EMC - TEST REPORT

Report Number	:	**68.730.14.045.01**	Date of Issue:	03 December 2014

Model	:	SoftAIR
Product Type	:	Alternating Control Unit
Applicant	:	SHL Healthcare Ltd.
Address	:	Room 810, Argyle Centre, 688 Nathan Road, Kowloon, Hongkong
Production Facility1	:	Med & Care (Shenzhen) Co., Ltd.
Address	:	Bld.8, A-6 Tongfuyu Industrial Park, Bu-Chong, Shajing Town, Baoan District, Shenzhen, PEOPLE'S REPUBLIC OF CHINA

Test Result	:	■ **Positive** ☐ **Negative**
Total pages including Appendices	:	48

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TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
Building 12&13, Zhiheng Wisdomland Business Park, Nantou Checkpoint Road 2, Nanshan District, 518052 Shenzhen, CHINA

2 Details about the Test Laboratory

Details about the Test Laboratory

Company name: TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
Building 12&13, Zhiheng Wisdomland Business Park,
Nantou Checkpoint Road 2, Nanshan District,
518052 Shenzhen, CHINA

Telephone: 86 755 8828 6998
Fax: 86 755 8828 5299

3 Description of the Equipment Under Test

Description of the Equipment Under Test

Product:	Alternating Control Unit
Model no.:	SoftAIR
Serial number:	NIL
Options and accessories:	NIL
Ratings:	220-240VAC, 50/60Hz, 0.3A
Description of the EUT:	Medical device
Remark:	NIL

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4 Summary of Test Standards

Test Standards	
IEC 60601-1-2:2014	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

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5 Summary of Test Results

Emission Tests				
IEC 60601-1-2:2014				
Test Condition Group1, Class B	Pages	Test Result		
		Pass	Fail	N/A
Radiated Emission (3m semi-anechoic chamber) 30MHz to 1000MHz	9	☒	☐	☐
Conducted Emission on AC 150kHz to 30MHz	12	☒	☐	☐
Harmonic Class A	15	☒	☐	☐
Flicker	18	☒	☐	☐

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Summary of Test Results

Immunity Tests		
IEC 60601-1-2:2014		
Test Condition Group1, Class B	Pages	Test Result Complies Level
Electrostatic Discharge (IEC 61000-4-2) ±2kV ±4kV ±6kV ±8kV ±15kV	21	Contact: ±8kV Air: ±15kV
Radiated Immunity (IEC 61000-4-3) 80MHz to 2700MHz 10V/m (rms) 380MHz to 390MHz 27V/m (rms) 430MHz to 470MHz 28V/m (rms) 704MHz to 787MHz 9V/m (rms) 800MHz to 960MHz 28V/m (rms) 1700MHz to1990MHz 28V/m (rms) 2400MHz to 2570MHz 28V/m (rms) 5100MHz to 5800MHz 9V/m (rms)	24	 10V/m, 80% Am at 1kHz PM at 18Hz FM ± 5 kHz deviation at 1kHz sine PM at 217 Hz PM at 18Hz PM at 217 Hz PM at 217 Hz PM at 217 Hz
Electrical Fast Transient (IEC 61000-4-4) ±1kV ±2kV, 100 kHz repetition frequency	26	Power supply lines: ±2kV
Surge (IEC 61000-4-5) ±0.5kV ±1kV ±2kV	28	Line to line: ±1kV
Conducted Immunity (IEC 61000-4-6) 150KHz to 80MHz 3Vrms ISM and amateur radio bands between 150KHz to 80MHz 6Vrms	30	3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz
Voltage Dips and Interruption (IEC 61000-4-11) 0%, 70%, 0% of U_T	32	0% for 0.5 cycle 0% for 1 cycle 70% for 25 cycles 0% for 250 cycles
Power Frequency Magnetic Field (IEC 61000-4-8) 50Hz, 60Hz 30A/m	34	50Hz: 30A/m 60Hz: 30A/m

System Measurement Uncertainty	
Test Items	Extended Uncertainty
Uncertainty for Radiated Emission in 3m chamber 30MHz-1000MHz	Horizontal: 4.83dB; Vertical: 4.91dB;
Uncertainty for Conducted Emission 150kHz-30MHz (for test using AMN ENV216 or ENV4200)	3.50dB
Uncertainty for Harmonic test	3.26%
Uncertainty for Flicker test	4.76%
Uncertainty for RS test	19%, K=2
Uncertainty for CS test	29%, K=2
Uncertainty for ESD test	The immunity measurement system uncertainty is within standard requirement and is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95%.
Uncertainty for EFT test	
Uncertainty for Surges test	
Uncertainty for Voltage Dips, Voltage Variations and Short Interruptions Test	
Uncertainty for PFMF test	

6 General Remarks

Remarks

NIL

SUMMARY:

All tests according to the regulations cited on page 5 were

■ - Performed

☐ - **Not** Performed

The Equipment Under Test

■ - **Fulfills** the general approval requirements.

☐ - **Does not** fulfill the general approval requirements.

Sample Received Date: 21 November 2014

Testing Start Date: 26 November 2014

Testing End Date: 28 November 2014

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Reviewed by: Phoebe Hu
EMC Project Manager

Prepared by: Trevor You
EMC Project Engineer

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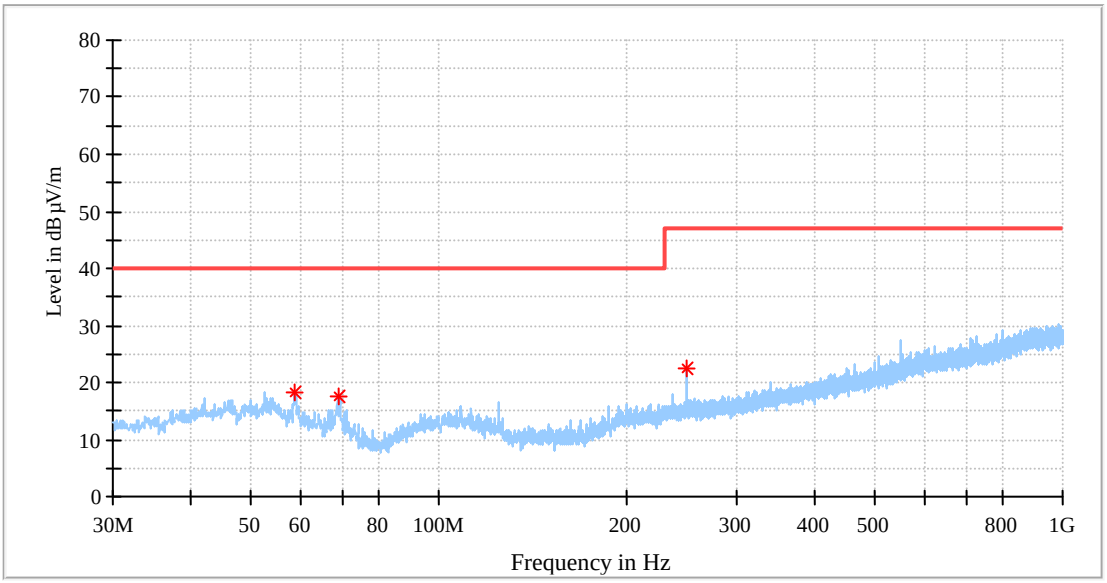
7 Emission Test Results

7.1 Radiated Emission Test 30MHz – 1000MHz

Date of test	:	26 November 2014
Test requirement	:	IEC 60601-1-2
Test method	:	CISPR 11
Operating mode	:	Continuous operating mode
Tested on	:	Horizontal
Model No	:	SoftAIR
Comment	:	230V/50Hz

Test Result
■ Passed
☐ Not Passed

Temperature (°C): 22.4 Relative Humidity (%): 66.7 Atmospheric Pressure(mbar) : 1015



Critical_Freqs

Frequency (MHz)	MaxPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB)
58.736250	18.35	40.00	21.65	---	---	100.0	H	235.0	14.1
68.921250	17.44	40.00	22.56	---	---	100.0	H	80.0	11.7
249.947500	22.50	47.00	24.50	---	---	200.0	H	38.0	14.6

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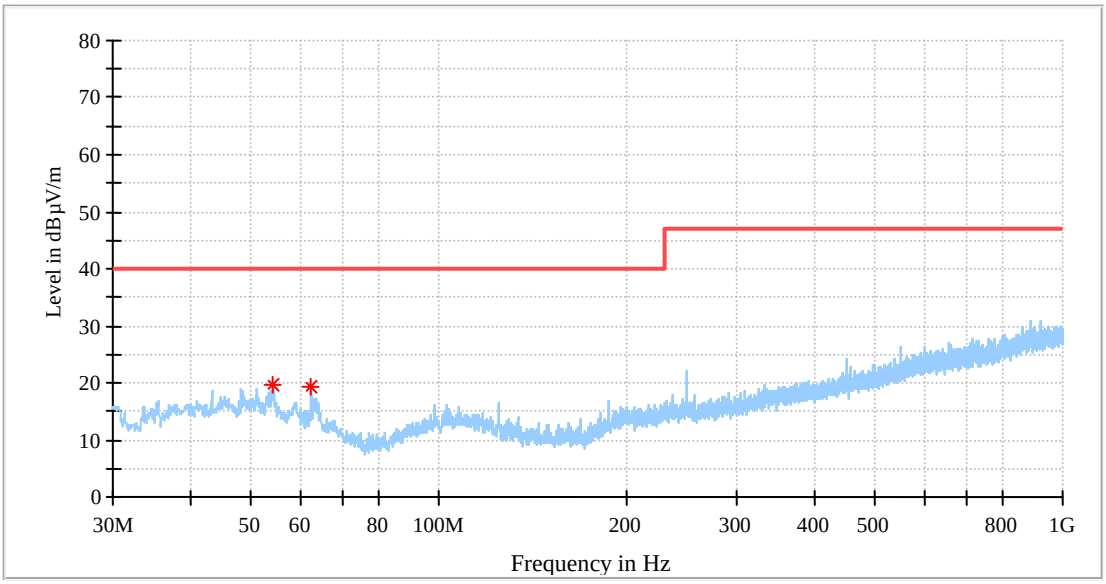
Radiated Emission Test 30MHz- 1000MHz

