




| RADIO REPORT FCC 47 CFR Part 15C ISED Canada RSS-210 License exempt radio equipment | |
|--|--|
| Report Reference No | G0M-1905-8256-TFC209LP-V01 |
| Testing Laboratory | Eurofins Product Service GmbH |
| Address | Storkower Str. 38c 15526 Reichenwalde Germany |
| Accreditation |  <p>A2LA Accredited Testing Laboratory, Certificate No.: 1983.01 FCC Test Firm Designation Number: DE0008 ISED Testing Laboratory site: 3470A-2</p> |
| Applicant | BIOTRONIK SE & Co. KG |
| Address | Woermannkehre 1 12359 Berlin GERMANY |
| Test Specification | According to FCC/ISED rules |
| Standard | 47 CFR Part 15C RSS-210, Issue 9, 2016-08 |
| Non-Standard Test Method | None |
| Equipment under Test (EUT): | |
| Product Description | programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs |
| Model(s) | Renamic Neo |
| Additional Model(s) | None |
| Brand Name(s) | BIOTRONIK |
| Hardware Version(s) | A.x |
| Software Version(s) | RIO_PGFW_1_18_x |
| FCC-ID | QRI-RENAMICNEO |
| IC | 4708A-RENAMICNEO |
| Test Result | PASSED |

| | | |
|--|------------------|--|
| Possible test case verdicts: | | |
| required by standard but not tested | N/T | |
| not required by standard | N/R | |
| not applicable to EUT | N/A | |
| test object does meet the requirement | P(PASS) | |
| test object does not meet the requirement | F(FAIL) | |
| Testing: | | |
| Test Lab Temperature | 20 - 23 °C | |
| Test Lab Humidity | 32 – 38 % | |
| Date of receipt of test item | 2019-05-22 | |
| Report: | | |
| Compiled by | Wilfried Treffke | |
| Tested by (+ signature) (Responsible for Test) | Wilfried Treffke |  |
| Approved by (+ signature) (Head of Lab) | Christian Weber |  |
| Date of Issue | 2019-12-17 | |
| Total number of pages | 32 | |
| General Remarks: | | |
| <p>The test results presented in this report relate only to the object tested.</p> <p>The results contained in this report reflect the results for this particular model and serial number. It is the responsibility of the manufacturer to ensure that all production models meet the intent of the requirements detailed within this report.</p> <p>This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.</p> | | |
| Additional Comments: | | |
| | | |

VERSION HISTORY

| Version History | | | |
|-----------------|------------|-----------------|------------|
| Version | Issue Date | Remarks | Revised By |
| 01 | 2019-12-17 | Initial Release | |

ABBREVIATIONS AND ACRONYMS

| Acronyms | |
|------------------|---|
| Acronym | Description |
| EUT | Equipment Under Test |
| FCC | Federal Communications Commission |
| ISED | Innovation, Science and Economic Development Canada |
| RBW | Resolution bandwidth |
| RMS | Root mean square |
| VBW | Video bandwidth |
| V _{NOM} | Nominal supply voltage |

REPORT INDEX

| | | |
|----------|---|-----------|
| 1 | Equipment (Test Item) Under Test..... | 6 |
| 1.1 | Photos – Equipment External..... | 7 |
| 1.2 | Photos – Equipment Internal..... | 13 |
| 1.4 | Support Equipment..... | 19 |
| 1.5 | Test mode duty cycle..... | 20 |
| 1.6 | Test Modes..... | 22 |
| 1.7 | Test Frequencies..... | 23 |
| 1.8 | Sample emission level calculation..... | 24 |
| 2 | Result Summary..... | 25 |
| 3 | Test Conditions and Results..... | 26 |
| 3.1 | Test Conditions and Results - Occupied bandwidth..... | 26 |
| 3.2 | Test Conditions and Results - Fundamental field strength emissions..... | 29 |
| 3.3 | Test Conditions and Results - Receiver radiated emissions..... | 31 |

