



Test Report issued under the responsibility of:



TEST REPORT

IEC 61326-1

Electrical equipment for measurement, control and laboratory use – EMC requirements

Part 1: General requirements

Report Reference No.: 28228533 002

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CB Testing Laboratory: TÜV Rheinland InterCert kft., MEEI Division

Address: H-1132 Budapest, Váci út 48/A-B., Hungary

Applicant's name: Celitron Medical Technologies Kft.

Address: H-2600 Vác, Szent László út 36.

Test specification:

Standard: IEC 61326-1:2012 (Second Edition)

Test procedure: CB

Non-standard test
method: N/A

Test Report Form No.: IEC61326_1B

Test Report Form(s) Originator: IMQ S.p.A.

Master TRF: Date 2013-09

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Test item description: Integrated Sterilizer & Shredder

Trade Mark



Manufacturer: Celitron Medical Technologies Kft.

Model/Type reference: ISS AC-575 Premium

Ratings: 3N~, 400V, 50Hz, 3x50A

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Testing procedure and testing location:	
☒ CB Testing Laboratory:	TÜV Rheinland InterCert kft., MEEI Division
Testing location/ address	H-1135 Budapest, Béke utca 43., Hungary
Tested by (name + signature).....	Tamás Novotny testing engineer
Approved by (name + signature) ...:	Ferenc Gyapjas testing engineer
☐ Associated CB Test Laboratory: Testing location/ address : Tested by (name + signature)..... Approved by (name + signature) ... :	
☐ Testing procedure: TMP Tested by (name + signature)..... : Approved by (name + signature) ... : Testing location/ address :	
☐ Testing procedure: WMT Tested by (name + signature)..... : Witnessed by (name + signature) .. : Approved by (name + signature) ... : Testing location/ address :	
☐ Testing procedure: SMT Tested by (name + signature)..... : Approved by (name + signature) ... : Supervised by (name+ signature).. : Testing location/ address :	
☐ Testing procedure: RMT Tested by (name + signature)..... : Approved by (+ signature)..... : Supervised by (+ signature)..... : Testing location/ address :	

Test item description	Integrated Sterilizer & Shredder
Trade Mark	
Manufacturer.....	Celitron Medical Technologies Kft.
Model/Type reference.....	ISS AC-575 Premium
Ratings.....	3N~, 400V, 50Hz, 3x50A
Possible 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.....	2016-11-22
Date (s) of performance of tests.....	2016-11-22...2016-11-24
General remarks:	
The test results presented in this report relate only to the object tested. The results contained in this report reflect the results for this particular model and serial number. It is the responsibility of the manufacturer to ensure that all production models meet the intent of the requirements detailed within this report. This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory. "(see Enclosure #)" refers to additional information appended to the report. "(see appended table)" refers to a table appended to the report. Throughout this report the decimal separator is comma.	

General product information:

This device is a Steam Sterilizer with an integrated Shredder, intended for treatment of Medical Waste in hospitals and clinics. This device's model is an electrically heated Bio-hazard sterilizer, which operates with saturated steam as a sterilizing agent, and has a temperature range of up to 137°C (278,6°F) and pressure up to 2.5 bars (36 psi).

Report history:

28228533 001: Testing of type ISS AC-575 SG.

28228533 002: Testing of modified type ISS AC-575 Premium. Based on the changes in electronics, a complete retest was conducted, no results were referenced from the previous report version.

For documentation of the test sample, see attachment A (Photo documentation).

Place of manufacture:

Cellitron Medical Technologies Kft.

H-2600 Vác, Szent László u.36., Hungary

1.0 Equipment Description

This device is a Steam Sterilizer with an integrated Shredder, intended for treatment of Medical Waste in hospitals and clinics. This device's model is an electrically heated Bio-hazard sterilizer, which operates with saturated steam as a sterilizing agent, and has a temperature range of up to 137°C (278,6°F) and pressure up to 2.5 bars (36 psi).

Software version :	-		
Firmware version :	3.56		
Number of tested samples :	1		
Serial number :	43160003		
Equipment class :	☒	A	☐ B
Electromagnetic environment :	☐	Residential locations	
	☒	Industrial locations	
	☐	Controlled electromagnetic environment	

1.1 Equipment Marking Plate

	Integrated Sterilizer & Shredder	
	Model :	ISS AC-575 Premium
 MADE IN HUNGARY	 SN :	43160001
	 :	2016
	Supply :	3N~400V, 50 Hz, 3x50A, 6kA
	Total Power :	60kW
	 :	Celitron Medical Technologies Kft. 2600 Vác, Szent László út 36. Hungary

1.2 Supporting Equipment Used During Test:

Use	Product Type	Manufacturer	Model	Comments
EUT	Integrated Sterilizer & Shredder	Celitron Medical Technologies Kft.	ISS AC-575 Premium	None
Note: * Use EUT - Equipment Under Test AE - Auxiliary/Associated Equipment SIM - Simulator (Not Subjected to Test)				

1.3 Input/Output Ports:

Port No.	Name	Type*	Cable Max. >3m	Cable Shielded	Comments
0	Enclosure	N/E	—	—	None
1	Mains	AC	Yes	No	None
*Note: AC = AC Power Port DC = DC Power Port N/E = Non-Electrical I/O = Signal Input or Output Port TP = Telecommunication Ports					

1.4 EUT Internal Operating Frequencies:

Frequency (MHz)	Description	Frequency (MHz)	Description
40	Main clock frequency		

1.5 Power Interface

Mode No.	Voltage (V)	Current (A)	Power (kW)	Frequency (DC/AC-Hz)	Phases (No.)	Comments
Rated	3x400	3x50	60	50	3	None

1.6 EUT Operation Modes:

Mode #	Description
1	Normal cyclic operation mode.
2	The test item was operated in continuous shredding mode.

1.7 EUT Configuration Modes

Mode #	Description
1	Mains supply: 3x400V, 50Hz.

1.8 EUT Technical Documentation

Document	Reference
Operation Manual	QA16-0051 v.01.1 - Integrated Sterilizer & Shredder (ISS AC-575 Premium) - Operation Manual
Installation Manual	QA16-0048-v.01.0-ISS AC-575 Premium Installation Guide

1.9 Immunity Performance Criteria

The test results shall be classified in terms of the loss of function or degradation of performance of the equipment under test, relative to a performance level defined by its manufacturer or the requestor of the test, or agreed between the manufacturer and the purchaser of the product.

Definition related to the performance level:

- ☒ based on the used product standard
☐ based on the declaration of the manufacturer, requestor or purchaser

Criterion A:

Definition: The equipment shall continue to operate as intended during and after the test. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the equipment is used as intended. The performance level may be replaced by a permissible loss of performance. If the minimum performance level or the permissible performance loss is not specified by the manufacturer, either of these may be derived from the product description and documentation and what the user may reasonably expect from the equipment if used as intended.

Representative parameter	Acceptable level of performance
Audial and visual observation of operating state.	No change in settings.

Criterion B:

Definition: The equipment shall continue to operate as intended after the test. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the equipment is used as intended. The performance level may be replaced by a permissible loss of performance. During the test, degradation of performance is however allowed. No change of actual operating state or stored data is allowed. If the minimum performance level or the permissible performance loss is not specified by the manufacturer, either of these may be derived from the product description and documentation and what the user may reasonably expect from the equipment if used as intended.

Representative parameter	Acceptable level of performance
Audial and visual observation of operating state.	The device can change operating state during the test, but should return to the original mode after that automatically.

Criterion C:

Definition: Temporary loss of function is allowed, provided the function is self-recoverable or can be restored by the operation of the controls.

Representative parameter	Acceptable level of performance
Audial and visual observation of operating state.	The device can change operating state during the test, but should return to the original mode with operator intervention.

2.0 Result Summary

IEC 61326-1			
Clause	Requirement – Test	Result	Verdict
7.2	Limits of terminal disturbance voltages in the frequency range 150 kHz to 30 MHz		Pass
7.2	Limits of radiated disturbance in the frequency range 30 MHz to 1000 MHz		Pass
7.2	Harmonics current emission		N/A
7.2	Voltage Fluctuations and Flicker		N/A
Clause	Requirement – Test	Result	Verdict
6.2	Electrostatic Discharges (ESD)		Pass
6.2	Radiated RF electromagnetic Fields		Pass
6.2	Electrical Fast Transients and bursts		Pass
6.2	Surges		Pass
6.2	Conducted Disturbances, induced by RF fields ..		Pass
6.2	Voltage Dips, Interruptions, and variations		Pass
6.2	Power-frequency Magnetic Fields		Pass
Summary of compliance with National Differences: N/A			

2.1 Test Conditions and Results – Conducted Emissions

TEST: Limits of mains terminal disturbance voltage				Verdict
Reference standard: CISPR 11:2009 + A1:2010				Pass
Laboratory Parameters	Required prior to the test		During the test	
Ambient Temperature	10 to 40 °C		24 °C	
Relative Humidity	10 to 90 %		35 %	
Fully configured sample scanned over the following frequency range	Frequency range on each side of line		Measurement Point	
	150kHz to 30MHz		Mains	
Limits – Group 1 - Class A equipment with rated input power of ≤ 20 kVA				
Frequency (MHz)	Limit dB (µV)			
	Quasi-Peak	Result	Average	Result
0,15 to 0,50	79	Pass	66	Pass
0,50 to 30	73	Pass	60	Pass
Supplementary information: Rated power is higher than 20kVA, but the device is connectable to the low voltage network, so the limits for equipment with rated power lower than 20kVA were used.				

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
EMI Test Receiver	Narda	PMM 9010F	020WW41001	2015-11	2016-11
Artificial mains network	Schwarzbeck	NNLK-8129 Opt 400/700V	8129-201	2016-05	2019-05

Photo of test setup for Mains Terminal Disturbance Voltage



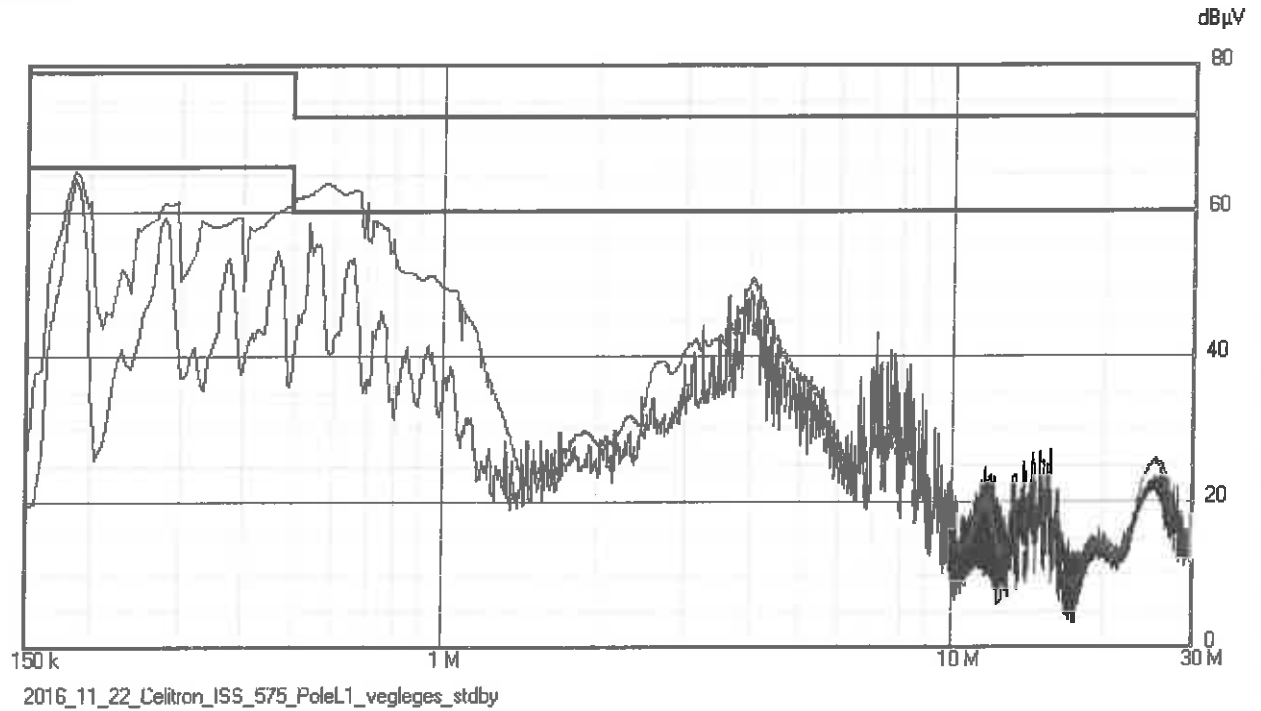
EUT Operation mode: 1,2 EUT configuration mode: 1

Tabulated Results for Mains Terminal Disturbance Voltage						
Terminal	Test Frequency (MHz)	Detector (Pk/QP/Av)	Correction Factor (dB)	Level dB (µV)	Limit dB (µV)	Margin (dB)
N	0,185	QP	0	65,66	79	13,34
N	0,185	Av	0	64,49	66	1,5
N	0,57	QP	0	65,98	73	7,02
N	0,57	Av	0	56,4	60	3,6
N	0,66	QP	0	65,44	73	7,56
N	0,66	Av	0	56,33	60	3,67
Note: Worst-case results presented in tabulated results, for other results see graphical representations.						

