



Test report No:  
 NIE: 59276REM.001

## Partial Test report

**EN 60601-1-2 (2015): Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.**

Identification of item tested	Class II-A Sanitary Product
Trademark	CRYOSENSE-Whole Body Cryotherapy Cabin
Model and /or type reference	TCT
Other identification of the product	HW Version: 7.2/ Cryosense XL 3.2/ Cryosense MD 1.0 SW Version: 13.0
Features	Cabin size (length x width x height): 1,82 x 0,95 x 2,3m Max Weight: 150 Kg.
Manufacturer	TIME-TECNOLOGÍA E INNOVACIÓN MÉDICO-ESTÉTICA, S.L. C/ Isabel Colbrand, 10. Nave 81. 28050. Madrid. Spain.
Test method requested, standard	EN 60601-1-2 (2015)
Summary	See results in "Summary" section and Appendix A.
Approved by (name / position & signature)	Rafael López EMC Lab Manager
Date of issue	2018-12-10
Report template No	FDT08_21

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## Competences and guarantees

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The results presented in this Test Report apply only to the particular item under test established in this document.

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## General conditions

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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.
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## Uncertainty

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Uncertainty (factor  $k=2$ ) was calculated according to the DEKRA Testing and Certification internal document PODT000.

The total uncertainty of the measurement system for the measured conducted disturbance characteristics of EUT from 150 kHz to 30 MHz is  $I = \pm 3,9$  dB for quasi-peak measurements,  $I = \pm 3,2$  dB for peak measurements ( $k = 2$ ).

The total uncertainty of the measurement system for the measured radio disturbance characteristics of EUT from 30 MHz to 1000 MHz is  $I = \pm 5$  dB for quasi-peak measurements,  $I = \pm 4,7$  dB for peak measurements ( $k = 2$ ).

The total uncertainty of the measurement system for the measured radio disturbance characteristics of EUT from 1 to 6GHz is  $I = \pm 4,2$  dB for peak & average measurements ( $k = 2$ ).

The total uncertainty of the measurement system for the harmonic current measurement, is:

Current Harmonics: Intensity =  $\pm 0,73\%$

Voltage Harmonics: Voltage =  $\pm 0,58\%$

Confidence level:  $k=2$ .

The total uncertainty of the measurement system for the voltage fluctuations and flicker measurement is:

Pst Meter:  $I = \pm 0,58\%$

Plt Meter:  $I = \pm 0,58\%$

Idc =  $0,58\%$

Idmax =  $0,58\%$

Confidence level:  $k=2$ .

## Data provided by the client

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Cryosense cabins consist on three main compartments and different moving parts inside. The first compartment is the place where the customer can enter inside through a door and a lifting platform. The second part is the “cabinet” where the mechanical components exist. The purpose of the cabin is giving pulsed air injection to the first compartment. The air is then cooled due to nitrogen action.

DEKRA declines any responsibility with respect to the information provided by the client and that may affect the validity of results.

## Usage of samples

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Samples under test have been selected by: The client.

Sample S/01 is composed of the following elements:

Control Nº	Description	Model	Serial Nº	Date of reception
59276/001	Cryotherapy equipment	CRYOSENSE-Whole Body Cryotherapy Cabin. TCT.	Prototype	2018-11-08
59276/002	Storage for Cryotherapy equipment	CRYOSENSE-Whole Body Cryotherapy Cabin. TCT.	Prototype	2018-11-08

## Test sample description

Ports..... :	Port name and description	Cable					
		Specified length [m]	Attached during test	Shielded			
	N/A		<input type="checkbox"/>	<input type="checkbox"/>			
	N/A		<input type="checkbox"/>	<input type="checkbox"/>			
	N/A		<input type="checkbox"/>	<input type="checkbox"/>			
	N/A		<input type="checkbox"/>	<input type="checkbox"/>			
	N/A		<input type="checkbox"/>	<input type="checkbox"/>			
Supplementary information to the ports..... :	N/A						
Rated power supply .....	Voltage and Frequency	Reference poles					
		L1	L2	L3	N	PE	
	<input checked="" type="checkbox"/>	AC: 230Vac.	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	<input type="checkbox"/>	AC of positioner:	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	DC:					
<input type="checkbox"/>	DC:						
Rated Power .....	Not provided data						
Clock frequencies .....	Not provided data						
Other parameters..... :	Not provided data						
Software version .....	13.0						
Hardware version..... :	7.2/ Cryosense XL 3.2/ Cryosense MD 1.0						
Dimensions in cm (L x W x D) .....	1,82 x 0,95 x 2,3 m. Max Weight: 150kg.						
Mounting position..... :	<input type="checkbox"/>	Table top equipment					
	<input type="checkbox"/>	Wall/Ceiling mounted equipment					
	<input checked="" type="checkbox"/>	Floor standing equipment					
	<input type="checkbox"/>	Hand-held equipment					
	<input type="checkbox"/>	Other:					
Modules/parts .....	Module/parts of test item		Type	Manufacturer			
	N/A						
	N/A						
	N/A						
	N/A						

Accessories (not part of the test item) .....	Description	Type	Manufacturer
	N/A		
	N/A		
	N/A		
	N/A		
Documents as provided by the applicant.....	Description	File name	Issue date
	N/A		
	N/A		
	N/A		
	N/A		

## Identification of the client

TIME-TECNOLOGÍA E INNOVACIÓN MÉDICO-ESTÉTICA, S.L.  
 Calle Isabel Colbrand, 10. Nave 81. 28050. Madrid. España.

## Testing period and place

<b>Test Location</b>	DEKRA Testing and Certification S.A.U.
<b>Date (start)</b>	2018-11-12
<b>Date (finish)</b>	2018-11-14

## Document history

Report number	Date	Description
59276REM.001	2018-12-10	First release

## Environmental conditions

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In the control chamber, the following limits were not exceeded during the test:

<b>Temperature</b>	Min. = 15 °C Max. = 35 °C
<b>Relative humidity</b>	Min. = 30 % Max. = 75 %
<b>Air pressure</b>	Min. = 860 mbar Max. = 1060 mbar

In the semianechoic chamber, the following limits were not exceeded during the test.