1 Equipment (Test Item) Under Test

| | | |
|---------------------------|---|----------------------|
| Description | programming device for BIOTRONIK pacemakers, ICDs, CRT-devices and ICMs | |
| Model | Renamic Neo | |
| Additional Model(s) | None | |
| Brand Name(s) | BIOTRONIK | |
| Serial Number(s) | 80001071 | |
| Hardware Version(s) | A.x | |
| Software Version(s) | RIO_PGFW_1_18_x | |
| PMN | Renamic Neo | |
| HVIN | Renamic Neo | |
| FVIN | N/A | |
| HMN | N/A | |
| FCC-ID | QRI-RENAMICNEO | |
| IC | 4708A-RENAMICNEO | |
| Equipment type | End Product | |
| Radio type | Transceiver | |
| Operating frequency range | 64 kHz | |
| Radio technology | ULP-AMI | |
| Modulation | OOK | |
| Number of antenna ports | 1 | |
| Antenna type | Inductive loop coil transmitter | |
| Antenna | Type | Integrated |
| | Model | Programming Head |
| | Manufacturer | BIOTRONIK SE & Co KG |
| | Gain | Not specified |
| Supply Voltage | V_{NOM} | 120 VAC |
| Operating Temperature | T_{NOM} | 25 °C |
| AC/DC-Adaptor | Model | ATM090T-P190 |
| | Vendor | Adapter Tech |
| | Input | 100 VAC – 240 VAC |
| | Output | 19 VDC |
| Manufacturer | BIOTRONIK SE & Co. KG Woermannkehre 1 12359 Berlin GERMANY | |

1.4 Support Equipment

| Product Type | Device | Manufacturer | Model | Comment |
|--------------|-------------------------------------|----------------------|-------------|---------|
| AE 1 | Companion device for coil telemetry | BIOTRONIK SE & Co KG | Implant | - |
| AE 2 | Programing head | BIOTRONIK SE & Co KG | Renamic PGH | - |
| Description: | | | | |
| AE | Auxiliary Equipment | | | |
| SIM | Simulator | | | |
| CBL | Connecting Cable | | | |
| SFT | Software | | | |
| Comment: | | | | |

1.5 Test mode duty cycle

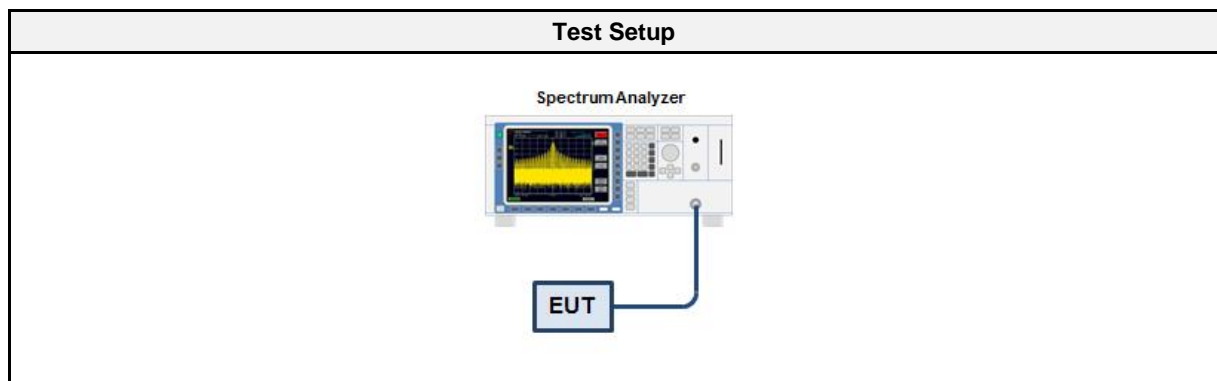
1.5.1 Information

| Test Information | |
|--------------------|------------------|
| Measurement Method | ANSI C63.10 11.6 |

