Safety Issues regarding the use of VitalStim Therapy

Created by VitalStim Therapy Instructors
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Introduction

This document has been prepared by the instructors of the VitalStim Certification Seminar. It does not represent the opinion of the manufacturer of the VitalStim Therapy stimulator but is intended to provide clinicians using VitalStim Therapy with guidelines regarding conditions of possible concern. The information is based on best available evidence and guidance documents from regulatory organizations and manufacturers. Clinicians are advised to consult the professional literature and manufacturers of various devices for information specific to that condition or device.

The FDA defines precautions, warnings, and contraindications as follows: A *warning* alerts the reader about a situation which, if not avoided, could result in death or serious injury. It may also describe potential serious adverse reactions and safety hazards. The "warning" designation is reserved for the most significant problems. The term *precaution* is used for the statement of a hazard alert that warns the reader of a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property. The term *contraindication* is used to alert the reader about conditions under which the device should not be used because the risk of use clearly outweighs any possible benefit.[1]

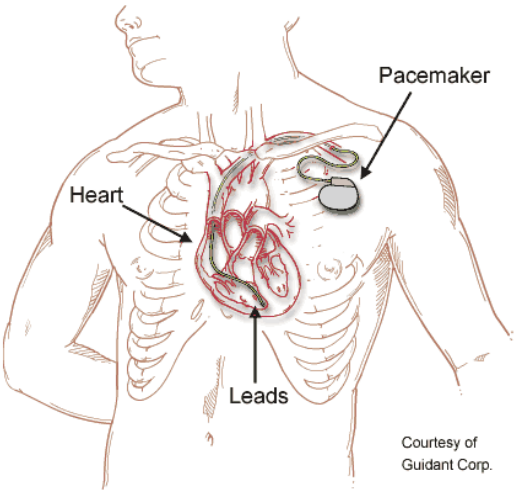
In all instances the responsibility to choose whether or not to utilize a certain treatment intervention rests with the clinician. The clinician will make the risk/benefit assessment based on the best information available from regulatory bodies, published material in the professional literature and personal experience. It may occur that a clinician chooses to utilize VitalStim Therapy in a situation where the FDA warns the clinician against such use.

Many of the special considerations in this document relate to implanted medical devices. Patients with such devices usually carry an ID card listing the manufacturer's contact information and device serial number. This information enables you to discuss precautionary measures with the device manufacturer if desired.

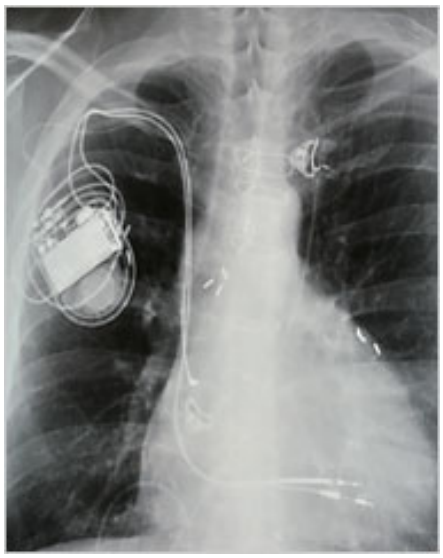
Pacemakers and Implantable Cardioverter Defibrillators (ICD)

Description

A pacemaker is a device used primarily to correct some types of bradycardia, or slow heart rhythms. The pacemaker is implanted under the skin, usually above the left breast below the collarbone. A specialized wire is attached on one end to the heart muscle and on the other end to the pacemaker. The pacemaker unit generates an electrical impulse, which is transmitted via the pacemaker lead to the heart muscle, causing it to contract. Traditional pacemakers prevent the heart from beating too slowly but have no effect on rapid heart beating, chest discomfort, or weakened heart muscle contractions.



An implanted cardioverter defibrillator is a specialized device designed to directly treat a cardiac tachydysrhythmia. If a patient has a ventricular ICD and the device senses a ventricular rate that exceeds the programmed cut-off rate of the ICD, the device performs cardioversion/defibrillation. Alternatively, the device, if so programmed, may attempt to pace rapidly for a number of pulses to attempt pace-termination of the ventricular tachycardia. Newer devices are a combination of ICD and pacemaker in one unit. These combination ICD/pacemakers are implanted in patients who require both devices.