Graphical representation of Mains Terminal Disturbance Voltage Measurement (Optional)

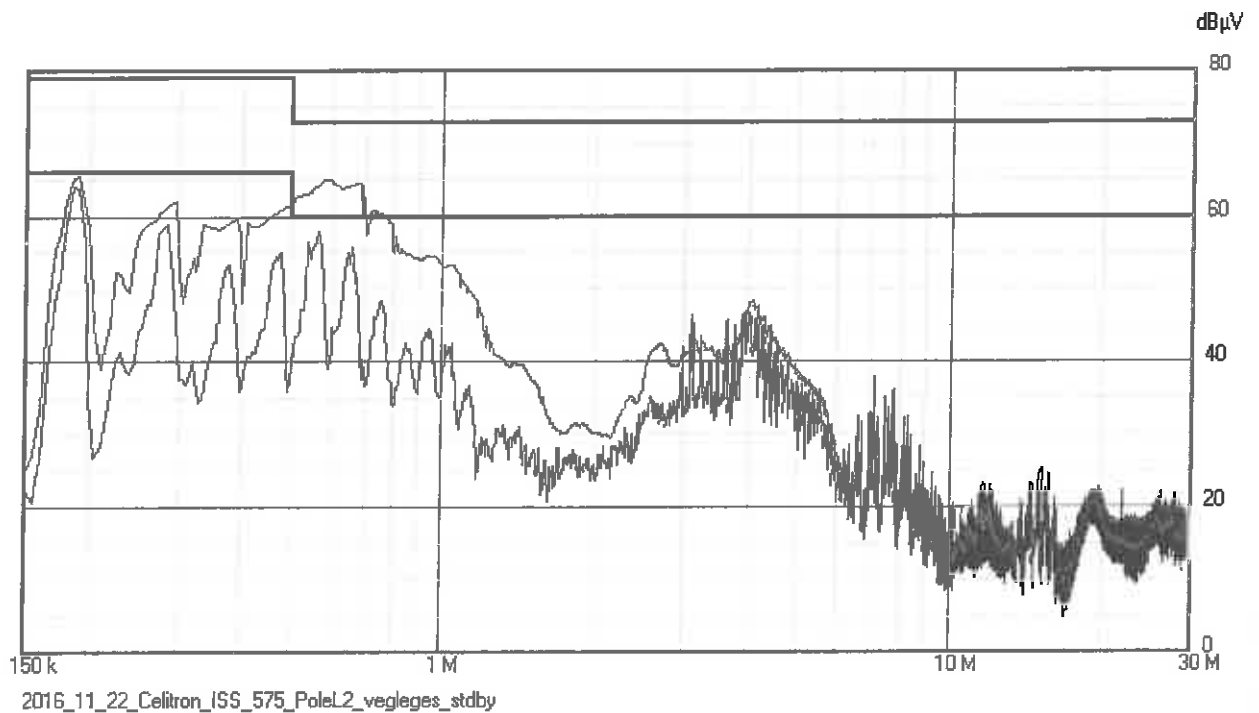
Operation mode 1.:

Pole L1:



Operation mode 1.:

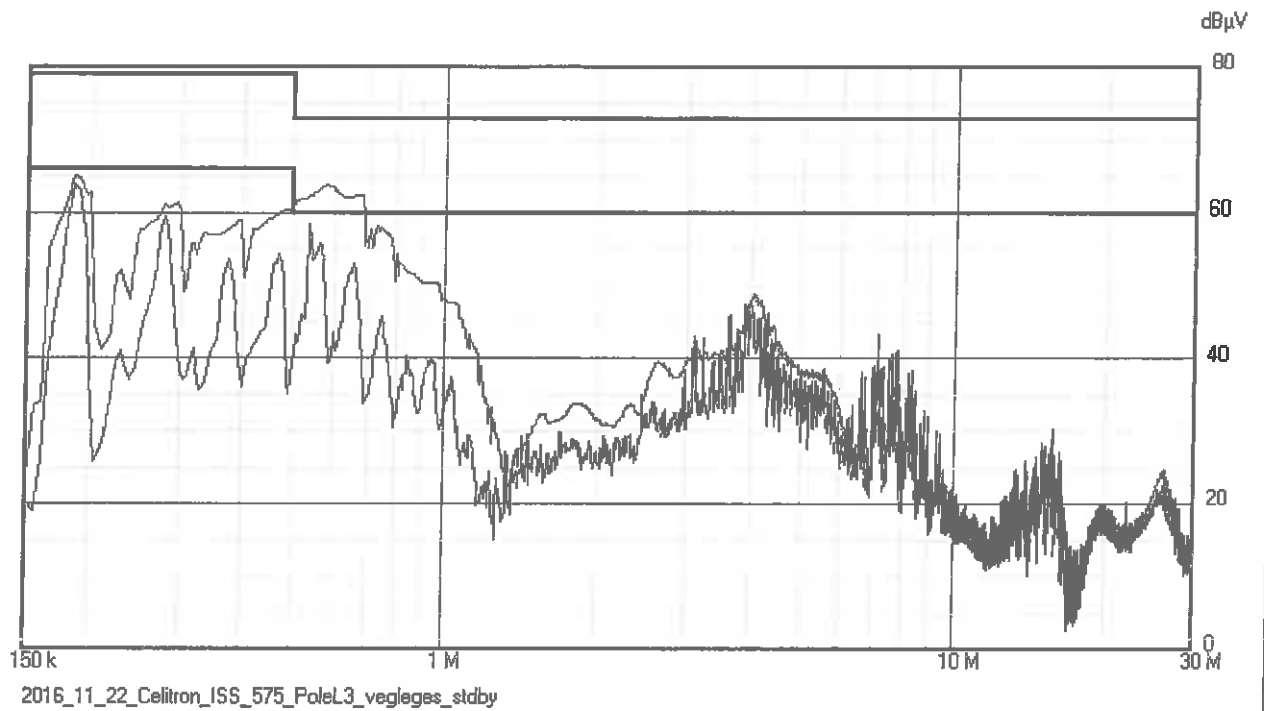
Pole L2:



Graphical representation of Mains Terminal Disturbance Voltage Measurement (Optional)

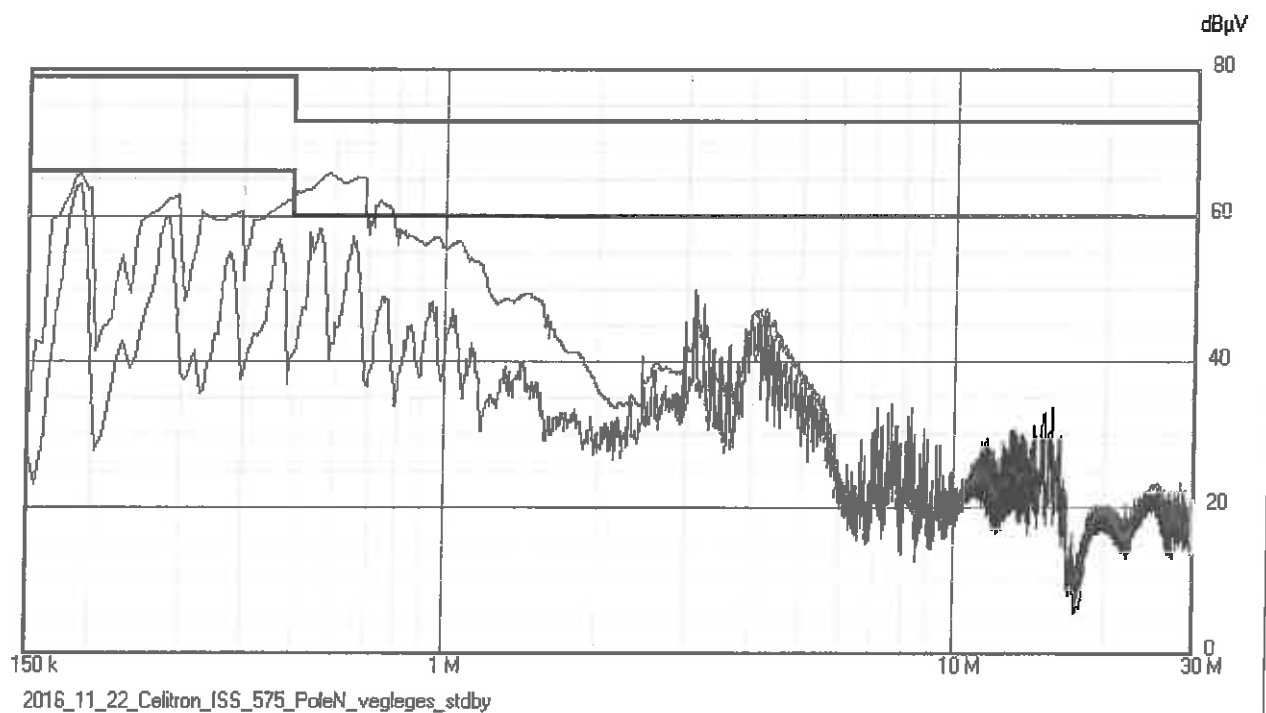
Operation mode 1.:

Pole L3:



Operation mode 1.:

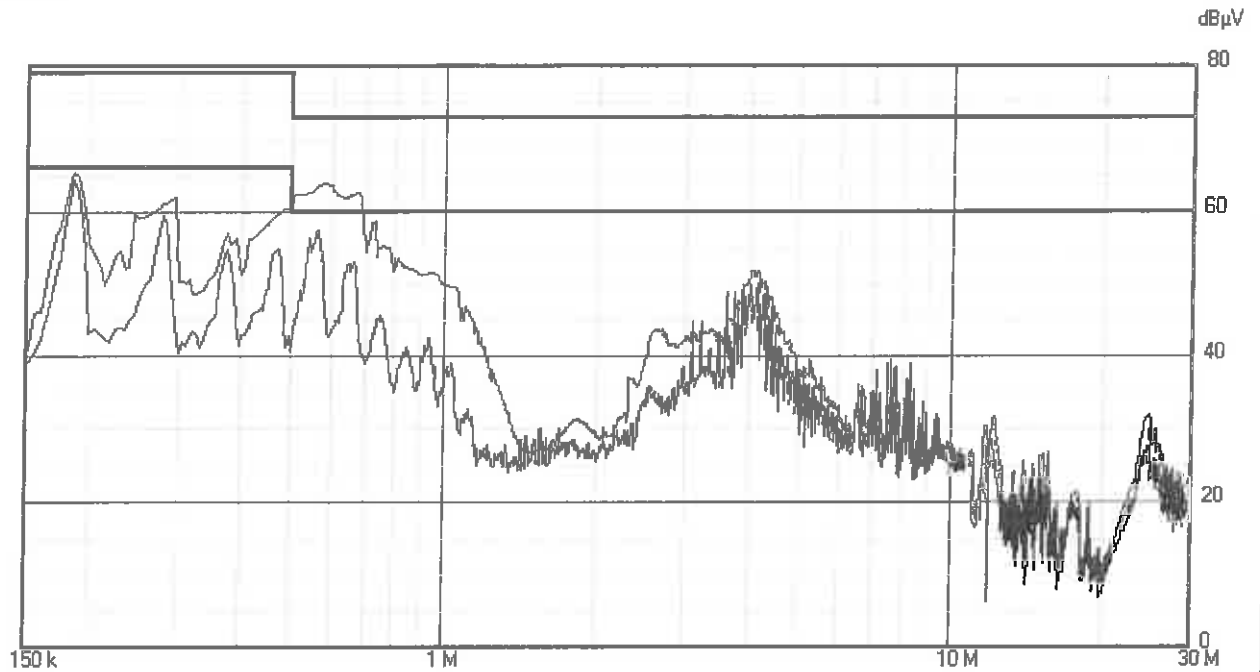
Pole N:



