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|--|--|--|--|--|---|
| Prüfbericht - Nr.: | | ULR-TC568819300000029F 001 | | Seite 1 von 20 <i>Page 1 of 20</i> | |
| <i>Test Report No.:</i> | | | | | |
| Auftraggeber: <i>Client:</i> | | Hill-rom Services Private Limited 1 Yishun Avenue 7, Singapore 768923 | | | |
| Gegenstand der Prüfung: <i>Test item:</i> | | Airway clearance device | | | |
| Bezeichnung: <i>Identification:</i> | | POPT1 | Serien-Nr.: <i>Serial No.</i> | | U044OP0050 |
| Wareneingangs-Nr.: <i>Receipt No.:</i> | | 166120073 | Eingangsdatum: <i>Date of receipt:</i> | | 01-04-2019 |
| Prüfort: <i>Testing location:</i> | | Refer Page 5 of 20 for Test site details | | | |
| Prüfgrundlage: <i>Test specification:</i> | | FCC Part 15 Subpart C - 15.225 & ANSI C63.10-2013 | | | |
| Prüfergebnis: <i>Test Result:</i> | | Der Prüfgegenstand entspricht oben genannter Prüfgrundlage(n). <i>The test items passed the test specification(s).</i> | | | |
| Prüflaboratorium: <i>Testing Laboratory:</i> | | TÜV Rheinland (India) Pvt. Ltd. 27/B, 2nd Cross, Electronic City , Phase 1 Bangalore – 560 100, FCC Test Site Registration no.: 496599 | | | |
| geprüft / tested by: | | | kontrolliert / reviewed by: | | |
| 08.04.2019 | Pramod Sharma R Engineer |  | 25.06.2019 | Mahammadgouse Kaladagi Senior Engineer |  |
| Datum <i>Date</i> | Name/Stellung <i>Name/Position</i> | Unterschrift <i>Signature</i> | Datum <i>Date</i> | Name/Stellung <i>Name/Position</i> | Unterschrift <i>Signature</i> |
| Sonstiges / Other Aspects: | | FCC ID: 2AJKO-OPTIMUS | | | |
| Abkürzungen: | | Abbreviations: | | | |
| P(ass) = entspricht Prüfgrundlage | | P(ass) = passed | | | |
| F(ail) = entspricht nicht Prüfgrundlage | | F(ail) = failed | | | |
| N/A = nicht anwendbar | | N/A = not applicable | | | |
| N/T = nicht getestet | | N/T = not tested | | | |
| <p>Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens.</p> <p><i>This test report relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.</i></p> | | | | | |

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Test Summary

| Test Item | FCC Clause | Result | Remarks |
|--|---|--------|---------|
| Frequency tolerance | FCC part 15 Subpart C Section 15.225 (e) | Pass | - |
| Radiated Spurious Emission & Field Strength Measurement within the band 13.110-14.010 MHz | FCC part 15 Subpart C Section 15.225 (a,b,c,d) / (15.209) | Pass | - |

Discipline: Electronics Testing
Group: EMC Test Facility

Product Variants:

| Variant | Model Number | Modes available |
|---------|--------------|---------------------------|
| 1 | POPT1 | Maximus™ System |
| 2 | PSC1 | Synclara™ Cough System |
| 3 | PVL1 | Volara™ Cough System |

Note:

1. Model POPT1 is the highest configuration where it has both synclara and volara modes available , hence the testing is carried out on this model.
2. Measurements were performed as the procedure mentioned in ANSI C63.10-2013

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1 GENERAL REMARKS

1.1 Complimentary Materials

All attachments are integral part of this test report. This applies especially to the following items.

1. TEST SETUP PHOTOS
- 2: EUT EXTERNAL PHOTOS
- 3: EUT INTERNAL PHOTOS
- 4: FCC LABEL AND LABEL LOCATION
- 5: BLOCK DIAGRAM
- 6: SPECIFICATION OF EUT
- 7: SCHEMATIC DIAGRAM
- 8: BILL OF MATERIAL
- 9: USER MANUAL

2 TEST SITES

2.1 Testing Facilities

TÜV Rheinland (India) Pvt.Ltd.,
27/B, 2nd Cross,
Electronic City , Phase 1
Bangalore – 560 100,

TUV Rheinland (India) Private Limited
108 , Beside ISBR Business School,
Electronic city Phase I
Bangalore - 560 100.

