

Model MD-1a / MD-2 Product Information Page

Indications for Use

The MD-1a / MD-2 Galvanic units are indicated for use in the treatment of palmar or plantar hyperhidrosis (abnormal sweating not related to exercise or resulting from another underlying condition) using the technique of tapwater iontophoresis.

Important Notice

THIS EQUIPMENT IS FOR PROFESSIONAL USE ONLY AND IS NOT DESIGNED OR INTENDED FOR SELF-USE EXCEPT UNDER THE SUPERVISION OF A PHYSICIAN.

Federal law restricts this device to sale or use only by a licensed medical practitioner. Use by non-medical personnel is permitted only by prescription and such use **MUST** be supervised by a licensed practitioner. R.A. Fischer Company, Inc. assumes no liability for use of this equipment by untrained or non-licensed personnel.

If used under prescription, the patient must obtain instructions on safe and proper use from the prescribing physician. A schedule of regular follow-up visits with the physician should be maintained during and after treatment.

Contraindications

- Do not use this device on patients with cardiac demand pacemakers, electrically sensitive support systems or implants of any kind.
- Do not use this device on cancer patients or patients who are electrically sensitive.
- Avoid treatment in areas where sensation is absent or impaired, and do not apply current over damaged or denuded skin or over skin eruptions of any kind.

Warnings

- Do not apply electrical currents through the cardiac or brain areas, or over the sinus area. Introduction of electrical current into the heart may cause arrhythmias.
- Avoid treatment in patients with suspected or diagnosed heart problems or epilepsy.
- Avoid treatment in areas exhibiting potentially malignant lesions or acute localized infections or over swollen, broken, or inflamed areas. Do not use over areas exhibiting phlebitis, thrombo phlebitis, or varicose veins, or any conditions which may be stimulated or adversely affected by electrical currents.
- Avoid application of current in excess of that which can be safely and comfortably tolerated by the patient. Always treat carefully and observe patient reaction. (As a rule, avoid current intensity greater than .5 - 1.0 milliamperes per square inch of active electrode area.)
- Safety of the use of electrical currents during pregnancy has not been established.
- The long-term effects of chronic electrical stimulation has not been established.
- Keep this device out of reach of children.

Precautions

- For electrical safety, prevent contact between the patient and any metal objects or fixtures during treatment. Avoid personal contact with the electrodes while adjusting panel controls.
- Never operate or place the unit where it may become wet or immersed.
- Some patients may experience skin irritation or hypersensitivity due to the application of electrical current. Irritation can usually be reduced by alternate electrode placement or use of lower current levels.
- Upon evidence of any malfunction, or if there is any sign of electrode or cord deterioration, discontinue

Adverse Effects

- Possible side effects, or results of overtreatment with Galvanic current include erythema (skin redness), transient vesicles, or bulla (blisters). Discontinue treatment and seek medical aid.
- Skin irritation or burns at the areas of electrode contact have been reported with the use of electrical stimulators.