Graphical representation of Mains Terminal Disturbance Voltage Measurement (Optional)

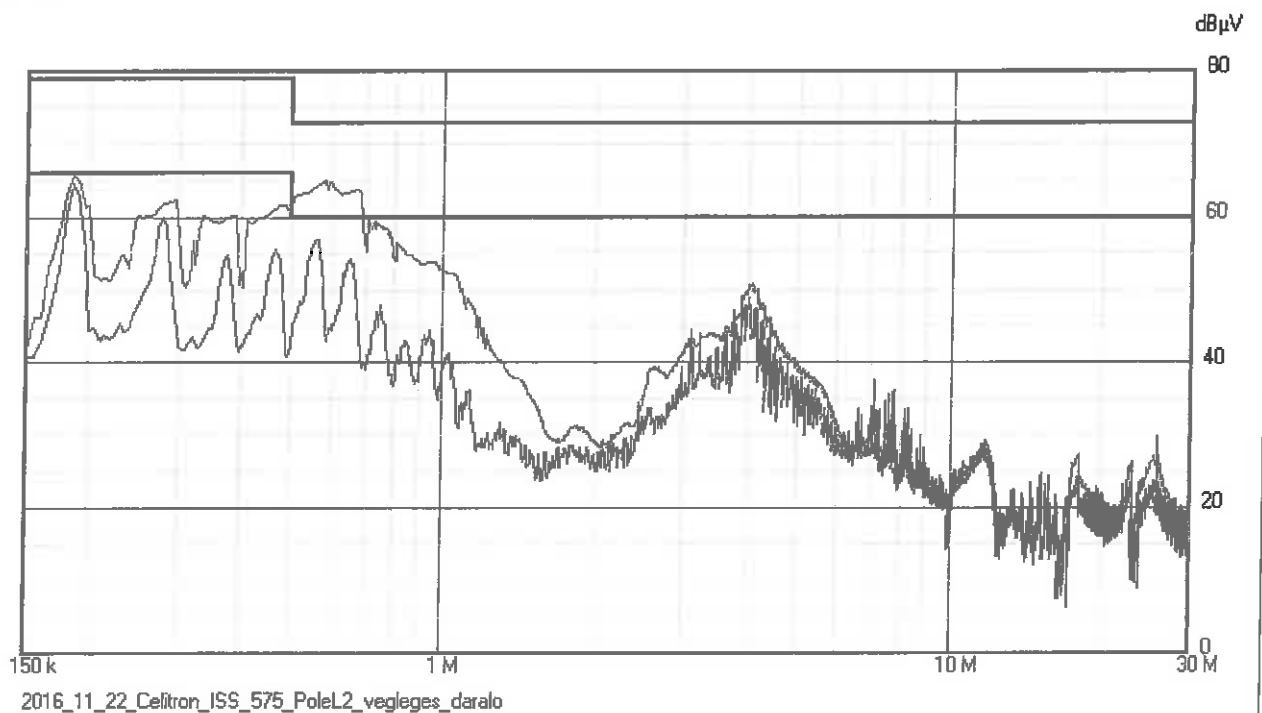
Operation mode 2.:

Pole L1:



Operation mode 2.:

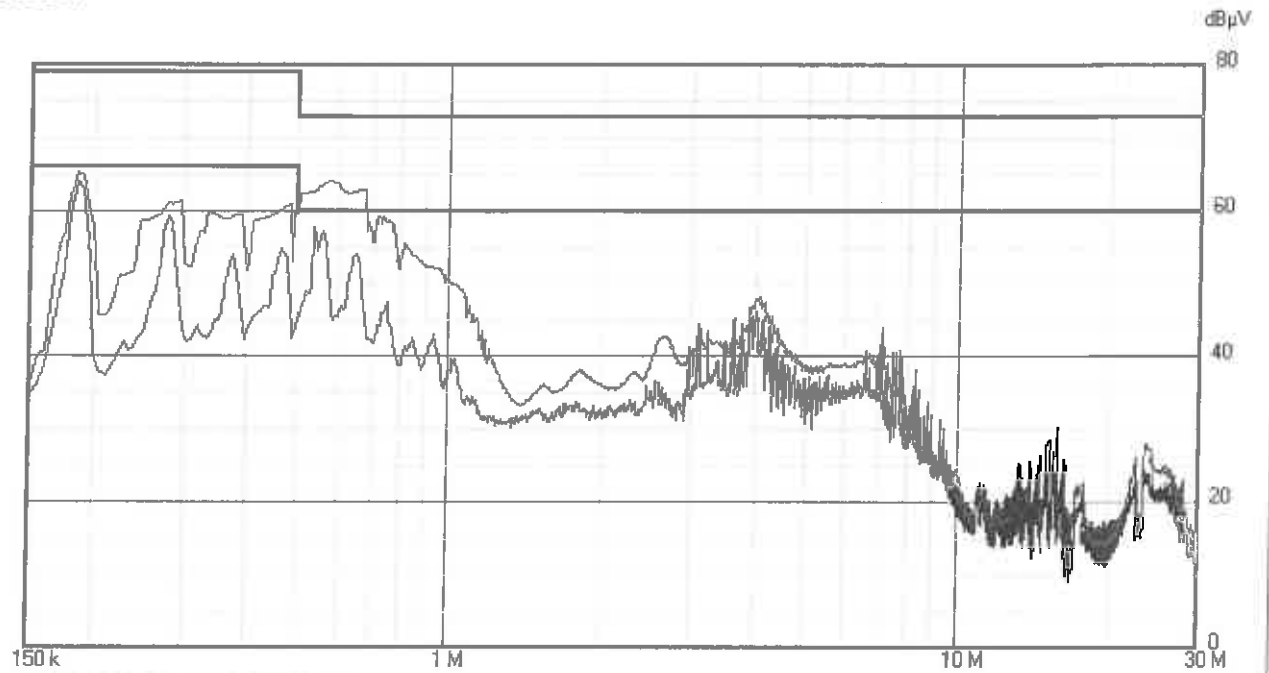
Pole L2:



Graphical representation of Mains Terminal Disturbance Voltage Measurement (Optional)

Operation mode 2.:

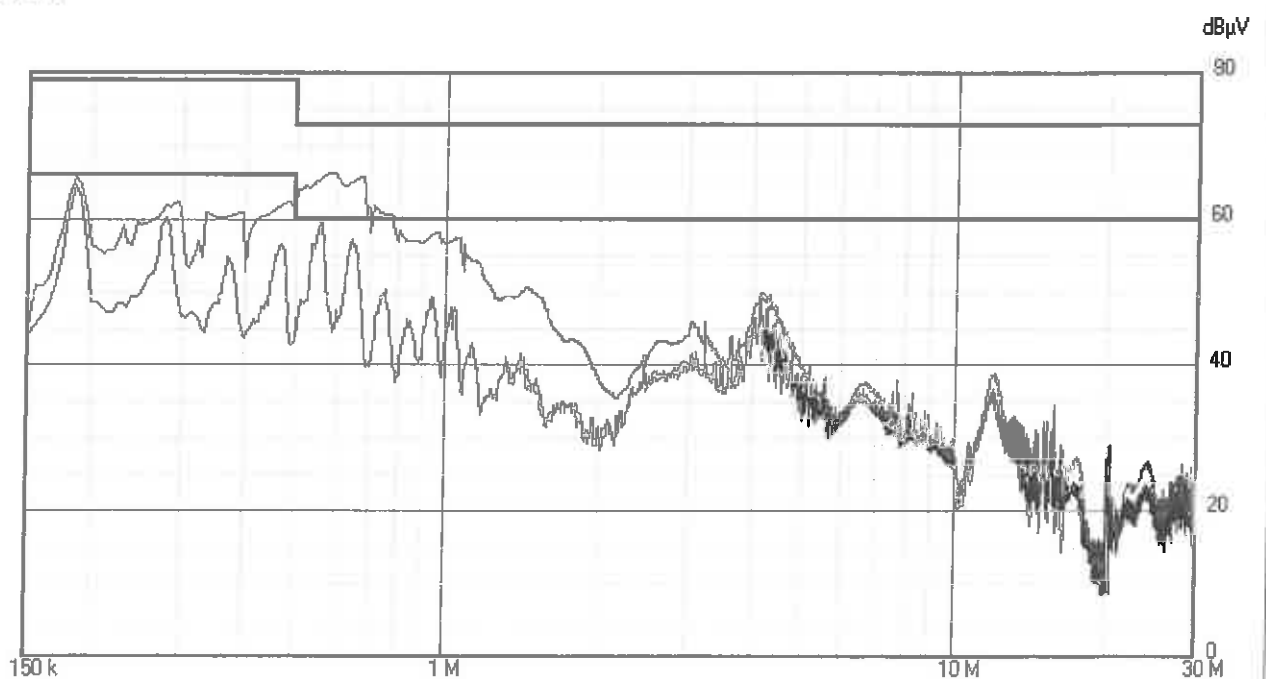
Pole L3:



2016_11_22_Celtron_ISS_575_PoleL3_vegleges_daralo

Operation mode 2.:

Pole N:



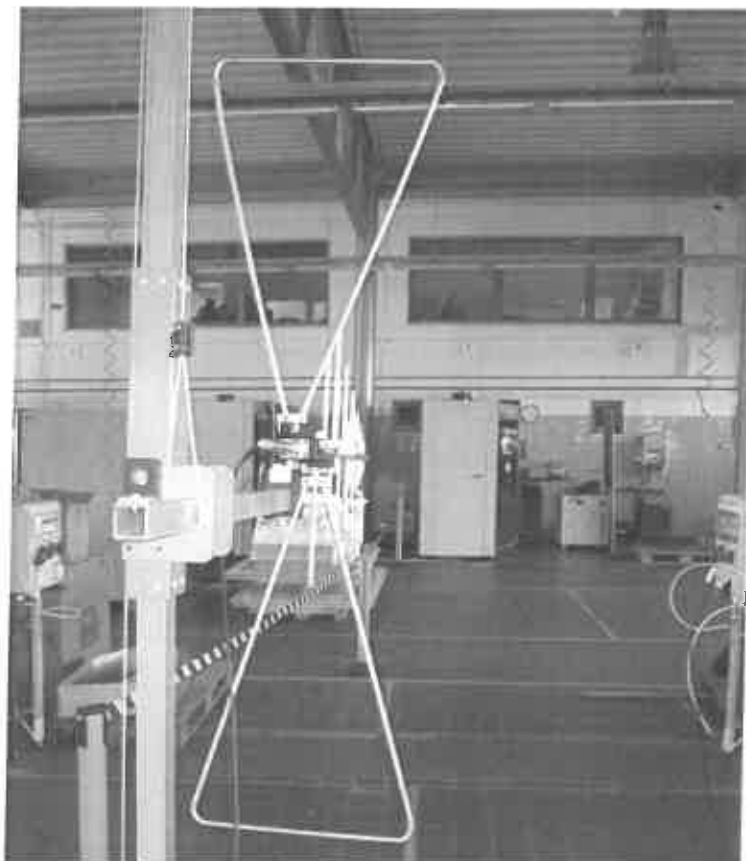
2016_11_22_Celtron_ISS_575_PoleN_vegleges_daralo

2.2 Test Conditions and Results – Radiated Emissions, from 30 MHz to 1 GHz

TEST: Limits for radiated disturbance 30 MHz – 1 GHz			Verdict
Reference standard: CISPR 11:2009 + A1:2010			Pass
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	10 to 40 °C	24 °C	
Relative Humidity	10 to 90 %	42 %	
Fully configured sample scanned over the following frequency range	Frequency range on each side of line	Measurement Point	
	30MHz – 1GHz	10 m measurement distance	
Limits – Group 1 Class A equipment with rated input power of ≤ 20 kVA			
Frequency (MHz)	Limit dB (µV/m)		
	Quasi-Peak	Results	
30 to 230	40	Pass	
230 to 1000	47	Pass	
Supplementary information: Rated power is higher than 20kVA, but the device is connectable to the low voltage network, so the limits for equipment with rated power lower than 20kVA were used.			

