



The clauses marked with * are not covered by the ENAC accreditation. See clauses out of laboratory scope on page 3.

Compliance Laboratory.

IDNEO TECHNOLOGIES S.A.U.

Polígon Industrial Can Mitjans s/n
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PRODUCT: Automatic Actuator System for Manual Resuscitators

APPLICANT: Protofy

MODEL: OxyGEN2 #HOPE

STANDARD: IEC 60601-1:2005/A1:2012/COR1:2012/COR1:2014

EN 60601-1:2006/CORR:2010/A1:2013/AC:2014/A12:2014

UNE EN 60601-1:2008/CORR:2010/A12:2015

TEST REPORT ID. 2020003

Commercial-in-confidence

Testing by

Approved by

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ACCREDITED TESTING LABORATORY

IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No.....:	2020003
Date of issue	03/04/2020
Total number of pages.....:	29
Testing Laboratory	IDNEO Technologies, S.A.U.
Address	Pol. Ind, Can Mitjans S/N 08232 Viladecavalls (Barcelona)
Applicant's name.....:	Protofy
Address	Planta Martorell, Autovía A-2, Km 585. 08760 Martorell. Spain.
Test specification: Standard IEC 60601-1:2005/A1:2012/COR1:2012/COR1:2014 EN 60601-1:2006/CORR:2010/A1:2013/AC:2014/A12:2014 UNE EN 60601-1:2008/CORR:2010/A12:2015 Non-standard test method.....:	
Test item description	Automatic Actuator System for Manual Resuscitators
Trade Mark	OxyGEN2
Manufacturer Plant's name	----
Model/Type reference	OxyGEN2 #HOPE
Ratings	230Vac / 50Hz / 100W
Name and address of factory (ies) . : Assembled in SEAT, S.A. Autovía A2, Km. 585, Martorell.	
Testing verdict: PASS "[Test verdict is according to test results included in this report]"	

Clauses out of Laboratory scope:

Clauses out of Laboratory scope are written with italic letter and marked with *.

Are considered as out of scope the following clauses: 9.5.2; 9.6; 9.7; 9.8.2; 9.8.3.2 a); 9.8.3.3; 10.4; 11.2; 11.4; 15.4.7.1; Annex G; Annex L.

Competence and guarantees according to ISO17025

IDNEO Technologies is a testing laboratory competent to carry out the test described in this report.

In order to assure the traceability to other national and international laboratories, IDNEO Technologies has a calibration and maintenance programmer for this measurement equipment.

Basic environmental test procedures according to:

EN 60068-1

EN 60068-3-5

IDNEO Technologies guarantees the reliability of the data presented in this report, which is the result of the measurements and the tests performed to the item under test on the date and under the conditions stated on the report and, it is based on the knowledge and technical facilities available at IDNEO Technologies at time of performance of the test.

IDNEO Technologies is liable to the client for the maintenance of the confidentiality of all information related to the item under test and the results of test.

Competence and guarantees

1. This report is only referred to the item that has undergone the test.
2. This report does not constitute or imply on its own an approval of the product by the Certification Bodies or competent Authorities.
3. This document is only valid if complete; no partial reproduction can be made without previous written permission of IDNEO Technologies.
4. This test report cannot be used partially or in full for publicity and/or promotional purposes without previous written permission of IDNEO Technologies and the Accreditation Bodies, if applicable.

Environmental Laboratory conditions::

The following limits were not exceeded during the test:

Temperature: Min. = 15°C / Max. =35°C

Relative Humidity 70% as maximum for 35°C.

Altitude: up to 2000 m

Uncertainty:

Uncertainty was calculated according to the IDNEO Technologies internal document PROC1002. Which are kept on file and available for review on demand.

List of Attachments (including a total number of pages in each attachment):

ANNEX 01 – DUT appearance

ANNEX 02 – Impedance and current-carrying capability of protective earth connections. Test Points referents.

ANNEX 03 – Switch Power Supply certification.

SUMMARY OF TESTING**Tests performed (name of test and test clause):**

The equipment has been tested according to:

8.6 – Protective and functional earthing and potential equalization of ME EQUIPMENT

8.7 – Leakage currents and patient auxiliary currents.

**Exempted of humidity pre-condition (See "General product Information")*

8.8.3 - Dielectric Strength.

Of the standards:

IEC 60601-1:2005/A1:2012

EN 60601-1:2006/A1:2013/A12:2014

UNE EN60601-1:2008/A12.

Testing location:**IDNEO Technologies, S.A.U.**

Pol. Industrial Can Mitjans S/N

08232 Viladecavalls – Barcelona (Spain)

COPY OF MARKING PLATE

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

External Marking plate

Ensamblado en SEAT, S.A., Autovía A2, km. 585, Martorell
Modelo: OxyGEN2 #HOPE
Núm. de serie y fecha de fabricación: ver etiqueta código QR
"EXCLUSIVAMENTE PARA INVESTIGACIONES CLÍNICAS"
Tensión y frecuencia de alimentación:



AC INPUT	Voltage	Power	Frecuency
	230V	100W	50Hz



Este dispositivo debe ser utilizado únicamente por personal sanitario cualificado y formado.

Comprobar que el equipo no presente daños o desperfectos.

No acceder a las partes móviles del equipo durante su funcionamiento.

