



Conformity Report
Electromagnetic Compatibility
according to EMC Directive 2004/108/EEC

Test Report No.: **R11CS136E**
Issue Date: 2011-08-17
Test Dates: 2011-07-12 to 2011-07-15

Equipment Under Test (EUT)

Type/Model:	Model 64X
Description:	Wheelchair Washer
Serial Number:	N/A
Applicant:	Medco Equipment
Address:	30 Hilltop Road Houlton, WI 54082

Tested and Report by:

Adam Hulsey

This report consists of 51 numbered pages. All results refer exclusively to the equipment that was tested.

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1 Measurements and Test Specifications

Emissions – Requirements according to

- | | |
|--|---|
| <input type="checkbox"/> 47 CFR FCC PART 15 | Limits and methods of measurement of radio disturbance for non-intentional radiators |
| <input type="checkbox"/> ICES-003 | Industry Canada Interference-Causing Equipment Standard |
| <input type="checkbox"/> EN 61000-6-3: 2007 | Electromagnetic Compatibility - Generic Standards - Emissions for Residential, Commercial and Light-industrial Environments |
| <input type="checkbox"/> EN 61000-6-4 | Electromagnetic Compatibility - Generic Standards - Emissions for Industrial Environments |
| <input checked="" type="checkbox"/> EN 55011 | Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) |

Tests:

- | | |
|--|---|
| <input checked="" type="checkbox"/> Radiated/Conducted Emissions
EN 55011: 2007 | Limits and methods of measurement of radio disturbance characteristics of industrial, scientific and medical (ISM) |
| <input type="checkbox"/> Radiated/Conducted Emissions
EN 61000-6-3: 2007 | Limits and methods of measurement of radio disturbance characteristics of Residential, Commercial and Light-industrial Environments |
| <input type="checkbox"/> Radiated/Conducted Emissions
FCC Part 15 | Limits and methods of measurement of radio disturbance for non-intentional radiators |
| <input checked="" type="checkbox"/> EN 61000-3-2: 2006 | Harmonic currents emissions |
| <input checked="" type="checkbox"/> EN 61000-3-3: 2008 | Limitation of voltage fluctuations and flicker |

Immunity – Requirements according to

- | | |
|--|--|
| <input type="checkbox"/> EN 61000-6-1: 2007 | Electromagnetic Compatibility - Generic Standards - Immunity for Residential, Commercial and Light-industrial Environments |
| <input type="checkbox"/> EN 61000-6-2: 2001 | Electromagnetic Compatibility - Generic Standards - Immunity for - Industrial Environments |
| <input checked="" type="checkbox"/> EN 60601-1-2 | Electrical equipment for medical use - EMC requirements |
| <input type="checkbox"/> EN 55024: 1998, A2 2003 | Information technology equipment - Immunity characteristics Limits and methods of measurement |

Tests:

- | | |
|---|--|
| <input checked="" type="checkbox"/> EN 61000-4-2: 2001 | Electrostatic discharge requirements (ESD) |
| <input checked="" type="checkbox"/> EN 61000-4-3: 2008 | Radiated, radio-frequency electromagnetic field |
| <input checked="" type="checkbox"/> EN 61000-4-4: 2008 | Electrical fast transients (Burst) |
| <input checked="" type="checkbox"/> EN 61000-4-5: 2006 | Transients (Surge) |
| <input checked="" type="checkbox"/> EN 61000-4-6: 2007 | Conducted disturbances induced by radio-frequency fields |
| <input checked="" type="checkbox"/> EN 61000-4-8: 2007 | Magnetic Fields |
| <input checked="" type="checkbox"/> EN 61000-4-11: 2004 | Voltage interruptions, dips, fluctuations |

2 Test Results – Overview

Emissions	Requirement	Passed	Passed with modification	Not passed
Conducted Emissions – EN55011	Class A	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Radiated Emissions – EN55011	Class A	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Harmonic Currents – EN61000-3-2	Class A	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Flicker Disturbances – EN61000-3-3	Pass/ Fail	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Minimum Margin to Class A Limits

Conducted Emissions	Radiated Emissions
6.42 dB μ V @ 150 kHz	25.3 dB μ V/m @ 30.406 MHz

Immunity	Requirement	Passed	Passed with modification	Not passed
Electrostatic Discharge (ESD)	± 6 kV, ± 8 kV	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Radiated Electromagnetic Fields	3 V/m- 80MHz – 2GHz, 1V/m- 2- 2.8GHz	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Electrical fast transients (Burst)	± 1 kV, ± 2 kV	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Transients –Surges	± 1 kV, ± 2 kV	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Conducted Radio-frequency Fields	3 V	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Magnetic Fields	3 A/m	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Voltage Interruptions, Dips, Fluctuations	100% 1cyc, 100% 250 cyc 60% 12 cyc 30% 25 cyc	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3 Performance Criteria

For Immunity testing the following performance criteria was applied, as given by **EN 60601-1-2**.

Performance criterion A: During testing normal performance within the specification limits.

Example 1: If electronic equipment has a central processing unit and is required to work with high reliability, the processor shall operate without any apparent degradation from the manufacture's specification.

Performance criterion B: During testing, temporary degradation, or loss of function or performance which is self-recovering.

Example 1: A data transfer is controlled/checked by parity check or by other means. In the case of malfunctioning, such as caused by a lightning strike, the data transfer will be repeated automatically. The reduced data transfer rate at this time is acceptable.

Example 2: During testing, an analogue function value deviates by an allowed margin. After the test, the deviation vanishes.

Example 3: In the case of a monitor used only for man-machine monitoring, it is acceptable that some degradation takes place for a short time, such as flashes during the burst application.

Performance criterion C: During testing, temporary degradation, loss of function or performance, which requires operator intervention, or system reset occurs.

Example 1: in the case of an interruption in the mains longer than the specified buffer time, the power supply unit of the equipment is switched off. The switch-on may be automatic or carried out by the operator.

Example 2: After a program interruption caused by a disturbance, the processor functions of the equipment shall stop at a safe position and not be left in a "crashed state". Operator's decision prompts may be necessary.

For performance criteria B and C, the EUT has passed the test if it has shown its specified immunity throughout the period of application of the test signal and, at the end of the test, the EUT fulfils the functional requirements established in the technical product specification. The performance criterion D is normally not acceptable.

4 Description of EUT

4.1 General

The EUT is a wheelchair washer consisting of pumps and electrical components enclosed inside a fully metal enclosure. A single start/stop switch begins a timed cycle lasting for approximately five minutes. The cycle can be stopped by pushing the start/stop button.

4.2 Configuration / Operating Conditions

☐ table-top EUT ☒ floor-standing EUT ☐ rack mount EUT

The EUT was configured to operate in continuous mode as prescribed by the manufacturer. All Immunity tests were performed at 230Vac, 50Hz supply voltage.

4.3 EUT Monitoring During Immunity Test

For immunity testing the EUT was configured to operate as described above. The EUT was monitored visually for any indication of malfunction. While in the chamber, a video camera was utilized. The test levels and performance criteria applied are taken from EN60601-1-2. The environmental conditions during immunity testing were 24°C at 35% RH.

4.4 Peripheral Devices Used During Testing

Device Type	Model Number
None	

4.5 Interconnection Cables Used During Testing

Cables	Length in meters	shielded	non-shielded
(1) AC Power Cord	2.0 m	<input type="checkbox"/>	<input checked="" type="checkbox"/>

5 Emissions

5.1 Conducted Emissions 150 kHz - 30 MHz

Normative references

Generic Standard:	EN 60601-1-2
Basic Standard:	EN 55011

Test requirement

Frequency range	150KHz - 30MHz Class A
-----------------	------------------------

Place of measurement

- ☐ In situ, at customer factory
☒ Shielded semi anechoic chamber, EMC Test Systems, Serial No. SL 12168

Measurement equipment

Measurement equipment	Type/model	Manufacturer	SN	Calibration due
EMI Test Receiver 9 kHz-1000MHz	ESPC	Rohde & Schwarz	841852/005	2012.01.07
Line Impedance Stabilization Network	ESH3-Z5	Rohde & Schwarz	8843331/013	2012.01.07

Test results:

☒ passed

☐ passed with
modification

☐ not passed

Comments:

The EUT was tested for conducted emissions 230V/50Hz. The highest quasi-peak value was 6.42 dB μ V below the Class A quasi-peak limit at 150 kHz. The highest Average value was 19.05 dB μ V below the Class A Average limit at 150 kHz. See the tables below for detailed results.