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Test receiver	Rohde & Schwarz	ESCS 30	836858/003	2016-07	2017-07
Biconilog antenna	Schwarzbeck	VULB 9161	9161-4156	2014-12	2017-12

Photo of test setup for Radiated Disturbance, from 30 MHz to 1 GHz

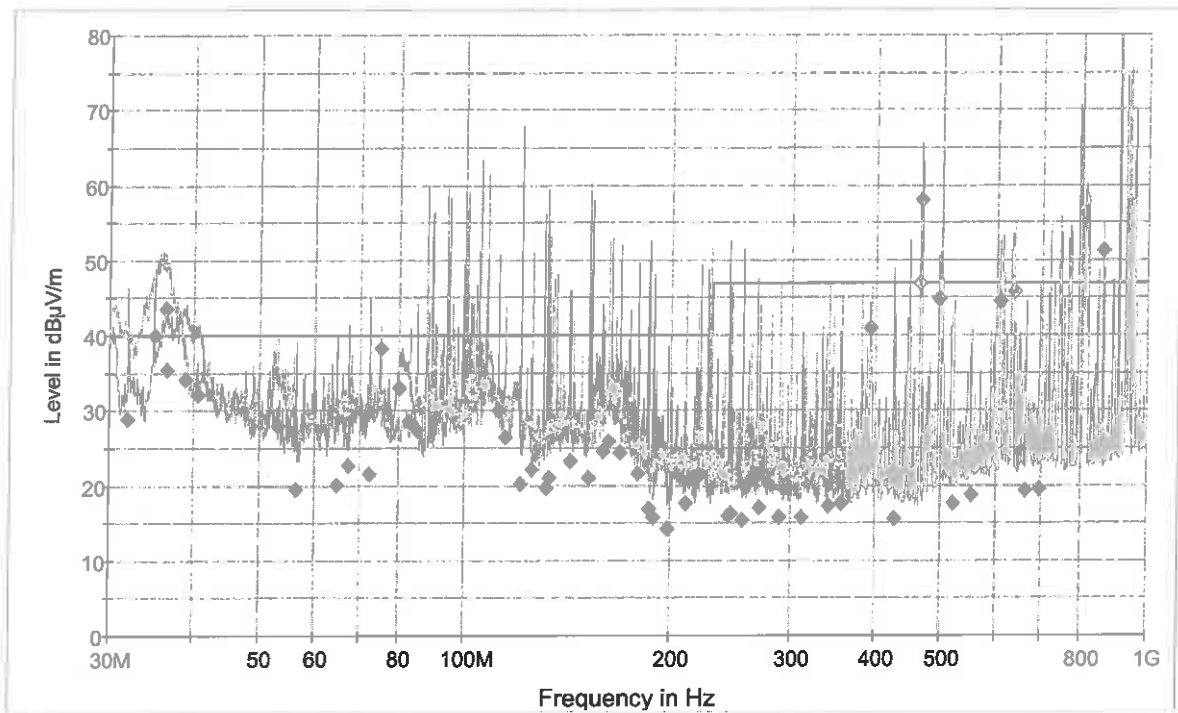


EUT Operation mode: 2

EUT configuration mode: 1

Tabulated Results for Radiated Disturbance									
Test Frequency (MHz)	Detector (Pk/QP/Av)	Polarity (V/H)	Azimuth (Degrees)	Antenna Height (cm)	Antenna Factor(dB)	Ambient noise (dB)	Level dB(µV/m)	Limit dB(µV/m)	Margin (dB)
31,98	QP	V	-	150	10,4	29,4	28,9	40,0	11,1
34,98	QP	H	-	150	10,3	40,9	39,9	40,0	0,1
36,24	QP	H	-	150	10,5	42,3	43,7	40,0	-3,7
36,48	QP	V	-	150	10,5	36,7	35,5	40,0	4,5
38,70	QP	V	-	150	10,7	33,1	34,3	40,0	5,7
40,50	QP	V	-	150	10,8	31,1	32,1	40,0	7,9
53,16	QP	H	-	150	10,7	27,2	28,0	40,0	12,0
56,40	QP	V	-	150	10,4	20,2	19,5	40,0	20,5
64,74	QP	V	-	150	8,6	20,0	20,1	40,0	19,9
67,38	QP	V	-	150	8,0	21,5	22,6	40,0	17,4
72,36	QP	V	-	150	7,4	21,5	21,5	40,0	18,5
75,00	QP	H	-	150	7,3	23,3	38,4	40,0	1,6
79,92	QP	V	-	150	7,7	29,4	33,1	40,0	6,9
82,68	QP	V	-	150	8,3	28,0	28,5	40,0	11,5
84,96	QP	V	-	150	8,7	20,9	27,5	40,0	12,5
112,26	QP	V	-	150	10,9	29,0	30,1	40,0	9,9
114,78	QP	H	-	150	11,0	23,5	26,4	40,0	13,6
121,02	QP	V	-	150	12,0	20,0	20,3	40,0	19,7
125,58	QP	H	-	150	12,9	20,8	22,1	40,0	17,9
131,52	QP	V	-	150	14,7	20,8	19,8	40,0	20,2
133,32	QP	V	-	150	15,3	21,1	21,1	40,0	18,9
142,56	QP	V	-	150	17,4	24,7	23,3	40,0	16,7
152,28	QP	H	-	150	18,2	24,0	20,9	40,0	19,1
159,12	QP	V	-	150	19,0	23,6	24,7	40,0	15,4
162,18	QP	H	-	150	18,9	25,2	25,9	40,0	14,1
169,02	QP	V	-	150	17,2	24,5	24,4	40,0	15,6
179,58	QP	V	-	150	13,8	19,9	21,6	40,0	18,4
186,12	QP	V	-	150	12,4	16,4	17,0	40,0	23,0
188,70	QP	V	-	150	12,0	14,9	15,8	40,0	24,2
198,30	QP	V	-	150	11,3	13,8	14,2	40,0	25,8
211,38	QP	H	-	150	11,9	17,8	17,7	40,0	22,3
221,76	QP	V	-	150	11,1	21,7	21,4	40,0	18,6
243,12	QP	V	-	150	10,9	15,9	15,9	47,0	31,1
246,06	QP	V	-	150	10,9	16,4	16,4	47,0	30,6
255,30	QP	V	-	150	11,3	15,2	15,4	47,0	31,6
269,94	QP	V	-	150	11,8	17,3	17,0	47,0	30,0

Tabulated Results for Radiated Disturbance (continued)									
Test Frequency (MHz)	Detector (Pk/QP/Av)	Polarity (V/H)	Azimuth (Degrees)	Antenna Height (cm)	Antenna Factor(dB)	Ambient noise (dB)	Level dB(µV/m)	Limit dB(µV/m)	Margin (dB)
289,20	QP	H	-	150	12,4	16,1	15,8	47,0	31,2
311,52	QP	V	-	150	12,9	15,6	15,7	47,0	31,3
341,34	QP	H	-	150	13,6	17,3	17,3	47,0	29,7
356,10	QP	H	-	150	14,0	17,0	17,7	47,0	29,3
391,32	QP	V	-	150	14,8	44,5	41,0	47,0	6,0
426,54	QP	V	-	150	15,6	14,9	15,6	47,0	31,4
462,96	QP	V	-	150	16,5	47,3	46,9	47,0	0,1
465,06	QP	V	-	150	16,5	58,3	58,0	47,0	-11,0
494,88	QP	V	-	150	16,7	44,7	45,0	47,0	2,0
520,44	QP	V	-	150	17,1	17,6	17,7	47,0	29,3
555,60	QP	H	-	150	17,8	18,6	18,8	47,0	28,2
606,96	QP	H	-	150	18,8	44,8	44,4	47,0	2,6
635,58	QP	H	-	150	19,6	45,9	45,8	47,0	1,2
662,70	QP	V	-	150	19,7	18,8	19,3	47,0	27,7
696,54	QP	H	-	150	20,0	19,0	19,5	47,0	27,5
860,70	QP	H	-	150	21,8	20,2	51,3*	47,0	-4,3
Note: Frequencies which are originating from the EUT are marked with bold characters, the other frequencies are originating from the ambient. * Level at EUT switched on is higher than ambient noise because the ambient noise at that frequency is not constant in time.									

Graphical representation of Radiated Disturbance Measurement (Optional)

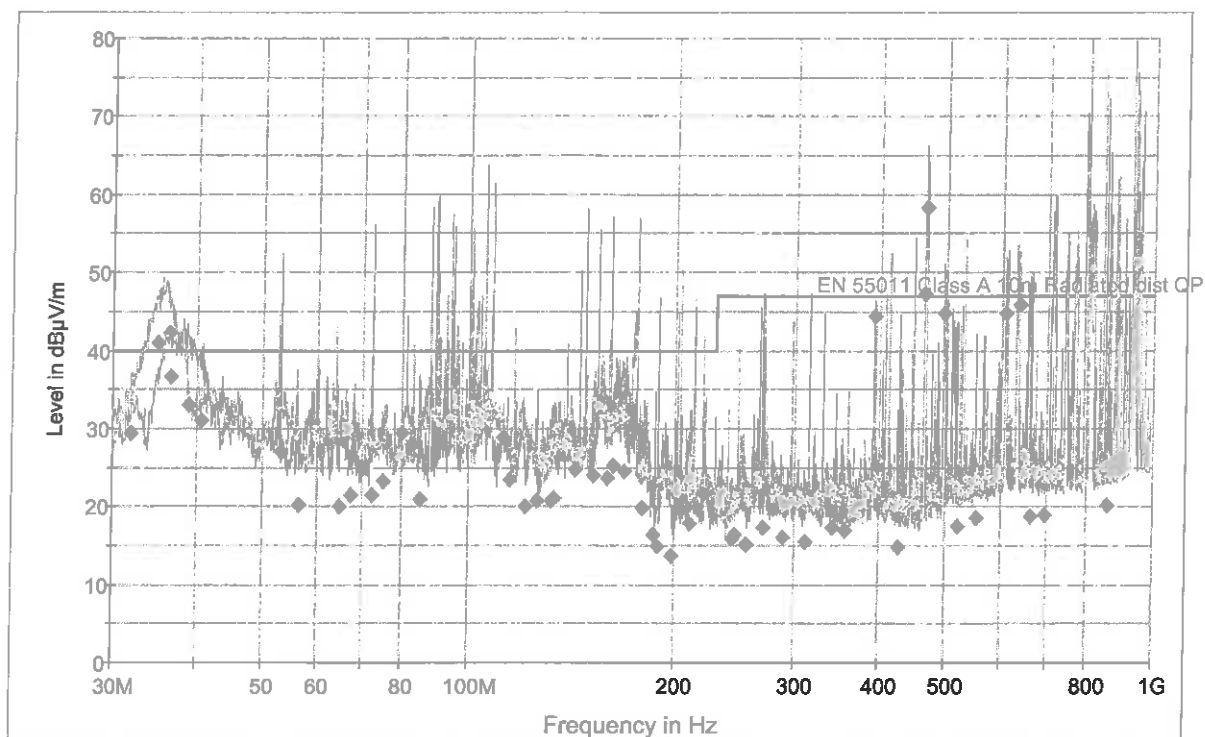
Measurement with EUT switched on

Red line: Preliminary measurement with peak detector, performed at vertical antenna polarisation

Blue line: Preliminary measurement with peak detector, performed at horizontal antenna polarisation

Blue rombus: Final measurement results.

Graphical representation of Radiated Disturbance Measurement (Optional)



Background measurement (EUT switched off)

Red line: Preliminary measurement with peak detector, performed at vertical antenna polarisation

Blue line: Preliminary measurement with peak detector, performed at horizontal antenna polarisation

Blue rombus: Final measurement results.