El equipo no está previsto para ser usado en ambiente esterilizado.

No realizar ninguna alteración del dispositivo.

Para realizar el cambio de levas, siga detenidamente las instrucciones.

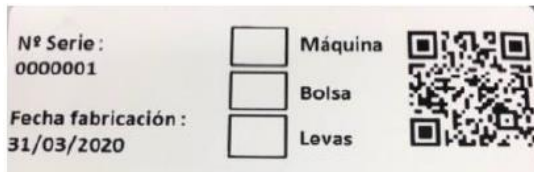
El equipo no debe ser expuesto a ningún derrame de agua ni de cualquier otro líquido.



Lea el manual de instrucciones completamente antes de usar el dispositivo

Hotline 24h/7d: 900 600 400

QR label: (internal label)



Fuse marking:

F1AL250V

Warning mark:



Marking of Emergency Stop button:



Informative markings:

CAMBIO DE LEVA

Nº LEVA	RATIO I:E	Volumen (ml aire)
2XS	1:2	450
2S	1:2	500
2M	1:2	545
2L	1:2	600
2XL	1:2	650

¡ Atención!

El cambio de leva debe realizarse con la máquina parada.

Accionar el interruptor de emergencia cuando el Ambu no quede presionado, la flecha marcada en la leva debe quedar visible en la parte superior.

Abrir la tapa superior.

Desplazar el retenedor de la leva hacia el lado motor y mantenerlo separado.

Extraer la leva tirando hacia arriba.

Seleccionar la leva adecuada según la tabla.

Desplazar el retenedor de la leva hacia el lado motor y mantenerlo separado.

Insertar la leva en el eje.

¡ Atención!

Comprobar la posición de montaje de la leva antes de insertar.

La flecha marcada en la leva debe coincidir con la marca de la carcasa.

Comprobar que la leva queda correctamente posicionada en los pines del eje.

Cerrar la tapa superior.

Accionar el interruptor de emergencia girando en el sentido marcado.

Ajustar la revoluciones con el selector de velocidad.





AMBUs compatibles con dispositivo OxyGEN

INDISPENSABLE con válvula incorporada de presión máxima a 40cmH + bolsa reservorio + adaptador válvula PEEP

- AMBU SPUR II DISPOSABLE RESUCITADOR 1547 ml. (ADULTOS)
- AMBU OVAL SILICONE RESUCITADOR 1475 ml. (ADULTOS)

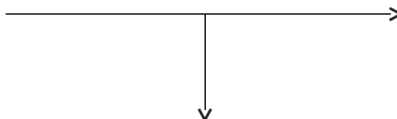


El funcionamiento del equipo se muestra mediante indicación lumínica.

Material no esterilizado



CAMBIO DE LEVAS ALINEAR FLECHA CON EJE



GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use	: <u>transportable</u> / portable / stationary / mobile / fixed / permanently installed / hand-held
Device type (component/sub-assembly/ equipment/ system)	: Equipment
Intended use (Including type of patient, application location)	: Equipment intended to use with a Manual Resuscitator.
Mode of operation	: <u>Continuous</u> / non-continuous
Supply connection	: internally powered / permanently installed / <u>appliance coupler</u> / non-detachable cord
Accessories and detachable parts included	: AC Cord Power
Other options include	: --
Testing	
Date of receipt of test item(s)	: 02/04/2020
Dates tests performed	: 02/04/2020
Possible test case verdicts:	
- test case does not apply to the test object	: N/A
- test object does meet the requirement	: Pass (P)
- test object does not meet the requirement	: Fail (F)
- required document verified but not validated <small>(note 1)</small>	: Verified (V)
<small>(note 1) The existence of documents required for this standard and the reference to the required clauses have been verified by written evidence. But the correct application of these documents is under applicant's responsibility.</small>	
Abbreviations used in the report:	
- normal condition:	N.C.
- means of Operator protection :	MOOP
- single fault condition	: S.F.C.
- means of Patient protection	: MOPP
General remarks:	
<p>"(see Annex #)" refers to additional information appended to the report.</p> <p>"(see appended table)" refers to a table appended to the report.</p> <p>The tests results presented in this report relate only to the object tested.</p> <p>This report shall not be reproduced except in full without the written approval of the testing laboratory.</p> <p>List of test equipment must be kept on file and available for review.</p> <p>Additional test data and/or information provided in the attachments to this report.</p>	

General product information:

► ME System composed by:

The automatic actuator system for manual resuscitators, OxyGEN2 #HOPE, is a breathing assistance equipment based on the automatic operation of a manual resuscitator.

OxyGEN2 #HOPE acts automatically compressing manual resuscitator's bag. OxyGEN2 #HOPE is intended as an electromechanical system for continuous operation.

Manual resuscitator is NOT part of OxyGEN2 #HOPE neither an accessory. Manual resuscitator has not been submitted under test. Therefore, it has not been taken in consideration in this Test evaluation.

OxyGEN2 #HOPE is not intended to be used in an Oxygen rich environment

OxyGEN2 #HOPE is not intended to be connected during the defibrillation maneuver

OxyGEN2 #HOPE is a Non-commercial equipment. It's considered as a prototype for clinical purposes.

Sample serial number: 0000004.

