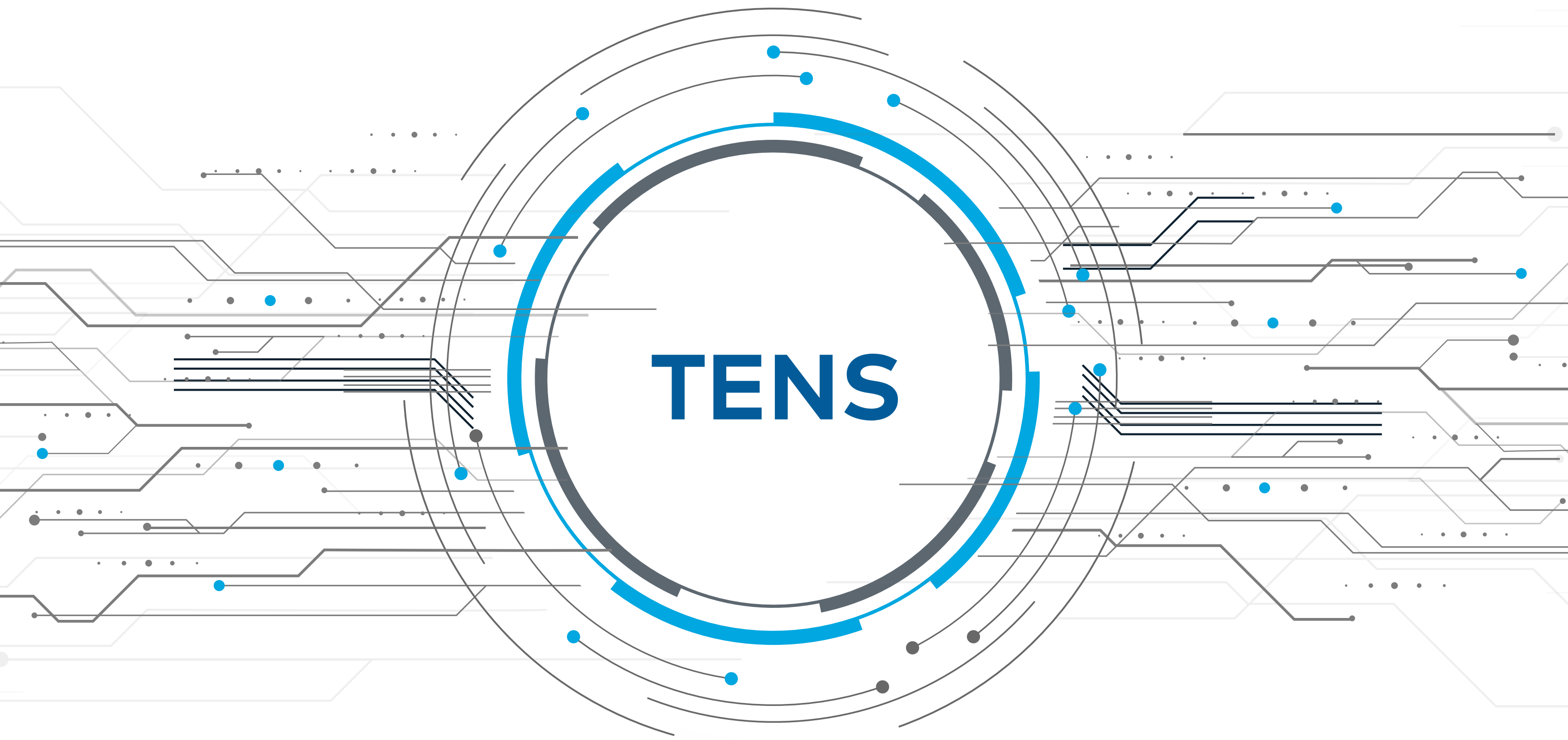
# Under THE HOOD

A Series Exploring How Transcutaneous Electrical Nerve Stimulation Devices Work




Quell®

Wearable Pain Relief Technology™

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TABLE OF

# CONTENTS

# INTRODUCTION

In this ebook, we explore how TENS (Transcutaneous Electrical Nerve Stimulation devices work. Our intention is to go “under the hood” of these valuable pain relief devices to help you understand their operation, and we will explore key technical specifications and operating principles. We hope this information is useful when deciding on a TENS device for your particular needs.

# MAXIMUM
# VOLTAGE

In this chapter we address one of the most important technical attributes of a TENS device, **maximum voltage**, and why it's important for obtaining effective pain relief.