2.2 List of Test and Measurement Instruments

Table 1: List of test and measurement instruments

| Equipment | Manufacturer | Model Name | Serial Number | Calibration Due Date | Periodicity | Used for Test Items |
|------------------------|-----------------------------|----------------------|---------------|----------------------|-------------|----------------------------------|
| Signal Analyzer | Rohde & Schwarz | FSV7 | 101644 | 29-12-2019 | Yearly | Antenna Port Measurements |
| Environmental Chamber | Envisys | EM80-40H | ET/022/14-15 | 21-05-2020 | Yearly | |
| EMI Test Receiver | Rohde & Schwarz | ESU 40 | 100288 | 11-10-2019 | Yearly | Radiated Spurious Emission |
| Active loop antenna | Frankonia | LAX-10 | LAX-10-800 | 15-01-2020 | Yearly | |
| Biconical Antenna | Schwarzbeck mess-elektronik | VHBB-9124 / BBA-9106 | 9124-656 | 16-01-2020 | Yearly | |
| Log-Periodic Antenna | Schwarzbeck mess-elektronik | VUSLP-9111B | 9111B-111 | 17-01-2020 | Yearly | |
| Broadband Horn Antenna | Frankonia | HAX-18 | HAX18-802 | 17-05-2019 | Yearly | |
| Semi Anechoic Chamber | Frankonia | - | - | - | - | AC Power line conducted emission |
| EMI Receiver | Rohde & Schwarz | ESR7 | 101133 | 16-01-2020 | Yearly | |
| LISN | Rohde & Schwarz | ENV 216 | 100022 | 18-10-2019 | Yearly | |
| Pulse Limiter | Rohde & Schwarz | ESH3-Z2 | 100811 | 09-08-2019 | Yearly | |

3 GENERAL PRODUCT INFORMATION

3.1 Product Function and Intended Use

The **Synclara™ Cough System** is intended for use on patients who are unable to cough or clear secretions effectively due to reduced peak cough expiratory flow, as a result of high spinal cord injuries, neuromuscular deficits, or severe fatigue associated with intrinsic lung disease.

The **Volara™ System** is intended for the mobilization of secretions, lung expansion therapy, the treatment and prevention of pulmonary atelectasis, and has the ability to provide supplemental oxygen when used with oxygen supply.

The **Maximus™ System, when used as a Synclara™ Cough System** is indicated for, but is not limited to patients with these conditions:

- Muscular dystrophy
- Spinal muscular atrophy
- Amyotrophic lateral sclerosis
- Spinal cord injuries
- Myasthenia gravis
- Post-polio
- COPD patient with a weak and ineffective cough

The **Maximus™ System, when used as a Volara™ System** is indicated for, but is not limited to patients with these conditions:

- Difficulty in clearance of secretions
- Pulmonary atelectasis

Model differences:

The model POPT1 (Maximus™ System) provides features of both the Synclara™ System and the Volara™ System. The model PSC1 (Synclara™ System) only provides feature of Synclara™ System. It doesn't have the OLE-module. And it's identical to model POPT1 (Maximus™ System) with same rated voltage and rated power, same power supply unit, same output character, except for the circuit diagram, PCB layout and construction.

The model PVL1 (Volara™ System) only provides feature of Volara™ System. And it's identical to model POPT1 (Maximus™ System) with same rated voltage and rated power, same power supply unit, same output character, same the circuit diagram, same PCB layout and same construction.

3.2 Ratings and System Details

Table 2: Ratings and System Details

| | |
|---------------------------|-----------------------------|
| Operating Frequency Range | 13.56 MHz |
| No. of Channel | Single Channel |
| Radio Protocol | Short-range devices |
| Modulation | Amplitude shift keying(ASK) |
| Number of antennas | 1 |
| Antenna Gain & Type | PCB Antenna |
| Supply Voltage to Product | 100-240VAC/50-60Hz |
| Environmental conditions | Operating: +5 °C to +35 °C |
| Dimensions | 22.3cm x 23.3cm x 27cm |

3.3 Measurement Uncertainty:

Table 3: Measurement Uncertainty

| Parameter | Uncertainty |
|-------------------------------|-------------|
| RF output power, conducted | ±1.5 dB |
| Unwanted Emissions, conducted | ±3 dB |
| All emissions, radiated | ±6 dB |
| Temperature | ±3 °C |
| Supply Voltages | ±3 % |
| Time | ±5 % |

4 TEST SET-UP AND OPERATION MODE

4.1 Principle of Configuration Selection

Continuous transmission was enabled upon power up of EUT.

4.2 Test Operation and Test Software

- Hardware version 1
- Software version MCB 0.0.21.0
- Software version DCB 0.0.21.0

4.3 Special Accessories and Auxiliary Equipment

1. Stand Mount
2. Foot switch

4.4 Countermeasures to achieve EMC Compliance

- None

4.5 Test modes – data rates and modulations

For Radiated spurious emissions, the tests were performed for the worst case operating mode and results are reported in this report.

Note:

EUT serial number:

Conducted measurement sample: U044OP0052

Radiated measurement sample : U044OP0050

5 TEST METHODOLOGY

5.1 Radiated Emission Test

The radiated emission measurement was performed according to the procedures in ANSI C63.10-2013. The equipment under test (EUT) was placed at the middle of the 80 cm high turntable for below 1 GHz & 1.5 m height for above 1 GHz measurement, and the EUT is 3 meters far from the measuring antenna. The turntable was rotated 360° for obtaining the maximum emission. The height of the measuring antennas was scanned between 1 m and 4 m, and the antenna rotated to repeat the measurements for both the horizontal and vertical antenna polarizations. Repeat the measurement steps until the maximum emissions were obtained. The measurement above 1000 MHz was performed by horn antenna, The measurement below 30 MHz was performed by loop antenna, Measurement from 30 MHz to 200 MHz was performed by Baloon and Biconical Antenna, and mesurement from 200 MHz to 1 GHz was performed by Log-Periodic Antenna.

