Quell Fibromyalgia™

USER MANUAL

℞ Only

Contents

Chapter 1

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 that attaches to an electrode worn on a leg band. The Quell Fibromyalgia app is used to control and customize treatment. The device may be worn during sleep and is labeled for use only with compatible NeuroMetrix electrodes.

Quell Fibromyalgia is available by prescription only.

Federal law restricts this device to sale by or on the order of a health care provider.

Contraindications

Do not use Quell Fibromyalgia if:

- You have a cardiac pacemaker, implanted defibrillator, other implanted electronic device, or implanted metal near the device. This may cause risk of electric shock, burns, interference, or death.
- 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.

⚠ Warnings

Placement and Application

- Do not place electrodes across or through the head, directly on the eyes, covering the mouth, on the front of the neck, on the chest or upper back, or across the heart.
- Do not apply stimulation over open wounds, rashes, over swollen, red, infected, or inflamed areas, or over skin eruptions (e.g., phlebitis, thrombophlebitis, or varicose veins).
- Do not apply stimulation near or over cancerous lesions.
- Apply stimulation only to normal, intact, clean, healthy skin.
- Do not remove the device before treatment has stopped. Confirm that the indicator light is off before removing to avoid discomfort.

Situations to Avoid

- Do not use the device while bathing, showering, driving, operating machinery, or during activities where electrical stimulation could create a risk of injury.
- Do not apply stimulation over the neck (risk of airway closure, breathing difficulty, or adverse effects on heart rhythm and blood pressure).

- Do not apply stimulation across the chest. Electrical current into the chest may cause a risk of heart rhythm disturbances, which could be life-threatening.
- Do not use the device if it has been damaged or the housing has opened, as unexpected shock may result.
- No modification of the device is allowed.

Medical Risks and Equipment Interference

- Simultaneous connection to high-frequency surgical equipment may cause burns at the electrode sites and damage the stimulator.
- Operation near shortwave or microwave therapy equipment (within ~1 meter) may cause output instability.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may malfunction during stimulation.
- Use caution if you have a tendency to bleed internally (e.g., after injury or fracture).
- Consult your health care provider before use after recent surgery, as stimulation may disrupt healing.

Age and Usage Limits

- Do not use the device on children under 18 years old.
- Keep the device out of reach of children.
- Daily use should not exceed 8 hours of stimulation and 15 hours of wear. The safety and effectiveness of use beyond these limits has not been established.

⚠ Precautions

- If stimulation becomes uncomfortable and you cannot stop it through the mobile app, double-tap the device enclosure to stop stimulation, then remove the device.
- You may experience skin irritation or hypersensitivity from the electrical stimulation or electrode gel.
- Use caution when applying stimulation to areas of skin that lack normal sensation.
- Use this device only with NeuroMetrix-recommended electrodes and accessories.
- Quell Fibromyalgia is intended specifically for fibromyalgia, which is believed to be linked to central sensitization and reduced pain inhibition. TENS has not been shown to be effective for other central-origin pain conditions, such as headache.
- TENS is not a substitute for pain medications or other pain management therapies.
- TENS devices provide symptom relief only; they have no curative value.
- TENS is a symptomatic treatment. It suppresses pain sensations that would otherwise serve as protective signals.
- The long-term effects of electrical stimulation are unknown.
- Because the effects of brain stimulation are unknown:
    - Do not apply stimulation across the head.
    - Do not place electrodes 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 their health care provider's recommendations before using the device.
- Patients with suspected or diagnosed epilepsy should follow their health care provider's recommendations before using the device.
- The device is MR Unsafe and must not be used in a magnetic resonance imaging (MRI) environment, as it presents a projectile hazard.

Adverse Reactions

Some users may experience skin irritation or burns beneath the electrodes.

Patients should stop using the device and should consult with a health care provider if they experience adverse reactions from the device.

