Quell

Fibromyalgia

USER MANUAL

Rx Only

Contents

Chapter 1

Fibromyalgia Symptom Relief with Quell® Fibromyalgia

Introduction

Quell Fibromyalgia is a transcutaneous electrical nerve stimulation (TENS) device indicated as an aid for reducing the symptoms of fibromyalgia in adults with high pain sensitivity. It consists of a device, a wearable band, an electrode that attaches to the device, and the Quell Fibromyalgia mobile app to control and customize your treatment. The device may be used during sleep. The device is labeled for use only with compatible NeuroMetrix electrodes.

Quell Fibromyalgia is for prescription use only. The device is contraindicated for use by patients who have a cardiac pacemaker, implanted defibrillator, other implanted electronic device, or implanted metal near the device, because this may cause electric shock, burns, electrical interference, or death. The stimulation electrodes should not be placed 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. The device cannot be used while driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.

The sale, distribution, and use of Quell Fibromyalgia are restricted to prescription use in accordance with 21 CFR 801.109.

Many participants in a pivotal clinical study were also taking medication for fibromyalgia and it was difficult to assess the effects of the device compared to medication.

Quell Fibromyalgia provides symptom relief by comfortably stimulating sensory nerves in your calf. The nerves carry neural pulses to the brain that trigger a natural response to reduce your fibromyalgia symptoms.

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

You should use Quell when you are experiencing symptoms. For best results, use it daily. We recommend that new users use Quell Fibromyalgia for a minimum of 3 treatment sessions per day at a strong, but comfortable intensity for at least the first 30 days. A treatment session (also called treatment hour) represents 1-hour of continuous stimulation. Therefore, the recommended minimum of 3 treatment sessions per day is equivalent to 3-hours of daily stimulation. To limit skin irritation, please first refer to Chapter 7 (Skin Care) if you plan to use Quell for long periods of time (e.g., more than 5 hours). Daily use of the device should not exceed 8-hours of stimulation and 15-hours of wear. The safety and effectiveness of the device when used for more than 8 treatment hours per day is not well characterized.

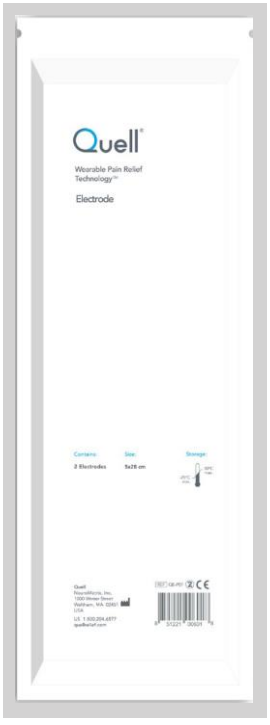
If you have any questions about how to use Quell Fibromyalgia, please call Customer Care at 1-800-204-6577 or email us at CustomerCare@quellfibromyalgia.com.

What's Included

Upon receiving your Quell Fibromyalgia Starter Kit, you should inspect its contents to make sure all of the following are included:

Device

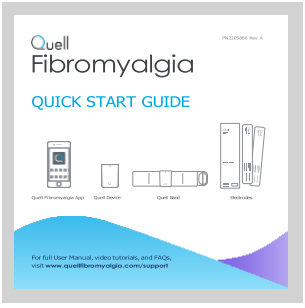
Band



Electrode Pack*
(packaging may vary)

USB Cable

AC Adapter
(Adapter may vary)



Quick Start Guide

* Only use electrodes manufactured by NeuroMetrix, Inc.

Chapter 2

Getting Started & Device Basics

Getting Started

1. Fully charge your Quell Fibromyalgia 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 Quell Fibromyalgia app to your smartphone or tablet from the App Store or Google Play.

   Quell Fibromyalgia
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 treatment.

For additional details on each step, follow instructions below.

Charging the Battery

A fully charged battery can provide up to 25 hours of treatment 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.

