

Quell[®]

Wearable Pain Relief
Technology™



User Manual

Contents

2 Chapter 1: Pain Relief with Quell

- 2 Introduction
- 3 What You Should Have Received
- 4 Device Components

5 Chapter 2: Getting Started

7 Chapter 3: Device Basics

- 7 Checking Battery
- 7 Charging Battery
- 8 Attaching Electrode
- 9 Device Placement

10 Chapter 4: Calibration

- 10 Option A: App Calibration (Recommended)
- 10 Option B: Manual Calibration

11 Chapter 5: Pain Relief Therapy

- 11 Preparing for Therapy Session
- 11 Starting Therapy Session
- 11 What Therapy Feels Like
- 12 Adjusting Intensity During Therapy Session
- 12 Ending Therapy Session

14 Chapter 6: Overnight Therapy

15 Chapter 7: Electrodes

16 Chapter 8: Skin Care

17 Chapter 9: Using the Mobile App

- 17 Download the App
- 17 Create an Account
- 18 Personalization Features

19 Chapter 10: Maintenance, Safety, and Service

- 19 Maintenance
- 19 Cleaning Device
- 19 Cleaning Band
- 19 Device Storage
- 19 Disposal
- 19 Limited Warranty

20 APPENDIX A: Indicator Lights

22 APPENDIX B: Troubleshooting

27 APPENDIX C: Frequently Asked Questions

29 APPENDIX D: Alternate Placement Sites

30 APPENDIX E: Therapy Dose

31 APPENDIX F: Technical Specifications

33 APPENDIX G: Precautions and Warnings

35 APPENDIX H: Symbols

36 APPENDIX I: Electromagnetic Compatibility Declaration

39 APPENDIX J: FCC and IC

40 APPENDIX K: Bluetooth®

41 APPENDIX L: Declaration of Conformity

Chapter 1

Pain Relief with Quell®

Introduction

Quell Wearable Pain Relief Technology™ is patented, non-invasive nerve stimulation technology that provides relief from chronic pain. It consists of a device and an electrode that attaches to the device. The device is worn on your upper calf, a few inches below the knee, and is controlled by a single button on the device or by the "Quell Relief" smartphone app.

Quell provides pain relief by comfortably stimulating the nerves that carry normal, non-painful sensations to your brain, which decreases the perception of pain.

Pain relief is initiated by simply clicking a button on the device or using the app on your smartphone. Regular therapy sessions are 60 minutes. After your first session, therapy will automatically restart every other hour. Pain relief may begin in as little as fifteen minutes after the start of a therapy session and may last up to an hour following the end of a session. You have complete control and can start or end therapy anytime from your device or smartphone.

You should review this User Manual carefully. Chapter 2 shows you how to get started. Chapters 3-5 provide detailed instructions on device use. Chapter 6 describes device use during sleep. Chapter 7 offers tips for taking care of the electrodes. Chapter 8 provides information on preventing skin irritation, particularly if you have sensitive or dry skin. Chapter 9 provides information about the optional smartphone app. APPENDIX C gives answers to frequently asked questions.

If you have any questions about how to use Quell, please call Quell Customer Care at 1-800-204-6577 or, if calling from outside the US, please call +1-781-890-9989.



What You Should Have Received

Upon receiving your Quell Wearable Pain Relief System you should inspect its contents to make sure all of the following are included and undamaged.



Quell Device



Sports Band



Quell Electrode Pack*
(packaging may vary)