1.5.2 Requirements

| Requirements | |
|--------------|---|
| Duty cycle | Duty cycle correction |
| ≥ 98 % | No correction required |
| < 98 % | Correction required ($10 \times \log_{10}(1/DC)$) |

1.5.3 Setup



1.5.4 Equipment

| Test Equipment | | | | | |
|-------------------|--------------|-------|------------|-----------|----------|
| Description | Manufacturer | Model | Identifier | Cal. Date | Cal. Due |
| Spectrum Analyzer | R&S | FSU 3 | EF00241 | 2017-07 | 2019-07 |

1.5.5 Procedure

| Test Procedure |
|--|
| <ol style="list-style-type: none"> 1. EUT set to test mode 2. Span is set to zero span 3. Detector set to peak 4. Sweep time is set long enough to capture at least 5 bursts 5. Envelope peak value of emission spectrum is selected 6. The maximum burst duration T_{ON} is measured using two markers set to the start and the end of the longest burst 7. The minimum idle duration T_{OFF} is measured using two markers set to the start and the end of the shortest idle period 8. The duty cycle is calculated by $DC = T_{ON} / (T_{ON} + T_{OFF})$ 9. The duty cycle correction is calculated by $DC = 10 \times \log_{10}(T_{ON} / (T_{ON} + T_{OFF}))$ |

1.5.6 Results

| Duty Cycle Results | | |
|--------------------|------------|------------------------|
| Mode | Duty Cycle | Correction Factor [dB] |
| Transmit | 1 (100%) | 0 |

1.6 Test Modes

| Mode | Description |
|----------|---|
| Transmit | Mode = Transmit Modulation = OOK Duty cycle = 100 % |
| Receive | Mode = Receive Modulation = OOK |
| Comment: | |

1.7 Test Frequencies

| Designator | Mode | Channel | Frequency [kHz] |
|------------|-------|---------|-----------------|
| F1 | Tx/RX | F1 | 64 |

1.8 Sample emission level calculation

The following is a description of terms and a sample calculation, as appears in the radiated emissions data table. The numbers used in the calculation are for example only. There is no direct correlation to the specific data taken for the product described in this document:

Reading:

This is the reading obtained on the spectrum analyzer in dBµV. Any external preamplifiers used are taken into account through internal analyzer settings.

A.F.:

This is the antenna factor for the receiving antenna. It is a conversion factor, which converts electric fields strengths to voltages, which can be measured directly on the spectrum analyzer. It is treated as a loss in dB. Cable losses have been included with the A.F. to simplify the calculations. The antenna factor is used in calculations as follows:

$$\text{Reading on Analyzer (dB}\mu\text{V)} + \text{A.F. (dB)} = \text{Net field strength (dB}\mu\text{V/m)}$$

Net:

This is the net field strength measurement (as shown above).

Limit:

This is the FCC Class B radiated emission limit (in units of dBµV/m). The FCC limits are given in units of µV/m. The following formula is used to convert the units of µV/m to dBµV/m:

$$\text{Limit (dB}\mu\text{V/m)} = 20 \cdot \log(\mu\text{V/m})$$

Margin:

This is the margin of compliance below the FCC limit. The units are given in dB. A negative margin indicates the emission was below the limit. A positive margin indicates that the emission exceeds the limit.