<b>Temperature</b>	Min. = 15 °C Max. = 35 °C
<b>Relative humidity</b>	Min. = 30 % Max. = 75 %
<b>Air pressure</b>	Min. = 860 mbar Max. = 1060 mbar

In the chamber for conducted measurements, the following limits were not exceeded during the test:

<b>Temperature</b>	Min. = 15 °C Max. = 35 °C
<b>Relative humidity</b>	Min. = 30 % Max. = 60 %
<b>Air pressure</b>	Min. = 860 mbar Max. = 1060 mbar

## Remarks and comments

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The tests have been performed by the technical personnel: Daniel López, Miguel Quesada, Lorena Oviedo & Victoria Olmedo.

## Testing verdicts

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Not applicable :	N/A
Pass :	P
Fail :	F
Not measured :	N/M



## Summary

Emission Test		
Requirement – Test case	Verdict	Remark
Radiated emission test (EN 55011)	Pass	-
Conducted emission test (EN 55011)	Pass	-
Discontinuous disturbance (clicks) on AC power leads (EN 55014)	Pass	-
Harmonic current emissions (EN 61000-3-2)	N/A	*1
Voltage changes, voltage fluctuations and flicker (EN 61000-3-3)	N/A	*2
<u>Supplementary information and remarks:</u>		
<p>*1: The equipment overcomes the 16A per phase in a cycle stage, and therefore, according to section 7.2.1 in EN 60601-1-2 (2015), this test is not applicable. The client declares in the user manual a nominal power of 3,5kW and therefore, according to section 7 in EN 61000-3-2 and considering that the equipment is declared as Class A “Professional equipment”, this standard has not limits for this equipment type. Measured only as reference.</p> <p>*2: The equipment overcomes the 16A per phase in a cycle stage, and therefore, according to section 7.2.2 in EN 60601-1-2 (2015), this test is not applicable. Measured only as reference.</p>		

Immunity test		
Requirement – Test case	Verdict	Remark
Radiated electromagnetic fields immunity test (EN 61000-4-3)	N/M	*3
Conducted electromagnetic fields immunity test on power leads (EN 61000-4-6)	Pass	-
Fast transients (EN 61000-4-4)	Pass	-
Surges (EN 61000-4-5)	Pass	-
Voltage dips and short interruptions (EN 61000-4-11)	Pass	-
Power frequency magnetic fields (EN 61000-4-8)	N/M	*3
Electrostatic discharge (EN 61000-4-2)	N/M	*3
<u>Supplementary information and remarks:</u>		
<p>*3: Test not performed. See results in report 57750REM001.</p>		

## List of equipment used during the test

CONTROL NUMBER	DESCRIPTION	MANUFACTURER	MODEL	CALIBRATION (LAST/NEXT)
2942	EMI Test Receiver	ROHDE & SCHWARZ	ESU40	2018-03-14/ 2020-06-19
4578	Bilog Antenna	ETS LINDGREN	3142E	2017-04-03/ 2020-04-03
4612	Horn Antenna	SCHWARZBECK	BBHA 9120 D	2016-12-19/ 2019-12-19
3783	Preamplifier	BONN ELEKTRONIK	BLMA 0118-3A	2018-05-03/ 2019-03-28
4656	Horn Antenna	SCHWARZBECK	BBHA 9170	2017-03-24/ 2020-03-24
4570	Thermohigrometer	HW GROUP	HWg-STE	2018-04-25/ 2019-04-03
4567	Thermohigrometer	HW GROUP	HWg-STE	2018-04-25/ 2019-04-04
4522	EMC measurement software	ROHDE & SCHWARZ	EMC32 V10.20	N/A
6121	Preamplifier	BONN ELEKTRONIK	BLNA 0160-01N	2018-07-19/ 2019-03-20
4729	Preamplifier	BONN ELEKTRONIK	BLMA 1840-1M	2017-12-02/ 2020-02-23
1650	Artificial network	SCHWARZBECK	NNLK8121	2017-09-20/ 2019-09-20
5881	Signal Generator	KEYSIGHT TECHNOLOGIES	N5173B	2016-08-23/ 2018-08-23
0753	Power meter	ROHDE & SCHWARZ	URV5	N/A
3541	Hybrid Bilog Antenna	SUNOL SCIENCES CORPORATION	JB6	2015-09-07/ 2018-09-07
6192	Preamplifier	ROHDE AND SCHWARZ	BBA150	N/A
6227	Amplifier	ROHDE AND SCHWARZ	BBA150	N/A
6234	Power Meter	ROHDE AND SCHWARZ	NRP2	N/A
6236	Amplifier	ROHDE AND SCHWARZ	BBA150- BC250D110+E100	N/A
6237	Amplifier	ROHDE AND SCHWARZ	BBA150-A2500	N/A
0870	Current Injection Probe	SOLAR ELECTRONICS COMPANY	9144-1N	2017-06-30 / 2019-06-30
3889	Amplifier	AMPLIFIER RESEARCH	75A400	N/A
0921	Signal Generator	ROHDE AND SCHWARZ	SME03	N/A
5775	Attenuator	BIRD	100-A-FFN-06	2018-04-13 / 2020-04-13
4430	Power supply	CALIFORNIA INSTRUMENTS	MX30-3Pi	2018-05-24 / 2020-05-24
4431	Artificial network	CALIFORNIA INSTRUMENTS	OMNI 3-75-230	2018-01-19 / 2020-01-19
4225	Harmonics and Flikers analyzer	YOKOGAWA	760303	2018-01-18 / 2020-01-18
3598	Power supply	EM TEST	UCS 500N7	2018-01-23 / 2020-01-23
4432	Coupling Decoupling network	EM TEST	CNI503B7	2017-02-06 / 2019-02-06
4454	3 Phase AC Switch	TESEQ	NSG 2200-3	2017-02-10 / 2019-02-10
1456	Magnetic Field Loop Antenna	SCHAFFNER	---	2018-04-20 / 2020-04-20
6238	Electrostatic Discharge Simulator	EM TEST	esd NX30.1	2017-09-26 / 2018-09-26

## Appendix A: Test results

## Appendix A context

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## DESCRIPTION OF THE OPERATION MODES

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The operation modes described in this paragraph constitute a functionality of the sample under test for itself. Every operation mode takes a failure criteria for the immunity test that they were applying to it and a monitoring to guarantee performance of the same ones.

The operation modes used by the samples to which the present report refers, are shown in the following table:

OPERATION MODE	DESCRIPTION
OM#01	EUT ON. Equipment performing the "Continuous Cycle" treatment. WiFi connected. Power supply: 230Vac.