USB Cable



AC Adapter



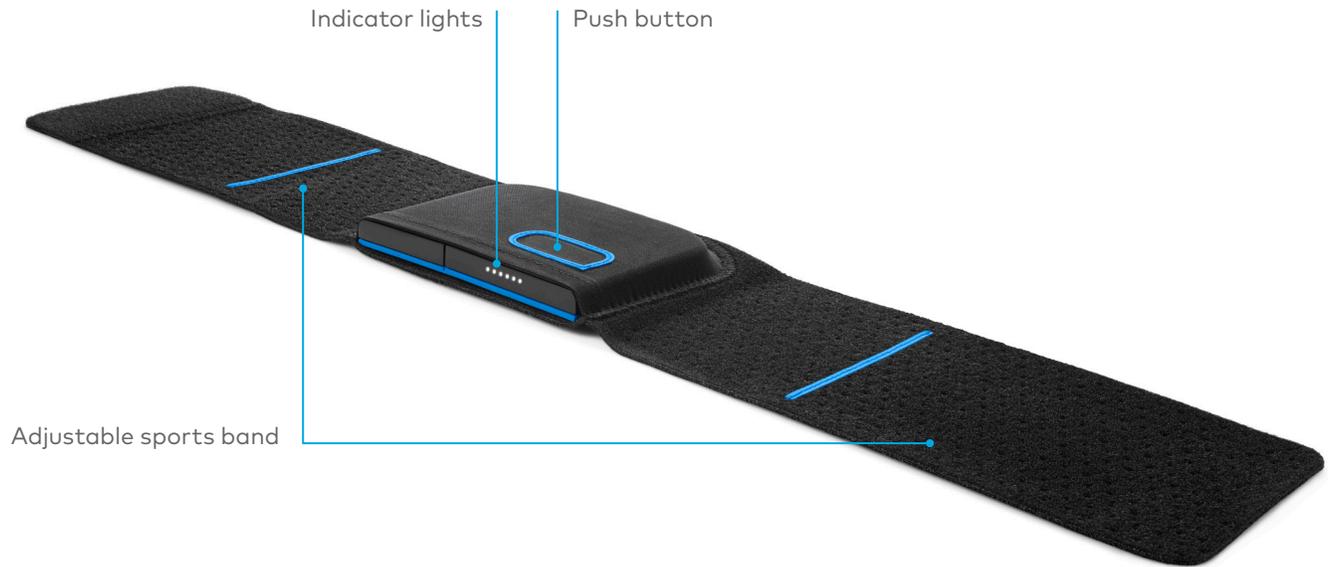
Travel Bag (available separately)



Quick Start Guide

* Only use electrodes manufactured by NeuroMetrix, Inc.

Device Components



Micro-USB port
(not seen in image, port is on bottom of device,
not accessible through sports band)

Two electrode
connector snaps

Chapter 2

Getting Started

The recommended way to get started is to use the Quell Relief smartphone app. Download the app and follow the set up screens.

You may also follow the steps below for manual set up and calibration. **For additional details on each step, please review Chapters 3-5** or call Customer Care with any questions at 1-800-204-6577.

1. Check Battery

Click the button and check the indicator lights. The number of white lights indicates the charge remaining in the battery. A single orange light indicates the unit needs charging. If the battery needs to be recharged, use the USB cable and AC adapter.



2. Insert Device

Slide your device into the band pouch so that the button is visible inside the blue-rimmed window, with the lights facing up.



3. Attach Electrode

Remove an electrode from the package, and snap it onto the connectors.

The electrode may be oriented in either direction. Carefully remove the liner and save it for storing the electrode between uses.



4. Place Device

Place your Quell band **directly** on your upper calf approximately 1 to 2 inches below the knee of either leg. Lights should face up.



5. Calibrate

Perform this step when using the device for the first time.

Option A: App Calibration (Recommended)

Once you have downloaded and launched the app, follow instructions to set up and calibrate.

Option B: Manual Calibration

Sit with foot flat on the floor and leg at a 90 degree angle. Calibration won't start if leg is extended horizontally.

Press and hold the button until you see the lights running back and forth, then release the button. Lights will continue running.

Wait until you feel the slightest tingle under the band, then immediately click the button one time.

When the sensation starts again, click the button again. You will typically click the button 3-6 times.

When the lights go off, calibration is complete. If you need to recalibrate, simply repeat the calibration steps. See next step to begin therapy.

6. Start Therapy

Click the button. One indicator light will blink. The sensation will increase for **2 minutes** until optimal intensity is reached. You should feel a strong but comfortable sensation under the electrode.

Decrease Intensity: **Click the button** to reduce intensity. Repeat if needed.

Increase Intensity: **Hold button down.** Intensity increases until you release the button.

