



|  |  |   |   |                                |
|--|--|---|---|--------------------------------|
| <b>Test Report No.:</b><br>Prüfbericht-Nr.:  | <b>US22NGJU 001 Rev1.0</b>   | <b>Order No.:</b><br>Auftrags-Nr.:                  | P00755351<br>234193356  | Page 1 of 62<br>Seite 1 von 62 |
| <b>Client Reference No.:</b><br>Kunden-Referenz-Nr.:   | 2361512  | <b>Order date:</b><br>Auftragsdatum:                | 7/6/2022  |                                |
| <b>Client:</b><br>Auftraggeber:  | Otsuka America Pharmaceutical, Inc.<br>3956 Point Eden Way<br>Hayward, CA 94545<br>USA |   |   |                                |
| <b>Test item:</b><br>Prüfgegenstand:   | Otsuka Patch   |   |   |                                |
| <b>Identification/ Type No.:</b><br>Bezeichnung / Typ-Nr.  | D-Tect   |   |   |                                |
| <b>Order content:</b><br>Auftrags-Inhalt:  | Radio Compliance Test Report   |   |   |                                |
| <b>Test specification:</b><br>Prüfgrundlage:   | CFR 47 Part 15.247: 2022 and RSS 247: 2017   |   |   |                                |
| <b>Date of sample receipt:</b><br>Wareneingangsdatum:  | 10/31/2022   | See Test Setup Exhibit for Photos                   |   |                                |
| <b>Test sample No.:</b><br>Prüfmuster-Nr.:   | 00182, 00196   |   |   |                                |
| <b>Testing period:</b><br>Prüfzeitraum:  | 10/31/2022- 11/2/2022  |   |   |                                |
| <b>Testing laboratory:</b><br>Prüflaboratorium:  | TUV Rheinland of North America<br>5015 Brandin Ct.<br>Fremont, CA 94538                |   |   |                                |
| <b>Test result*:</b><br>Prüfergebnis*:   | Pass   |   |   |                                |
| <b>tested by:</b><br>geprüft von:  |     | <b>authorized by: /</b><br>genehmigt von:           |  |                                |
| <b>Date:</b> 11/14/2022<br>Datum:  |  | <b>Issue Date:</b> 11/14/2022<br>Ausstellungsdatum: |   |                                |
| <b>Position / Stellung:</b>  | Expert   | <b>Position / Stellung:</b>                         | Expert  |                                |
| <b>Others /</b><br>Sonstiges:  |  |   |   |                                |
| <b>Condition of the test item at delivery:</b><br>Zustand des Prüfgegenstandes bei Anlieferung:  | Test sample complete and undamaged   |   |   |                                |
| * Legend: P(ass) = passed a.m. test specification(s)   | F(ail) = failed a.m. test specification(s)   | N/A = not applicable                                | N/T = not tested  |                                |
| * Legende: P(ass) = entspricht o.g. Prüfgrundlage(n)   | F(ail) = entspricht nicht o.g. Prüfgrundlage(n)  | N/A = nicht anwendbar                               | N/T = nicht getestet  |                                |
| <b>This test report only 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 test mark.</b> |  |   |   |                                |
| 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.              |  |   |   |                                |

TUV Rheinland of North America, Inc., 295 Foster St. Suite 100, Littleton, MA 01460 USA  
 Mail: info@us.tuv.com · Web: www.tuv.com

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**Remarks**  
*Anmerkungen*

|          |   |
|----------|---|
| <b>1</b> | <p>The equipment used during the specified testing period was calibrated according to our test laboratory calibration program. The equipment fulfils the requirements included in the relevant standards. The traceability of the test equipment used is ensured by compliance with the regulations of our management system. Detailed information regarding test conditions, equipment and measurement uncertainty is available in the test laboratory and could be provided on request.</p> <p><i>Alle eingesetzten Prüfmittel waren zum angegebenen Prüfzeitraum gemäß eines festgelegten Kalibrierungsprogramms unseres Prüfhauses kalibriert. Sie entsprechen den in den Prüfprogrammen hinterlegten Anforderungen. Die Rückverfolgbarkeit der eingesetzten Prüfmittel ist durch die Einhaltung der Regelungen unseres Managementsystems gegeben. Detaillierte Informationen bezüglich Prüfkonditionen, Prüfequipment und Messunsicherheiten sind im Prüflabor vorhanden und können auf Wunsch bereitgestellt werden.</i></p>  |
| <b>2</b> | <p>As contractually agreed, this document has been signed digitally only. TÜV Rheinland has not verified and unable to verify which legal or other pertaining requirements are applicable for this document. Such verification is within the responsibility of the user of this document. Upon request by its client, TÜV Rheinland can confirm the validity of the digital signature by a separate document. Such request shall be addressed to our Sales department. An environmental fee for such additional service will be charged.</p> <p><i>Wie vertraglich vereinbart, wurde dieses Dokument nur digital unterzeichnet. Der TÜV Rheinland hat nicht überprüft, welche rechtlichen oder sonstigen diesbezüglichen Anforderungen für dieses Dokument gelten. Diese Überprüfung liegt in der Verantwortung des Benutzers dieses Dokuments. Auf Verlangen des Kunden kann der TÜV Rheinland die Gültigkeit der digitalen Signatur durch ein gesondertes Dokument bestätigen. Diese Anfrage ist an unseren Vertrieb zu richten. Eine Umweltgebühr für einen solchen zusätzlichen Service wird erhoben.</i></p> |
| <b>3</b> | <p>Test clauses with remark of * are subcontracted to qualified subcontractors and described under the respective test clause in the report. Deviations of testing specification(s) or customer requirements are listed in specific test clause in the report.</p> <p><i>Prüfklausel mit der Note * wurden an qualifizierte Unterauftragnehmer vergeben und sind unter der jeweiligen Prüfklausel des Berichts beschrieben. Abweichungen von Prüfspezifikation(en) oder Kundenanforderungen sind in der jeweiligen Prüfklausel im Bericht aufgeführt.</i></p>   |
| <b>4</b> | <p>The test results contained in this report refer exclusively to the product(s) presented for testing. No liability may be assumed for models or products not referred to herein. This test report may not be published or duplicated in part without permission of the testing body. This test report by itself does not constitute authorization for the use of any TÜV Rheinland test mark. The report must not be used by the client to claim product certification, approval, or endorsement by A2LA.</p>   |
| <b>5</b> | <p>Radio Compliance Emissions Test Report. The above product was found to be Compliant to the above test standard(s).</p>   |

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**Product description**  
*Produktbeschreibung*

|   |   |   |
|---|---|---|
| 1 | <b>Product details:</b><br><i>Produkt details:</i>                | The Patch device is a component of the Core Medical Device (CMD) that gathers ingestion, physiological and behavioral metrics from a user. This data is then transmitted to a BLE-enabled gateway device. The data can be accessed by external applications for further processing or displayed directly to a user via a display. |
| 2 | <b>Dimensions / Weight:</b><br><i>Maße / Gewicht:</i>             | 11.3cm x 4.52cm x 0.68cm / 0.011 kg   |
| 3 | <b>Operating elements:</b><br><i>Bedienelemente:</i>              | 2.9VDC Battery Operated, Transmit bands 2.402-2.480GHz.   |
| 4 | <b>Equipment / Accessories:</b><br><i>Ausstattung / Zubehör:</i>  | N/A   |
| 5 | <b>Used materials:</b><br><i>Verwendete Materialien:</i>          | None.   |
| 6 | <b>Other:</b><br><i>Sonstiges:</i>                                | Test sample(s), as well sample information, description, product details and intended usage was provided by customer.   |
| 7 | <b>Test sample obtaining:</b><br><i>Prüfmusterbereitstellung:</i> | <input checked="" type="checkbox"/> Sending by customer <input type="checkbox"/> Sampling by TÜV Rheinland Group<br><input type="checkbox"/> others:  |