This equipment has been tested without humidity pre-conditioning treatment, the normal use is limited to the environmental Test condition:

Temperature: Min. = 15°C / Max. =35°C

Relative Humidity 70% as maximum for 35°C.

Altitude: up to 2000 m

► Accessories supplied with the equipment:

Detachable AC Cord Power.

► Optional Accessories:

Not optional accessories declared.

► Accompanying Documents supplied for the test:

Not disposed.

► ALTERNATIVE MEANS TO OR LESS THAN RESIDUAL RISK (cl. 4.5):

Not disposed.

► Dimensions:

*Weigth: ----

*HxWxL(cm): ----

*(Data not necessary for the test performed)

► Working Conditions:

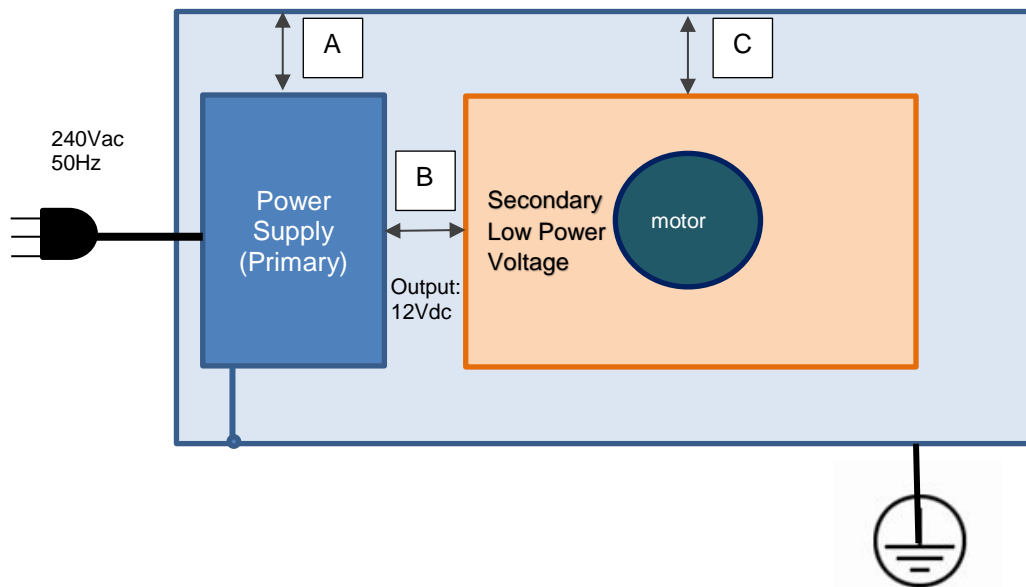
*Amb. Temp: ----

*Relative Humidity: -----

Altitude: <2000m

* (The normal use is limited to the environmental Test condition)

INSULATION DIAGRAM



INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

TABLE: To insulation diagram									PASS
Pollution degree				2					—
Overvoltage category				II					—
Altitude.....				2000m					—
Additional details on parts considered as applied parts				<input checked="" type="checkbox"/> None <input type="checkbox"/> Areas _____ (See Clause 4.6 for details)					—
Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIb, unless is known)	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			Vrms	Vpk					
A	1MOOP	IIb	240	339	2	2	N/A	N/A	See Note1
B	1MOOP	IIb	240	339	2	2	N/A	N/A	See Note1
C	1MOOP	IIb	12	—	0.4	0.4	N/A	N/A	According to Table 15
D									
E									
F									
G									
H									
I									
M									
N									
O									
COMMENTS: Note1: Measurement NOT applied by application of clause 8.9.1.2. Switch Power supply certified according IEC 60950-1 (See Table 8.10)									

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.6	Protective and functional earthing and potential equalization of ME EQUIPMENT		P
8.6.1	Requirements of 8.6.2 to 8.6.8 applied		P
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8	See table 8.10	P
8.6.2	PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR	Power Supply Cord	P
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL		N/A
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside	Not accessible	P
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		P
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		P
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part, except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE :	See RM.	P
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop	See appended Table 8.6.4	P
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits :	See appended Table 8.6.4 & Clause 8.7	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.6.5	Surface coatings		N/A
	Poorly conducting surface coatings on conductive elements removed at the point of contact	Not coating surfaces	N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		N/A
8.6.6	Plugs and sockets		P
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections		P
	- applied also where interchangeable parts are PROTECTIVELY EARTHED	Not such parts	N/A
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR		N/A
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE		N/A
	– RISK of accidental disconnection minimized in NORMAL USE		N/A
	– Terminal allows conductor to be detached without a TOOL		N/A
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		N/A
	– Terminal marked with symbol 8 of Table D.1 (i.e., symbol IEC 60417-5021)		N/A
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		N/A
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		N/A
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION		P
8.6.9	Class II ME EQUIPMENT		N/A
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow		N/A
	Two MEANS OF PROTECTION provided by insulation of internal screens and all internal wiring connected to them with a related explanation in technical description..... :		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		P
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3 :	See appended Tables 8.7 Such part is not provided with DUT	N/A
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7 :	See appended Tables 8.7 <u>Non-subjected to humidity pre-condition</u>	P
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		P
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		P
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		P
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		N/A
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		N/A
8.7.3	Allowable Values		P
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b :	See appended Table 8.7 Fig 12a)	P
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz :	See appended Table 8.7 Non Applicable Parts	N/A
	c) TOUCH CURRENT did not exceed 100 μ A in NORMAL CONDITION and 500 μ A in SINGLE FAULT CONDITION (I_{TNC} , I_{TSFC}) :	See appended Table 8.7	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC} , I_{ESFC}) :	See appended Table 8.7	P
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 :	See appended Table 8.7	N/A
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device) :	See appended Table 8.7	N/A
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements :	See appended Table 8.7	P
8.8	Insulation		P
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION and insulation between parts of opposite polarity of MAINS PART on SUPPLY MAINS side of mains fuse or OVER-CURRENT RELEASE		P
	Insulation exempted from test (complies with clause 4.8)	Power supply meets 4.8a) requirements.	P
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		P
8.8.2	Distance through solid insulation or use of thin sheet material		N/A
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:	Exempted by 4.8a)	N/A
	a) 0.4 mm, min, distance through insulation, or		N/A
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		N/A
	– at least two layers of material, each passed the appropriate dielectric strength test, or	See appended Table 8.8.3	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test	See appended Table 8.8.3	N/A
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		N/A
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		N/A
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		N/A
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		N/A
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L		N/A
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		N/A
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		N/A
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		N/A
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values		N/A
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension.....:		N/A
	Finished component complied with routine dielectric strength tests of 8.8.3	See appended Table 8.8.3	N/A
	Tests of Annex L not repeated since material data sheets confirm compliance	See Table 8.10 and Material Information Attachment	N/A
8.8.3	Dielectric Strength		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Solid insulating materials with a safety function withstood dielectric strength test voltages :	See appended Table 8.8.3	P