Turn off: To stop therapy, click the button **four times in sequence.**

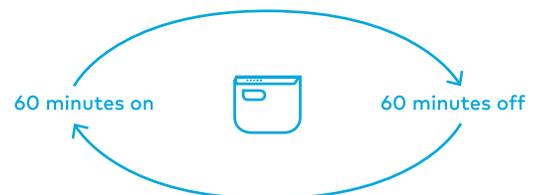
Regular therapy sessions last for 60 minutes with a 60 minute break between sessions. Sessions will continue until the device is removed from the leg. You may go about your normal activities during a therapy session.

To learn how to control your Quell device and personalize your therapy with the smartphone app, please review Chapter 9.



Tips for Success

- Calibrate properly so Quell delivers the right stimulation level for optimal pain relief.
- Use your Quell daily, at least 2 to 3 full therapy sessions, for the first month. Can also be used overnight.
- Give it time as it may take several weeks to experience optimal pain relief from using your Quell.



Chapter 3

Device Basics

Checking Battery

Your Quell will arrive fully charged. To check battery level, hold the device in your hand and briefly click the button. The indicator lights will flash white if the battery has sufficient charge. The number of illuminated white lights corresponds to the level of battery charge. Five white lights indicate a fully charged battery. If orange indicator light flashes, the battery needs to be recharged (see below for charging instructions).

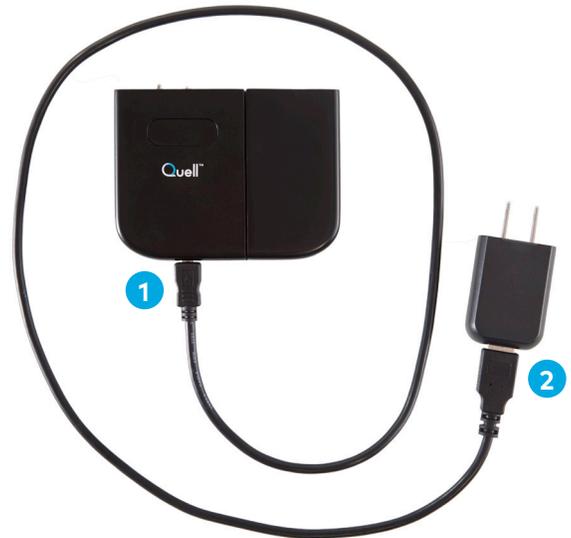


Charging Battery

A fully charged battery can provide up to 50 hours of therapy for most users.

To charge the battery:

- 1 Plug the USB cable into the micro-USB port on the bottom of the device.
- 2 Plug the other end of the cable into the AC Adapter. The cable should not be plugged into a computer USB port for charging.



The AC Adapter should then be **plugged into a standard electrical outlet**. The USB connector on many computers is not powerful enough to charge Quell. The white indicator lights on the device will show that the device is charging. The number of lights shown will increase as the battery charges. When the battery is fully charged, all 5 lights will be lit. 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.

If the battery is too low to start a therapy session, you can charge the device for approximately 20 minutes to provide enough battery life for one therapy session. To confirm, disconnect the USB cable from the device and briefly click the button. If at least 1 white indicator light flashes, battery has enough charge for one therapy session. If the orange light flashes, reconnect the USB cable and continue charging.

Do not use your device with the USB cable connected.

Attaching Electrode

You will need to attach a new electrode prior to first use of the device and 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. Slide device into band pouch with lights facing up.



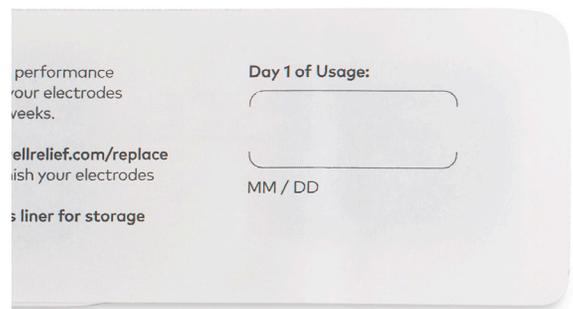
2. Align the snaps on the electrode to the snap connectors on the back of the device. Insert snaps until they are securely fastened.