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### Revisions

| Date<br>mm/dd/yy | Name   | Page Number of Change | Describe Change   |
|------------------|--------|-----------------------|-------------------|
| 11/14/2022       | Rev. 1 | N/A                   | Original Document |
|                  |        |                       |                   |
|                  |        |                       |                   |
|                  |        |                       |                   |
|                  |        |                       |                   |
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|                  |        |                       |                   |

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## 1 General Information

### 1.1 Scope

This report is intended to document the status of conformance with the requirements of the CFR 47 Part 15.247: 2022 and RSS 247: 2017 based on the results of testing performed from October 31, 2022 through November 2, 2022 on Otsuka Patch, Model D-Tect manufactured by Otsuka America Pharmaceutical, Inc. This report only applies to the specific samples tested under the stated test conditions. It is the responsibility of the manufacturer to assure that additional production units of this model are manufactured with identical or EMI equivalent electrical and mechanical components. This report is further intended to document changes and modifications to the EUT throughout its life cycle. All documentation will be included as a supplement.

### 1.2 Purpose

Testing was performed to evaluate the EMC performance of the EUT in accordance with the applicable requirements, procedures, and criteria defined in the application of regulations and application of standards listed in this report. The 2402 MHz to 2480 MHz frequency band for Bluetooth, Low Energy is covered in this document.

### 1.3 Summary of Test Results

Table 1 - Summary of Test Results

| Test                                  | Test Method<br>ANSI C 63.10 &<br>C63.4                 | Worse Case<br>(Measured)                               | Result          |
|---------------------------------------|--|--|-----------------|
| Maximum Output Power                  | CFR47 15.247 (b),<br>RSS 247 Sect. 5.4<br>(d)          | -8.21 dBm (0.000151 Watts) @ 2402MHz<br>Channel, 1Mbps | <b>Complied</b> |
| DTS Bandwidth (6dB)                   | CFR47 15.247<br>(a)(2), RSS 247<br>Sect. 5.2 (a)       | 0.702MHz @ 2402MHz Channel, 1Mbps                      | <b>Complied</b> |
| Peak Power Spectral Density           | CFR47 15.247 (e),<br>RSS 247 Sect. 5.2<br>(b)          | -24.35dBm/3kHz @ 2402MHz channel,<br>1Mbps             | <b>Complied</b> |
| Out of Band Emissions: Non-Restricted | CFR47 15.247 (d),<br>RSS 247 Sect.5.5                  | -38.35dBm @ 2400 MHz, Lower Band Edge                  | <b>Complied</b> |
| Out of Band Emissions: Restricted     | CFR47 15.205, RSS<br>GEN Sect.8.10                     | -27.11dB margin @ 2380.26 MHz, Average                 | <b>Complied</b> |
| Transmitter Spurious Emissions        | CFR47 15.209,<br>CFR47 15.247 (d),<br>RSS-GEN Sect.8.9 | -6.25dB Margin @ 168.02MHz, Quasi Peak                 | <b>Complied</b> |
| AC Power Conducted Emission           | CFR47 15.207,<br>RSS-GEN Sect.8.8                      | N/A- EUT is DC powered                                 | <b>N/A</b>      |

Note: This test report covers 2402 MHz to 2480 MHz band.  
Class B limits were applied where applicable.

### 1.4 Special Accessories

No special accessories were necessary in order to achieve compliance.

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## 2 Laboratory Information

### 2.1 Accreditations & Endorsements

#### 2.1.1 US Federal Communications Commission



TUV Rheinland of North America EMC test facilities located at 1279 Quarry Lane, Ste. A, Pleasanton, CA, 94566, and 5015 Brandin Ct, Fremont, CA. 94538, are recognized by the Commission for performing testing services for the general public on a fee basis.

These laboratory test facilities have been fully described in reports submitted to and accepted by the FCC (Pleasanton Registration No. US1131, Fremont Registration No. US1131). The laboratory Scopes of Accreditation include Title 47 CFR Parts 15, 18 and 90. The accreditations are updated every three years.

#### 2.1.2 A2LA



TUV Rheinland of North America EMC test facilities are accredited by the American Association for Laboratory Accreditation (A2LA). The laboratories have been assessed and accredited by A2LA in accordance with ISO Standard 17025:2017 (Testing Certificate #3331.02). The Scope of

Laboratory Accreditation includes emission and immunity testing. The accreditations are updated annually.

#### 2.1.3 Industry Canada



Industry  
Canada Industrie  
Canada

The Pleasanton 5-meter Semi-Anechoic Chamber, Registration No. 2932M-1, has been accepted by Industry Canada to perform testing to 3 and 5 meters based on the test procedures described in ANSI C63.4-2014. The Fremont 10-meter Semi-Anechoic Chamber, Registration No. 2932D-1, has been accepted by Industry Canada to perform testing to 3 and 10 meters based on the test procedures described in ANSI C63.4-2014.

#### 2.1.4 Japan – VCCI



The Voluntary Control Council for Interference by Information Technology Equipment (VCCI) is a group that consists of Information Technology Equipment (ITE) manufacturers and EMC test laboratories. The purpose of the Council is to take voluntary control measures against electromagnetic interference from Information Technology Equipment, and thereby contribute to the development of a socially beneficial and responsible state of affairs in the realm of Information Technology Equipment in Japan. TUV Rheinland of North America EMC test facilities located at 1279 Quarry Lane, Ste. A, Pleasanton, CA, 94566, and 5051 Brandin Ct, Fremont, CA. 94538, have been assessed and approved in accordance with the Regulations for Voluntary Control Measures.

VCCI Registration No. for Pleasanton: A-0399

VCCI Registration No. for Fremont: A-0398

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### 2.1.5 Acceptance by Mutual Recognition Arrangement



The United States has an established agreement with specific countries under the Asia Pacific Laboratory Accreditation Corporation (APLAC) Mutual Recognition Arrangement. Under this agreement, all TUV Rheinland at 1279 Quarry Ln, Pleasanton, CA 94566 test results and test reports within the scope of the laboratory NIST / A2LA accreditation will be accepted by each member

country.



## 2.2 Test Facilities & EMC Software

Test facilities are located at 1279 Quarry Lane, Ste. A, Pleasanton, California 94566, U.S.A. and 5015 Brandin Ct, Fremont, CA. 94538, U.S.A. (Fremont is the Pleasanton Annex).

### 2.2.1 Emission Test Facility

The Semi-Anechoic Chambers and AC Line Conducted measurement facilities used to collect radiated and conducted emissions data have been constructed in accordance with ANSI C63.7:1992. The Fremont 10 meter semi-anechoic chamber has been measured in accordance with and verified to comply with the theoretical volumetric normalized site attenuation of ANSI C63.4-2014 and SVSWR requirements of CISPR 16-1-4 Consol. Ed. 3.0 (2010-04), at test distances of 3 and 10 meters. This site has been described in reports dated November 1st, 2006, submitted to the FCC, and accepted by letter dated November 28, 2006. The site is listed with the FCC and accredited by A2LA (Testing Certificate #3331.02). The Pleasanton 5 meter semi-anechoic chamber has been verified to comply with the theoretical volumetric normalized site attenuation of ANSI C63.4-2014 and SVSWR requirements of CISPR 16-1-4 Consol. Ed. 3.0 (2010-04) at a test distance of 3 meters. This site has been described in reports dated November 1st, 2006, submitted to the FCC, and accepted by letter dated November 28, 2006. The site is listed with the FCC and accredited by A2LA (Testing Certificate #3331.02).