8.6.4	TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS			PASS
Type of ME EQUIPMENT & impedance measured between parts	Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)
PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part	N/A	N/A	N/A	100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a Bottom metal shield - (Test 01)	25A/ 10s	6V	64,1	100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a MOTOR ENCLOSURE (METAL ENCLOSURE) - (TEST 02)	25A/ 10s	6V	60,3	100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a Face A External Enclosure (METAL ENCLOSURE) - (TEST 03)	25A/ 10s	6V	66,2	100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a Top door (METAL ENCLOSURE)- (TEST 04)	25A/ 10s	6V	64,9	100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a Face B External Enclosure (METAL ENCLOSURE) - (TEST 05)	25A/ 10s	6V	60,6	100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and Hinge of the top cover (Fixed to metal enclosure) - (Test 06)	25A/ 10s	6V	70.9	100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a Spring fixation (External SCREW) - (TEST 07)	25A/ 10s	6V	67,3	100
ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part	N/A	N/A	N/A	200
Supplementary information: <i>Lab ambient temp: 19,1°C / 44,2%HR</i> See Annex 2 for Test Points reference				

8.7	TABLE: leakage current				PASS
Type of leakage current and test condition (including single faults)		Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks
Test 01 Power Switch ON – 12 RPPM					
Fig. 13 - Earth Leakage (ER) / B		—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
Normal Mains (S5 down)		263.2	50	0.042	5mA
Reverse Voltage (S5 up)		262.6	50	0.012	5mA
Normal Single Fault (S1 Open/S5 Down)		263.8	50	0.04	10mA
Reverse single Fault (S1 Open/S5 up)		263.8	50	0.03	10mA
Test 02 Power Switch ON – 32 RPPM					
Fig. 13 - Earth Leakage (ER) / B		—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
Normal Mains (S5 down)		262.1	50	0.045	5mA
Reverse Voltage (S5 up)		262.5	50	0.035	5mA
Normal Single Fault (S1 Open/S5 Down)		263.9	50	0.05	10mA
Reverse single Fault (S1 Open/S5 up)		263.8	50	0.01	10mA
Test 03 Power Switch OFF – 12 RPPM					
Fig. 13 - Earth Leakage (ER) / B		—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
Normal Mains (S5 down)		263.7	50	0.020	5mA
Reverse Voltage (S5 up)		263.7	50	0.007	5mA
Normal Single Fault (S1 Open/S5 Down)		263.8	50	0	10mA
Reverse single Fault (S1 Open/S5 up)		263.7	50	0.03	10mA
Test 04 Power Switch OFF – 32 RPPM					
Fig. 13 - Earth Leakage (ER) / B		—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
Normal Mains (S5 down)		263.8	50	0.037	5mA
Reverse Voltage (S5 up)		263.8	50	0.032	5mA
Normal Single Fault (S1 Open/S5 Down)		263.8	50	0.02	10mA
Reverse single Fault (S1 Open/S5 up)		263.7	50	0.01	10mA
S10 – Not apply (Non-Accessible Functional Ground connection)					
S12 – Not apply (Non-Patient Connections)					
Test 05 MD1 – PE & external enclosure connected to PE (accessible metal part) / Power Switch ON – 12RPPM					
Fig. 14 - Touch Current (TC) / B		—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down/S7 closed))		262.3	50	19.9	100uA
Reverse Voltage (S5 up/S7 closed)		262.6	50	35	100uA
Normal Single Fault (S1 Open/S5 Down/S7closed)		263.8	50	39.5	500uA
Reverse single Fault (S1 Open/S5 up/S7 closed)		263.7	50	15.4	500uA
Normal Mains (S5 down/S7 open)		262.4	50	424.3*	500uA (see Note3)
Reverse Voltage (S5 up/S7 open)		262.5	50	388.5*	500uA (see Note3)

