

FCC IC RF Test Report

Report No.: FCC_IC_RF_SL21011803-MED-004_Rev2.0

Models: 97800

FCC ID: LF597800

IC: 3408D-97800

Received Date: 06/24/2021

Test Date: 06/25/2021

Issued Date: 9/8/2022

Applicant name: Medtronic, Inc.

Address: 710 Medtronic Parkway N.E., Minneapolis, MN 55432

Manufacturer: Medtronic, Inc.

Address: 710 Medtronic Parkway N.E., Minneapolis, MN 55432

Issued By: Bureau Veritas Consumer Products Services, Inc.

Lab Address: 775 Montague Expressway, Milpitas, CA 95035

**FCC Registration /
Designation Number:** 540430

ISED# / CAB identifier: 4842D



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Release Control Record

| Issue No. | Description | Date Issued |
|-------------------------------------|--|-------------|
| FCC_IC_RF_SL21011803-MED-004 | Initial Release | 06/30/2021 |
| FCC_IC_RF_SL21011803-MED-004_Rev1.0 | Updated section 4.1.7 | 8/17/2022 |
| FCC_IC_RF_SL21011803-MED-004_Rev2.0 | Updated remark 5 on pg 13 and added remark 5 to pg 15. | 9/8/2022 |

1 Certificate of Conformity

Product: Ultra Low Power Active Medical Implant (ULP-AMI)

Brand: Medtronic

Test Model: 97800

Sample Status: Engineering sample

Applicant: Medtronic, Inc.

Test Date: 06/25/2021

Standards: 47 CFR FCC Part 15, Subpart C (Section 15.207/15.209)

ANSI C63.10:2013

RSS Gen Issue 5, March 2019

RSS-210 Issue 10 December 2019

The above equipment has been tested by **Bureau Veritas Consumer Products Services, Inc., Milpitas Branch**, and found compliance with the requirement of the above standards. The test record, data evaluation & Equipment Under Test (EUT) configurations represented herein are true and accurate accounts of the measurements of the sample's EMC characteristics under the conditions specified in this report.

Deon
Prepared by : _____, **Date:** _____
Deon Dai / Test Engineer

Gary Chou
Approved by : _____, **Date:** _____
Gary Chou / Engineer Reviewer

2 Summary of Test Results

| 47 CFR FCC Part 15, Subpart C (15.207/15.209) , RSS Gen Issue 5 | | | |
|---|-------------------------------|--------|--|
| FCC IC Clause | Test Item | Result | Remarks |
| 15.207 RSS Gen 8.8 | AC Power Conducted Emission | N/A | Work with battery |
| RSS Gen | Occupied Bandwidth | Pass | Referency Only |
| 15.209 RSS Gen | Transmitter Radiated Emission | Pass | Meet the requirement of limit. |
| 15.203 RSS Gen | Antenna Requirement | Pass | The EUT uses an Integral internal Antenna to permanently attach to the device. |

2.1 Measurement Uncertainty

Where relevant, the following measurement uncertainty levels have been estimated for tests performed on the EUT as specified in CISPR 16-4-2:

| Measurement | Frequency | Expanded Uncertainty (k=2) (\pm) |
|------------------------------------|----------------|--------------------------------------|
| Conducted Emissions at mains ports | 150kHz ~ 30MHz | 3.51dB |
| Radiated Emissions up to 1 GHz | 30MHz ~ 1GHz | 3.73dB |

2.2 Modification Record

There were no modifications required for compliance.

3 General Information

3.1 General Description of EUT

| | |
|---------------------|--|
| Product | Ultra Low Power Active Medical Implant (ULP-AMI) |
| Brand | Medtronic |
| Test Model | 97800 |
| Series Model | N/A |
| Model Difference | N/A |
| Status of EUT | Engineering sample |
| Power Supply Rating | Battery |
| Modulation Type | OOK burst, less than 1% duty cycle. |
| Operating Frequency | 175kHz |
| Number of Channel | 1 |
| Antenna Type | Integral internal antenna |
| Antenna Gain | None |

Note:

1. The above EUT information is declared by manufacturer and for more detailed features description, please refer to the manufacturer's specifications or user's manual.

3.2 Description of Test Modes

3.2.1 1 channel is provided to this EUT

| Channel | Freq. (MHz) |
|---------|-------------|
| 1 | 0.175 |

3.2.2 Test Mode Applicability and Tested Channel Detail

| EUT CONFIGURE MODE | APPLICABLE TO | | | | DESCRIPTION |
|--------------------|---------------|-----|----|----|---------------------------|
| | RE | PLC | FS | EB | |
| A | √ | - | - | √ | Power from battery |
| B | - | - | - | - | Power from USB via laptop |

Where **RE:** Radiated Emission
FS: Frequency Stability

PLC: Power Line Conducted Emission
EB: 20dB Bandwidth measurement

NOTE: The EUT had been pre-tested on the positioned of each 3 axis. The worst case was found when positioned on **Y-plane**.