Guidelines

The American Heart Association lists TENS devices under *Devices with Risk*. VitalStim is a similar device because of its limited current output. The following is the text from the AHA website.[2]

> *Transcutaneous electrical nerve stimulation (TENS) — Several electrodes are placed on the skin and connected to a pulse generator [the TENS unit]. Most studies have shown that TENS rarely inhibits bipolar pacing. It may sometimes briefly inhibit unipolar pacing. This can be treated by reprogramming the pulse generator [the pacemaker/ICD].*

The FDA lists the presence of a demand-type pacemaker as a contraindication for the use of powered muscle stimulators[3]. In the case of VitalStim however, the following statement is listed:

> *Use with caution in patients with cardiac demand pacemakers*

The literature is scarce and inconclusive on possible interference between NMES/TENS devices and pacemakers. Some references describe occasional interference even after initial testing appears safe[4,5,6] while others report testing in larger groups of patients without any occurrence of interference.[7,8]

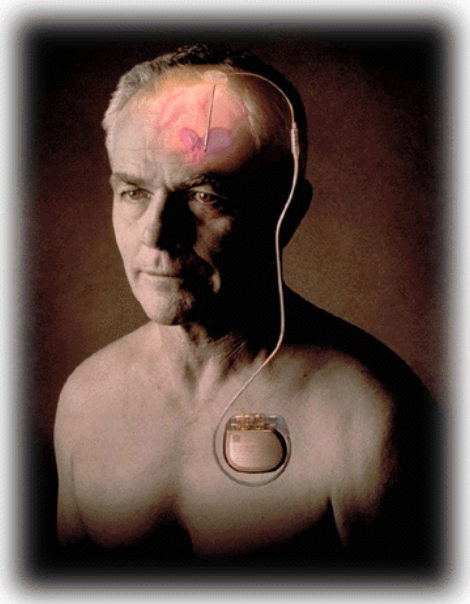
Pacemaker manufacturers have not evaluated VitalStim Therapy for possible interference with their devices and therefore recommend that clinicians and patients proceed with caution.[9]

The clinician can monitor pulse rate during the treatment. The cardiac nurse/tech can use equipment to read the pacemaker and cardiac parameters during VitalStim therapy if required.

Recommendation
The likelihood of the occurrence of interference between the VitalStim Therapy device and the pacemaker is small. The clinician should proceed with caution when using VitalStim Therapy in patients who have an implanted ICD and/or pacemaker. Monitor the patient for any signs of possible interference, including syncope, dizziness, palpitations, slow or fast heart rate, or, in the case of an ICD, inappropriate defibrillation. It is prudent to inform the physician and patient about possible interference. Discontinue treatment if interference occurs and refer the patient back to the physician for possible reprogramming of the pacemaker.

Deep Brain Stimulators (DBS)

Description
Deep brain stimulation involves surgical implantation of an electrical device that is able to send electrical impulses to specific areas of the brain to treat a variety of disabling neurological symptoms – most commonly the debilitating symptoms of Parkinson's disease (PD), such as tremor, rigidity, stiffness, slowed movement, and walking problems. Brain "pacemakers" were approved by the Food and Drug Administration (FDA) in 1997 as a treatment for Parkinson's disease as well as essential tremor. Since this time there have been other studies that have led to further indications including primary dystonia (April 2003) and treatment-resistant clinical depression (March 2005). There are many clinical trials underway evaluating the effectiveness of DBS in a variety of conditions. At present, the procedure is used only for patients whose symptoms cannot be adequately controlled with medications.



The procedure involves craniotomy for implantation of electrodes positioned within the targeted brain area that control movement, blocking the abnormal nerve signals that cause tremor and PD symptoms. The DBS system consists of three components: the lead, the extension, and the neurostimulator. The lead (also called an electrode)—a thin, insulated wire—is inserted through a

small opening in the skull and implanted in the brain. The tip of the electrode is positioned within the targeted brain area. The extension is an insulated wire that is passed under the skin of the head, neck, and shoulder, connecting the lead to the neurostimulator. The neurostimulator (the "battery pack") is the third component and is usually implanted under the skin near the collarbone. In some cases it may be implanted lower in the chest or under the skin over the abdomen. The neurostimulator is sealed inside a titanium shell and the platinum and iridium lead wires are insulated with polyurethane.

Swiping a special magnet over the device will deactivate it and patients generally turn it off at night as tremors cease and battery conservation is important.

Guidelines

No guidance is currently available from the FDA or from the DBS manufacturers and the professional literature is non-existent on the topic.

