

Certificate of Compliance

Certificate Number: AMD-60335-02-COC

Revision:

Date Issued: August 12, 2008.

Issued to: A Major Difference, Inc.
2950 S. Jamaica Court, Suite 300
Aurora, Colorado 80014
USA.
Attention: Mr. Neill Moroney

PRODUCTS

Electronic Detoxification System, model ionCleanse SOLO, cord connected, electrical supply input rated 20Vdc 2.5A. Provided with an external AC/DC Mains Adapter with Mains Supply input rated 100-240V~ 50/60Hz 1.35A and output rated 20Vdc 2.5A.

APPLICABLE REQUIREMENTS

General Requirements: EN 60335-1: Household and Similar Electrical Appliances
- Safety-Part 1: General Requirements

COMPLIANCE TO EU DIRECTIVE(S)

A sample of the subject product was evaluated and tested to, and found to be in compliance with, the Low Voltage Directive (2006/95/EC). The Manufacturer is therefore eligible to include the Low Voltage Directive in their Declaration of Conformity for CE Marking the subject product, subject to continuing compliance to all the provisions of the said Directive.

CONDITIONS OF ACCEPTABILITY

The equipment is supplied with a nationally approved detachable type power supply cordset for the external AC/DC Mains Adapter and Operating Instructions for its safe use in a national language that is acceptable to the authorities in the country where the equipment is to be installed.

Reference Test Report No: AMD-60335-2, August 12, 2008.





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John Itty
Technical Manager
Compliance Integrity Services
1822 Skyway Drive, Unit J
Longmont, Colorado 80504, USA.

SUMMARY TEST REPORT

EN 60335-1

Household and Similar Electrical Appliances Safety - Part 1: General requirements

Report Reference No.	AMD-60335-02	
Tested and Approved by (name and signature)	John Itty	
Date of issue	August 12, 2008	
Contents	43 Pages	
Testing Laboratory	Compliance Integrity Services	
Address	1334 Carnation Circle Longmont, Colorado 80503	
Testing location/procedure	Compliance Integrity Services	
Address	1822 Skyway Drive, Unit J Longmont, Colorado 80504.	
Applicant's Name	A Major Difference, Inc.	
Address	2950 S. Jamaica Court, Suite 300 Aurora, Colorado 80014.	
Test Specification:		
Standard	EN 60335-1: 2002 - Household and Similar Electrical Appliances Safety - Part 1: General requirements	
Non-standard test method	N/A	
Test item description	Electronic Detoxification System	
Tradenname	A Major Difference, Inc.	
Trademark		
Model/Type reference	ionCleanse SOLO	
Rating(s)	20Vdc 2.5A.	
	Note: Provided with an external Class I Medical Grade Power Supply with input rated 100-240V~ 50/60Hz 1.35A and output rated 20Vdc 2.5A.	
Equipment Mobility	portable / hand-held / floor-standing / fixed / built in	
Connection to mains supply	Permanent / <u>detachable cord set</u> / non detachable cord set	
Operating conditions	<u>continuous</u> / short-time / intermittent	

Overall size of the equipment (W x H x D)..... :	Main Unit: 15.0 cm x 4.3 - 7.2 cm x 20.0 cm
Mass of the equipment (kg) :	0.72 kg
Marked degree of protection to IEC 60529..... :	N/A
Accessories and detachable parts included in the evaluation..... :	Detachable type power supply cord-set & Foot-bath Arrays (SKU AMD1001 or SKU AMD 1003)
Options..... :	None
Test case verdicts:	
Test case does not apply to the test object..... :	N/A
Test object does meet the requirement..... :	P(Pass)
Test object does not meet the requirement..... :	F(Fail)
Testing :	
Date of receipt of test item..... :	May 8, 2008
Date (s) of performance of tests..... :	July 18, 2008 to August 1, 2008

Description of equipment function:

The electronic detoxification system is comprised of the "ionCleanse SOLO" Control Box and a Foot Array (consisting of DC electrodes) intended for immersion in a foot-tub.

The 20Vdc electrical power is derived from an external Medical Grade Power Supply (third-party certified, Class I type, certified to EN 60601-1). The Control Box is plastic and is intended to be table-top mounted. The active output current control circuitry acts a 2A Constant Current source for the Array.

The User is instructed to place their feet along with the Array in a tub containing salt water. When the Array output is turned on, electrolysis of the electrolytic solution is initiated. The maximum output applied to the electrodes is approx. 18Vdc (open circuit) and 2.2A. The User is instructed to increase the salt content of the foot-bath to reach a current of 1.8-2.2A as indicated on the digital display on the Control Box. The Operator Panel is simple, allowing the User to start and stop the session and set the DC polarity option and the treatment time. Both the output DC voltage and Amps are displayed on the LCD.

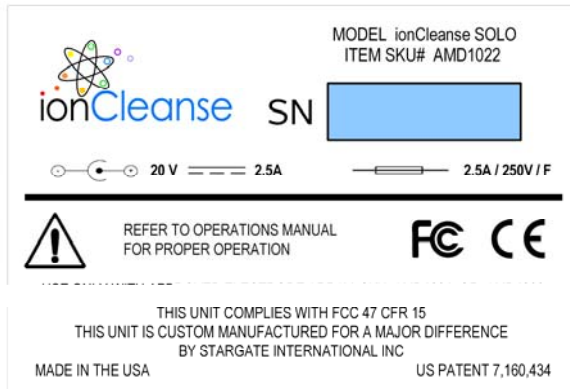
Note: the electrodes in the Array are enclosed (provided with a plastic housing) are not accessible (using the test finger probe) to the User. However, the electrical output is considered accessible for our testing purposes (to simulate worst case conditions) since it is immersed in a conductive saline solution and the presence of accessible mineralized deposits is considered a normal condition.

Please refer to Attachment 4 (Operating Instructions) for more information on product features and intended use. Construction details on the Foot-bath Arrays are kept on file in the Manufacturer's Technical File. The compliant product markings are as shown on page 3 and supersede those shown in Attachment 1.

Compliance Criteria:

1. Approved third party certified components (and components specially evaluated for the current investigation) are used in a suitable electrical/fire enclosure. The design and construction was examined for compliance so as to ensure that there are no Accessible Hazardous Voltage circuits and potential Fire Hazards under Normal and Single Fault Conditions.
2. A sample of the ionCleanse SOLO passed all the required testing.

Copy of markings, including symbols, on the ionCleanse SOLO:



Markings on the DC Power Switch



Marking adjacent Array Output Connector

TABLE: 1 - Documents attached to this report		
Document No.	Document description	No. of Pages
Attachment 1	Figures 1 - 10: Photographs	9
Attachment 2	Electrical Block Circuit Diagram	1
Attachment 3	Electrical Circuit Schematic	1
Attachment 4	Operating Instructions	20
	Test Equipment list	4


Supplementary Information on the ionCleanse SOLO**Enclosure:**

Overall dimensions of 15.0 cm W by 4.3 - 7.2 cm H by 20.0 cm D. The plastic Enclosure consists of 3 mm thick plastic Base and Top Cover. The Top Cover and Base are secured together with two machine screws.

There are no unused openings in the Top Cover or Base. The rear section of the Top Cover has two 3.8 cm diameter openings as shown for the Cooling Fan exhaust. The front section of the Base is provided with vents in two sections, each vent sized 7 mm by 3.5 cm. These two vent areas in the Base and the two Cooling Fan openings in the Top Cover are baffled by a metal screen (wire mesh diameter of 0.45 mm, not exceeding 2 mm X 2 mm center to center) secured internally by RTV Silicone adhesive.

FACTORY TESTS (Also known as **Routine Tests**)

Not required, since the external Power Supply is third-party certified.