3. Remove the liner covering the electrode prior to placing the device on your leg. **Remember to keep the liner as it should be re-applied to protect the electrode when not in use.**



4. The first time you use a new electrode, write the date on the liner. When placing liner on the electrode when it is not in use, ensure graphics on liner are facing up so that the paper side doesn't stick to the gel. The electrode should be replaced approximately 2 weeks from this date.



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 and the button is accessible. You may position the device with the button on the inside, outside, or back of the leg. You should avoid placing one of the device compartments 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 attach it with the Velcro®. 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 your skin.** If the pads are only partially on the skin, then the stimulation may feel uncomfortable.

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.



Chapter 4

Calibration

Option A: App Calibration (Recommended)

Watch the App Calibration video on the app or on quellrelief.com/quell-user before you use Quell for the first time.

1. Download the Quell Relief app from the App Store or Google Play.
2. Launch Quell Relief app. Follow instructions to pair your smartphone and calibrate your device.
3. Start Therapy.

If you do not have a smartphone, please follow Option B: Manual Calibration.



Option B: Manual Calibration

Watch the Manual Calibration Video on quellrelief.com/quell-user before you use Quell for the first time.

Read through all the steps below before you begin calibration. You must calibrate the first time you use Quell, so Quell will learn your nerve sensitivity. Sit in a quiet place where you can focus, with your foot flat on the floor and knee bent at 90° angle as shown.

Step 1:

Press and **HOLD** button until you see lights running back and forth, then release button. Lights will continue running.

Step 2:

Wait until you feel the slightest tingle under the band, then immediately **CLICK** the button one time.

Step 3:

Repeat Step 2 until the lights go off, meaning calibration is complete. People typically click the button 3-6 times during calibration.

You are now ready to begin therapy.

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

Chapter 5

Pain Relief Therapy

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, consult APPENDIX E to learn how to turn it off.

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 device 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 as described on page 12. **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 after the first two minutes of therapy and you should not need to adjust often. Please follow the steps on the following pages for 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. Place the device on your leg as described in Chapter 3.

Starting Therapy Session

To start a therapy session, tap the start button on the Dashboard screen in the app. Or, briefly click the button on the device. One indicator light will blink white for the duration of the therapy session.

What Therapy Feels Like

The intensity will gradually increase during the first two 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 as described in the next section. Therapy will continue for 60 minutes in Regular dose (see page 18 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 Therapy Session

Frequent adjustments should not be necessary; however, if the sensation feels uncomfortable or is not strong enough, you may make adjustments. The easiest way to adjust therapy intensity or to stop therapy is to tap the buttons on the Dashboard screen in the smartphone app. For manual adjustments, please follow the directions below.



Decrease Intensity: Click the button. Each click decreases intensity. Lights will flash and then go down to indicate intensity has decreased.

Increase Intensity: Press and hold button to increase the intensity. Intensity increases until



you release the button or for a maximum of 20 seconds. If you still need to increase intensity after 20 seconds, hold the button down again.

You may adjust intensity as needed at any time during a therapy session using the button on the device or the smartphone app.

Optimal pain relief will be obtained at the highest intensity that is also comfortable.

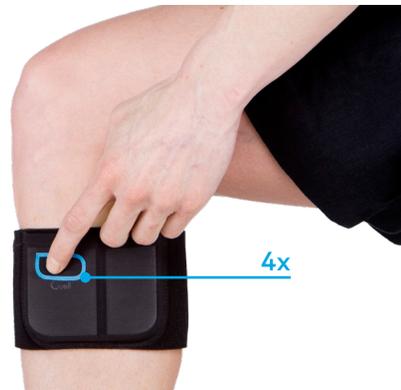
To learn how to control your Quell device with your smartphone app, please review Chapter 9.

Ending Therapy Session

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

To manually stop therapy during a session, click the button four times in sequence. **You should not remove the device while it is stimulating**, so make sure that the indicator light is not blinking white before removing the device and electrode from your leg. Otherwise you may experience an uncomfortable sensation when you remove the device.

After completing 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 15 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. Chapter 8 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 4-5 hours or overnight. After 4 hours of wear, device will pulse on and off for 1 minute as a reminder.

Chapter 6

Overnight Therapy

You may use Quell at bedtime and throughout the night.

