

# SPRACKLING CONSULTING COMPANY

324 Peery Parkway

Golden, Colorado 80403

## Safety Report Summarization Electronic Detoxification System CELLSPA

This report is a summary of the Compliance Integrity Services Product Safety Evaluation Findings Letter. The tests were performed on April 7, 2007 on the CELLSPA, 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 Marked Mains Supply Input vs. Actual Mains Supply Input, and the Emissions test. It is missing required designations on the test device and has some wiring issues.

The test results and findings are further explained below.

### **Mode of Usage**

This system is described as a "Dual System Ion Cleanse with mp3 and ionic hydrotherapy. It is designed for use by 2 people. It consists of a Main Unit, two submersible Arrays, two Wristbands, and two sets of headphones for music. The manual also lists some therapeutic medical uses that may not be FDA approved.

There are limited instructions for use of this device. The manual simply states to "Put array in the washbasin and wear wristband on your hand." Assumptions were made based on similar devices being tested, but this piece of equipment has very limited information for operation, safety, and troubleshooting.

The instructions for this product also recommend using the salt content of the bath to maintain the "ion density" level of the system between 1.6 and 2.0 and not to exceed 2.4. Adding salt to the bath increases the current carrying capacity of the saline solution.

In testing the "ion density" display of the test device was found to be erratic and unreliable although there is a possibility the test device as received was defective.

### **Equipment Rating**

#### **(Marked Mains Supply Input vs. Actual Mains Supply Input)**

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.

This test device failed this portion of the test, because it did not have marked Mains Supply Input Rating and there is no clear documentation that states what the maximum output voltage or maximum output current is for the components of this device.

However the device tested did not overheat during testing.

### **Electrical Current in the Saline Solution**

#### **(Accessibility of Hazardous Voltages)**

The test device uses 24 Vdc which is considered an Extra Low Voltage to minimize electrical shock. 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 (miliamperes). The International Standards set limits for voltages exceeding 42.4 V.

The DC Output circuit of the test device is considered accessible, because the user can come in contact with the Wristbands and in wet contact with the electrodes in the Arrays. It was noted that the electrodes in the array are enclosed and are not accessible (using the test finger probe) to the User. However because they are placed in a saline solution and use standard headphone jacks this circuit is considered to be "accessible" for testing purposes.

This test performed between the accessible electrodes in the Arrays reached unacceptable levels for US Standards, but passed for International Standards.

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

This test performed between the accessible electrodes in the Arrays and the Wristbands passed both Standards.

## **(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.

## **Transformer Tests**

The following three tests are run specifically on the transformer used in this device. A transformer is a device that transfers electrical energy from one circuit to another by magnetic coupling without requiring relative motion between its parts. In this case the transformer is used to reduce the voltage from 120 V to 24 V. It is important that transformers work correctly otherwise they can be a potential shock and/or fire hazard.

Power transformers are typically third party certified for safety and operation such as Underwriter's Laboratory or UL. The transformer in the device tested appeared to have a fake UL logo and did not indicate the manufacturer or model designation.

## **(Dielectric Strength)**

Dielectric strength is the electric field strength that the transformer can withstand without experiencing failure of its insulating properties. If the insulative properties of the transformer fail the transformer will not function and is a potential fire and shock hazard. The test device complied with this test.

## **Protective Earthing Resistance Measurement**

A protective earth connection ensures that all exposed conductive surfaces are at the same electrical potential as the surface of the Earth. It is important for a transformer to have a protective earth ground to avoid the risk of electrical shock if a person touches a device in which an insulation fault has occurred. The device tested complied with this test.

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## **Construction Deficiencies**

The unit has non-standard venting that could be unsafe by allowing small objects to penetrate the enclosure.

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.

There are standards in place for wiring and grounding to prevent injury both during use and during servicing of a device. The test device did not follow standards for wiring and grounding.

## **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 required by the US standards to have the mains supply electrical rating 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. It is also customary to put the name of a product on the device along with manufacturer information and identification.

The test device did not have markings designating the electrical ratings, nor safety information and the manufacturer is not designated on the product or in the supporting documentation.

## **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.