How Quell Fibromyalgia Works

Quell Fibromyalgia provides symptom relief by stimulating sensory nerves in your calf. These nerves send signals to the brain that trigger a natural response to reduce fibromyalgia symptoms. Treatment sessions are started through the Quell Fibromyalgia app on your smartphone. Each treatment lasts 60 minutes, and after your first session, treatments will automatically restart every other hour.

Recommended Use

You should use Quell Fibromyalgia whenever you are experiencing symptoms. Typically, the device is worn on the leg for about 5 hours, consisting of three 60-minute active sessions and two 60-minute break sessions. For best results, use it daily.

To limit skin irritation during extended use (more than 5 hours), refer to Chapter 6: Skin Care. Daily use should not exceed 8 hours of stimulation and 15 hours of wear. The safety and effectiveness of using the device for more than 8 hours of stimulation per day have not been established.

If you have any questions about how to use Quell Fibromyalgia, please call Customer Experience at 888-903-2673 or email us at customerservice@electrocore.com.

What's Included

Upon receiving your Quell Fibromyalgia Starter Kit, please check the contents to ensure all of the following items are included:

Device

Band

Electrode Pack*
(packaging may vary)

USB Cable

AC Adapter
(Adapter may vary)

Quick Start Guide

Electrode Care Tips

* 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 set up instructions in the app to pair your device and set up your Quell Health Cloud account while your device is charging. Please note that signing up for a Quell Health Cloud account is voluntary and your device will function fully without an account.
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. We recommend charging the device for 20–30 minutes each day.

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.
3. Connect the AC adapter to a standard electrical outlet.

When charging begins, the white indicator light will turn on.

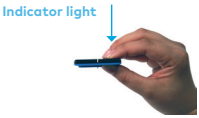
- A solid white light means the battery is fully charged.
- Charging an empty battery takes about 3 hours.
- Once fully charged, unplug the cable from the device.

NOTE: Only use the cable and AC adapter provided with your device to ensure proper charging.

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

If the orange light blinks while the device is connected to the outlet, charging has failed. Call Customer Experience at 888-903-2673. If the battery is too low to start a treatment session (<10%), charge the device for approximately 20 minutes to provide enough battery life for one treatment session.

Checking the Battery



To check the battery level, 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

To begin, download the Quell Fibromyalgia app from the App Store (iOS) or Google Play (Android) by searching "Quell Fibromyalgia." Once the app is installed, open it and follow the on-screen instructions to pair your device. Make sure your device is fully charged before completing setup and calibration (see Chapter 3 for details).

Download on the App Store

GET IT ON Google Play

Before setup, confirm the following on your smartphone:

- Bluetooth® is turned on.
- Your device is running iOS 14 or later or Android 8 or later.

NOTE: Creating a Quell Health Cloud account is voluntary and is not required for your Quell Fibromyalgia device to work. 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 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 towards the top. 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

1. 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 additional electrodes inside. Improper storage of electrodes will reduce their life.
2. Only use Quell electrodes manufactured by NeuroMetrix, Inc.
3. 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.
4. Remove the liner covering the electrode prior to placing the device on your leg. Remember to save the liner as it should be reapplied 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 matte side doesn't stick to the gel.
5. 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

1 Choose placement location

- Place the band on your upper calf, about 1–2 inches below the knee. You can use either leg.
- Do not place the device directly over your shinbone.

2 Check skin condition

- Only place the electrode on healthy skin.
- Avoid areas with cuts, irritation, or wounds.

3 Adjust device position

- You may place the device on the inside, outside, or back of the leg. It should feel comfortable.
- If the standard location does not work, see below for alternate sites.

4 Secure the band

- Wrap the band around your leg and fasten with the Velcro® end.
- The band should feel snug but comfortable.

5 Ensure electrode contact

- The electrode should lie flat and smooth against the skin.
- Make sure all four electrode pads are fully touching the skin.
- If any pads lift or buckle, smooth them down and re-secure the band.