Example only:

| | | | | | |
|--------------|-----------------------|---|-------------|---------------|-----------|
| Reading + AF | = Net Reading | : | Net reading | - FCC limit | = Margin |
| +21.5 dBµV | + 26 dB = 47.5 dBµV/m | : | 47.5 dBµV/m | - 57.0 dBµV/m | = -9.5 dB |

2 Result Summary

| FCC 47 CFR Part 15C, ISED RSS-247 | | | | |
|--|---|------------------|--------|--------------------|
| Product Standard Reference | Requirement | Reference Method | Result | Remarks |
| ISED RSS-Gen 6.6 Issue 5 | Occupied Bandwidth | ANSI C63.10-2013 | N/R | Informational only |
| FCC 15.35(c) ISED RSS-Gen 6.10 Issue 5 | Duty Cycle | ANSI C63.10-2013 | N/R | Information only |
| FCC 15.209 ISED RSS-210 4.3, 4.4 Issue 9 | Fundamental field strength emissions | ANSI C63.10-2013 | PASS | |
| ISED RSS-210 3.1 Issue 9 ISED RSS-Gen 7.1 Issue 5 | Receiver radiated spurious emissions | ANSI C63.10-2013 | PASS | |
| Comment: | | | | |

| Possible Test Case Verdicts | |
|-----------------------------|--|
| PASS | Test object does meet the requirements |
| FAIL | Test object does not meet the requirements |
| N/T | Required by standard but not tested |
| N/R | Not required by standard for the test object |

3 Test Conditions and Results

3.1 Test Conditions and Results - Occupied bandwidth

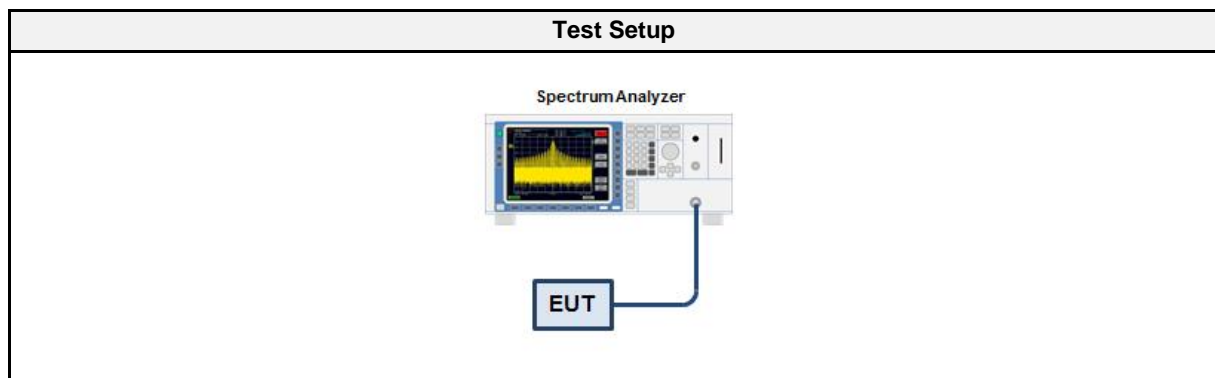
3.1.1 Information

| Test Information | |
|--------------------|-------------------|
| Reference | ISED RSS-Gen 6.6 |
| Measurement Method | ANSI C63.10 6.9.3 |
| Operator | Wilfried Treffke |
| Date | 2019-07-09 |

3.1.2 Limits

| Limits |
|---------------------------|
| None (Informational only) |

3.1.3 Setup



3.1.4 Equipment

| Test Equipment | | | | | |
|-------------------|--------------|-------|------------|-----------|----------|
| Description | Manufacturer | Model | Identifier | Cal. Date | Cal. Due |
| Spectrum Analyzer | R&S | FSU 3 | EF00241 | 2017-07 | 2019-07 |