5	General conditions for the tests		
	Tests performed according to cl. 5, e.g. nature of supply, sequence of testing, etc.		P
6	Classification		
6.1	Protection against electric shock: Class I, II, III:	External Power Supply: Class I. ionCleanse SOLO Unit: Class III	P
6.2	Protection against harmful ingress of water	External Power Supply & ionCleanse SOLO Unit: Ordinary Protection only.	N/A
7	Marking and Instructions		
7.1	Rated voltage or voltage range (V):	ionCleanse SOLO Unit: 20Vdc	P
	Single-phase appliances to be connected to the supply mains: 230 V covered		N/A
	Multi-phase appliances to be connected to the supply mains: 400 V covered		N/A
	Nature of supply:	DC	P
	Rated frequency (Hz):	(DC only)	N/A
	Rated power input (W):		N/A
	Rated current (A):	2.5A	P
	Manufacturer's or responsible vendor's name, trademark or identification mark:	"A Major Difference, Inc." 	P
	Model or type reference:	"ionCleanse SOLO"	P
	Symbol 5172 of IEC 60417, for Class II appliances		N/A
	IP number, other than IPX0:	Not Rated.	N/A
7.2	Warning for stationary appliances for multiple supply		N/A
	Warning placed in vicinity of terminal cover		N/A
7.3	Range of rated values marked with the lower and upper limits separated by a hyphen	Note: The external power supply is marked "100-240V~".	N/A
	Different rated values marked with the values separated by an oblique stroke		N/A
7.4	Appliances adjustable for different rated voltages, the voltage setting is clearly discernible		N/A

7.5	Appliances with more than one rated voltage or one or more rated voltage ranges, marked with rated input or rated current for each rated voltage or range, unless		N/A
	the power input is related to the mean value of the rated voltage range		N/A
	Relation between marking for upper and lower limits of rated power input or rated current and voltage is clear		N/A
7.6	Correct symbols used		P
7.7	Connection diagram fixed to appliances to be connected to more than two supply conductors and appliances for multiple supply		N/A
7.8	Except for type Z attachment, terminals for connection to the supply mains indicated as follows:		
	- marking of terminals exclusively for the neutral conductor (N)		N/A
	- marking of protective earthing terminals (symbol 5019 of IEC 60417)		N/A
	- marking not placed on removable parts		N/A
7.9	Marking or placing of switches which may cause a hazard		N/A
7.10	Indications of switches on stationary appliances and controls on all appliances by use of figures, letters or other visual means:	Equipment is portable type.	P
	The figure 0 indicates only OFF position, unless no confusion with the OFF position	Note: The DC Power Switch on the ionCleanse Unit is marked with the "I" and "⏻".	P
7.11	Indication for direction of adjustment of controls	Keypad and LCD.	P
7.12	Instructions for safe use provided		P
7.12.1	Sufficient details for installation supplied		P
7.12.2	Stationary appliances not fitted with means for disconnection from the supply mains having a contact separation in all poles that provide full disconnection under overvoltage category III, the instructions state that means for disconnection must be incorporated in the fixed wiring in accordance with the wiring rules	Equipment is portable type; the External Power Supply is provided with a detachable type power supply cord-set.	N/A
7.12.3	Insulation of the fixed wiring in contact with parts exceeding 50 K during clause 11; instructions stating that the fixed wiring must be protected		N/A
7.12.4	Instructions for built-in appliances:		
	- dimensions of space		N/A

	- dimensions and position of supporting means		N/A
	- distances between parts and surrounding structure		N/A
	- dimensions of ventilation openings and arrangement		N/A
	- connection to supply mains and interconnection of separate components		N/A
	- plug accessible after installation, unless		N/A
	a switch complying with 24.3		N/A
7.12.5	Replacement cord instructions, type X attachment with a specially prepared cord	Note: The External Power Supply is provided with a detachable type power supply cord-set.	N/A
	Replacement cord instructions, type Y attachment		N/A
	Replacement cord instructions, type Z attachment		N/A
7.13	Instructions and other texts in an official language	Manufacturer is aware that instructions will be provided in the national language of the country of installation. Operating Instructions in the English Language was reviewed for this application.	P
7.14	Marking clearly legible and durable		P
7.15	Marking on a main part	Refer to page 3. Note: The markings on the AC Mains connected AC/DC Adapter is provided by its manufacturer.	P
	Marking clearly discernible from the outside, if necessary after removal of a cover		P
	For portable appliances, cover can be removed or opened without a tool		N/A
	For stationary appliances, name, trademark or identification mark and model or type reference visible after installation		N/A
	For fixed appliances, name, trademark or identification mark and model or type reference visible after installation according to the instructions		N/A
	Indications for switches and controls placed on or near the components. Marking not on parts which can be positioned or repositioned in such a way that the marking is misleading		P

7.16	Marking of a possible replaceable thermal link or fuse link clearly visible with regard to replacing the link	Refer to Page 3 & Attachment 1.	P
8	Protection against access Live Parts		
	NOTE: Perform the test of 22.11 prior to the tests of Clause 8		
8.1	Adequate protection against accidental contact with live parts	No Accessible Live Parts.	P
8.1.1	Requirement applies for all positions, detachable parts removed		P
	Insertion or removal of lamps, protection against contact with live parts of the lamp cap		N/A
	Use of test probe B of IEC 61032: no contact with live parts		P
8.1.2	Use of test probe 13 of IEC 61032 through openings in class 0 appliances and class II appliances/ constructions: no contact with live parts		N/A
	Test probe 13 also applied through openings in earthed metal enclosures having a non-conductive coating: no contact with live parts		N/A
8.1.3	For appliances other than class II, use of test probe 41 of IEC 61032: no contact with live parts of visible glowing heating elements		N/A
8.1.4	Accessible part not considered live if:		
	- safety extra-low a.c. voltage: peak value not exceeding 42.4 V	The Array output is not AC.	N/A
	- safety extra-low d.c. voltage: not exceeding 42.4 V	The Array output is <20Vdc.	P
	-or separated from live parts by protective impedance		N/A
	If protective impedance: d.c. current not exceeding 2 mA, and		N/A
	a.c. peak value not exceeding 0.7 mA		N/A
	- for peak values over 42.4 V up to and including 450 V, capacitance not exceeding 0,1 μ F		N/A
	-for peak values over 450 V up to and including 15 kV, discharge not exceeding 45 μ C		N/A
8.1.5	Live parts protected at least by basic insulation before installation or assembly:		
	- built-in appliances		N/A
	-fixed appliances		N/A
	- appliances delivered in separate units		N/A

8.2	Class II appliances and constructions constructed so that there is adequate protection against accidental contact with basic insulation and metal parts separated from live parts by basic insulation only	The external Power Supply is Class 1.	N/A
	Only possible to touch parts separated from live parts by double or reinforced insulation		N/A
9	Starting of motor-operated appliances		
	Requirements and tests are specified in part 2 when necessary	No Part 2 Standards.	N/A
10	Power Input and current		
10.1	Power input at normal operating temperature, rated voltage and normal operation not deviating from rated power input by more than shown in table 1	The power input of the ionCleanse SOLO unit is not marked in Watts.	N/A
10.2	Current at normal operating temperature, rated voltage and normal operation not deviating from rated current by more than shown in table 2	See Table 2 in Standard and Test Data below.	P
	“ionCleanse SOLO”: 20Vdc Supply Input	See Results below	P
	Marked Output Rating of external AC/DC Adapter	20 Vdc 2.5 A	—

Condition: “ionCleanse SOLO” Array immersed in salt solution.
Salinity adjusted for maximum DC output.

Test No.	Input Voltage Vdc	DC Input Current A	DC Output Voltage Vdc	DC Output Loading Condition (Foot Bath Array)	Comments
1	20	1.17	16.0	1.00A	Polarity Option (Positive).
2	20	1.67	15.0	1.50A	“
3	20	2.17	14.0	2.00A	“
4	20	2.37	13.6	2.20A	“
5	20	2.50	11.7	2.25A	“

Results: At maximum sustained DC output (approx. 2.2A to the Foot Bath Array per Test No. 4 above), the Main Unit does not draw more than the 2.5A output rating of the external AC/DC Adapter and does not exceed the marked Input rating of 2.5A by the 120% limit. Note: Overload protection provided – output falls to <2V and <2A when the output exceeds 2.3A, requiring a reset of the controls.