Before going to sleep, make sure the device is placed securely and comfortably around your leg. Start a therapy session by briefly clicking the button. 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.

App users have multiple sleep mode options. To learn about the different sleep settings, please review Chapter 9, Using the Mobile App.

Chapter 7

Electrodes

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 8 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 electrode should be replaced prior to two 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 or from the location where you purchased your device.



Helpful Tips

- The entire electrode should contact the skin.
- To get the most use of your electrode, put the liner back on the gel pads when electrode is not on skin.
- Air-out skin or switch legs during the day or after overnight use. After 4 hours of wear, device will pulse on and off for 1 minute as a reminder.
- Change the electrode every 2 weeks.
- Do not use while showering or bathing.

Chapter 8

Skin Care

Quell works by electrically stimulating your sensory nerves 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.

Never use the device on open wounds or rashes or over swollen, red, infected, or inflamed skin.

Prevent Skin Irritation

Air-out Skin

Air-out skin after 4-5 hours of wear during the day or after overnight use. Many users simply switch the device to the other leg every 4-5 hours.

If you have sensitive skin, you may also consider the following:

Start Slow

Limit the time the device is on your skin to 3-4 hours per day in the first week. If you do not experience irritation you may increase use while closely monitoring your skin.

Check for Skin Irritation

Check for signs of irritation, including:

- 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 then 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 to 3-4 hours per day for a week to make sure that further irritation does not occur.

Chapter 9

Using the Mobile App

Download the App

The Quell App is optional and not required for the use of the device. From your mobile device search for “Quell Relief” by NeuroMetrix, Inc. and download the app. Before proceeding, make sure that Bluetooth® is enabled on your mobile device.

iOS and Android devices must have Bluetooth Low Energy (LE, also called Bluetooth Smart) compatibility.



For more insights on the data tracked with the app, visit www.quellrelief.com/how-quell-works/app/ and select Sleep, Therapy, Activity, or Pain.

Create a Health Cloud Account

Creating a Health Cloud account from the app provides a secure backup of your data and allows you to view data across multiple devices.

The tables below and on the next page describe app features and how they may help you optimize your Quell therapy during the day and at night.*

**Not all features available on all devices.*

Feature	Why is it important?
Sleep Position Tracking	Enables device to track sleep metrics including time slept on back or on sides, and the number of times position changed while sleeping.
Lights Out	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	Let Quell itself figure out 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.'
Sleep Mode	
Bedtime only	Therapy only while falling asleep.
Gentle overnight	Overnight therapy at reduced intensity.
Full power	Overnight therapy at daytime intensity.
As needed	Therapy only when Quell detects poor sleep quality.

Stimulation	Select the type of stimulation Quell will provide during therapy sessions. Standard and Alternate are equally effective, but one may feel more comfortable. Sensitive is an option if Standard and Alternative feel uncomfortable. Your selection will take effect with the next therapy session.
Standard	Feels like a constant vibration.
Alternative	Feels like a fast gentle pulse.
Sensitive	Feels like a low vibration.
Therapy Dose	You can select the duration and timing of your therapy sessions.
Regular	Therapy is 60 minutes and restarts every 60 minutes.
High	Therapy is 60 minutes and restarts every 30 minutes.
Low	Therapy is 30 minutes and restarts every 60 minutes.
Manual	Therapy is 60 minutes and does not restart automatically.
Time of Day Adjustment	Enable if stimulation feels particularly strong at certain times of day. If enabled, indicate the time of day when stimulation feels strongest. The device will then automatically compensate so the stimulation feels consistent to you.
Device Button	Disable device button to prevent unintended button presses, such as while sleeping. If the device button is disabled, then you must use the app to start therapy and control the intensity. You can always stop therapy by clicking the button 4 times in a row.
Calibration	Recommended method to set up your device the first time you use Quell.
Electrode	Keep track of how many days you have been wearing your electrodes.
Notifications	
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.
Intensity Display	When enabled, the stimulation intensity will be displayed on the Dashboard during therapy sessions.
Pairing	If paired, shows the serial number of the device to which it is paired. To pair with a different device, tap Un-Pair.
Account	Create a Health Cloud account.