Date of test	:	26 November 2014
Test requirement	:	IEC 60601-1-2
Test method	:	CISPR 11
Operating mode	:	Continuous operating mode
Tested on	:	Vertical
Model No	:	SoftAIR
Comment	:	230V/50Hz

Test Result
■ Passed
□ Not Passed

Temperature (°C): 22.4 Relative Humidity (%): 66.7 Atmospheric Pressure(mbar) : 101.5



Critical_Freqs

Frequency (MHz)	MaxPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB)
54.310625	19.66	40.00	20.34	---	---	100.0	V	0.0	14.9
62.434375	19.13	40.00	20.87	---	---	100.0	V	0.0	13.5

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Test Equipment List

Radiated Emission Test

DESCRIPTION	MANUFACTURER	MODEL NO.	SERIAL NO.	CAL. DUE DATE
EMI Test Receiver	Rohde & Schwarz	ESR 26	101269	2015-8-17
Trilog Super Broadband Test Antenna	Schwarzbeck	VULB 9163	707	2017-8-17
Horn Antenna	Rohde & Schwarz	HF907	102294	2017-8-17
Pre-amplifier	Rohde & Schwarz	SCU 18	102230	2015-8-17
3m Semi-anechoic chamber	TDK	9X6X6	----	2019-5-29

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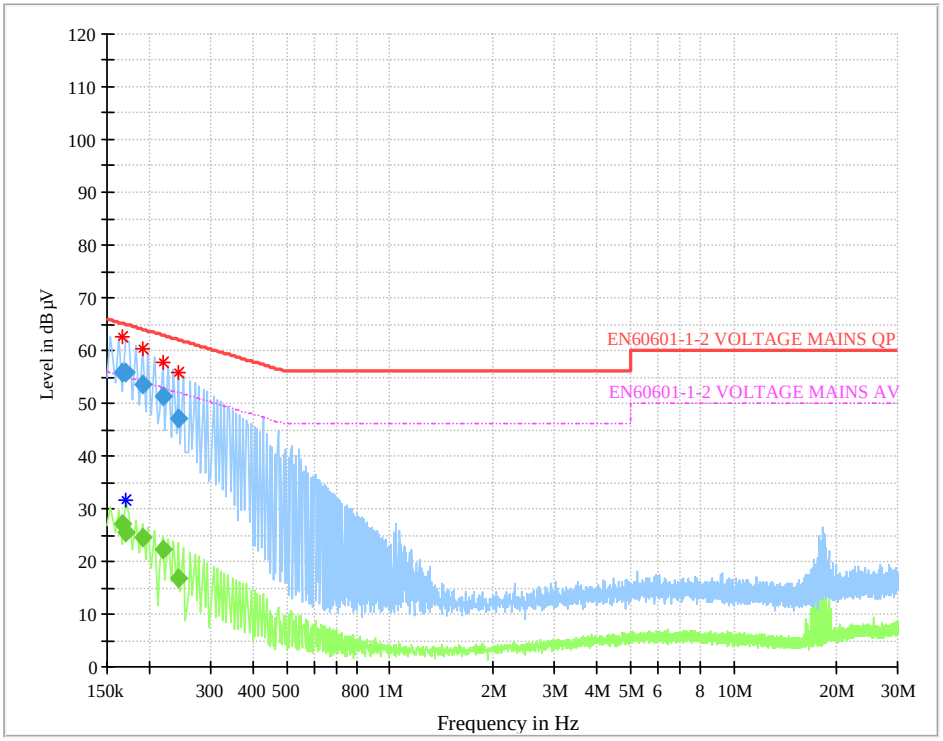
7.2 Conducted Emission Test 150kHz – 30MHz

Date of test	:	26 November 2014
Test requirement	:	IEC 60601-1-2
Test method	:	CISPR 11
Operating mode	:	Continuous operating mode
Tested on	:	Power Line, Live
Model No	:	SoftAIR
Comment	:	230V/50Hz

Test Result
■ Passed
□ Not Passed

Temperature (°C): 24.8 Relative Humidity (%): 65.4 Atmospheric Pressure(mbar) : 1013



Final_Result

Frequency (MHz)	QuasiPeak (dBµV)	Average (dBµV)	Limit (dBµV)	Margin (dB)	Line	Corr. (dB)
0.165500	---	27.13	55.18	28.05	L1	9.6
0.165500	55.68	---	65.18	9.50	L1	9.6
0.169500	---	25.45	54.98	29.53	L1	9.6
0.169500	55.76	---	64.98	9.22	L1	9.6
0.189500	---	24.42	54.06	29.64	L1	9.7
0.189500	53.46	---	64.06	10.60	L1	9.7
0.217500	---	22.14	52.91	30.77	L1	9.8
0.217500	51.35	---	62.91	11.56	L1	9.8
0.241500	---	16.68	52.04	35.36	L1	9.9
0.241500	47.13	---	62.04	14.91	L1	9.9

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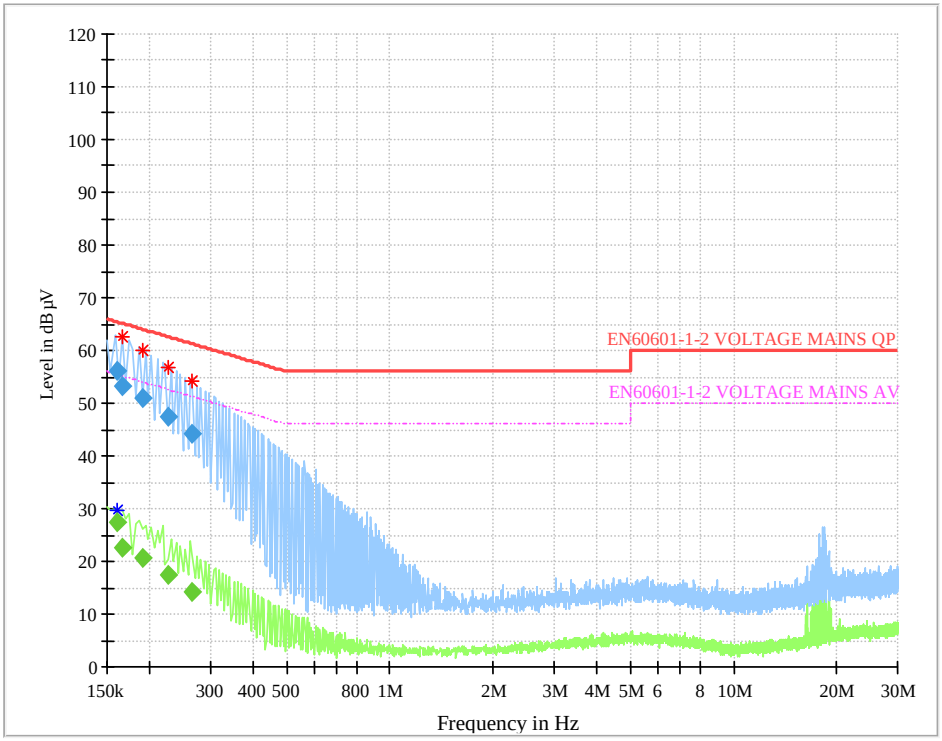
Conducted Emission Test 150kHz – 30MHz

Date of test	:	26 November 2014
Test requirement	:	IEC 60601-1-2
Test method	:	CISPR 11
Operating mode	:	Continuous operating mode
Tested on	:	Power Line, Neutral
Model No	:	SoftAIR
Comment	:	230V/50Hz

Test Result
■ Passed
□ Not Passed

Temperature (°C): 24.8 Relative Humidity (%): 65.4 Atmospheric Pressure(mbar) : 1013



Final_Result

Frequency (MHz)	QuasiPeak (dBµV)	Average (dBµV)	Limit (dBµV)	Margin (dB)	Line	Corr. (dB)
0.161500	56.11	---	65.39	9.28	N	9.7
0.161500	---	27.49	55.39	27.90	N	9.7
0.165500	53.30	---	65.18	11.88	N	9.7
0.165500	---	22.69	55.18	32.49	N	9.7
0.189500	---	20.52	54.06	33.54	N	9.7
0.189500	50.81	---	64.06	13.25	N	9.7
0.225500	---	17.30	52.61	35.31	N	9.9
0.225500	47.52	---	62.61	15.09	N	9.9
0.265500	---	14.15	51.26	37.11	N	10.0
0.265500	44.28	---	61.26	16.98	N	10.0

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Test Equipment List

Conducted Emission Test

DESCRIPTION	MANUFACTURER	MODEL NO.	SERIAL NO.	CAL. DUE DATE
EMI Test Receiver	Rohde & Schwarz	ESR 3	101782	2015-8-17
LISN	Rohde & Schwarz	ENV4200	100249	2015-8-17
LISN	Rohde & Schwarz	ENV216	100326	2015-8-17
ISN	Rohde & Schwarz	ENY81	100177	2015-8-17
ISN	Rohde & Schwarz	ENY81-CA6	101664	2015-8-17
High Voltage Proble	Rohde & Schwarz	TK9420(VT9420)	9420-58	2015-8-17
RF Current probe	Rohde & Schwarz	EZ-17	100816	2015-8-17