## FAILS CRITERIA FOR IMMUNITY TEST

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### **IMMUNITY pass/fail criteria EN 60601-1-2 (2015):**

The following list of degradations, that were not allowed with regard to the BASIC SAFETY and ESSENTIAL PERFORMANCE in response to the electromagnetic test signal, is intended as general examples. The MANUFACTURER of the ME EQUIPMENT or ME SYSTEM is required to specify specific IMMUNITY pass/fail criteria for the ME EQUIPMENT or ME SYSTEM under test before the test is performed.

### **General examples**

The following are examples that can be used to develop pass/fail criteria. For ME EQUIPMENT and ME SYSTEMS with multiple functions, the pass/fail criteria should be applied to each function, parameter and channel.

### **Examples of test failures:**

- malfunction;
- non-operation when operation is required;
- unwanted operation when no operation is required;
- deviation from normal operation that poses an unacceptable RISK to the PATIENT or OPERATOR;
- component failures;
- change in programmable parameters;
- reset to factory defaults (MANUFACTURER's presets);
- change of operating mode;
- a FALSE POSITIVE ALARM CONDITION;
- a FALSE NEGATIVE ALARM CONDITION (failure to alarm);
- cessation or interruption of any intended operation, even if accompanied by an ALARM SIGNAL;
- initiation of any unintended operation, including unintended or uncontrolled motion, even if accompanied by an ALARM SIGNAL;
- error of a displayed numerical value sufficiently large to affect diagnosis or treatment;
- noise on a waveform in which the noise would interfere with diagnosis, treatment or monitoring;
- artefact or distortion in an image in which the artefact would interfere with diagnosis, treatment or monitoring;
- failure of automatic diagnosis or treatment ME EQUIPMENT or ME SYSTEM to diagnose or treat, even if accompanied by an ALARM SIGNAL.

### **Example of performance during and after the applied testing stimulus required to pass the test:**

- for a mammography system, the compression full release and associated command remains fully operational;
  - for ULTRASOUND DIAGNOSTIC EQUIPMENT, the probe heating, dissipative power and temperature shall remain within specifications;
  - safety-related functions perform as intended;
  - false operation of alarms, "fail safe" modes and similar functions do not occur.
- NOTE This might require performing the test twice – once to ensure the functions occur as expected and again to ensure they do not occur falsely.

### **Examples of acceptable degradation:**

- an imaging system displays an image that could be altered, but in a way that would not affect the diagnosis or treatment;
- a heart rate monitor displays a heart rate that could be in error, but by an amount that is not clinically significant;
- a PATIENT monitor exhibits a small amount of noise or a transient on a waveform and the noise or transient would not affect diagnosis, treatment or monitoring.

**Examples of ME EQUIPMENT and ME SYSTEMS with multiple functions:** multi-parameter monitors;

- anesthesia system with monitors;
- ventilators with monitors;
- multiple instances of the same function (e.g. multiple invasive blood pressure sensors).

Failure of therapy equipment to terminate a treatment at the intended time can be considered cessation or interruption of an intended operation related to ESSENTIAL PERFORMANCE. If the effect of the test signal on an ME EQUIPMENT or ME SYSTEM is so brief as to be transparent to the PATIENT or OPERATOR and does not affect diagnosis, monitoring or treatment of the PATIENT, this can be considered not to be cessation or interruption of an intended operation. For example, if in response to the IMMUNITY TEST LEVEL a ventilator stops pumping for 50 ms and then resumes operation such that accuracy is within acceptable limits, this would not be considered cessation or interruption of an intended operation.

Note that it might be necessary to test the ME EQUIPMENT or ME SYSTEM multiple times, e.g. under one set of conditions to assure that it sounds an ALARM SIGNAL when it should, within the MANUFACTURER's specifications for sensitivity and response time, and under another set of conditions to assure that it does not sound an ALARM SIGNAL when it should not.

Example of IMMUNITY pass/fail criteria for a radiological table system.

Before, during, and after the IMMUNITY tests, the radiological table system provides freedom from unacceptable RISK.

This IMMUNITY pass/fail criteria determination example is an output of the RISK ANALYSIS.

## MONITORING FOR IMMUNITY TEST

For every operation mode, the monitoring performed over the samples under test is shown in the following table:

OPERATION MODE	CONTINUOUS PHENOMENA MONITORING	TRANSIENT PHENOMENA MONITORING
OM#01	It is monitored that the equipment remains working correctly according to the selected treatment. Undesired status changes or performance fails in the intended performance are not allowed. Wi-Fi connection is monitored. The device has to maintain the ESSENTIAL PERFORMANCE and the BASIS SAFETY during and after the test.	It is monitored that the equipment remains working correctly according to the selected treatment. Undesired status changes or performance fails in the intended performance are not allowed. WiFi connection is monitored. The device has to maintain the ESSENTIAL PERFORMANCE and the BASIS SAFETY during and after the test.

## CONDUCTED EMISSION. HARMONIC CURRENT MEASUREMENT

<b>LIMITS:</b>	Product Standard:	EN 60601-1-2 (2015)
	Test Standard:	EN 61000-3-2 (2014)

**Class A:**

ODDS HARMONICS		EVENS HARMONICS	
HARMONIC ORDER	MAXIMUM CURRENT (A)	HARMONIC ORDER	MAXIMUM CURRENT (A)
2	1.08	3	2.30
4	0.43	5	1.14
6	0.30	7	0.77
8 ≤ n ≤ 40	0.23*8/n	9	0.40
		11	0.33
		13	0.21
		15 ≤ n ≤ 39	0.15*15/n

<b>TESTED SAMPLES:</b>	S/01
<b>OPERATION MODES TESTED:</b>	OM#01
<b>TEST RESULTS:</b>	CCmmnnAF: CC, Conduction condition; mm: Sample nº; nn: Operation mode; AF: Test code, Fluctuating harmonics.