2.3 Test Conditions and Results – Radiated Emissions, from 1 GHz to 18 GHz

TEST: Limits for radiated disturbance 1 GHz – 18 GHz			Verdict
Reference standard: CISPR 11:2009 + A1:2010			N/A
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	10 to 40 °C	--- °C	
Relative Humidity	10 to 90 %	--- %	
Fully configured sample scanned over the following frequency range	Frequency range on each side of line	Measurement Point	
	1GHz – 18GHz	--- m measurement distance	

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
---	---	---	---	---	---

Photo of test setup for Radiated Disturbance, from 1 GHz to 18 GHz

EUT Operation mode:

EUT configuration mode:

Tabulated Results for Radiated Disturbance									
Test Frequency (MHz)	Detector (Pk/Av)	Polarity (V/H)	Azimuth (Degrees)	Antenna Height (cm)	Loss Factor (dB)	Antenna Factor(dB)	Level dB(μV/m)	Limit dB(μV/m)	Margin (dB)
---	---	---	---	---	---	---	---	---	---
Note: Other table formats are allowed as long as all information is included.									

Graphical representation of Radiated Disturbance Measurement (Optional)

2.4 Test Conditions And Results – Limits for Harmonic Current Emissions

TEST: Limits for Harmonic current emissions			Verdict
Reference standard: IEC 61000-3-2:2014			N/A
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	15 to 35 °C	--- °C	
Relative Humidity	30 to 60 %	--- %	
Classification of Equipment			--- Class

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
---	---	---	---	---	---

Photo of test setup for Harmonic Current Emissions

EUT Operation mode:

EUT configuration mode:

Tabulated Results for Harmonic Current Emissions

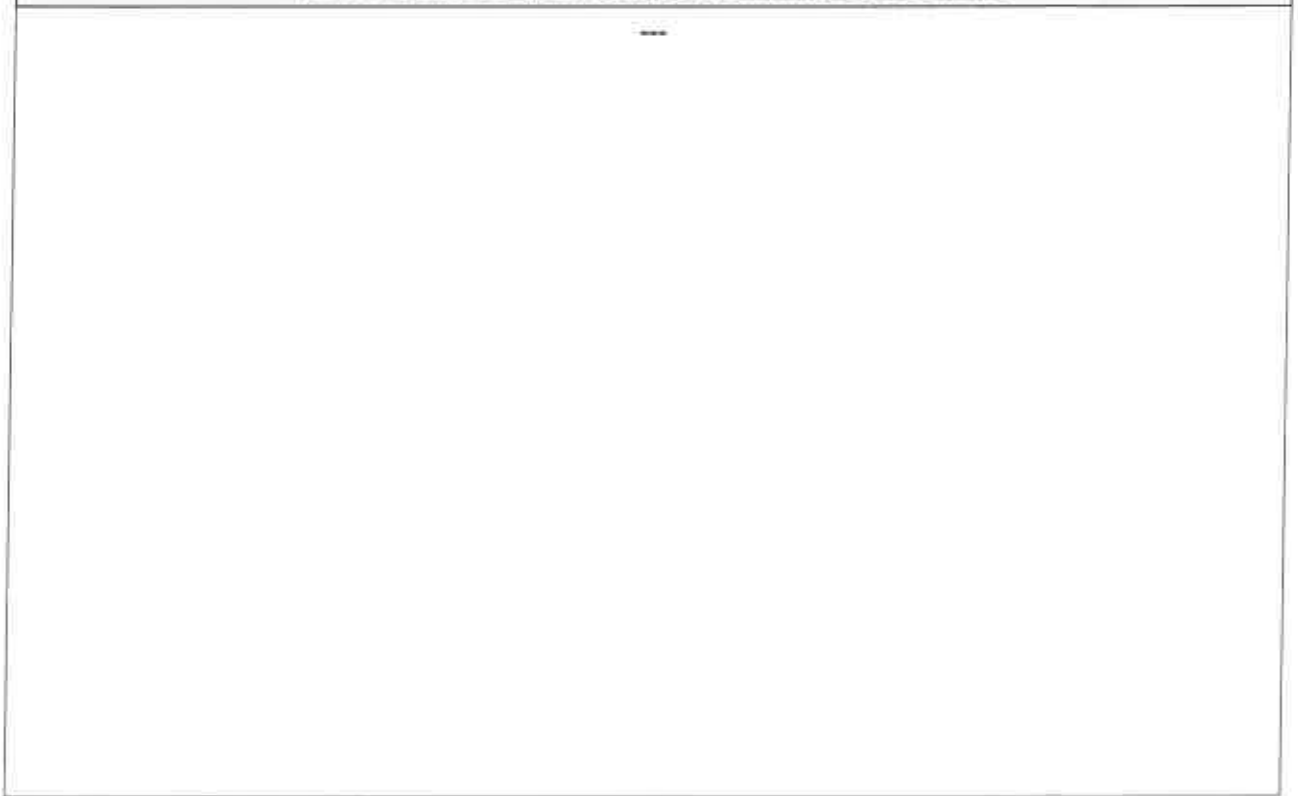
2.5 Test Conditions and Results – Limitation of Voltage Fluctuations and Flicker

TEST: Limitation of Voltage Fluctuations And Flicker			Verdict
Reference standard: IEC 61000-3-3:2013			N/A
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	15 to 35 °C	--- °C	
Relative Humidity	30 to 60 %	--- %	
Control Method of Equipment (see below)			---
1 - without additional conditions			
2 - switched manually, or switched automatically more frequently than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds), or manual restart, after a power supply interruption.			
3 - attended while in use (for example: hair dryers, vacuum cleaners, kitchen equipment such as mixers, garden equipment such as lawn mowers, portable tools such as electric drills), or switched on automatically, or is intended to be switched on manually, no more than twice per day, and also has either a delayed restart (the delay being not less than a few tens of seconds) or manual restart, after a power supply interruption.			
Supplementary information:			

Parameter	Limit	Result
Pst	0.65	---
Plt	1.0	---
d(t)	3.3 % for > 0.5 s	---
dc	3.3 %	---
dmax	☐ 4 % ☐ 6 % ☐ 7 %	---

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
---	---	---	---	---	---

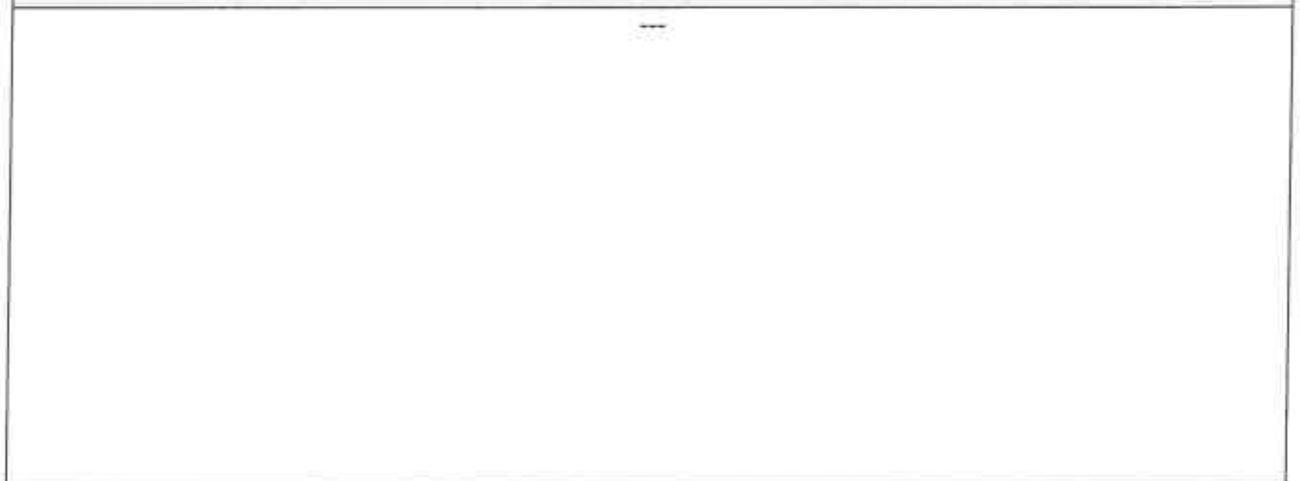
Photo of test setup for Voltage Fluctuations And Flicker



EUT Operation mode:

EUT configuration mode:

Tabulated Results for Voltage Fluctuations And Flicker

	
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2.6 Test Conditions and Results – Immunity to Electrostatic Discharges

TEST: Immunity to Electrostatic discharges (ESD)				Verdict
Reference standard: IEC 61000-4-2:2008				Pass
Laboratory Parameters:		Required prior to the test		During the test
Ambient Temperature		15 to 35 °C		22 °C
Relative Humidity		30 to 60 %		38 %
Test Levels for industrial electromagnetic environment				
Discharge type	Discharge Level (kV)		Number of discharges per location (each polarity)	Result
	Positive	Negative		
Air – Direct	8	8	10	Pass
Contact – Direct	4	4	10	Pass
Contact – Indirect	4	4	10	Pass
Discharge location	See photo documentation of the test set-up and tabulated results All external locations accessible by hand, Horizontal plate (HCP)			
Supplementary information: EUT powered at one of the Nominal input voltages and frequencies				

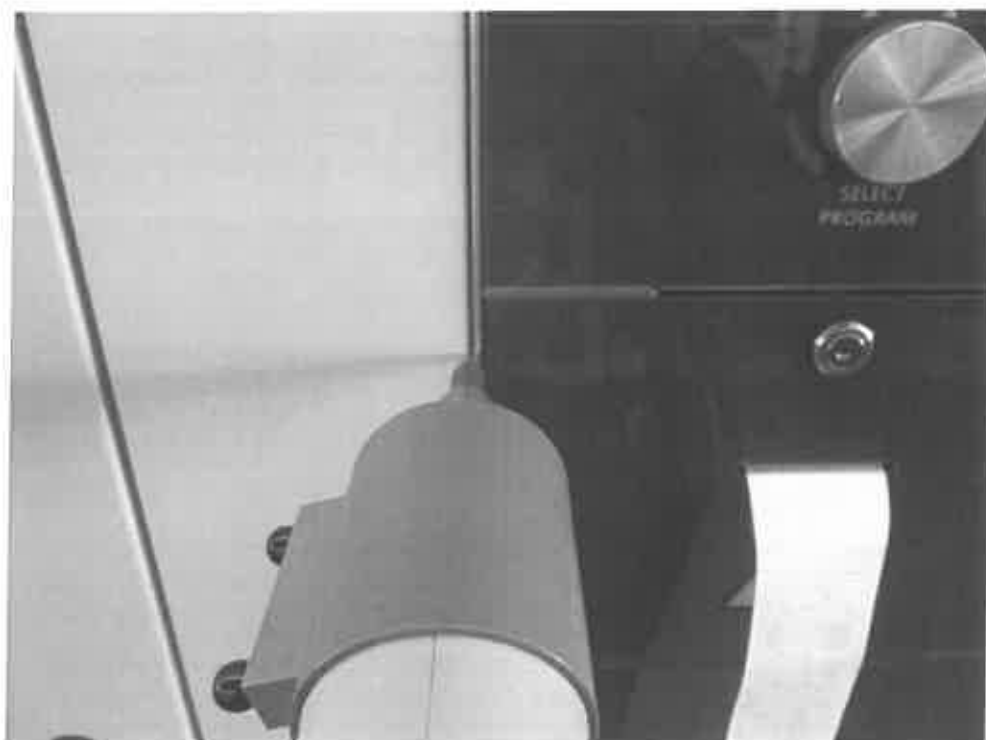
Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
ESD generator	EMC – Partner	ESD3000	497	2016-08	2017-08