INTERTest Systems Inc.

4179 Sinton Road

Colorado Springs, CO 80907

Phone: 1 (719) 522-1402

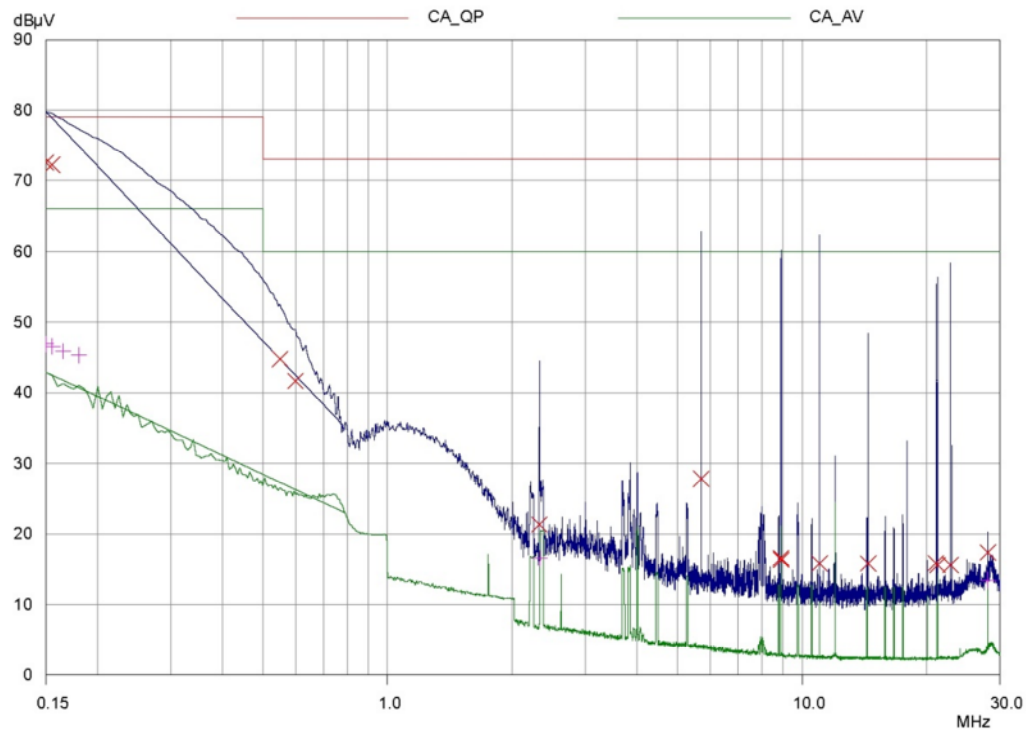
Fax: 1 (719) 522-1086

INTERTest Systems 5 Meter Semi-Anechoic Chamber
Conducted Emissions on Line and Neutral

12 Jul 2011 14:15

EUT: Model 64X
 Manuf: Medco Equipment
 Op Cond: 230 V, 50Hz
 Operator: Adam Hulsey
 Test Spec: EN55011, Class A
 Comment: P11CS136E

Scan Settings		(1 Range)			Receiver Settings		
Frequencies							
Start	Stop	Step	IF BW	Detector	M-Time	Atten	OpRge
150kHz	30MHz	5kHz	10kHz	PK+AV	20msec	Auto	60dB
Transducer	No.	Start	Stop	Name			
	22	150kHz	30MHz	ConFactor			
Final Measurement:		Detectors:	X QP / + AV				
		Meas Time:	1sec				
		Peaks:	8				
		Acc Margin:	25 dB				



PAGE 1

INTERTest Systems 5 Meter Semi-Anechoic Chamber
Conducted Emissions on Line and Neutral

12 Jul 2011 14:15

EUT: Model 64X
 Manuf: Medco Equipment
 Op Cond: 230 V, 50Hz
 Operator: Adam Hulsey
 Test Spec: EN55011, Class A
 Comment:
 P11CS136E

Scan Settings		(1 Range)		Receiver Settings			
Frequencies							
Start	Stop	Step	IF BW	Detector	M-Time	Atten	OpRge
150kHz	30MHz	5kHz	10kHz	PK+AV	20msec	Auto	60dB

Transducer	No.	Start	Stop	Name
	22	150kHz	30MHz	ConFactor

Final Measurement:	Detectors:	X QP / + AV
	Meas Time:	1sec
	Peaks:	8
	Acc Margin:	25 dB

Final Measurement Results

Frequency MHz	QP Level dBµV	QP Limit dBµV	QP Delta dB	Phase -	PE -
0.15	72.58	79.00	6.42	L1	gnd
0.155	72.24	79.00	6.76	L1	gnd
0.55	44.80	73.00	28.20	L1	gnd
0.6	41.68	73.00	31.32	L1	gnd
2.325	21.36	73.00	51.64	L1	gnd
5.705	27.88	73.00	45.12	N	gnd
8.88	16.56	73.00	56.44	N	gnd
8.905	16.30	73.00	56.70	L1	gnd
11.025	15.78	73.00	57.22	L1	gnd
14.45	15.80	73.00	57.20	N	gnd
21.05	15.84	73.00	57.16	N	gnd
21.21	15.56	73.00	57.44	N	gnd
22.8	15.54	73.00	57.46	L1	gnd
28.055	17.34	73.00	55.66	L1	gnd

Frequency MHz	AV Level dBµV	AV Limit dBµV	AV Delta dB	Phase -	PE -
0.15	46.95	66.00	19.05	L1	gnd
0.155	46.57	66.00	19.43	N	gnd
0.165	45.91	66.00	20.09	N	gnd
0.18	45.34	66.00	20.66	L1	gnd
2.325	16.52	60.00	43.48	L1	gnd
28.055	13.46	60.00	46.54	N	gnd

* limit exceeded

Indicated Phase/PE shows Configuration of max. Emission

Conducted Emissions Setup



5.2 Radiated Emissions 30 MHz – 1000 MHz

Normative references

Generic Standard:	EN 60601-1-2
Basic Standard:	EN 55011

Test requirement

Frequency range	30 MHz – 1000 MHz
Distance Antenna – EUT	3 m
Class	A

Place of measurement

- ☐ In situ, at customer factory site
☒ Shielded semi anechoic chamber, EMC Test Systems, Serial No. SL 12168

Measurement equipment

Measurement equipment	Type	Manufacturer	SN	Calibration due
Biconilog Antenna 26 MHz-2 GHz	3141	EMCO	9805-1097	2012.01.07
Pre-amplifier 100 KHz-1300 MHz	8447D	Hewlett Packard	1937A01758	2012.01.07
EMC Analyzer 9kHz- 22GHz	8593E	Hewlett Packard	3801A00233	2012.01.07

Test results:

☒ passed

☐ passed with
modification

☐ not passed

Comments:

The EUT was tested for radiated emissions at 230V/50Hz. The highest quasi-peak value was 25.3 dBµV/m below the Class A limit at 30.406 MHz, when rotated to 90 degrees azimuth with the antenna at 1.5 meter height in the vertical polarization.

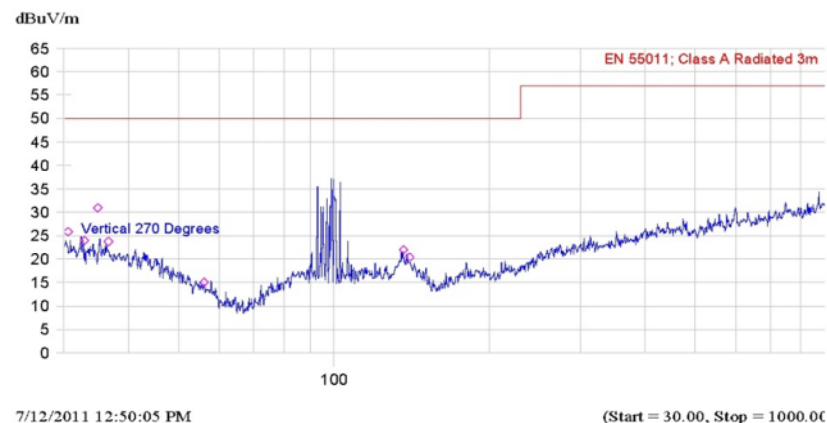
See data tables below for detailed test results.