CCmmnnAF	DESCRIPTION	RESULT
CC0101AF	The equipment overcomes the 16A per phase in a cycle stage, and therefore, according to section 7.2.1 in EN 60601-1-2 (2015), this test is not applicable. The client declares in the user manual a nominal power of 3,5kW and therefore, according to section 7 in EN 61000-3-2 and considering that the equipment is declared as Class A "Professional equipment", this standard has not limits for this equipment type.	N/A*

\*Results are shown below as reference



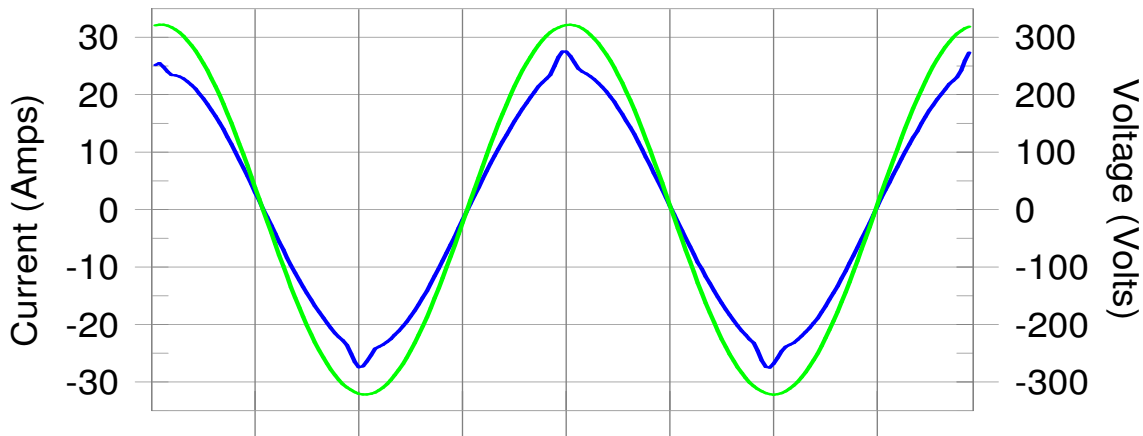
CC0101AF

Harmonics – Class-A per Ed. 4.0 (2014) incl. inter-harmonics

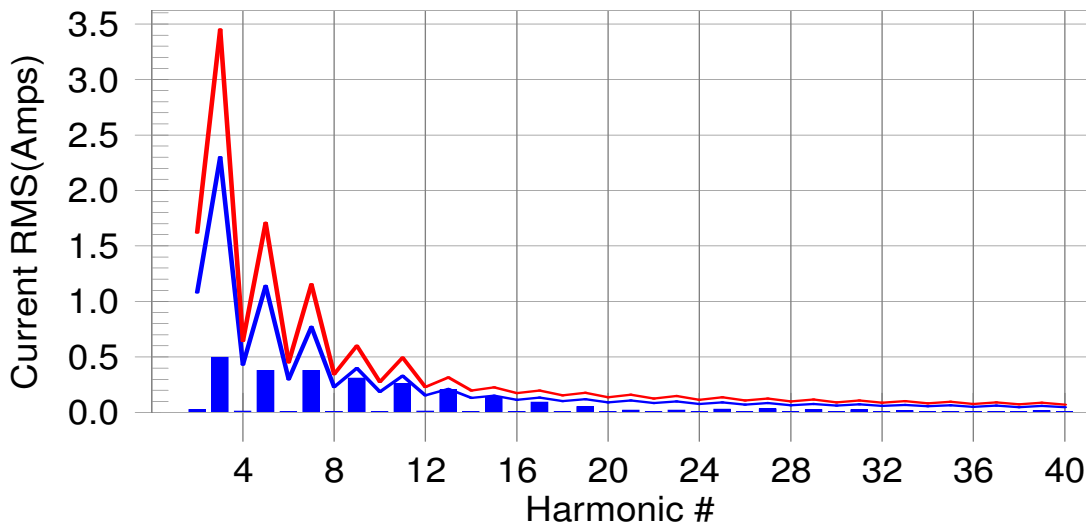
Test category: Class-A per Ed. 4.0 (2014) (European limits)      Test Margin: 100  
Test date: 11/12/2018      Start time: 14:27:27      End time: 14:32:49  
Test duration (min): 5      Data file name: H-000779.cts\_data  
Comment: S/01 OM#01

Test Result: Pass      Source qualification: Normal

Current & voltage waveforms



Harmonics and Class A limit line European Limits



Test result: Pass      Worst harmonic was #13 with 81.5% of the limit.

**CC0101AF (cont.)**

**Current Test Result Summary (Replay)**

Test category: Class-A per Ed. 4.0 (2014) (European limits) Test Margin: 100  
 Test date: 11/12/2018 Start time: 14:27:27 End time: 14:32:49  
 Test duration (min): 5 Data file name: H-000779.cts\_data  
 Comment: S/01 OM#01

Test Result: Pass Source qualification: Normal  
 THC(A): 0.880 I-THD(%): 20.9 POHC(A): 0.068 POHC Limit(A): 0.251

**Highest parameter values during test:**

V\_RMS (Volts): 230.28 Frequency(Hz): 50.00  
 I\_Peak (Amps): 27.604 I\_RMS (Amps): 17.206  
 I\_Fund (Amps): 16.843 Crest Factor: 4.365  
 Power (Watts): 3840.1 Power Factor: 1.000

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.027	1.080	2.5	0.111	1.620	6.8	Pass
3	0.496	2.300	21.6	0.616	3.450	17.8	Pass
4	0.012	0.430	2.7	0.066	0.645	10.3	Pass
5	0.379	1.140	33.2	0.500	1.710	29.3	Pass
6	0.010	0.300	3.3	0.039	0.450	8.7	Pass
7	0.379	0.770	49.2	0.486	1.155	42.0	Pass
8	0.009	0.230	N/A	0.031	0.345	N/A	Pass
9	0.309	0.400	77.1	0.396	0.600	65.9	Pass
10	0.011	0.184	6.2	0.024	0.276	8.6	Pass
11	0.259	0.330	78.3	0.328	0.495	66.2	Pass
12	0.012	0.153	7.7	0.021	0.230	9.1	Pass
13	0.203	0.210	96.9	0.257	0.315	81.5	Pass
14	0.009	0.131	N/A	0.017	0.197	N/A	Pass
15	0.139	0.150	92.8	0.175	0.225	78.0	Pass
16	0.008	0.115	N/A	0.015	0.173	N/A	Pass
17	0.094	0.132	71.5	0.118	0.198	59.7	Pass
18	0.007	0.102	N/A	0.013	0.153	N/A	Pass
19	0.053	0.118	44.6	0.066	0.178	36.9	Pass
20	0.006	0.092	N/A	0.012	0.138	N/A	Pass
21	0.022	0.107	20.5	0.033	0.161	20.3	Pass
22	0.006	0.084	N/A	0.012	0.125	N/A	Pass
23	0.020	0.098	20.6	0.029	0.147	19.4	Pass
24	0.005	0.077	N/A	0.010	0.115	N/A	Pass
25	0.030	0.090	33.3	0.042	0.135	31.2	Pass
26	0.004	0.071	N/A	0.010	0.107	N/A	Pass
27	0.032	0.083	39.0	0.041	0.125	33.2	Pass
28	0.003	0.066	N/A	0.009	0.099	N/A	Pass
29	0.028	0.078	35.8	0.035	0.116	30.1	Pass
30	0.003	0.061	N/A	0.009	0.092	N/A	Pass
31	0.025	0.073	34.4	0.032	0.109	29.7	Pass
32	0.003	0.058	N/A	0.008	0.086	N/A	Pass
33	0.015	0.068	22.4	0.022	0.102	21.6	Pass
34	0.003	0.054	N/A	0.008	0.081	N/A	Pass
35	0.008	0.064	N/A	0.014	0.096	N/A	Pass
36	0.003	0.051	N/A	0.008	0.077	N/A	Pass
37	0.009	0.061	N/A	0.017	0.091	N/A	Pass
38	0.003	0.048	N/A	0.008	0.073	N/A	Pass
39	0.015	0.058	25.3	0.021	0.087	24.0	Pass
40	0.003	0.046	N/A	0.009	0.069	N/A	Pass