## Nerve stimulation

TENS provides pain relief by passing an electric current between electrodes placed on the skin. The current flows across the skin underneath the electrodes and through the body where it stimulates nearby nerves. This current initiates nerve impulses, called **action potentials**, that travel to your spinal cord and brain to activate a complex neurological circuit that produces pain relief.

## Why maximum voltage matters?

How does a TENS device produce the stimulation current? Although the flow of current through the electrode and skin is complex, the basic concept can be understood using Ohm's law that you may remember from high school physics:

**Voltage** = Current x Resistance

Resistance is the tendency of your skin to impede electric current. Dry skin has a higher resistance than hydrated skin because the dry skin acts as a barrier to current flow. Ohm's law tells us that as the resistance increases more voltage is required to generate the same current.

Most people need between 15 and 50 milliamps (a milliamp is 1000th of an amp) for a strong but comfortable stimulation to produce pain relief. Let's assume you need 25 milliamps and have healthy and well hydrated skin and therefore a resistance of 1000 ohms. Well then you need (25/1000 x 1000) = 25 volts, which most OTC TENS devices can provide.

But what if you need 50 milliamps for pain relief and have dry skin with a resistance of 2000 ohms? Now you need (50/1000*2000) = 100 volts. Few OTC devices can generate such a high voltage. A larger maximum voltage can be critical, providing flexibility for cases needing higher stimulation current and having greater skin resistance.

## Differences among TENS devices

Portable TENS devices are powered by small batteries that only provide a few volts; for example, 2 AA batteries create 3 volts. Therefore, the devices must boost the low battery voltage to a high nerve stimulation voltage, requiring a specialized electronic circuit.
Basic TENS devices have simple circuits that typically generate no more than 40-60 volts. Prescription devices may provide 100 volts. Quell® has an advanced stimulation circuit based on a proprietary neurostimulation microchip that reliably generates up to 120 volts, which is 2-3 times higher than most OTC TENS devices.

# STIMULATION
# PULSE

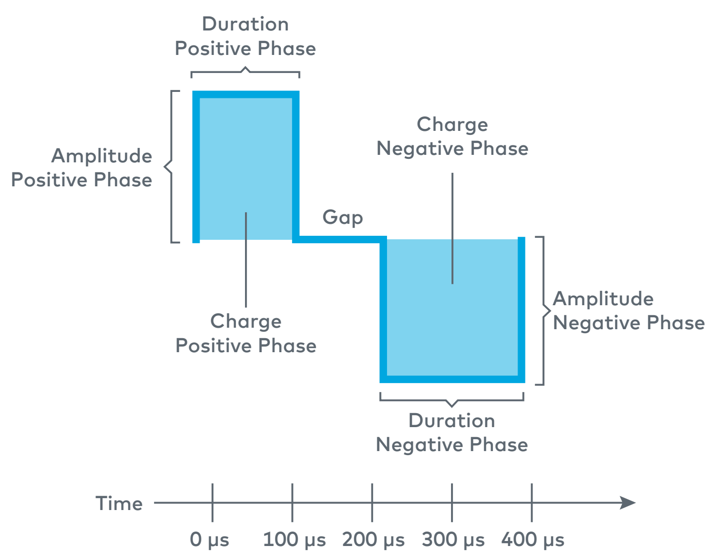
In this chapter we cover the **stimulation pulse**, which is central to how TENS devices activate nerves. Read on to learn what it is and why its characteristics are important to effective pain relief.

## What is the stimulation pulse?

TENS provides pain relief by passing an electric current between electrodes placed on the skin. The current flows across the skin underneath the electrodes and through the body where it stimulates nearby nerves. This current is not applied continuously such as would be the case with a battery, but rather in discrete packets called stimulation pulses. The reason is that nerves transmit information such as the sensation of touch or pain using impulses called **action potentials**. In this respect, nerves are like communication lines in computers. However, unlike computers that transmit millions or billions of impulses per second, human nerves communicate with only a few hundred impulses per second.

## Stimulation pulse characteristics

A stimulation pulse has several key characteristics. To help explain, we will refer to the figure below that schematically represents the Quell® stimulation pulse.




The pulse is comprised of two **phases**, a positive phase and a negative phase, with a short gap between them. Charge in the positive phase activates nerves underneath one of the electrodes and charge in the negative phase activates nerves underneath the other electrode.

An essential feature of the stimulation pulse is the height of each phase, called **amplitude**. It is measured in milliamps, which are one-thousandth of an amp (a unit of electric current). In typical use, the amplitude is between 5 and 100 milliamps. As a point of reference, this is far less current than common appliances such as light bulbs or computers require.