NOTE: "-" means no effect.

Radiated Emission Test:

- Pre-Scan has been conducted to determine the worst-case mode from all possible combinations between available modulations, data rates and antenna ports (if EUT with antenna diversity architecture).
- Following channel(s) was (were) selected for the final test as listed below.

| EUT Configure Mode | Available Channel | Tested Channel | Modulation Type |
|--------------------|-------------------|----------------|-----------------|
| A | 1 | 1 | OOK |

Power Line Conducted Emission Test:

- Pre-Scan has been conducted to determine the worst-case mode from all possible combinations between available modulations, data rates and antenna ports (if EUT with antenna diversity architecture).
- Following channel(s) was (were) selected for the final test as listed below.

| EUT Configure Mode | Available Channel | Tested Channel | Modulation Type |
|--------------------|-------------------|----------------|-----------------|
| A | 1 | 1 | OOK |

Frequency Stability:

- Pre-Scan has been conducted to determine the worst-case mode from all possible combinations between available modulations, data rates and antenna ports (if EUT with antenna diversity architecture).
- Following channel(s) was (were) selected for the final test as listed below.

| EUT Configure Mode | Available Channel | Tested Channel | Modulation Type |
|--------------------|-------------------|----------------|-----------------|
| A | 1 | 1 | OOK |

Test Condition:

| APPLICABLE TO | ENVIRONMENTAL CONDITIONS | INPUT POWER | TESTED BY |
|---------------|--------------------------|-------------|-----------|
| RE | 25deg. C, 65%RH | 5Vdc | Deon Dai |
| EB | 25deg. C, 65%RH | 5Vdc | Deon Dai |

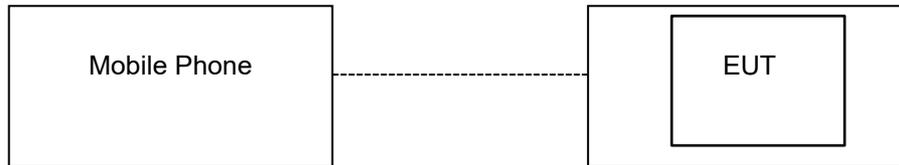
3.3 Description of Support Units

The EUT has been tested as an independent unit together with other necessary accessories or support units. The following support units or accessories were used to form a representative test configuration during the tests.

| ID | Product | Brand | Model No. | Serial No. | FCC ID | Remarks |
|----|--------------|-----------|-----------|------------|---------|----------------------|
| A. | Communicator | Medtronic | TM90 | NPA11462N | LF5TM90 | Provided by Customer |
| B. | Mobile Phone | Sunsang | Galaxy J3 | - | - | Provided by Customer |

| ID | Descriptions | Qty. | Length (m) | Shielding (Yes/No) | Cores (Qty.) | Remarks |
|----|--------------|------|------------|--------------------|--------------|---------|
| 1. | - | - | - | - | - | - |

3.3.1 Configuration of System under Test



3.4 General Description of Applied Standards

The EUT is a RF Product. According to the specifications of the manufacturer, it must comply with the requirements of the following standards:

47 CFR FCC Part 15, Subpart C (Section 15.207)

47 CFR FCC Part 15, Subpart C (Section 15.209)

ANSI C63.10:2013

RSS Gen Issue 5, March 2019

RSS-210 Issue 10 December 2019

All test items have been performed and recorded as per the above standards.

4 Test Types and Results

4.1 Radiated Emission Measurement

4.1.1 Limits of Radiated Emission Measurement

| Frequencies (MHz) | Field Strength (microvolts/meter) | Measurement Distance (meters) |
|-------------------|-----------------------------------|-------------------------------|
| 0.009 ~ 0.490 | 2400/F(kHz) | 300 |
| 0.490 ~ 1.705 | 24000/F(kHz) | 30 |
| 1.705 ~ 30.0 | 30 | 30 |
| 30 ~ 88 | 100 | 3 |
| 88 ~ 216 | 150 | 3 |
| 216 ~ 960 | 200 | 3 |
| Above 960 | 500 | 3 |

NOTE:

1. The lower limit shall apply at the transition frequencies.
2. Distance extrapolation factor = $40 \log (\text{specific distance} / \text{test distance})$
 Limit Line (dBuV/m) = $20 \log \text{Emission level (uV/m)} + \text{Distance extrapolation factor}$
3. 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.
4. For frequencies above 1000MHz, the field strength limits are based on average detector, however, the peak field strength of any emission shall not exceed the maximum permitted average limits, specified above by more than 20dB under any condition of modulation.