**CC0101AF (cont.)**

**Voltage Source Verification Data (Replay)**

Test category: Class-A per Ed. 4.0 (2014) (European limits)      Test Margin: 100  
 Test date: 11/12/2018      Start time: 14:27:27      End time: 14:32:49  
 Test duration (min): 5      Data file name: H-000779.cts\_data  
 Comment: S/01 OM#01

Test Result: Pass      Source qualification: Normal

Highest parameter values during test:

Voltage (Vrms): 230.28      Frequency(Hz): 50.00  
 I\_Peak (Amps): 27.604      I\_RMS (Amps): 17.206  
 I\_Fund (Amps): 16.843      Crest Factor: 4.365  
 Power (Watts): 3840.1      Power Factor: 1.000

Harm#	Harmonics V-rms	Limit V-rms	% of Limit	Status
2	0.060	0.460	13.06	OK
3	0.450	2.049	21.95	OK
4	0.044	0.455	9.65	OK
5	0.229	0.920	24.86	OK
6	0.018	0.456	4.01	OK
7	0.145	0.690	21.04	OK
8	0.016	0.460	3.45	OK
9	0.146	0.460	31.73	OK
10	0.016	0.460	3.45	OK
11	0.145	0.230	63.03	OK
12	0.016	0.228	6.95	OK
13	0.127	0.230	55.11	OK
14	0.016	0.230	6.80	OK
15	0.105	0.230	45.82	OK
16	0.014	0.230	5.92	OK
17	0.085	0.230	37.08	OK
18	0.014	0.230	6.06	OK
19	0.064	0.230	27.97	OK
20	0.013	0.228	5.65	OK
21	0.040	0.230	17.44	OK
22	0.013	0.228	5.73	OK
23	0.029	0.230	12.64	OK
24	0.009	0.230	3.70	OK
25	0.030	0.228	13.30	OK
26	0.006	0.229	2.78	OK
27	0.033	0.228	14.58	OK
28	0.009	0.228	3.99	OK
29	0.032	0.230	13.79	OK
30	0.010	0.228	4.60	OK
31	0.036	0.230	15.46	OK
32	0.008	0.228	3.30	OK
33	0.028	0.230	12.09	OK
34	0.005	0.230	2.02	OK
35	0.023	0.230	9.89	OK
36	0.010	0.228	4.29	OK
37	0.014	0.230	5.99	OK
38	0.009	0.228	3.84	OK
39	0.017	0.230	7.24	OK
40	0.008	0.228	3.53	OK

## CONDUCTED EMISSION. VOLTAGE FLUCTUATIONS AND FLICKER MEASUREMENT

**LIMITS:**

Product standard:	EN 60601-1-2 (2015)
Test standard:	EN 61000-3-3 (2013)

Pst < 1	Short duration flicker indicator
Plt < 0,65	Long duration flicker indicator
Dc ≤ 3,3%	Relative steady-state voltage variation
Dmax ≤ 4%	Maximum relative voltage variation
d(t) ≤ 3,3%	For a duration of 500ms

**TESTED SAMPLES:**

S/01

**OPERATION MODES TESTED:**

OM#01

**TEST RESULTS:**

CCmmnnFK: CC, Conducted Condition; mm: Sample number; nn: Operation mode; FK: Flicker test code.

CCmmnnFK	DESCRIPTION	RESULT
CC0101FK	The equipment overcomes the 16A per phase in a cycle stage, and therefore, according to section 7.2.2 in EN 60601-1-2 (2015), this test is not applicable.	N/A*

\*Results are shown below as reference

**CC0101FK**

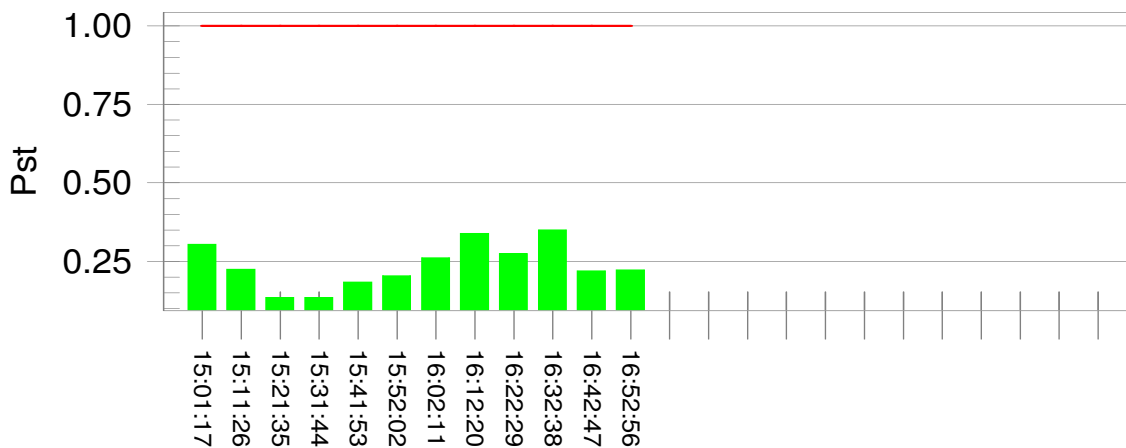
**Flicker Test Summary per EN/IEC61000-3-3 Ed. 3.0 (2013) (Run time)**

Test category: All parameters (European limits)      Test Margin: 100  
 Test date: 12/11/2018      Start time: 14:50:46      End time: 16:52:57  
 Test duration (min): 120      Data file name: F-000781.cts\_data  
 Comment: S/01 OM#01