Note: If the electrode pads are not fully on the skin, stimulation may feel uncomfortable, or the device may not start treatment.

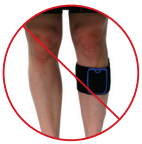
The band was designed to stretch and fit most legs. If the band does not fit your leg, contact Customer Experience at 888-903-2673 for information on how to get a small or large band.

Recommended Positioning On Leg

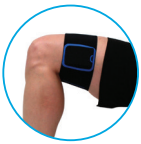
Outside of Calf | Back of Calf | Inside of Calf

Avoid Positioning

Front of Shin



If you are unable to place your Quell Fibromyalgia device in the recommended location just below the knee, for example, if you have a wound or skin irritation, you may use one of the following alternate placement sites:



Above the knee or lower thigh

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

Chapter 3

Calibration

Before using your device for the first time, you must complete the calibration process. Begin by watching the Calibration video in the Quell Fibromyalgia app. Use caution when applying stimulation to areas of skin that lack normal sensation.

Calibration teaches the device your sensation threshold so it can deliver a stimulation level tailored to you. During calibration, the device will gradually increase stimulation several times to measure this threshold.

Once calibration is complete, you're ready to start your first treatment session. You can recalibrate your device at any time through the app if needed.

For best results, sit in a quiet place where you can focus, with your feet flat on the floor. If you experience neuropathy or paresthesia in one leg, we recommend calibrating the device on the opposite leg to help prevent the treatment from feeling too intense.

The first time you use the app, you will automatically be prompted to calibrate. To recalibrate later, open the app, tap the menu icon, and go to Settings > Calibration.

During calibration:

- Review the instructions on the "How to Calibrate" screen and tap Start Calibration.
- When you feel the slightest tingle under the electrode, immediately tap the TAP HERE button in the app.
- This may take 20–30 seconds the first time and may feel very light.
- Do not wait for the sensation to feel strong.
- Subsequent stimulations will be felt more quickly.
- If you need to stop at any point or feel that you have made a mistake, tap the "Stop Calibration."

When calibration is complete, the app will display Calibration Success. Your treatment intensity will then be set to the optimal level. During actual treatment, stimulation will feel stronger than during calibration, but should always be comfortable.

Chapter 4

Treatment

The experience of fibromyalgia is different for everyone. Please be patient, as it may take several weeks of consistent use before you start to experience symptom relief. You should use Quell Fibromyalgia whenever you are experiencing symptoms, but for best results, use Quell Fibromyalgia daily.

A treatment session lasts 60 minutes of continuous stimulation. The device will automatically start a new session every other hour unless you change this setting in the app. We recommend completing at least 3 treatment sessions per day (3 hours total). There is no need to remove the band from the leg between treatments. For extended use (more than 5 hours), please refer to Chapter 6: Skin Care to help reduce the risk of skin irritation. Daily use should not exceed 8 hours of stimulation and 15 hours of wear. The safety and effectiveness of use beyond these limits have not been established.

During a session, Quell Fibromyalgia gently stimulates the nerves in your leg to help reduce symptoms. For best results, you should feel a strong but comfortable sensation. The initial intensity level is estimated during calibration, but because each person is different, it may feel too weak or too strong. If needed, adjust the intensity in the app. The greatest relief is typically achieved at the highest comfortable intensity.

Any changes made to intensity during the first 10 minutes of a session will be remembered by the device if the session is completed successfully. This means you should not need to adjust intensity often.

Below, you will find step-by-step instructions for starting a treatment session.

Preparing for a Treatment Session

Before starting a treatment session, make sure an electrode is securely attached to the device. Check the battery to confirm it has enough charge. If the indicator light is blinking white, the device has sufficient power for a session. Once ready, 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 on the app. Once the session begins, the indicator light will blink white for the duration of the treatment session.

