**FDA REGULATIONS**

***CONTRAINDICATION***

Powered muscle stimulators should not be used on patients with cardiac demand pacemakers.

page9image4266425328page9image4266425584page9image4266425840

***WARNINGS***

1. The long-term effects of chronic electrical stimulation are unknown.
2. Stimulation should not be applied over the carotid sinus nerves, particularly in patients with a known sensitivity to the carotid sinus reflex.
3. Stimulation should not be applied over the neck or mouth. Severe spasm of the laryngeal and pharyngeal muscles may occur and the contractions may be strong enough to close the airway or cause difficulty in breathing.
4. Stimulation should not be applied transthoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
5. Stimulation should not be applied transcerebrally.
6. Stimulation should not be applied over swollen, infected, or inflamed areas or skin eruptions, e.g., phlebitis, thrombophlebitis, varicose veins, etc.
7. Stimulation should not be applied over, or in proximity to, cancerous lesions.

***PRECAUTIONS***

1. Safety of powered muscle stimulators for use during pregnancy has not been established.
2. Caution should be used for patients with suspected or diagnosed heart problems.
3. Caution should be used for patients with suspected or diagnosed epilepsy.
4. Caution should be used in the presence of the following:
   1. When there is a tendency to hemorrhage following acute trauma or fracture;
   2. Following recent surgical procedures when muscle contraction may disrupt the healing process;
   3. Over the menstruating or pregnant uterus; and
   4. Over areas of the skin which lack normal sensation.
5. Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternate conductive medium, or alternate electrode placement.
6. Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.
7. Powered muscle stimulators should be kept out of the reach of children.
8. Powered muscle stimulators should be used only with the leads and electrodes recommended for use by the manufacturer.
9. [FOR PORTABLE DEVICES ONLY]: Portable powered muscle stimulators should not be used while driving, operating machinery, or during any activity in which involuntary muscle contractions may put the user at undue risk of injury.

page10image4227795792page10image4227796048

***ADVERSE REACTIONS***

Skin irritation and burns beneath the electrodes have been reported with the use of powered muscle stimulators.