

3. Is TENS Safe? Can Everyone Use It? Warnings/Precautions?

It is safe for most people to use a TENS unit and most will not usually experience any side effects. Serious side effects from TENS units are rare. Some people may be allergic to the adhesive pads and experience some mild skin irritation. Anyone who experiences skin redness and irritation can switch to using hypoallergenic pads instead.

The electrical impulses that a TENS unit produces cause a buzzing, tingling, or prickling sensation, which some people may find uncomfortable.

Obtain clearance from your healthcare professional before you use a TENS unit and always follow the directions provided by the manufacturer.

The following are warnings for the iReliev TENS units. While most units contain similar warnings, make sure to read the precautions and contraindications for your unit.

WARNINGS

If you are in the care of a physician, consult with your physician before using this device. If you have had medical or physical treatment for your pain, consult with your physician before using this device.

If your pain does not improve, becomes more than mild, or continues for more than five days, stop using the device and consult with your physician.

Do not apply stimulation over your neck because this could cause severe muscle spasms resulting in closure of your airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.

Do not apply stimulation across your chest because the introduction of electrical currents into the chest may cause rhythmic disturbances to your heart, which could be lethal.

Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g. phlebitis, thrombophlebitis, varicose veins).

Do not apply stimulation over, or in proximity to, cancerous lesions.

Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.

Do not apply stimulation when in the bath or shower.

Do not apply stimulation while sleeping.

Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put you at risk of injury.

Do not use the device on children, if it has not been evaluated for pediatric use.

We also recommend the following:

Consult with your physician before using this device, because the device may cause lethal rhythmic disturbances to the heart in susceptible individuals.

Apply stimulation only to normal, intact, clean, healthy skin.

PRECAUTIONS

We also advise users of the following:

TENS is not effective for pain of central origin including headaches.

TENS is not a substitute for pain medications and other pain management therapies.

TENS devices have no curative value.

TENS is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism. Effectiveness is highly dependent upon the individual using the device. Results may vary.

Additionally, the long-term effects of electrical stimulation are unknown. Since the effects of stimulation of the brain are unknown, stimulation should not be

applied across your head and electrodes should not be placed on opposite sides of your head.

The safety of electrical stimulation during pregnancy has not been established.

You may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).

If you have suspected or diagnosed heart disease, you should follow precautions recommended by your physician.

If you have suspected or diagnosed epilepsy, you should follow precautions recommended by your physician.

We also recommend the following:

Use caution if you tend to bleed internally, such as following an injury or fracture.

Consult with your physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.

Use caution if stimulation is applied over the menstruating or pregnant uterus.

Use caution if stimulation is applied over areas of skin that lack normal sensation.

Keep this device out of the reach of children.

Use this device only with the electrodes and accessories recommended by the manufacturer to avoid adverse reactions.

Please be aware of adverse reactions and precautions below:

You may experience skin irritation and burns beneath the stimulation electrodes applied to your skin.

You may experience headaches and other painful sensations during or following the application of electric stimulation near your eyes and to your head and face.

You should stop using the device and should consult with your physician if you experience adverse reactions from the device.