Test 06				
MD1 – PE & external enclosure connected to PE (accessible metal part) / Power Switch ON – 32RPPM				
Fig. 14 - Touch Current (TC) / B	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down/S7 closed))	262.3	50	38	100uA
Reverse Voltage (S5 up/S7 closed)	262.5	50	20.6A	100uA
Normal Single Fault (S1 Open/S5 Down/S7closed)	263.7	50	18.1	500uA
Reverse single Fault (S1 Open/S5 up/S7 closed)	263.7	50	43.5	500uA
Normal Mains (S5 down/S7 open)	262.4	50	445.9*	500uA (see Note3)
Reverse Voltage (S5 up/S7 open)	262.1	50	373.3*	500uA (see Note3)
Test07				
MD1 – PE & external enclosure connected to PE (accessible metal part) / Power Switch OFF – 12RPPM				
Fig. 14 - Touch Current (TC) / B	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down)	263.8	50	7.2	100uA
Reverse Voltage (S5 up)	263.8	50	26.3	100uA
Normal Single Fault (S1 Open/S5 Down)	263.7	50	33.6	500uA
Reverse single Fault (S1 Open/S5 up)	263.8	50	30.8	500uA
Normal Mains (S5 down/S7 open)	263.8	50	1.7*	500uA (see Note3)
Reverse Voltage (S5 up/S7 open)	263.7	50	0*	500uA (see Note3)
Test08				
MD1 – PE & external enclosure connected to PE (accessible metal part) / Power Switch OFF – 32RPPM				
Fig. 14 - Touch Current (TC) / B	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down)	262.1	50	0.2	100uA
Reverse Voltage (S5 up)	262	50	0	100uA
Normal Single Fault (S1 Open/S5 Down)	263.7	50	0.5	500uA
Reverse single Fault (S1 Open/S5 up)	263.7	50	0.2	500uA
Normal Mains (S5 down/S7 open)	262.1	50	20.9*	500uA (see Note3)
Reverse Voltage (S5 up/S7 open)	262.9	50	1.5*	500uA (see Note3)
Test09				
MD1 – PE & Top door (insolation material) / Power Switch ON 12RPPM				
Fig. 14 - Touch Current (TC) / B	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down/S7 closed))	260.8	50	0.5	100uA
Reverse Voltage (S5 up/S7 closed)	262.1	50	0.2	100uA
Normal Single Fault (S1 Open/S5 Down/S7closed)	263.7	50	0.5	500uA
Reverse single Fault (S1 Open/S5 up/S7 closed)	263.7	50	0.2	500uA
Normal Mains (S5 down/S7 open)	261.4	50	14.4*	500uA (see Note3)
Reverse Voltage (S5 up/S7 open)	262.4	50	0*	500uA (see Note3)

Test10				
MD1 – PE & Top door (insolation material) / Power Switch ON 32RPPM				
Fig. 14 - Touch Current (TC) / B	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down/S7 closed))	262.3	50	1.2	100uA
Reverse Voltage (S5 up/S7 closed)	262.3	50	0.5	100uA
Normal Single Fault (S1 Open/S5 Down/S7closed)	263.6	50	0.5	500uA
Reverse single Fault (S1 Open/S5 up/S7 closed)	263.6	50	0	500uA
Normal Mains (S5 down/S7 open)	262.5	50	7*	500uA (see Note3)
Reverse Voltage (S5 up/S7 open)	262.5	50	0*	500uA (see Note3)
Test11				
MD1 – PE & Top door (insolation material) / Power Switch OFF 12RPPM				
Fig. 14 - Touch Current (TC) / B	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down)	263.8	50	0.5	100uA
Reverse Voltage (S5 up)	263.7	50	0.2	100uA
Normal Single Fault (S1 Open/S5 Down)	263.6	50	0.2	500uA
Reverse single Fault (S1 Open/S5 up)	263.7	50	0.5	500uA
Normal Mains (S5 down/S7 open)	263.7	50	10.4*	500uA (see Note3)
Reverse Voltage (S5 up/S7 open)	263.7	50	0*	500uA (see Note3)
Test12				
MD1 – PE & Top door (insolation material) / Power Switch OFF 32RPPM				
Fig. 14 - Touch Current (TC) / B	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down)	263.7	50	0.5	100uA
Reverse Voltage (S5 up)	263.7	50	0.5	100uA
Normal Single Fault (S1 Open/S5 Down)	263.8	50	1	500uA
Reverse single Fault (S1 Open/S5 up)	263.7	50	0.7	500uA
Normal Mains (S5 down/S7 open)	263.6	50	3.7*	500uA (see Note3)
Reverse Voltage (S5 up/S7 open)	263.7	50	0*	500uA (see Note3)
Test13				
MD1 – PE & sharp edge protection (not conductive material) / Power Switch ON – 12RPPM				
Fig. 14 - Touch Current (TC) / B	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down/S7 closed))	262.5	50	0.7	100uA
Reverse Voltage (S5 up/S7 closed)	262.1	50	0.5	100uA
Normal Single Fault (S1 Open/S5 Down/S7closed)	263.7	50	0.7	500uA
Reverse single Fault (S1 Open/S5 up/S7 closed)	263.7	50	0.5	500uA
Normal Mains (S5 down/S7 open)	262.5	50	1.7*	500uA (see Note3)
Reverse Voltage (S5 up/S7 open)	263	50	0.2*	500uA (see Note3)