EN 55011; Class A Radiated (3m)

Test Header

Description: 230 V, 50 Hz
 Setup Name: FCC Part 15, Class A Radiated [3m]
 Customer Name: Medco Equipment
 Project Number: P11CS136E
 Operator Name: ARH
 EUT Name: Model 64X
 Date Created: 7/12/2011 9:42:55 AM
 Date Modified: 7/12/2011 1:04:35 PM

Current Graph



Current List

Frequency MHz	Peak dBuV/m	Pk-Limit dB	QP dBuV/m	QP-Limit dB	Trace Name	Comment
30.406	25.7	-24.3	24.7	-25.3	Vertical 90 Degrees	
41.805	21.7	-28.3	22.4	-27.6	Vertical 90 Degrees	
30.567	25.8	-24.2	21.8	-28.2	Vertical 180 Degrees	
31.226	25.0	-25.0	19.9	-30.1	Horizontal 0 Degrees	

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 Fax: 1 (719) 522-1086

32.454	23.0	-27.0	18.2	-31.8	Horizontal 0 Degrees
32.884	24.0	-26.0	18.1	-31.9	Vertical 180 Degrees
36.599	23.8	-26.2	18.1	-31.9	Vertical 180 Degrees
34.903	30.9	-19.1	17.9	-32.1	Vertical 180 Degrees
34.635	23.6	-26.4	17.9	-32.1	Horizontal 0 Degrees
37.788	22.4	-27.6	17.3	-32.7	Horizontal 0 Degrees
39.207	22.3	-27.7	16.5	-33.5	Horizontal 0 Degrees
40.086	23.0	-27.0	16.2	-33.8	Vertical 90 Degrees
135.642	21.5	-28.5	15.8	-34.2	Horizontal 0 Degrees
136.317	22.0	-28.0	15.8	-34.2	Vertical 180 Degrees
134.642	20.9	-29.1	15.7	-34.3	Vertical 90 Degrees
137.307	21.2	-28.8	15.6	-34.4	Horizontal 0 Degrees
137.145	20.9	-29.1	15.6	-34.4	Vertical 90 Degrees
140.249	20.9	-29.1	14.9	-35.1	Horizontal 0 Degrees
133.323	20.5	-29.5	14.9	-35.1	Vertical 90 Degrees
140.241	20.4	-29.6	14.8	-35.2	Vertical 180 Degrees
56.120	15.0	-35.0	10.2	-39.8	Vertical 180 Degrees

Radiated Emissions Setup



5.3 Harmonic Current Emissions

Normative references

Generic Standard:	EN 60601-1-2
Basic Standard:	EN 61000-3-2

Test requirement

Device Class A	Harmonic Number 2 – 40
----------------	------------------------

Place of measurement

- ☐ In situ, at customer factory
☒ Immunity test area 1

Measurement equipment

Measurement equipment	Type/model	Manufacturer	SN	Calibration due
Programmable Power Supply	SW Series 5250AE	Elgar	0025A1049	2011.09.15
Power Analyzer	EST5250-4	Elgar	118	2011.09.15
Test Software	EST 1.7	Elgar	N/A	N/A

Test results:
☒ passed
 ☐ passed with modification
 ☐ not passed

Comments:

The EUT was shown to comply with the limits given for harmonic disturbances induced on the Public Utilities mains supply. Refer to the following tables for detailed test results.

Test Summary:

Line Voltage (V)	Line Frequency (Hz.)	Device Class	Pk Current (Amp)
230.00	50.00	A	0.15

Meas Delay (s)	%Class	%Class	Real Power (W)	K-Factor
30.00	-----	-----	7.18	2.48

VoltageTHD(%)	Current THD(%)	Power Factor(W/VA)	DC Draw (A-DC)	Steady/Fluctuating
0.01	42.06	0.41	0.00	STEADY

Reactive Power(VAR)	Dis Power Factor	UseAdder
16.02	0.44	NO

MinClassC Pwr(W)	MinClassD Pwr (W)	MaxClassC Fund Current(Amp)
25.00	75.00	6.50

Final Results

Harmonic Number	MaxValue %	MeanValue %	StdDev %	Pass/Fail	Pct50	Pct75 %	Pct90	Pct95 %	Pct100
2	0.34	0.05	0.01	P	0.00	0.00	0.00	0.00	0.00
3	1.33	1.31	0.03	P	0.00	0.00	0.00	0.00	0.00
4	0.27	0.04	0.01	P	0.00	0.00	0.00	0.00	0.00
5	0.21	0.20	0.02	P	0.00	0.00	0.00	0.00	0.00
6	0.22	0.03	0.01	P	0.00	0.00	0.00	0.00	0.00
7	0.32	0.15	0.03	P	0.00	0.00	0.00	0.00	0.00
8	0.34	0.01	0.01	P	0.00	0.00	0.00	0.00	0.00
9	0.58	0.35	0.04	P	0.00	0.00	0.00	0.00	0.00
10	0.05	0.01	0.01	P	0.00	0.00	0.00	0.00	0.00
11	0.64	0.52	0.01	P	0.00	0.00	0.00	0.00	0.00
12	0.33	0.01	0.01	P	0.00	0.00	0.00	0.00	0.00
13	0.58	0.54	0.02	P	0.00	0.00	0.00	0.00	0.00
14	0.15	0.01	0.01	P	0.00	0.00	0.00	0.00	0.00
15	0.69	0.66	0.02	P	0.00	0.00	0.00	0.00	0.00
16	0.24	0.02	0.01	P	0.00	0.00	0.00	0.00	0.00
17	0.58	0.55	0.04	P	0.00	0.00	0.00	0.00	0.00
18	0.24	0.02	0.01	P	0.00	0.00	0.00	0.00	0.00
19	0.54	0.49	0.01	P	0.00	0.00	0.00	0.00	0.00
20	0.12	0.02	0.01	P	0.00	0.00	0.00	0.00	0.00
21	0.69	0.52	0.02	P	0.00	0.00	0.00	0.00	0.00

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22	0.31	0.02	0.02	P	0.00	0.00	0.00	0.00	0.00
23	0.60	0.47	0.03	P	0.00	0.00	0.00	0.00	0.00
24	0.10	0.03	0.01	P	0.00	0.00	0.00	0.00	0.00
25	0.61	0.56	0.02	P	0.00	0.00	0.00	0.00	0.00
26	0.26	0.02	0.02	P	0.00	0.00	0.00	0.00	0.00
27	0.58	0.54	0.02	P	0.00	0.00	0.00	0.00	0.00
28	0.16	0.03	0.02	P	0.00	0.00	0.00	0.00	0.00
29	0.57	0.52	0.02	P	0.00	0.00	0.00	0.00	0.00
30	0.20	0.02	0.02	P	0.00	0.00	0.00	0.00	0.00
31	0.57	0.52	0.02	P	0.00	0.00	0.00	0.00	0.00
32	0.21	0.03	0.02	P	0.00	0.00	0.00	0.00	0.00
33	0.54	0.48	0.02	P	0.00	0.00	0.00	0.00	0.00
34	0.14	0.03	0.02	P	0.00	0.00	0.00	0.00	0.00
35	0.56	0.50	0.02	P	0.00	0.00	0.00	0.00	0.00
36	0.30	0.02	0.02	P	0.00	0.00	0.00	0.00	0.00
37	0.56	0.50	0.02	P	0.00	0.00	0.00	0.00	0.00
38	0.11	0.03	0.02	P	0.00	0.00	0.00	0.00	0.00
39	0.54	0.47	0.02	P	0.00	0.00	0.00	0.00	0.00
40	0.23	0.03	0.02	P	0.00	0.00	0.00	0.00	0.00

5.4 Fluctuations and Flicker

Normative references

Generic Standard:	EN 61000-3-3
Basic Standard:	EN 61000-3-3

Test requirement

Rated Current 16 Amps or Less	
-------------------------------	--

Place of measurement

- ☐ In situ, at customer factory
☒ Immunity test area 1

Measurement equipment

Measurement equipment	Type/model	Manufacturer	SN	Calibration due
Programmable Power Supply	SW Series 5250AE	Elgar	0025A1049	2011.09.15
Power Analyzer	EST5250-4	Elgar	118	2011.09.15
Test Software	EST 1.7	Elgar	N/A	N/A

<u>Test results:</u>	<input checked="" type="checkbox"/> passed	<input type="checkbox"/> passed with modification	<input type="checkbox"/> not passed
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Comments:

The EUT was shown to comply with the limits given for fluctuations and flicker disturbances induced on the Public Utilities mains supply. Refer to the following tables for detailed test results.