Chapter 10

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.

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 Lights

Device on Skin

Device State	Indicator Light Status	Explanation
Standby	No lights illuminated	Device in standby, no therapy or calibration in progress
Calibration	Waterfall White (lights running back and forth)	Calibration in progress
Therapy	Single Blinking White Light	Therapy session in progress
	Lights running one direction or the other	Intensity increase or decrease as a result of button press or adjustment via app.
Stimulation halted earlier than expected	Orange light blinks for 2 minutes	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 blink of 1 white light	Adequate charge for one therapy session
	Single blink of 2, 3, or 4 white lights	The number of illuminated white lights correspond to the level of battery charge. The higher the number, the closer it is to being fully charged.
	Single blink of 5 white lights	Fully Charged Battery
	Single blink of orange light	Battery needs to be charged.
Therapy Dose	1 white light or 5 lights illuminate while button is held	With a 10 second press off-skin, 5 white lights indicate Regular therapy dose is selected (60 min on, 60 min off, automatically). 1 white light indicates Manual dosage; 60 min on and then user has to restart. Regular is the default setting.

Charging

Device State	Indicator Light Status	Explanation
Charging	1, 2, 3, or 4 lights solid, one light blinking	Device is charging
	5 lights on solid	Device is fully charged
	Orange light blinking	Charging issue
	Outer 2 lights on or all 6 lights illuminate while button is held	With a 10 second press during charging, all 6 lights indicate Bluetooth being enabled, outer 2 lights indicate Bluetooth being disabled. Bluetooth is enabled by default.

APPENDIX B

Troubleshooting

Calibration

I cannot start the calibration procedure (the lights are not running waterfall motion).

If you are using the app, the Calibration option can be found under the Settings menu. To start calibration using the app, tap "Start Calibration."

If you are calibrating manually, you should be sitting down with your lower leg at a 90° angle (or perpendicular to the floor) with your foot flat on the floor. Make sure the electrode is snapped onto the device, the liner has been removed, and the device is properly placed on your leg (on the upper calf, 1-2" below your knee). Electrode should be making complete contact with the skin. Click and hold the button on the device down for at least 5 seconds until you see the white waterfall pattern.

I can start calibration and see the waterfall lights briefly, but then they turn off.

Check your positioning (seated with leg at 90° angle) and device (upper calf, 1-2" below the knee). Electrode should be making complete contact with the skin. Try smoothing the electrode over your skin (while it is snapped to the device), before securing the sports band.

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

Confirm electrode liner has been removed and that the lights have been running back and forth for at least 30 seconds. 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 (or press the button), 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.

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

- Do not calibrate right after a therapy session (of >30 minutes) 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 (or by pressing the button) 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.

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 is 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 or press and hold the button to increase the intensity until you feel a **strong but comfortable** sensation. Alternatively, calibrate the device again.

The device isn't automatically restarting.

If you are using the app, 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.

You can check and change settings manually by holding the device off your leg without the electrode connected. Hold the button down for 10 seconds to toggle between settings.

1 white light = Manual. 5 white lights = Regular

The therapy stings or feels uncomfortable.

Turn off the device by using the app or clicking the button 4 times. 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. 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 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 rapid and intense, you may have inadvertently pressed the button. This can sometimes happen if you have your legs crossed or are resting your legs against an object, like a piece of furniture or the car door while driving. App users can disable the button to prevent unintentional changes.

If intensity is increasing on its own and waterfall pattern is shown, calibration is running. Pressing the button 4x in a row will stop calibration. If this was accidental, the device will remember your previous calibration settings.

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 4 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 4 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 four hours of overnight wear, or while you are sleeping.

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," or "As Needed" mode.

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

Make sure you wait 60 minutes to see if device will restart on its own. If you had the device off your skin for more than 60 minutes or charged it while it was off, you will need to restart manually.

Use the app to check Sleep Mode. If Sleep Mode was set to "Bedtime," 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 therapy, 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 7.

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

Remove the device when not in use to allow the gel to cool.

Minimize use outdoors 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 4-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 4 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 if 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 8 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 1st white light to begin flashing after connecting the device to the charging adaptor plugged into a wall outlet. The 1st light needs to be solid white before device has enough charge to provide a single therapy session.