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7.3 Harmonic Test

Temperature (°C): 24.7 Relative Humidity (%): 62.4 Atmospheric Pressure(mbar) : 1015

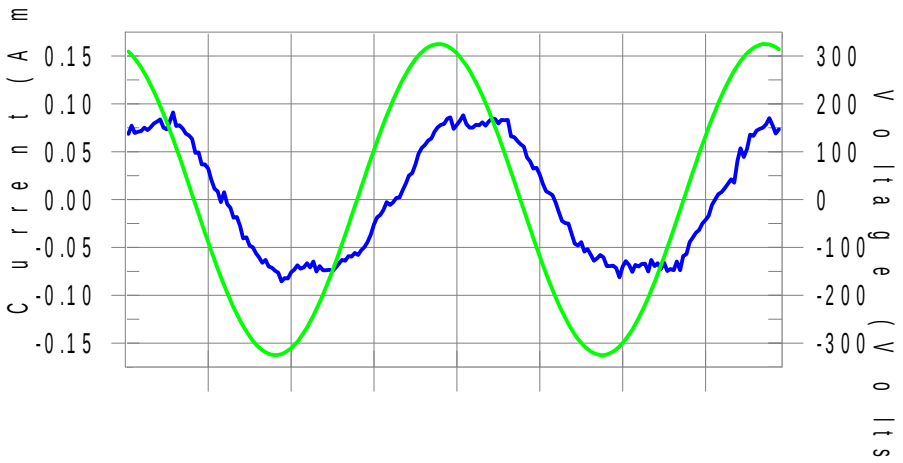
EUT: SoftAIR **Tested by: LEON**
Test category: Class-A per Ed. 3.2 (2009) (European limits) **Test Margin(%): 100**
Test date: 2014/11/27 **Start time: 12:24:14** **End time: 12:27:07**
Test duration (min): 2.5 **Data file name: CTSMXL_H-000589.cts_data**
Comment: continuous operator mode
Customer: Customer

Test Result: Pass **Source qualification: Normal**
THC(A): 0.000 **I-THD(%): 0.000** **POHC(A): 0.000** **POHC Limit(A): 0.320**
Highest parameter values during test:

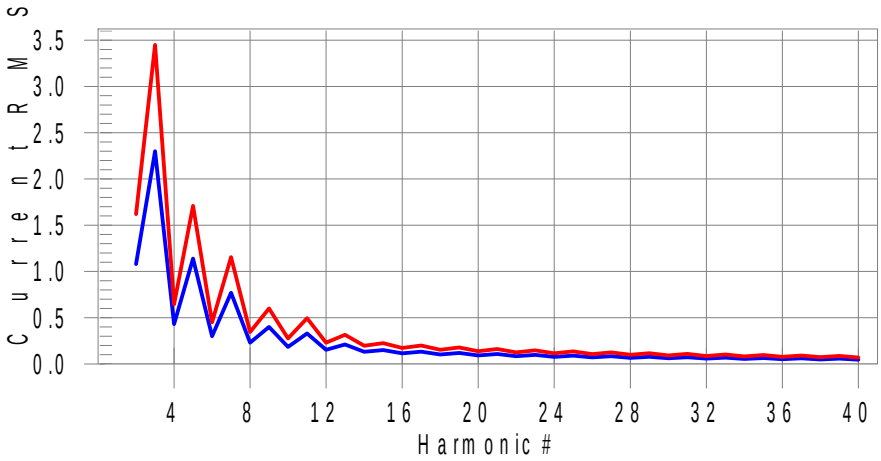
V_RMS (Volts):	**229.95**	**Frequency(Hz):**	**50.00**
I_Peak (Amps):	**0.109**	**I_RMS (Amps):**	**0.061**
I_Fund (Amps):	**0.060**	**Crest Factor:**	**1.890**
Power (Watts):	**11.3**	**Power Factor:**	**0.825**

Maximum Harmonic Current Results

Current(blue) & voltage(green) waveforms



Harmonics and Class A limit line **European Limits – 100%(blue) & 150%(red)**



Test result: Pass Worst harmonic was #3 with 0.18% of the limit.

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Maximum Harmonic Current Results

Harm#	Harms(avg)	100%Limit	%of Limit	Harms(max)	150%Limit	%of Limit	Status
2	0.002	1.080	0.0	0.002	1.620	0.11	Pass
3	0.005	2.300	0.2	0.006	3.450	0.18	Pass
4	0.001	0.430	0.0	0.001	0.645	0.13	Pass
5	0.003	1.140	0.0	0.003	1.710	0.16	Pass
6	0.000	0.300	0.0	0.000	0.450	0.07	Pass
7	0.000	0.770	0.0	0.001	1.155	0.07	Pass
8	0.000	0.230	0.0	0.000	0.345	0.14	Pass
9	0.000	0.400	0.0	0.001	0.600	0.12	Pass
10	0.000	0.184	0.0	0.000	0.276	0.09	Pass
11	0.000	0.330	0.0	0.001	0.495	0.12	Pass
12	0.000	0.153	0.0	0.000	0.230	0.10	Pass
13	0.000	0.210	0.0	0.000	0.315	0.11	Pass
14	0.000	0.131	0.0	0.000	0.197	0.10	Pass
15	0.000	0.150	0.0	0.000	0.225	0.17	Pass
16	0.000	0.115	0.0	0.000	0.173	0.07	Pass
17	0.000	0.132	0.0	0.000	0.199	0.12	Pass
18	0.000	0.102	0.0	0.000	0.153	0.13	Pass
19	0.000	0.118	0.0	0.000	0.178	0.13	Pass
20	0.000	0.092	0.0	0.000	0.138	0.18	Pass
21	0.000	0.107	0.0	0.000	0.161	0.17	Pass
22	0.000	0.084	0.0	0.000	0.125	0.21	Pass
23	0.000	0.098	0.0	0.000	0.147	0.17	Pass
24	0.000	0.077	0.0	0.000	0.115	0.16	Pass
25	0.000	0.090	0.0	0.000	0.135	0.17	Pass
26	0.000	0.071	0.0	0.000	0.106	0.20	Pass
27	0.000	0.083	0.0	0.000	0.125	0.15	Pass
28	0.000	0.066	0.0	0.000	0.099	0.22	Pass
29	0.000	0.078	0.0	0.000	0.116	0.18	Pass
30	0.000	0.061	0.0	0.000	0.092	0.18	Pass
31	0.000	0.073	0.0	0.000	0.109	0.16	Pass
32	0.000	0.058	0.0	0.000	0.086	0.22	Pass
33	0.000	0.068	0.0	0.000	0.102	0.19	Pass
34	0.000	0.054	0.0	0.000	0.081	0.20	Pass
35	0.000	0.064	0.0	0.000	0.096	0.19	Pass
36	0.000	0.051	0.0	0.000	0.077	0.23	Pass
37	0.000	0.061	0.0	0.000	0.091	0.23	Pass
38	0.000	0.048	0.0	0.000	0.073	0.24	Pass
39	0.000	0.058	0.0	0.000	0.087	0.18	Pass
40	0.000	0.046	0.0	0.000	0.069	0.22	Pass

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Test Equipment List

Harmonic Test

DESCRIPTION	MANUFACTURER	MODEL NO.	SERIAL NO.	CAL. DUE DATE
Three Phase Harmonic flicker test system	CI	MX45-3PI-400-413-CTSHL-LF-SNK	1424A00547	2015-8-17

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7.4 Flicker Test

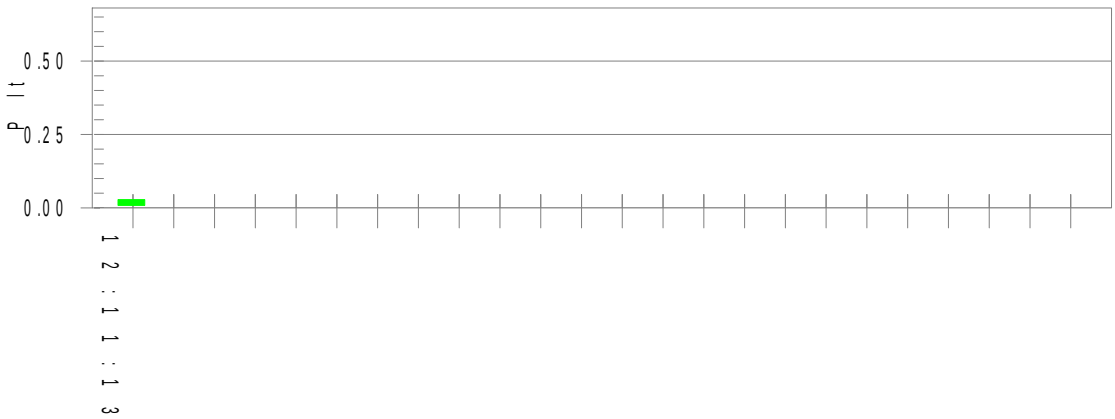
Temperature (°C): 24.7 Relative Humidity (%): 62.4 Atmospheric Pressure(mbar) : 1015

EUT: SoftAIR **Tested by: LEON**
Test category: All parameters (European limits) **Test Margin: 100**
Test date: 2014/11/27 **Start time: 12:00:53** **End time: 12:11:14**
Test duration (min): 10 **Data file name: CTSMXL_F-000587.cts_data**
Comment: continuous operating mode
Customer:

Test Result: Pass **Status: Test Completed**

Pst_i and limit line **European Limits**

Plt and limit line



Parameter values recorded during the test:

Vrms at the end of test (Volt): 229.97

Time(mS) > T(max):	**0.0**	**Test limit (mS):**	**500.0**	**Pass**
Highest dc (%):	**0.00**	**Test limit (%):**	**3.30**	**Pass**
Highest dmax (%):	**0.00**	**Test limit (%):**	**4.00**	**Pass**
Highest Pst (10 min. period):	**0.064**	**Test limit:**	**1.000**	**Pass**
Highest Plt (2 hr. period):	**0.028**	**Test limit:**	**0.650**	**Pass**

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Test Equipment List

Flicker Test

DESCRIPTION	MANUFACTURER	MODEL NO.	SERIAL NO.	CAL. DUE DATE
Three Phase Harmonic flicker test system	CI	MX45-3PI-400-413-CTSHL-LF-SNK	1424A00547	2015-8-17

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8 Performance Criteria

Compliance criteria	The functions to be tested and the specific, detailed IMMUNITY pass/fail criteria should be derived from one or more sources. This includes identification of:
	-- the HAZARDS;
	-- the functions to be tested for IMMUNITY to verify freedom from unacceptable RISK;
	-- the criteria on which to base the pass/fail decision;
	-- operating modes;
	-- characteristics of simulated PATIENT physiological signals;
	-- specification of locations of INTENDED USE;
	-- the characteristics of the test, where these are at the discretion of the MANUFACTURER.
	Part 2 standards in the IEC 60601 family can specify particular ESSENTIAL PERFORMANCE and IMMUNITY pass/fail criteria. IMMUNITY pass/fail criteria can specify degradations that are acceptable because they do not result in unacceptable RISK.

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9 Immunity Test Results

9.1 Electrostatic Discharge Test

Applicant : SHL Healthcare Ltd.
Project no. : 68.730.14.045.01
Model : SoftAIR
Description : Alternating Control Unit Serial No. : NIL
Operating Mode : Continuous operating mode ☒Table Top ☐Floor Stand

Ambient Temperature (°C) : 27.2 Relative Humidity (%): 54.2 Atmospheric Pressure(mbar) : 1011

Test regulation :
☒IEC 60601-1-2 ☐EN 50082-2 ☐EN 55014-2
☐EN 55024 ☐IEC 1000-4-2 ☐IEC 801-2
☐EN 61547 ☒IEC 61000-4-2

Indirect discharge : ☐Draw points in the appendix

Point	Contact kV			Number and Polarity at each voltage level	
1: VCP-Front Side	☒..2	☐..3	☒..4	☐..25 pos	☐..25 neg
	☒..6	☐..8	☐..	☒..10 pos	☒..10 neg
2: VCP-Right Side	☒..2	☐..3	☒..4	☐..25 pos	☐..25 neg
	☒..6	☐..8	☐..	☒..10 pos	☒..10 neg
3: VCP-Rear Side	☒..2	☐..3	☒..4	☐..25 pos	☐..25 neg
	☒..6	☐..8	☐..	☒..10 pos	☒..10 neg
4: VCP-Left Side	☒..2	☐..3	☒..4	☐..25 pos	☐..25 neg
	☒..6	☐..8	☐..	☒..10 pos	☒..10 neg
5: HCP-Front Side	☒..2	☐..3	☒..4	☐..25 pos	☐..25 neg
	☒..6	☐..8	☐..	☒..10 pos	☒..10 neg
6: HCP-Right Side	☒..2	☐..3	☒..4	☐..25 pos	☐..25 neg
	☒..6	☐..8	☐..	☒..10 pos	☒..10 neg
7: HCP-Rear Side	☒..2	☐..3	☒..4	☐..25 pos	☐..25 neg
	☒..6	☐..8	☐..	☒..10 pos	☒..10 neg
8: HCP-Left Side	☒..2	☐..3	☒..4	☐..25 pos	☐..25 neg
	☒..6	☐..8	☐..	☒..10 pos	☒..10 neg
9:_____	☐..2	☐..3	☐..4	☐..25 pos	☐..25 neg
	☐..6	☐..8	☐..	☐..10 pos	☐..10 neg

Remarks: VCP = Vertical Coupling Plane; HCP = Horizontal Coupling Plane.
No degradation of performance was found during test.

Result: ☒Complies ☐Does not comply ☐Photo done

Criterion Required : **Annex I.2.3**

Date : 28 November 2014 Test Engineer : Trevor You

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
Building 12&13, Zhiheng Wisdomland Business Park, Nantou Checkpoint Road 2, Nanshan District, 518052 Shenzhen, CHINA

Electrostatic Discharge Test

Applicant : SHL Healthcare Ltd.
Project no. : 68.730.14.045.01
Model : SoftAIR
Description : Alternating Control Unit Serial No. : NIL
Operating Mode : Continuous operating mode ☒Table Top ☐Floor Stand

Ambient Temperature (°C) : 27.2 Relative Humidity (%) : 54.2 Atmospheric Pressure(mbar) : 1011

Test regulation :
☒IEC 60601-1-2 ☐EN 50082-2 ☐EN 55014-2
☐EN 55024 ☐IEC 1000-4-2 ☐IEC 801-2
☐EN 61547 ☒IEC 61000-4-2

Indirect discharge : ☐Draw points in the appendix

Point	Contact kV			Air kV		Number and Polarity at each voltage level	
1. Each conductive Location touchable by hand	☒..2	☐..3	☒..4	☒..2	☒..4	☐..25 pos	☐..25 neg
	☒..6	☐..8	☐..	☒..8	☐..	☒..10 pos	☒..10 neg
2. Each nonconductive Location touchable by hand	☐..2	☐..3	☐..4	☒..2	☒..4	☐..25 pos	☐..25 neg
	☐..6	☐..8	☐..	☒..8	☐..	☒..10 pos	☒..10 neg
3.	☐..2	☐..3	☐..4	☐..2	☐..4	☐..25 pos	☐..25 neg
	☐..6	☐..8	☐..	☐..8	☐..	☐..10 pos	☐..10 neg
4.	☐..2	☐..3	☐..4	☐..2	☐..4	☐..25 pos	☐..25 neg
	☐..6	☐..8	☐..	☐..8	☐..	☐..10 pos	☐..10 neg
5.	☐..2	☐..3	☐..4	☐..2	☐..4	☐..25 pos	☐..25 neg
	☐..6	☐..8	☐..	☐..8	☐..	☐..10 pos	☐..10 neg
6.	☐..2	☐..3	☐..4	☐..2	☐..4	☐..25 pos	☐..25 neg
	☐..6	☐..8	☐..	☐..8	☐..	☐..10 pos	☐..10 neg
7.	☐..2	☐..3	☐..4	☐..2	☐..4	☐..25 pos	☐..25 neg
	☐..6	☐..8	☐..	☐..8	☐..	☐..10 pos	☐..10 neg
8.	☐..2	☐..3	☐..4	☐..2	☐..4	☐..25 pos	☐..25 neg
	☐..6	☐..8	☐..	☐..8	☐..	☐..10 pos	☐..10 neg
9.	☐..2	☐..3	☐..4	☐..2	☐..4	☐..25 pos	☐..25 neg
	☐..6	☐..8	☐..	☐..8	☐..	☐..10 pos	☐..10 neg

Remarks: No degradation of performance was found during test.

Result: ☒Complies ☐Does not comply ☐Photo done

Criterion Required : **Annex I.2.3**

Date : 28 November 2014 Test Engineer : Trevor You

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
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Test Equipment List

Electrostatic Discharge Test

DESCRIPTION	MANUFACTURER	MODEL NO.	SERIAL NO.	CAL. DUE DATE
Electrostatic Discharge Simulator	Noiseken	ESS-2002	ESS0615075	2015-8-17

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9.2 Radiated Immunity Test

Applicant : SHL Healthcare Ltd.
Project no. : 68.730.14.045.01
Model : SoftAIR
Description : Alternating Control Unit
Operating Mode : Continuous operating mode ☒Table Top ☐Floor Stand

Ambient Temperature (°C) : 23.6 Relative Humidity (%): 67.9 Atmospheric Pressure(mbar) : 1017

Test regulation :
☒IEC 60601-1-2 ☐EN 50082-2 ☐EN 55014-2
☐EN 55024 ☐IEC 1000-4-2 ☐IEC 801-2
☐EN 61547 ☒IEC 61000-4-3 ☐EN 61000-6-1

Frequency range MHz	Field Strength V/m		Antenna Polarization	EUT Direction	
	☐..1	☐..3	☒..Horizontal	☒..Front	☒..Right
1. 80-2700	☒..10	☐..	☐..Vertical	☒..Back	☒..Left
	☐..1	☐..3	☐..Horizontal	☒..Front	☒..Right
2. 80-2700	☒..10	☐..	☒..Vertical	☒..Back	☒..Left
	☐..1	☐..3	☒..Horizontal	☒..Front	☒..Right
3. 380-390	☐..10	☒..27	☒..Vertical	☒..Back	☒..Left
	☐..1	☐..3	☒..Horizontal	☒..Front	☒..Right
4. 430-470	☐..10	☒..28	☒..Vertical	☒..Back	☒..Left
	☐..1	☐..3	☒..Horizontal	☒..Front	☒..Right
5. 704-787	☐..10	☒..9	☒..Vertical	☒..Back	☒..Left
	☐..1	☐..3	☒..Horizontal	☒..Front	☒..Right
6. 800-960	☐..10	☒..28	☒..Vertical	☒..Back	☒..Left
	☐..1	☐..3	☒..Horizontal	☒..Front	☒..Right
7. 1700-1990	☐..10	☒..28	☒..Vertical	☒..Back	☒..Left
	☐..1	☐..3	☒..Horizontal	☒..Front	☒..Right
8. 2400-2570	☐..10	☒..28	☒..Vertical	☒..Back	☒..Left
	☐..1	☐..3	☒..Horizontal	☒..Front	☒..Right
9. 5100-5800	☐..10	☒..9	☒..Vertical	☒..Back	☒..Left
	☐..1	☐..3	☐..Horizontal	☐..Front	☐..Right
10.	☐..10	☐..	☐..Vertical	☐..Back	☐..Left

Remarks: No degradation of performance was found during test.