4.1.2 Test Instruments

| DESCRIPTION & MANUFACTURER | MODEL NO. | SERIAL NO. | DATE OF CALIBRATION | DUE DATE OF CALIBRATION |
|------------------------------------|-----------|--------------------------|---------------------|-------------------------|
| EMI Test Receiver Keysight | ESW 44 | 1328.4100K- 101662-MH | 08/30/2020 | 08/30/2021 |
| Passive Loop Antenna (9k-30MHz) | 6512 | 49120 | 11/25/2019 | 11/25/2021 |
| Preamplifier RF Bay, Inc. | LNA-150 | 12170607 | 06/18/2021 | 06/18/2022 |

4.1.3 Test Procedures

For Radiated emission below 30MHz

- a. The EUT was placed on the top of a rotating table 0.8 meters above the ground at a 3 meter chamber room. The table was rotated 360 degrees to determine the position of the highest radiation.
- b. The EUT was set 3 meters away from the interference-receiving antenna, which was mounted on the top of a variable-height antenna tower.
- c. Parallel, perpendicular, and ground-parallel orientations of the antenna are set to make the measurement.
- d. For each suspected emission, the EUT was arranged to its worst case and the rotatable table was turned from 0 degrees to 360 degrees to find the maximum reading.
- e. The test-receiver system was set to Quasi-Peak Detect Function and Specified Bandwidth with Maximum Hold Mode.

NOTE:

1. The resolution bandwidth and video bandwidth of test receiver/spectrum analyzer is 9 kHz at frequency below 30MHz.

For Radiated emission above 30MHz

- a. The EUT was placed on the top of a rotating table 0.8 meters (for 30MHz ~ 1GHz) / 1.5 meters (for above 1GHz) above the ground at 3 meter chamber room for test. The table was rotated 360 degrees to determine the position of the highest radiation.
- b. The EUT was set 3 meters away from the interference-receiving antenna, which was mounted on the top of a variable-height antenna tower.
- c. The height of antenna is varied from one meter to four meters above the ground to determine the maximum value of the field strength. Both horizontal and vertical polarizations of the antenna are set to make the measurement.
- d. For each suspected emission, the EUT was arranged to its worst case and then the antenna was tuned to heights from 1 meter to 4 meters and the rotatable table was turned from 0 degrees to 360 degrees to find the maximum reading.
- e. The test-receiver system was set to quasi-peak detect function and specified bandwidth with maximum hold mode when the test frequency is below 1 GHz.
- f. The test-receiver system was set to peak and average detects function and specified bandwidth with maximum hold mode when the test frequency is above 1 GHz. If the peak reading value also meets average limit, measurement with the average detector is unnecessary.

Note:

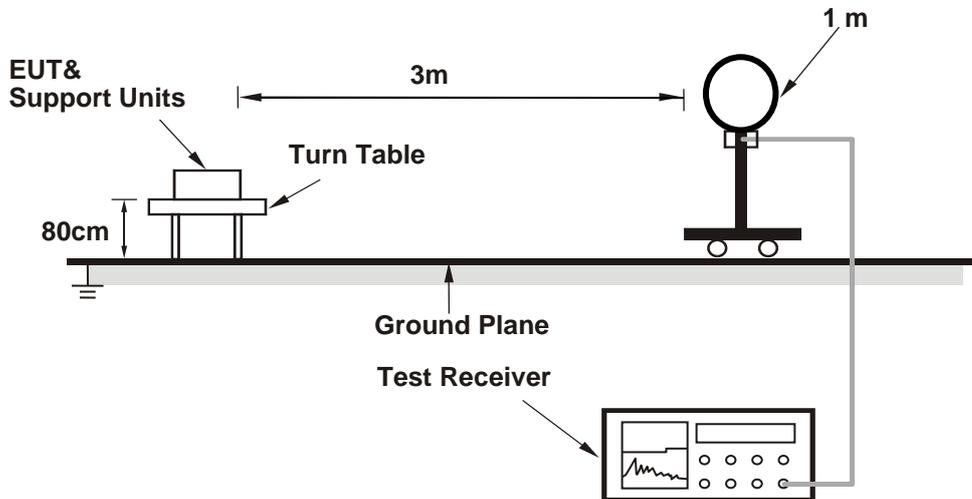
1. The resolution bandwidth and video bandwidth of test receiver/spectrum analyzer is 120 kHz for Quasi-peak detection (QP) at frequency below 1GHz.
2. The resolution bandwidth of test receiver/spectrum analyzer is 1 MHz and the video bandwidth is 3 MHz for Peak detection (PK) at frequency above 1GHz.
3. The resolution bandwidth of test receiver/spectrum analyzer is 1MHz and the video bandwidth is $\geq 1/T$ (Duty cycle < 98%) or 10Hz (Duty cycle $\geq 98\%$) for Average detection (AV) at frequency above 1GHz.
4. All modes of operation were investigated and the worst-case emissions are reported.