Photo of test setup for Immunity to Electrostatic Discharges



Direct Contact Discharges

Photo of test setup for Immunity to Electrostatic Discharges



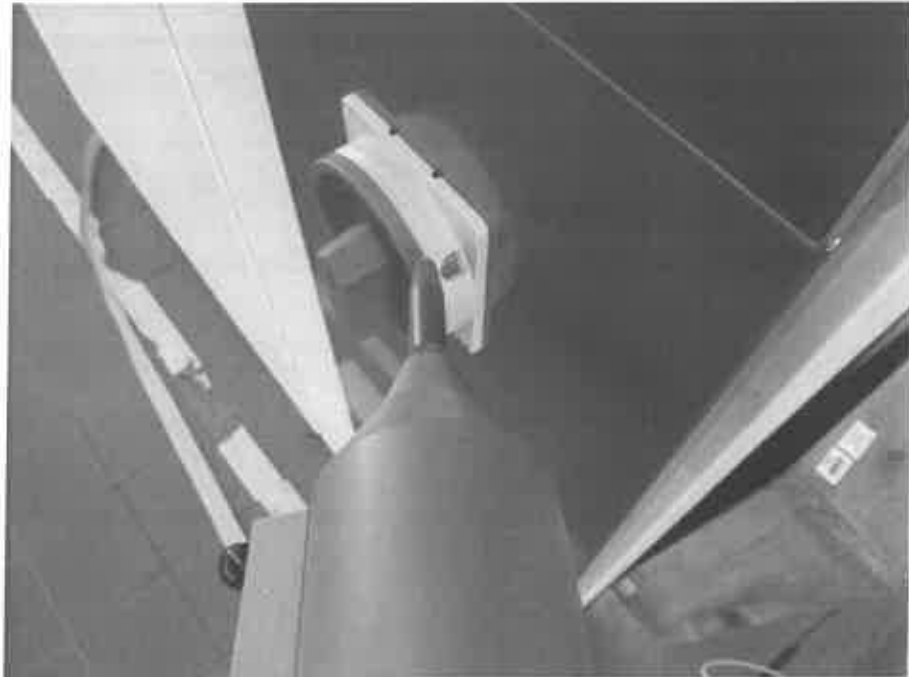
Direct Contact Discharges

Photo of test setup for Immunity to Electrostatic Discharges

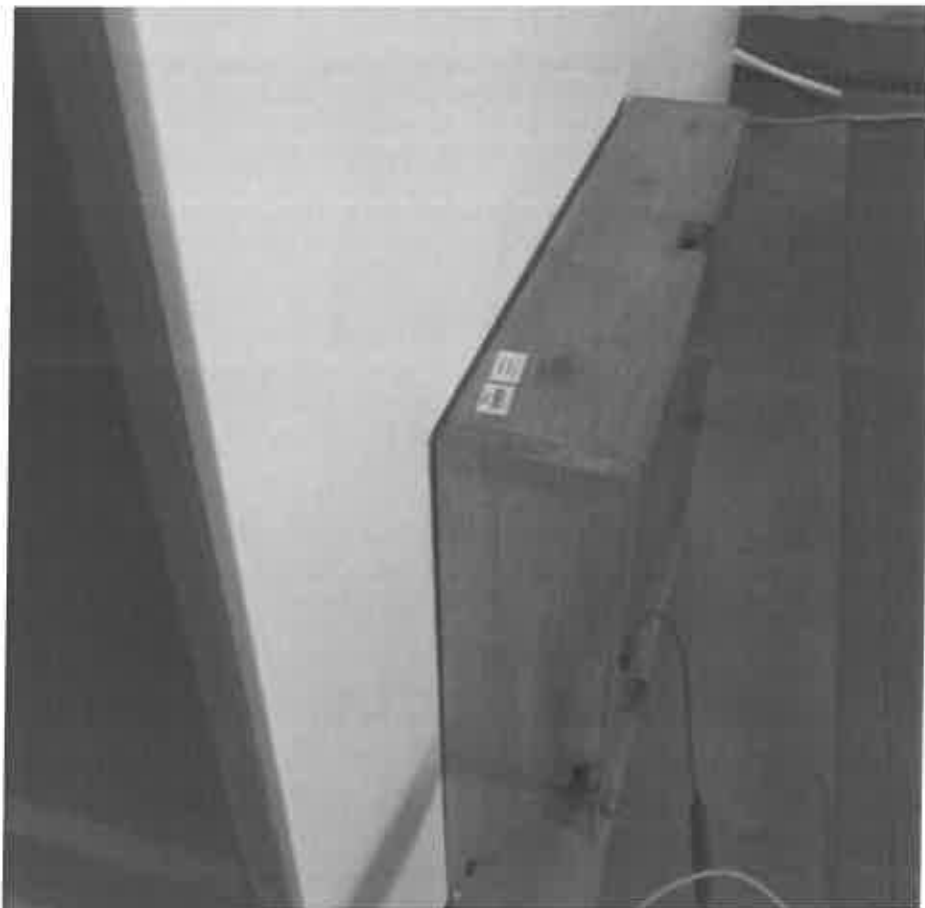


Direct Contact Discharges

Photo of test setup for Immunity to Electrostatic Discharges



Air Discharges



Indirect Contact Discharges

EUT Operation mode: 1 EUT configuration mode: 1

Tabulated Results for Electrostatic Discharges				
Nominal Rated Voltage (V)..... :			3x400	
Nominal Rated Frequency (Hz) . :			50	
Direct discharges				
	Discharge location	Air discharge voltage (kV)	Polarity	Remark
Contact Discharges	Metallic parts of enclosure	4	+/-	1
	Discharge location	Contact discharge voltage (kV)	Polarity	Remark
Air Discharges	Plastic parts of enclosure	8	+/-	1
Indirect discharges				
	Discharge location	Contact discharge voltage (kV)	Polarity	Remark
HCP	Side of HCP	4	+/-	1
	Discharge location	Contact discharge voltage (kV)	Polarity	Remark
VCP	---	---	---	---

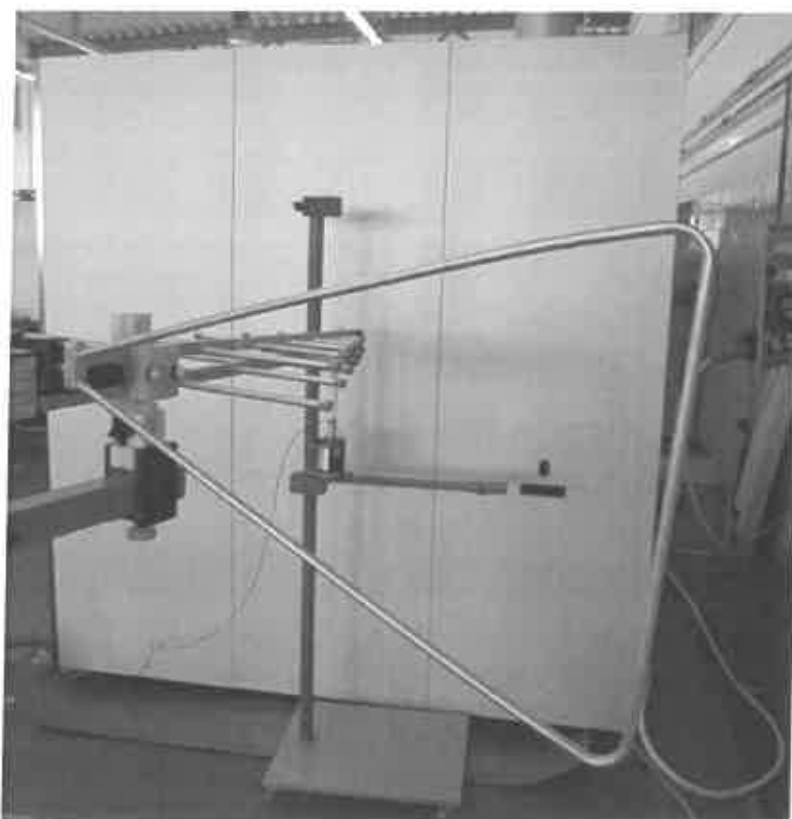
Table of remark	
X	Not performed
1	No observed/perceived response from EUT.
Note:	

2.7 Test Conditions and Results - Immunity to Radio Frequency Electromagnetic Fields

TEST: Immunity to RF electromagnetic fields					Verdict
Reference standard: IEC 61000-4-3:2006+A1:2007+A2:2010					Pass
Laboratory Parameters:		Required prior to the test		During the test	
Ambient Temperature		15 to 35 °C		22 °C	
Relative Humidity		30 to 60 %		38 %	
Test specifications					
Frequency bandwidth		80 MHz to 2700 MHz			Result
Level	Industrial EM environment	Amplitude modulation (80% - 1KHz - sine wave)	80 – 1000MHz	10 V/m	Pass
			1400 – 2000MHz	3 V/m	Pass
			2000 – 2700MHz	1 V/m	Pass
Frequency step		1% with 1s dwell time			
Supplementary information:					
EUT powered at one of the Nominal input voltages and frequencies					

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Signal generator	R&S	SMT 06	100634	2016-08	2017-08
Power amplifier	Ophir	5127F	1029	2016-08	2017-08
Power amplifier	Bonn	BLMA1020-50	004781	2016-08	2017-08
Power amplifier	Bonn	BLMA2040-60	045631	2016-08	2017-08
Portable field strength meter	PMM	8051	0110J70307	2016-05	2017-05
Antenna for measurement of field strength	PMM	BA01	02010J70303	2016-05	2017-05
Optic repeater (for BA01)	PMM	OR01	0210K70306	2016-05	2017-05
Biconilog antenna	Schwarzbeck	VULB 9161	9161-4156	2014-12	2017-12

Photo of test setup for Radio Frequency Electromagnetic Fields



EUT Operation mode: 1

EUT configuration mode: 1

Tabulated Results for RF Electromagnetic Field 80 MHz to 2700 MHz			
Nominal Rated Voltage (V)		3x400	
Nominal Rated Frequency (Hz)...		50	
Side of the equipment under test	Frequency (MHz)	Antenna polarization (V/H)	Remark
Front	80 – 1000	V	1
Front	1400 – 2000	V	1
Front	2000 – 2700	V	1
Front	80 – 1000	H	1
Front	1400 – 2000	H	1
Front	2000 – 2700	H	1

Table of remark	
X	Not performed
1	No observed/perceived response from EUT.
Note:	

2.8 Test Conditions and Results – Immunity to Electrical Fast Transients

TEST: Immunity to Electrical Fast Transients			Verdict
Reference standard: IEC 61000-4-4:2012			Pass
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	15 to 35 °C	29 °C	
Relative Humidity	30 to 60 %	39 %	
Industrial EM environment			
Application Point	(kV)	Repetition Frequency (kHz)	Result
Input A.C. Power Ports	±2	5	Pass
Input D.C. Power Ports	±2	5	N/A
Signal/control Ports**	±1	5	N/A
Signal/control Ports connected directly to mains supply	±2	5	N/A
Supplementary information: EUT powered at one of the Nominal input voltages and frequencies ** - Only in case of lines longer than 3 m.			

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
EMC Test System	EMC PARTNER	EXT-TRA 3000S	1562	2016-03	2017-03
Coupling and Decoupling Network	HAEFELY	FP 16/3-1	082632-019	2016-05	2019-05

Photo of test setup for Electrical Fast Transients



EUT Operation mode: 1 EUT configuration mode: 1

Tabulated Results for Fast Transient		
Nominal Rated Voltage (V).....:		3x400
Nominal Rated Frequency (Hz) .:		50
Point of application	Polarity	Remark
Input A.C.	Positive	1
	Negative	1

Table of remark	
X	Not performed
1	No observed/perceived response from EUT.
Note:	

2.9 Test Conditions and Results – Immunity to Surge

TEST: Immunity to Surge				Verdict
Reference standard: IEC 61000-4-5:2014				Pass
Laboratory Parameters:		Required prior to the test	During the test	
Ambient Temperature		15 to 35 °C	24 °C	
Relative Humidity		30 to 60 %	42 %	
Industrial EM environment				
Application Point	[kV]	Phase angle	Repetition rate	Result
Input A C /D.C Power Ports	±1.0 (Line to Line)	0°, 90°, 180°, 270°	1 min.	Pass
	±2.0 (Line to Earth)	0°, 90°, 180°, 270°	1 min.	Pass
Signal/control Ports**	---	---	---	N/A
	±1.0 (Line to Earth)	---	---	N/A
Signal/control Ports connected directly to mains supply	±1.0 (Line to Line)	---	---	N/A
	±2.0 (Line to Earth)	---	---	N/A
Supplementary information:				
EUT powered at one of the Nominal input voltages and frequencies				
** - Only in case of lines within a building which are longer than 30 m, or which leave the building.				