11	Heating		
11.1	No excessive temperatures in normal use	See Table 3 in Standard and Test Data below.	P
11.2	Placing and mounting of appliance as described		N/A
11.3	Temperature rises, other than of windings, determined by thermocouples		P
	Temperature rises of windings determined by resistance method, unless		N/A
	the windings makes it difficult to make the necessary connections	Winding integral to the encapsulated 24Vdc to 5Vdc Converter.	P
11.4	Heating appliances operated under normal operation at 1.15 times rated power input :		N/A
11.5	Motor-operated appliances operated under normal operation at most unfavorable voltage between 0.94 and 1.06 times rated voltage:		N/A
11.6	Combined appliances operated under normal operation at most unfavorable voltage between 0.94 and 1.06 times rated voltage:		N/A
11.7	Operation duration corresponding to the most unfavorable conditions of normal use		P
11.8	Temperature rises not exceeding values in table 3	See Table 3 in Standard and Test Data below.	P
	Protective devices do not operate		P
	Sealing compound does not flow out		P
	“ionCleanse SOLO”:	See Results below	P
	Test voltage (V):	20 Vdc	
	Ambient (°C):	25.0	
Condition: Array Output current set at 2.1A. Unit was cycled to operate continuously for 2 hr			
	Thermocouple # / location	Measured (C)	dT (C)
			Max. dT (C) allowed
	TDK/Lamda Converter housing	46.1	21.1
	Heatsink of CVL1 Regulator	70.8	45.8
	Heatsink of 1Ω Power Film Resistor	38.4	13.4
	Top of Plastic Enclosure	37.0	12.0
	Room Ambient	25.0	-
			-

Clause	Requirement -Test	Remark	Result
13	Leakage Current & Electric Strength at Operating Temperature		
13.1	Leakage current not excessive and electric strength adequate	Note: The ionCleanse SOLO is powered from an external Medical Grade Power Supply.	P
	Heating appliances operated at 1.15 times rated power input:		N/A
	Motor-operated appliances and combined appliances supplied at 1.06 times rated voltage:		N/A
	Protective impedance and radio interference filters disconnected before carrying out the tests		N/A
13.2	Leakage current measured by means of the circuit described in figure 4 of IEC 60990	See Table below.	P
	Heating appliances: 1.15 x rated input:		N/A
	Motor-operated and combined appliances: 1.06 x rated voltage:		N/A

Leakage current measurements					P
Supply Voltage	Enclosure/Earth (Ground Open) Normal or Reverse Polarity	Foot Array Electrodes to Ground (Ground Closed) Normal or Reverse Polarity	Foot Array Electrodes to Ground (Ground Open) Normal or Reverse Polarity	Max. Allowed	Compliance
V	mA	mA	mA	mA	Pass/Fail
264V~ 60Hz (AC/DC Adapter)	0.10	0.02	0.12	0.75	Pass

13.3	Electric strength tests according to table 4	See Table below	P
	No breakdown during the tests		P
Test voltage applied between:		Voltage (V)	Breakdown (Yes/No)
Primary and Array		3000	No
Primary and PE		1000	No

14	Transient Overvoltages		
	Note: Perform the tests of clause 14 AFTER the tests of clause 29		
	Appliances withstand the transient over-voltages to which they may be subjected	EUT utilizes a power supply approved to EN60601-1.	N/A
	Clearances having a value less than specified in table 16 subjected to an impulse voltage test, the test voltage specified in table 6		N/A
	No flashover during the test, unless of functional insulation		N/A
	In case of flashover of functional insulation, the appliance complies with clause 19 with the clearance short circuited		N/A
15	Moisture resistance		
15.1	Enclosure provides the degree of moisture protection according to classification of the appliance	EUT is classified IPX0	N/A
	Compliance checked as specified in 15.1.1, taking into account 15.1.2, followed by the electric strength test of 16.3		N/A
	No trace of water on insulation which can result in a reduction of clearances and creepage distances below values specified in clause 29		N/A
15.1.1	Appliances, other than IPX0, subjected to tests as specified in IEC 60529:	<u>Note:</u> The Foot Array is intended to be immersed but is operated from SELV circuit.	N/A
15.1.2	Hand-held appliance turned continuously through the most un-favourable positions during the test		N/A
	Built-in appliances installed according to the instructions		N/A
	Appliances placed or used on the floor or table placed on a horizontal un-perforated support		N/A
	Appliances normally fixed to a wall and appliances with pins for insertion into socket-outlets are mounted on a wooden board		N/A
	For IPX3 appliances, the base of wall mounted appliances is placed at the same level as the pivot axis of the oscillating tube		N/A
	For IPX4 appliances, the horizontal centre line of the appliance is aligned with the pivot axis of the oscillating tube		N/A

	However, for appliances normally used on the floor or table, the movement is limited to two times 90° for a period of 5 min, the support being placed at the level of the pivot axis of the oscillating tube		N/A
	Wall-mounted appliances, take into account the distance to the floor stated in the instructions		N/A
	Appliances with type X attachment fitted with a flexible cord as described		N/A
	Detachable parts tested as specified		N/A
15.2	Spillage of liquid does not affect the electrical insulation	Note: The cord-connected Foot Array is immersed in a liquid container; spillage of liquid on to the ionCleanse SOLO Unit does not constitute a shock hazard.	N/A
	Appliances with type X attachment fitted with a flexible cord as described		N/A
	Appliances incorporating an appliance inlet tested with or without an connector, whichever is most unfavorable		N/A
	Detachable parts removed		N/A
	Overfilling test with additional amount of water, over a period of 1 min (I):		N/A
	The appliance withstands the electric strength test of 16.3		N/A
	No trace of water on insulation that can result in a reduction of clearances and creepage distances below values specified in clause 29		N/A
15.3	Appliances proof against humid conditions	EUT utilizes an external plastic enclosed power supply approved to EN 60601-1.	P
	Humidity test for 48 h in a humidity cabinet		N/A
	The appliance withstands the tests of clause 16		N/A
16	Leakage Current & Electric Strength		
16.1	Leakage current not excessive and electric strength adequate	See tables below.	P
	Protective impedance disconnected from live parts before carrying out the tests		N/A
16.2	Single-phase appliances: test voltage 1.06 times rated voltage:		P
	Three-phase appliances: test voltage 1.06 times rated voltage divided by $\sqrt{3}$:		N/A

Leakage current measurements					P
Supply Voltage	Enclosure/Earth (Ground Open) Normal or Reverse Polarity	Foot Array Electrodes to Ground (Ground Closed) Normal or Reverse Polarity	Foot Array Electrodes to Ground (Ground Open) Normal or Reverse Polarity	Max. Allowed	Compliance
V	mA	mA	mA	mA	Pass/Fail
264V~ 60Hz (AC/DC Adapter)	0.10	0.02	0.12	0.75	Pass

16.3	Electric strength tests according to table 7	See Table below.	P
	No breakdown during the tests		P
Test voltage applied between:		Voltage (V)	Breakdown (Yes/No)
Primary and Array		3000	No
Primary and PE		1250	No

17	Overload Protection of transformers & Associated Circuits		
	No excessive temperatures in transformer or associated circuits in event of short-circuits likely to occur in normal use	EUT utilizes a power supply approved to EN60601-1 and is short-circuit protected.	P
	Appliance supplied with 1.06 or 0.94 times rated voltage and the most unfavorable short-circuit or overload likely to occur in normal use applied:		N/A
	Temperature rise of insulation of the conductors of safety extra-low voltage circuits not exceeding the relevant value specified in table 3 by more than 15 K		N/A
	Temperature of the winding not exceeding the value specified in table 8,		N/A
	however limits do not apply to fail-safe transformers complying with sub-clause 15.5 of IEC 61558-1		N/A
18	Endurance		
	Requirements and tests are specified in part 2 when necessary	No part 2 standard	N/A