4.1.4 Deviation from Test Standard

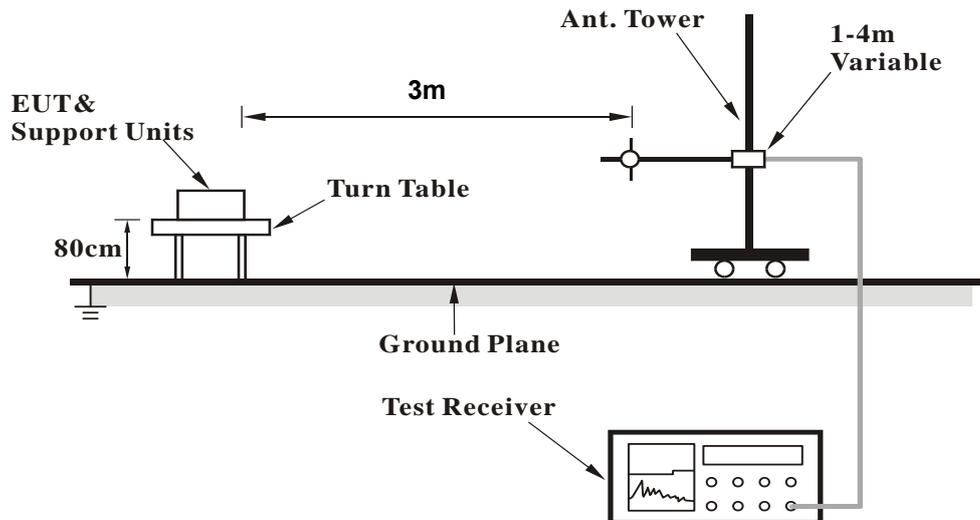
No deviation.

4.1.5 Test Setup

For Radiated emission below 30MHz



For Radiated emission 30MHz to 1GHz



4.1.6 EUT Operating Conditions

- a. Set the EUT work at continue transmit mode.

4.1.7 Test Results

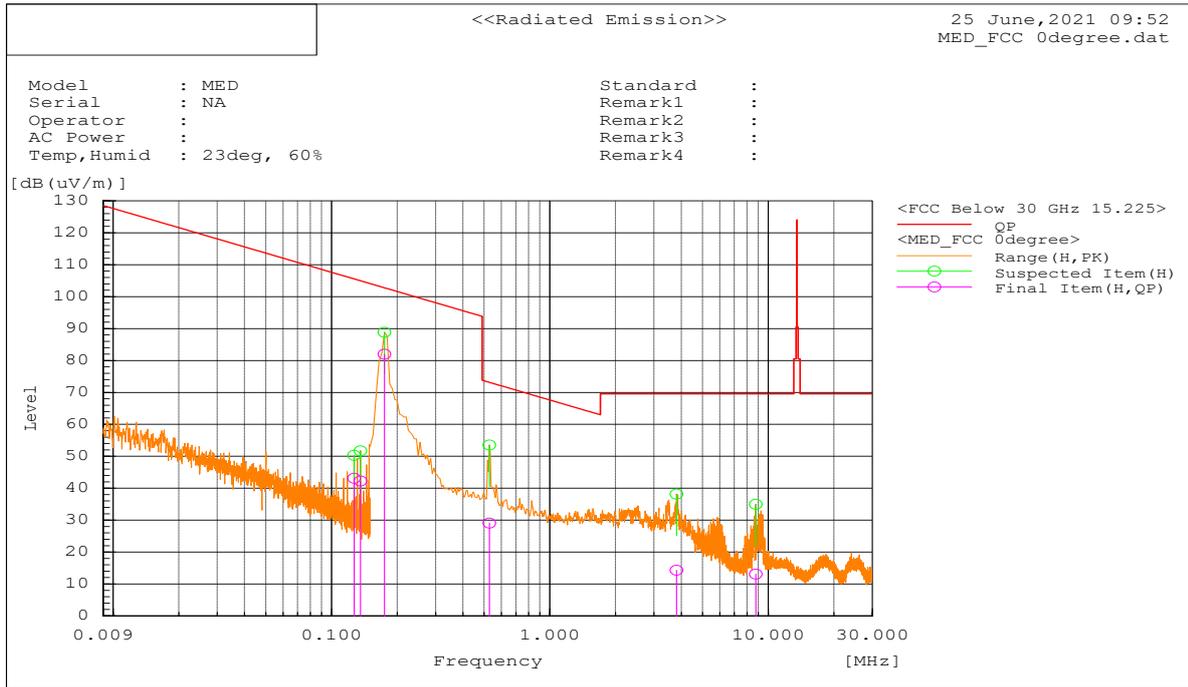
Radiated Emissions (9 kHz~30 MHz)