Automatic Start

You can choose to have treatment start automatically when the device is placed on your leg. To enable this feature, open the app and go to the Dashboard. Tap the Automatic Start icon (the letter "A" in the top left corner) and select Enable. You can also turn this feature on by going to Settings and then Treatment Automation.

Once enabled, treatment will begin automatically within one minute of placing the device on your leg. You will no longer need to start sessions manually in the app.

To stop a treatment at any time, either tap the STOP button in the app or double-tap the device firmly with your fingers.

What Treatment Feels Like

At the start of a session, the intensity gradually increases over the first 2 minutes to a level that is strong but comfortable based on your calibration. The sensation may feel strong at first, but usually settles after a few minutes. If it feels uncomfortable, lower the intensity in the app.

Each treatment session lasts 60 minutes. You may cover the device with clothing, but try not to disturb it. You can continue normal activities during treatment, but do not shower, bathe, or swim while wearing the device.

Adjusting Intensity During a Treatment Session

The stimulation intensity can be set anywhere from 0 to 100 milliamps (mA) and changes in 0.5 mA steps. Most users won't need to adjust often, but if the sensation feels too weak or uncomfortable, you can change it using the app.

On the Dashboard screen in the app:

- Tap "+" to increase intensity. Each tap raises the level slightly (about 1–2%).
- Tap "–" to decrease intensity. Each tap lowers the level by about 5%.

You can adjust intensity at any time during a treatment session. For best results, aim for the highest intensity that still feels comfortable. If you notice you're adjusting frequently, consider recalibrating your device to reset the baseline.

Ending a Treatment Session

Regular treatment sessions run automatically for 60 minutes on, 60 minutes off. You don't need to take the device off during the one-hour break between sessions. Once treatment begins, it will automatically start and stop every other hour until you turn it off. You can stop a session anytime by tapping the STOP button in the app or by double-tapping the device firmly with your fingers while keeping your leg still.

NOTE: Turn the device off, and wait until the white indicator light stops blinking before removing the device or electrodes to avoid discomfort.

After a session, you may leave the device on or remove it. If removing, handle the electrode carefully and reapply the liner (see page 14) so it doesn't dry out. To prevent skin irritation, check your skin regularly, air it out for 15–30 minutes after 5 hours or after overnight use, or switch legs.

If an issue occurs, the device will stop automatically, and the orange light will blink for 2 minutes. The app may also display a message that the session has halted. See Appendix B for troubleshooting.

After 5 hours of daytime wear, the device will briefly pulse to remind you to check your skin.

Personalizing Treatment

Treatment can be personalized in the app to fit your needs. In the Settings menu, you can adjust options such as Treatment Schedule and Treatment Automation. Any changes you make will apply starting with your next treatment session.

Overnight Treatment

You can use Quell Fibromyalgia at bedtime and while you sleep. Before going to sleep, make sure the device is secured comfortably on your leg and that the electrode pads are in full contact with your skin. Start a treatment session in the app.

The default sleep setting is "Gentle Overnight." In this mode, the first session runs at your regular intensity, and additional sessions automatically restart every other hour through the night at a reduced intensity. Device auto-returns to daytime intensity in the morning. To avoid skin irritation, remove or switch legs after waking.

Other Sleep Mode options are available in the app under Settings. Any changes you make will take effect at the start of your next overnight session.

Chapter 5

Electrodes

A Quell Fibromyalgia electrode is designed to work consistently for up to 2 weeks. Over time, the gel may peel or dry out, reducing adhesion, but the electrode can still be used until replacement is needed.

Electrode Removal

- Ensure the device is turned off.
- Peel the electrode off your calf slowly to avoid damaging it.
- Make sure the gel pads stay attached to the electrode as you remove it.
- Avoid touching the gel with your fingers, as this can damage it and shorten electrode life.
- After removal, cover the electrode with the liner.

If removal is difficult, see Chapter 6: Skin Care for tips.