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
EMC Test System	EMC PARTNER	EXT-TRA 3000S	1562	2016-03	2017-03
3 phase surge coupler	MEEI	CH-3/1	HI 2002	2016-05	2017-05

Photo of test setup for Surge



EUT Operation mode: 1 EUT configuration mode: 1

Tabulated Results for Surges			
Nominal Rated Voltage (V)			3x400
Nominal Rated Frequency (Hz) .			50
Mode of Application	Mode of coupling	Polarity	Remark
Input A.C./D.C. Power ports	Line to Line	Positive	1
		Negative	1
	Line to Earth	Positive	1
		Negative	1

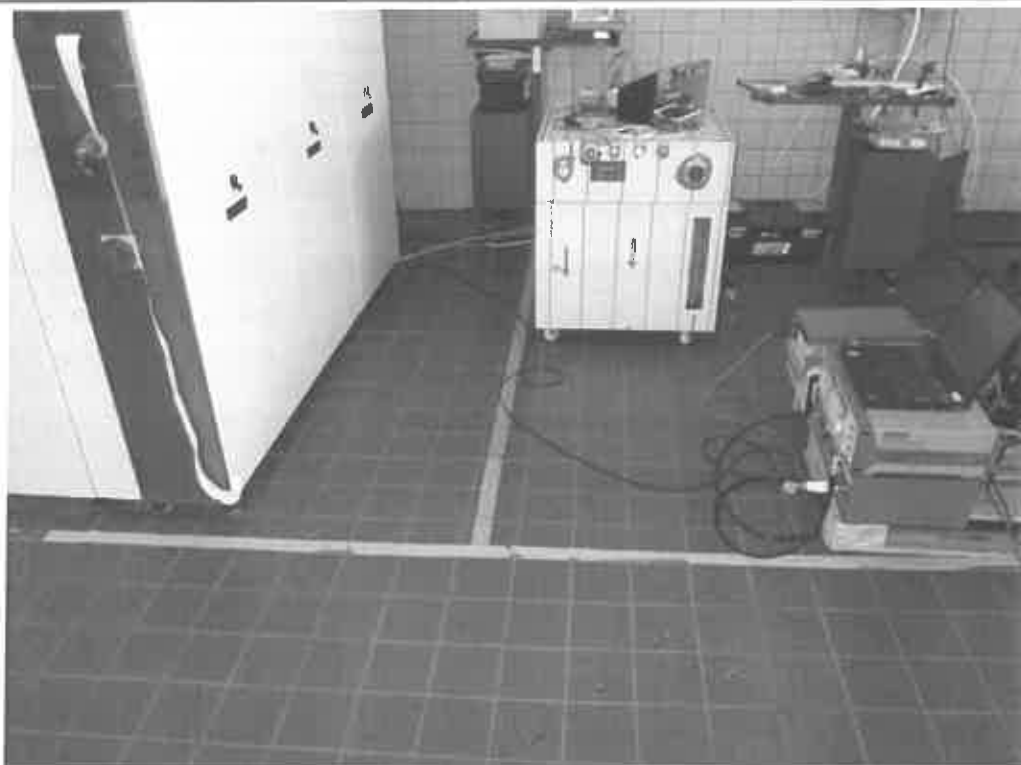
Table of remark	
X	Not performed
1	No observed/perceived response from EUT.
Note:	

2.10 Test Conditions and Results – Immunity to Conducted Disturbances

TEST: Immunity to RF Continuous Conducted disturbances			Verdict
Reference standard: IEC61000-4-6:2013			Pass
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	15 to 35 °C	24 °C	
Relative Humidity	30 to 60 %	42 %	
Frequency step	1% with 3s dwell time		
Frequency bandwidth	150 KHz to 80 MHz		
Industrial EM environment			
Application Point	Modulation	Level	Result
Input A.C. Power Ports	Amplitude modulation (80% - 1KHz - sine wave)	3V	Pass
Input D.C. Power Ports		3V	N/A
Signal/control Ports**		3V	N/A
Signal/control Ports connected directly to mains supply		3V	N/A
Supplementary information:			
EUT powered at one of the Nominal input voltages and frequencies			
** - Only in case of lines longer than 3 m.			

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Signal generator	Rhode & Schwarz	SMY 01	844146 / 052	2016-01	2017-01
Amplifier	Amplifier Research	25A250A	18727	2016-10	2017-10
RF millivoltmeter	Rhode & Schwarz	URV 5	894296/004	2016-07	2017-07
Injection clamp	Lüthi Elektronik	EM101	35692	2016-07	2019-07

Photo of test setup for Conducted Disturbances



EUT Operation mode: 1 EUT configuration mode: 1

Tabulated Results for Conducted Disturbances		
Nominal Rated Voltage (V)		3x400
Nominal Rated Frequency (Hz) .		50
Point of Application	Application mode	Remark
Input A.C.	EM101 Clamp	1

Table of remark	
X	Not performed
1	No observed/perceived response from EUT.
Note:	

2.11 Test Conditions and Results – Immunity to Voltage Dips, Interruptions, and Variations

TEST: Immunity to Voltage Dips, Interruptions and Variations			Verdict
Reference method: IEC 61000-4-11:2004			Pass
Laboratory Parameters:		Required prior to the test	During the test
Ambient Temperature		15 to 35 °C	22 °C
Relative Humidity		30 to 60 %	38 %
Fully configured subjected to the levels indicated below.	Measurement Point		
	Input A.C. Power Ports		
Industrial EM environment			
Voltage Dips % U _T	Period (Cycles)	Result	
30	25/30	Pass	
60	10/12	Pass	
100	1	Pass	
Voltage Interruption % U _T	Period (Cycles)	Result	
100	250/300	Pass	
Supplementary information:			
Test is performed at the minimum rated input voltages and at the minimum rated frequency.			
Test was performed on a single phase at a time.			

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
EMC Test System	EMC PARTNER	EXT-TRA 3000S	1562	2016-03	2017-03
DMM	Hioki	3257-50	40418901	2016-08	2017-08

Photo of test setup for Voltage Dips, Interruptions, and Variations

Photo not available

Tabulated Results for Voltage Dips and Interruptions

Minimum Rated Voltage (V)			3x400
Maximum Rated Frequency (Hz)			50
Point of application	Voltage reduction	Period (Cycles)	Remark
Mains – L1	161 V	25	1
Mains – L1	92 V	10	1
Mains – L1	0 V	1	1
Mains – L1	0 V	250	3
Mains – L2	161 V	25	1
Mains – L2	92 V	10	1
Mains – L2	0 V	1	1
Mains – L2	0 V	250	3
Mains – L3	161 V	25	2
Mains – L3	92 V	10	2
Mains – L3	0 V	1	1
Mains – L3	0 V	250	3

Table of remark

X	Not performed
1	No observed/perceived response from EUT.
2	A relay loses contact during the dip, but returns automatically after the dip. Operation is not affected by this.
3	The device restarts and returns to it's previous operating state after the dip.

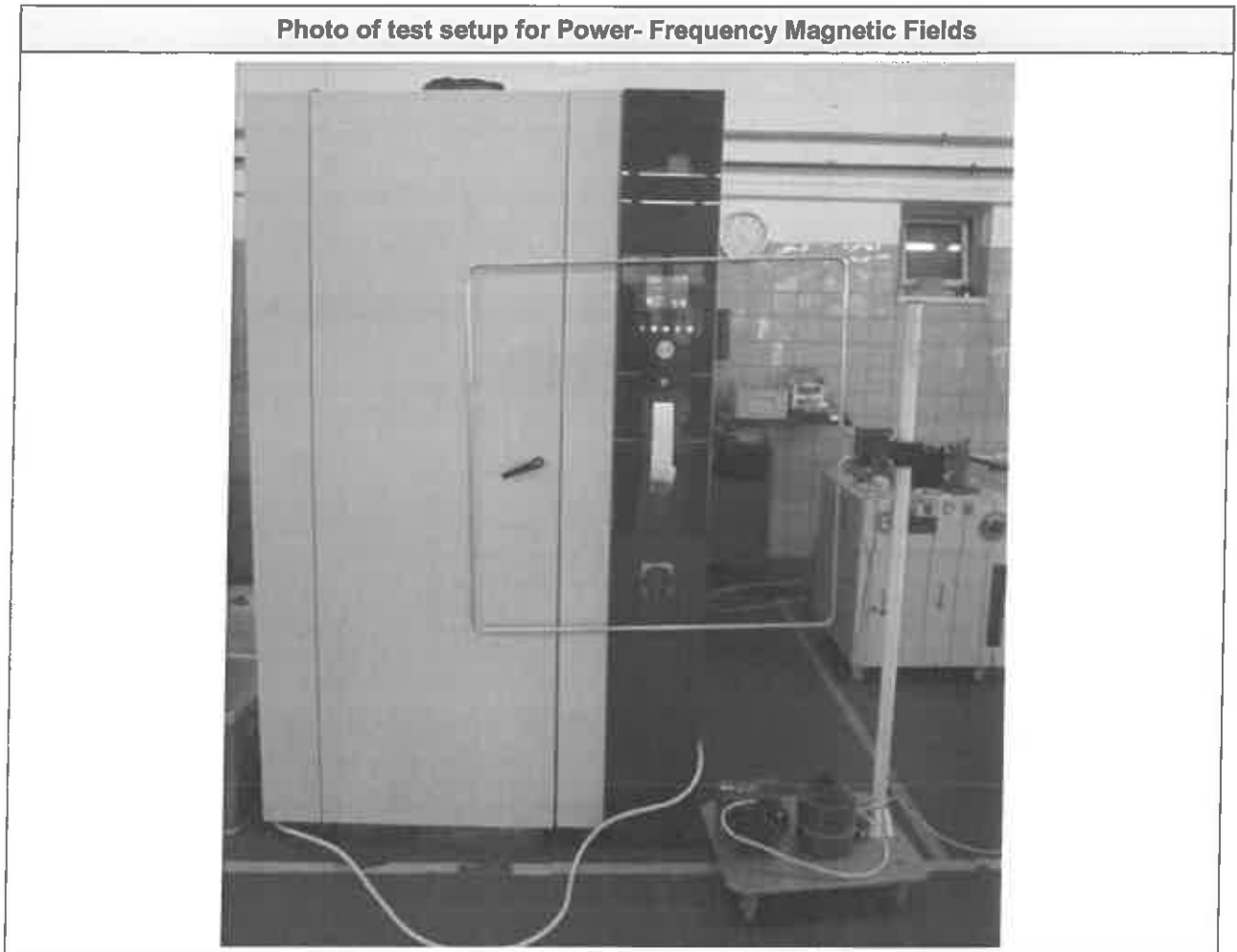
Note:

2.12 Test Conditions and Results – Immunity to Power- Frequency Magnetic Fields

TEST: Immunity to Power-frequency magnetic field			Verdict
Reference method: IEC 61000-4-8:2009			Pass
Laboratory Parameters:	Required prior to the test	During the test	
Ambient Temperature	15 to 35 °C	24 °C	
Relative Humidity	30 to 60 %	42 %	
Fully configured sample tested at the power line frequency	Frequency	Application Point	
	50Hz	Enclosure	
Industrial EM environment*			
Frequency (Hz)	Test Level (A/m)	Result	
50	30	Pass	
Supplementary information:			

Test Equipment Used					
Description	Manufacturer	Model	Identifier	Cal. Date	Cal. Due
Inductive coil	EMTEST	MS100	-	2016-07	2019-07
Digital multimeter	HIOKI	3257-50	040418901	2016-08	2017-08
Clamp	HIOKI	9018	040435909	2016-08	2017-08

Photo of test setup for Power- Frequency Magnetic Fields



Tabulated Results for Power Frequency Magnetic Field		
Nominal Rated Voltage (V).....		3x400
Point of application	Remark	
	50 Hz	60 Hz
X-Axis	1	X
Y-Axis	1	X
Z-Axis	1	X

Table of remark	
X	Not performed
1	No observed/perceived response from EUT.
Note:	

Fotó dokumentáció
Photo documentation

Melléklet A / Attachment A

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Applicant:	Celitron Medical Technologies Kft.	Test engineer:	Tamás Novotny
Product:	Integrated Sterilizer & Shredder	Type(s):	ISS AC-575 Premium