Another important feature of the stimulation pulse is the **duration** of the phases, which is usually between 100 and 200 microseconds (millionth of a second, abbreviated μs). The intensity of nerve stimulation is a function of **charge**, which is equal to the amplitude multiplied by the duration (i.e., shaded area in figure). The greater the charge the stronger the nerve stimulation. However, the form in which the charge is delivered matters. A large amplitude and short duration (i.e., narrow and tall) is more effective than a low amplitude and long duration (i.e., wide and short). The reason is that short pulses pass across the skin more easily and more effectively stimulate nerves. The technical challenge for TENS devices is that short pulses require greater amplitude and most OTC TENS devices are limited to about 50 milliamps. Quell generates up to 100 milliamps and therefore uses efficient short pulses.

As a final point, the gap between the phases is important because, in its absence, the two phases interfere with one another to reduce the effectiveness of nerve stimulation. Quell is one of a few TENS devices with this feature.

# INTENSITY
# **CONTROL**

Stimulation intensity, which determines how strong TENS feels, has the greatest influence on pain relief among all TENS parameters. An intensity that is not felt will not provide pain relief. Scientific studies and clinical experience suggest that effective pain relief occurs at an intensity that is perceived as "strong but comfortable." In this chapter we will discuss how TENS devices control stimulation intensity.

## How is Intensity Controlled?

The most important control on a TENS device is for intensity. It is analogous to the volume control on your car radio or smartphone which determines loudness. Originally, TENS devices had an analog knob that the user turned to increase or decrease intensity. Now most TENS devices are digital and use up and down buttons. Quell® goes further with algorithms that automatically manage intensity, so the user only needs to occasionally adjust with a smartphone app.

Analog Control


Digital Control

Automation Smartphone App

What actually happens when the stimulation intensity is increased or decreased? Generally speaking, either the current passing through the electrodes or the voltage applied to the electrodes is changed. The former is called **current regulation** and the latter is called **voltage regulation.** Does it matter which one is used? In fact, there is an important difference because current rather than voltage is the determining factor for nerve stimulation.

To explore further, we revisit Ohm's law introduced in the first chapter (Maximum Voltage).

**Voltage** = Current x Resistance

Since current is the driver of nerve stimulation, it is useful to re-arrange Ohm's law as follows:

**Current** = Voltage / Resistance

The equation above shows that current depends on both voltage and resistance. Recall that the resistance is determined by the user's skin and by the interface between their skin and the electrode, both of which may change day to day, and even hour to hour. A current regulated TENS device automatically sets the voltage to produce the desired current irrespective of the resistance. If the resistance increases then the device compensates by increasing the voltage, and if the resistance decreases the device adjusts the voltage down. In either case, the current remains at the intended value.

A voltage regulated TENS device controls the voltage rather than the current. As a result, changes in resistance will lead to changes in current even if the voltage is unchanged. If the resistance increases then the current decreases and if the resistance decreases then the current increases. This may cause unstable nerve stimulation and can impact pain relief. At a minimum, it is inconvenient to have to "hunt" for the right intensity with every use due to changes in resistance. Moreover, current regulation is safer than voltage regulation because the current will not spike if the resistance quickly drops.

## Design of Current and Voltage Regulated TENS

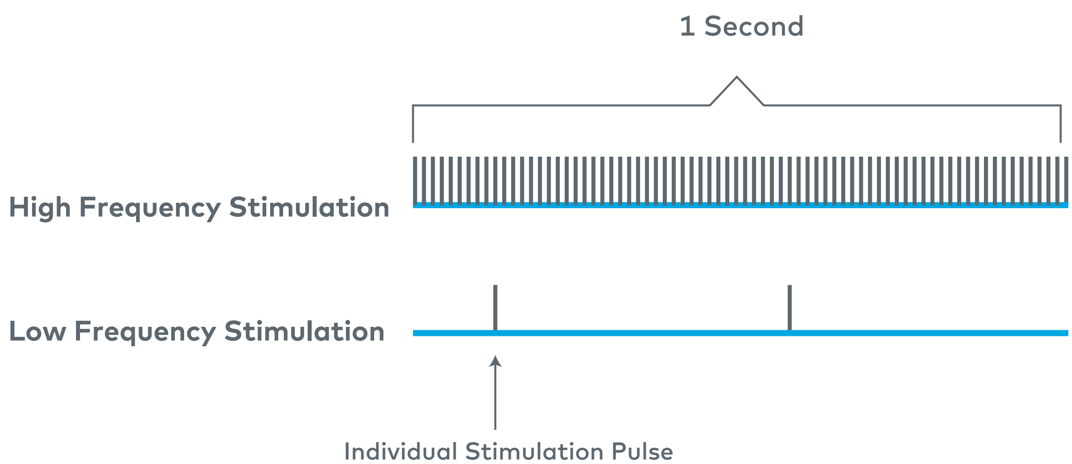
Since the benefits are clear, why don't all TENS devices utilize current regulation? The reason is that reliable current regulation is technically challenging and requires specialized electronic circuits. As a result, most TENS devices use some variant of voltage regulation. When TENS therapy is used occasionally for short periods, the repeated inconvenience of finding an effective intensity is acceptable. In more demanding applications, such as Quell, where users typically wear the device for 8-12 hours a day, stable stimulation current is required. For this reason, Quell utilizes sophisticated current regulation.