Only use the cable and AC adapter that was provided with your device to ensure proper charging. 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 light on the device will show that the device is charging.

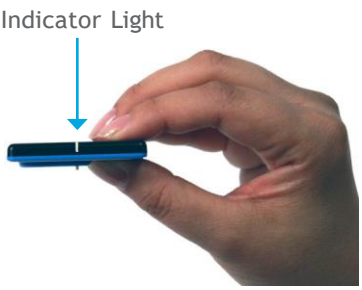
When the battery is fully charged, the white indicator light will remain solid. It will take approximately 3 hours to charge an empty battery. When the battery is fully charged, unplug the cable from the device.

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

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

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

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 treatment session. If no indicator light flashes, the battery needs to be recharged following the steps above.

Downloading the Quell Fibromyalgia App

Using your smartphone, open the App Store or Google Play. Search "Quell Fibromyalgia" and download the app to your device. Ensure that your smartphone's Bluetooth is turned on and that your device is running iOS 14 or later, or Android 8 or later. Launch the Quell Fibromyalgia app and follow the step by step instruction within the app to pair and setup a Quell Health Cloud account. Once your device is fully charged, you can finish setup and complete calibration (See Chapter 3 for more information on Calibration).

Creating a Quell Health Cloud account is voluntary. The performance and features of your Quell device are not affected if you do not create an account. By signing up for a Quell Health Cloud account your utilization, sleep and fibromyalgia severity tracking data are backed up and can be shared among multiple mobile devices. You can sign up for a Quell Health Cloud account at any time.

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 treatment.

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 for information on how to get a Small or Large band.

Recommended Positioning On Leg

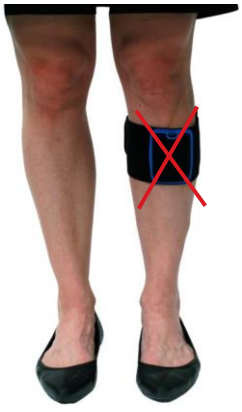
Outside of Calf

Back of Calf

Inside of Calf

Avoid Positioning

Front of Shin



Chapter 3

Calibration

The calibration process must be completed before first using the device. Watch the Calibration video on the app before you calibrate for the first time.

Calibration allows the device to learn your sensation threshold. Based on your sensation threshold, the device will deliver a customized stimulation level. During the calibration process, the device will slowly increase stimulation several times to determine your sensation threshold. Once you have completed the calibration process, you are ready to begin your first treatment session.

Follow the instructions in the app to calibrate your device for first use. If needed, you can recalibrate your device at any time within the app.

Please Note:

- We recommend you sit in a quiet place where you can focus, with your feet flat on the floor during the calibration process.
- The first time you use your device with the app, you will automatically be prompted to complete calibration. If at any time you wish to repeat calibration, open the Quell Fibromyalgia app, click the menu icon, select Settings and then Calibration. Read the instructions on the How to Calibrate screen, and then click Start Calibration to begin the calibration process.
- Wait until you feel the slightest tingle under the electrode, then immediately tap the button labeled TAP HERE 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 strong before tapping the button.
- You will feel subsequent stimulation slightly faster.
- If you need to stop at any point or feel that you have made a mistake, tap the "Stop Calibration" button within the app. You can always recalibrate your device at any time.
- Once completed, a screen titled "Calibration Success" will appear in the app and your treatment intensity should be set to the optimal level for you. Therapeutic stimulation will feel stronger than the sensation you felt during calibration. Treatment should always feel strong, but comfortable.

Chapter 4

Treatment

The experience of fibromyalgia is different for everyone. Please be patient. It may take several weeks of consistently using Quell Fibromyalgia before you start to experience symptom relief. You should use Quell when you are experiencing symptoms. For best results, use Quell daily. We recommend using Quell Fibromyalgia for a minimum of 3 treatment sessions every day. A treatment session (also called treatment hour) represents 1-hour of continuous stimulation. Therefore, the recommended minimum of 3 treatment sessions per day is equivalent to 3-hours of daily stimulation. To limit skin irritation, please first refer to Chapter 7 (Skin Care) if you plan to use Quell for long periods of time (e.g., more than 5 hours). Daily use of the device should not exceed 8-hours of stimulation and 15-hours of wear. The safety and effectiveness of the device when used for more than 8 treatment hours per day is not well characterized.