Recommendation

The likelihood of the occurrence of interference between the VitalStim Therapy device and the DBS is small. The clinician should proceed with caution when using VitalStim Therapy in patients with an implanted DBS system, even though the DBS extension wire (running subcutaneously and posterior to the sternocleidomastoid muscle) is theoretically outside the stimulation field of the VitalStim electrodes.[10] It is prudent to inform the physician and patient about possible interference. Discontinue treatment if interference occurs.

Vagal Nerve Stimulators

Description

Vagus nerve stimulation involves the implantation of a generator that stimulates the vagus nerve for the treatment of seizure activity and treatment refractory depression. Stimulation of the vagus nerve is thought to affect some of its connections to areas in the brain that are prone to seizure activity.

Patients who suffer from complex partial seizures or generalized seizures where consciousness is lost, and who do not respond to anticonvulsant medication, and patients who cannot undergo brain surgery are considered good candidates for vagus nerve stimulation therapy. It also may be recommended as a treatment for photosensitive epilepsy and epilepsy resulting from head injury.

The procedure involved implantation of a small stimulator in the upper left area of the chest. A connecting wire is run under the skin from the device to the vagus nerve in the left side of the neck. Three small leads (electrodes) are attached to the nerve.

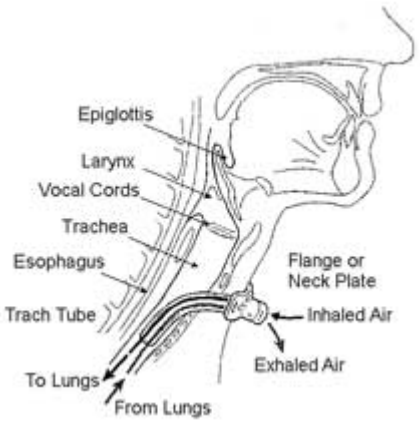
The stimulator is programmed to stimulate the Vagus nerve at regular intervals to suppress seizure activity. The patient can also activate the stimulator by swiping a magnet over their chest at the location where the device is implanted.

Guidelines
No guidance is currently available from the FDA or from the VNS manufacturer and the professional literature is non-existent on the topic.

Recommendation
The likelihood of the occurrence of interference between the VitalStim Therapy device and the VNS system is small. The clinician should proceed with caution when using VitalStim Therapy in adult patients with an implanted VNS system, even though the VNS electrodes and lead wire are theoretically outside the stimulation field of the VitalStim electrodes. It is prudent to inform the physician and patient about possible interference. Discontinue treatment if interference occurs. Signs of interference might include seizure activity, altered heart rate, voice alteration, breathing difficulty, increased coughing, numbness and/or soreness of the throat or tingling sensation of the neck or throat.
In pediatric patients, consult the referring physician prior to commencing treatment for the exact location of the implanted VNS system; the small size of the neck could inadvertently cause the current to flow through the implanted circuit.

Tracheostomy

Description
A tracheostomy tube is placed when a patient is going to require relatively long-term intubation, or if there is blockage of the oral cavity, pharynx, or larynx. The tracheostomy tube is inserted into the trachea below the level of the vocal cords. The basic parts of the tracheostomy tube include the outer and inner cannula, the flange, the hub, and the cuff. Other components may include a button, and a mask or collar used for humidification.



There are different types of tracheostomy tubes that are characterized by their components: single versus double cannula, cuffed versus cuffless, fenestrated versus unfenestrated, and silicone versus metal. When a patient is on the ventilator, some therapists choose to wait until the patient is in an active progressive weaning process of 15 minutes or more to begin therapy. The SLP and/or Respiratory therapist will monitor O2 saturation levels during the treatment.

For patients with a tracheostomy, research suggests that the use of a speaking valve may help in preventing aspiration. Some therapists will work on tolerance of cuff deflation and speaking valve placement before active dysphagia treatment interventions.