19	Abnormal Operation		
19.1	The risk of fire or mechanical damage under abnormal or careless operation obviated	Tests of 19.11 and 19.12	P
	Electronic circuits so designed and applied that a fault will not render the appliance unsafe	Tests of 19.11 and 19.12	P
19.2	Test of appliance with heating elements with restricted heat dissipation; test voltage (V): power input of 0.85 times rated power input:		N/A
19.3	Test of 19.2 repeated; test voltage (V): power input of 1.24 times rated power input:		N/A
19.4	Test conditions as in cl. 11, any control limiting the temperature during tests of cl. 11 short-circuited		N/A
19.5	Test of 19.4 repeated on Class 0I and I appliances with tubular sheathed or embedded heating elements. No short-circuiting, but one end of the element connected to the elements sheath		N/A
	The test repeated with reversed polarity and the other end of the heating element connected to the sheath		N/A
	The test is not carried out on appliances intended to be permanently connected to fixed wiring and on appliances where an all-pole disconnection occurs during the test of 19.4		N/A
19.6	Appliances with PTC heating elements tested at rated voltage, establishing steady conditions		N/A
	The working voltage of the PTC heating element is increased by 5% and the appliance is operated until steady conditions are re-established. The voltage is then increased in similar steps until 1.5 times working voltage or until the PTC heating element ruptures		N/A
19.7	Stalling test by locking the rotor if the locked rotor torque is smaller than the full load torque or locking moving parts of other appliances	With fan stopped and Array Output set at 2.1A output, temperatures stabilized within allowed limits: No Hazards. Note: The temperature of the CVL1 Regulator heatsink rose by 100.5°C and the over-temperature alarm sounded.	P
	Locked rotor, motor capacitors open-circuited or short-circuited, if required		N/A
	Locked rotor, capacitors open-circuited one at a time		N/A

	Test repeated with capacitors short-circuited one at a time, if required		N/A
	Appliances with timer or programmer supplied with rated voltage for each of the tests, for a period equal to the maximum period allowed		N/A
	Other appliances supplied with rated voltage for a period as specified		N/A
	Winding temperatures not exceeding values specified in table 8		N/A
19.8	Three-phase motors operated at rated voltage with one phase disconnected		N/A
19.9	Running overload test on appliances incorporating motors intended to be remotely or automatically controlled or liable to be operated continuously		N/A
	Winding temperatures not exceeding values as specified		N/A
19.10	Series motor operated at 1.3 times rated voltage for 1 min:		N/A
	During the test, parts not being ejected from the appliance		N/A
19.11	Electronic circuits, compliance checked by evaluation of the fault conditions specified in 19.11.2 for all circuits or parts of circuits, unless they comply with the conditions specified in 19.11.1.		P
19.11.1	Before applying the fault conditions a) to f) in 19.11.2, it is checked if circuits or parts of circuit meet both of the following conditions:		
	- the electronic circuit is a low-power circuit, that is, the maximum power at low-power points does not exceed 15 W according to the tests specified		N/A
	- the protection against electric shock, fire hazard, mechanical hazard or dangerous malfunction in other parts of the appliance does not rely on the correct functioning of the electronic circuit		P
19.11.2	Fault conditions applied one at a time, the appliance operated under conditions specified in cl. 11, but supplied at rated voltage, the duration of the tests as specified:		
	a) short circuit of functional insulation if clearances or creepage distances are less than the values specified in 29		N/A
	b) open circuit at the terminals of any component		P

	c) short circuit of capacitors, unless they comply with IEC 60384-14		N/A
	d) short circuit of any two terminals of an electronic component, other than integrated circuits. This fault condition is not applied between the two circuits of an opto-coupler	Short-circuiting of the Array output circuit.	P
	e) failure of triacs in the diode mode		N/A
	f) failure of an integrated circuit. The possible hazardous situations of the appliance are assessed to ensure that safety does not rely on the correct functioning of such a component		P
19.11.3	If the appliance incorporates a protective electronic circuit which operates to ensure compliance with clause 19, the relevant test is repeated with a single fault simulated, as indicated in a) to f) of 19.11.2	A 2.5A fuse is provided in the 20Vdc supply input circuit.	P
	During and after each test the following is checked:		
	- the temperature rise of the windings do not exceed the values specified in table 8		P
	- the appliance complies with the conditions specified in 19.13		P
	-any current flowing through protective impedance not exceeding the limits specified in 8.1.4		N/A
	If a conductor of a printed board becomes open-circuited, the appliance is considered to have withstood the particular test, provided all three of the following conditions are met:		
	- the material of the printed circuit board withstands the burning test of annex E		N/A
	- any loosened conductor does not reduce the clearances or creepage distances between live parts and accessible metal parts below the values specified in cl. 29		N/A
	- the appliance withstands the tests of 19.11.2 with open-circuited conductor bridged		N/A
19.12	If the safety of the appliance for any of the fault conditions specified in 19.11.2 depends on the operation of a miniature fuse-link complying with IEC 60127, the test is repeated, measuring the current flowing through the fuse-link; measured current (A); rated current of the fuse-link (A):	Fuse did not operate.	N/A
19.13	During the tests the appliance does not emit flames, molten metal, poisonous or ignitable gas in hazardous amounts		P

	Temperature rises not exceeding the values shown in table 9		P
	Enclosures not deformed to such an extent that compliance with cl. 8 is impaired		P
	If the appliance can still be operated it complies with 20.2		P
	Insulation, other than of class III appliance, withstand the electric strength test of 16.3, the test voltage specified in table 4:		
	- basic insulation:	Note: The ionCleanse SOLO is a Class III appliance.	N/A
	- supplementary insulation:		N/A
	- reinforced insulation:		N/A
20	Stability and Mechanical Hazards		
20.1	Adequate stability		P
	Tilting test through an angle of 10° (appliance placed on an inclined plane/horizontal plane); appliance does not overturn		P
	Tilting test repeated on appliances with heating elements, angle of inclination increased to 15°		N/A
	Possible heating test in overturned position; temperature rise does not exceed values shown in table 9		N/A
20.2	Moving parts adequately arranged or enclosed as to provide protection against personal injury	Molded finger-guards are provided for the Cooling Fan.	P
	Protective enclosures, guards and similar parts are non-detachable		P
	Adequate mechanical strength and fixing of protective enclosures		P
	Self-resetting thermal cut-outs and over-current protective devices not causing a hazard, by unexpected re-closure	Not provided.	N/A
	Not possible to touch dangerous moving parts with test probe		P
21	Mechanical Strength		
	Appliance has adequate mechanical strength and is constructed as to withstand rough handling	Power Supply has EN 60601-1 approval.	N/A
	No damage after three blows applied to various parts of the enclosure, impact energy 0,5 ± 0,04 J		N/A
	If necessary, supplementary or reinforced insulation subjected to the electric strength test of 16.3	Power supply approved to EN 60601-1 is used.	N/A

	If necessary, repetition of groups of three blows on a new sample		N/A
22	Construction		
22.1	Appliance marked with the first numeral of the IP system, relevant requirements of IEC 60529 are fulfilled	EUT is IPX0.	N/A
22.2	Stationary appliance: means to provide all-pole disconnection from the supply provided, the following means being available:		
	- a supply cord fitted with a plug	For the external portable-type power supply.	P
	- a switch complying with 24.3		N/A
	- a statement in the instruction sheet that a disconnection incorporated in the fixed wiring is to be provided		N/A
	- an appliance inlet	For the external portable-type power supply.	P
	Single-pole switches and single-pole protective devices for the disconnection of heating elements in single-phase permanently connected class I appliances, connected in the phase conductor		N/A
22.3	Appliance provided with pins: no undue strain on socket-outlets		N/A
	Applied torque not exceeding 0.25 Nm		N/A
	Pull force of 50N to each pin after the appliance has been placed in the heating cabinet; when cooled to room temperature the pins are not displaced by more than 1mm		N/A
	Each pin subjected to a torque of 0.4Nm; the pins are not rotating unless rotating does not impair compliance with the standard		N/A
22.4	Appliance for heating liquids and appliance causing undue vibration not provided with pins for insertion into socket-outlets		N/A
22.5	No risk of electric shock when touching the pins of the plug	Power Supply approved to EN 60601-1.	P
22.6	Electrical insulation not affected by condensing water or leaking liquid	Power Supply approved to EN 60601-1.	P
	Electrical insulation of Class II appliances not affected in case of a hose rupture or seal leak		N/A
22.7	Adequate safeguards against the risk of excessive pressure in appliances provided with steam-producing devices		N/A
22.8	Electrical connections not subject to pulling during cleaning of compartments to which access can be gained without the aid of a tool, and that are likely to be cleaned in normal use		N/A