### 2.2.2 Immunity Test Facility

ESD, EFT, Surge, PQF: These tests are performed in an environmentally controlled room with a 3.7 m x 4.8 m x 3.175 mm thick aluminum floor connected to PE ground.

For ESD testing, tabletop equipment is placed on an insulated mat with a surface resistivity of  $10^9$  Ohms/square on a 1.6 m x 0.8 m x 0.8 m high non-conductive table with a 3.175 mm aluminum top (Horizontal Coupling Plane). The HCP is connected to the main ground plane via a low impedance ground strap through two 470-k $\Omega$  resistors. The Vertical Coupling Plane consists of an aluminum plate 50 cm x 50 cm x 3.175 mm thick. The VCP is connected to the main ground plane via a low impedance ground strap through two 470-k $\Omega$  resistors.

For EFT, Surge, PQF, the HCP and VCP are removed.

RF Field Immunity testing is performed in a 7.3 m x 4.3 m x 4.1 m anechoic chamber.

RF Conducted and Magnetic Field Immunity testing is performed on a 4.8 m x 3.7 m x 3.175 mm thick aluminum ground plane.

All test areas allow a minimum distance of 1 meter from the EUT to walls or conducting objects.

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### 2.2.3 EMC Software – Pleasanton and Fremont

| Manufacturer             | Name        | Version            | Test Type                          |
|--------------------------|-------------|--------------------|------------------------------------|
| Rohde & Schwarz          | EMC32       | 10.40.10           | Radiated Emissions                 |
| ETS-Lindgren             | TILE        | 3.4.K.14 @ 4.0.A.5 | Radiated & Conducted Emissions     |
| Agilent                  | Agilent MXE | A.11.02            | Radiated & Conducted Emissions     |
| ETS-Lindgren             | TILE        | 3.4.K.14           | Radiated & Conducted Immunity      |
| Thermo Electron - Keytek | CEWare32    | 4.00               | EFT/Surge/Voltage Dips & Interrupt |
| Voltech                  | IEC61000-3  | 1.21.07RC2         | Harmonic & Flicker                 |

### 2.3 Measurement Uncertainty

Two types of measurement uncertainty are expressed in this report, per *ISO Guide to the Expression of Uncertainty in Measurement*, 1<sup>st</sup> Edition, 1995.

*The Combined Standard Uncertainty* is the standard uncertainty of the result of a measurement when that result is obtained from the values of a number of other quantities; it is equal to the positive square root of the sum of the variances or co-variances of these other quantities, weighted according to how the measurement result varies with changes in these quantities. The term *standard uncertainty* is the result of a measurement expressed as a standard deviation.

*The Expanded Uncertainty* defines an interval about the result of a measurement that may be expected to encompass a large fraction of the distribution of values that could reasonably be attributed to the measurement. The fraction may be viewed as the coverage probability or level of confidence of the interval.

#### 2.3.1 Sample Calculation – radiated & conducted emissions

The field strength is calculated by subtracting the Amplifier Gain and adding the Cable Loss and Antenna Correction Factor to the measured reading. The basic equation is as follows:

$$\text{Field Strength (dB}\mu\text{V/m)} = \text{RAW} - \text{AMP} + \text{CBL} + \text{ACF}$$

Where: RAW = Measured level before correction (dBμV)

AMP = Amplifier Gain (dB)

CBL = Cable Loss (dB)

ACF = Antenna Correction Factor (dB/m)

$$\mu\text{V/m} = 10^{\frac{\text{dB}\mu\text{V/m}}{20}}$$

#### Sample radiated emissions calculation @ 30 MHz

**Measurement +Antenna Factor–Amplifier Gain+Cable loss=Radiated Emissions (dBuV/m)**

$$25 \text{ dBuV/m} + 17.5 \text{ dB} - 20 \text{ dB} + 1.0 \text{ dB} = 23.5 \text{ dBuV/m}$$

### 2.3.2 Measurement Uncertainty

#### Measurement Uncertainty Emissions

| Per CISPR 16-4-2                               | $U_{lab}$ | $U_{cispr}$ |
|--|-----------|-------------|
| <b>Radiated Disturbance @ 10 meters</b>        |           |             |
| 30 – 1,000 MHz                                 | 2.25 dB   | 4.51 dB     |
| <b>Radiated Disturbance @ 3 meters</b>         |           |             |
| 30 – 1,000 MHz                                 | 2.26 dB   | 4.52 dB     |
| 1 – 6 GHz                                      | 2.12 dB   | 4.25 dB     |
| 6 – 40 GHz                                     | 2.47 dB   | 4.93 dB     |
| <b>Conducted Disturbance @ Mains Terminals</b> |           |             |
| 150 kHz – 30 MHz                               | 1.09 dB   | 2.18 dB     |

#### Voltech PM6000A

|  |                                |
|--|--------------------------------|
| The estimated combined standard uncertainty for harmonic current and flicker measurements is $\pm 5.0\%$ . | Per CISPR<br>16-4-2<br>Methods |
|--|--------------------------------|

#### Measurement Uncertainty Immunity

|   |                   |
|---|-------------------|
| The estimated combined standard uncertainty for ESD immunity measurements is $\pm 8.2\%$ .                | Per IEC 61000-4-2 |
| The estimated combined standard uncertainty for radiated immunity measurements is $\pm 4.10$ dB.          | Per IEC 61000-4-3 |
| The estimated combined standard uncertainty for conducted immunity measurements with CDN is $\pm 3.66$ dB | Per IEC 61000-4-6 |
| The estimated combined standard uncertainty for power frequency magnetic field immunity is $\pm 2.9\%$ .  | Per IEC 61000-4-8 |

#### Thermo KeyTek EMC Pro

|   |
|---|
| The estimated combined standard uncertainty for EFT fast transient immunity measurements is $\pm 2.6\%$ .         |
| The estimated combined standard uncertainty for surge immunity measurements is $\pm 2.6\%$ .                      |
| The estimated combined standard uncertainty for voltage variation and interruption measurements is $\pm 1.74\%$ . |

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### Measurement Uncertainty – Radio Testing

|  |
|--|
| The estimated combined standard uncertainty for frequency error measurements is $\pm 3.88$ Hz                |
| The estimated combined standard uncertainty for carrier power measurements is $\pm 0.70$ dB.                 |
| The estimated combined standard uncertainty for adjacent channel power measurements is $\pm 1.47$ dB.        |
| The estimated combined standard uncertainty for modulation frequency response measurements is $\pm 0.46$ dB. |
| The estimated combined standard uncertainty for transmitter conducted emission measurements is $\pm 2.06$ dB |

The expanded uncertainty at a level of 95% confidence is obtained by multiplying the combined standard uncertainty by a coverage factor of 2. Compliance criteria are not based on measurement uncertainty.

### 2.4 Calibration Traceability

All measurement instrumentation is traceable to the National Institute of Standards and Technology (NIST). Measurement method complies with ANSI/NCSS Z540-1-1994 and ISO Standard 17025:2017. Equipment calibration records are kept on file at the test facility.

### 3 Product Information

#### 3.1 Product Description

The Otsuka America Pharmaceutical, Inc. Feedback Device consists of a miniaturized, wearable sensor (Otsuka Patch) for ambulatory recording of physiological and behavioral metrics such as heart rate, activity, body angle relative to gravity (body position), and time-stamped patient logged events, including events signaled by the co-occurrence with, or co-ingestion with, the ingestible sensor accessory. When the ingestible sensor is ingested, the Otsuka America Pharmaceutical, Inc. Feedback Device is intended to log, track and trend intake times. When co-ingested with medication, the tracking and trending of intake times may be used as an aid to measure medication adherence. The Otsuka America Pharmaceutical, Inc. Feedback Device may be used in any instance where quantifiable analysis of event associated physiological and behavioral metrics is desirable and enables unattended data collection for clinical and research applications.