| EUT Test Condition | | Measurement Detail | |
|--------------------|---------|--------------------|----------------------|
| Frequency | 175KHz | Frequency Range | 9 kHz~30 MHz |
| Input Power | Battery | Detector Function | Quasi-Peak (Average) |

| Antenna Polarity & Test Distance: Loop Antenna 0 degree At 3m | | | | | | | | | | |
|---|-----------------|---------------------|-------------------------|------------------|-------------------------|------------------------|--------------------|-------------|-------------|-----------|
| No. | Frequency (MHz) | Polarization (0/90) | Reading QP(AV) [dB(uV)] | Factor [dB(1/m)] | Level QP(AV) [dB(uV/m)] | Limit QP (AV) dB(uV/m) | Margin QP(AV) [dB] | Height (cm) | Angle (Deg) | Pass/Fail |
| 1 | 0.127 | 0 | 13.8 | 29.3 | 43.1 | 105.5 | -62.4 | 100 | 0.1 | Pass |
| 2 | 0.136 | 0 | 13.4 | 28.8 | 42.2 | 105 | -62.8 | 100 | 0 | Pass |
| 3 | 0.175 | 0 | 54.8 | 27.1 | 81.9 | 102.7 | -20.8 | 100 | 321 | Pass |
| 4 | 0.528 | 0 | 11.1 | 18 | 29.1 | 73.1 | -44 | 100 | 357 | Pass |
| 5 | 3.807 | 0 | 10.8 | 3.5 | 14.3 | 69.5 | -55.2 | 100 | 261 | Pass |
| 6 | 8.772 | 0 | 10.7 | 2.4 | 13.1 | 69.5 | -56.4 | 100 | 351 | Pass |

REMARKS:

1. Level (dBuV) = Reading (dBuV) + Factor (dB(1/m)).
2. Factor (dB(1/m)) = Antenna Factor(AF) (dB(1/m)) + Cable Loss (dB)
3. Margin value = Emission level – Limit value.
4. Here the frequency bands 9-90 kHz and 110-490 kHz are use average detector.
5. The limits in CFR 47, Part 15, Subpart C, paragraph 15.209 (a), are identical to those in RSS-GEN Section 8.9, Table 6, since the measurements are performed in terms of magnetic field strength and converted to electric field strength levels (as reported in the table) using the free space impedance of 377Ω. For example, the measurement frequency 11 KHz resulted in a level of 62.6 dBuV/m, which is equivalent to 62.6 -51.5 = 11.1 dBuA/m, which has the same margin, 64.2 dB, to the corresponding RSS-GEN Table 6 limit as it has to the 15.209(a) limit.