Electrode Storage

Always store an electrode with the liner covering the gel pads. Place the liner with the graphic side up so the paper doesn't stick to the gel.

- For short-term storage, you may leave the electrode snapped into the device.
- For long-term storage, keep electrodes in the pouch or a sealed bag at room temperature, away from direct sunlight.

Electrode Replacement

Because the gel pads on the electrode are mostly water, normal wear may include:

- Irregular edges
- Color fading
- Gel spreading
- Exposed silver traces

Replace the electrode if:

- Stimulation feels uncomfortable or painful despite proper placement, or
- The orange error light blinks when starting treatment.

Even without issues, an electrode should be replaced every 2 weeks for optimal comfort and performance. You can set a replacement reminder in the app.

For questions or replacement electrodes, contact Customer Experience at 888-903-2673.

Electrode Options

- Quell Standard Electrodes (included in the Starter Kit) are optimized for daily use year-round. They provide consistent, comfortable stimulation and last about 2 weeks with normal use.
- Quell Sport Electrodes are designed for humid conditions or heavy perspiration. The gel absorbs less moisture but otherwise works the same as the Standard Electrodes.

Chapter 6

Skin Care

Quell Fibromyalgia works by stimulating sensory nerves in your upper calf through the skin. Because some people have dry or sensitive skin, it's important to regularly check the area under the electrode to prevent irritation. Using the device on irritated skin may be uncomfortable.

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

Preventing Skin Irritation

Air out your skin: After 5 consecutive hours of daytime wear or after overnight use, remove the device and allow your skin to breathe for 15–30 minutes.

- You may also switch the device to the other leg every 5 hours or upon waking.
- After 5 hours of daytime wear, the device will briefly pulse to remind you to air out your skin.

Start slowly: If you have sensitive skin, limit wear time during the first week. If no irritation occurs, gradually increase use while monitoring your skin.

Signs of Skin Irritation

- Itching while the device is on or after removal.
- Redness where the electrode was placed.
- Raised or reddened hair follicles.

If Skin Irritation Occurs

- Do not place the device over the irritated area until it fully heals.
- A topical steroid cream may help reduce irritation and speed healing.
- Try using the device on the other leg or at alternate locations. See Device Placement (page 8) for alternate sites.
- Limit use for about one week to prevent further irritation.

Chapter 7

Maintenance and Safety

Maintenance

- Quell Fibromyalgia has no user-serviceable parts. If your device stops working, contact Customer Experience at 888-903-2673.

Device Cleaning

- Wipe the exterior with a damp cloth.
- Do not use cleaning solutions or immerse in water/liquids, as this may damage the device.

Band Cleaning

- Remove the device before washing.
- Handwash the band with gentle detergent and let it air dry.
- If the band becomes stretched, it may be placed in a gentle dryer cycle (make sure Velcro® is fastened before drying).
- For sizing questions or replacement bands, contact Customer Experience at 888-903-2673.

Device Storage

- When not in use, store the device in a dry location away from direct sunlight.

Disposal

- Used electrodes can be disposed of in regular household trash.
- The device contains a lithium-ion battery and must be disposed of in accordance with local, state, and national regulations.

Limited Warranty

NeuroMetrix, Inc. warrants the Quell Fibromyalgia device to be free from defects in materials and workmanship at the time of shipment. This warranty covers out-of-the-box failures and ensures that the product meets established standards. It does not cover damage caused by accident, abuse, misuse, improper electrical power, failure to follow product instructions, lack of required maintenance, or the use of parts or components not supplied by NeuroMetrix. In addition, products purchased from unauthorized resellers or altered by anyone other than NeuroMetrix or an authorized representative are not covered under this warranty.