Result: ☒Complies ☐Does not comply ☐Photo done

Criterion Required : **Annex I.2.3**

Date : 28 November 2014 Test Engineer : Trevor You

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
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Test Equipment List

Radiated Immunity Test

DESCRIPTION	MANUFACTURER	MODEL NO.	SERIAL NO.	CAL. DUE DATE
Signal Generator	Rohde & Schwarz	SMB100A	177600	2015-8-17
Power Amplifier	Rohde & Schwarz	BBA100	101238	2015-8-17
Power Amplifier	Rohde & Schwarz	BBA150	101671	2015-8-17
Log-Periodic Antenna	Rohde & Schwarz	HL046E	100160	N/A
Power Meter	Rohde & Schwarz	NRP2	103497	2015-8-19
Fully Anechoic Chamber	TDK	8X4X4	--	2019-8-29

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9.3 Electrical Fast Transient Test

Applicant : SHL Healthcare Ltd.
Project no. : 68.730.14.045.01
Model : SoftAIR
Description : Alternating Control Unit Serial No. : NIL
Operating Mode : Continuous operating mode ☒Table Top ☐Floor Stand

Ambient Temperature (°C) : 24.8 Relative Humidity (%): 71.2 Atmospheric Pressure(mbar) : 1015

Test regulation :
☒IEC 60601-1-2 ☐EN 50082-2 ☐EN 55014-2
☐EN 55024 ☐IEC 1000-4-4 ☐IEC 801-2
☐EN 61547 ☒IEC 61000-4-4

Coupling: ☒Network ☐Clamp

Repetition Rate: ☐5 kHz ☒100 kHz Coupling Time: ☐1 minute ☒2 minutes

Point	Test Voltage (kV)				
L1 (pos) to Ref Gnd	☐..0.5	☐..1	☒..2	☐..4	☐..__
L1 (neg) to Ref Gnd	☐..0.5	☐..1	☒..2	☐..4	☐..__
N (pos) to Ref Gnd	☐..0.5	☐..1	☒..2	☐..4	☐..__
N (neg) to Ref Gnd	☐..0.5	☐..1	☒..2	☐..4	☐..__
PE (pos) to Ref Gnd	☐..0.5	☐..1	☐..2	☐..4	☐..__
PE (neg) to Ref Gnd	☐..0.5	☐..1	☐..2	☐..4	☐..__
L1+N (pos) to Ref Gnd	☐..0.5	☐..1	☒..2	☐..4	☐..__
L1+N (neg) to Ref Gnd	☐..0.5	☐..1	☒..2	☐..4	☐..__
L1+N+PE (pos) to Ref Gnd	☐..0.5	☐..1	☐..2	☐..4	☐..__
L1+N+PE (neg) to Ref Gnd	☐..0.5	☐..1	☐..2	☐..4	☐..__

Remarks: No degradation of performance was found during test.

Result: ☒Complies ☐Does not comply ☐Photo done

Criterion Required : **Annex I.2.3**

Date : 28 November 2014 Test Engineer : Trevor You

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
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Test Equipment List

Electrical Fast Transients Test

DESCRIPTION	MANUFACTURER	MODEL NO.	SERIAL NO.	CAL. DUE DATE
Immunity simulator	EMTEST	UCS 500N7	P1313116005	2015-8-17
7kV Coupling network 3-phase	EMTEST	CNI 503B5	P1425134991	2015-8-17
Capacitive Coupling Clamp	EMTEST	HFK	P1426135389	2015-8-17

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9.4 Surges Test

Applicant : SHL Healthcare Ltd.
Project no. : 68.730.14.045.01
Model : SoftAIR
Description : Alternating Control Unit Serial No. : NIL
Operating Mode : Continuous operating mode ☒Table Top ☐Floor Stand

Ambient Temperature (°C) : 24.8 Relative Humidity (%): 71.2 Atmospheric Pressure(mbar) : 1012

Test regulation : ☒IEC 60601-1-2 ☐EN 50082-2 ☐EN 55014-2
☐EN 55024 ☐IEC 1000-4-5 ☐IEC 801-2
☐EN 61547 ☒IEC 61000-4-5

TEST LEVEL kV	PHASE ANGLE	# OF SURGES (+)	# OF SURGES (-)	SURGE L/PE	SURGE N/PE	SURGE L/N	EUT COMPLIES? YES	EUT COMPLIES? NO	Remarks
0.5,1	0°	5		☐	☐	☒	Y		
0.5,1	0°		5	☐	☐	☒	Y		
0.5,1	90°	5		☐	☐	☒	Y		
0.5,1	90°		5	☐	☐	☒	Y		
0.5,1	180°	5		☐	☐	☒	Y		
0.5,1	180°		5	☐	☐	☒	Y		
0.5,1	270°	5		☐	☐	☒	Y		
0.5,1	270°		5	☐	☐	☒	Y		
				☐	☐	☐			
				☐	☐	☐			
				☐	☐	☐			
				☐	☐	☐			
				☐	☐	☐			
				☐	☐	☐			
				☐	☐	☐			
				☐	☐	☐			
				☐	☐	☐			
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				☐	☐	☐			
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				☐	☐	☐			
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				☐	☐	☐			
				☐	☐	☐			
				☐	☐	☐			
				☐	☐	☐			
				☐	☐	☐			

Remarks: No degradation of performance was found during test.

Result: ☒Complies ☐Does not comply ☐Photo done

Criterion Required : **Annex I.2.3**

Date : 28 November 2014 Test Engineer : Trevor You

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
Building 12&13, Zhiheng Wisdomland Business Park, Nantou Checkpoint Road 2, Nanshan District, 518052 Shenzhen, CHINA

Test Equipment List

Surges Test

DESCRIPTION	MANUFACTURER	MODEL NO.	SERIAL NO.	CAL. DUE DATE
Immunity simulator	EMTEST	UCS 500N7	P1313116005	2015-8-17
7kV Coupling network 3-phase	EMTEST	CNI 503B5	P1425134991	2015-8-17
Telecom Surge Module	EMTEST	Tsurge 7	P1420134206	2015-8-17
4kV coupling/decoupling network	EMTEST	CNV 504 N1	P1420124192	2015-8-17
4kV CDN for 8 telecom lines	EMTEST	CNV 504 S1	P1421134530	2015-8-17

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9.5 Conducted Immunity Test

Applicant : SHL Healthcare Ltd.
Project no. : 68.730.14.045.01
Model : SoftAIR
Description : Alternating Control Unit
Operating Mode : Continuous operating mode ☒Table Top ☐Floor Stand

Ambient Temperature (°C) : 24.6 Relative Humidity (%): 70.4 Atmospheric Pressure(mbar) : 1014

Test regulation :
☒IEC 60601-1-2 ☐EN 50082-2 ☐EN 55014-2
☐EN 55024 ☐IEC 1000-4-6 ☐IEC 801-2
☐EN 61547 ☒IEC 61000-4-6 ☐EN 61000-6-1

Frequency range MHz	Field Strength V/m		Modulation	Dwell time s	
	☐..1	☒..3	☒..80% AM at 1kHz	☐..1	☐..
1. 0.15-80	☐..6	☐..	☐..80% AM at __kHz	☒..3	
	☐..1	☐..3	☒..80% AM at 1kHz	☐..1	☐..
2. ISM and amateur radio bands between 0.15 MHz and 80 MHz	☒..6	☐..	☐..80% AM at __kHz	☒..3	
	☐..1	☐..3	☐..80% AM at 1kHz	☐..1	☐..
3.	☐..6	☐..	☐..80% AM at __kHz	☐..3	
	☐..1	☐..3	☐..80% AM at 1kHz	☐..1	☐..
4.	☐..6	☐..	☐..80% AM at __kHz	☐..3	
	☐..1	☐..3	☐..80% AM at 1kHz	☐..1	☐..
5.	☐..6	☐..	☐..80% AM at __kHz	☐..3	
	☐..1	☐..3	☐..80% AM at 1kHz	☐..1	☐..
6.	☐..6	☐..	☐..80% AM at __kHz	☐..3	
	☐..1	☐..3	☐..80% AM at 1kHz	☐..1	☐..
7.	☐..6	☐..	☐..80% AM at __kHz	☐..3	
	☐..1	☐..3	☐..80% AM at 1kHz	☐..1	☐..
8.	☐..6	☐..	☐..80% AM at __kHz	☐..3	
	☐..1	☐..3	☐..80% AM at 1kHz	☐..1	☐..
9.	☐..6	☐..	☐..80% AM at __kHz	☐..3	
	☐..1	☐..3	☐..80% AM at 1kHz	☐..1	☐..
10.	☐..6	☐..	☐..80% AM at __kHz	☐..3	

Remarks: No degradation of performance was found during test.