Results:

Line Voltage (V)	Line Freq (Hz.)	TShort (Amp)	Peak Current	N x T Short	
230.00	50.00	10.00	7.79	12.00	
Use Pst Pass/Fail	Use Plt Pass/Fail	Plt1000-3-3	Plt868	Use Multiplier	Steady State %
YES	NO	YES	NO	NO	0.10

FINAL RESULTS:

Final Pst	Final dc	P01s	P1s	P3s	P10s	P50s
0.958	0.54	79.00	1.38	0.02	0.00	0.00
dt over Limit (sec)	Final Plt	dMax %	Final dt %			
	0.63	5.26	1.74			

Setup for Harmonics, Flicker and Voltage Drops



6 Immunity

6.1 Electrostatic Discharge (ESD)

Normative references

Generic Standard:	EN 60601-1-2
Basic Standard:	EN 61000-4-2

Test requirements

Test voltage – Contact discharge	$\pm 4\text{kV}, \pm 6\text{kV}$
Test voltage – Air discharge	$\pm 2\text{kV}, \pm 4\text{kV}, \pm 8\text{kV}$
Vertical and Horizontal Coupling Planes	$\pm 4\text{kV}, \pm 6\text{kV}$
Performance criteria	B

Place of measurement

- ☒ Immunity test area 1
☐ Shielded Semi-Anechoic Chamber, EMC Test Systems, Serial No. SL 12168
☐ In situ, at customer factory site

Measurement device

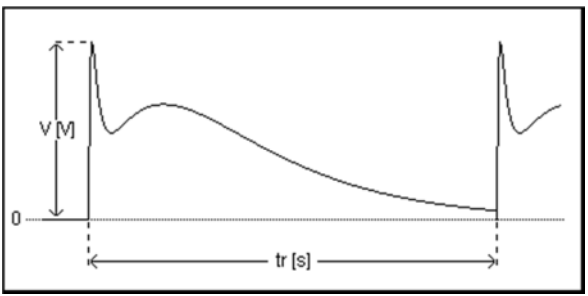
Measurement equipment	Type	Manufacturer	SN	Calibration due
ESD-Generator	SESD200	Schlöder	512123	2011.12.12

Test results:	<input checked="" type="checkbox"/> passed	<input type="checkbox"/> passed with modification	<input type="checkbox"/> not passed
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Comments:

The EUT exhibited adequate immunity to electrostatic discharges of 6kV contact and 8kV air. The EUT continued to operate as intended without degradation, meeting Performance Criteria A. Ten applications of each polarity and level were applied to each test point. Refer to the following tables for detailed test results.

Contact Discharge

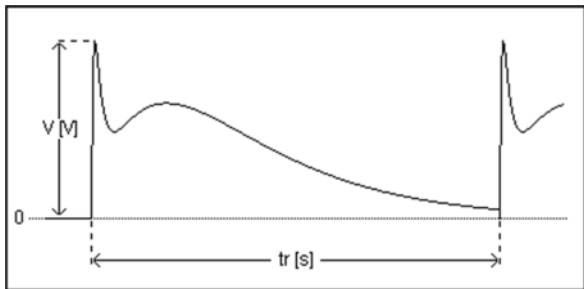
Test Procedure		EN 60601-1-2: EN 61000-4-2	
Test setup:			
tr:	1 s		
Testpoints	25		
			
Mode:	Contact Discharge (CD)		
Polarity:	Positive and Negative		
Trigger:	Internal		
Test Voltages:	$\pm 4\text{kV}$, $\pm 6\text{kV}$		

Test Results:

	Test level 1 4 kV		Test level 2 6 kV		Test level 3 8 kV		Test level 4 15 kV	
	+	-	+	-	+	-	+	-
Enclosure (x22)	Pass	Pass	Pass	Pass				
Door Handle	Pass	Pass	Pass	Pass				
Start/Stop Button	Pass	Pass	Pass	Pass				
Rear Door Handle	Pass	Pass	Pass	Pass				

pass: Performance criteria fulfilled
 fail: Performance criteria not fulfilled

Air discharge

Test Procedure			EN 60601-1-2: 61000-4-2
Test setup:			
			
tr:	1	s	
Testpoints	4		
Mode:		Air Discharge (AD)	
Polarity:		Positive and Negative	
Trigger:		Manual	
Test Voltages:		± 2kV, ± 4kV, ± 8kV	

Test Results:

	Test level 1 2 kV		Test level 2 4 kV		Test level 3 8 kV		Test level 4 15 kV	
	+	-	+	-	+	-	+	-
LED	Pass	Pass	Pass	Pass	Pass	Pass		
Start/Stop Button	Pass	Pass	Pass	Pass	Pass	Pass		
AC Inlet	Pass	Pass	Pass	Pass	Pass	Pass		
Manual Discharge Button	Pass	Pass	Pass	Pass	Pass	Pass		

pass: Performance criteria fulfilled
 fail: Performance criteria not fulfilled

ESD



6.2 Radio-Frequency Electromagnetic Field Immunity

Normative references

Generic Standard:	EN 60601-1-2
Basic Standard:	EN 61000-4-3

Test requirements

Frequency range 1	80 MHz – 2000 MHz	Noise level	3 V/M
	2-2.8 GHz		1V/m
Modulation	80% AM		
Step	1% of freq.		
Dwell time	1 sec.		
Distance Antenna – EUT	3 M		
Antenna polarization	Vertical, Horizontal		
EUT-orientation	0°, 90°, 180°, 270°		
Performance criteria	A		

Place of measurement

☒ Semi-Anechoic Chamber, EMC Test Systems, Serial No. SL 12168

Measurement device

Measurement equipment	Type	Manufacturer	SN	Cal. due
Signal Generator	8648B	Hewlett Packard	3623A02244	2011.09.26
HF-Amplifier	737-CE	Kalmus	F488/1-70-492-00	2011.09.26
HF-Amplifier	AR	PST	8404-1	2011.09.26
Biconilog Antenna	3141	EMCO	9805-1097	2011.09.26

Test results:

☒ passed

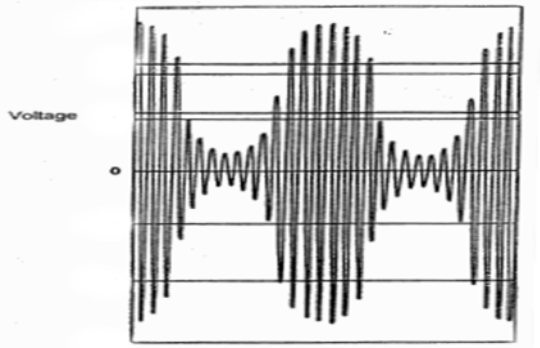
☐ passed with
modification

☐ not passed

Comments:

The EUT was illuminated on all 4 sides (0°, 90°, 180°, 270°) both in a vertical and horizontal polarization with an 80% AM modulated electromagnetic field. The EUT maintained normal operation throughout testing, satisfying Acceptance Criteria A.