22.9	Insulation, internal wiring, windings, commutators and slip rings not exposed to oil, grease or similar substances		N/A
	Adequate insulating properties of oil or grease to which insulation is exposed		N/A
22.10	Location or protection of reset buttons of non-self-resetting controls is so that accidental resetting is unlikely		N/A
NOTE: Perform the tests of 22.11 prior to the tests of Clause 8			
22.11	Reliable fixing of non-detachable parts that provide the necessary degree of protection against electric shock, moisture or contact with moving parts	Plastic enclosure of external power supply is solvent welded. No access to the Cooling Fan when tested with the test probe.	P
	Obvious locked position of snap-in devices used for fixing such parts		N/A
	No deterioration of the fixing properties of snap-in devices used in parts that are likely to be removed during installation or servicing		N/A
	Tests as described		N/A
22.12	Handles, knobs etc. fixed in a reliable manner		N/A
	Fixing in wrong position of handles, knobs etc. indicating position of switches or similar components not possible		N/A
	Axial force 15 N applied to parts, the shape being so that an axial pull is unlikely to be applied		N/A
	Axial force 30 N applied to parts, the shape being so that an axial pull is likely to be applied		N/A
22.13	Unlikely that handles, when gripped as in normal use, make the operators hand touch parts having a temperature rise exceeding the value specified for handles which are held for short periods only		N/A
22.14	No ragged or sharp edges creating a hazard for the user in normal use, or during user maintenance		P
	No exposed pointed ends of self tapping screws etc., liable to be touched by the user in normal use or during user maintenance		P
22.15	Storage hooks and the like for flexible cords - smooth and well rounded		N/A
22.16	Automatic cord reels cause no undue abrasion or damage to the sheath of the flexible cord, no breakage of conductors strands, no undue wear of contacts		N/A

	Cord reel tested with 6000 operations, as specified		N/A
	Electric strength test of 16.3, voltage of 1000 V applied		N/A
22.17	Spacers not removable from the outside by hand or by means of a screwdriver or a spanner		N/A
22.18	Current-carrying parts and other metal parts resistant to corrosion under normal conditions of use	Electrodes in the Foot Array are replaceable; corrosion does not result in a safety hazard.	P
22.19	Driving belts not used as electrical insulation		N/A
22.20	Direct contact between live parts and thermal insulation effectively prevented, unless material used is non-corrosive, non-hygroscopic and non-combustible		N/A

22.30	Parts serving as supplementary or reinforced insulation fixed so that they cannot be removed without being seriously damaged, or		N/A
	so constructed that they cannot be replaced in an incorrect position, and so that if they are omitted, the appliance is rendered inoperable or manifestly incomplete		N/A
22.31	Clearances and creepage distances over supplementary and reinforced insulation not reduced below values specified in clause 29 as a result of wear		N/A
	Clearances and creepage distances between live parts and accessible parts not reduced below values for supplementary insulation, if wires, screws etc. become loose		N/A
22.32	Supplementary and reinforced insulation designed or protected against deposition of dirt or dust		N/A
	Supplementary insulation of natural or synthetic rubber resistant to ageing, or arranged and dimensioned so that creepage distances are not reduced below values specified in 29.2		N/A
	Ceramic material not tightly sintered, similar material or beads alone not used as supplementary or reinforced insulation		N/A
	Oxygen bomb test at 70 °C for 96 h and 16 h at room temperature		N/A
22.33	Conductive liquids that are or may become accessible in normal use are not in direct contact with live parts	Conductive fluid in the Foot Bath Tub are located away from any Live Parts.	N/A
	Electrodes not used for heating liquids		N/A
	For class II constructions, conductive liquids that are or may become accessible in normal use, not in direct contact with basic or reinforced insulation		N/A
	For class II constructions, conductive liquids which are in contact with live parts, not in direct contact with reinforced insulation		N/A
22.34	Shafts of operating knobs, handles, levers etc. not live, unless the shaft is not accessible when the part is removed		N/A
22.35	Handles, levers and knobs, held or actuated in normal use, not becoming live in the event of an insulation fault		N/A

	Such parts being of metal, and their shafts or fixings are likely to become live in the event of an insulation fault, they are either adequately covered by insulation material, or their accessible parts are separated from their shafts or fixings by supplementary insulation		N/A
	This requirement does not apply to handles, levers and knobs on stationary appliances other than those of electrical components, provided they are either reliably connected to an earthing terminal or earthing contact, or separated from live parts by earthed metal		N/A
22.36	Handles continuously held in the hand in normal use are so constructed that when gripped as in normal use, the operators hand is not likely to touch metal parts, unless they are separated from live parts by double or reinforced insulation		N/A
22.37	Capacitors in Class II appliances not connected to accessible metal parts, unless complying with 22.42		N/A
	Metal casings of capacitors in Class II appliances separated from accessible metal parts by supplementary insulation, unless complying with 22.42		N/A
22.38	Capacitors not connected between the contacts of a thermal cut-out		P
22.39	Lamp holders used only for the connection of lamps		N/A
22.40	Motor-operated appliances and combined appliances intended to be moved while in operation, or having accessible moving parts, fitted with a switch to control the motor. The actuating member of the switch being easily visible and accessible		N/A
22.41	No components, other than lamps, containing mercury		N/A
22.42	Protective impedance consisting of at least two separate components	Protective impedance circuits are not used.	N/A
	Values specified in 8.1.4 not exceeded if any one of the components are short-circuited or open-circuited		N/A
22.43	Appliances adjustable for different voltages, accidental changing of the setting of the voltage unlikely to occur		N/A
22.44	Appliances are not allowed to have an enclosure that is shaped and decorated so that the appliance is likely to be treated as a toy by children		P

22.45	When air is used as reinforced insulation, clearances not reduced below the values specified in 29.1.4 due to deformation as a result of an external force applied to the enclosure		N/A
23	Internal Wiring		
23.1	Wireways smooth and free from sharp edges		P
	Wires protected against contact with burrs, cooling fins etc.		P
	Wire holes in metal well rounded or provided with bushings		N/A
	Wiring effectively prevented from coming into contact with moving parts		P
23.2	Beads etc. on live wires cannot change their position, and are not resting on sharp edges or corners		P
	Beads inside flexible metal conduits contained within an insulating sleeve		N/A
23.3	Electrical connections and internal conductors movable relatively to each other not exposed to undue stress		N/A
	Flexible metallic tubes not causing damage to insulation of conductors		N/A
	Open-coil springs not used		N/A
	Adequate insulating lining provided inside a coiled spring, the turns of which touch one another		N/A
	No damage after 10 000 flexings for conductors flexed during normal use or 100 flexings for conductors flexed during user maintenance		N/A
	Electric strength test, 1000 V between live parts and accessible metal parts		N/A
23.4	Bare internal wiring sufficiently rigid and fixed		N/A
23.5	The insulation of internal wiring withstanding the electrical stress likely to occur in normal use		N/A
	No breakdown when a voltage of 2000 V is applied for 15 min between the conductor and metal foil wrapped around the insulation		N/A
23.6	Sleeving used as supplementary insulation on internal wiring retained in position by positive means		N/A
23.7	The color combination green/yellow used only for earthing conductors	Note: The external Power Supply is third-party certified to EN 60601-1.	P

23.8	Aluminum wires not used for internal wiring		P
23.9	No lead-tin soldering of stranded conductors where they are subject to contact pressure, unless		P
	clamping means so constructed that there is no risk of bad contact due to cold flow of the solder		P
24	Components		
24.1	Components comply with safety requirements in relevant IEC standards	External Power Supply with detachable type power supply cord, fuse in the ionCleanse SOLO Unit, etc.	P
	List of components	Refer to List of Components on page 4.	P
	Components not tested and found to comply with relevant IEC standard for the number of cycles specified are tested in accordance with 24.1.1 to 24.1.6		N/A
	Components not tested and found to comply with relevant IEC standard, components not marked or not used in accordance with its marking, tested under the conditions occurring in the appliance		N/A
24.1.1	Capacitors likely to be permanently subjected to the supply voltage and used for radio interference suppression or for voltage dividing, complying with IEC 60384-14, or	Note: The external Power Supply is third-party certified to EN 60601-1.	P
	tested according to annex F		N/A
24.1.2	Safety isolating transformers complying with IEC 61558-2-6, or	Note: The external Power Supply is third-party certified to EN 60601-1.	P
	tested according to annex G		N/A
24.1.3	Switches complying with IEC 61058-1, the number of cycles of operation being at least 10 000, or		N/A
	tested according to annex H		N/A
24.1.4	Automatic controls complying with IEC 60730-1 with relevant part 2. The number of cycles of operation being:		
	- thermostats: 10 000		N/A
	- temperature limiters: 1 000		N/A
	- self-resetting thermal cut-outs: 300		N/A
	- non-self-resetting thermal cut-outs: 30		N/A
	- timers: 3 000		N/A
	- energy regulators: 10 000		N/A