The Otsuka America Pharmaceutical, Inc. Feedback Device has no items of Essential Performance; there are no specifications or Risk mitigations needed to avoid unacceptable Risks.

The Patch device is a component of the Core Medical Device (CMD) that gathers ingestion, physiological and behavioral metrics from a user. This data is then transmitted to a BLE-enabled gateway device. The data can be accessed by external applications for further processing or displayed directly to a user via a display.

#### 3.2 Equipment Configuration

A description and justification of the equipment configuration is given in the EMC Test Plan. The EUT was tested as described in the EMC Test Plan and was configured and operated in a manner consistent with its intended use. The EUT was connected to rated power and allowed to warm up to normal operating conditions. The placement of the EUT system components was guided by the test standard and selected to represent typical installation conditions.

In the case of a EUT that can operate in more than one configuration, preliminary testing was performed to determine the configuration that produced maximum radiation.

The final configuration was selected to produce worst case radiation and place the EUT in the most susceptible state. There were no deviations from the description of the Equipment Configuration given in the EMC Test Plan.

#### 3.3 Operating Mode

A description and justification of the operation mode is given in the EMC Test Plan.

In the case of a EUT that can operate in more than one state, preliminary testing was performed to determine the operating mode that produced maximum radiation.

The final operating mode was selected to produce worst case radiation and place the EUT in the most susceptible state. There were no deviations from the description of the Operation Mode given in the EMC Test Plan.

### 3.4 Unique Antenna Connector

An intentional radiator shall be designed to ensure that no antenna other than that furnished by the responsible party shall be used with the device. The use of a permanently attached antenna or of an antenna that uses a unique coupling to the intentional radiator shall be considered sufficient to comply with the provisions of this Section. The manufacturer may design the unit so that a broken antenna can be replaced by the user, but the use of a standard antenna jack or electrical connector is prohibited. This requirement does not apply to carrier current devices or to devices operated under the provisions of CFR47 Parts 15.211, 15.213, 15.217, 15.219, or 15.221.

#### 3.4.1 Results

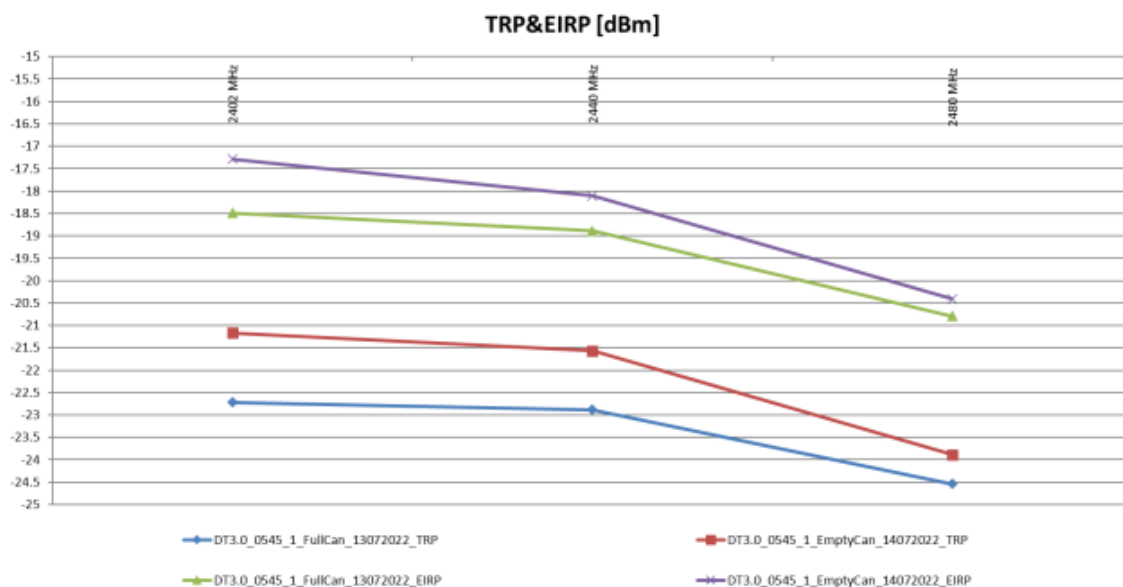
The Otsuka Patch, Model D-Tect has 1 dedicated Bluetooth Patch antenna that has maximum gain of -10.1dBi. It is not easily accessible to the end user.

It is integrated into the PCB of the device and is not easily accessible to the end user.

Antenna gain measurement results included in D-Tect Bluetooth antenna report provided by Manufacturer. The measured TRP (Total Radiated Power) and EIRP (Effective Isotropic Radiated Power) values for the filled and empty canister cases are shown in Figure 15 of D-Tect Bluetooth antenna report. For the antenna in free-space, the EIRP value at 2440 MHz (mid-band) is about -18.1 dBm. For the loaded antenna (salt water in canister), the EIRP is about -18.9 dBm.

Thus, for the used -8 dBm transmission power, the measured realized antenna gains to be -10.1 dBi (empty canister) and -10.9 dBi (filled canister), respectively. These are average gain values over the full radiation sphere.

The difference between the empty and filled canister test cases is only 0.8 dB which shows good immunity to the proximity of lossy materials such as human tissue.



## 4. Emissions

Testing was performed in accordance with CFR 47 Part 15.247: 2022 and RSS 247: 2017. These test methods are listed under the laboratory's A2LA Scope of Accreditation. This test measures the levels emanating from the EUT, thus evaluating the potential for the EUT to cause radio frequency interference to other electronic devices. Procedures described in section 8 of the standard were used.

### 4.1 Output Power Requirements

The maximum output power requirement is the maximum equivalent isotropic radiated power delivering at the transmitting antenna under specified conditions of measurements in the presence of modulation.

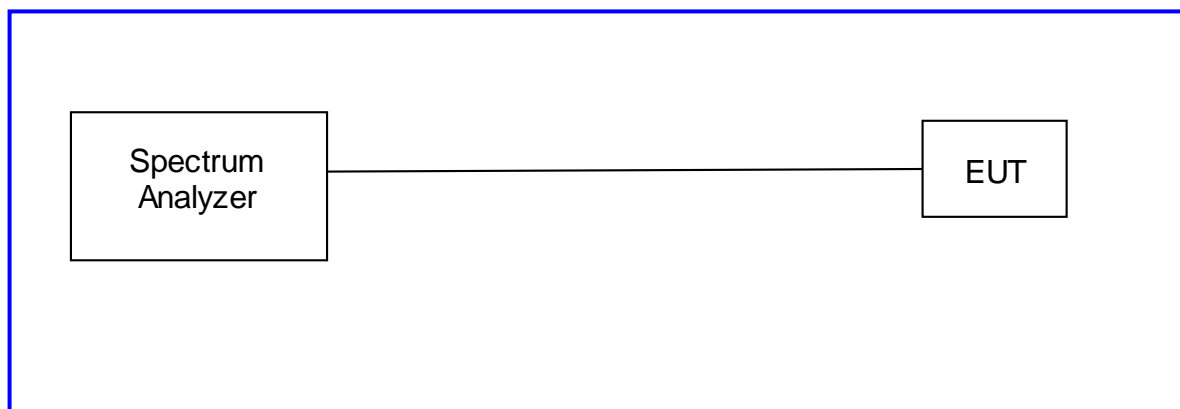
The maximum output power and harmonics shall not exceed CFR47 Part 15.247 (b) and RSS 247 Sect. 5.4.(d).