Test14				
MD1 – PE & sharp edge protection (not conductive material) / Power Switch ON – 32RPPM				
Fig. 14 - Touch Current (TC) / B	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down/S7 closed))	262.4	50	1	100uA
Reverse Voltage (S5 up/S7 closed)	262.3	50	0.5	100uA
Normal Single Fault (S1 Open/S5 Down/S7closed)	263.7	50	0.5	500uA
Reverse single Fault (S1 Open/S5 up/S7 closed)	263.6	50	0	500uA
Normal Mains (S5 down/S7 open)	262.3	50	0.5*	500uA (see Note3)
Reverse Voltage (S5 up/S7 open)	262.6	50	1.5*	500uA (see Note3)
Test15				
MD1 – PE & sharp edge protection (not conductive material) / Power Switch OFF 12RPPM				
Fig. 14 - Touch Current (TC) / B	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down)	263.6	50	1	100uA
Reverse Voltage (S5 up)	263.7	50	0.5	100uA
Normal Single Fault (S1 Open/S5 Down)	263.7	50	0.5	500uA
Reverse single Fault (S1 Open/S5 up)	263.6	50	0.5	500uA
Normal Mains (S5 down/S7 open)	263.7	50	0.5*	500uA (see Note3)
Reverse Voltage (S5 up/S7 open)	263.7	50	0*	500uA (see Note3)
Test16				
MD1 – PE & sharp edge protection (not conductive material) / Power Switch OFF 32RPPM				
Fig. 14 - Touch Current (TC) / B	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down)	263.7	50	0.5	100uA
Reverse Voltage (S5 up)	263.8	50	0.2	100uA
Normal Single Fault (S1 Open/S5 Down)	263.7	50	0.5	500uA
Reverse single Fault (S1 Open/S5 up)	263.7	50	0.5	500uA
Normal Mains (S5 down/S7 open)	263.7	50	20.6*	500uA (see Note3)
Reverse Voltage (S5 up/S7 open)	263.6	50	0*	500uA (see Note3)
Test17				
MD2 – Top door (insolation material) & Sharp edge protection / Power Switch ON				
Fig. 14 - Touch Current (TC) / B	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down/S7 closed))	262.3	50	0	100uA
Reverse Voltage (S5 up/S7 closed)	262.1	50	0	100uA
Normal Single Fault (S1 Open/S5 Down/S7closed)	263.7	50	0	500uA
Reverse single Fault (S1 Open/S5 up/S7 closed)	263.7	50	0.5	500uA
Normal Mains (S5 down/S7 open)	262.1	50	0	500uA
Reverse Voltage (S5 up/S7 open)	262.4	50	1	500uA

Test12 MD2 – Top door (insulation material) & Sharp edge protection / Power Switch OFF				
Fig. 14 - Touch Current (TC) / B	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
Normal Mains (S5 down)	263.7	50	0.2	100uA
Reverse Voltage (S5 up)	263.8	50	0	100uA
Normal Single Fault (S1 Open/S5 Down)	263.7	50	0	500uA
Reverse single Fault (S1 Open/S5 up)	263.7	50	0.2	500uA
Normal Mains (S5 down/S7 open)	263.7	50	0.2	500uA
Reverse Voltage (S5 up/S7 open)	263.7	50	0.7	500uA
Supplementary information: <i>Non- external temperature increase detected: B/Test: 18,7°C – E/Test: 19,4°C</i> <i>Laboratory ambient temp: 18,7°C / 48,8%HR</i> Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5; Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6; Note 3: Informative data, S7 (Earth line fault test) is not required because Power supply is certified according IEC60950-1, Internal Insulated components shall be considered as High Integrity components according clause 4.7a). ER - Earth leakage current TC – Touch current P - Patient leakage current PA – Patient auxiliary current TP – Total Patient current PM - Patient leakage current with mains on the applied parts MD - Measuring device A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition				