3.1.5 Procedure

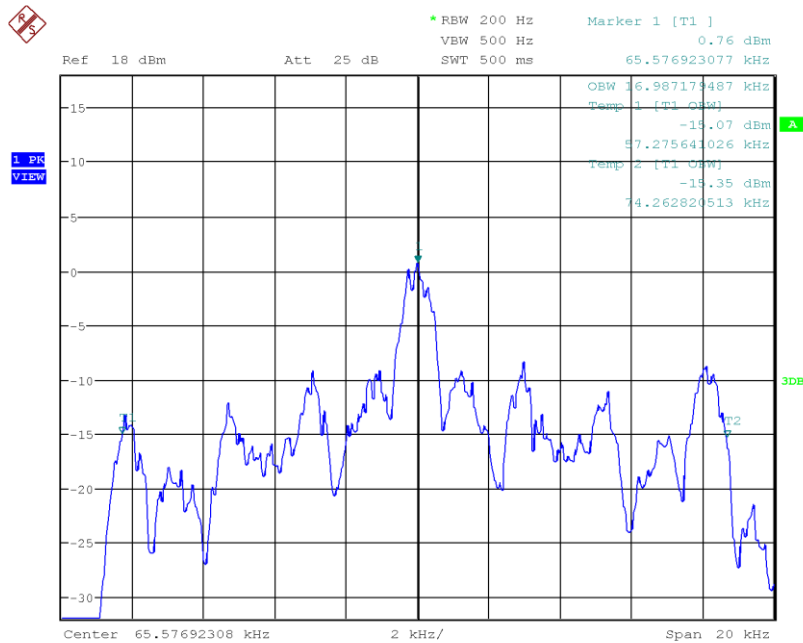
| Test Procedure |
|--|
| <ol style="list-style-type: none"> 1. EUT transmitter is activated in test mode under normal conditions 2. The spectrum analyzer is set to peak detection and maximum hold with a span twice the emission spectrum 3. Resolution bandwidth set to 1% to 5% of Occupied Bandwidth 4. The occupied bandwidth (99%) is measured with the build-in analyzer function |

3.1.6 Results

| Test Results | | |
|--------------|------------------|--------------------|
| Mode | Channel [kHz] | Bandwidth [kHz] |
| Transmit | 64 | 17.0 |

Occupied Bandwidth acc. to RSS-Gen

Project Number: G0M-1905-8256
 Applicant: Biotronik SE & Co.KG
 Model Description: Renamic Neo Programming
 Model: Renamic Neo
 Test Sample ID: 24166
 Operator: Wilfried Treffke
 Test Site: Eurofins Product Service GmbH
 Test Date: 2019-07-09
 Operating Conditions: Tnom/Vnom
 Mode: Tx 64 kHz
 Note 1: A spectrum analyzer with an integrated 99% power bandwidth function is used
 Note 2: Near-field measurement test fixture / 64 kHz system