Radiated Immunity

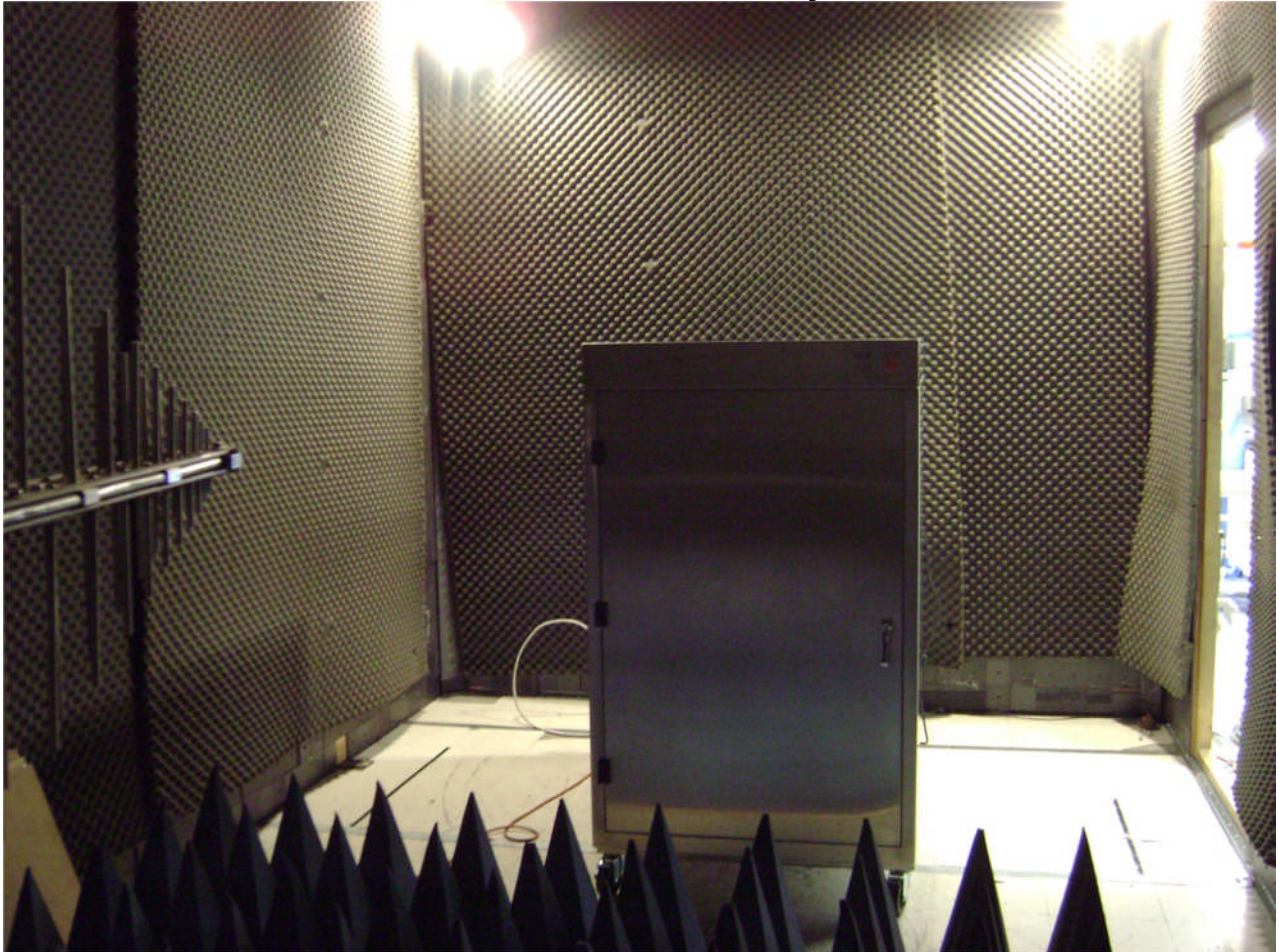
Test Procedure			EN 60601-1-2: EN 61000-4-3		
Test setup:					
Wave form of electromagnetic disturbance					
Dwell Time:	3	s			
Coupling Sides	4				
Mode:	1KHz 80% AM Modulation				
Polarization:	Vertical and Horizontal				
Step :	1% of Previous Frequency				
Test Voltages:	3 Volts per meter, 1 volt per meter				
Antenna Distance:	3 Meters				

Test Results:

Coupling side	Antenna-polarization	Test Result
Front 0°	horizontal	Pass
Front 0°	vertical	Pass
Right side 90°	horizontal	Pass
Right side 90°	vertical	Pass
Back 180°	horizontal	Pass
Back 180°	vertical	Pass
Left side 270°	horizontal	Pass
Left side 270°	vertical	Pass

pass: Performance criteria fulfilled
 fail: Performance criteria not fulfilled

Radiated Immunity



6.3 Electrical Fast Transients (Burst)

Normative references

Generic Standard:	EN 60601-1-2
Basic Standard:	EN 61000-4-4

Test requirement

coupling to	Test level	Repetition-frequency	Waveform	Duration	Performance criteria
AC Mains	$\pm 2\text{kV}$	5 kHz	5/50 ns	1 Min	B
I/O ports	$\pm 1\text{kV}$	5 kHz	5/50 ns	1 Min	B

Place of measurement

- ☒ Immunity test area 1
☐ Semi-Anechoic Chamber, EMC Test Systems, Serial No. SL 12168
☐ In situ, at customer factory site

Measurement device

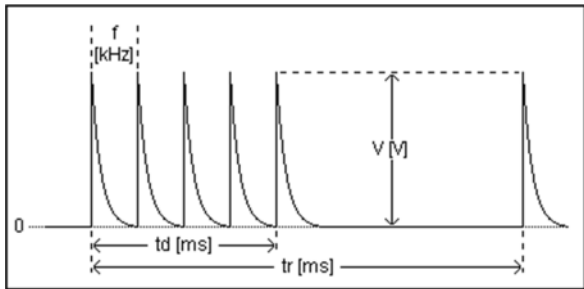
Measurement equipment	Type	Manufacturer	SN	Calibration due
Burst-Generator	SFT 400	Schlöder	30338.0	2011.09.26
Capacitive Coupling Clamp	SFT410	Schlöder	01	2011.09.26

<u>Test results:</u>	<input checked="" type="checkbox"/> passed	<input type="checkbox"/> passed with modification	<input type="checkbox"/> not passed
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Comments:

The EUT exhibited adequate immunity to Electrical Fast Transients and Bursts of the type and at the locations indicated in the following tables. The EUT maintained normal operation without loss of function or degradation of performance, meeting Acceptance Criteria A.

Burst on AC Input Port

Test Procedure			EN 60601-1-2: EN61000-4-4		
Test setup:					
					
U:	2000	V			
f:	5	kHz			
td:	15	ms			
tr:	300	ms			
Mode:			Asynchronous		
Polarity:			Alternating negative/positive		
Coupling:			L, N, PE, L+N, L+PE, N+PE, L+N+PE		
Test duration:	70	m	Time between Tests:	2	s

Test Results.

Coupling	Test Level	Pass / Fail
Line	± 2000 V	Pass
Neutral	± 2000 V	Pass
Line and Neutral	± 2000 V	Pass
Line and PE	± 2000 V	Pass
Neutral and PE	± 2000 V	Pass
Line, Neutral and PE	± 2000 V	Pass

Burst on I/O Ports

Test Procedure			EN 60601-1-2: EN61000-4-4					
Test setup:								
						U:	1000	V
						f:	5	kHz
						td:	15	ms
						tr:	300	ms
Mode:			Asynchronous					
Polarity:			Alternating negative/positive					
Coupling:			I/O Signal Ports					
Test duration:	10	m	Time between Tests:	2	s			

Test Results: Not Applicable- No I/O's greater than 3 meters

Coupling	Test Level	Pass / Fail

pass: Performance criteria fulfilled
 fail: Performance criteria not fulfilled

EFT/ Burst on AC Line



6.4 Transients – Surges

Normative references

Generic Standard:	EN 60601-1-2
Basic Standard:	EN 61000-4-5

Test requirements

Coupling between Line and Neutral	± 1kV
Coupling between Line(s) and Earth	± 2kV
Performance criteria	B

Place of measurement

- ☒ Immunity test area 1
☐ Semi-Anechoic Chamber, EMC Test Systems, Serial No. SL 12168

Measurement device

Measurement equipment	Type	Manufacturer	SN	Calibration due
Surge – Generator / CDN	PSURGE 4010	Haefeley	58333466	2011.09.26

Test results:

☒ passed

☐ passed with
modification

☐ not passed

Comments:

The EUT exhibited adequate immunity to Surges of the type and at the locations indicated in the following tables. The EUT maintained normal operation without loss of function or degradation of performance, meeting Acceptance Criteria A.

Surge on AC Input Port

Test Procedure			EN 60601-1-2: EN61000-4-5	
Pulse (Open circuit)	1.2/50 us		Pulse (Short circuit)	8/20 us
Test setup:				
tr	60	s		
Angle (Start):	0	°		
Angle (Stop):	270	°		
Angle (Step):	90	°		

Mode:	Synchronous
Polarity:	Alternating positive/negative
Line to Line: (L-N)	500 V, 1000V
Line(s) to Earth: (L-PE, N-PE)	500 V , 1000 V, 2000 V
Coupling	L-N , L-PE, N-PE

Test Results.