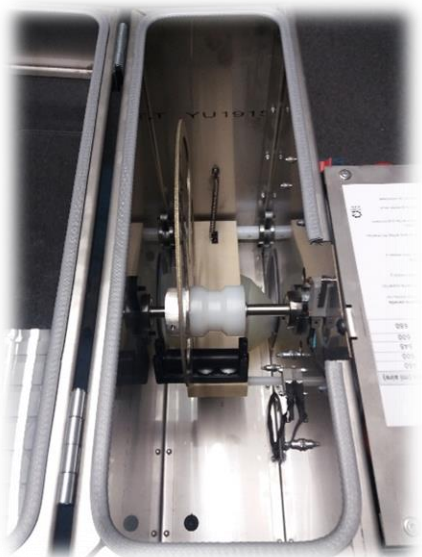
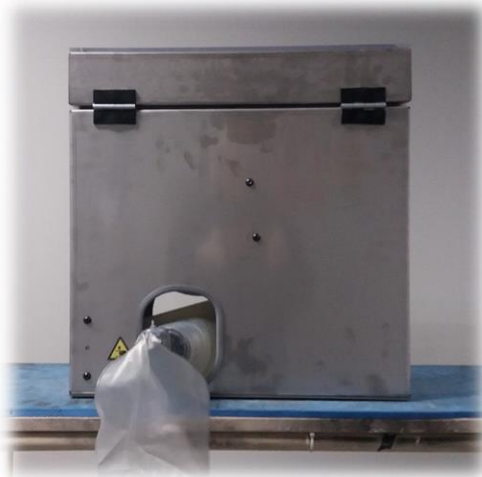
8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				PASS
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s ¹	Dielectric breakdown after 1 minute Yes/No ²
		PEAK WORKING VOLTAGE (U) V _{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
A - (Switch ON)	1MOOP	339V	-	1500	NO (2.041mA)/ --
A - (Switch OFF)	1MOOP	339V	-	1500	NO (0mA)/ --
B – (Switch ON)	1MOOP	339V	-	N/A	NOTE ¹
B – (Switch OFF)	1MOOP	339V	-	N/A	NOTE ¹
C	1MOOP	-	12	Not apply (Table 7)	Not Apply
Supplementary information: <i>NOTE¹: Secondary circuit not accessible. "B Insulation are" is assure but Switch Power Supply, which is certified according to IEC 60950-1. (See table 8.10).</i> <i>Lab ambient temp: 18,7°C / 44,6%HR</i> ¹ Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used. ² A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).					

8.10	TABLE: List of critical components					PASS
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity ¹	
Switch power supply	CoolBox	ECO500 85+	Class I Input: 230Vac / 50Hz / 5A Output: +3,3V / 15A +5V / 14A +12,1V / 17A 12,2V / 17A -12V / 0.3A +5Vsb / 2A	IEC 60950-1	POWCA140501.00	
Switch power supply (alternative)	Interchangeable	--	Class I Input: 230Vac / 50Hz / 5A Output: +3,3V / 15A +5V / 14A +12,1V / 17A 12,2V / 17A -12V / 0.3A +5Vsb / 2A	IEC 60950-1	--	
External enclosure	SEAT	N/A	Conductive Metal part	N/A	N/A	
PLUG	VOLEX	M2511	Class I 250V /16A	IEC 60884-1	Nemko P07207677	
PLUG (Alternative)	Interchangeable	--	Class I 250V /16A	IEC 60884-1	--	
CORD	Ta Hsing Industries	H05VV-F	500V 3G1mm ²	IEC 60227	VDE 40009794	
CORD (Alternative)	Interchangeable	--	500V 3G1mm ²	IEC 60227	--	
CONNECTOR	VOLEX	V1625	C13 250V / 10A Max. T:	EN 60320-1	VDE 40030955	
CONNECTOR (Alternative)	Interchangeable	--	C13 250V / 10A Max. T:	EN 60320-1	--	
Supplementary information:						

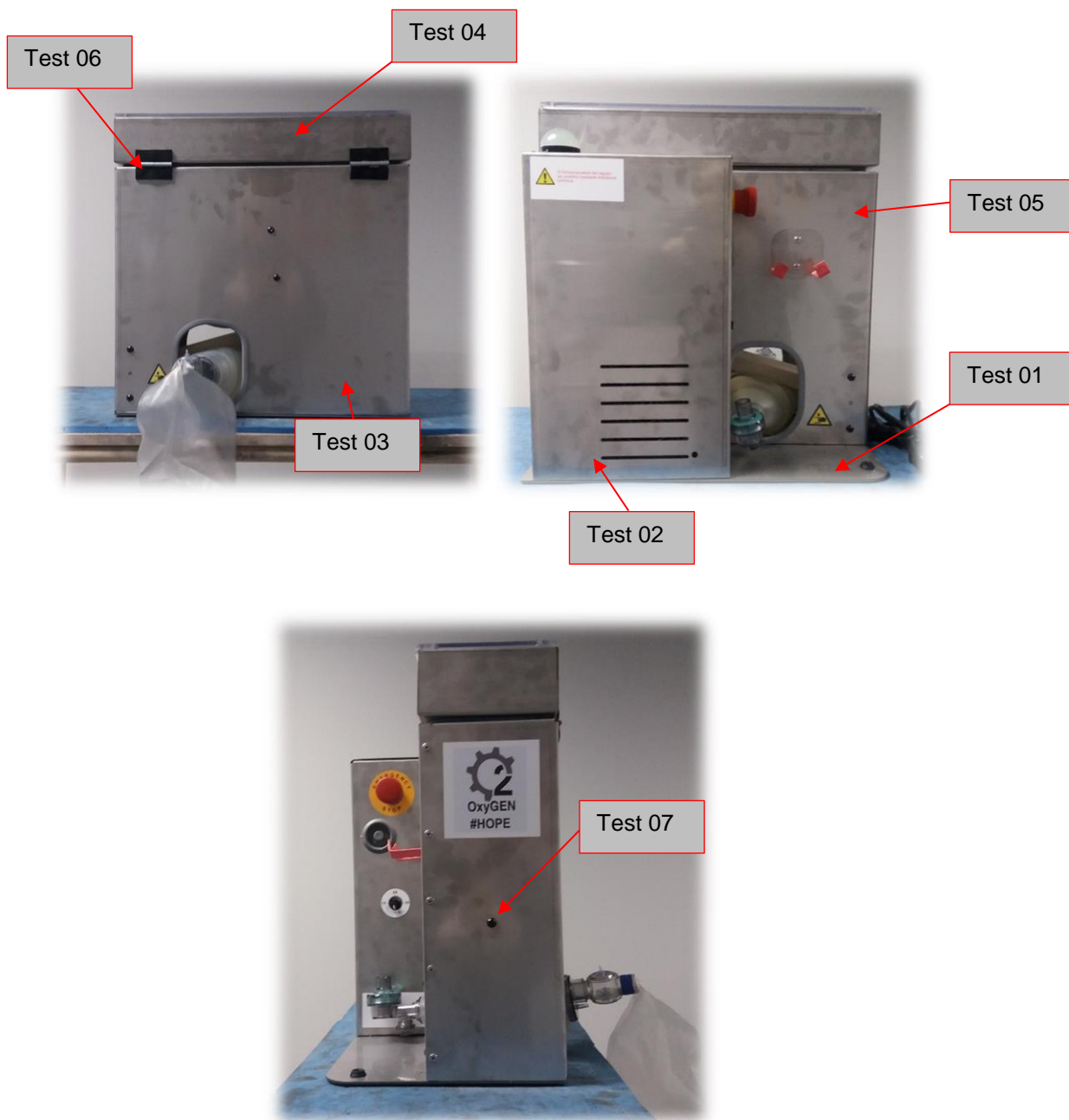
List of test equipment used:

Test Equipment	Manufacturer / Model	Internal Code
Electrical safety analyzer	Chroma 19032	ID.768
Ground Bond Tester	Chroma 19572	ID.620
Thermometer	TME 2020	ID.634
AC Power Supply	KIKUSUI PCR-600L	ID.902


ANNEX 01 - Device under Test (DUT) Appearance



ANNEX 02 - Impedance and current-carrying capability of protective earth connections. Test Points referents



ANNEX 03 – Switch Power Supply Certification

TECNOCREA ADVANCED TESTS & INTERNATIONAL CERTIFICATION AGREEMENTS		Certif. Ref. No. POWCA140501.00
CERTIFICADO DE ENSAYO PARA EQUIPOS ELÉCTRICOS		TEST CERTIFICATES FOR ELECTRICAL EQUIPMENT
CERTIFICADO DE ENSAYO		TEST CERTIFICATE
Producto Product	Fuente de alimentación conmutada Switch power supply	
Nombre y dirección del solicitante Name and address of the applicant	POWER CASE IBERICA, S.L. Polígono Industrial Alquería de Moret C/ Sequia de Mestalla, 5 46210 Picaña – Valencia (España/Spain)	
Nombre y dirección del fabricante Name and address of the manufacturer	Igual que el solicitante Same as applicant	
Nombre y dirección de la fábrica Name and address of the factory	Igual que el solicitante Same as applicant	
Nota: Cuando haya más de una fábrica, por favor indicarlo en la página 2 Note: When more than one factory, please report on page 2		
Valores y características principales Ratings and principal characteristics	Ver página 2 See page 2	
Marca (si existe) Trademark (if any)	COOLBOX	
Modelo / Ref. de tipo Model / Type Ref.	ECO500 85+	
Información adicional (si es necesaria puede ser indicada en la página 2) Additional information (if necessary may also be reported on page 2)		
Una muestra del producto se ha ensayado y se considera conforme con A sample of the product was tested and found to be in conformity with	EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011 + A2:2013 Directive (2006/95/EC) – LVD	
	EN 55022:2010 + AC:2011 EN 55024:2010 EN 61000-3-2:2006 + A1:2009 + A2:2009 EN 61000-3-3:2013 Directive (2004/108/EC) – EMC	
	Directive (2011/65/EU) – RoHS	
Como se muestra en el Informe de Ensayo No. el cual forma parte de este certificado As shown in the Test Report Ref. No. which forms part of this Certificate	T1405043-406; DECE1405043; A140630016002; SAFEPOWCA140501.00.	
		TECNOCREA ADVANCED TESTS & INTERNATIONAL CERTIFICATION AGREEMENTS C/ Colón, 41. 46210 Picaña Valencia – España (Spain)
Fecha/Date: 30/09/2014		Firma/Signature: Jorge Hernández (Documento firmado mediante firma electrónica) (Document signed by means of electronic signature)
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TECNOCREA ADVANCED TESTS & INTERNATIONAL CERTIFICATION AGREEMENTS		Certif. Ref. No. POWCA140501.00	
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Valores y características principales:
Ratings and principal characteristics

Entrada:
Input

230 VAC	50 Hz	5 A
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Salida:
Output

+3,3 V	+5 V	+12 V1	+12 V2	-12 V	+5 Vsb
15 A	14 A	17 A	17 A	0,3 A	2 A

Potencia máxima de salida:
Maximum output power
300 W

Movilidad del equipo:
Equipment mobility

Para empotrar
For buidnq-in


Clase de equipo:
Class of equipment

I

Clase de protección IP:
IP protection class

IPX0

Información adicional (si es necesaria)
Additional information (if necessary)



Firma/Signature: Jorge Hernández
(Documento firmado mediante firma electrónica)
(Document signed by means of electronic signature)

Fecha/Date: 30/09/2014 Página/Page: 2 de/of 2