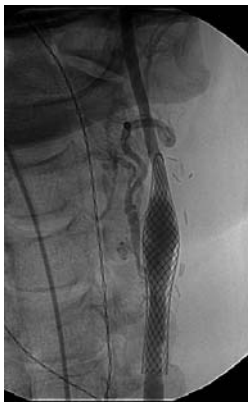
Guidelines
No specific guidance is issued by either the FDA or the manufacturer on the use of NMES in patients with a tracheostomy tube. The general guideline applicable to

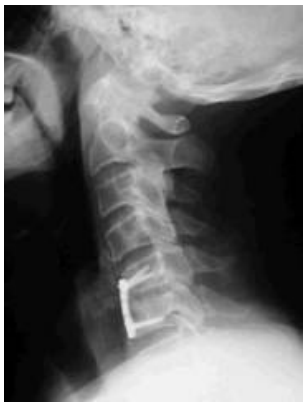
electrotherapy is to not allow the current to flow through indwelling metal. Electrodes will therefore have to be placed superior to the tracheostomy tube in the case of a metal tube. Because of the anatomical location of the tracheostomy below the cricoid cartilage this should not be a problem with VitalStim Therapy.

Recommendation
The therapist should initiate therapy using the VitalStim device when the patient is stable enough to engage in active treatment. In some cases, only two electrodes may be used when the neck does not offer enough available space because of the presence of the tracheostomy tube. Electrodes should be placed according to general electrode placement guidelines and should not be placed on either side of ("bracketing") the tracheostomy.

Implanted Metal

Description
There are many different types of metal that are implanted into the body for a variety of reasons. Some of the more common types in the neck region are carotid stents, hardware in the cervical spine and titanium implants in the mandible. Carotid stents are mesh wire sleeves that are inserted in the carotid artery to keep it open. Cervical hardware is used to fuse parts of the cervical spine and consists of screws and/or plates. Titanium mandibular implants are used to stabilize the mandible after fracture or tumor resection.


Stent


Cervical hardware


Titanium mandible

Guidelines
The accepted rule of thumb when using electrotherapy is to apply the electrodes in such a manner so that the current will not flow through the implanted metal. Metal has a high conductivity to current causing it to flow through the metal rather than through the tissues. This may cause high current density at the point of entry and possible tissue irritation. As long as electrodes are placed correctly so as to avoid this situation, there is no reason to withhold electrotherapy from patients.

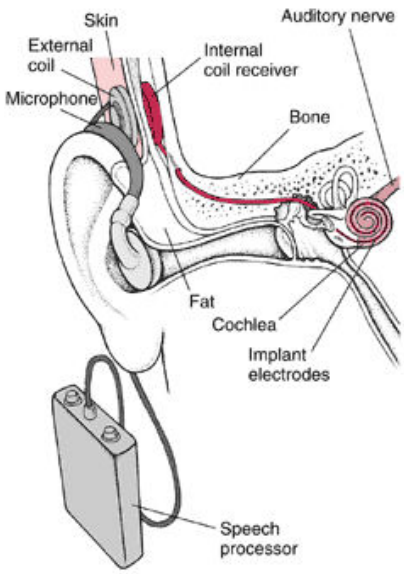
Recommendation
VitalStim Therapy can safely be used in patients with metal implants in patients with carotid stents, cervical hardware or titanium mandible. The likelihood of current to flow

through the implanted metal is very low when applying VitalStim Therapy according to recommended electrode placement guidelines.

Cochlear Implants

Description

Cochlear implants are small electronic devices that can help to provide a sense of sound to a person who is profoundly deaf or severely hard-of-hearing. The implant consists of a small electronic device, which is surgically implanted under the skin behind the ear, and an external speech processor, which is usually worn on a belt or in a pocket. A microphone is also worn outside the body as a headpiece behind the ear to capture incoming sound. The speech processor translates the sound into distinctive electrical signals. These 'codes' travel up a thin cable to the headpiece and are transmitted across the skin via radio waves to the implanted electrodes in the cochlea. The electrodes' signals stimulate the auditory nerve fibers to send information to the brain where it is interpreted as meaningful sound.



An implant does not restore normal hearing. Instead, it can give a deaf or hard-of-hearing individual a useful representation of sounds in the environment and help him or her to understand speech.

Cochlear implants directly stimulate the auditory nerve. Signals generated by the implant are sent by way of the auditory nerve to the brain, which recognizes the signals as sound. Hearing through a cochlear implant is different from normal hearing and takes time to learn or relearn.

Guidelines

No guidance is currently available from the FDA nor have manufacturers of cochlear implants evaluated VitalStim Therapy for possible interference with their devices. However, no adverse events have been reported to either FDA or manufacturers in patients with cochlear implants receiving electrotherapy, either short term or long term.