Test Result: Pass      Status: Test Completed

**Pst<sub>i</sub> and limit line**

**European Limits**



**Plt and limit line**



**Parameter values recorded during the test:**

Vrms at the end of test (Volt):228.14				
Highest dt (%):	-0.95	Test limit (%):	N/A	N/A
T-max (mS):	0	Test limit (mS):	500.0	Pass
Highest dc (%):	-0.99	Test limit (%):	3.30	Pass
Highest dmax (%):	-1.01	Test limit (%):	4.00	Pass
Highest Pst (10 min. period):	0.350	Test limit:	1.000	Pass
Highest Plt (2 hr. period):	0.256	Test limit:	0.650	Pass

## CONTINUOUS CONDUCTED EMISSION ON POWER LEADS

<b>LIMITS:</b>	Product standard:	EN 60601-1-2 (2015)
	Test standard:	EN 55011 (2016) / A1 (2017)

### Limits EN 55011 (2016) / A1 (2017) for Group 1 Class A Main Ports:

Frequency range (MHz)	Limit (dB $\mu$ V)	
	Quasi-peak	Average
0.15 to 0.5	79	66
0.5 to 30	73	60

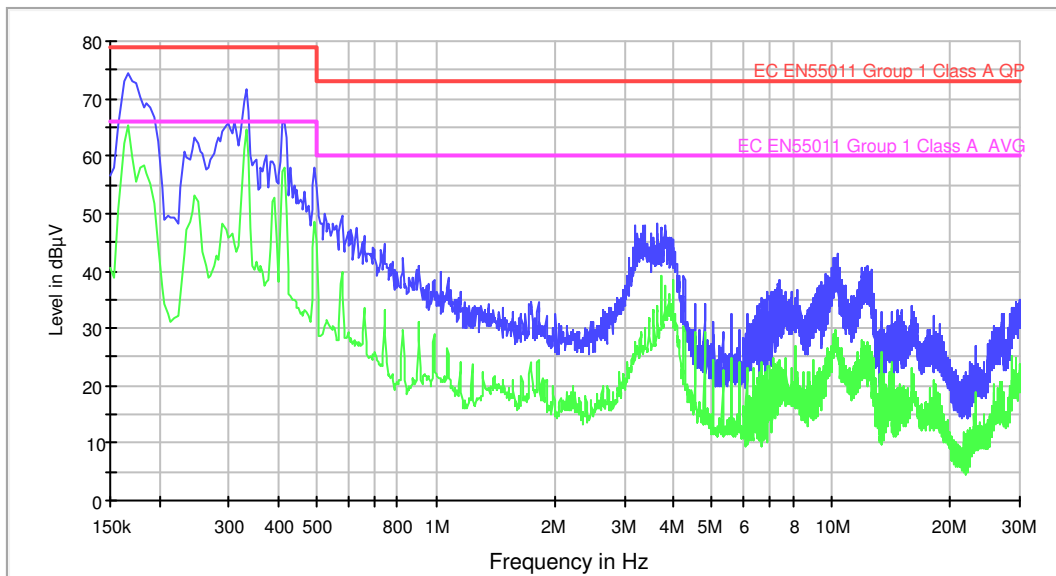
<b>TESTED SAMPLES:</b>	S/01
<b>TESTED OPERATION MODES:</b>	OM#01
<b>TEST RESULTS:</b>	CCmmnnhh: CC, Conducted Condition; mm: Sample number; nn: Operation mode; hh: wire

CCmmnnhh	DESCRIPTION	RESULT
CC01010N	Range: 150kHz – 30MHz. Neutral wire noise.	P
CC0101L1	Range: 150kHz – 30MHz. Phase wire noise.	P

**Continuous Conducted Emission: CC01010N**

Project: 59276REM.001  
 Company: TECNOLOGÍA E INNOVACIÓN MÉDICO ESTÉTICA S.L  
 Sample: S/01  
 Operation mode: OM#01  
 Description: EUT ON. Team performing Continuous Cycle.WiFi ON. Power supply: 230Vac. Neutral wire noise

**EN 55011 Group 1 Class A**



— Peak Scan  
 — EC EN55011 Group 1 Class A QP  
 — Average Scan  
 — EC EN55011 Group 1 Class A AVG

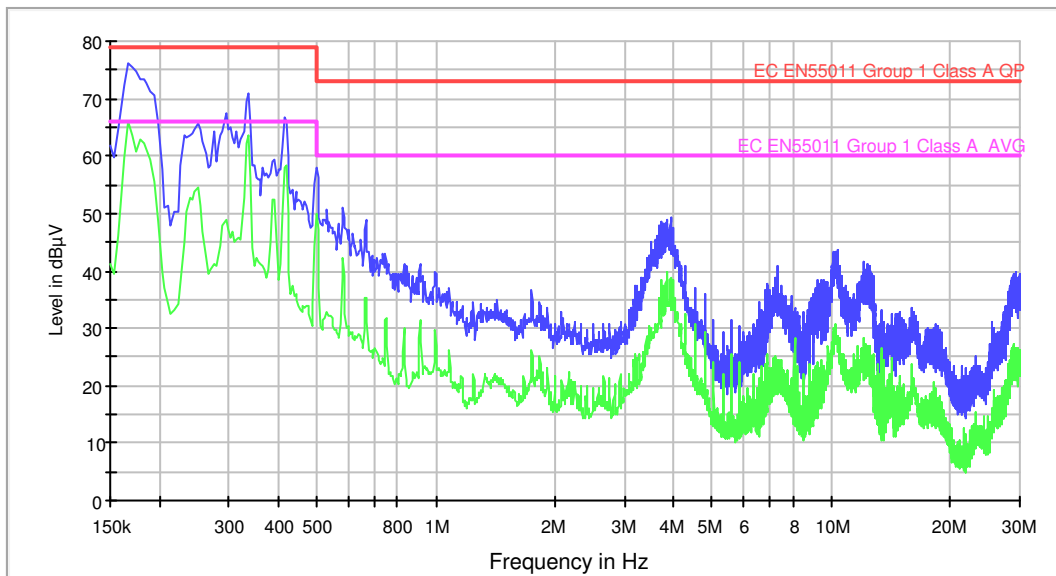
**Subrange Maxima**

Frequency (MHz)	MaxPeak-ClearWrite (dBµV)	Average-ClearWrite (dBµV)
0.166000	74.5	65.4
0.330000	71.6	64.7
0.494000	57.9	48.5
0.738000	44.6	30.9
1.814000	34.6	24.4
3.386000	48.0	30.0
3.634000	48.0	34.0
10.386000	42.9	27.6
12.378000	40.7	26.4
29.962000	34.8	22.1