The EUT was rotated around the X-, Y-, and Z-Axis and the results from worst case axis are recorded.

5.1.1 Test Setup Configuration

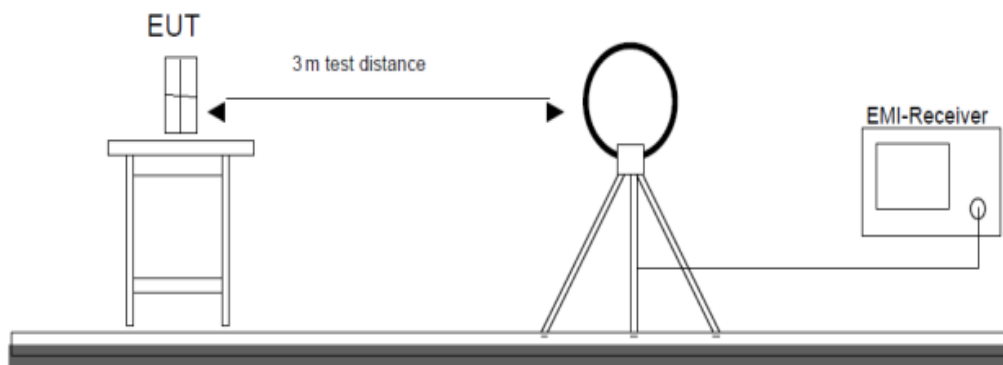


Figure 1: Frequency Range 9 kHz- 30 MHz

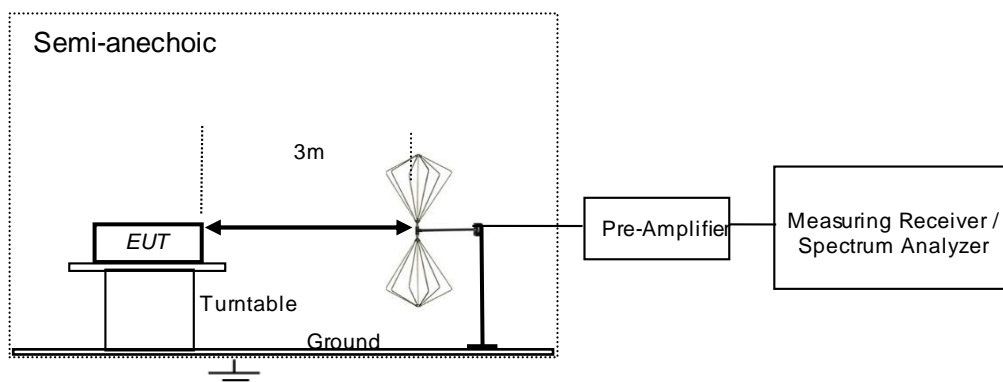


Figure 2: Frequency Range 30 MHz – 200 MHz

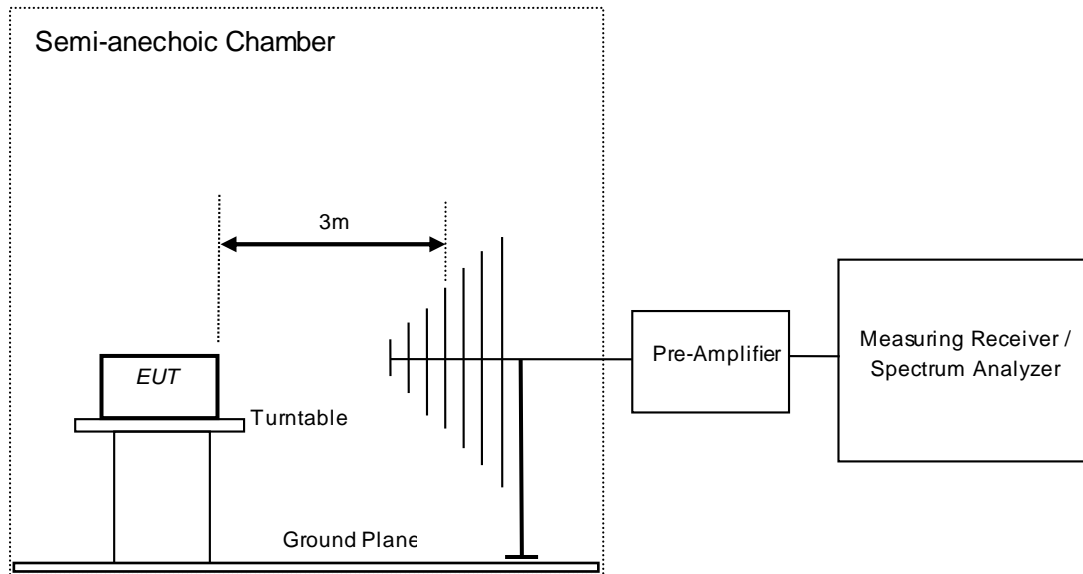


Figure 3: Frequency Range 200 MHz - 1GHz

6 TEST RESULTS

6.1 Frequency tolerance

Result

Pass

| | |
|--------------------|----------------------------------|
| Test Specification | FCC part 15 Subpart C 15.225 (e) |
| Measurement | 10KHz |
| Bandwidth | |
| Detector | Peak |