During a treatment session, the device will comfortably stimulate the nerves in your leg. Regular treatment 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 Treatment Schedule under Settings within the app.

To optimize symptom relief, you should feel a strong but comfortable sensation during treatment. 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 symptom 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 during the first 10 minutes of treatment if the treatment session is successfully completed, and you should not need to adjust often. Please follow the steps below for initiating a treatment session.

Preparing for Treatment Session

Before starting a treatment 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 treatment session. Place the device on your leg as described in Chapter 2, Getting Started & Device Basics.

Starting a Treatment Session

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

Automatic Start

You can also set treatment to start automatically after attaching the device to your leg. Open the app to the Dashboard, press the Automatic Start icon (letter A) in the top left corner and select Enable. You can also go to the Settings menu and select Treatment Automation to turn on Automatic Start. Once enabled, treatment will begin automatically within one minute of placing the device on your leg. You will no longer need to start treatment within the app. You can always stop treatment by tapping the STOP button within the app, or by double tapping the device firmly with your fingers.

What Treatment 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. Treatment 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 treatment session. Do not shower, bathe or swim with the device on your leg.

Adjusting Intensity During a Treatment Session

The stimulation intensity can range from 0 to 100 milliamps and can be changed in 0.5 milliamp increments. Frequent adjustments should not be necessary; however, if the sensation feels uncomfortable or is not strong enough, you may make adjustments. To adjust treatment intensity or to stop treatment, tap the "+/-" buttons on the Dashboard screen in the smartphone app. Each time the "+" button is tapped the intensity will increase by 1.25% (with a minimum increase of 0.5 milliamps). The device will allow up to 4 such increases each second over the course of a 60-minute treatment session. Each time the "-" button is tapped the intensity will decrease by 5%.

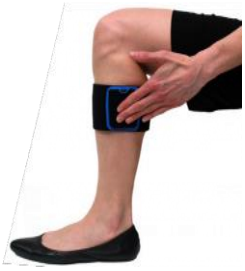
You may adjust intensity as needed at any time during a treatment session using the smartphone app. Optimal symptom relief will be obtained at the highest intensity that is also comfortable.

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

Ending a Treatment Session

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

To stop an active treatment 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 treatment 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.



Double tap the device firmly with your fingers to stop treatment manually.

After ending a treatment 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 treatment session, stimulation will stop and the indicator light will blink orange for 2 minutes. You may also see a message on the app Dashboard that the last session halted. Refer to APPENDIX B for troubleshooting assistance.

You should air out your 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 Treatment

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

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

Chapter 5

Overnight Treatment

You may use Quell Fibromyalgia at bedtime and while you sleep.

Before going to sleep, make sure the device is placed securely and comfortably around your leg. All 4 gel pads on the electrode must be making complete contact with the skin. Start a treatment session within the app. The default sleep setting is "Gentle Overnight." In this setting, the first treatment session will stimulate at your regular intensity level. Subsequent treatment sessions will start automatically every other hour throughout the night at a reduced 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 treatment session.

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

Chapter 6

Electrodes

Quell Fibromyalgia 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. You may snap the electrode into the device for convenient storage. For long term storage, electrodes should be stored in the electrode pouch or a sealed bag at room temperature out of direct sunlight.

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 treatment feels uncomfortable and/or you see the orange error light on the Quell device blink when you attempt to start treatment.

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. It is recommended that electrode is replaced at 2 week interval to maximize treatment comfort and efficacy. A date can be set in the app to remind you when it is time to replace the electrode.