NeuroMetrix will, at its discretion, replace the product once it has been returned under a NeuroMetrix-issued Return Material Authorization (RMA). To initiate a return, customers must contact Customer Experience at 888-903-2673. NeuroMetrix makes no warranties beyond those stated in this warranty statement and expressly disclaims all other warranties, express or implied, including, without limitation, any implied warranties of merchantability or fitness for a particular purpose. NeuroMetrix's liability is strictly limited to the replacement of defective products under the terms of this warranty, and under no circumstances will NeuroMetrix be liable for special, incidental, or consequential damages arising from the use of the device.

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 Customer Experience at 888-903-2673.

APPENDIX B

Troubleshooting

Category	Problem	Solution
Calibration	**Don't feel anything during calibration**	Confirm liner is removed and light is blinking. Wait 20–30 seconds and tap at the first tingle. Do not wait for a strong sensation. If no sensation is ever felt, intensity defaults to maximum.
Treatment	**Treatment stopped; light blinking orange**	Check electrode contact: snapped on, gel pads flat, band snug. Restart session. Replace electrode if issue repeats.
Treatment	**Device not auto-restarting**	Select Regular, Low, or High Dose under Treatment Schedule. Restart manually if previous session was stopped, device was calibrated, or device was charged.
Treatment	**Treatment stings/uncomfortable**	Stop session. Inspect or replace electrode. Moisturize skin 20–30 minutes before use. Reapply band smoothly. Recalibrate if needed.
Treatment	**Leg cramps or soreness**	Lower intensity or recalibrate. Try the other leg. Reposition away from back of calf. Avoid compression against bed.
Treatment	**Device pulses at the end of treatment**	Remove device for 15–30 minutes or switch legs. Pulsing continues after each session until device is removed. Does not pulse during overnight wear.
Sleep	**Device doesn't restart in the morning**	Ensure electrodes are attached; wait up to 60 minutes. If Sleep Mode was Bedtime Only, restart manually.
Electrodes	**Gel dry/losing stickiness**	Electrode is still usable; band maintains contact. Replace at 2 weeks and store properly when not in use.
Electrodes	**Gel spreading/coming off**	Electrode is usable if comfortable and no persistent orange light. Loosen the band, store the device in a cool dry place, remove when not in use, or consider Sport Electrodes.
Electrodes	**Lost electrode liner**	Use wax paper or place electrode in a flat plastic bag with gel facing outward. Do not let pads touch.
Charging	**Device not charging**	Confirm the wall outlet is on. Use only provided cable/adapter. Do not use computer USB ports or phone chargers.
Charging	**No flashing light while charging**	Allow the device to charge for 20 minutes until the white light flashes.
Charging	**Flashing orange light while charging**	Contact Customer Experience at 888-903-2673.

If you are still experiencing a problem,
please call Customer Experience at 888-903-2673.

APPENDIX C

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/cm2 into 500Ω load
Maximum Average Current	4.5 mA into 500Ω load
Maximum Average Power Density	8 mW/cm2 into 500Ω load
Maximum Pulse Energy (pulse duration <0.1s)	3.3 mJ per pulse

Output Trips	
No Load	Device not connected to patient. The purpose of the trip condition is to prevent potentially unsafe stimulation with maximum output voltage.
Insufficient Charge	Charge delivered during stimulation below target. The purpose of the trip condition is to prevent stimulation that may be sub-therapeutic.
Overload	Charge delivered during stimulation above target. The purpose of the trip condition is to prevent potentially unsafe stimulation.
Electrode Peel	Electrode dislodging from skin. The purpose of the 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. The purpose of the trip condition is to prevent treatment from starting or continuing if the battery charge is low, and ensure that sufficient charge remains for the 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 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 (41° F to 95° F)
Atmospheric Pressure Range	70 kPa to 106 kPa
Relative Humidity Range	15% to 93%
Transport and Storage	
Temperature Range	-25° C to 70° C (-13° F to 158° F)
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 D