Date: 9.JUL.2019 04:38:57

3.2 Test Conditions and Results - Fundamental field strength emissions

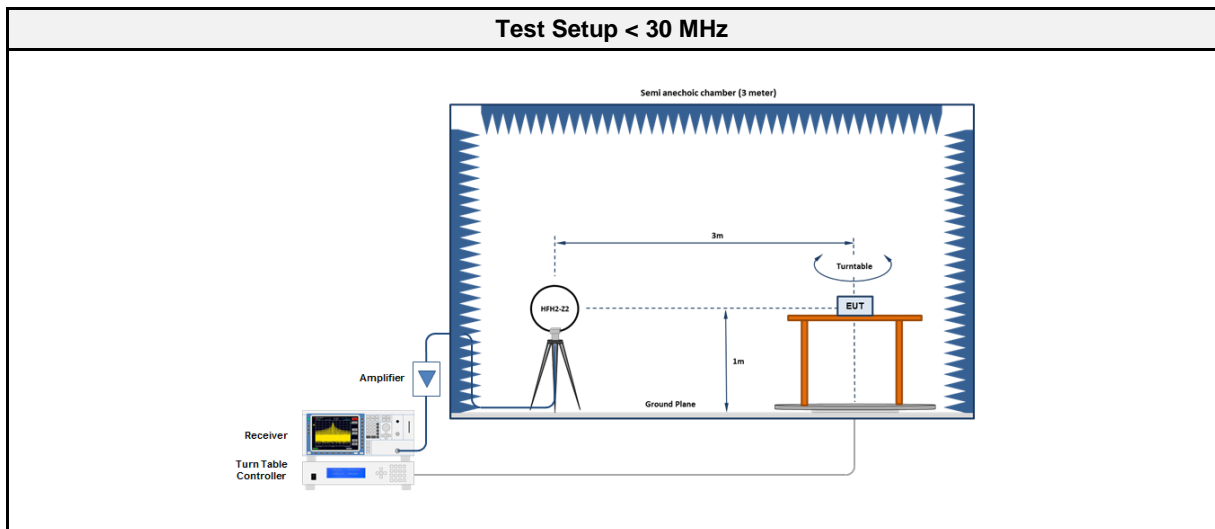
3.2.1 Information

| Test Information | |
|--------------------|------------------------------------|
| Reference | FCC 15.209 / ISED RSS-210 4.3, 4.4 |
| Measurement Method | ANSI C63.10 |
| Operator | Select operator from list |
| Date | 2019-07-09 |

3.2.2 Limits

| Limits | | | | |
|-----------------------|------------|----------------------------------|---|--------------------|
| Frequency range [MHz] | Detector | Limit [$\mu\text{V}/\text{m}$] | Limit [$\text{dB}\mu\text{V}/\text{m}$] | Limit Distance [m] |
| 0.009 - 0.490 | Quasi-Peak | 2400/F[kHz] | 48.5 - 13.8 | 300 |
| 0.490 - 1.705 | Quasi-Peak | 2400/F[kHz] | 13.8 - 1.4 | 30 |
| 1.705 - 30 | Quasi-Peak | 30 | 29.5 | 30 |
| 30 - 88 | Quasi-Peak | 100 | 40 | 3 |
| 88 - 216 | Quasi-Peak | 150 | 43.5 | 3 |
| 216 - 960 | Quasi-Peak | 200 | 46 | 3 |
| 960 - 1000 | Quasi-Peak | 500 | 54 | 3 |
| >1000 | Average | 500 | 54 | 3 |

3.2.3 Setup



3.2.4 Equipment

| Test Equipment >30 MHz | | | | | |
|------------------------|--------------|----------------|------------|-----------|----------|
| Description | Manufacturer | Model | Identifier | Cal. Date | Cal. Due |
| Anechoic Chamber | Frankonia | AC1 | EF00062 | - | - |
| Measurement Receiver | Agilent | N9038A-526/WXP | EF01070 | 2018-08 | 2019-08 |
| Loop Antenna | R&S | HFH2-Z2 | EF00184 | 2017-12 | 2019-12 |

3.2.5 Procedure

| Test Procedure |
|---|
| <ol style="list-style-type: none"> 1. EUT set to test mode 2. Span it set according to measurement range 3. Resolution bandwidth below 1 GHz is set according to CISPR 16 with peak/quasi-peak detector and RBW of 1 MHz with peak/average detector is used above 1 GHz 4. Markers are set to maximum emission levels |

3.2.6 Results

| Test Results | | | | | | |
|---|----------------|----------------------|---------------|----------------------|---------------------|-------------|
| Channel [kHz] | Emission [kHz] | Level [dB μ V/m] | Detector Pol. | Limit [dB μ V/m] | Limit distance [m]* | Margin [dB] |
| 64 | 65.5 | -65.9 | AV | 31.3 | 3 | -97.19 |
| Comments: * Physical distance between EUT and measurement antenna | | | | | | |