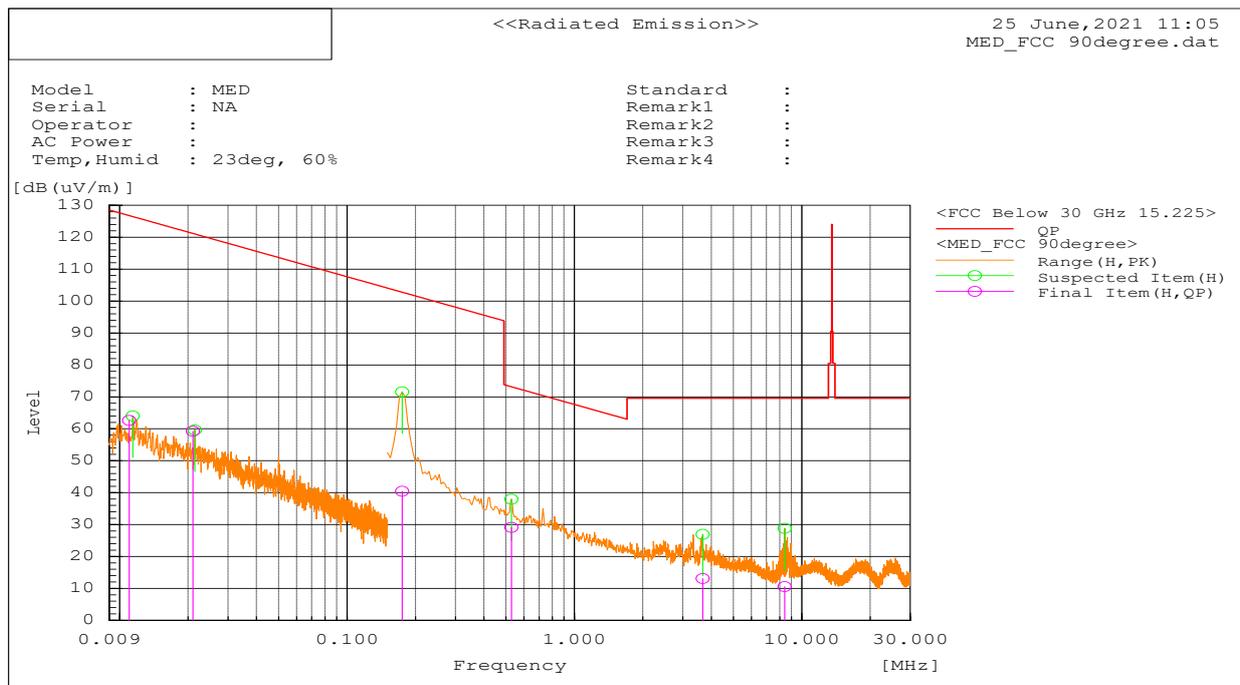


| EUT Test Condition | | Measurement Detail | |
|--------------------|---------|--------------------|----------------------|
| Frequency | 175KHz | Frequency Range | 9 kHz~30 MHz |
| Input Power | Battery | Detector Function | Quasi-Peak (Average) |

| Antenna Polarity & Test Distance: Loop Antenna 0 degree At 3m | | | | | | | | | | |
|---|-----------------|---------------------|-------------------------|------------------|-------------------------|------------------------|--------------------|-------------|-------------|-----------|
| No. | Frequency (MHz) | Polarization (0/90) | Reading QP(AV) [dB(uV)] | Factor [dB(1/m)] | Level QP(AV) [dB(uV/m)] | Limit QP (AV) dB(uV/m) | Margin QP(AV) [dB] | Height (cm) | Angle (Deg) | Pass/Fail |
| 1 | 0.011 | 90 | 11.2 | 51.4 | 62.6 | 126.8 | -64.2 | 100 | 4.2 | Pass |
| 2 | 0.021 | 90 | 12.5 | 46.7 | 59.2 | 121.2 | -62 | 100 | 0 | Pass |
| 3 | 0.528 | 90 | 11.1 | 18 | 29.1 | 73.1 | -44 | 100 | 189 | Pass |
| 4 | 3.667 | 90 | 9.4 | 3.7 | 13.1 | 69.5 | -56.4 | 100 | 189 | Pass |
| 5 | 8.413 | 90 | 8.1 | 2.5 | 10.6 | 69.5 | -58.9 | 100 | 3.2 | Pass |
| 6 | 0.175 | 90 | 13.3 | 27.1 | 40.4 | 102.7 | -62.3 | 100 | 0 | Pass |

REMARKS:

1. Level (dBuV) = Reading (dBuV) + Factor (dB(1/m)).
2. Factor (dB(1/m)) = Antenna Factor(AF) (dB(1/m)) + Cable Loss (dB)
3. Margin value = Emission level – Limit value.
4. Here the frequency bands 9-90 kHz and 110-490 kHz are use average detector.
5. The limits in CFR 47, Part 15, Subpart C, paragraph 15.209 (a), are identical to those in RSS-GEN Section 8.9, Table 6, since the measurements are performed in terms of magnetic field strength and converted to electric field strength levels (as reported in the table) using the free space impedance of 377Ω. For example, the measurement frequency 11 KHz resulted in a level of 62.6 dBuV/m, which is equivalent to 62.6 -51.5 = 11.1 dBuA/m, which has the same margin, 64.2 dB, to the corresponding RSS-GEN Table 6 limit as it has to the 15.209(a) limit.