| | |
|-------------|--|
| Requirement | The frequency tolerance of the carrier signal shall be maintained within $\pm 0.01\%$ of the operating frequency over a temperature variation of -20 degrees to $+ 50$ degrees C at normal supply voltage, and for a variation in the primary supply voltage from 85% to 115% of the rated supply voltage at a temperature of 20 degrees C |
|-------------|--|

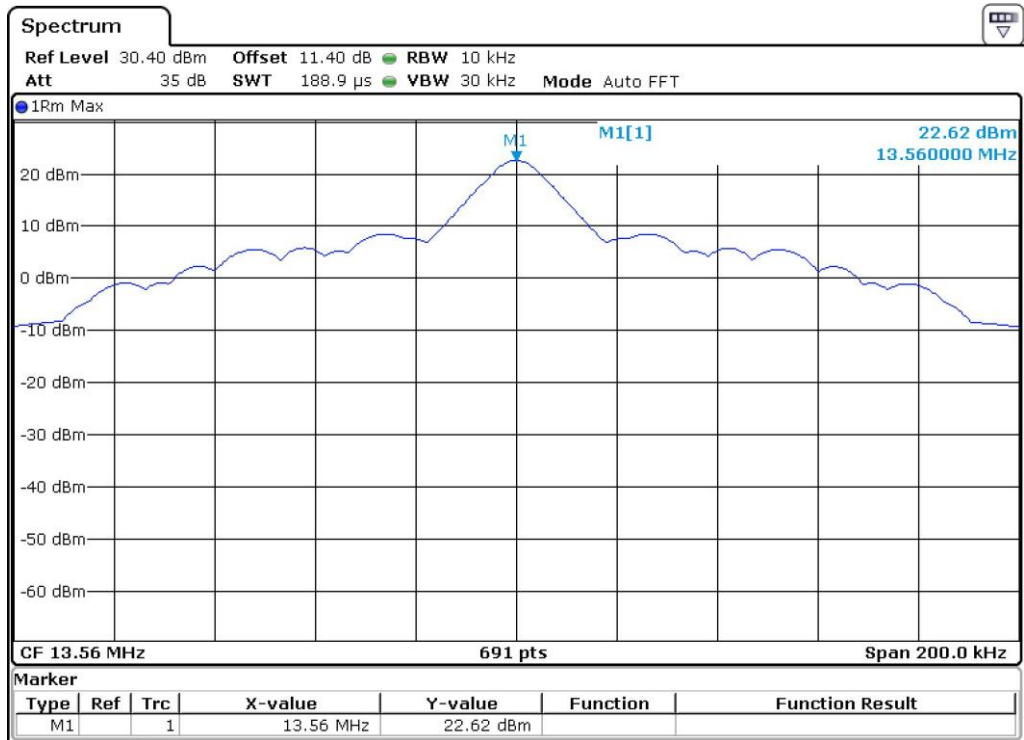
Cable Loss & attenuation loss are considered in the test results

Normal Test Condition:

Temperature (Norm) = $+ 25$ °C Voltage (Vnorm) = 230 VAC RH= 62 %

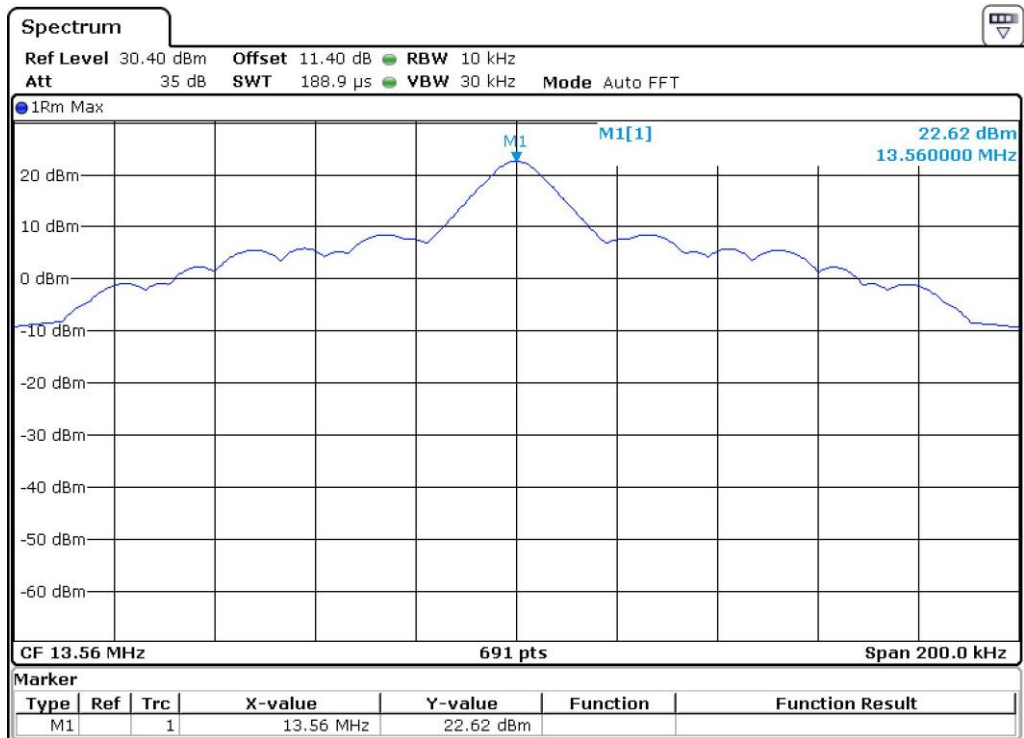
Extreme Test Condition:

Temperature: Low = $+5$ °C
High = $+35$ °C



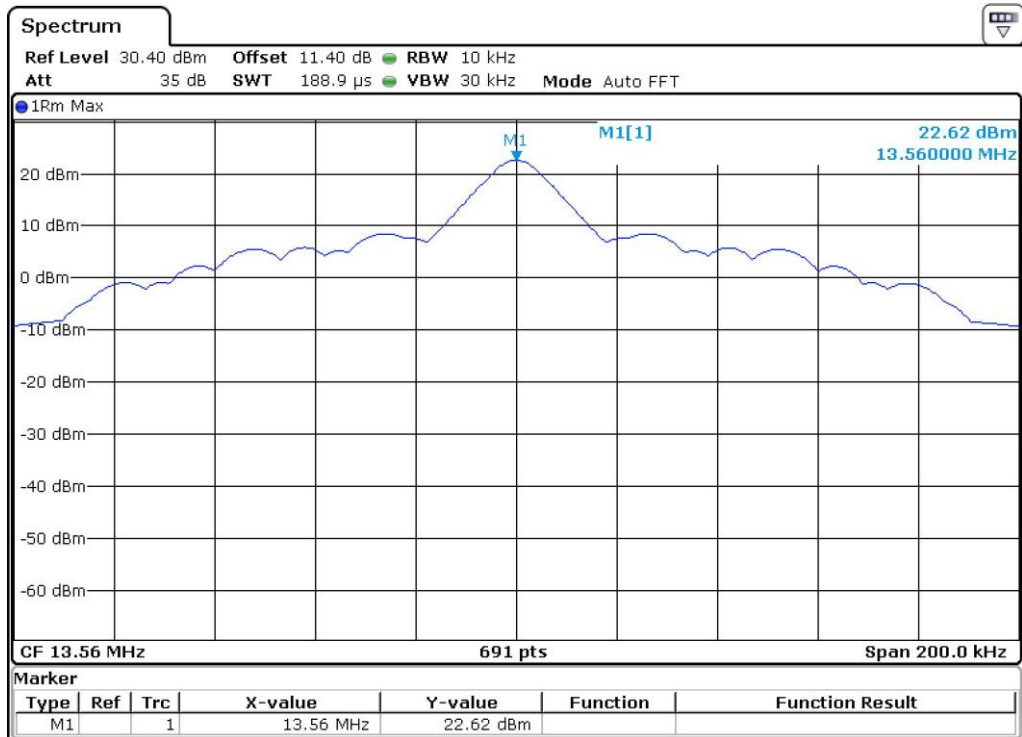
Test plot 1: Frequency tolerance

Temperature: +5 °C



Test plot 2: Frequency tolerance

Temperature: -Normal



Test plot 3: Frequency tolerance

Temperature: +35°C

6.2 Radiated Spurious Emission & Field Strength Measurement within the band 13.110-14.010 MHz

Result

Pass

| | |
|----------------------|---|
| Test Specification | FCC part 15 Subpart C Section 15.225 (a,b,c,d) / (15.209) |
| Test Method | ANSI C 63.10 - 2013 |
| Measurement Location | Semi Anechoic Chamber |
| Measuring Distance | 3 m |
| Detector | QP for frequency below 1 GHz, average for frequency above 1 GHz |
| Requirement | As per the limits mentioned in the below table |

Table 4: Transmitter limits for Radiated emission

| Frequency (MHz) | Field strength (μV/m) | Field strength (dBμV/m) | Distance of Measurement (m) |
|-----------------|-----------------------|-------------------------|-----------------------------|
| 0.009 – 0.490 | 2400/F(kHz) | 48.50 – 13.80 | 300* |
| 0.490 – 1.705 | 24000/F(kHz) | 33.80 – 23.00 | 30* |
| 1.705 -30 | 30 | 29.54 | 30* |
| 30-88 | 100 | 40.0 | 3 |
| 88-216 | 150 | 43.5 | 3 |
| 216-960 | 200 | 46.0 | 3 |
| Above 960 | 500 | 54.0 | 3 |

Remark: * The limit shows in the table above of frequency range 0.009 – 0.490, 0.490 – 1.705 MHz and 1.705-30MHz is at 300 meter, 30 meter and 30 meter range respectively, which corresponds to 128.51 – 93.80, 73.80 – 62.96 and 69.54 dBμV/m at 3m range by extrapolation calculation and the measurement of loop antenna.