The maximum transmitted power in the frequency band 2400-2483.5 MHz: 1 W

#### 4.1.1 Test Method

Conducted method was used to measure the channel power output. The worst findings were conducted on 3 channels in each operating range per CFR47 Part 15.247(b) and RSS 247 Sect. 5.4(d); 2400 MHz to 2483.5 MHz The worst mode results indicated below.

#### 4.1.2 Test Setup: (Conducted)



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### 4.1.3 Results

As originally tested, the EUT was found to be compliant to the requirements of the test standard(s). Worst case data for each mode reported below. Plots of highest power included for low, medium, and high channels.

**Table 2: RF Output Power at the Antenna Port – Test Results**

| <b>Test Date:</b> November 01, 2022                          |                         |                              | <b>Test By:</b> Rachana Khanduri    |             |             |
|--|-------------------------|------------------------------|-------------------------------------|-------------|-------------|
| <b>Test Method:</b> Conducted Measurements                   |                         |                              | <b>Power Setting:</b> -8 dBm        |             |             |
| <b>Antenna Type:</b> Patch                                   |                         |                              | <b>Max. Antenna Gain:</b> -10.1 dBi |             |             |
| <b>Ambient Temp.:</b> 21 °C                                  |                         |                              | <b>Relative Humidity:</b> 37%       |             |             |
| Bluetooth LE – RF Output Power                               |                         |                              |                                     |             |             |
| Data Rate  | Operating Channel (MHz) | Measured Peak Output [Watts] | Measured Peak Output [dBm]          | Limit [dBm] | Margin [dB] |
| 1Mbps  | 2402                    | 0.000151                     | -8.21                               | +30.00      | -38.21      |
|  | 2440                    | 0.000138                     | -8.61                               | +30.00      | -38.61      |
|  | 2480                    | 0.000095                     | -10.20                              | +30.00      | -40.20      |
| 2Mbps  | 2402                    | 0.000149                     | -8.27                               | +30.00      | -38.27      |
|  | 2440                    | 0.000136                     | -8.66                               | +30.00      | -38.66      |
|  | 2480                    | 0.000093                     | -10.31                              | +30.00      | -40.31      |
| <b>Note:</b> The highest power output observed was at 1 Mbps |                         |                              |                                     |             |             |



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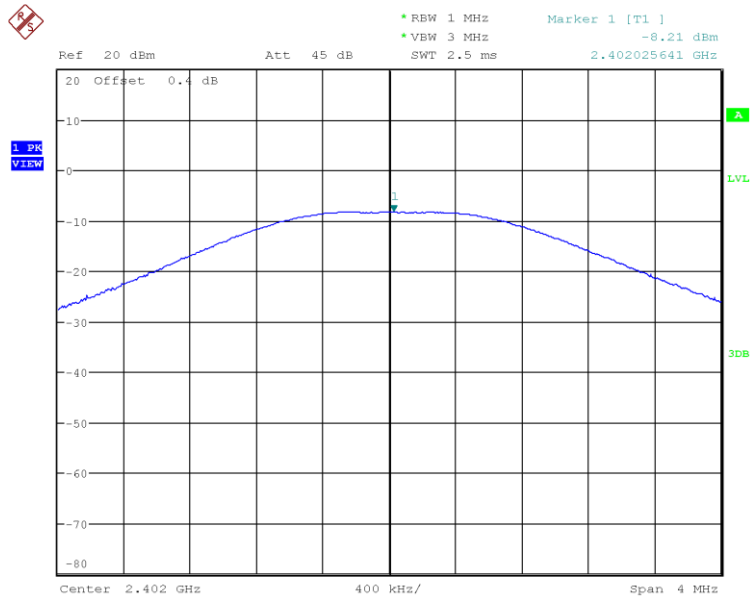


Figure 1: Maximum Conducted Power, 2402 MHz, 1Mbps

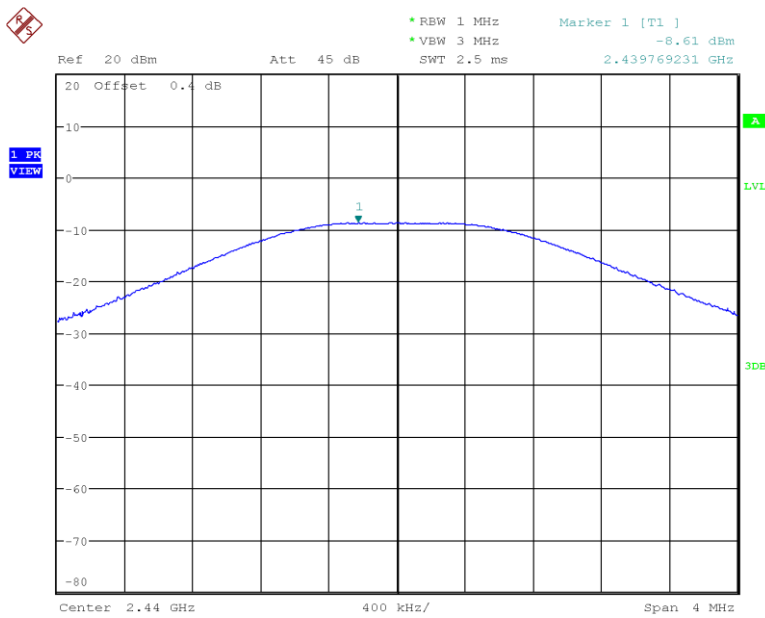


Figure 2: Maximum Conducted Power, 2440MHz, 1Mbps

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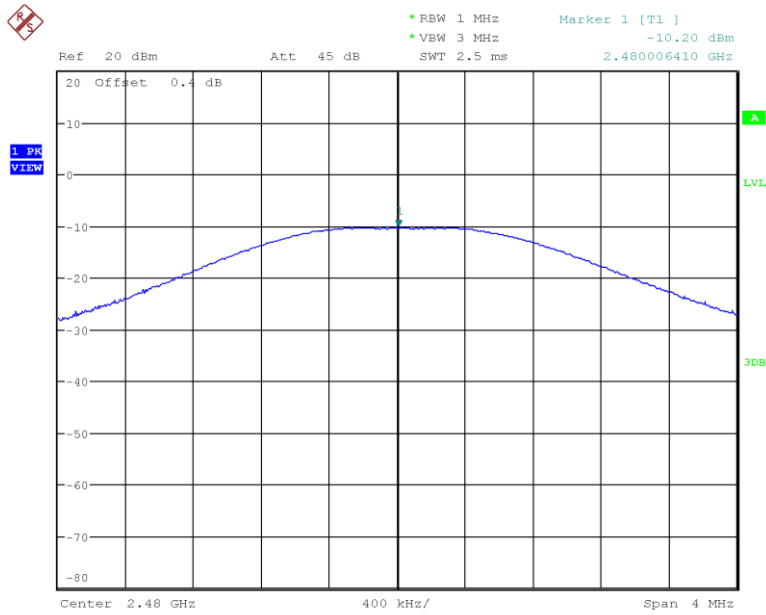


