radio/TV technician for help.

## FCC RF Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter meets both portable and mobile limits as demonstrated in the RF Exposure Analysis. Quell 2.0 contains the Nordic nRF52832 pre-qualified design.

**FCC ID: XUL-QUELL2-0**

APPENDIX J

# Bluetooth®

The Bluetooth word mark and logos are owned by the Bluetooth SIG, Inc. and any use of such marks by NeuroMetrix, Inc. is under license.

Communication between the Quell Device and the Smartphone is via Bluetooth.

## Disabling Bluetooth

If Bluetooth is disabled on your smartphone or tablet, then the Quell Relief app will not function. Your Quell device will only function if you have previously enabled Automatic Start within the app.

Bluetooth Specifications	
Bluetooth Pre-Qualified Design:	Nordic nRF52832 4.2 Low Energy
FCC Rules:	Part 15C
Security:	Encryption

## Connect with us!

Join the conversation with other Quell users.

@QuellRelief



Quell<sup>®</sup> 2.0

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