Coupling / Phase angle L-N	Test level 1 0.5 kV		Test level 2 1 kV		Test level 3 2 kV		Test level 4 4 kV	
	+	-	+	-	+	-	+	-
0	Pass	Pass	Pass	Pass				
90	Pass	Pass	Pass	Pass				
180	Pass	Pass	Pass	Pass				
270	Pass	Pass	Pass	Pass				

Test Results.

Coupling / Phase angle L-PE / N-PE	Test level 1 0.5 kV		Test level 2 1 kV		Test level 3 2 kV		Test level 4 4 kV	
	+	-	+	-	+	-	+	-
0	Pass	Pass	Pass	Pass	Pass	Pass		
90	Pass	Pass	Pass	Pass	Pass	Pass		
180	Pass	Pass	Pass	Pass	Pass	Pass		
270	Pass	Pass	Pass	Pass	Pass	Pass		

Surge Test



6.5 Conducted Disturbances Induced by RF Fields

Normative references

Generic Standard:	EN 60601-1-2
Basic Standard:	EN 61000-4-6

Test requirements

Frequency range	150 kHz - 80 MHz
Noise level	3 V
Modulation	AM Modulation depth: 80 % Modulation frequency: 1 kHz
Step width	1 % of freq.
Dwell time	1 sec
Performance criteria	A

Place of measurement

- ☐ Immunity Test Area 1
☒ Semi-Anechoic Chamber, EMC Test Systems, Serial No. SL 12168
☐ In situ, at customer factory site

Measurement device

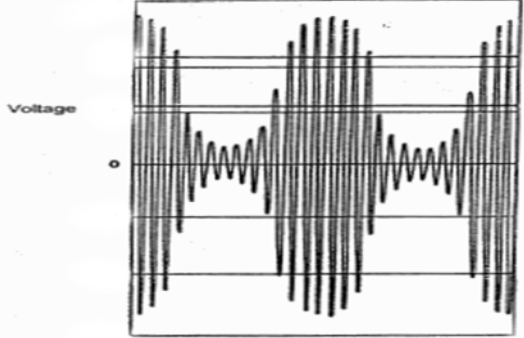
Measurement equipment	Type	Manufacturer	SN	Cal. due
Signal Generator	8648B	Hewlett Packard	3623A02244	2011.09.26
Low Freq-Power Amplifier	25A100	Amp Research	8643	2011.09.26
Bulk Current Injection Clamp	F-120-9A	Fisher Com Corp	80	2011.09.26

<u>Test results:</u>	<input checked="" type="checkbox"/> passed	<input type="checkbox"/> passed with modification	<input type="checkbox"/> not passed
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Comments:

The EUT exhibited adequate immunity to 3V Conducted RF Fields of the type and at the locations indicated in the following table. The EUT maintained normal operation without loss of function or degradation of performance, satisfying Acceptance Criteria A.

Conducted Immunity

Test Procedure		EN 60601-1-2: EN 61000-4-6
Test setup:		
Wave form of continuous conducted disturbance		
Mode:	1KHz 80% AM Modulation	
Frequency Range	0.15MHz to 80.0MHz	
Step :	1% of Previous Frequency	
Test Voltages:	3 Volts	

Test Results:

Coupling	Noise level 3 V, Modulation: AM / 1 kHz / 80% .15 MHz to 80 MHz
AC Input	Pass

pass: Performance criteria fulfilled
 fail: Performance criteria not fulfilled

Conducted Immunity Setup



6.6 Frequency Magnetic Field Immunity

Normative references

Generic Standard:	EN 60601-1-2
Basic Standard:	EN 61000-4-8

Test requirements

Frequency range	50 - 60 Hz
Field strength	3 A/m
Performance criteria	A

Place of measurement

- ☒ Immunity Test Area 1
☐ Semi-Anechoic Chamber, EMC Test Systems, Serial No. SL 12168
☐ In situ, at customer factory site

Measurement device

Measurement equipment	Type	Manufacturer	SN	Calibration due
Metered Variac	W20MT3A	Tucker	614111	2011.09.26
Magnetic Field Probe	480824	Extech	81371	2011.09.26
Induction Coil	N/A	INTERTest	N/A	N/A

Test results:

☒ passed

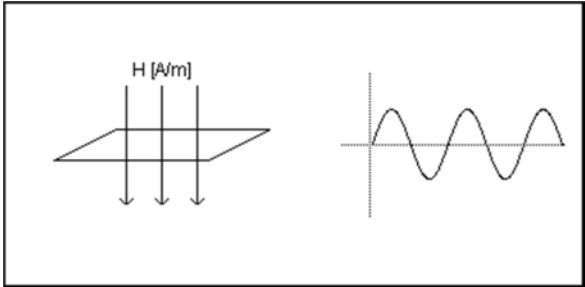
☐ passed with
modification

☐ not passed

Comments:

The EUT exhibited adequate immunity to 3 A/m magnetic fields of the type and at the locations indicated in the following table. The EUT maintained normal operation without loss of function or degradation of performance, satisfying Acceptance Criteria A.

Magnetic Field Immunity

Test Procedure			EN 60601-1-2: EN61000-4-8
Test setup:			
			
Field strenght	3	A	
Antenna factor	0.917	1/m	
XFM factor	0.0403	A/V	
Test frequency		50 Hz	
Antenna orientation		Vertical / Horizontal	
Exposure method		Emersion	
Test duration		10 min.	

Not Applicable – The EUT Was Not Tested

Magnetic Power Frequency (Hz)	Loop Position on EUT	Level 1 1 A/m	Level 2 3 A/m	Level 3 10 A/m	Level 4 30 A/m	Level 5 100 A/m
50	Vertical	Pass	Pass			
50	Horizontal	Pass	Pass			

pass: Performance criteria fulfilled
 fail: Performance criteria not fulfilled

Magnetic Field Immunity



6.7 Voltage Interruptions, Dips, Fluctuations

Normative references

Generic Standard:	EN 60601-1-2
Basic Standard:	EN 61000-4-11

Test requirements

Voltage dips	100% reduction	0.5 periods	Criteria B
Voltage dips	30% reduction	25 periods	Criteria C
Voltage dips	60% reduction	5 periods	Criteria B
Voltage Interruptions	100% reduction	250 Periods	Criteria C

Place of measurement

- ☐ In situ, at customer factory
☒ Immunity test area 1

Measurement equipment

Measurement equipment	Type/model	Manufacturer	SN	Calibration due
Programmable Power Supply	SW Series 5250AE	Elgar	0025A1049	2011.09.15
Power Analyzer	EST5250-4	Elgar	118	2011.09.15
Test Software	EST 1.7	Elgar	N/A	N/A

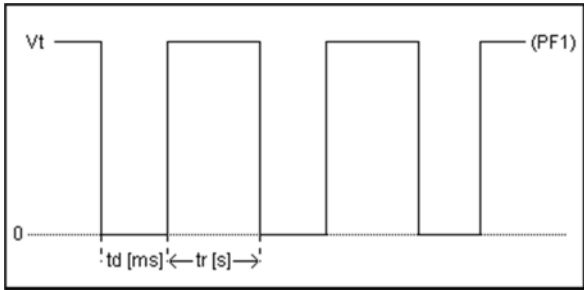
<u>Test results:</u>	<input checked="" type="checkbox"/> passed	<input type="checkbox"/> passed with modification	<input type="checkbox"/> not passed
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Comments:

The EUT exhibited adequate immunity to Voltage Fluctuations of the type indicated in the following tables. See below for detailed results.

100% Reduction for 0.5 Cycle

Test Procedure		EN 60601-1-2: EN61000-4-11	
Test setup: 100% reduction			
V:	0	V	
td:	0.5	Cycles	
tr:	10	s	
Angle:	0	°	



Mode:	Synchronous		
Test Type:	PF1		
Events:	3 each polarity	Time between Tests:	10 s

Test results:

☒ passed

☐ passed with
modification

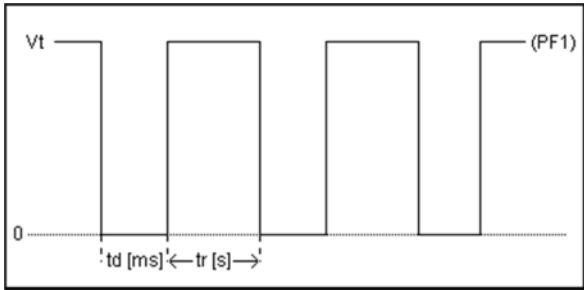
☐ not passed

Comments:

The EUT satisfied Voltage Interruption immunity testing. The EUT lost operation but restarted the wash cycle from the beginning upon the resuming of proper voltage, meeting criteria B.