24.1.5	Appliance couplers complying with IEC 60320-1	Note: The external Power Supply is third-party certified to EN 60601-1.	P
	However, appliances classified higher than IPX0, the appliance couplers complying with IEC 60320-2-3		N/A
24.1.6	Small lamp holders similar to E10 lamp-holders complying with IEC 60238, the requirements for E10 lamp-holders being applicable		N/A
24.2	No switches or automatic controls in flexible cords		P
	No devices causing the protective device in the fixed wiring to operate in the event of a fault in the appliance		P
	No thermal cut-outs that can be reset by soldering		P
24.3	Switches intended for all-pole disconnection of stationary appliances are directly connected to the supply terminals and having a contact separation in all poles, providing full disconnection under overvoltage category III conditions		N/A
24.4	Plugs and socket-outlets for extra-low voltage circuits and heating elements, not interchangeable with plugs and socket-outlets listed in IEC 60083 or IEC 60906-1 or with connectors and appliance inlets complying with the standard sheets of IEC 60320-1	Note: The Array Output jack is a standard Headphone Jack.	P
24.5	Capacitors in auxiliary windings of motors marked with their rated voltage and capacitance and used accordingly		N/A
	Capacitors in appliances for which 30.2.3 is applicable and that are permanently connected in series with a motor winding, are of class P1 or P2 of IEC 60252		N/A
	Voltage across capacitors in series with a motor winding does not exceed 1,1 times rated voltage, when the appliance is supplied at 1,1 times rated voltage under minimum load		N/A
24.6	Working voltage of motors connected to the supply mains and having basic insulation that is inadequate for the rated voltage of the appliance, not exceeding 42V.		N/A
	In addition, the motors are complying with the requirements of Annex I		N/A

25	Supply Connection & External Flexible Cords		
25.1	Appliance not intended for permanent connection to fixed wiring, means for connection to the supply:		
	- supply cord fitted with a plug	Detachable type power supply cord for the external power supply.	P
	- an appliance inlet having at least the same degree of protection against moisture as required for the appliance	The external power supply is provided with an appliance inlet.	P
	- pins for insertion into socket-outlets		N/A
25.2	Appliance not provided with more than one means of connection to the supply mains	For the external power supply unit.	P
	Stationary appliance for multiple supply may be provided with more than one means of connection, provided electric strength test of 1250 V for 1 min between each means of connection causes no breakdown		N/A
25.3	Connection of supply conductors for appliance intended to be permanently connected to fixed wiring possible after the appliance has been fixed to its support		N/A
	Appliance provided with a set of terminals for the connection of cables or fixed wiring, cross-sectional areas specified in 26.6		N/A
	Appliance provided with a set of terminals allowing the connection of a flexible cord		N/A
	Appliance provided with a set of supply leads accommodated in a suitable compartment		N/A
	Appliance provided with a set of terminals and cable entries, conduit entries, knock-outs or glands, allowing connection of appropriate type of cable or conduit		N/A
25.4	Cable and conduit entries, rated current of appliance not exceeding 16 A, dimensions according to table 10		N/A
	Introduction of conduit or cable does not reduce clearances or creepage distances below values specified in 29		N/A
25.5	Method for assemble supply cord with the appliance:		
	- type X attachment	Detachable type power supply cordset is provided for the external power supply.	P
	- type Y attachment		N/A
	- type Z attachment, if allowed in part 2		N/A

	Type X attachment, other than those with a specially prepared cord, not used for flat twin tinsel cords		P
25.6	Plugs fitted with only one flexible cord		P
	Supply cords of single-phase portable appliances having a rated current not exceeding 16 A, fitted with a plug complying with the following standard sheets of IEC 60083:1975:		P
	-for Class I appliances: standard sheet C2b,C3b or C4 :	Nationally Approved plug rated 250V~ 16A max. are incorporated in the detachable type power supply cordset for the external Power Supply..	P
	-for Class II appliances: standard sheet C5 orC6:		N/A
25.7	Supply cord not lighter than:		
	- braided cord (60245 IEC 51)		N/A
	- ordinary tough rubber sheathed cord (60245 IEC 53)		N/A
	- ordinary polychloroprene sheathed flexible cord (60245 IEC 57)		N/A
	-flat twin tinsel cord (60227 IEC 41)		N/A
	- light polyvinyl chloride sheathed cord (60227 IEC 52), appliance not exceeding 3 kg		P
	- ordinary polyvinyl chloride sheathed cord(60227 IEC 53), appliance exceeding 3 kg		N/A
	Supply cords having high flexibility, not lighter than:		
	- rubber insulated and sheathed cord (60245 IEC 86)		N/A
	- rubber insulated, cross-linked PVC sheathed cord (60245 IEC 87)		N/A
	- cross-linked PVC insulated and sheathed cord (60245 IEC 88)		N/A
	Temperature rise of external metal parts exceeding 75 K, PVC cord not used, unless		N/A
	appliance so constructed that the supply cord is not likely to touch external metal parts in normal use, or		N/A
	the supply cord is appropriate for higher temperatures, type Y or type Z attachment used		N/A

25.8	Nominal cross-sectional area of supply cords according to table 11; rated current (A); cross-sectional area (mm ²):	The conductors in the detachable type power supply cordset for the external power supply is sized 0.75mm ² .	N/A
25.9	Supply cord not in contact with sharp points or edges		P
25.10	Green/yellow core for earthing purposes in Class I appliance		P
25.11	Conductors of supply cords not consolidated by lead-tin soldering where they are subject to contact pressure, unless		N/A
	clamping means so constructed that there is no risk of bad contacts due to cold flow of the solder		N/A
25.12	Molding the cord to part of the enclosure does not damage the insulation of the supply cord		N/A
25.13	Inlet opening so shaped as to prevent damage to the supply cord	An Appliance Inlet is provided in the external Power Supply.	N/A
	Unless the enclosure at the inlet opening is of insulation material, a non-detachable lining or bushing complying with 29.3 for supplementary insulation provided		N/A
	If unsheathed supply cord, a similar additional bushing or lining is required, unless		N/A
	the appliance is class 0		N/A
25.14	Supply cords adequately protected against excessive flexing	The detachable type power supply cordset for the external Power Supply is third-party certified.	P
	Flexing test:		
	- applied force (N):		N/A
	- number of flexings:		N/A
	The test does not result in:		
	- short circuit between the conductors		N/A
	- breakage of more than 10% of the strands of any conductor		N/A
	- separation of the conductor from its terminal		N/A
	- loosening of any cord guard		N/A
	- damage, within the meaning of the standard, to the cord or the cord guard		N/A
	- broken strands piercing the insulation and becoming accessible		N/A

25.15	Conductors of the supply cord relieved from strain, twisting and abrasion by use of cord anchorage	The external Power Supply is provided with a detachable type power supply cordset.	N/A
	The cord cannot be pushed into the appliance to such an extent that the cord or internal parts of the appliance can be damaged		N/A
	Pull and torque test of supply cord, values shown in table 10: pull (N); torque (not on automatic cord reel) (Nm):		N/A
	Max. 2 mm displacement of the cord, and conductors not moved more than 1 mm in the terminals		N/A
	Creepage distances and clearances not reduced below values specified in 29.1		N/A
25.16	Cord anchorages for type X attachments constructed and located so that:		
	- replacement of the cord is easily possible	Note: The external Power Supply is provided with a detachable type power supply cordset.	N/A
	- it is clear how the relief from strain and the prevention of twisting are obtained		N/A
	- they are suitable for different types of cord		N/A
	- cord cannot touch the clamping screws of cord anchorage if these screws are accessible, unless separated from accessible metal parts by supplementary insulation		N/A
	- the cord is not clamped by a metal screw which bears directly on the cord		N/A
	-at least one part of the cord anchorage securely fixed to the appliance, unless part of a specially prepared cord		N/A
	- screws which have to be operated when replacing the cord do not fix any other component, if applicable		N/A
	- if labyrinths can be bypassed the test of 25.15 is nevertheless withstood		N/A
	-for Class 0, 0I and I appliances: they are of insulating material or are provided with an insulating lining, unless a failure of the insulation of the cord does not make accessible metal parts live		N/A
	-for Class II appliances: they are of insulating material, or if of metal, they are insulated from accessible metal parts by supplementary insulation		N/A
25.17	Adequate cord anchorages for type Y and Z attachment		N/A