Symbols

	Expiration date		Follow operating instructions
	Lot number		Manufacturer
	Catalog number / Reference number	IP22	IEC 60529/Degrees of protection provided by enclosures (IP Code). Rating only applies when Quell Device is worn inside of provided band
	Electric shock hazard		Type BF applied part
	Serial number		Storage temperature
	Non-sterile	**X26YYYYY** (on packaging label)	Date of Manufacture on package label, where "26" is the year of manufacture, e.g. 82600001 indicates the year of manufacture is 2026
	**WARNING**: Failure to follow instructions may result in serious injury or death to the patient or user		Non-ionizing electromagnetic radiation
	**PRECAUTION**: Failure to follow instructions may result in damage to the equipment or degradation in the quality of treatment		Magnetic resonance unsafe
	Refer to user manual		Keep away from sunlight
	Information or additional information available		Do not use if package is damaged
	Separate collection for waste of electrical and electronic equipment		Medical device
	Date of Manufacture		Keep dry

APPENDIX E

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 Fibromyalgia 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 F

FCC

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

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

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

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.

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

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

FCC RF Radiation Exposure Statement

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

FCC ID: XUL-QUELL2-0

APPENDIX G

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 H

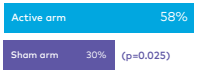
Clinical Summary

Quell Fibromyalgia was studied in a double-blind, randomized, sham-controlled trial.[1]

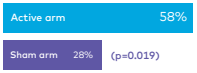
- 119 subjects with physician-diagnosed fibromyalgia.
- Subjects were randomized to active (N = 62) or sham (N = 57) treatment for 3 months and used their device for at least 2 hours per day.
- Analyses were conducted on the intention-to-treat population (ITT, N=119) and a prespecified high pain sensitivity subgroup (N=60). The primary endpoint was a statistically significant mean difference in the 3-month Patient Global Impression of Change (PGIC[2]) scores between the treatment arms.

The trial did not meet the primary endpoint in the ITT population. However, the primary endpoint was statistically significant in the high pain sensitivity subgroup. This is the patient population for which the FDA granted De Novo authorization.

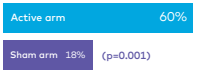
Key Study Results (in high pain sensitivity subgroup)



58% of subjects in the active arm compared to 30% in the sham arm (p=0.025) reported at least moderately better symptoms and overall quality of life.[2]



58% of subjects in the active arm compared to 28% in the sham arm (p=0.019) reported a clinically meaningful reduction (≥15%) in fibromyalgia impact.[3]



60% of subjects in the active arm compared to 18% in the sham arm (p<0.001) reported at least a moderate reduction (≥30%) in pain intensity.[4,5]

1. Jamison RN, Curran S, Wan L, Ross EL, Gilligan CJ, Edwards RR. Higher Pain Sensitivity Predicts Efficacy of a Wearable Transcutaneous Electrical Nerve Stimulation Device for Persons With Fibromyalgia: A Randomized Double-Blind Sham-Controlled Trial. Neuromodulation. 2022 Dec;25(8):1410-1420. doi: 10.1111/ner.13463. Epub 2022 Jun 14. PMID: 34056781.
2. PGIC, patient global impression of change. Subject responds to the question "Since beginning treatment at this clinic, how would you describe the change (if any) in activity limitations, symptoms, emotions and overall quality of life, related to your painful condition?" using a 7-point categorical scale that ranges from (1) "no change or condition has gotten worse" to (7) "a great deal better and a considerable improvement that has made all the difference."
3. Fibromyalgia Impact Questionnaire (FIQR) total score.
4. Fibromyalgia Impact Questionnaire (FIQR) pain item.
5. The assessment of pain intensity was not anatomically specific and therefore it was not possible to determine the locations of pain relief. A conservative consensus view of transcutaneous electrical nerve stimulation is that pain relief occurs in the dermatomal distribution of the stimulated nerves. Therefore, the primary area of pain relief should be assumed to be the ipsilateral lower extremity.

Notes

Notes

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Quell Fibromyalgia User Manual

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