100% Reduction for 250 Cycles

Test Procedure		EN 60601-1-2: EN61000-4-11	
Test setup: 60% reduction			
V:	0	V	
td:	250	Cycles	
tr:	10	s	
Angle:	0	°	



Mode:	Synchronous		
Test Type:	PF1		
Events:	3 each polarity	Time between Tests:	10 s

Test results:

☒ passed

☐ passed with
modification

☐ not passed

Comments:

The EUT satisfied Voltage Interruption immunity testing. The EUT lost operation but restarted the wash cycle from the beginning upon the resuming of proper voltage, meeting criteria B.

30% Reduction for 25 Cycles

Test Procedure		EN 60601-1-2: EN61000-4-11	
Test setup: 100% reduction			
V:	161	V	
td:	25	Cycles	
tr:	10	s	
Angle:	0	°	
Mode:		Synchronous	
Test Type:		PF1	
Events:	3 each polarity	Time between Tests:	10 s

Test results:

☒ passed

☐ passed with
modification

☐ not passed

Comments:

The EUT satisfied Voltage Interruption immunity testing. The EUT maintained normal operation, meeting Criteria A.

60% Reduction for 5 Cycles

Test Procedure		EN 60601-1-2: EN61000-4-11	
Test setup: 100% reduction			
V:	92	V	
td:	5	Cycles	
tr:	10	s	
Angle:	0	°	
Mode:		Synchronous	
Test Type:		PF1	
Events:	3 each polarity	Time between Tests:	10 s

Test results:

☒ passed

☐ passed with
modification

☐ not passed

Comments:

The EUT satisfied Voltage Interruption immunity testing. The EUT maintained normal operation with some audible slowing of the pumps, meeting Criteria A.

7 Measurement Protocol

Conducted and Radiated Emissions testing were performed in accordance to the procedures of ANSI C63.4-1992, CNS-13438, and CISPR 55016.

7.1 Conducted Emissions

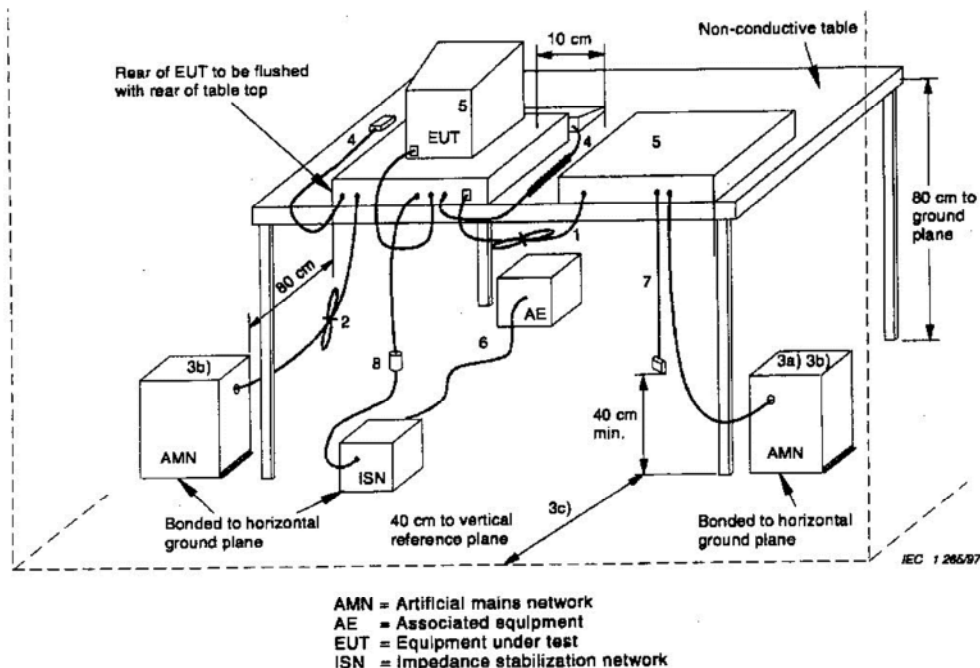
Conducted emissions on the 50 Hz and/or 60 Hz power interface of the EUT were measured in the frequency range of 150 kHz to 30 Mhz. The measurements are performed using an EMI receiver having a CISPR bandwidth and quasi-peak and average detectors, and a Line Stabilization Network (LISN) with 50 Ω / 50 μ H (CISPR 16) characteristics. Tabletop equipment is placed on a non-conductive table 80 centimeters above the floor (ground plane) and is positioned 40 centimeters from the vertical ground plane (wall) of the screen room.

7.2 Radiated Emissions

Radiated emissions from the EUT are measured in the frequency range of 30 Mhz to 1 Ghz using an EMI receiver with CISPR 16 characteristics. Measurements are made with a 120 kHz / 6db bandwidth and quasi peak detection. Measurements above 1 Ghz are made with a spectrum analyzer and appropriate broadband linearly polarized antennas. Measurements are taken with 1 Mhz / 6db bandwidth and average detection. Tabletop equipment is placed on a 1.0 X 1.5 meter non-conductive table 80 centimeters above the ground plane. Floor standing equipment is placed directly on the turntable/ground plane. Interface cables that are closer than 40 centimeters from the ground plane are bundled in the center in a serpentine fashion so they are at least 40 centimeters from the ground plane. Cables to simulators or support equipment (if used) are routed outside the test chamber. The receiving antenna is positioned 3 meters from the EUT at a measurement height of 1 meter. To locate the maximum emissions the EUT is rotated 360 degrees on the turntable and the antenna height varied from 1 meter to 2 meters. Measurements are made with the antenna polarized vertically and horizontally.

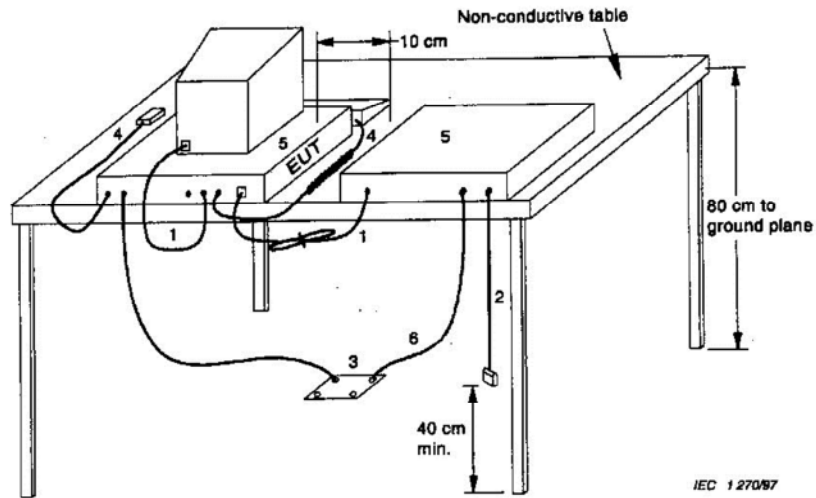
7.3 Statement of Measurement Uncertainty

The data and results referenced in this document are true and accurate. The measurement uncertainty for Conducted Emissions in the frequency range of 150 KHz to 30 Mhz is calculated to be ± 2.3 db, and for Radiated Emissions is calculated to be ± 4.38 db in the frequency range from 30 Mhz to 18000 Mhz.