Result: ☒Complies ☐Does not comply ☐Photo done

Criterion Required : **Annex I.2.3**

Date : 28 November 2014 Test Engineer : Trevor You

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
Building 12&13, Zhiheng Wisdomland Business Park, Nantou Checkpoint Road 2, Nanshan District, 518052 Shenzhen, CHINA

Test Equipment List

Conducted Immunity Test

DESCRIPTION	MANUFACTURER	MODEL NO.	SERIAL NO.	CAL. DUE DATE
Continuous Wave Simulator	EMTEST	CWS 500N1	P1420134224	2015-8-17
Attenuator	EMTEST	ATT6/80	P1402129090	2015-8-17
CDN	EMTEST	CDN-M2/M3	P1420134163	2015-8-17
CDN	EMTEST	CDN-M4	P1346125919	2015-8-17
Electromagnetic Injection Clamp	EMTEST	EM101	P1411132453	2015-8-17

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9.6 Voltage Dips, Voltage Variations and Short Interruptions Test

Applicant : SHL Healthcare Ltd.
Project no. : 68.730.14.045.01
Model : SoftAIR
Description : Alternating Control Unit Serial No. : NIL
Operating Mode : Continuous operating mode ☐Table Top ☐Floor Stand

Ambient Temperature (°C) : 24.8 Relative Humidity (%): 72.6 Atmospheric Pressure(mbar) : 1015

Test regulation : ☒IEC 60601-1-2 ☐EN 50082-2 ☐EN 55014-2
☐EN 55024 ☐IEC 1000-4-11 ☐IEC 801-2
☐EN 61547 ☒IEC 61000-4-11

U_T : 230V AC

Test Level %U	Dips & Interruptions %U T	Duration (in period) / s
0	>95	0.5 / 10 ms
0	>95	1 / 20 ms
70	>30	25 / 500 ms
0	>95	250 /5 s

Remarks: The EuT stopped working when 100%(5s) voltage interruption was applied. But it can be restorable to normal operation by operator intervention after test.

Result: ☒Complies ☐Does not comply ☐Photo done

Criterion Required : **Annex I.2.3**

Date : 28 November 2014 Test Engineer : Trevor You

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
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Test Equipment List

Voltage Dips and Interruptions Test

DESCRIPTION	MANUFACTURER	MODEL NO.	SERIAL NO.	CAL. DUE DATE
Immunity simulator	EMTEST	UCS 500N7	P1313116005	2015-8-17
Motorized Variac	EMTEST	MV2616	P1401128623	2015-8-17
Switch-Box fo phase by phase	EMTEST	PFLS 32N1	P1251107106	2015-8-17

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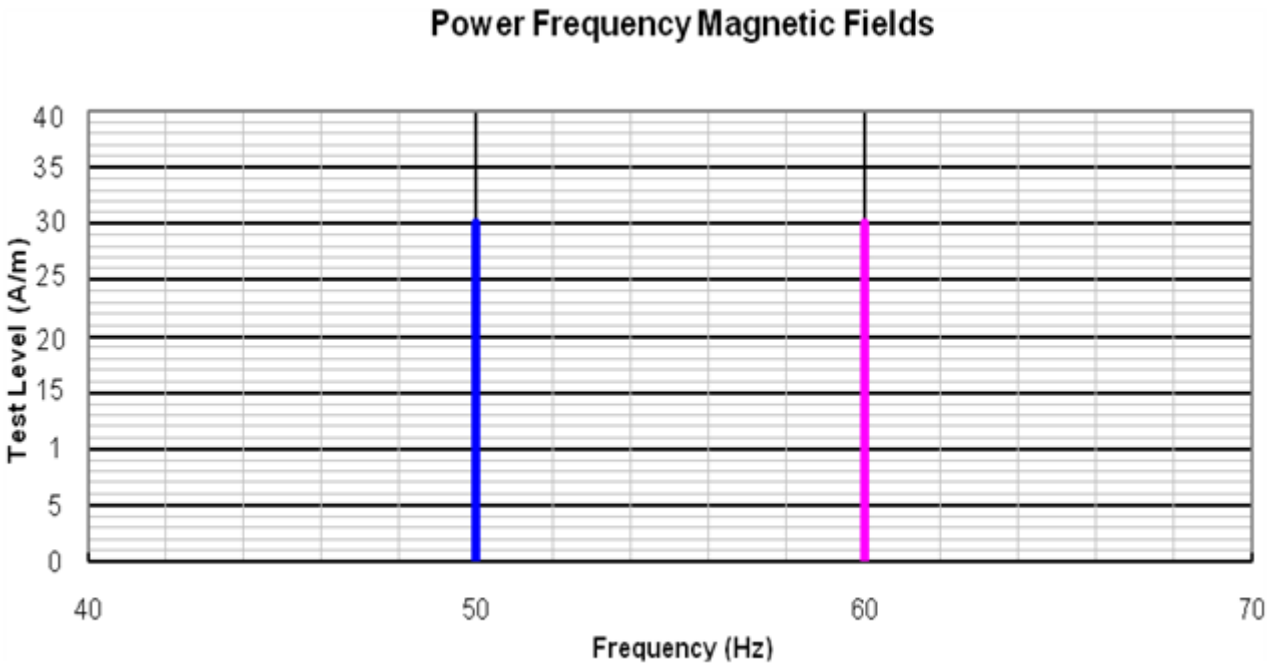
9.7 Power-frequency magnetic field

Applicant : SHL Healthcare Ltd.
Project no. : 68.730.14.045.01
Model : SoftAIR
Description : Alternating Control Unit Serial No. : NIL
Operating Mode : Continuous operating mode ☐Table Top ☐Floor Stand

Ambient Temperature (°C) : 24.8 Relative Humidity (%): 71.2 Atmospheric Pressure(mbar) : 1015

Test regulation : ☒IEC 60601-1-2 ☐EN 50082-2 ☐EN 55014-2
☐EN 55024 ☐IEC 1000-4-8 ☐IEC 801-2
☐EN 61547 ☒IEC 61000-4-8



Remarks: No degradation of performance was found during test.

Result: ☒Complies ☐Does not comply ☐Photo done

Criterion Required : **Annex I.2.3**

Date : 28 November 2014 Test Engineer : Trevor You

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
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Test Equipment List

Power-frequency magnetic field Test

DESCRIPTION	MANUFACTURER	MODEL NO.	SERIAL NO.	CAL. DUE DATE
Immunity simulator	EMTEST	UCS 500N7	P1313116005	2015-8-17
7kV Coupling network 3-phase	EMTEST	CNI 503B5	P1425134991	2015-8-17
Current Transformer	EMTEST	MC 2630	P1408131875	2015-8-17
Magnetic Field Coil	EMTEST	MS 100N	P1325119613	2015-8-17

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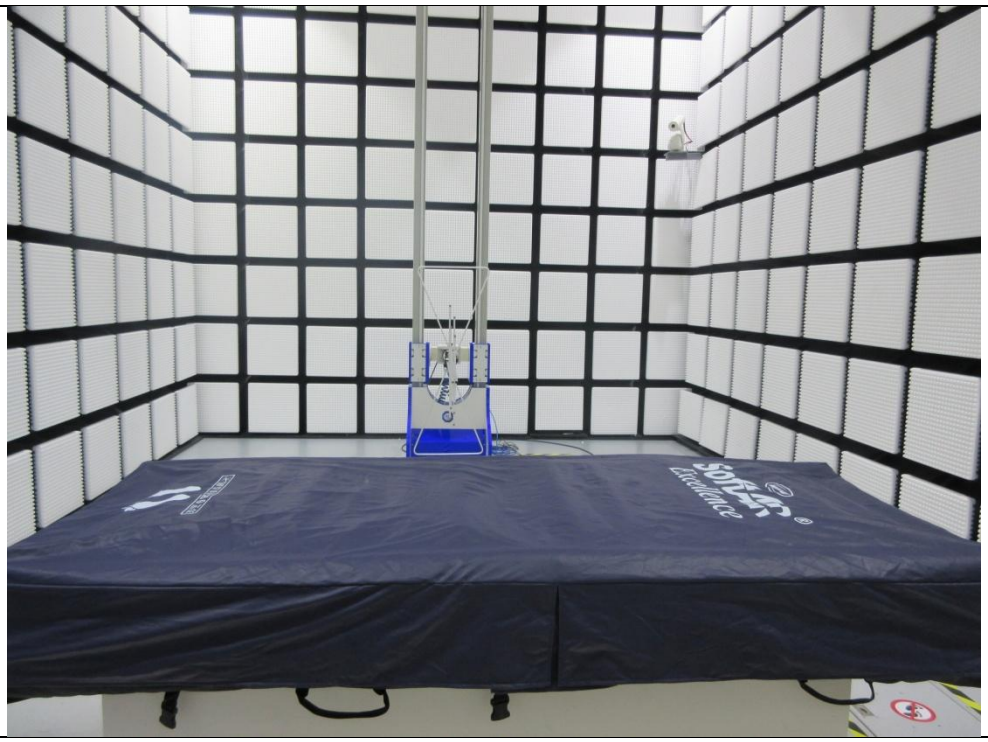
10 Appendix A

Radiated Emission Test



Conducted Emission Test

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
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Appendix A

Harmonics Test

Flicker Test

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
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Appendix A

Electrostatic Discharge Test

Radiated Immunity Test

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
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Appendix A

Electrical Fast Transients Test

Surges Test

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
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Appendix A

Conducted Immunity Test

Voltage Dips and Short Interruptions Test

TÜV SÜD Certification and Testing (China) Co., Ltd. Shenzhen Branch
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Appendix A