Photo 1



Photo 2

Fotó dokumentáció
Photo documentation

Melléklet A / Attachment A

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Photo 3



Photo 4

Fotó dokumentáció
Photo documentation

Melléklet A / Attachment A

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Photo 5



Photo 6

Fotó dokumentáció
Photo documentation

Melléklet A / Attachment A

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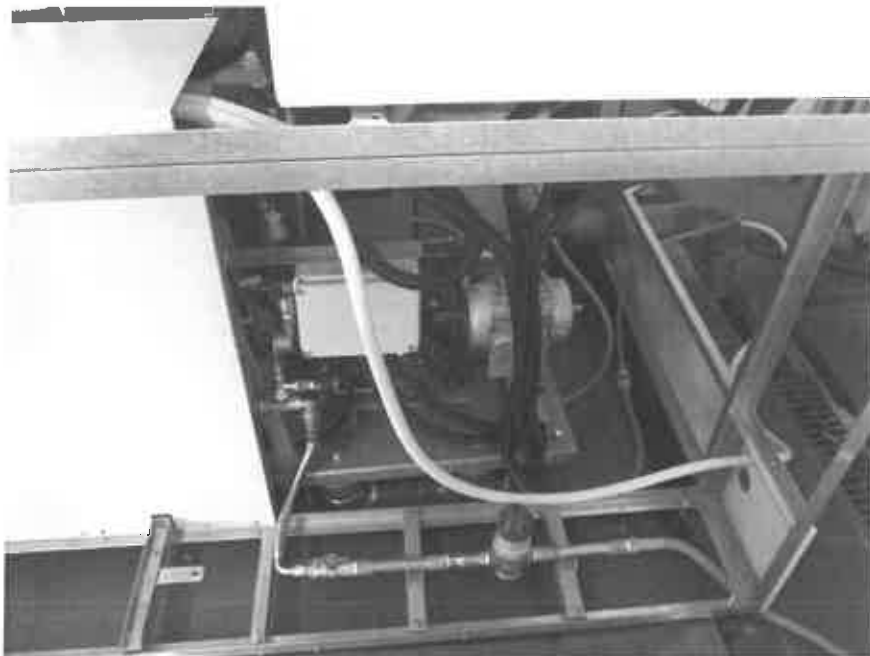


Photo 7



Photo 8

Fotó dokumentáció
Photo documentation

Melléklet A / Attachment A

Jegyzőkönyv szám / Test report No. 28228533 002

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Photo 9

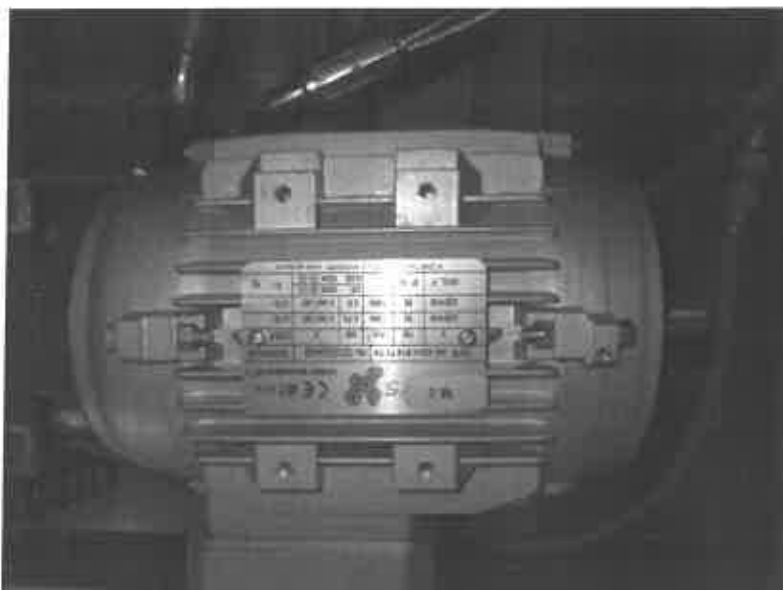


Photo 10

Fotó dokumentáció
Photo documentation

Melléklet A / Attachment A

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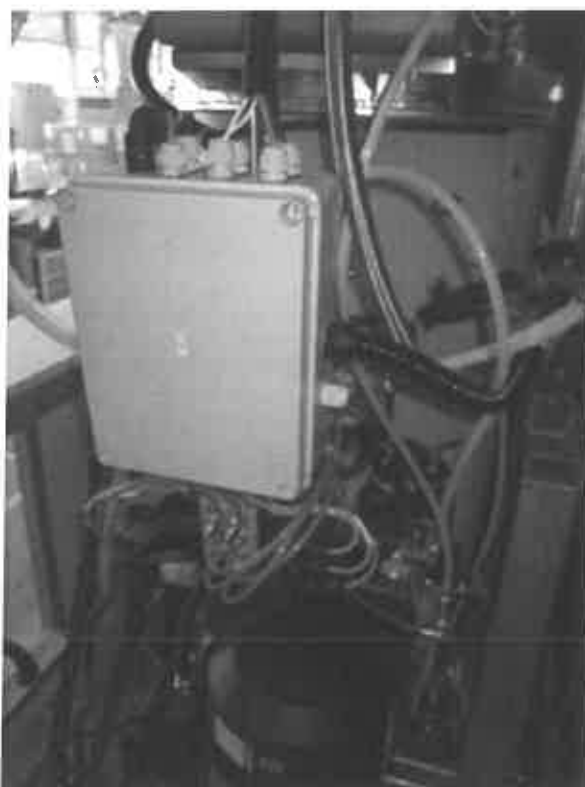


Photo 11



Photo 12

Fotó dokumentáció
Photo documentation

Melléklet A / Attachment A

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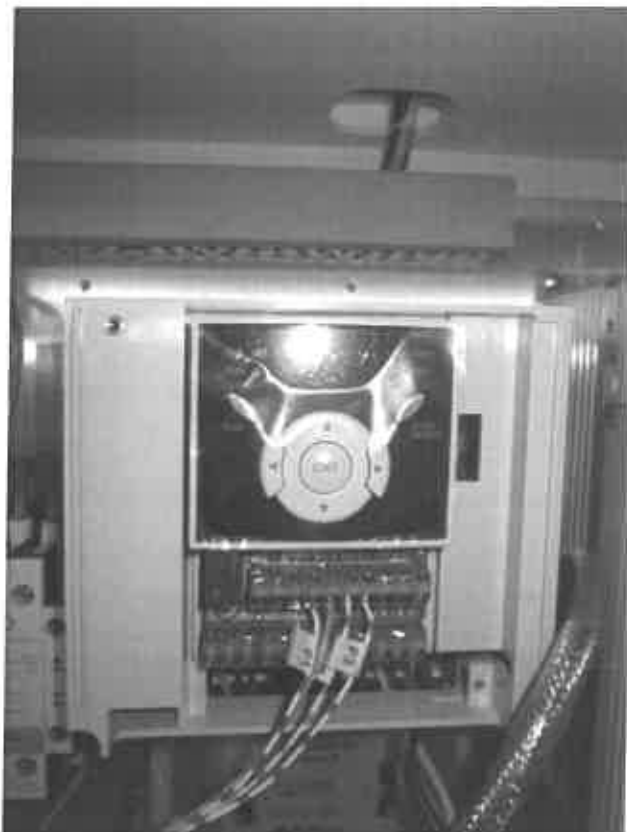


Photo 13



Photo 14

Fotó dokumentáció
Photo documentation

Melléklet A / Attachment A

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Photo 15



Photo 16

Fotó dokumentáció
Photo documentation

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Photo 17



Photo 18

Fotó dokumentáció
Photo documentation

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Photo 19



Photo 20

Fotó dokumentáció
Photo documentation

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Photo 21



Photo 22

Fotó dokumentáció
Photo documentation

Melléklet A / Attachment A

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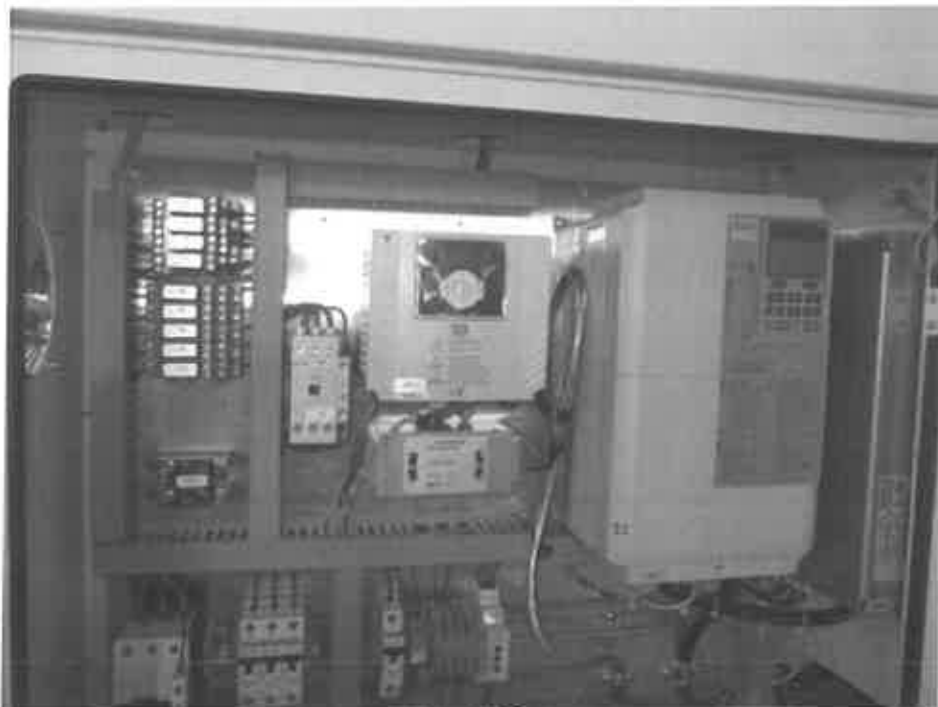


Photo 23

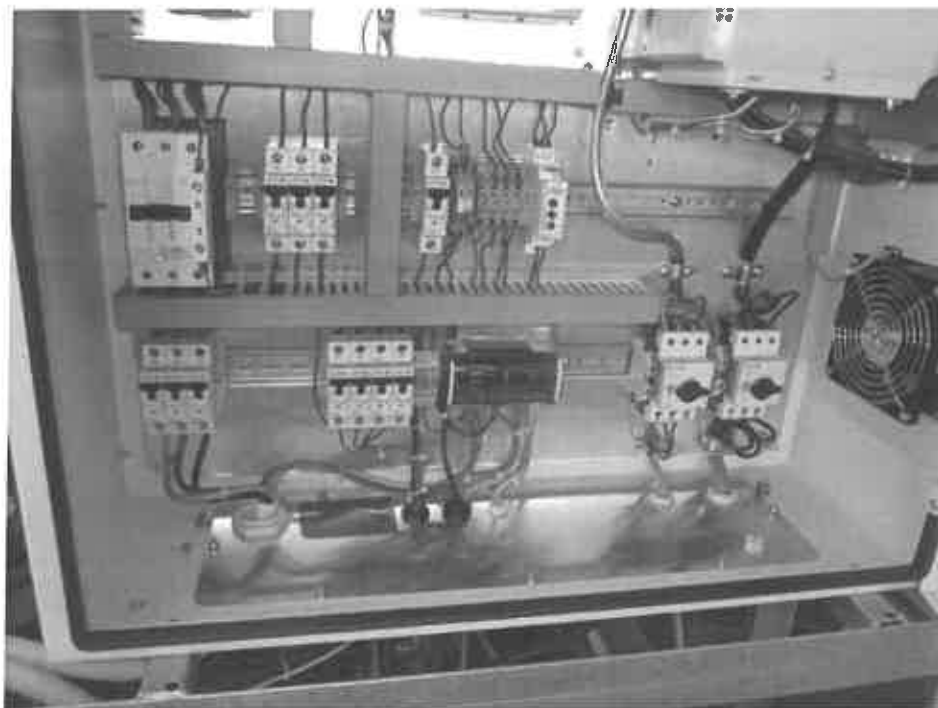


Photo 24

Fotó dokumentáció
Photo documentation

Melléklet A / Attachment A

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Photo 25