The emission limits shown in the above table are based on measurements employing a CISPR quasi-peak detector except for the frequency bands 9–90 kHz, 110–490 kHz and above 1000 MHz Radiated emission limits in these three bands are based on measurements employing an average detector.

Test Conditions:

Supply Voltage: 110 VAC, 60 Hz

Environmental conditions:

Temperature: +25 °C RH: 61.76 %

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Test results:

Table 5:Tranmitter test results for frequency 9kHz to 30MHz

| Polarization | Measured Frequency (MHz) | Field Strength (dBµV/m) | Limit (dBµV//m) | Margin (dB) |
|---------------|--------------------------|-------------------------|-----------------|-------------|
| Parallel | 0.071 | 21.41 | 110.58 | -89.17 |
| | 0.092 | 32.68 | 108.33 | -75.65 |
| | 0.127 | 33.2 | 105.33 | -72.13 |
| Perpendicular | 0.086 | 30.97 | 108.91 | -77.94 |
| | 0.128 | 26.31 | 105.46 | -79.15 |

Table 6: Transmitter test results in the frequency band of 13.11MHz to 14.01MHz

| Polarization | Frequency Range (MHz) | Measured Frequency (MHz) | Field Strength (dBµV/m) | Limit (dBµV//m) | Margin (dB) |
|---------------|-----------------------|--------------------------|-------------------------|-----------------|-------------|
| Parallel | 13.11-13.41 | 13.135 | 31.88 | 125.24 | -93.36 |
| | 13.41-13.553 | 13.535 | 45.9 | 124.98 | -79.08 |
| | 13.553-13.567 | 13.56 | 62.67 | 124.96 | -62.29 |
| | 13.567-13.71 | 13.585 | 40.35 | 124.94 | -84.59 |
| | 13.71-14.01 | 13.825 | 27.95 | 124.79 | -96.84 |
| Perpendicular | 13.11-13.41 | 13.39 | 29.39 | 125.07 | -95.68 |
| | 13.41-13.553 | 13.435 | 28.03 | 125.04 | -97.01 |
| | 13.553-13.567 | 13.56 | 61.15 | 124.96 | -63.81 |
| | 13.567-13.71 | 13.61 | 41.22 | 124.93 | -83.71 |
| | 13.71-14.01 | 13.735 | 27.93 | 124.85 | -96.92 |

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Table 7: Transmitter test results for the frequency 30 MHz – 1 GHz

Table Top:

Volara Mode:

| Polarization | Frequency (MHz) | Measured value (dBµV/m) | Limit (dBµV/m) | Margin (dB) |
|--------------|-----------------|-------------------------|----------------|-------------|
| Vertical | 40.676 | 33.67 | 40 | -6.33 |
| | 46.88 | 34.09 | 40 | -5.91 |
| | 83.992 | 33.55 | 40 | -6.45 |
| | 221.36 | 40.12 | 46 | -5.88 |
| | 336.02 | 36.73 | 46 | -9.27 |
| Horizontal | 89.98 | 31.90 | 43.5 | -11.6 |
| | 193.9 | 35.19 | 43.5 | -8.31 |
| | 335.95 | 39.33 | 46 | -6.67 |

Syncara Mode:

| Polarization | Frequency (MHz) | Measured value (dBµV/m) | Limit (dBµV/m) | Margin (dB) |
|--------------|-----------------|-------------------------|----------------|-------------|
| Vertical | 42.24 | 21.75 | 40 | -18.25 |
| | 81.87 | 22.92 | 40 | -17.08 |
| | 163.35 | 16.87 | 43.5 | -26.63 |
| | 503.9 | 22.64 | 46 | -23.36 |
| | 672.11 | 28.46 | 46 | -17.54 |
| Horizontal | 42.36 | 21.83 | 40 | -18.17 |
| | 45.27 | 21.12 | 40 | -18.88 |
| | 73.68 | 17.19 | 40 | -22.81 |
| | 504.02 | 25.92 | 46 | -20.08 |
| | 672.14 | 26.14 | 46 | -19.86 |

Stand Mount:

| Polarization | Frequency (MHz) | Measured value (dBµV/m) | Limit (dBµV/m) | Margin (dB) |
|--------------|-----------------|-------------------------|----------------|-------------|
| Vertical | 89.96 | 34.83 | 40 | -5.17 |
| | 149.95 | 34.8 | 40 | -5.2 |
| | 233.68 | 37.13 | 40 | -2.87 |
| | 755.78 | 37.15 | 46 | -8.85 |
| Horizontal | 89.98 | 32.05 | 43.5 | -11.45 |
| | 191.55 | 33.81 | 43.5 | -9.69 |
| | 238.85 | 44.02 | 46 | -1.98 |
| | 335.94 | 38.8 | 46 | -7.2 |

