

SPRACKLING CONSULTING COMPANY

324 Peery Parkway

Golden, Colorado 80403

Safety Report Summarization Electronic Detoxification System Ion-Spa

This report is a summary of the Compliance Integrity Services Product Safety Evaluation performed on April 7, 2007 on the Ion-Spa, Electronic Detoxification System. Compliance Integrity Services stated that, "The Standard IEC 60335-1 was used as a Guide and there is no Part 2 Particular Standard that covers the subject 'Electronic Detoxification System'."

This report also summarizes the Emissions testing performed by EMC Integrity. This device was evaluated in accordance with EN 55011, "Limits and methods of measurement of radio disturbance characteristics of industrial scientific and medical (ISM) radio-frequency equipment".

The device tested failed various safety tests and was non-compliant in other areas. This test device failed the Accessibility of Hazardous Voltages and the Leakage Current tests for US Standards, the DC Input and DC Electrode Output, and the Emissions Test. It is missing required designations on the test device and the ground circuit is not wired correctly.

The test results and findings are further explained below.

Mode of Usage

This system is described as an "Electronic Detoxification Unit". It consists of an external desktop power supply, a Control Unit, an "Ionizer Foot Bath Array" or submersible electrodes, and a foot bath tub.

Use of the Ion Spa requires the user to place their feet in a foot bath containing salt water with the Ionizer Foot Bath Array. The instructions for this product recommend using the salt content of the bath to maintain the voltage level of the system between 9 and 24 Vdc. Adding salt to the bath increases the current carrying capacity of the saline solution.

Equipment Rating

(DC Input and DC Electrode Output)

Power equipment is rated for specific voltages and currents. It is important to design equipment so that the power rating for any component is not exceeded. If the power rating for a component is exceeded it can overheat and become a fire hazard or potential shock hazard as the equipment may fail.

The test device failed this test, because it drew more electrical current than the ratings for the external AC/DC adapter that converts the power from 120 VAC to 24 VDC.

During this test the Ion Spa test device overheated, started smoking and some internal components on the printed circuit board failed.

Electrical Current in the Saline Solution

(Accessibility of Hazardous Voltages)

It is important to avoid personal exposure to hazardous voltages and currents. The test device uses 24 Vdc which is considered an Extra Low Voltage to minimize electrical shock; however voltage as low as 16 V with a direct path through the heart can potentially be fatal. Electrical shock can also cause discomfort, burns and fibrillation of the heart. Current and voltage combine to cause electrical shock so this test looks at both factors to determine an unsafe level for humans. The US Standards set limits for voltages exceeding 21.2 Vdc at 2 mA (milliamperes). The International Standards do not set limits for voltages under 42.4 Vdc.

The DC Output circuit of the test device is considered accessible, because the electrodes in the Ionizer Foot Bath Array are not enclosed and the user can come in contact with the electrodes.

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This test was performed between the accessible electrodes and between the accessible electrodes and electrical ground. Electrical ground can be any conductive surface at electrical ground such as plumbing including bathroom faucets.

The test device tested reached unacceptable levels for US standards, but passed International Standards for both tests.

Further notes were added that normal use of this device is not represented by this test and the actual use of this device can result in much higher electrical current in the saline solution.

(Leakage Current)

The electronic detoxification system is designed to generate low levels of direct current (DC power) that flows through the user's body accessible through placing body parts in the saline bath with the Spa Module. Leakage current represents currents that should not be present and could result in electrical shock by touching two accessible components of the test device. Some medical devices are regulated to permit electrical current flow, but this device is not certified as a medical device. The United States and International standards require exposure to this electrical current to be limited.

The device tested reached unacceptable levels for US standards, but passed International Standards. The device uses 24 Vdc. The International Standards do not set limits for voltages under 42.4 Vdc where the US Standards are for voltages exceeding 21.2 Vdc.

This limitation of leakage current also applies to alternating current (AC or wall power). The test device passed this test for both US and International Standards.

Non-Standard or Non-Existent Power Markings

It is important to designate the ratings of electrically powered equipment to prevent injury and unsafe use of a product. It is also customary to use standard symbols so that the use of the equipment becomes intuitive in all situations.

It is required by the US standards to have the rated DC Voltage and Amperes (current) to be marked on a device. It is also required that the Control Unit include markings to refer to the User Manual for instructions on the safe use of the equipment.

The test device did not have markings designating the electrical ratings, nor safety information, and it did not have a standard off/on switch.

Construction Deficiencies

The test device is a potential fire hazard, because a shaving of the plastic enclosure of the test device indicated that the material is not the self-extinguishing type.

The grounding circuit of this test device was not wired correctly. It is possible to short circuit the Ionizer Foot Bath Array to any conductive surface that is at electrical ground such as plumbing including bathroom faucets. If a person touches the Ionizer Foot Bath Array and the plumbing the system will short circuit through their body.

Emissions Testing

An Emissions test was performed on this device to determine its electromagnetic emissions. Devices have to be designed in a way that their electromagnetic emissions or disturbances do not interfere with the operation of radio and telecommunication and other devices in accordance with their purpose.

The test device failed this test.