# STIMULATION
# FREQUENCY

In this chapter we will discuss **stimulation frequency,** which is an important but misunderstood attribute of TENS therapy.

## What is Stimulation Frequency?

As we have covered in the first three chapters (Maximum Voltage, Stimulation Pulse, Intensity Control), TENS produces pain relief by passing an electric current between electrodes separated on the skin to stimulate nearby nerves. This current is usually generated as individual pulses at a certain rate, called stimulation frequency. For example, a device stimulating at 80 **Hertz** (abbreviated **Hz**) generates 80 pulses per second. A device stimulation at 2 Hz outputs far fewer pulses; only 2 per second. TENS stimulation frequency is labeled "low" if it is below 10 Hz and "high" if it is above 50 Hz. High frequency stimulation has a buzzing sensation. Low frequency stimulation feels like a strong tapping. See the figure below for a visual comparison of high and low frequency stimulation.




## Does Stimulation Frequency Matter?

This question has vexed researchers, and despite studies on the topic, remains unresolved. On balance, high frequency or both low and high frequency stimulation is preferred when using TENS at a strong but comfortable intensity. One reason is that low and high frequency stimulation have distinct pain relief mechanisms. Low frequency stimulation increases endorphins, an endogenous pain-relief molecule, while high frequency stimulation increases enkephalins, a different pain-relief molecule. Most prescription pain medications mimic endorphins, so individuals currently (or recently) taking these drugs may not experience pain relief from low frequency stimulation. Another reason is that high frequency stimulation is usually more comfortable than low frequency stimulation for regular TENS users.

Most TENS devices stimulate at a single frequency. Some devices offer options such as frequency sweeps, alternating frequencies, high frequency bursts and random frequencies. Although unique benefits have been proposed for these patterns, they have not been proven in clinical studies.

## Technical Considerations

In many TENS devices, stimulation intensity decreases at high frequencies, which may lead to reduced pain relief. Due to its novel electronic design, Quell® exhibits stable stimulation at all frequencies. Another issue is that TENS devices have poor battery life when used at high frequency. Every stimulation pulse consumes the same amount of battery charge. So, for example, stimulating at 80 Hz will drain the battery much faster than stimulating at 8 Hz. Quell's battery technology is designed to provide 20-30 hours (3-5 days of typical use) of high frequency stimulation before having to recharge the battery.

# INTENSITY
# AUTOMATION

**Automation** is the automatic handling of operations that would otherwise be undertaken by humans. A contemporary example is home automation like the Nest® smart thermostat. Medical devices are increasingly adopting automation technology to enhance performance and improve safety. Examples include robotic surgery and computer aided mammography.

Automation can make TENS devices easier and more effective. There are several aspects of TENS therapy that can benefit from automation. We will focus on control of **stimulation intensity**, which was discussed in our third chapter (Intensity Control) and is the most important TENS parameter for achieving pain relief.

## Variation in Optimal Intensity

The stimulation intensity that is optimal for pain relief effectiveness and comfort is generally not constant. It can change during the course of a typical 30 to 60-minute therapy session and over the course of the day and night. At the start of a therapy session, the intensity is increased to a "strong but comfortable" level within a minute or two. During a therapy session, the intensity should be intermittingly increased to counter nerve desensitization, a process whereby nerves become less responsive to stimulation over time. In the absence of this periodic adjustment, pain relief may be reduced. The intensity may require further modifications to account for changes in body position during a therapy session to maintain comfortable stimulation.

If therapy extends over hours or days, as in wearable TENS applications, then further tuning may be necessary. Nerve sensitivity changes during the day, usually following a circadian rhythm. In some individuals, the same stimulation intensity feels stronger in the morning or afternoon compared to other times of the day. Stimulation during sleep, which may be helpful in controlling overnight pain, may require a lower stimulation intensity to avoid disturbing sleep.