> *The long term effects of chronic electrical stimulation are unknown. Clinical experience with the system since 1991 has shown no adverse effects of chronic electrical stimulation on patient performance, electrical thresholds, or dynamic range.*[11]

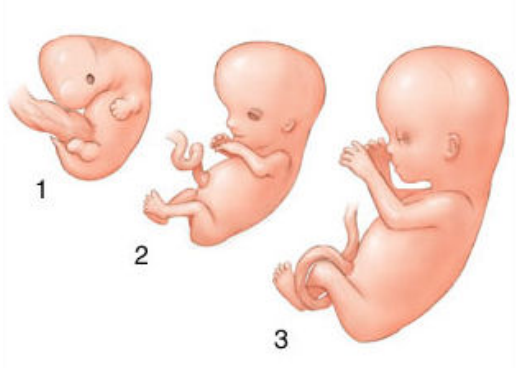
Some therapists using VitalStim Therapy in this population have reported patients noticing "sounds" during treatment, especially when using electrode placements on the face, which would be indicative of the subcutaneous receiver picking up some electromagnetic interference from the VitalStim application. Temporarily turning the cochlear implant off resolves this issue.

Recommendation

The likelihood of the occurrence of interference between the VitalStim Therapy device and the cochlear implant system is small. The clinician should encourage the patient to turn the implant off for the duration of the VitalStim Therapy treatment if any interference is reported by the patient.

Pregnancy

Description



The entire process of pregnancy from conception to birth takes about nine months, or 40 weeks. The pregnancy is divided into 3 trimesters. During the 1st trimester (week 1-12) most of the baby's organs are formed. Many consider the unborn child to be most sensitive at this stage to environmental influences such as chemicals, drugs and viruses. During the 2nd trimester (week 13-28) the fetus begins to grow and its organs mature. During the 3rd trimester (week 29-40) the baby continues to grow and put on weight, as much as about ½ pound per week in the last month. Significant hormonal changes occur during this last period to prepare for birth.

Guidelines

Authors of electrotherapy textbooks have varied positions on the safety of using electrotherapy during pregnancy. Most authors consider it a precaution as long as the application of the current is not over the pelvic, lumbar or abdominal anatomy. The following statements reflect the opinions in these textbooks.

> *Major embryonic development occurs during the first trimester of pregnancy and effect of low level electrical currents is unknown. Even though there are no reports of a tendency to develop birth defects in women who have been stimulated during early pregnancy, the use of electrical stimulation is theoretical concern. During the third trimester, there is some concern that the use of NMES may in some way trigger the contractions of delivery prematurely. There is no evidence to substantiate or refute this concern.* [12]

> *NMES is contraindicated over the trunk or abdomen. TENS is contraindicated over the uterus or during first trimester. (TENS)-effects on fetal development are unknown, although there are no reports of it being detrimental.*[13]

> *No type of ES should be applied over the abdominal, lumbosacral or pelvic regions during pregnancy since the effects of electrical currents on the developing fetus are unknown. Motor-level stimulations should not be used since this may induce intrauterine contractions. ES may be used to control pain during uncomplicated labor and delivery.*[14]

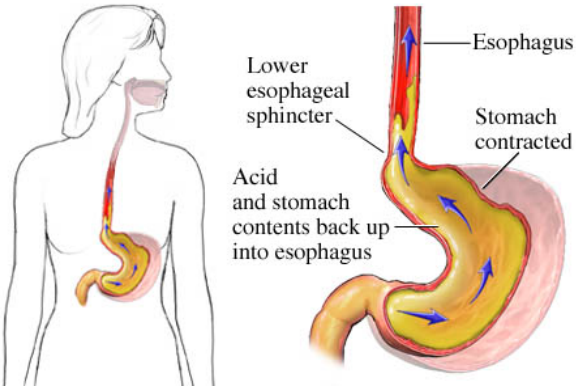
Effects of TENS on pregnancy are unknown. Its use is not contraindicated, but care should be taken. There are several reports describing successful use of TENS with labor and delivery without complications. We have also experienced success in managing pain in the sacral and coccygeal regions in pregnant women who sustained injury as a result of falling. This therapy was administered under the close observation of the obstetrician, without adverse side effects or complications.[15]

Recommendation

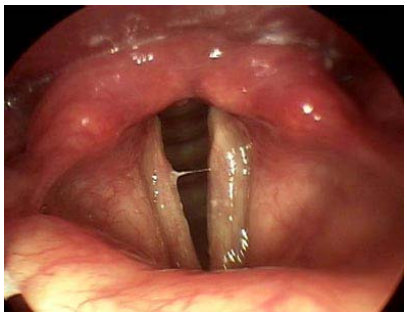
The likelihood of the use of VitalStim Therapy inadvertently interfering with fetal development is extremely small. VitalStim Therapy can safely be used on pregnant patients.