Electrode Options

Quell Standard Electrodes are included in the Quell Fibromyalgia Starter Kit. They are designed to deliver comfortable, effective symptom 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 device. The Sport Electrode has a unique gel developed to be more robust in situations with high levels of humidity and perspiration. The Sport Electrode has a gel that absorbs less moisture, but is otherwise comparable to the Standard Electrode included in the Starter Kit.

Chapter 7

Skin Care

Quell Fibromyalgia 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 Fibromyalgia.

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

You should air out your 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 Fibromyalgia” 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 14 or later, or Android 8 or later.


Quell Fibromyalgia

Create a Quell Health Cloud Account

Creating a Quell Health Cloud account is voluntary. The performance and features of your Quell device are not affected if you do not create an account. By signing up for a Quell Health Cloud account your utilization, sleep and pain tracking data are backed up and can be shared among multiple mobile devices. You can sign up for a Quell Health Cloud account at any time.

Settings/Personalization Features

The tables below and on the next page describe app personalization features and settings, and how they may help you optimize your Quell Fibromyalgia treatment during the day and at night.

Feature	Why is it important?
Treatment Schedule	You can select the duration and timing of your treatment sessions.
Manual	Treatment is 60 minutes and does not restart automatically.
Low Dose	Treatment is 30 minutes and restarts every 60 minutes.
Regular Dose	Treatment is 60 minutes and restarts every 60 minutes. (Default Setting)
High Dose	Treatment is 60 minutes and restarts every 30 minutes.
Treatment Automation	
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. Treatment intensity will automatically compensate so stimulation feels consistent when you are lying down.
Automatic Start	Enables device to begin treatment automatically within one minute of placing the device on your leg. When enabled, you do not need the app to start treatment.
Weather	When enabled, you will receive an alert when weather conditions may worsen your pain if your profile indicates weather sensitivity.

Electrode	Keep track of how many days have passed since you replaced your electrodes.
Calibration	Used to determine the optimal treatment stimulation level.
Sleep Position Tracking	Enables device to track certain 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.
Lights Out	Use if device 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 device 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.
Sleep Mode	This setting may only be used when Treatment Schedule is set to Low, Regular, or High.
Bedtime only	Treatment is only delivered while falling asleep.
Gentle overnight	Overnight treatment is delivered at reduced intensity. (Default setting)
Full power	Overnight treatment is delivered at daytime intensity.
Account	Create an optional Quell Health Cloud Account to backup your data and contribute de-identified data to fuel scientific research. 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.
Notifications	
Push Notifications	When enabled, you will get notifications with customized insights to exhance your Quell Fibromyalgia experience and to keep you updated on new features.
Electrode Replacement	When enabled, you will get a notification that it is time to replace your electrodes.
Rate My Fibromyalgia	When enabled, you will get a notification to remind you to rate your fibromyalgia symptoms every few days. Tracking your fibromyalgia symptoms helps uncover patterns and triggers.
Pairing	Shows the serial number of the device to which it is paired. To pair with a different device, tap Un-Pair.

Tracking

Fibromyalgia can decrease your quality of life and impact your sleep and activity levels. Your Quell Fibromyalgia device and app can track treatment usage, sleep, and fibromyalgia symptoms over time. This data can be viewed by day, week, month, or in 3 month periods. Reviewing this data over time can help improve your condition management by identifying patterns and triggers, and by improving communication with your doctor and other health care professionals.

Treatment Tracking - Your device will track the number of treatment sessions completed per day. For best results, use Quell Fibromyalgia daily. We recommend wearing Quell Fibromyalgia for a minimum of 3 treatment sessions per day. The more you use Quell Fibromyalgia, the better the chance of experiencing symptom relief.

Sleep Tracking - Fibromyalgia is a common cause of poor sleep, and insufficient sleep may worsen the condition. It is essential that you get as much high quality sleep as possible. Quell Fibromyalgia can help by decreasing your symptoms overnight and monitoring your sleep. Note: Sleep is only tracked when wearing the device overnight.