Power-frequency magnetic field

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11 Appendix B

Details of: Overall view

Details of: Overall view of control unit

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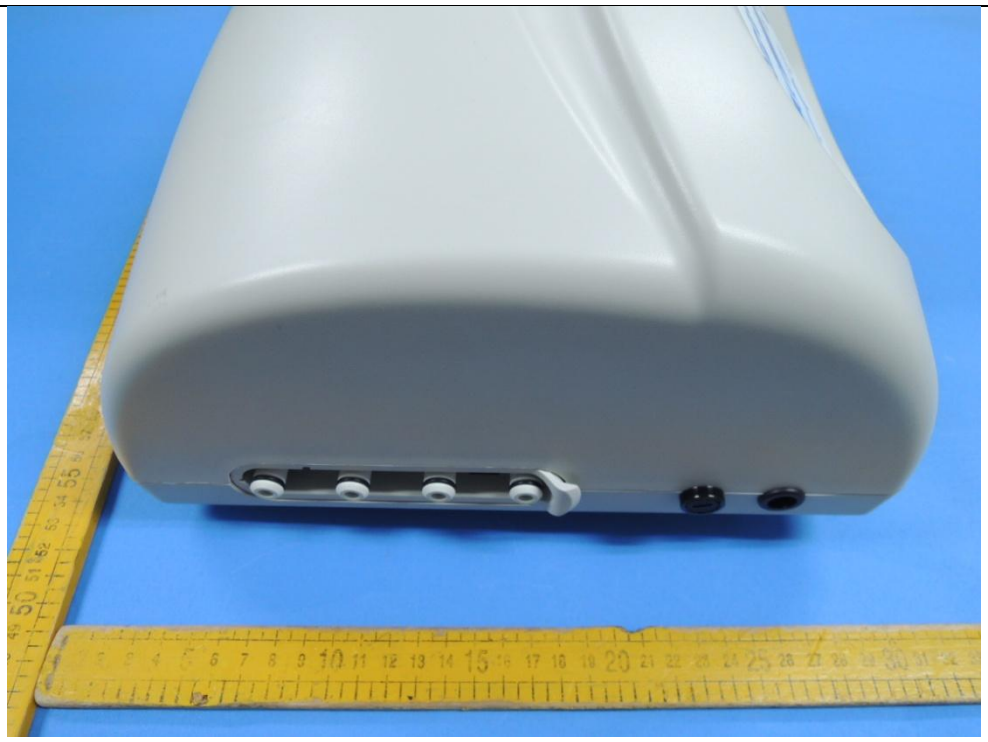
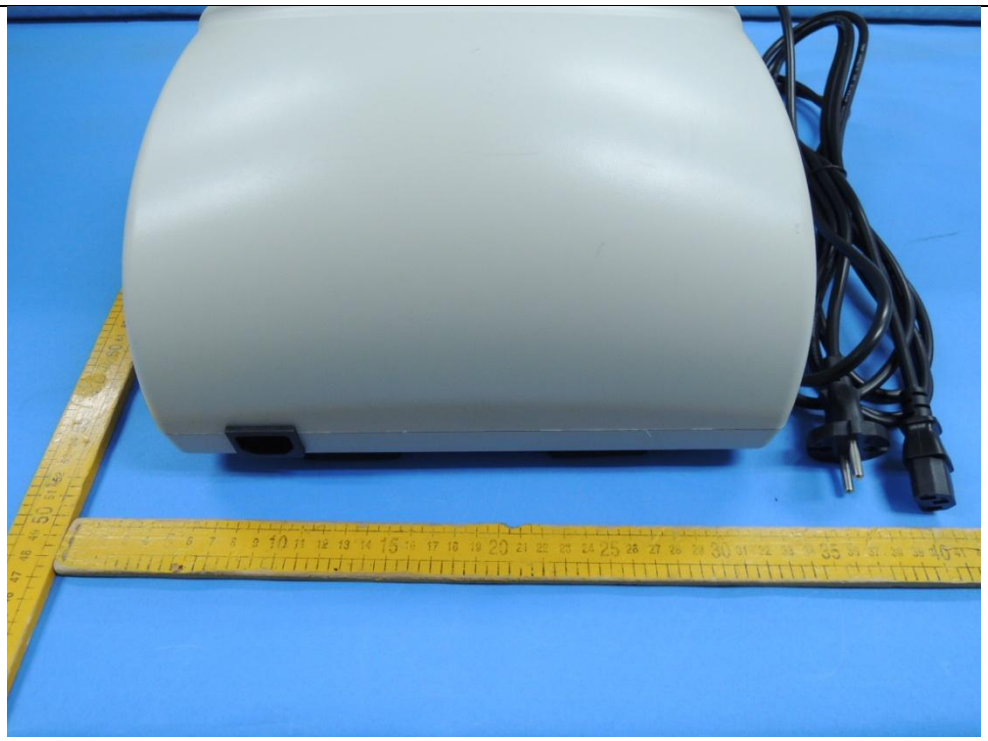
Appendix B

Details of: Side view of control unit



Details of: Rear view of control unit



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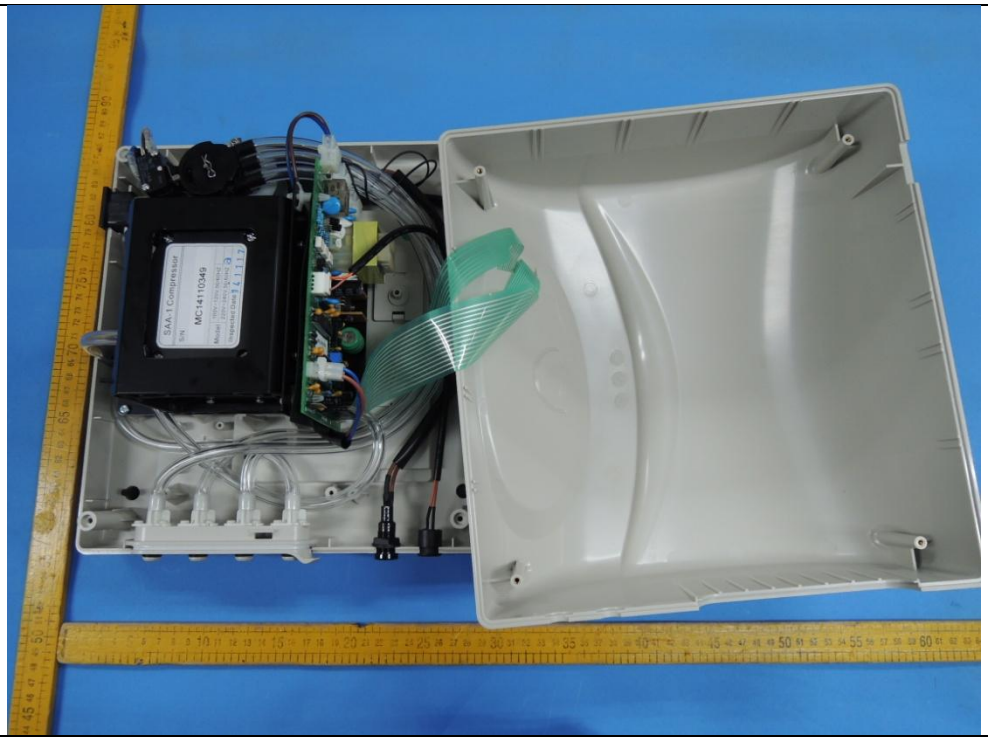
Appendix B

Details of: Bottom view of control unit

Details of: Internal view 1 of control unit



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Appendix B

Details of: Internal view 2 of control unit

Details of: Internal view 3 of control unit

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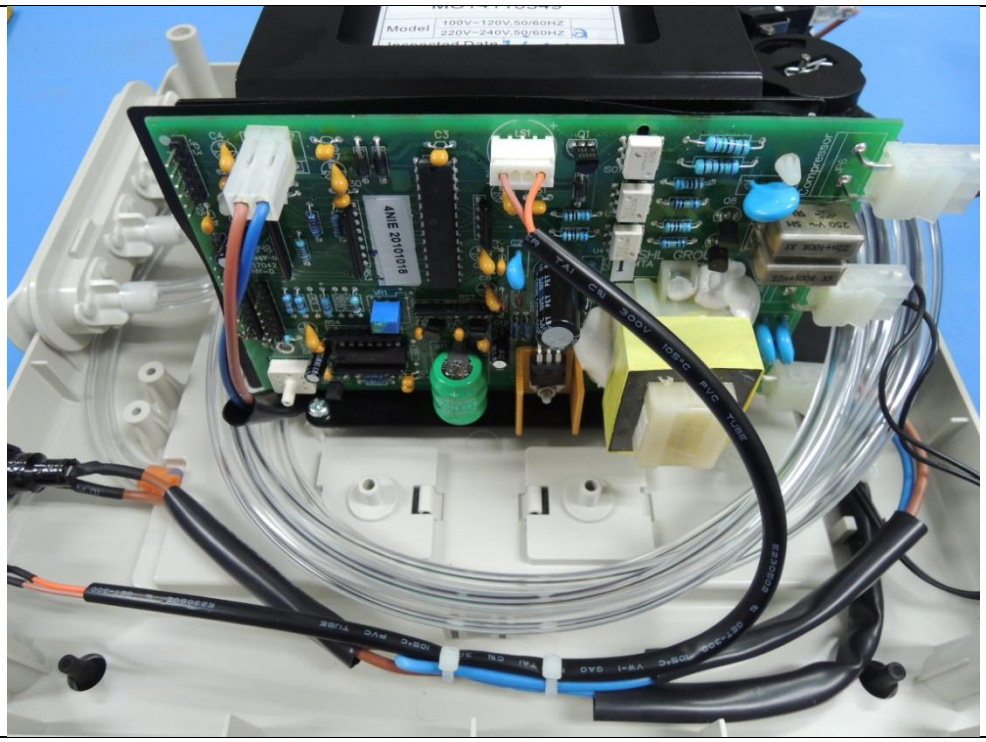
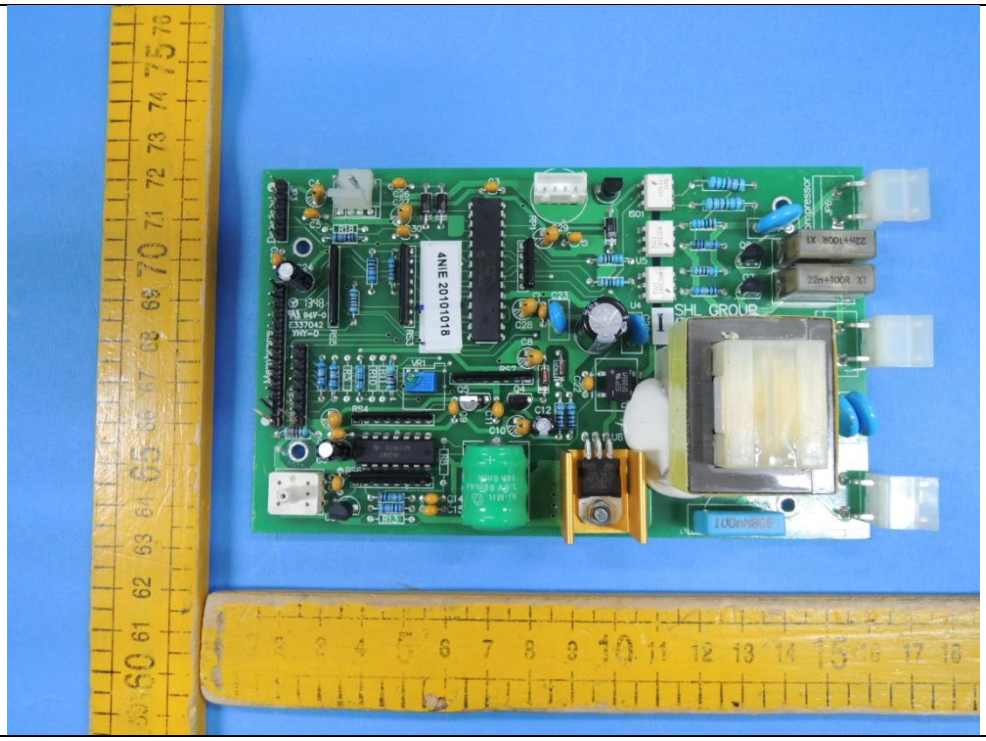
Appendix B