25.18	Cord anchorages only accessible with the aid of a tool, or		N/A
	so constructed that the cord can only be fitted with the aid of a tool		N/A
25.19	Type X attachment, glands not used as cord anchorage in portable appliances		N/A
	Tying the cord into a knot or tying the cord with string not used		N/A
25.20	Conductors of the supply cord for type Y and Z attachment adequately additionally insulated		N/A
25.21	Space for supply cord for type X attachment or for connection of fixed wiring constructed to permit checking of conductors with respect to correct positioning and connection before fitting any cover, no risk of damage to the conductors when fitting the cover, no contact with accessible metal parts if a conductor becomes loose, etc.		N/A
	For portable appliances, the un-insulated end of a conductor prevented from any contact with accessible metal parts, unless the end of the cord is such that the conductors are unlikely to slip free		N/A
25.22	Appliance inlet:		
	- live parts not accessible during insertion or removal	Appliance Inlet of the external Power Supply complies with EN 60320-1.	P
	- connector can be inserted without difficulty		P
	- the appliance is not supported by the connector		P
	- is not for cold conditions if temp. rise of external metal parts exceeds 75 K, unless the supply cord is not likely to touch such metal parts		N/A
25.23	Interconnection cords comply with the requirements for the supply cord, except as specified		N/A
	If necessary, electric strength test of 16.3		N/A
25.24	Interconnection cords not detachable without the aid of a tool if compliance with the standard is impaired when they are disconnected		N/A
25.25	Dimensions of pins compatible with the dimensions of the relevant socket-outlet. Dimensions of pins and engagement face in accordance with the relevant plug in IEC 60083	Nationally approved power supply cord sets are provided with the external power Supply.	P

26	Terminals for External Conductors		
26.1	Appliances provided with terminals or equally effective devices for connection of external conductors		N/A
	Terminals only accessible after removal of a non-detachable cover		N/A
26.2	Appliances with type X attachment and appliances for connection to fixed wiring provided with terminals in which connections are made by means of screws, nuts or similar devices, unless the connections are soldered		N/A
	Screws and nuts serve only to clamp supply conductors, except		N/A
	internal conductors, if so arranged that they are unlikely to be displaced when fitting the supply conductors		N/A
	If soldered connections used, the conductor so positioned or fixed that reliance is not placed on soldering alone		N/A
	Soldering alone used, barriers provided, clearances and creepage distances satisfactory if the conductor becomes free at the soldered joint		N/A
26.3	Terminals for type X attachment and for connection to fixed wiring so constructed that the conductor is clamped between metal surfaces with sufficient contact pressure and without damaging the conductor		N/A
	Terminals for type X attachment and those for connection to fixed wiring so fixed that when tightening or loosening the clamping means:		
	- the terminal does not loosen		N/A
	- internal wiring is not subjected to stress		N/A
	- clearances and creepage distances are not reduced below the values in 29		N/A
	Compliance checked by inspection and by the test of subclause 8.6 of IEC 60999-1, the torque applied being equal to two-thirds of the torque specified. Nominal diameter of thread (mm); screw category; torque (Nm):		N/A
26.4	Terminals for type X attachment, except those with a specially prepared cord, and those for connection to fixed wiring, no special preparation of conductors required, and so constructed or placed that conductors prevented from slipping out		N/A

26.5	Terminals for type X attachment so located or shielded that if a wire of a stranded conductor escapes, no risk of accidental connection to other parts that result in a hazard		N/A
	Stranded conductor test, 8 mm insulation removed		N/A
	No contact between live parts and accessible metal parts and, for class II constructions, between live parts and metal parts separated from accessible metal parts by supplementary insulation only		N/A
26.6	Terminals for type X attachment and for connection to fixed wiring suitable for connection of conductors with required cross-sectional area according to table 13; rated current (A); nominal cross-sectional area (mm ²):		N/A
	Terminals only suitable for a specially prepared cord		N/A
26.7	Terminals for type X attachment accessible after removal of a cover or part of the enclosure		N/A
26.8	Terminals for the connection to fixed wiring, including the earthing terminal, located close to each other		N/A
26.9	Terminals of the pillar type constructed and located as specified		N/A
26.10	Terminals with screw clamping and screw-less terminals not used for flat twin tinsel cords, unless conductors ends fitted with a device suitable for screw terminals		N/A
	Pull test of 5 N to the connection		N/A
26.11	For type Y and Z attachment: soldered, welded, crimped and similar connections may be used		N/A
	For Class II appliances: the conductor so positioned or fixed that reliance is not placed on soldering, welding or crimping alone		N/A
	For Class II appliances: soldering, welding or crimping alone used, barriers provided, clearances and creepage distances satisfactory if the conductor becomes free		N/A
27	Provision for Earthing		
27.1	Accessible metal parts of Class 0I and I appliances, permanently and reliably connected to an earthing terminal or contact of the appliance inlet	The Class I external Power Supply does not have any accessible metal parts.	N/A

	Earthing terminals not connected to neutral terminal		N/A
	Class 0, II and III appliance have no provision for earthing		N/A
	Safety extra-low voltage circuits not earthed, unless protective extra-low voltage circuits		P
27.2	Clamping means adequately secured against accidental loosening		N/A
	Terminals used for the connection of external equipotential bonding conductors allow connection of conductors of 2.5 to 6 mm ² , and		N/A
	do not provide earthing continuity between different parts of the appliance		N/A
	Conductors cannot be loosened without the aid of a tool		N/A
27.3	For appliances with supply cord, current-carrying conductors become taut before earthing conductor, if the cord slips out of the cord anchorage		N/A
27.4	No risk of corrosion resulting from contact between metal of earthing terminal and other metal		N/A
	Adequate resistance to corrosion of coated or uncoated parts providing earthing continuity, other than parts of a metal frame or enclosure		N/A
	Parts of steel providing earthing continuity provided at the essential areas with an electroplated coating, thickness at least 5 µm		N/A
	Adequate protection against rusting of parts of coated or uncoated steel, only intended to provide or transmit contact pressure		N/A
	In case of aluminum alloys precautions taken to avoid risk of corrosion		N/A
27.5	Low resistance of connection between earthing terminal and earthed metal parts		N/A
	This requirement does not apply to connections providing earthing continuity in the protective extra-low voltage circuit, provided that clearances of basic insulation are based on the rated voltage of the appliance		N/A
	Resistance not exceeding 0,1 Ω at the specified low-resistance test		N/A
27.6	The printed conductors of printed circuit boards not used to provide earthing continuity in hand held appliances		N/A

	They may be used in other appliances if:		
	- at least two tracks are used with independent soldering points and the appliance complies with requirements of 27.5 for each circuit		N/A
	- the material of the printed circuit board complies with IEC 60249-2-4 or IEC 60249-2-5		N/A
28	Screws and Connections		
28.1	Fixings, electrical connections and connections providing earthing continuity withstand mechanical stresses	No Protective Earthing connections apart from those integral to the Class I external Power Supply.	N/A
	Screws not of soft metal liable to creep, such as zinc or aluminum		N/A
	Diameter of screws of insulating material min.3 mm		N/A
	Screws of insulating material not used for any electrical connection or connections providing earthing continuity		N/A
	Screws used for electrical connections or connections providing earthing continuity screw into metal		N/A
	Screws not of insulating material if their replacement by a metal screw can impair supplementary or reinforced insulation		N/A
	Type X attachment, screws to be removed for replacement of supply cord or for user maintenance, not of insulating material if their replacement by a metal screw can impair basic insulation		N/A
	For screws and nuts; test as specified		N/A
28.2	Electrical connections and connections providing earthing continuity constructed so that contact pressure not transmitted through insulating material liable to shrink or distort, unless shrinkage or distortion compensated		N/A
	This requirement does not apply to electrical connections in circuits carrying a current not exceeding 0.5A		N/A
28.3	Space-threaded (sheet metal) screws only used for electrical connections if they clamp the parts together		N/A
	Thread-cutting (self-tapping) screws only used for electrical connections if they generate a full-form standard machine screw thread		N/A