## Automatic Control of Intensity

In a typical TENS device, the user must manually adjust the intensity to maintain an optimal level of nerve stimulation. This requires constant vigilance and regular interaction with the TENS device, which complicates use and may lead to sub-optimal pain relief. Quell® has **Autopilot**™ technology that automatically controls the stimulation intensity based on the user's physiological characteristics and preferences. Like cruise control on your car, this technology automatically manages stimulation intensity, while allowing the user to take manual control at any time.

Given the obvious value of automatic intensity control, why is it not widely available in TENS devices? The reason is that this technology is complex and requires sophisticated software algorithms and sensors that are only found in Quell.

CHARGE

# BALANCING

As was covered in a previous chapter (Stimulation Pulse), TENS devices send electric current through electrodes on the skin in the form of short pulses. The primary physiological effect of these pulses is to trigger impulses in nearby nerves that travel to the spinal cord to initiate pain relief. Another biological effect of current flow across skin is the movement of charged molecules within the skin. If not carefully managed, this can result in skin irritation. Read on to learn about **charge balancing** and why it is important for protecting your skin during TENS therapy.

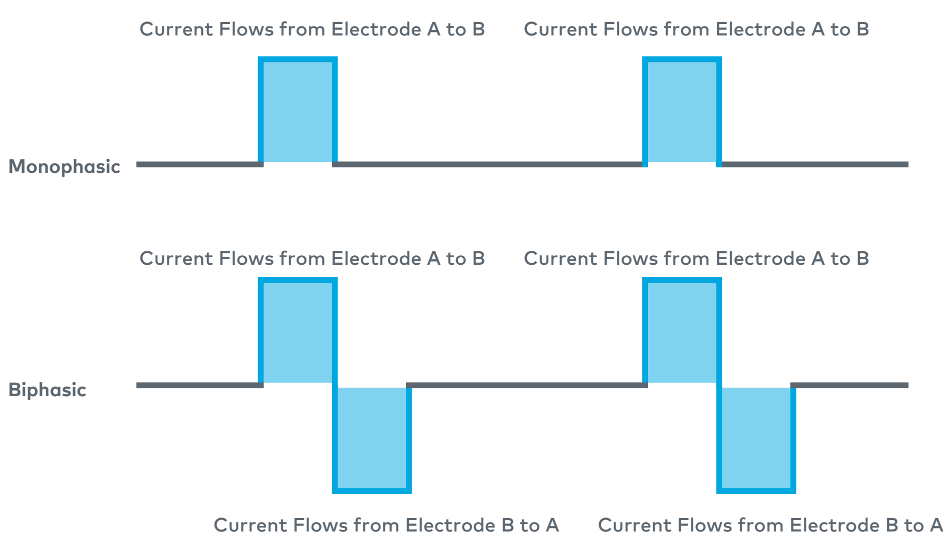
## Skin pH and Electrical Stimulation

Skin pH is normally between 4.7 and 5.7, so it is mildly acidic (i.e., pH below 7). When electricity flows across the skin, it causes charged molecules such as hydrogen ions (H+) and hydroxide ions (OH−) to move to towards one or the other electrode. If this process continues, then the skin area accumulating hydrogen ions becomes more acidic (i.e., lower pH) and that aggregating hydroxide ions becomes more alkaline (i.e., higher pH). If the pH deviates from the normal range, then the user may experience skin irritation, which can be severe if the pH shifts are large.

There are two strategies to mitigate this potential side effect of TENS therapy. The first is to limit stimulation to a short time period (e.g., 15-30 minutes) with a long interval (e.g., hours) between treatment sessions. This allows buildup of ions to diffuse away before altering the pH. In the second approach, the TENS device balances current flow to minimize accumulation of ions.

## Charge Balancing

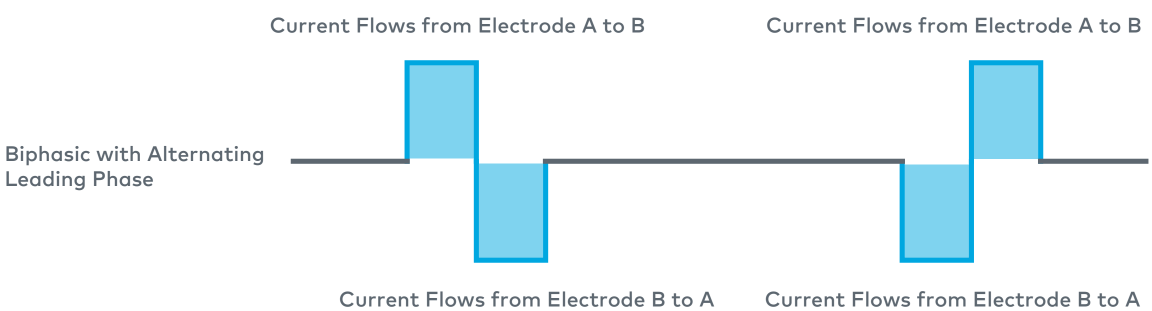
The figure below shows the two basic types of stimulation pulses: **monophasic** and **biphasic.**