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 vibrating or light pressure sensation. You may reduce the intensity if it feels uncomfortable.

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 2-3 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 wearing your Quell for 2-3 therapy sessions per day for the first month. 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 app users 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.

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 on 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 50 therapy sessions.

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.

If you place the device on your thigh, you must stand straight up to perform calibration.

APPENDIX E

Therapy Dose

Therapy Dose settings determine whether therapy will restart automatically or must be restarted manually.

The easiest way to check and change therapy dose is to use the app. Go to Settings -> Therapy Dose to select dosage. Regular is the default setting, which delivers 60 minutes of therapy followed by a 60 minute break, automatically.

You may also check the setting manually. With the device in your hand, without an electrode attached, click and hold the button for at least 10 seconds. You will see either one or five white lights. 1 light means that it is set to manual restart. 5 lights means it is set to automatically restart at the "Regular" dose.



Manual restart is on



Regular dose will restart automatically

APPENDIX F

Technical Specifications

Output	
Waveform	Biphasic with alternating leading phase, asymmetrical, rectangular
Regulated Current or Voltage	Current
Net Charge per Pulse	Nominally 8 μC @ 500 per pulse; nominally 0 μC per sequential pair of pulses; zero net current
Maximum Output Voltage ($\pm 10\%$)	100 V
Maximum Output Current (<1K Ω load) ($\pm 10\%$)	100 mA
Pulse Duration ($\pm 4\%$)	280 μsec
Pulse Frequency ($\pm 4\%$)	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 80 Hz.
Pulse Pattern	Continuous or burst (4 pulse bursts, randomly 15-25 Hz with mean 20 Hz)
Maximum Phase Charge	18 μC
Maximum Current Density	0.6 mA/cm ² into 500 Ω load
Maximum Average Current	2.8 mA into 500 Ω load
Maximum Average Power Density	5 mW/cm ² into 500 Ω load
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	Click button once or via app
Stop Therapy	Click button 4 times or via app
Manual Intensity Increase/Decrease	0.5-2 mA / sec
Habituation Compensation	Adaptive stepwise increase in intensity during session
Electrode	
Type	Self-adhering, single-patient use, multiple applications
Materials	Mylar substrate, silver electrode pads
Number of Electrodes	2, outer electrode area 28 cm ² , inner electrode area 33 cm ²
Connector	Medical snap (male)
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 μ A
Patient Leakage Current, Enclosure	< 100 μ A
Physical	
Dimensions	98 mm x 74 mm x 11 mm
Weight (without straps)	66 g
Environmental	
IP Classification	IP20
Operating Temperature Range	-5° C to 40° 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

APPENDIX G

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 metallic or electronic device. Such use could cause electric shock, burns, electrical interference, or death.

Precautions

- Transcutaneous electrical nerve stimulation is not effective for pain of central origin, including headache.
- Transcutaneous electrical nerve stimulation is not a substitute for pain medications and other pain management therapies.
- Transcutaneous electrical nerve stimulation devices have no curative value.
- Transcutaneous electrical nerve stimulation is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.
- The long-term effects of electrical stimulation are unknown.
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.
- The safety of electrical stimulation during pregnancy has not been established.
- You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.
- If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.
- Use caution if you have a tendency to bleed internally, such as following an injury or fracture.
- Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
- Use caution if stimulation is applied over the menstruating or pregnant uterus.
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- Keep this device out of the reach of children.
- 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.
- You may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.
- You should stop using the device and should consult with your physician if you experience adverse reactions from the device.

Warnings

- If you are in the care of a physician, consult with your physician before using this device.
- If you have had medical or physical treatment for your pain, consult with your physician before using this device.
- If your pain does not improve, becomes more than mild, or continues for more than 5 days, stop using the device and consult with your physician.
- Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation across your chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal.
- 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 in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- 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.
- Consult with your physician before using this device, because it may cause lethal rhythm disturbances to the heart in susceptible individuals.
- Apply stimulation only to normal, intact, clean, healthy skin.
- No modification of this device is allowed.
- Do not use the device on children.