**Continuous Conducted Emission: CC0101L1**

Project: 59276REM.001  
 Company: TECNOLOGÍA E INNOVACIÓN MÉDICO ESTÉTICA S.L  
 Sample: S/01  
 Operation mode: OM#01  
 Description: EUT ON. Team performing Continuous Cycle.WiFi ON. Power supply: 230Vac. Phase wire noise

**EN 55011 Group 1 Class A**



— Peak Scan  
 — Average Scan  
 — EC EN55011 Group 1 Class A QP  
 — EC EN55011 Group 1 Class A AVG

**Subrange Maxima**

Frequency (MHz)	MaxPeak-ClearWrite (dBµV)	Average-ClearWrite (dBµV)
0.166000	76.2	65.9
0.334000	71.1	63.6
0.498000	58.0	50.0
0.746000	43.1	31.6
1.746000	36.7	26.3
3.498000	45.2	30.2
3.922000	49.4	38.7
10.162000	43.4	29.1
10.414000	43.6	28.7
29.266000	39.7	25.9



## DISCONTINUOUS CONDUCTED EMISSION ON POWER LEADS

<b>LIMITS:</b>	Product standard:	EN 60601-1-2 (2015)
	Test standard:	EN 55014-1 (2006) / A1 (2009) / A2 (2011)

### Limits for mains ports:

FRECUENCY	CUASI-PEAK LIMITS (dB $\mu$ V)
150 kHz	79
500 kHz	73
1,4 MHz	73
30 MHz	73

<b>TESTED SAMPLES:</b>	S/01
<b>TESTED OPERATION MODES:</b>	OM#01
<b>TEST RESULTS:</b>	CCmmnnhh: CC, Conducted Condition; mm: Sample number; nn: Operation mode; hh: wire

CCmmnnhh	DESCRIPTION	RESULT
CC01010N	Neutral wire noise (worst case). No clicks detected.	P

**RADIATED EMISSION. ELECTROMAGNETIC FIELD MEASURE**

<b>LIMITS:</b>	Product standard:	EN 60601-1-2 (2015)
	Test standard:	EN 55011 (2016) / AC (2017)

**Limits for EN 55011 (2016) / A1 (2017) Class A:**

Frequency range (MHz)	Measured field limit at 10 m (dB $\mu$ V/m) Quasi-Peak measurement
30 to 230	40
230 to 1000	47

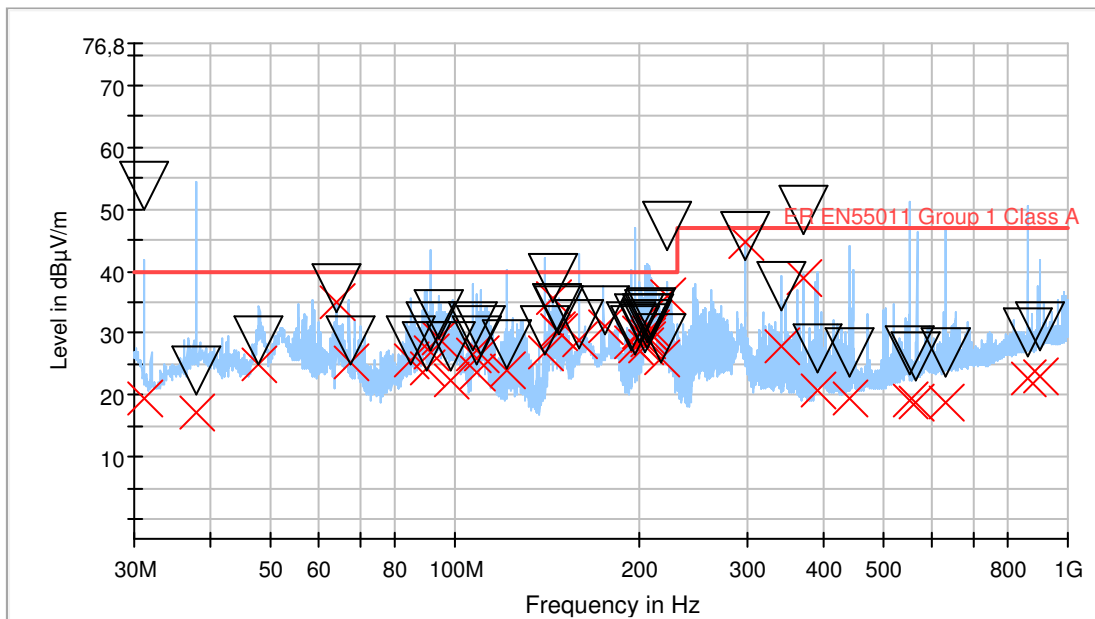
<b>TESTED SAMPLES:</b>	S/01
<b>TESTED OPERATION MODES:</b>	OM#01
<b>TEST RESULTS:</b>	CRmmnn: CR, Radiated condition; mm: Sample number; nn: Operation mode; RR: Measured range.

CRmmnnRR	DESCRIPTION	RESULT
CR0101	Range: 30 MHz - 1000 MHz.	P

## Radiated Emission: CR0101

Project: 59276REM.001  
Company: Tecnología e Innovación  
Sample: S/01  
Operation mode: OM#01  
Description: EUT ON. Team performing Continuous Cycle.WiFi ON. 230 Vac power.