Symptom Severity Rating - You can review your symptom severity rating and see how severe symptoms have been and its impact on your sleep, activity, and mood in the last 7 days to track your treatment progress.

My Information

A profile can help Quell Fibromyalgia personalize your treatment. Your profile can include information including, gender, height, weight, worst symptoms, pain sites, and weather sensitivity. Weather sensitivity must be completed in order to receive Weather Alerts.

Rate My Fibromyalgia

Inputting your rating is useful to track your fibromyalgia symptoms over time. The app will ask you how would you describe the severity of your fibromyalgia symptoms and the impact on your life over the past 7 days.

Videos

View the Videos section of the app menu for useful videos about Calibration, Getting Started and more.

Support

The Support section of the app menu features NeuroMetrix contact info, device info, the Set up Assistant (repeat of onboarding guidance for putting on the device), important information statement and links to the Quell Fibromyalgia website.

Chapter 9

Maintenance

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. If you have any questions or need a different size, please contact Customer Care at 1-800-204-6577.

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 Fibromyalgia device to be free from defects in materials and workmanship at the time of shipment. The warranty guarantees against any out of box failures and warrants that the Products shall meet the Product Standard.

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. Quell products purchased from unauthorized resellers are not covered by this warranty.

To initiate a return, contact Customer Care at 1-877-903-2673.

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, 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 treatment or calibration in progress
Calibration	Double Blinking White Light	Calibration in progress
Treatment	Double Blinking White Light	Treatment session in progress
Stimulation halted earlier than expected	Orange Light Blinking Once Per Second	Treatment 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 (after picking up device)	Single Blinking White Light Once Every 3 Seconds	Battery has adequate charge to run treatment
	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 device and band are 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 tap the button labeled TAP HERE within the app. Do not wait until the sensation feels very strong to tap the screen. 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 treatment session because the sensation threshold will be artificially elevated. You should wait at least 1 hour and preferably 2 hours after a treatment session.

Treatment

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

I am not getting symptom relief.
We recommend that you **use Quell Fibromyalgia daily for at least 3 treatment sessions per day for the first month.** Make sure you feel a **strong but comfortable** sensation during treatment 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.

The treatment 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 (e.g., the electrode needs to be replaced). 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 treatment again. If the problem recurs, remove the device and inspect the electrode. Place the device back on the leg and restart the treatment 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 Treatment Schedule. If "Manual" is selected, you need to manually restart treatment. With any other selection (Regular, Low, or High Dose), treatment 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.

Treatment may also need to be manually restarted if your last treatment was manually stopped/halted, your last treatment was halted because of a trip condition, you calibrated your device since your last treatment, or you charged your device since your last treatment session.

The treatment 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 placing the band on 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 treatment 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 treatment, 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 by using the app, 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 treatment session, the habituation ramp is too steep for you. The device is designed to increase intensity throughout a treatment session to compensate for nerve habituation. For some people, this ramp is too steep, in which case the treatment intensity should be decreased during the treatment session. If you allow treatment to run the full 60 minutes, the device will remember the adjustment for future treatment sessions.

My device is pulsing at the end of treatment.

Pulsing serves as a reminder that you have been wearing the device on the same place for at least 5 hours. You should remove the device for 15-30 minutes 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 treatment 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 treatment. 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 treatment, the device will restart at normal intensity.

The device is waking me up when treatment 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" or "Bedtime Only" 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 treatment 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., device 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 another charger other than the one provided with Quell Fibromyalgia, i.e., a cell phone charger, isn't advisable. Only use the cable and charger that was provided with your device to ensure proper charging.

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 treatment 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 Fibromyalgia?
You should use Quell when you are experiencing symptoms. 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 Fibromyalgia for at least 3 treatment sessions per day for the first month.** A treatment session (also called treatment hour) represents 1-hour of continuous stimulation. Therefore, the recommended minimum of 3 treatment sessions per day is equivalent to 3-hours of daily stimulation. To limit skin irritation or hypersensitivity, please first refer to Chapter 7 (Skin Care) if you plan to use Quell for long periods of time (e.g., more than 5 hours). Daily use of the device should not exceed 8-hours of stimulation and 15-hours of wear. The safety and effectiveness of the device when used for more than 8 treatment hours per day is not well characterized.