3.3 Test Conditions and Results - Receiver radiated emissions

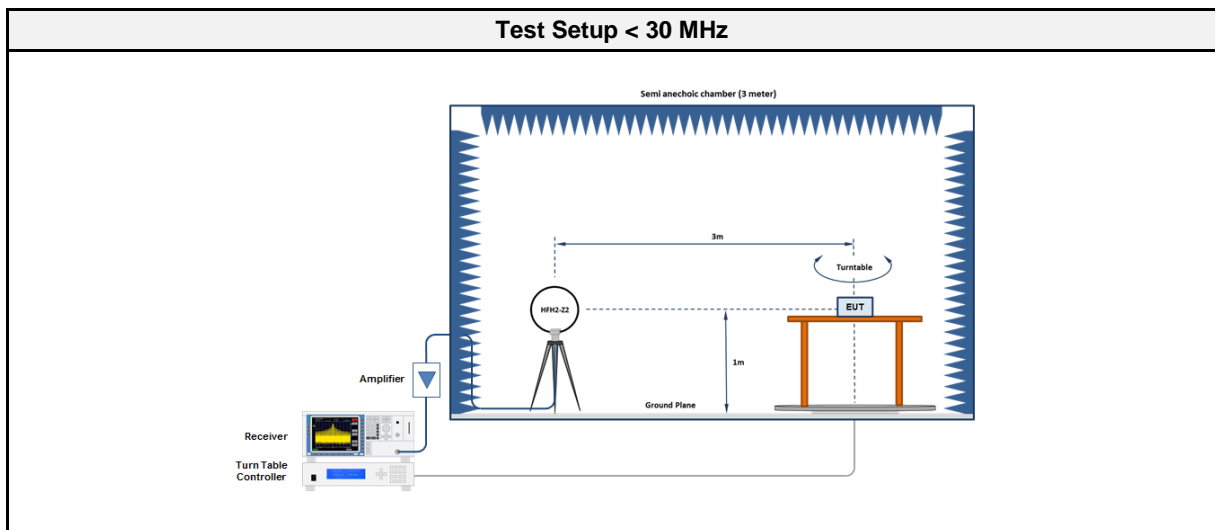
3.3.1 Information

| Test Information | |
|--------------------|------------------|
| Reference | ISED RSS-210 3.1 |
| Measurement Method | ANSI C63.10 |
| Operator | Wilfried Treffke |
| Date | 2019-07-09 |

3.3.2 Limits

| Limits | | | | |
|-----------------------|------------|----------------------------------|---|--------------------|
| Frequency range [MHz] | Detector | Limit [$\mu\text{V}/\text{m}$] | Limit [$\text{dB}\mu\text{V}/\text{m}$] | Limit Distance [m] |
| 30 - 88 | Quasi-Peak | 100 | 40 | 3 |
| 88 - 216 | Quasi-Peak | 150 | 43.5 | 3 |
| 216 - 960 | Quasi-Peak | 200 | 46 | 3 |
| 960 - 1000 | Quasi-Peak | 500 | 54 | 3 |
| >1000 | Average | 500 | 54 | 3 |

3.3.3 Setup



3.3.4 Equipment

| Test Equipment >30 MHz | | | | | |
|------------------------|--------------|----------------|------------|-----------|----------|
| Description | Manufacturer | Model | Identifier | Cal. Date | Cal. Due |
| Anechoic Chamber | Frankonia | AC1 | EF00062 | - | - |
| Measurement Receiver | Agilent | N9038A-526/WXP | EF01070 | 2018-08 | 2019-08 |
| Loop Antenna | R&S | HFH2-Z2 | EF00184 | 2017-12 | 2019-12 |

3.3.5 Procedure

| Test Procedure |
|--|
| <ol style="list-style-type: none"> 1. EUT set to receive mode 2. Span it set according to measurement range 3. Resolution bandwidth below 1 GHz is set according to CISPR 16 with peak/quasi-peakdetector and RBW of 1 MHz with peak/average detector is used above 1 GHz 4. Markers are set to peak emission levels |

3.3.6 Results

| Test Results | | | | | |
|---------------|----------------|----------------------|-----------|----------------------|-------------|
| Channel [kHz] | Emission [MHz] | Level [dB μ V/m] | Det. Pol. | Limit [dB μ V/m] | Margin [dB] |
| 64 | 65.5 | -62 | AV | 31.2 | -93.20 |