In the monophasic case, current flows in the same direction with each pulse (shown as from electrode A to B). Since current is always flowing into one electrode and out the other, hydrogen ions will accumulate under one electrode and hydroxide ions will accumulate under the other. Even though ion accumulation is small for each pulse, the cumulative effect over an hour of stimulation can be large enough to disrupt skin pH and cause skin irritation. As a result, TENS devices using monophasic stimulation should only be used for a short time with a substantial wait before resuming stimulation.

In the biphasic case, the current flows in one direction during the first phase of the pulse (shown as from electrode A to B) and in the opposite direction in the second phase (i.e., shown as electrode B to A). If the charge in each phase (i.e., shaded area) is the same, then there is no net current flow. So even over the millions of individual pulses occurring during hours of TENS treatment, there should be no net current flow and thereby no significant change in skin pH. In practice, because the circuits generating the first and second phase usually have small differences, there may be a residual mismatch that results in a small net current flow during each pulse. Although biphasic stimulation is safer than monophasic, this residual current flow can lead to adverse changes in skin pH. This is particularly true when stimulation is nearly continuous as in the case of wearable devices.

Quell® utilizes an improvement over traditional biphasic stimulation that addresses the mismatch issue described above. It is called **phase alternation** and is shown in the figure below.




The direction of current flow alternates with each sequential pulse so that mismatches in the current generating electronics are balanced and no ion accumulation occurs. This is the most sophisticated charge balancing approach and is only found in Quell because of the need for circuits that rapidly switch current flow direction.

# TRIP
# CONDITIONS

TENS devices are most often characterized by their stimulation specifications such as maximum voltage (Chapter 1: Maximum Voltage), which is understandable given that nerve activation directly drives pain relief. However, device safety features are equally important, despite garnering far less attention. Most TENS devices have **trip conditions**, which act like the circuit breakers in your home that trip to protect against an excess current surge. Read on to learn about trip conditions found in TENS devices and the role they play in keeping you safe during TENS therapy.

## Open Circuit

Detection of an **open circuit** is a standard trip condition. An open circuit occurs when the flow of electric current from the device, into one of the electrodes, through the body, into the other electrode and back to the device is broken. The most likely cause is an electrode coming off the skin or the device and electrode disconnecting. It is essential for a TENS device to halt stimulation if an open circuit occurs. The reason is that the user may accidentally "close the circuit" if they touch the electrode or device resulting in a painful shock. All TENS devices should provide this trip condition.

## Overload

A trip condition that is found in some TENS devices, such as Quell®, detects when the stimulation pulse is delivering more current than intended, called an **overload**. This is an important safety feature to prevent painful and potentially dangerous nerve stimulation. The cause of an overload is usually a defect in the electronic circuit that controls stimulation. A common reason for this defect is damage due to a "static shock," which is technically described as electrostatic discharge (ESD).

## Electrode Peel

A novel trip condition found only in Quell devices is detection of **electrode peeling**. It is not uncommon for electrodes to peel from the skin, particularly after prolonged use. Electrode peeling may also occur if a TENS device is worn during sleep due to frequent body position changes and the lack of awareness by the asleep user. Electrode peeling reduces the contact area between the electrode and the skin. This can make stimulation painful, and in extreme cases, can lead to skin damage. Quell implements a patented electrode peel detector that automatically halts stimulation if the area between the electrode and the skin decreases to a critical level. Quell is the only TENS device specifically cleared by the FDA for use during sleep.

POWERING
# TENS DEVICES

TENS devices rapidly consume battery charge because they stimulate nerves non-invasively across the skin for up to several hours a day or longer. As discussed in our first chapter (Maximum Voltage), skin has a high resistance to current flow and therefore nerve stimulation requires high voltage and substantial electric power. This chapter covers how TENS devices are powered to overcome this challenge.

