



Quick Reference Training
Contra-Indications, Warnings,
Cautions & Precautions

BEST™ Devices
Biofeedback Electro-Stimulation Technology



Get Started

NOTE: The information in this Quick Reference Training is not intended to be medical advice and is not a substitute for personal medical care. It is general health information and does not take into account your particular health status.

Only your personal physician or other health professional can best advise you

1. **Caution:** U.S. federal law restricts this device to sale by or on the order of a physician.
2. **Read Owner's Manual** for important safety information, including contraindications for pacemakers and pregnancy.
3. **Use only as directed** for pain relief.

on matters of your health. Your physician or other health professional can assess your medical history and your family's medical history and help explain how the information provided in this booklet may apply to your personal situation.



Safety Precautions

(Excerpt from AVAZZIA Owner's Manual)

Read all safety instructions before operating. The device should only be used for the purpose for which it is intended.

DANGER

This device can generate output pulses up to 650 volts. To avoid skin irritations such as burns, do not use device for prolonged periods of time in a single location, while sleeping or other unattended use. Misuse could result in fire hazard.

Contraindications

Do not use on persons with a demand-type cardiac pacemaker.

Warnings

- Safety of electro-stimulation devices for use during pregnancy or birth has not been established.

- Device is not effective for pain of central origin such as headaches.
- Device has no curative value.
- Device is a symptomatic treatment and as such may suppress the sensation of pain which would otherwise serve as a protective mechanism.
- The long-term effects of chronic electrical stimulation are unknown.
- Stimulation should not be applied over the carotid sinus nerves.
- 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.

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Safety Precautions

(Excerpt from AVAZZIA Owner's Manual – Continued)

- Stimulation should not be applied trans-thoracically in that the introduction of electrical current into the heart may cause cardiac arrhythmias.
- Do not allow any electrode placement that applies current flow trans-cerebrally (through the head.)
- Stimulation should not be applied over swollen, infected or inflamed areas or skin eruptions such as phlebitis, thrombophlebitis, varicose veins, etc.
- Stimulation should not be applied over, or in proximity to, cancerous lesions.
- Keep device out of reach of children. It is not a toy. It should not be used as a weapon.
- Device is not a life-saving device.
- Do not use in or near water.
- Do not operate while operating machinery or vehicles.
- Do not operate if unit has been dropped. Do not operate if case is damaged. Do not operate if unit does not function properly.
- Electronic monitoring equipment, such as ECG monitors and ECG alarms, may not operate properly when device stimulation is in use. Electro-pulses may interfere with pacemakers and/or other electronic and radiological equipment.
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Safety Precautions

(Excerpt from AVAZZIA Owner's Manual -- Continued)

Read all safety instructions before operating. The device should only be used for the purpose for which it is intended.

Precautions

- Isolated cases of skin irritation may occur at the site of electrode placement following long-term application.
- Effectiveness is highly dependent upon subject selection by a person qualified in the management of pain.
- Do not use the device on persons who may be under the influence of alcohol or other drugs. Do not use on the eyeball or over the vessels that may contain a blood clot.
- Do not allow any electrode placement that applies current to the carotid sinus (neck) region.
- Do not use device for undiagnosed pain syndromes until etiology is established.
- Caution should be used for persons with suspected or diagnosed heart problems.
- Caution should be used for persons with suspected or diagnosed epilepsy.
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Safety Precautions

(Excerpt from AVAZZIA Owner's Manual – Continued)

Caution should be used in the presence of the following:

- When there is a tendency to hemorrhage following acute trauma or fracture.
- Following recent surgical procedures when muscle contraction may disrupt healing process.
- Over the menstruating or pregnant uterus; and
- Over areas of the skin which lack normal sensation.

Some persons may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium. The irritation can usually be reduced by using an alternative conductive

medium, or alternative electrode placement.

Electrode placement and stimulation settings should be based on the guidance of the prescribing practitioner.

Results of use may be influenced by person's psychological state and use of drugs.

Adverse Reactions

Skin irritation and electrode burns have been reported. To reduce risk of skin burns, keep electrodes directly against skin during application.

Treatment with an AVAZZIA device is not a replacement for professional healthcare.

Safety Precautions

- Avazzia devices require a prescription from a licensed healthcare professional.
- Avazzia devices should not be shared with people who have not seen the doctor.
- Clean the device's treatment surfaces after each patient. Use a cotton ball moistened with isopropyl alcohol.
- Do not reuse self-adhesive pads on more than one patient. Pads may be saved for a patient to reuse on themselves.
- If a patient reports unwanted side effects from using the BEST devices, discontinue use. Report the side effects to your doctor, and follow your doctor's advice.