Figure 3: Maximum Conducted Power, 2480MHz, 1Mbps

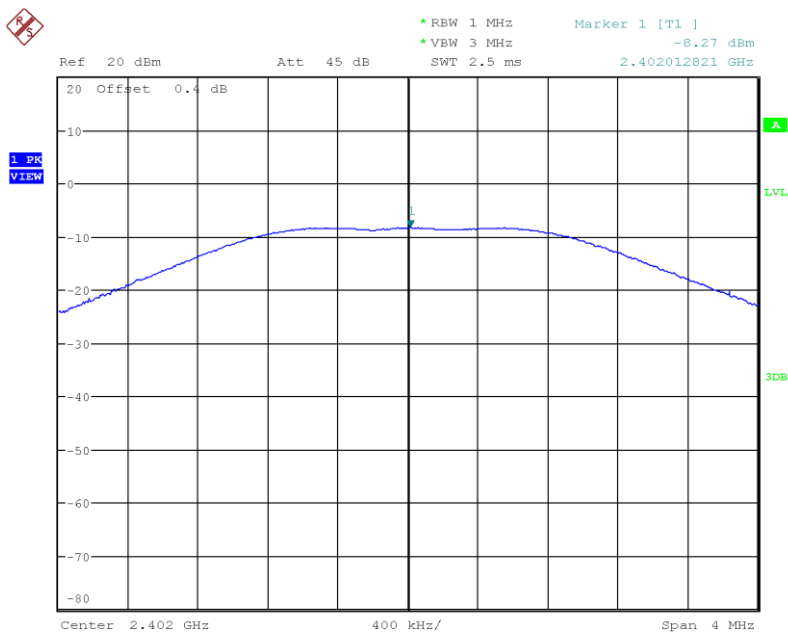


Figure 4: Maximum Conducted Power, 2402 MHz, 2Mbps

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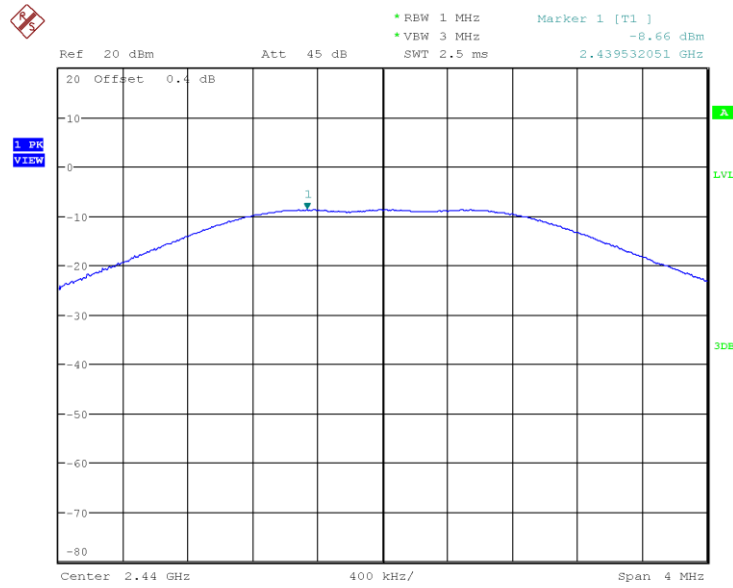


Figure 5: Maximum Conducted Power, 2440MHz, 2Mbps

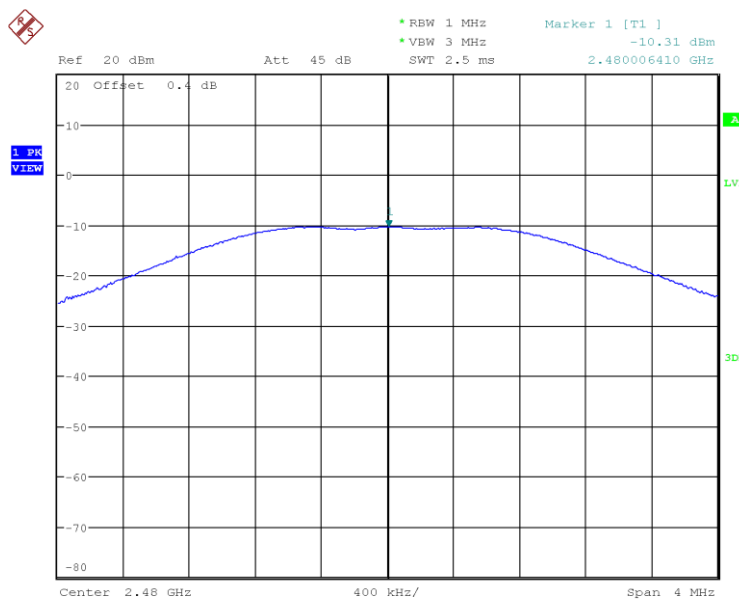


Figure 6: Maximum Conducted Power, 2480MHz, 2Mbps

## 4.2 DTS Bandwidth (6dB) and Occupied Bandwidth

The occupied bandwidth is measured at an amplitude level reduced from the reference level by a specified ratio. The reference level is the level of the highest amplitude signal observed from the transmitter at the fundamental frequency.

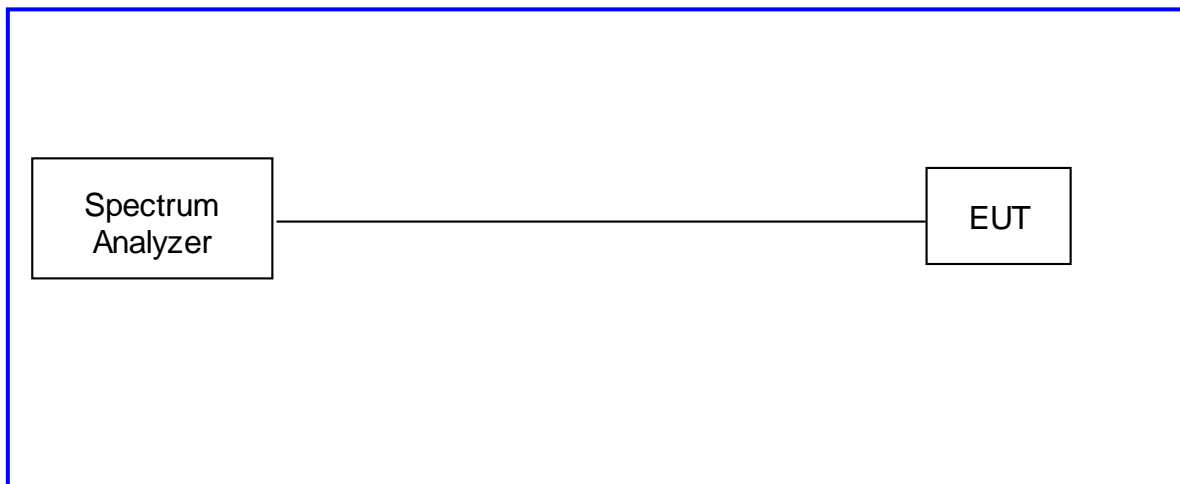
The 99% bandwidth is the bandwidth in which 99% of the transmitted power occupied.

The minimum 6 dB bandwidth shall be at least 500 kHz.

### 4.2.1 Test Method

The conducted method was used to measure the occupied bandwidth according to ANSI C63.10:2013 Section 11.8. The measurement was performed with modulation per CFR47 15.247 (a) (2) and RSS Gen Sect. 6.6. Measurements were performed on the low, middle and high channels of the operating frequency range; 2402 MHz to 2480 MHz.