Reflux

Description



Gastroesophageal reflux, often referred to as GERD, occurs when acid from the stomach backs up into the esophagus. The lower esophageal sphincter (LES) contracts to keep the acidic contents of the stomach from refluxing into the esophagus. In those who have GERD, the LES does not close properly, allowing acid to move up the esophagus. When stomach acid touches the sensitive tissue lining the esophagus and throat, it causes a reaction similar to squirting lemon juice in your eye. This is why GERD is often characterized by the burning sensation known as heartburn. In some cases, reflux can be SILENT, with no symptoms until a problem arises. Almost all individuals have experienced reflux (GER), but the disease (GERD) occurs when reflux happens on a frequent basis often over a long period of time.



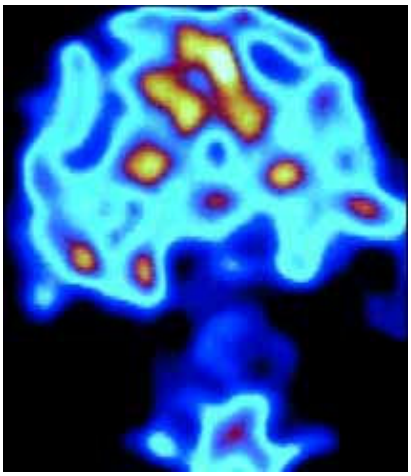
During gastroesophageal reflux, the acidic stomach contents may reflux all the way up the esophagus, beyond the upper esophageal sphincter (a ring of muscle at the top of the esophagus), and into the back of the throat and possibly the back of the nasal airway. This is known as laryngopharyngeal reflux (LPR), which can affect anyone. Adults with LPR often complain that the back of their throat has a bitter taste, a sensation of burning, or something "stuck." Some may have difficulty breathing if the voice box is affected. In infants and children, LPR may cause breathing problems such as: cough, hoarseness, stridor (noisy breathing), croup, asthma, sleep disordered breathing, feeding difficulty (spitting up), turning blue (cyanosis), aspiration, pauses in breathing (apnea), apparent life threatening event (ALTE), and even a severe deficiency in growth. Proper treatment of LPR, especially in children, is critical.

Reflux affects the swallow in several ways but primarily by disrupting normal pressure gradients between the pharynx and the esophagus. The UES may also show hyperactivity to prevent LPR, possibly interfering with a normal swallow.

Guidelines
Patients with reflux are managed by their physician with medication and lifestyle changes (diet).

Recommendation
Dysphagic patients with reflux may be treated with VitalStim Therapy for their muscle dysfunction causing dysphagia provided the underlying reflux disease is addressed.

Seizures, Epilepsy



Description
Epilepsy is a recurrent seizure disorder caused by abnormal electrical discharges from brain cells in the cerebral cortex. It is not a distinct disease, it is a group of disorders for which recurrent seizures are the main symptom. Different forms of epilepsy are either secondary to a particular brain abnormality or neurological disorder, or are said to be idiopathic.

Guidelines
Authors on the subject of electrotherapy have varied positions on the safety of using electrotherapy in patients with epilepsy. The following statements reflect the opinions of these authors.

> *It is recommended that ES not be applied on the craniofacial or cervical region of patients with a history of CVAs or seizures due to concern that the applied electrical current may alter conduction in the CNS.*[14]

> *The use of electrotherapy is a precaution with CVA, TIA and/or epilepsy and other seizure disorders. The authors suggest appropriate patient monitoring when applying stimulation to the head or upper cervical spine regions (until more definitive information is available regarding the effects of stimulation).*[15]

> *The use of TENS may be contraindicated in patients with seizure activity. The authors describe a case report in which seizures and absences increased during the period of TENS use. This increased seizure activity lasted for 2 days after cessation of TENS.*[16]

Recommendation
The likelihood of the use of VitalStim Therapy exacerbating seizure activity is small. The clinician should proceed with caution when using VitalStim Therapy in patients with epilepsy and seizure activity. It is prudent to inform the patient about possible exacerbation of symptoms. Ensure knowledge of the patient's prior history of seizure

activity. Monitor compliance with the medication schedule. Discontinue treatment if exacerbation of symptoms occurs and refer patient back to the referring physician.

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