## Power Conservation

We start by discussing **power conservation**. Most of the power consumed by a TENS device is attributable to nerve stimulation. For now, we will ignore power consumed by other important TENS device components such as the microprocessor and the display. The voltage used to generate the nerve stimulation current is much higher than the battery voltage (for example 80 volts versus 3 volts). That means the battery voltage must be increased or "stepped-up" by the TENS device. Circuitry that increases the voltage also affects the current, so the current drawn on the high voltage side of the circuit will be different than the current drawn on the low voltage side. To calculate the current on the low voltage, or battery side, we rely on the fact that power is conserved across the circuit boundary. That means the electric power provided by the battery equals the electric power used by the high voltage side of the device plus losses due to inefficiencies such as generation of heat. Electric power is defined as the product of voltage and current. This leads us to the principle of power conservation:

**Stimulation voltage x stimulation current =** efficiency x battery voltage x battery current

In other words, the power used to stimulate nerves equals the power produced by the battery, subject to an efficiency factor (typically between 0.5 and 0.7). When evaluating battery life, we are primarily concerned with the battery current so we re-write the power conservation equation as:

**Battery current =** (stimulation voltage x stimulation current) / (efficiency x battery voltage)

As we can see from this equation, the greater the stimulation voltage and stimulation current and the lower the efficiency, the more current that will be drawn from the battery. The reason we focus on battery current is that it determines how long a battery will last before needing to be replaced or recharged. Battery capacity is rated in milliamp hours, abbreviated mAh. For example, 2 AA batteries in series have a battery voltage of 3 volts and a battery capacity of about 2000 mAh.

We will use an example to demonstrate how battery current and battery capacity interact to determine battery life. Let's say that nerve stimulation requires a stimulation voltage of 50 volts and stimulation current of 10 milliamps (stimulation current and the intensity of the stimulation pulse are proportional but the relationship is a bit complicated and so won't be covered in this post), and the TENS device has an efficiency of 0.5. Under these conditions, battery current = (50 volts x 10 milliamps)/(0.5 x 3 volts) = 333 milliamps, and the 2 AA batteries will provide about 2000/333 = 6 hours of stimulation. We see that battery life is maximized by keeping the stimulation voltage as low as possible and efficiency as high as possible. These are both important attributes of TENS circuit design. Quell® utilizes a novel voltage control algorithm that minimizes the stimulation voltage needed to stimulate nerves.

## Different Ways to Power a TENS Device

There are three ways to power a TENS device: replaceable batteries (like most toys), an embedded rechargeable battery (like your mobile phone) and AC power (like your TV). OTC TENS devices are powered by replaceable or rechargeable batteries. The only TENS devices that use AC power are professional units used by health care professionals in their clinic.

The most attractive option for consumers is an embedded rechargeable battery, such as in Quell, because it relieves the user of the cost and inconvenience of regularly changing the batteries. The reason that not all TENS devices uses an embedded rechargeable battery is that this approach requires specialized electronic circuits to safely charge and operate, which increase complexity and cost.

# TREATMENT
# MONITORING

Throughout this ebook we have focused how TENS devices stimulate nerves. Although nerve activation is the core purpose of a TENS device, it is also essential to guide the user towards a safe and effective pain relief outcome. In this respect, a TENS device should be a pain relief solution rather than only a tool. Read on to learn about functionality that has been incorporated into some TENS devices to achieve this goal.

## Therapy Monitoring

Most people with chronic pain experience daily pain that may persist throughout the day and disrupt sleep at night. TENS is believed to produce analgesia during stimulation and for a short time afterwards. Therefore, frequent treatment is required for effective chronic pain management. Adhering to a schedule can be challenging due to time constraints and competing priorities. Wearable TENS devices, such as Quell®, facilitate regular use by reducing the need to interact with the device. Adherence can also be encouraged by providing feedback through **therapy monitoring.** Useful treatment variables include the number of completed sessions (each typically 30-60 minutes) and total treatment time each day. Quell goes further with a **therapy coach** that guides the user during the first 60-days to help establish an effective TENS habit. The figure below shows therapy tracking screens from the Quell mobile app.


**Quell Mobile App Therapy Tracking Screens**

## Skin Health Monitoring

A potential downside of frequent TENS treatment is the development of skin irritation due to the prolonged presence of electrodes on the skin. It is generally safe to keep electrodes on the skin for 4-5 hours at a time or overnight.  Therefore, it is important to remind the user to regularly ventilate the skin under the electrodes to prevent a skin reaction. Quell is the only TENS device that has a patented **on-skin time** alert that reminds the user to air out their skin (e.g., for 10-15 minutes) every few hours and in the morning after overnight use.

# PAST
# AND FUTURE

In this final chapter, we "close the hood" and take a step back to briefly consider the history and future of TENS technology. Read on to learn about electrical eels, the Magneto-Electric machine, Dr. Normal Shealy and likely directions for TENS innovation.

