



# HYDROGEL ELECTRODES

## What you should know about Hydrogel Electrodes

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### INTRODUCTION

Modern electrodes used for electrical stimulation are called Cutaneous Electrodes by the Food and Drug Administration and in scientific literature related to electrodes. The medical device industry and clinical care community use the common name “electrodes.” Electrodes are necessary for the safe and effective therapeutic use of various forms of electrotherapy such as Transcutaneous Electrical Nerve Stimulation (TENS), Interferential Current therapy (IF or IFC), Neuromuscular Electrical Stimulation (NMES), High Volt Galvanic Stimulation (HVGS), Microcurrent Stimulation (MCS) and other less common forms of electrotherapy.

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### CONSTRUCTION

The vast majority of electrodes available to patients today are of a type that utilizes a hydrogel interface between the electrode and the patient’s skin. The hydrogel serves two purposes:

1. Efficient conducting (transfer) of the electrical stimulator’s therapeutic electrical current to the patient’s skin in a dispersed manner and,
2. Attachment to the patients skin via the adhesive properties of the hydrogel

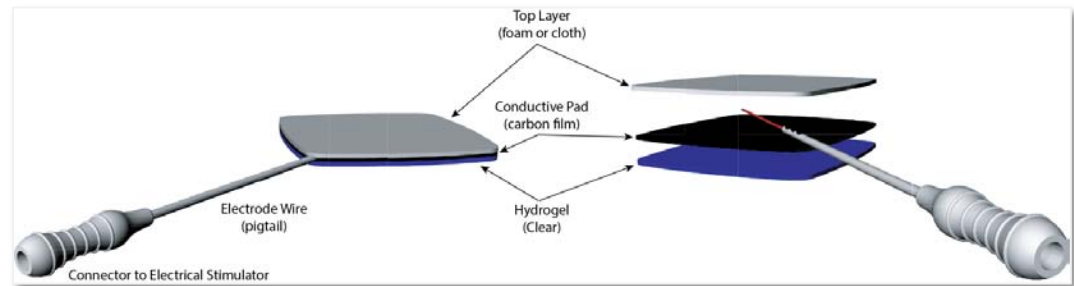


Fig 1 - 3D image courtesy of TheraSigma, LLC. All rights reserved. Use for any other purpose is prohibited

Fig. 1 illustrates a typical hydrogel electrode assembly. The hydrogel is clear but shown in blue for distinction from the other parts of the electrode.

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## MOISTURE

Largely composed of water, hydrogel must remain wet to perform the two purposes mentioned above. A high level of hydrogel moisture ensures high levels of electrical conductivity (reduced electrical resistance) and good adhesion. High levels of moisture also ensure multiple electrode reuse .

Reductions in moisture either through drying out or “fouling” of the hydrogel by dirt, skin oils, dander and other contaminants will result in reduced electrical conductivity (poor performance) and reduced adhesion (unsafe condition). Patient safety is the highest concern in the design, fabrication and utilization of hydrogel electrodes. A straight line can be drawn between patient adverse effects (shocking and burns) and dried out electrodes. It is also very important to note that all cutaneous electrodes are approved for marketing by the FDA based on an evaluation that the electrode is “safe and effective for its intended use”<sup>1</sup>

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<sup>1</sup> FDA Premarket Approval (PMA) - <http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarket submissions/premarketapprovalpma/>

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## ADDRESSING SAFETY CONCERNS

There are three main categories of patient complaints relative to hydrogel electrode use. They are listed here in increasing degree of severity:

1. Skin irritation
2. Shocking
3. Skin burns

### SKIN IRRITATION

*Skin irritation* is typically short lived and can be alleviated by either

- discontinuing the use of the irritating electrodes
- changing to a different brand and therefore a different hydrogel formula, or
- using a hydrogel employing a “sensitive skin” formula. Note that sensitive skin formulas typically have reduced adhesive properties and are not recommended for general use.

### SHOCKING

*Shocking* is typically attributed by the patient to the electrical stimulation device and not the electrode. Although each case is different we have learned after investigation that it is usually the electrode that causes shocking. Hydrogel drying or fouling leads to non-adhesion of the electrode to the skin. Areas that typically dry out early are close to the edge of the electrode where they meet air, which results in reduced adhesion that in turn causes electrode edges or corners to lift away from the patient’s skin. In this situation electrical current carried by the carbon dispersion pad through the hydrogel continues to flow and will seek a conductive path to ground and the completion of the circuit. Sometimes the electrical current will jump to the patient’s skin. This is called arcing.