6.1 Conducted Spurious Emission Test on AC Power Line

Result

Pass

Test Specification : FCC Part 15 Section 15.207
RSS-Gen Issue 4 section 8.8
Test Method : ANSI C63.10-2013
Testing Location : Screened room
Measurement Bandwidth : 9kHz
Frequency Range : 150kHz – 30MHz
Supply Voltage : 110VAC, 60Hz

Limits: FCC Part 15 section 15.207 and RSS-Gen Issue 4 section 8.8

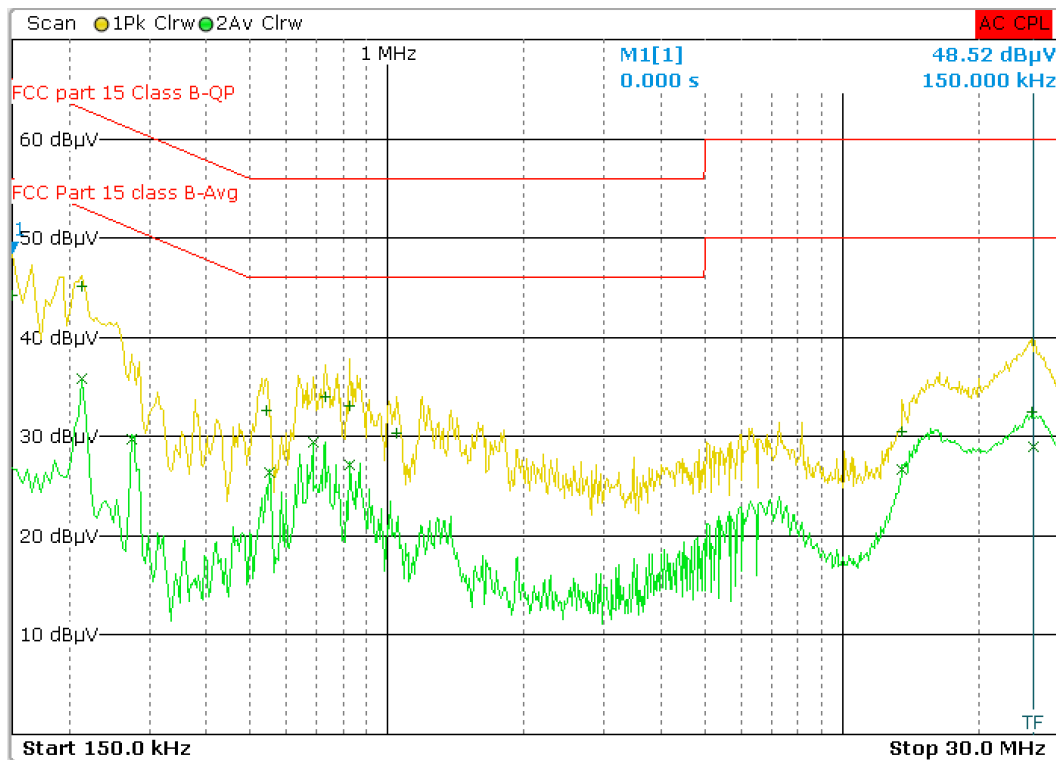
| Frequency of emission (MHz) | QP Limit (dBμV) | AV Limit (dBμV/m) |
|-----------------------------------|--------------------|----------------------|
| 0.15 – 0.5 | 66 – 56* | 56 – 46* |
| 0.5 – 5 | 56 | 46 |
| 5 – 30 | 60 | 50 |