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 treatment sensation becomes uncomfortable/too strong.

Do I need to calibrate the device before each treatment 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 Fibromyalgia is designed to be worn on the upper calf.

How long will it take to experience relief?
We recommend using Quell Fibromyalgia for at least 3 treatment 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 treatment 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. 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. The first day of use with the electrode can be indicated on the app so it will automatically remind you when to replace your eletrode.

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. If you experience skin irritation, please contact Customer Care at 800-204-6577.

Can I use it with pain medications?
Speak to your doctor about your medication use in conjunction with Quell Fibromyalgia.

Can multiple people share the device?
No. The device is calibrated for one person and should not be shared.

Can I use Quell Fibromyalgia while sleeping?
Yes.

What does device do while I am sleeping?
It starts 60 minute treatment sessions every other hour throughout the night to help control your symptoms. You may also change the default behavior under the app Sleep Mode menu.

Do I need to set up device differently for sleep use?
No, but you may choose from 3 sleep setting options.

What if I only want a single 60 minute treatment 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 treatment session by tapping Start Treatment within the app.

Will wearing device 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 Fibromyalgia 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 approximately 3 hours when connecting to the charging adaptor plugged into a wall outlet.

How long should the battery last?
Battery life is heavily dependent on your particular treatment intensity and frequency of use but a fully charged battery can last **up to 25 treatment 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 out of box 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 treatment.

APPENDIX E

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 (±5%)	118V[1]
Maximum Output Current (<1KΩ load) (±10%)	100 mA
Pulse Duration	280 µsec (includes inter-phase delay)
Pulse Frequency (±4%)	60-100 Hz, randomly varying, 30-50Hz randomly varying, or 120-200Hz randomly varying
Pulse Pattern	Continuous
Maximum Phase Charge	18 µC
Maximum Current Density (r.m.s.)	0.76 mA/cm^2 into 500Ω load
Maximum Average Current	4.5 mA into 500Ω load
Maximum Average Power Density	8 mW/cm^2 into 500Ω load
Maximum Pulse Energy (pulse duration <0.1s)	3.3 mJ per pulse

Output Trips	
No Load	Device not connected to patient. Purpose of trip condition is to prevent potentially unsafe stimulation with maximum output voltage.
Insufficient Charge	Charge delivered during stimulation below target. Purpose of trip condition is to prevent stimulation that may be sub-therapeutic.
Over Load	Charge delivered during stimulation above target. Purpose of trip condition is to prevent potentially unsafe stimulation.
Electrode Peel	Electrode dislodging from skin. Purpose of trip condition is to prevent potentially unsafe stimulation due to small electrode area resulting from unrecognized electrode peeling such as during sleeping.
Low Battery	Insufficient battery charge to start (<10%) or continue (≤5%) stimulating. Purpose of trip condition is to prevent treatment from starting or continuing if battery charge is low, and ensure that sufficient charge remains for device to operate reliably in standby mode.

[1] Typical maximum voltage is 118V; with expected tolerance maximum 121V.

User Interface	
Tap	Ability to recognize double-tap to enclosure for stimulation halt
Mobile App	Control to calibrate, start treatment, stimulation halt, and intensity adjustment
USB	Micro USB B socket for charging
LEDs	1 white, 1 orange
Bluetooth®	Device supports Bluetooth LE 4.2

Electrode	
Type	Cutaneuos electrode, disposable, single-patient use
Materials	Conductive hydrogel, PET, silver
Number of Electrodes	Four pads, configured as two electrically connected pairs
Connector	Male snap
Dimensions	Skin contact area: 33cm^2 inner pair, 28cm^2 outer pair Exterior: 0.2 cm x 5.3 cm x 28.3 cm