### 4.2.2 Test Setup: (Conducted)



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#### 4.2.3 Results

As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

**Table 3:** Occupied Bandwidth – Test Results

| <b>Test Date:</b> November 02, 2022   |                         | <b>Test By:</b> Rachana Khanduri    |                           |
|---|-------------------------|-------------------------------------|---------------------------|
| <b>Test Method:</b> Conducted Measurements  |                         | <b>Power Setting:</b> -8 dBm        |                           |
| <b>Antenna Type:</b> Patch  |                         | <b>Max. Antenna Gain:</b> -10.1 dBi |                           |
| <b>Ambient Temp.:</b> 21 °C   |                         | <b>Relative Humidity:</b> 37%       |                           |
| <b>Bluetooth LE – Occupied Bandwidth</b>  |                         |                                     |                           |
| Data Rate   | Operating Channel (MHz) | 99% Bandwidth (MHz)                 | 6dB (DTS) Bandwidth (MHz) |
| 1Mbps   | 2402                    | 1.053                               | 0.702                     |
|   | 2440                    | 1.053                               | 0.712                     |
|   | 2480                    | 1.058                               | 0.702                     |
| 2Mbps   | 2402                    | 2.051                               | 0.737                     |
|   | 2440                    | 2.051                               | 0.745                     |
|   | 2480                    | 2.059                               | 0.745                     |
| <b>Note:</b> 1. The narrower bandwidth was measured at 1 Mbps.<br>2. Emission Designator is 1M05F1DXX based upon the 99% Bandwidth. |                         |                                     |                           |

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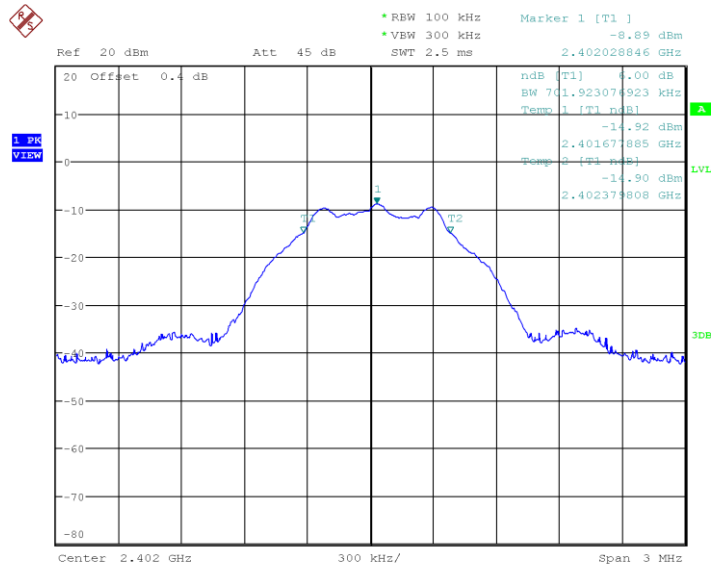


Figure 7: 2402MHz, 1Mbps, 6dB Bandwidth

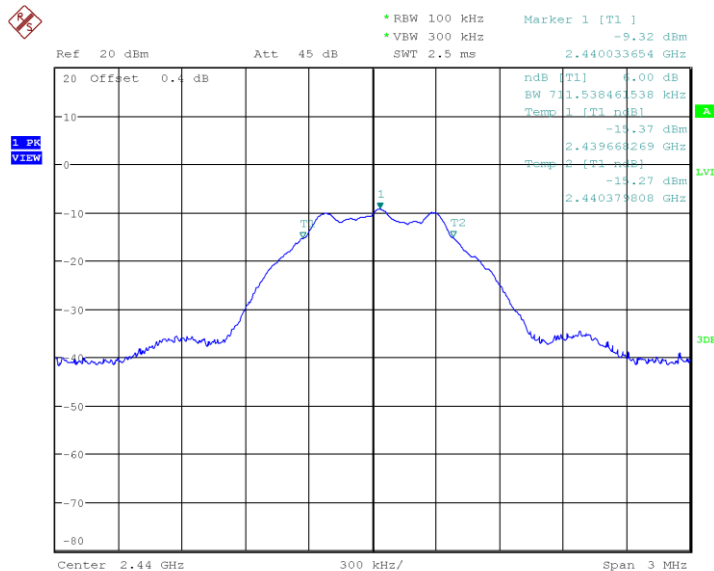


Figure 8: 2440MHz, 1Mbps, 6dB Bandwidth

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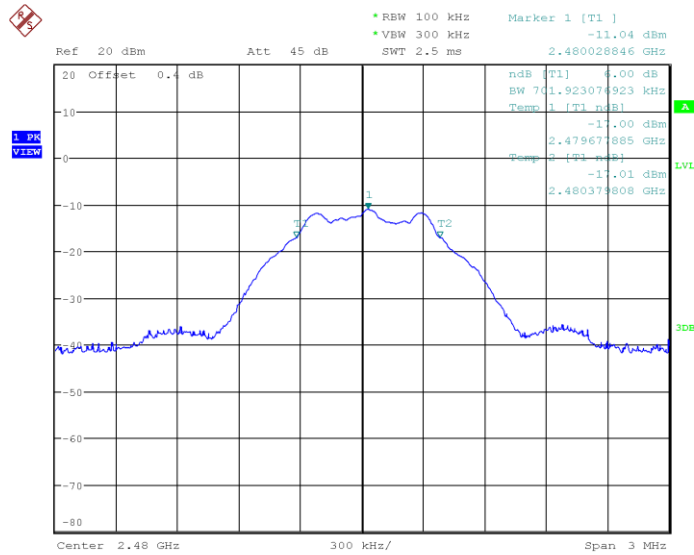


Figure 9: 2480MHz, 1Mbps, 6dB Bandwidth

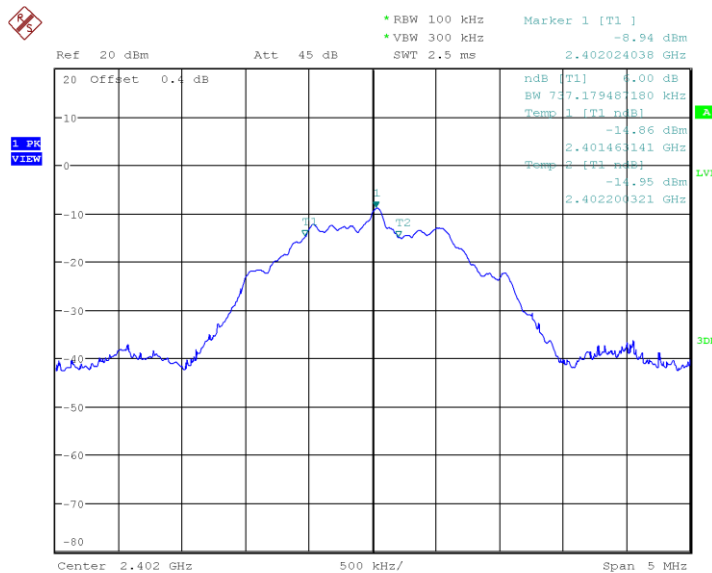


Figure 10: 2402MHz, 2Mbps, 6dB Bandwidth

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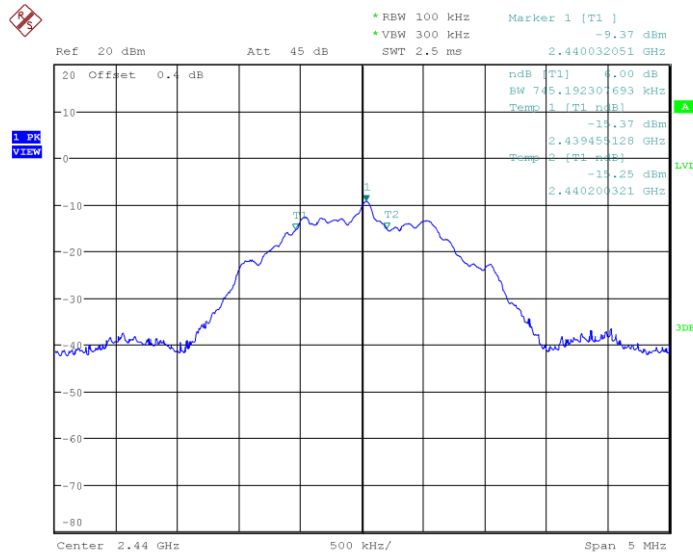