4.2 Occupied Bandwidth

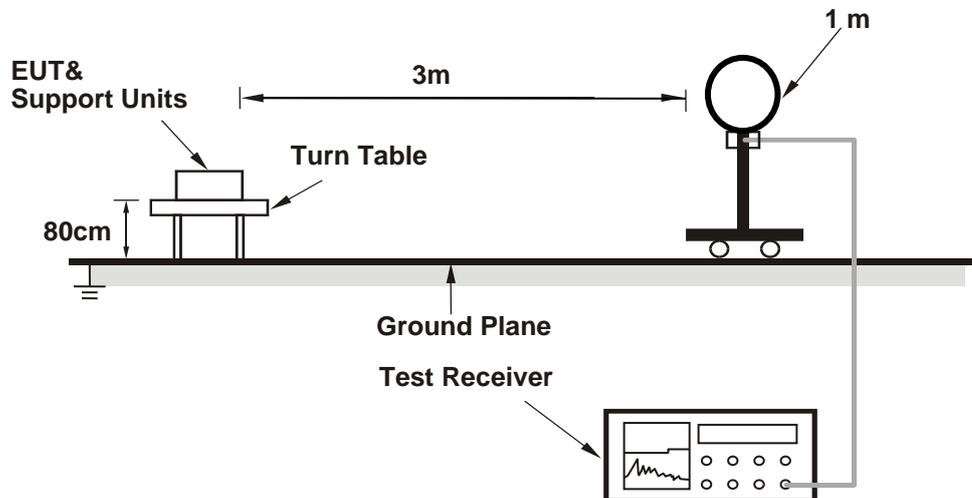
4.2.1 Test Instruments

| DESCRIPTION & MANUFACTURER | MODEL NO. | SERIAL NO. | DATE OF CALIBRATION | DUE DATE OF CALIBRATION |
|------------------------------------|-----------|------------|---------------------|-------------------------|
| Spectrum Analyzer Keysight | N9010A | MY51440112 | 10/23/2020 | 10/23/2021 |
| Passive Loop Antenna (9k-30MHz) | 6512 | 49120 | 11/25/2019 | 11/25/2021 |

4.2.2 Test Procedures

- Set resolution bandwidth (RBW) = 9 kHz
- Set the video bandwidth (VBW) $\geq 3 \times$ RBW, Detector = Peak.
- Trace mode = max hold.
- Sweep = auto couple.
- Measure the 20dB bandwidth (IC: 99% emission bandwidth)

4.2.3 Test Setup



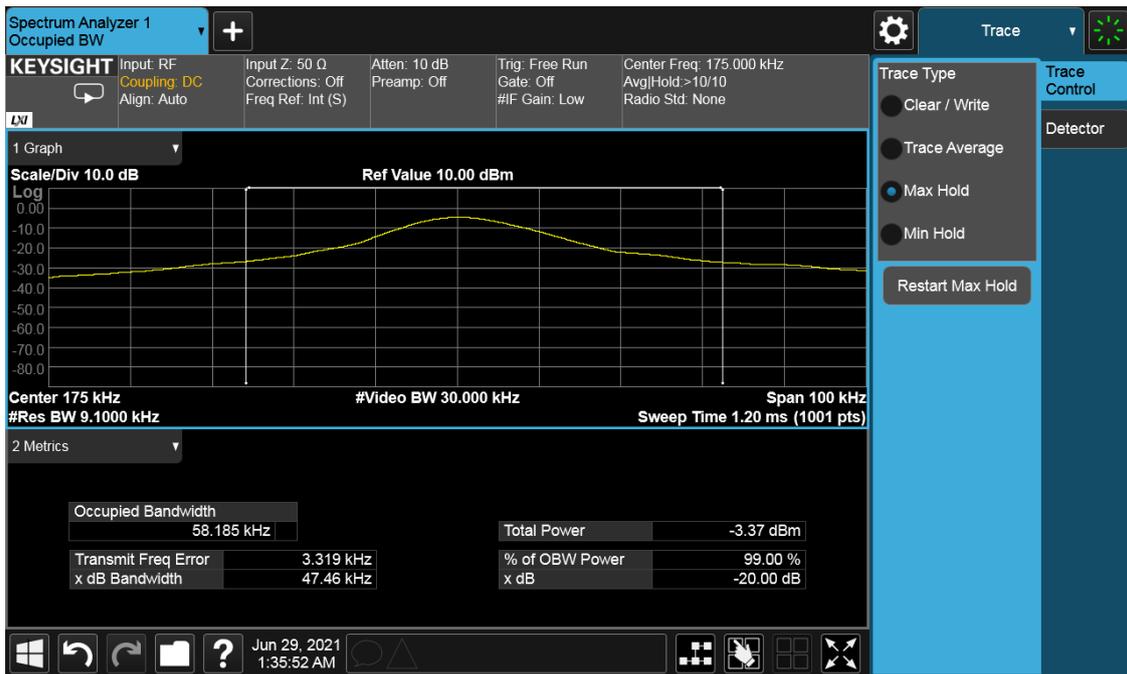
4.2.4 EUT Operating Conditions

- Set the EUT work at continue transmit mode.