- 1) If cables, which hang closer than 40 cm to the horizontal metal groundplane, cannot be shortened to appropriate length, the excess shall be folded back and forth forming a bundle 30 cm to 40 cm long.
- 2) Excess mains cord shall be bundled in the centre or shortened to appropriate length.
- 3) EUT is connected to one artificial mains network (AMN). All AMNs and ISNs may alternatively be connected to a vertical reference plane or metal wall (see figures 5 and 6).
 - a) All other units of a system are powered from a second AMN. A multiple outlet strip can be used for multiple mains cords.
 - b) AMN and ISN are 80 cm from the EUT and at least 80 cm from other units and other metal planes.
 - c) Mains cords and signal cables shall be positioned for their entire lengths, as far as possible, at 40 cm from the vertical reference plane.
- 4) Cables of hand operated devices, such as keyboards, mice, etc. shall be placed as for normal usage.
- 5) Peripherals shall be placed at a distance of 10 cm from each other and from the controller, except for the monitor which, if this is an acceptable installation practice, shall be placed directly on the top of the controller.
- 6) I/O signal cable intended for external connection.
- 7) The end of the I/O signal cables which are not connected to an AE may be terminated, if required, using correct terminating impedance.
- 8) If used, the current probe shall be placed at 0,1 m from the ISN.

Test configuration: tabletop equipment (conducted measurement)



- 1) If cables which hang closer than 40 cm to the horizontal metal ground plane cannot be shortened to appropriate length, the excess shall be folded back and forth forming a bundle 30 cm to 40 cm long.
- 2) The end of the I/O signal cables which are not connected to a peripheral may be terminated if required for proper operation using correct terminating impedance.
- 3) Mains junction box(s) shall be flush with, and bonded directly to, the metal ground plane.
 NOTE – If used, the AMN shall be installed under the horizontal metal ground plane.
- 4) Cables of hand operated devices, such as keyboards, mouses, etc. shall be placed as for normal usage.
- 5) Peripherals shall be placed at a distance of 10 cm from each other and from the controller, except for the monitor which, if for an acceptable installation practice, shall be placed directly on the top of the controller.
- 6) Mains cables shall drape to the floor and then be routed to receptacle. No extension cords shall be used to mains receptacle.

Test configuration: table-top equipment (radiated measurement)

8 User Information and Labeling

Once compliance with the standards has been determined (see page 3 of this report) the following information should be provided on the product label and in the User Manual.

8.1 User Information: United States (FCC)

In accordance with 47 CFR Part 15 section 105(a) the following, or similar, statement should appear in a prominent location of the User Manual.

Note: This equipment has been tested and found to comply with the limits for a Class () digital device, pursuant to part 15 of the FCC Rules. These Limits are designed to provide reasonable protection against harmful interference when the equipment is operated in its installation. This equipment generates, uses and can radiated radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. If this equipment does cause harmful interference the user will be required to correct the interference.*

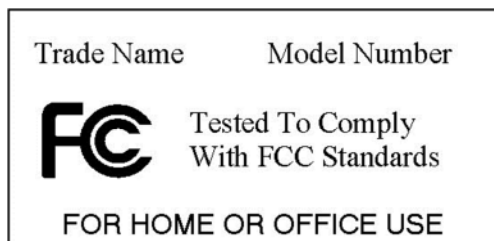
8.2 Labeling: United States (FCC)

In accordance with 47 CFR Part 15 section 19(3) the following should appear on the product label and be placed in a conspicuous location.

Class A Device:

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Class B Device:



8.3 User Information and Labeling: Canada

Canada has two official languages, English and French. A label indicating compliance to **Industry Canada Standard ICES-003** is required on the product in one or the other language, or both. The same wording is required in the User Manual. There is no specific wording for this notice; however, the following suggested text is provided, in English and in French, in the Annex of ICES-003:

This Class () digital apparatus complies with Canadian ICES-003*

Cet appareil numérique de la classe () est conforme à la norme NMB-003 du Canada*

*** Insert either "A" or "B", whichever is applicable.**

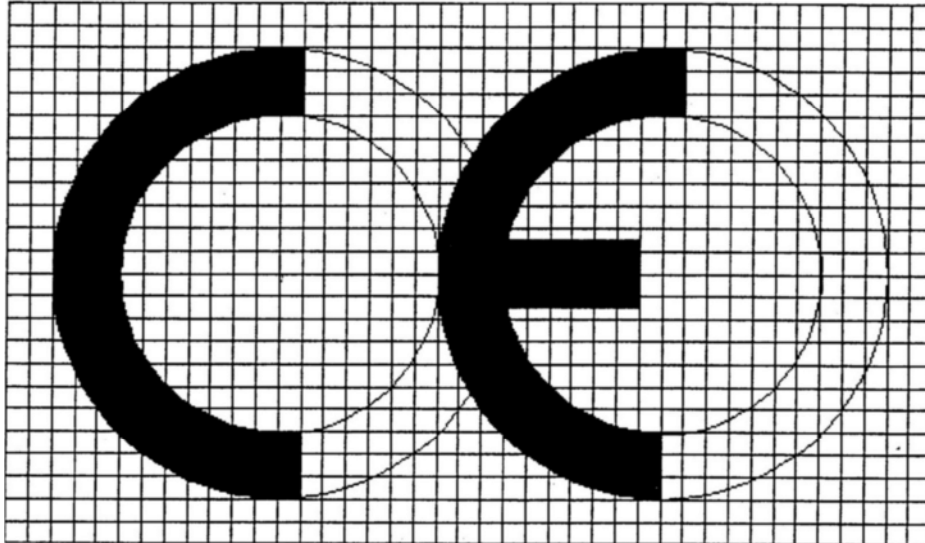
9 Declaring Conformity (CE)

Once compliance with the applicable European Directives and associated standards has been determined (see pages 3 and 4 of this report) and the CE Mark is affixed to the product the manufacturer must prepare a Declaration of Conformity. A copy of the declaration must accompany each shipment and a signed original must be available upon request. An official form for the declaration does not exist but should normally contain the following:

- The manufacturers legal name and address including any alternate manufacturing locations.
- The manufacturers trade name or trademark.
- The complete model designation.
- A description of the product (intended use or function).
- A clear explanation of the European Directives and technical standards to which compliance is being declared. Refer to the Product Safety and EMC Reports for the specific Directives and Standards applicable to this specific product. **(NOTE: the Directives and Standards shown below may not apply to this specific product)**
- The name, title and signature of a person empowered to enter into commitments on behalf of the manufacturer.
- The name and address of the European Community "authorized representative" (if applicable).

(Sample) DECLARATION OF CONFORMITY	
Manufacturer's Name:	
Manufacturer's Address:	
EC Representative's Name:	
EC Representative's Address:	
Equipment Description:	
Equipment Model Designation:	
Application of Council Directive: 73/23/EEC on the harmonization of the laws related to Member States relating to electrical equipment designed for use within certain voltage limits, as amended by: Council Directive 93/68/EEC and	
Council Directive 2004/108/EEC on the approximation of the laws related to Member States relating to electromagnetic compatibility.	
Referenced Safety Standards:	Referenced EMC Standards:
EN 60335-2-82	EN61000-6-3, Class A
	EN61000-6-1
	EN 61000-3-2
	EN 61000-3-3
	EN 61000-4-2
	EN 61000-4-3
	EN 61000-4-4
	EN 61000-4-5
	EN 61000-4-6
	EN 61000-4-11
I, the undersigned, hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s).	
Signature: _____	
Printed Name: _____	
Title: _____	

CE Marking



The CE marking depicted above shall be used by the manufacturer, or the manufacturer's representative in the European Community to designate conformance to the essential requirements of the applicable directives.

The marking shall be applied, wherever possible, to the equipment. If this is not practicable, the marking may be applied to the packaging or other documentation such as the instructions or guarantee certificate. The marking shall be legible, easily visible and indelible.

The marking shall be reduced, or enlarged proportionally. Its form shall be as represented above, and the letter height shall not be less than 5 mm.

Manufacturer's Responsibilities

1. A Declaration of Conformity attesting to the products conformance to the appropriate European Community Directive (s) shall accompany each product, or the accompanying product documentation displaying the required CE marking.
2. The manufacturer shall insure the product is manufactured as represented by the technical documentation in the technical file. Changes to the equipment shall be evaluated as to their effect on compliance to the applicable Directive(s) and Standard(s).
3. The technical file shall remain available and at the disposal of the relevant national authorities for inspection purposes for at least ten years after the product has been manufactured. It shall be maintained by the manufacturer, the manufacturer's authorized representative in the Community, or, in lieu of either of these, by the person who places the product on the Community market.
4. The manufacturer shall insure that the instructions and other documentation are written in the official language of the country in which the equipment is sold.