	Such screws not used if they are likely to be operated by the user or installer unless the thread is formed by a swaging action		N/A
	Thread-cutting and space-threaded screws may be used in connections providing earthing continuity, provided unnecessary to disturb the connection and at least two screws are used for each connection		N/A
28.4	Screws and nuts that make mechanical connection secured against loosening if they also make electrical connections or connections providing earthing continuity		N/A
	Rivets for electrical connections or connections providing earthing continuity secured against loosening if subjected to torsion		N/A
29	Clearances, Creepage Distances, and Solid Insulation		
	NOTE: Perform the tests of Clause 14 and 22.24 AFTER the tests of Clause 29		
	Clearances, creepage distances and solid insulation withstand electrical stress	Note: The external Power Supply is third-party certified to EN 60601-1.	N/A
	For coatings used on printed circuits boards to protect the microenvironment or to provide basic insulation, annex J applies		N/A
29.1	Clearances not less than the values specified in table 16, taking into account the rated impulse voltage for the overvoltage categories of table 15		N/A
	The values specified may be smaller for basic insulation and functional insulation if the clearance meets the impulse voltage test of clause 14		N/A
	Appliances are in overvoltage category II		N/A
	Clearances less than specified in table 16 not allowed for basic insulation of class 0 and class 0I appliances,		N/A
	or if pollution degree 3 is applicable		N/A
	Compliance is checked by inspection and measurements as specified		N/A
29.1.1	Clearances of basic insulation withstand the over-voltages, taking into account the rated impulse voltage		N/A
	Clearance at the terminals of tubular sheathed heating elements may be reduced to 1mm if the microenvironment is pollution degree 1		N/A

	Lacquered conductors of windings assumed to be bare conductors, but the clearances specified in table 16 are reduced by 0.5mm for rated impulse voltages of at least 1500V		N/A
29.1.2	Clearances of supplementary insulation not less than those specified for basic insulation in table 16		N/A
29.1.3	Clearances of reinforced insulation not less than those specified for basic insulation in table 16, but using the next higher step for rated impulse voltage		N/A
29.1.4	For functional insulation, the values of table 16 are applicable, unless		N/A
	the appliance complies with clause 19 with the functional insulation short-circuited		N/A
	Clearances at crossover points of lacquered conductors not measured		N/A
	Clearance between surfaces of PTC heating elements may be reduced to 1mm		N/A
	Lacquered conductors of windings assumed to be bare conductors, but the clearances specified in table 16 are reduced by 0.5mm for rated impulse voltages of at least 1500V		N/A
29.1.5	Appliances having higher working voltage than rated voltage, the voltage used for determining clearances from table 16 is the sum of the rated impulse voltage and the difference between the peak value of the working voltage and the peak value of the rated voltage		N/A
	If the secondary winding of a step-down transformer is earthed, or if there is an earthed screen between the primary and secondary windings, clearances of basic insulation on the secondary side not less than those specified in table 16, but using the next lower step for rated impulse voltage		N/A
	Circuits supplied with a voltage lower than rated voltage, clearances of functional insulation based on the working voltage used as the rated voltage in table 15		N/A
29.2	Creepage distances not less than those appropriate for the working voltage, taking into account the material group and the pollution degree		N/A
	Pollution degree 2 applies, unless		N/A
	precautions taken to protect the insulation; pollution degree 1		N/A

	insulation subjected to conductive pollution; pollution degree 3		N/A
	Compliance is checked by inspection and measurements as specified		N/A
29.2.1	Creepage distances of basic insulation not less than specified in table 17		N/A
	For pollution degree 1, creepage distance not less than the minimum specified for the clearance in table 16, if the clearance has been checked according to the test of clause 14		N/A
29.2.2	Creepage distances of supplementary insulation at least as specified for basic insulation in table 17		N/A
29.2.3	Creepage distances of reinforced insulation at least double as specified for basic insulation in table 17		N/A
29.2.4	Creepage distances of functional insulation not less than specified in table 18		N/A
	Creepage distances may be reduced if the appliance complies with clause 19 with the functional insulation short-circuited		N/A
29.3	Solid insulation having a minimum thickness of 1mm for supplementary insulation,		N/A
	and 2mm for reinforced insulation		N/A
	This requirement does not apply if the supplementary insulation, other than mica or similar scaly material, consists of at least two layers, each of the layers withstands the electric strength test of 16.3		N/A
	This requirement does not apply if the reinforced insulation, other than mica or similar scaly material, consists of at least three layers, any two layers together withstand the electric strength test of 16.3		N/A
	This requirement also does not apply to inaccessible insulation and does not exceed the maximum permissible temperature values, or		N/A
	if the insulation, after conditioning as specified, withstands the electric strength test of 16.3		N/A
30	Resistance to heat and Fire		
30.1	External parts of non-metallic material,	Plastic enclosure of the ionCleanse SOLO unit is flammability rated UL94V-0.	P
	parts supporting live parts, and	No LIVE parts in the ionCleanse SOLO unit.	N/A

	thermoplastic material providing supplementary or reinforced insulation,		N/A
	sufficiently resistant to heat		P
	Ball-pressure test according to IEC 60695-10-2		N/A
	External parts: at 40 °C plus the maximum temperature rise determined during the test of clause 11, or at 75 °C, whichever is the higher; temperature (°C):		P
	Parts supporting live parts: at 40°C plus the maximum temperature rise determined during the test of clause 11, or at 125°C, whichever is the higher; temperature (°C):		N/A
	Parts of thermoplastic material providing supplementary or reinforced insulation, 25°C plus the maximum temperature rise determined during clause 19, if higher; temperature (°C):		N/A
30.2	Relevant parts of non-metallic material adequately resistant to ignition and spread of fire		P
30.2.1	Glow-wire test of IEC 60695-2-11 at 550 °C, unless		N/A
	the material is classified at least HB40 according to IEC 60695-11-10		N/A
	Parts for which the glow-wire test cannot be carried out meet the requirements in ISO9772 for category FH3 material		N/A
30.2.2	Appliances operated while attended, parts of insulating material supporting current-carrying connections and parts within a distance of 3mm subjected to the glow-wire test of IEC 60695-2-11 at a temperature of:		N/A
	-750°C, for connections carrying a current exceeding 0,5A during normal operation		N/A
	-650°C, for other connections		N/A
	Test not applicable to conditions as specified		N/A
30.2.3	Appliances operated while unattended, tested as specified in 30.2.3.1 and 30.2.3.2	The ionCleanse SOLO is considered to be an attended appliance.	N/A
	Test not applicable to conditions as specified		N/A
30.2.3.1	Parts of insulating material supporting connections carrying a current exceeding 0.2A during normal operation, and		N/A
	parts of insulating material within a distance of 3mm,		N/A
	having a glow-wire flammability index of at least 850°C according to IEC 60695-2-12		N/A

30.2.3.2	Parts of insulating material supporting current-carrying connections, and		N/A
	parts of insulating material within a distance of 3mm,		N/A
	subjected to glow-wire test of IEC 60695-2-11		N/A
	Test not carried out on material having a glow-wire ignition temperature according to IEC 60695-2-13 as specified		N/A
	Glow-wire test of IEC 60695-2-11, the temperature being:		
	-750°C, for connections carrying a current exceeding 0,2A during normal operation		N/A
	-650°C, for other connections		N/A
	Parts that during the test produce a flame persisting longer than 2 s, tested as specified		N/A
	If a flame persists longer than 2 s during the test, parts above the connection, as specified, subjected to the needle-flame test of annex E, unless		N/A
	the material is classified as V-0 or V-1 according to IEC 60695-11-10		N/A
30.2.4	Base material of printed circuit boards subjected to needle-flame test of annex E		N/A
	Test not applicable to conditions as specified		N/A
31	Resistance to Rusting		
	Relevant ferrous parts adequately protected against rusting	Corrosion of the electrodes in the Foot Array does not present a hazard.	P
32	Radiation, Toxicity, and Similar Hazards		
	Appliance does not emit harmful radiation		P
	Appliance does not present a toxic or similar hazard		P
	Description of routine tests to be carried out by the manufacturer	No routine factory testing is required since the external power supply is third-party certified.	N/A