4.2.5 Test Results

| Frequency (KHz) | 20 dB Bandwidth (KHz) | 99% Bandwidth (KHz) |
|-----------------|-----------------------|---------------------|
| 175 | 47.46 | 58.185 |

Test Plots:



Note: This measurement was taken using the Radiated method. No attenuators and filters were used for the measurement.

4.3 Conducted Emission Measurement

4.3.1 Limits of Conducted Emission Measurement

| Frequency (MHz) | Conducted Limit (dBuV) | |
|-----------------|------------------------|---------|
| | Quasi-peak | Average |
| 0.15 - 0.5 | 66 - 56 | 56 - 46 |
| 0.50 - 5.0 | 56 | 46 |
| 5.0 - 30.0 | 60 | 50 |

Note: 1. The lower limit shall apply at the transition frequencies.

2. The limit decreases in line with the logarithm of the frequency in the range of 0.15 to 0.50MHz.

4.3.2 Test Instruments

| Description & Manufacturer | Model No. | Serial No. | Date Of Calibration | Due Date Of Calibration |
|--------------------------------------|-----------|------------|---------------------|-------------------------|
| EMI Test Receiver ROHDE & SCHWARZ | ESIB 40 | 100179 | 01/29/2021 | 01/29/2022 |
| Transient Limiter ELECTRO-METRICS | EM-7600-5 | 106 | 01/29/2021 | 01/29/2022 |
| LISN EMCO | 3816/2NM | 214372 | 01/29/2021 | 01/29/2022 |

4.3.3 Test Procedures

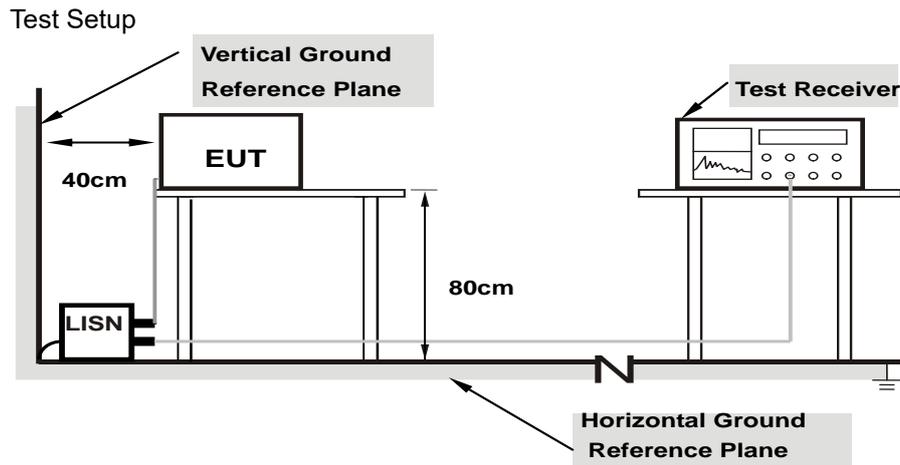
- a. The EUT was placed 0.4 meters from the conducting wall of the shielded room with EUT being connected to the power mains through a line impedance stabilization network (LISN). Other support units were connected to the power mains through another LISN. The two LISNs provide 50 ohm/ 50uH of coupling impedance for the measuring instrument.
- b. Both lines of the power mains connected to the EUT were checked for maximum conducted interference.
- c. The frequency range from 150 kHz to 30MHz was searched. Emission levels under (Limit - 20dB) was not recorded.

NOTE: The resolution bandwidth and video bandwidth of test receiver is 9 kHz for quasi-peak detection (QP) and average detection (AV) at frequency 0.15MHz-30MHz.

4.3.4 Deviation from Test Standard

No deviation.

4.3.5



Note: 1.Support units were connected to second LISN.

For the actual test configuration, please refer to the attached file (Test Setup Photo).

4.3.6 EUT Operating Conditions

Same as 4.1.6.

4.3.7 Test Results

N/A (Work with battery)

5 Pictures of Test Arrangements

Please see setup photo file.

Appendix – Information on the Testing Laboratories

Bureau Veritas is a global leader in testing, inspection and certification (TIC) services. We help businesses improve safety, sustainability and productivity; and our clients include the majority of leading brands in retail, manufacturing and other industries. With a presence in every major country around the world, our quality assurance and compliance solutions are vital in helping our customers enhance product quality and concept-to-consumer journeys. We also assist with increasing speed to market, profitability and brand equity throughout the supply chain. Bureau Veritas is a leading wireless/IoT testing, inspection, audit and certification provider, with a global network of test laboratories to support the IoT industry in areas of connectivity, security, interoperability as well as quality, health & safety, and environmental/chemical requirements.

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The address and road map of all our labs can be found in our web site also.

--- END ---