## A Brief History of Electrotherapy

TENS is a branch of **electrotherapy** which means the treatment of disease using electricity, as opposed to drugs or chemicals. Although this may seem like a novel idea that belongs in the 21st century, electrotherapy dates back thousands of years to the ancient Romans and Greeks. Physicians in ancient Greece discovered that electrical impulses emitted from electric eels in foot baths relieved pain, arthritis and improved blood circulation. Amazingly, electric eels can generate up to 600 volts in a discharge.

Other than the use of electric leeches in the dark ages, little further happened in electrotherapy until the 18th and 19th centuries when physiologists discovered that many biological systems, such as the heart and nervous system, utilized electrical signaling. This led to an explosion of commercial electrotherapy devices that were peddled for every possible ailment, including pain. Among the most popular such devices was the Magneto–Electric machine that was developed in the US and initially commercialized in the 1850s.

**Magneto–Electric Machine,** circa 1854 - 1870

The manufacturer claimed that the device could relieve pain, as well as cure cancer, tuberculosis, diabetes, gangrene, heart disease, tetanus, and others. An operator turned the crank which generated an alternating current to the patient through the two handles, with the magnitude proportional to the rotational speed. As the proud owner of a Magneto-Electric machine, I doubt the health claims but can confirm that it still generates quite a jolt after 150 years.

## Modern TENS Devices

The modern TENS device is credited to Dr. Normal Shealy in the early 1970s. As a neurosurgeon, Dr. Shealy was initially motivated to develop a screening technique for predicting which chronic pain patients would respond to implantable stimulators before proceeding to surgery. However, it quickly became apparent that a significant percentage of patients attained substantial pain relief from TENS alone. Dr. Shealy inspired the development of several early commercial TENS devices including the Neuromod® device manufactured and sold by Medtronic, Inc. in the 1970s.

**Neuromod TENS Device from Medtronic, Inc.**

A comparison of the Neuromod and other TENS units from the 1970s with modern TENS shows that today's devices have become smaller, transitioned from analog to digital electronics, replaced dials and knobs with push buttons and LCDs, and adopted better battery technology. However, their fundamental operation has not changed. In typical use, the pain sufferer still attaches the device to electrodes on the skin via lead wires, dials up the intensity, and the device proceeds to stimulate for some period of time. Quell® wearable pain relief technology, launched in 2015, represented the first fundamental innovation in TENS technology in decades.

## The Future of TENS Technology

Lacking a crystal ball, we can only offer educated guesses as to how TENS technology will evolve in the near future. First, we anticipate that the devices will become increasingly wearable, along the lines of Quell. To maximize the pain relief benefits of TENS, the devices must fit into to the user's life rather than the other way around. Wearable devices allow users to go about their daily activities uninterrupted and even use TENS while sleeping. However, achieving true wearability is difficult. It requires development of small but powerful devices that are discreet and comfortable. It requires smart devices which automate the manual tasks that users must undertake with typical TENS. Automation is challenging and requires sophisticated algorithms and body sensors, such as accelerometers. And, as for other wearables like smart watches, adequate battery life is critical.

Another direction for TENS technology is integration with mobile devices. Like Quell, several TENS devices support Bluetooth and communicate with mobile apps running on Apple and Android smartphones and tablets. At a basic level, these mobile apps serve as a sophisticated remote control. However, the potential benefits of mobile apps go much further. For example, they can help guide users to optimally use the associated device, monitor and motivate adherence to improve pain relief, track user reported outcomes such as pain relief and quality of life which can provide feedback to the user and their physician, and connect users with others in the pain community to help break the isolation felt by so many pain sufferers. The possibilities are unlimited, and we expect that substantial innovation will occur with TENS associated mobile apps.

Finally, we believe that more high-quality clinical studies will be conducted to confirm and expand on the clinical utility of TENS for pain in general, and chronic pain specifically. Although TENS devices have been used for five decades and thousands of studies have been conducted, controversy remains over their efficacy. Unfortunately, this has led insurance companies to withhold reimbursement thus limiting access for many individuals in need of pain relief. The inconclusive evidence on TENS can be attributed to low study fidelity, which means that many of the clinical studies were performed with ineffective TENS devices at inadequate doses. These issues have been identified by thought leaders in TENS research and some studies conducted over the past five years have improved and yielded definitive positive results.

## Concluding Remark

TENS has been used for five decades and helped millions of people suffering from pain. Although the field has not historically been one of great innovation, recent trends are encouraging. TENS represents a safe, non-pharmacological approach to pain management. Given the dual challenges of the chronic pain and opioid misuse epidemics, TENS holds great promise and has a bright future.