## Full Spectrum



— Peak Preview  
— ER EN55011 Group 1 Class A  
X QuasiPeak  
▽ MaxPeak

## Radiated Emission: CR0101 (Cont)

### Maximizations

Frequency (MHz)	QuasiPeak (dBµV/m)	MaxPeak (dBµV/m)	Height (cm)	Pol	Azimuth (deg)
31.177000	19.63	53.74	223.0	H	343.0
37.885000	17.18	23.93	333.0	H	301.0
48.006000	25.07	28.90	292.0	H	235.0
64.028000	34.96	37.30	391.0	H	266.0
67.492000	25.27	28.73	114.0	V	-1.0
85.052000	25.54	28.93	400.0	H	299.0
89.948000	24.37	27.94	374.0	H	88.0
91.421000	26.97	31.22	400.0	H	282.0
94.038000	29.25	32.96	381.0	H	282.0
98.870000	22.35	28.00	352.0	H	64.0
107.116000	26.58	31.09	304.0	H	253.0
108.837000	23.72	28.84	287.0	H	279.0
110.531000	26.47	30.53	309.0	H	119.0
121.206000	23.94	28.32	115.0	V	136.0
140.367000	27.03	30.43	400.0	V	187.0
144.670000	35.51	38.89	232.0	H	104.0
147.225000	30.60	33.92	286.0	H	127.0
148.146000	30.06	33.82	218.0	H	126.0
159.339000	28.84	31.32	356.0	V	108.0
175.235000	31.13	33.76	318.0	V	177.0
193.773000	28.40	31.19	100.0	V	149.0
197.473000	27.92	30.51	111.0	V	295.0
199.696000	30.11	32.49	104.0	V	300.0
204.116000	27.76	30.74	275.0	V	213.0
206.371000	28.76	31.58	260.0	V	212.0
206.460000	29.59	32.36	283.0	V	203.0
206.884000	30.13	32.48	285.0	V	211.0
207.991000	30.06	33.17	276.0	V	14.0
209.464000	30.70	33.34	292.0	V	212.0
216.343000	25.94	29.15	356.0	V	10.0
222.748000	36.06	47.37	147.0	H	302.0
297.000000	44.68	45.86	252.0	V	345.0
341.587000	27.97	37.63	100.0	H	204.0
371.237000	38.99	50.01	296.0	H	103.0
389.261000	20.62	27.45	296.0	H	96.0
440.594000	19.62	26.90	150.0	V	90.0
552.735000	19.10	27.13	382.0	H	61.0
566.429000	18.95	26.27	248.0	H	322.0
631.359000	18.98	26.98	311.0	V	80.0
860.442000	22.62	30.12	400.0	V	219.0
898.624000	22.91	31.15	215.0	V	196.0

## IMMUNITY TO CONDUCTED DISTURBANCES, INDUCED BY RADIOFREQUENCY FIELDS

<b>LIMITS:</b>	Product standard:	EN 60601-1-2 (2015)
	Test standard:	EN 61000-4-6 (2014)

RANGE	FREQUENCY	MODULATION	STEP	LEVEL
A	150 kHz - 80 MHz	AM 1 kHz 80%	1%	3 Vrms
B*	6,765 MHz-6,795MHz; 13,553MHz- 13,567MHz; 26,957MHz-27,283MHz; 40,66MHz - 40,70MHz	AM 1 kHz 80%	1%	6 Vrms

\* ISM Bands.

<b>TESTED SAMPLES:</b>	S/01
<b>TESTED OPERATION MODES:</b>	OM#01
<b>FAIL CRITERIA AND MONITORING:</b>	A
<b>ZONES/COUPLING CABLES (CPL):</b>	

CPL	DESCRIPTION
1	AC power supply input
2	Ethernet cable

### TEST RESULTS:

CPL	RANGE	S/	OM#	COMMENTS	RESULT
1	A	01	01	Ok, no fails detected	P
1	B	01	01	Ok, no fails detected	P
2	A	01	01	Ok, no fails detected	P
2	B	01	01	Ok, no fails detected	P

## ELECTRICAL FAST TRANSIENT / BURST IMMUNITY TEST

<b>LIMITS:</b>	Product standard:	EN 60601-1-2 (2015)
	Test standard:	EN 61000-4-4 (2012)

TYPE	APPLICATION	LEVEL(kV)	REPETITION RATE(kHz)
1	AC Power Supply Line	±2kV	5kHz & 100kHz
2	Communication Lines	±1kV	5kHz & 100kHz

**TESTED SAMPLES:** S/01

**TESTED OPERATION MODES:** OM#01

**FAIL CRITERIA AND MONITORING:** B

**ZONES/COUPLING CABLES (CPL):**

CPL	DESCRIPTION	TYPE
A	AC power supply line (N = Neutral wire)	1
B	AC power supply line (L1 = Phase wire)	1
C	AC power supply line (P.E = Ground)	1
D	Ethernet cable	2

**TEST RESULTS:**

CPL	S/	OM#	COMMENTS	RESULT
A	01	01	Ok, no fails detected	P
B	01	01	Ok, no fails detected	P
C	01	01	Ok, no fails detected	P
D	01	01	Ok, no fails detected	P

## SURGE IMMUNITY TEST

<b>LIMITS:</b>	Product standard:	EN 60601-1-2 (2015)
	Test standard:	EN 61000-4-5 (2014)

TYPE	APPLICATION	LEVEL (kV) SYMMETRICAL COUPLING	LEVEL (kV) ASYMMETRICAL COUPLING
1	AC Power Supply	± 0.5 kV; ± 1 kV	± 0.5 kV; ± 1 kV; ± 2 kV

<b>TESTED SAMPLES:</b>	S/01
<b>TESTED OPERATION MODES:</b>	OM#01
<b>ZONES/COUPLING CABLES (CPL):</b>	

CPL	DESCRIPTION	TYPE
A	Single phase AC power supply line. Symmetrical: L1→N.	1
B	Single phase AC power supply line. Asymmetrical on L1: L1→PE.	1
C	Single phase AC power supply line. Asymmetrical on N: N→PE.	1

### TEST RESULTS:

CPL	S/	OM#	COMMENTS	RESULT
A	01	01	Ok, no fails detected	P
B	01	01	Ok, no fails detected	P
C	01	01	Ok, no fails detected	P

## VOLTAGE DIPS, SHORT INTERRUPTIONS AND VOLTAGE VARIATIONS IMMUNITY TEST

<b>LIMITS:</b>	Product standard:	EN 60601-1-2 (2015)
	Test standard:	EN 61000-4-11 (2004)

**Immunity levels for voltage interruptions:**

TEST	SEVERITY LEVEL
A	100% during 5 s

**Immunity levels for voltage dips and variations:**

TEST	SEVERITY LEVEL
B	100% during 10 ms
C	100% during 20 ms
D	30% during 500 ms

<b>TESTED SAMPLES:</b>	S/01
<b>TESTED OPERATION MODES:</b>	OM#01
<b>FAIL CRITERIA AND MONITORING:</b>	According to standard
<b>ZONES/COUPLING CABLES (CPL):</b>	

TEST	S/	OM#	COMMENTS	RESULT
A	01	01	EUT shutdowns during the test and successfully recovers after it.	P
B	01	01	OK, no fails detected.	P
C	01	01	OK, no fails detected.	P
D	01	01	The EUT changes its acoustic noise during the disturbances but it continues working without any warning.	P



## Appendix B: Photographs