Details of: Internal view 3 of control unit



Details of: PCB Layout view1 of control unit



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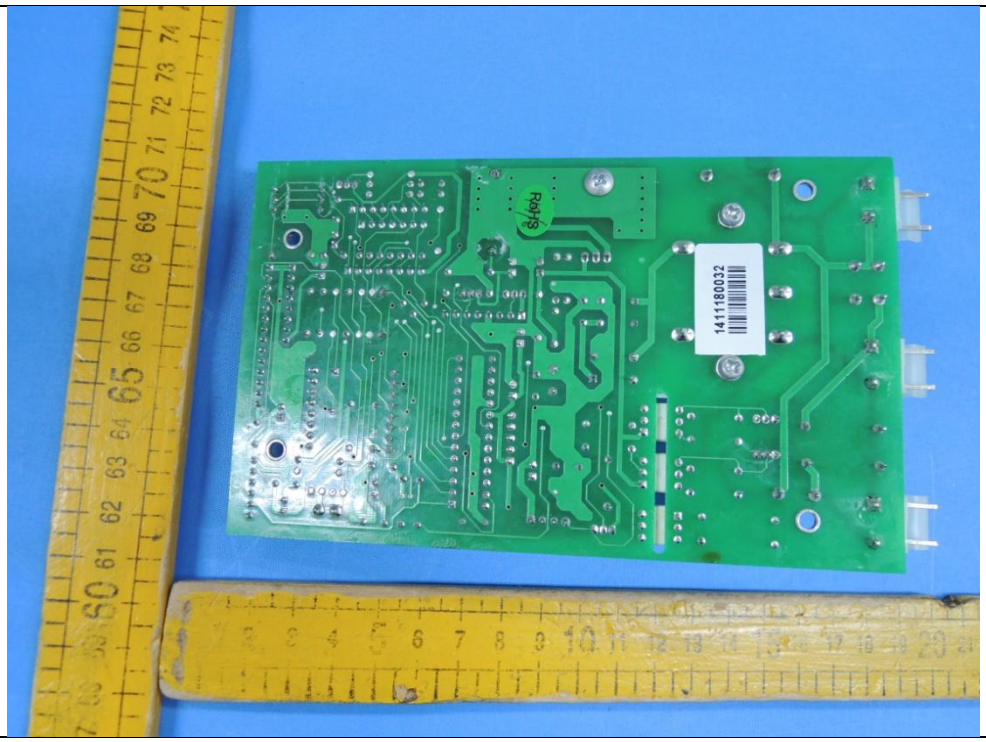
Appendix B

Details of: PCB Layout view2 of control unit



Details of: Compressor view of control unit

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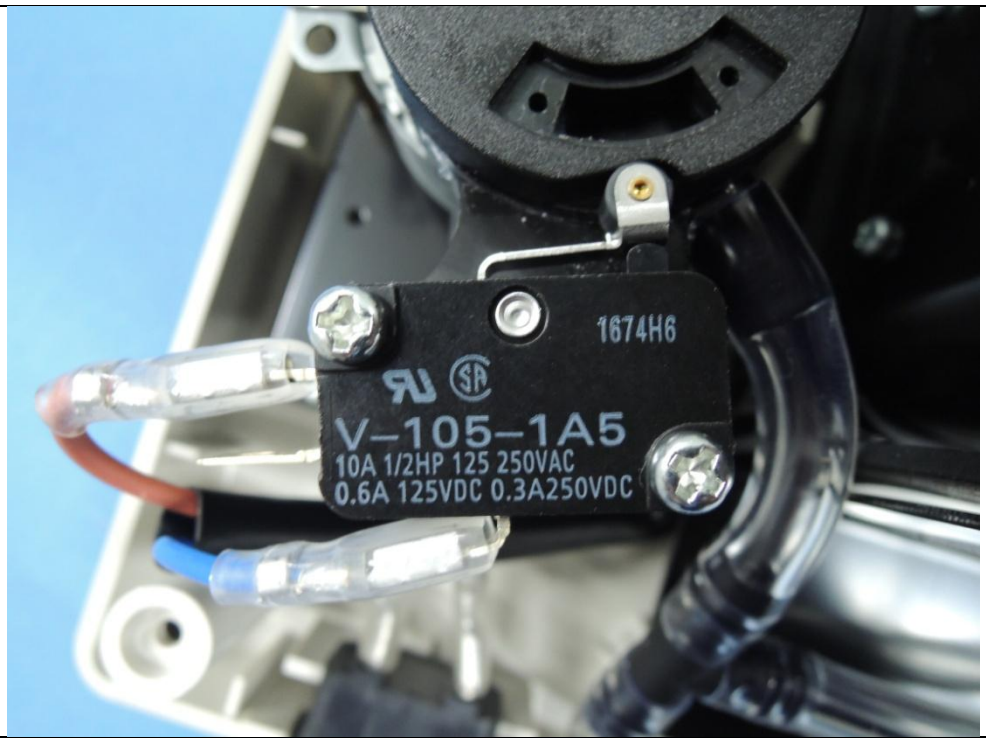
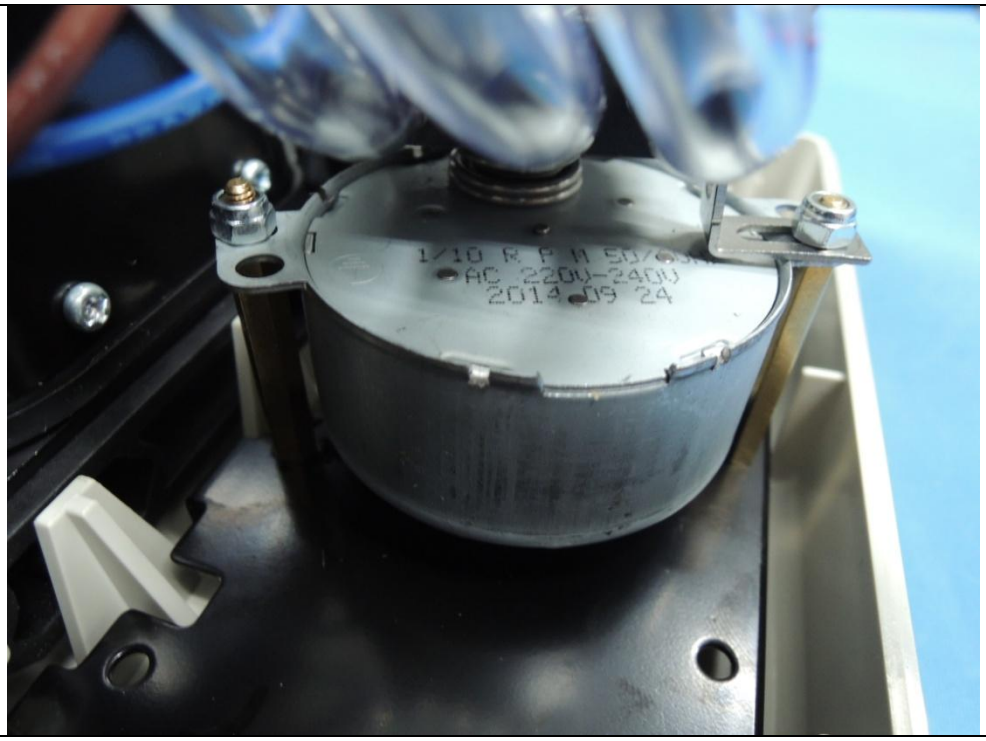
Appendix B

Details of: Micro switch view of control unit



Details of: Motor view of control unit



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