Power	
Source	Permanent rechargeable battery
Battery Type	Rechargeable 3.7V Lithium-Ion battery
Charging Source	AC line adapter - Manuf: Shenzhen Dapter Electronic Science Co., LTD.; Model #: KA25-0501000US; Voltage: Input 100-240V~ Output: 5V; Frequency: 50/60Hz; Rated Power: 5 watts
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)	32 g

Environmental	
IP Classification	IP22 (placed inside the band)
Operating	
Temperature Range	5° C to 35° C^2
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 60601-1-11; IEC 60601-2-10
Other	ISO 10993-1; CISPR 11; ETSI EN 301-489-1, -17

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

APPENDIX F

Precautions and Warnings

Indications

Quell Fibromyalgia is a transcutaneous electrical nerve stimulation (TENS) device indicated as an aid for reducing the symptoms of fibromyalgia in adults with high pain sensitivity. The device may be used during sleep. The device is labeled for use only with compatible NeuroMetrix electrodes.

The sale, distribution, and use of Quell Fibromyalgia are restricted to prescription use in accordance with 21 CFR 801.109.

Many participants in the clinical study were also taking medication for fibromyalgia and it was difficult to assess the effects of the device compared to medication.

Contraindications

The device is contraindicated for use by patients who have a cardiac pacemaker, implanted defibrillator, other implanted electronic device, or implanted metal near the device, because this may cause electric shock, burns, electrical interference, or death.

The stimulation electrodes should not be placed 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.

The device cannot be used while driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.

Precautions

- Federal Law restricts this device to sale by or on the order of a physician.
- If you are experiencing uncomfortable stimulation and cannot control the device via your mobile app then stop stimulation immediately by double-tapping the enclosure and remove the device.
- 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.
- Fibromyalgia is believed to be, at least partially, a central nervous system condition resulting from central sensitization and deficient descending pain inhibition. TENS has not been demonstrated to be effective for other pain conditions of central origin, including headache.
- TENS is not a substitute for pain medications and other pain management therapies.
- TENS devices have no curative value.
- TENS 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.
- Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians; and
- Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
- The device is MR Unsafe and should not be used in a magnetic resonance imaging environment. The device presents a projectile hazard.

Adverse Reactions

- You may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.
- You should stop using the device and should consult with a physician if you experience adverse reactions from the device.

Warnings

- Do not place the stimulation electodes 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 treatment has stopped. Check that the light is not illuminated on device, otherwise you may experience an uncomfortable sensation when you remove the device.
- Do not use the device if it has been accidentally damaged, causing the housing to come open, or an unexpected shock may result.
- Do not apply stimulation over the neck because this could cause severe muscle spasms resulting in airway closure, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation across the chest, because the introduction of electrical current into the chest may cause heart rhythm disturbances, which could be lethal.
- 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.
- 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.
- Keep this device out of the reach of children.
- Daily use of the device should not exceed 8-hours of stimulation and 15-hours of wear. The safety and effectiveness of the device when used for more than 8 treatment hours per day is not well characterized.

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

℞Only

Caution: Federal (US) law restricts this device to sale by or on the order of a physician.

MR Unsafe

IP22

IEC 60529/Degrees of protection provided by enclosures (IP Code).
Rating only applies when Quell Device is worn inside of provided band

APPENDIX H

Electromagnetic Compatibility Declaration

Quell Fibromyalgia 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	Device 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	Device 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 Fibromyalgia 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 device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
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,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 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 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 Fibromyalgia Device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 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 modifcations 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 Fibromyalgia 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 Fibromyalgia device and the Smartphone is via Bluetooth.

Disabling Bluetooth

If Bluetooth is disabled on your smartphone or tablet, then the Quell Fibromyalgia app will not function. Your 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

APPENDIX K

Summary of Clinical Information

Clinical Information from FDA Decision Summary to be provided when published.

Quell
Fibromyalgia

200 Forge Way, Suite 205
Rockaway, NJ 07866
(877) 903-2673
www.quellfibromyalgia.com