* Decreases with the logarithm of the frequency

Test Result

110V AC_60Hz_Line

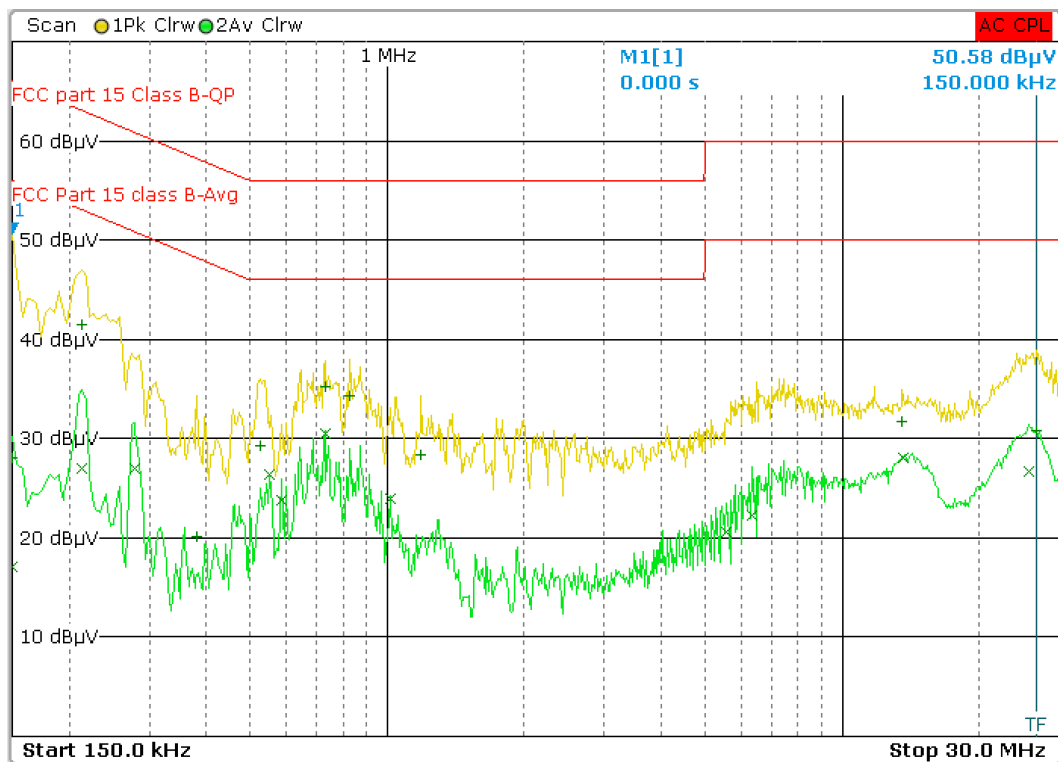
| Trace | Frequency | Level (dBµV) | Phase | Detector | Delta Limit/dB |
|-------|-------------------|--------------|-------|------------|----------------|
| 2 | 686.000000000 kHz | 29.49 | | Average | -16.51 |
| 2 | 214.000000000 kHz | 35.79 | | Average | -17.26 |
| 1 | 214.000000000 kHz | 45.12 | | Quasi Peak | -17.93 |
| 2 | 826.000000000 kHz | 27.09 | | Average | -18.91 |
| 2 | 550.000000000 kHz | 26.34 | | Average | -19.66 |
| 2 | 26.398000000 MHz | 29.02 | | Average | -20.98 |
| 2 | 274.000000000 kHz | 29.79 | | Average | -21.21 |
| 2 | 274.000000000 kHz | 29.71 | | Average | -21.29 |
| 1 | 150.000000000 kHz | 44.27 | | Quasi Peak | -21.73 |
| 1 | 730.000000000 kHz | 34.01 | | Quasi Peak | -21.99 |
| 1 | 826.000000000 kHz | 33.07 | | Quasi Peak | -22.93 |
| 2 | 13.562000000 MHz | 26.76 | | Average | -23.24 |
| 1 | 542.000000000 kHz | 32.59 | | Quasi Peak | -23.41 |
| 1 | 1.046000000 MHz | 30.36 | | Quasi Peak | -25.64 |
| 1 | 26.222000000 MHz | 32.44 | | Quasi Peak | -27.56 |
| 1 | 13.562000000 MHz | 30.49 | | Quasi Peak | -29.51 |



Line: Graph

110V AC_60Hz_Neutral

| Trace | Frequency | Level (dBµV) | Phase | Detector | Delta Limit/dB |
|-------|-------------------|--------------|-------|------------|----------------|
| 2 | 730.000000000 kHz | 30.56 | | Average | -15.44 |
| 2 | 550.000000000 kHz | 26.38 | | Average | -19.62 |
| 1 | 730.000000000 kHz | 35.28 | | Quasi Peak | -20.72 |
| 1 | 214.000000000 kHz | 41.55 | | Quasi Peak | -21.50 |
| 1 | 826.000000000 kHz | 34.31 | | Quasi Peak | -21.69 |
| 2 | 13.622000000 MHz | 28.04 | | Average | -21.96 |
| 2 | 1.014000000 MHz | 23.94 | | Average | -22.06 |
| 2 | 586.000000000 kHz | 23.79 | | Average | -22.21 |
| 2 | 25.682000000 MHz | 26.63 | | Average | -23.37 |
| 2 | 278.000000000 kHz | 26.94 | | Average | -23.94 |
| 2 | 214.000000000 kHz | 27.03 | | Average | -26.02 |
| 1 | 526.000000000 kHz | 29.32 | | Quasi Peak | -26.68 |
| 1 | 1.190000000 MHz | 28.30 | | Quasi Peak | -27.70 |
| 2 | 6.362000000 MHz | 22.23 | | Average | -27.77 |
| 1 | 13.558000000 MHz | 31.75 | | Quasi Peak | -28.25 |
| 1 | 26.818000000 MHz | 30.78 | | Quasi Peak | -29.22 |
| 2 | 5.578000000 MHz | 20.66 | | Average | -29.34 |
| 1 | 150.000000000 kHz | 28.07 | | Quasi Peak | -37.93 |
| 1 | 382.000000000 kHz | 20.13 | | Quasi Peak | -38.11 |
| 2 | 150.000000000 kHz | 17.06 | | Average | -38.94 |



Neutral: Graph

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| | | |
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*****END OF TEST REPORT*****