

Stimkit I

General User Information

Introduction:

The Stimkit I is an audio/stereo electro-stimulator “Powerbox” that has been designed to be used in conjunction with audio “e-stim” files. These files can be in WAV, MP3 or other formats some specifically designed to be played through proprietary software players. These audio e-stim files can be played back to the Stimkit I Powerbox via a computer software or any number of commercially available media players. There are many resources on the internet regarding audio/stereo stimulation including large collections of free “stim” files available to download.

The Stimkit I Powerbox features:

- * 2 Isolated Channels, A and B.
- * Master Output Level Control.
- * Fine Output Level Adjustment for each channel.
- * Normal/Reverse Channel Switching
- * Normal/Triphase Output Switching
- * Audio Input via Bluetooth or 3.5mm Stereo Input Jack.

FRONT PANEL CONTROLS:

OUTPUT LEVEL:

Controls CHANNEL A and CHANNEL B output level with equal gain.

CHANNEL A/CHANNEL B VARIABLE:

In normal operation both controls when initially set to “center” (0) provide the ability to make fine adjustments to their respective channel outputs by increasing or decreasing the gain of the individual channel.

NORMAL CHANNEL/REVERSE CHANNEL:

In NORMAL CHANNEL mode the left channel signal is on CHANNEL A OUTPUT and the right channel signal is on CHANNEL B OUTPUT. In REVERSE CHANNEL mode the left channel signal is on CHANNEL B OUTPUT and the right channel signal is on CHANNEL A OUTPUT.

NORMAL/TRIPHASE:

In NORMAL switch position the output signal of both channels is electrically isolated from each other. In the TRIPHASE switch position the low or common side of both output channels is connected together thus allowing for a 3-wire electrode hook-up.

AUDIO INPUT:

Choice of Bluetooth pairing from a Bluetooth capable audio playback source or analog audio via a 3.5mm stereo jack.

CHANNEL A OUTPUT/CHANNEL B OUTPUT:

Output signal jack(s) for 3.5mm electrode cord sets.

GENERAL AUDIO SETUP:

E-stim audio may be input to the Stimkit I Powerbox via Bluetooth link or by a direct cable from the audio source to the 3.5mm jack designated “AUDIO INPUT”. If you are using Bluetooth do not insert an audio cable into the “AUDIO INPUT” jack. Likewise if you are using an audio cable to link your Stimkit I Powerbox to your playback device disconnect or unpair the Bluetooth playback on your audio device. Using the input cable in combination with Bluetooth will cause conflicts with the Stimkit I Powerbox input levels.

Bluetooth Pairing in Linux: With the Stimkit I Powerbox turned on click the Bluetooth Icon in the system tray. When the Bluetooth menu is displayed locate HW-BT Audio or XWF-M18-M28-M38 then click “Connect”.

Bluetooth Pairing in Windows: With the Stimkit I Powerbox turned on, right click on the “Start” menu and select Settings/Devices/Add bluetooth or other device, then select HW-BT Audio or XWF-M18-M28-M38.

Use care in setting the output level of the audio playback device. Like most devices, over-driving the input of the Stimkit I Powerbox will result in distorted or “clipped” audio output.

PLAY SAFE:

There are many resources outlining the generally accepted basic rules for safe electrical play available on the internet. Also, please read the following section.

The following information is copied from the FDA Guidance Document for Powered Muscle Stimulator 510(k)s. This IS NOT medical advice nor is it to be considered as medical advice. It is merely the most authoritative thinking on the safe use of these types of devices.

CONTRAINDICATION

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

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 difficult 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:
 - a. When there is a tendency to hemorrhage following acute trauma or fracture;
 - b. Following recent surgical procedures when muscle contraction may disrupt the healing process;
 - c. Over the menstruating or pregnant uterus; and
 - d. 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.

ADVERSE REACTIONS

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

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