Arcing can be uncomfortable because it is accompanied by a concentration of electrical current. Rather than evenly dispersing over an area the current is

concentrated into a mini lightning bolt that patients characterize as a biting, stinging or burning feeling. The electrode industry and clinical care community calls this effect “edge biting”. It is an unwelcome and uncomfortable experience and at times leads to patient non-compliance. Arcing without burning does not represent a patient safety issue because the

#### TIP 1

Edge biting and associated burns can be eliminated by replacing the dried out electrodes with fresh moisturized electrodes. Edge biting is not a characteristic of electrodes per se; it is a characteristic of over-used dried out electrodes.

arcing is transient and the electrical charge levels, although alarming, remain safe.

## SKIN BURNS

*Skin burns* are caused by arcing when the duration of the arcing event is prolonged or the size of the arc is large. As the electrical charge meets oxygen (air) in the micro-gap between the hydrogel and the patient's skin a small contained flame is created which will burn tissue. The degree of the burn (first, second or third) is dependent on the patient's skin condition and toughness, any mitigating skin moisture, the time duration of arc contact and the size of the electrical charge both in dimensional area and level of electrical charge in terms of current strength.

Burns of a "serious nature" require notification to regulatory bodies in the country where the burn occurred. Serious nature means burns that permanently damage a body structure or require medical attention to prevent permanent damage to a body structure. To our knowledge, although there have been reports of electrode burns no burn event has risen to the level of permanent damage to a body structure or required medical intervention to prevent permanent damage to a body structure.

Burns must be taken seriously and investigated fully to determine the cause of the burn and the extent of the burn. In our experience the burns are first and second degree (blisters). Our investigations also discovered the patients were using exhausted electrodes, sharing electrodes between patients, and attempting to extend the life of the subject electrodes by wetting them with water.

### TIP

All of these electrode life extending practices are discouraged by most electrode manufacturers and are the leading cause of reduced safety and effectiveness of electrodes.

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## REUSABILITY

The term re-usable is intended to convey the concept that they are not single use only. That does *not* mean they are indefinitely re-usable. One of the most oft-asked questions is "how many times can I use the electrode". This is an important marketing concept as greater sales can be achieved by promising a large number of re-uses. The accurate answer to the question is "it depends." It depends on:

- the initial quality of the electrode,
- the care given to the handling and storage of the electrode by the patient,
- the patients skin condition (consider the extremes of old dry skin and young fully hydrated oily skin),
- the degree of cleaning of the patient's skin prior to use of the electrode,
- the duration of each use (some patients wear their electrodes all day/every day and some wear them for a half hour every few days),
- environmental conditions during use (hot humid summer or cool dry winter), particulates in the air such as dust, animal dander, second hand smoke etc.

Considering the factors above it is impossible to provide an answer to the question. Every patient is different and their re-uses will reflect the influence of the factors above. Premium electrodes are designed to provide the highest number of re-uses possible and modern hydrogels provide more reusability than the older formulas.

Certain hydrogels have an amalgamating action which actually draws surface contaminants into the hydrogel body. This amalgamating process brings fresher hydrated gel to the surface further extending hydrogel life but eventually even these advanced gels succumb to time and use and must be replaced.

A few manufacturers suggest the topical application of water to the hydrogel to extend the life of the electrodes. This is not a good practice over the long-term and should only be performed on an emergency basis while waiting for fresh electrodes to arrive. Adding water to the hydrogel dilutes the adhesive properties and leads to accelerated deterioration of the adhesive qualities which in turn may lead to shocking and burns. Although wetting an electrode allows the electrode to be used and provides a safe and effective therapy AT THE TIME it will eventually lead to an unsafe experience for the patient and should not be recommended or attempted.

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## CONCLUSION AND RECOMMENDATIONS

Premium electrodes provide the greatest electrical conductivity and high quality gel formulas enable the greatest re-uses so premium electrodes should be used. Premium electrodes often are the same price as inferior electrodes due to up-pricing of inferior electrodes to premium electrode prices. Considering the foregoing the best recommendation for the SAFE and EFFECTIVE use of hydrogel cutaneous electrodes is to use fresh premium grade electrodes.

Patient compliance is greater when there is benefit from the therapy and fresh electrodes provide superior therapy experiences and outcomes. Patient comfort also contributes greatly to patient compliance. It is important to note that all major and most minor health insurance plans routinely reimburse for therapy electrodes. The rate of reimbursement is usually set by fee schedule and the common HCPCS code for hydrogel electrodes is A4595.