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Safety Report Summarization
Electronic Detoxification System
AQUA DETOX

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 AQUA DETOX, 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'. "

The Findings Letter also states that, "This product has been certified as a Medical Device by a Notified Body in the European Union.". This device will also be tested based on the additional requirements in Standard EN 60601-1, the Safety of Medical Electrical Equipment.

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 passed most of the safety tests and was compliant in all areas. This test device did fail the Accessibility of Hazardous Voltages and Leakage Current for US Standards, but passed for European and International Standards. In the European Union, when a MDD Notified Body approves the device for a specified therapeutic medical use it effectively passes this test.

The test device is wired and grounded correctly.

This unit has also been tested in accordance with the European Notified Body SIQ and was found to be in compliance with the requirements for a medical device under the European Medical Device Directive.

The test results and findings are further explained below.

Mode of Usage

This system includes a "Detox 5000 Medical" or Control Box, an "Aqua Detox Array" or submersible electrodes, and a foot spa tub. The operating manual states the system is listed as a medical therapeutic device, under the European Medical Device Directive (MDD), for the detoxification of the body and organs.

The instructions for this device state that the user places their feet with the Aqua Detox Array in a tub containing salt water. The manual recommends increasing the salt content of the bath to maintain an electrical current of 2 A indicated on the digital display. Adding salt to the bath increases the current carrying capacity of the saline solution.

During testing the electrical current display of the test device was found to be within 1% accuracy.

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 passed this portion of the test. It has acceptable marked Mains Supply Input Ratings for medical equipment, and the test device fell within these ratings during the test.

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 25-31 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 do not set limits for voltages under 42.4 Vdc.

The DC Output circuit of the test device is considered accessible, because the user can come in wet contact with the electrodes in the Aqua Detox Array. It was noted that the electrodes in the array are enclosed and are not accessible to the User. However for the purpose of investigation, this circuit is considered to be accessible for testing purposes.

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

In the European Union, when a MDD Notified Body approves the device for a specified therapeutic medical use, it effectively passes this test.

The 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.

(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. This device is listed as medical therapeutic device under the European Medical Device Directive (MDD). 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 25-31 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.

The findings letter states the following in respect to leakage current. "Although the Medical Electrical Standards specify very low enclosure, earth and patient leakage currents, these apply only to unintended energy flows. Functional voltage or current can be high, as allowed by product specific standards. Acceptance parameters for medical practices are set by cost-benefit considerations, including the risks associated with alternate therapies."

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.

Output Short Circuit

A short circuit is the connection between two nodes of an electrical circuit that are meant to be at different voltages resulting in a large electrical current. It is important that the output circuits or devices such as the Aqua Detox Array are protected against short circuits using fuses or circuit breakers to prevent potential shock and fire hazards.

The device tested complied with this test for the Aqua Detox Array because it did not overheat and the thermal protection worked.

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 25-31 V. It is important that transformers work correctly otherwise they can be a potential shock and/or fire hazard.

The power transformer in the device tested was third party certification and met the additional requirements for medical equipment.

(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 is Class 2 Equipment and not provided with a Protective Earth Conductor. Therefore this test does not apply.

(Short Circuit)

A short circuit is the connection between two nodes of an electrical circuit that are meant to be at different voltages resulting in a large electrical current. It is important that equipment such as transformers is protected against short circuits using fuses or circuit breakers. The device tested complied with this test, because it did not overheat and the fuse and thermal protection worked.

Construction Deficiencies

Overall the test device was found to have no obvious deficiencies in its construction.

The flammability rating of the plastic enclosure was unable to be determined.

There are some symbols on the Control Box that are not described in the Operating Manual and the operating manual claims that the unit has additional certification that is not specified on the Control Box.

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. This device does have markings designating the correct electrical ratings.

Because this device is certified as a medical device in Europe, it has additional information provided such as the CE marking and a Notified Body Number “1304”. The Notified Body Number indicates the approval of this device for medical device regulatory compliance by the Slovenian Institute of Quality and Metrology (SIQ). For approval as a medical device in the US, the FDA must issue its own marketing clearance.

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 passed this test.