APPENDIX H 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



Mark identifying compliance with council directive 93/42/EEC. Identification mark of the Notified Body. TÜV SÜD responsible for evaluation of the CE Technical File.

APPENDIX I

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 Common mode	
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	
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
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	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. Recommended separation distance $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m	3 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, ^a should be less than the compliance level in each frequency range. ^b 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.

^a 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.

^b 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 <i>P</i>	Separation distance according to frequency of transmitter <i>m</i>		
	150 kHz to 80 MHz <i>d</i> = 1.2√ <i>P</i>	80 MHz to 800 MHz <i>d</i> = 1.2√ <i>P</i>	800 MHz to 2.5 GHz <i>d</i> = 2.3√ <i>P</i>
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 J

FCC and IC

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.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions:

1. This device may not cause interference, and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

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. The Bluegiga BLE Bluetooth Module contains Transmitter Module:

FCC ID: QOQBLE113

IC: 5123A-BGTBLE113

APPENDIX K

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

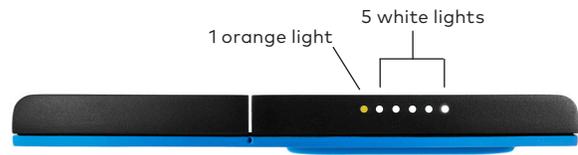
While all sensitive data transmission is encrypted, Bluetooth functionality can be turned off for increased privacy. If Bluetooth is disabled, then the Quell Relief App will not function, but all other functions of the Quell device will operate normally. To turn off Bluetooth:

1. Plug the Quell device into the charger/wall outlet,
2. Click and hold the button on the Quell Device for approximately 10 seconds until the one orange and one white indicator light flashes.
3. The Bluetooth module is now disabled.

To reactivate Bluetooth functionality, repeat the above steps. All six indicator lights should be illuminated.



Bluetooth is Disabled



Bluetooth is Enabled

Bluetooth Specifications

Bluetooth Module:	Bluegiga BLE 113 Bluetooth® Module with Bluetooth® 4.0 low energy radio
Transmit Power:	+0 dBm
Receiver Sensitivity:	-93 dBm
FCC Rules:	Part 15C
Frequency Range:	2402.0 - 2480.0
Output Watts:	0.0011
Security:	Encryption

APPENDIX L

Declaration of Conformity

Product Identification

Product name	Model/number
QUELL Transcutaneous Electrical Nerve Stimulator	QE-001 Quell 1 Device QE-002 Quell 2 Device QE-P01 Electrode QE-P02 Sport Electrode

Manufacturer

Name of company	Address	Representative	CE Certificate Number
NeuroMetrix, Inc.	1000 Winter St. Waltham, MA 02451 U.S.A.	Rainer Maas	G1 16 10 40014 014

European Authorized Representative

Name of company	Address	Telephone/email
EMERGO Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 – phone +31.70.346.7299 – fax europe@emergogroup.com

Notified Body (Annex II Products Only)

Name of company	Address	Telephone/email
TÜV SÜD Product Service GmbH Notified Body Number 0123	Zertifizierstelle Ridlerstrasse 65 80339 München, Germany	+49.89.5008.4477 – phone +49.89.5008.4327 – fax medical_devices@tuev-sued.de

Conformity Assessment

Device classification	Route to compliance	Standards applied
QE-001 Class IIa	Annex II w/o (4) of MDD	IEC 60601-1
QE-002 Rule 9	93/42/EEC Council Directive	IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-10 IEC 62304 ISO 14971
QE-P01 Class 1	Annex VII of MDD	ISO 10993
QE-P02 Rule 1	93/42/EEC Council Directive	

NeuroMetrix, Inc. declares, under our exclusive responsibility, that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices until the expiration of the above referenced CE certificate.

Company Representative: Rainer Maas

Title: Director of QA/RA/Compliance

Date: March 14, 2017

Place: Waltham, Massachusetts

Signature:





1000 Winter Street
Waltham, MA 02451, USA
(800) 204-6577, (781) 890-9989
www.quellrelief.com

Quell User Manual
©2017 NeuroMetrix, Inc. All Rights
Reserved. PN2204482 Rev. B