Figure 11: 2440MHz, 2Mbps, 6dB Bandwidth

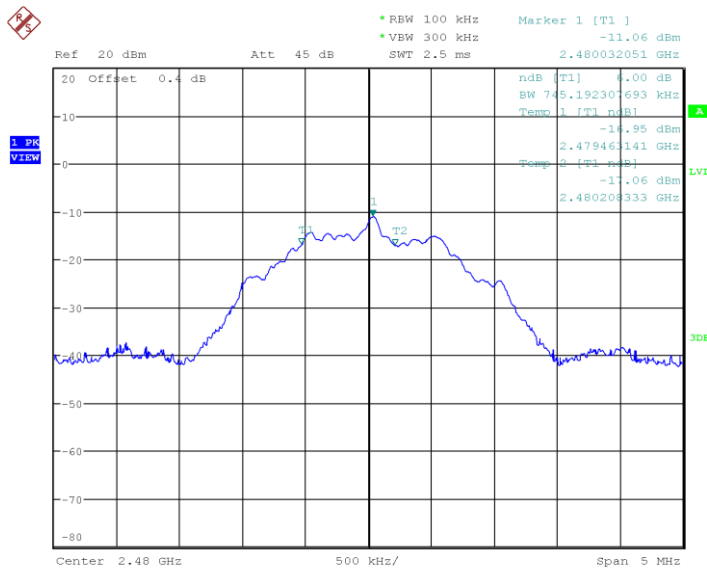


Figure 12: 2480MHz, 2Mbps, 6dB Bandwidth



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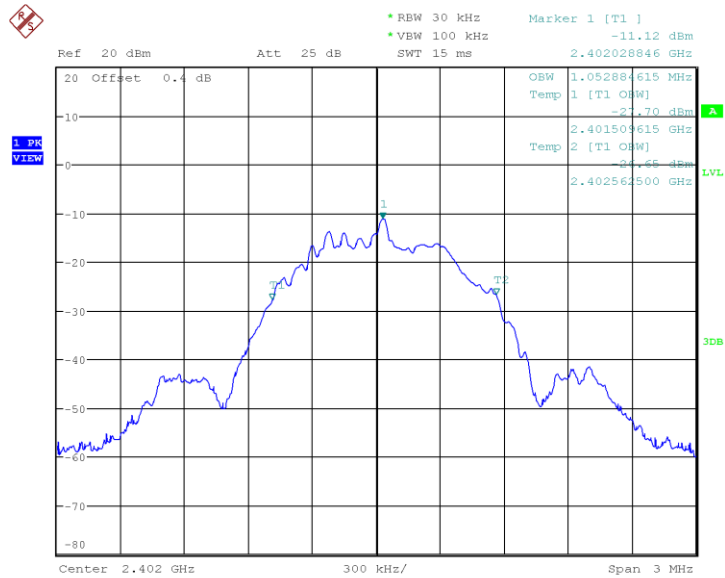


Figure 13: 2402MHz, 1Mbps, 99% Bandwidth

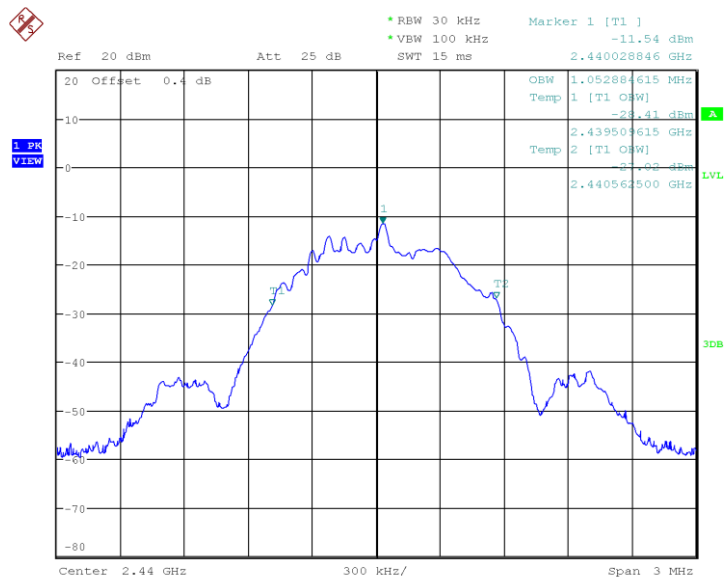


Figure 14: 2440MHz, 1Mbps, 99% Bandwidth

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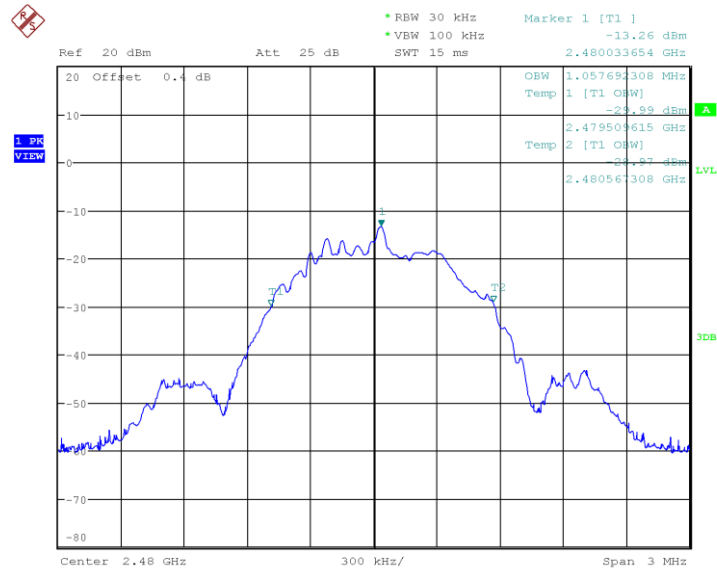


Figure 15: 2480MHz, 1Mbps, 99% Bandwidth

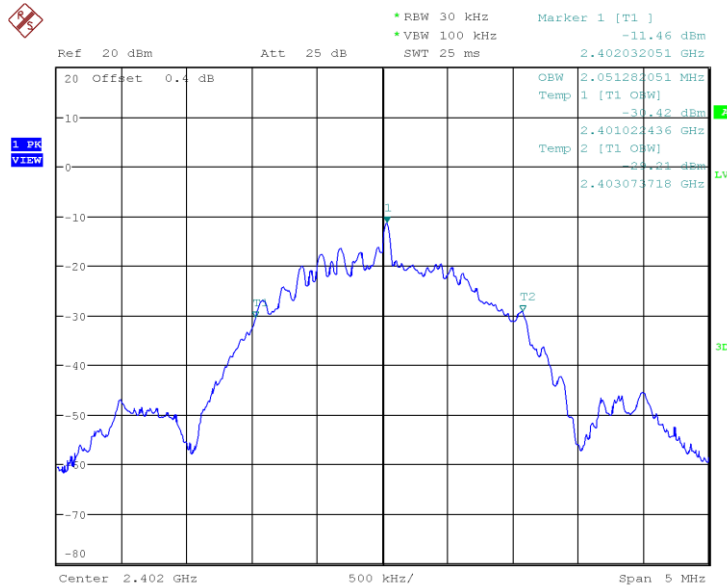


Figure 16: 2402MHz, 2Mbps, 99% Bandwidth

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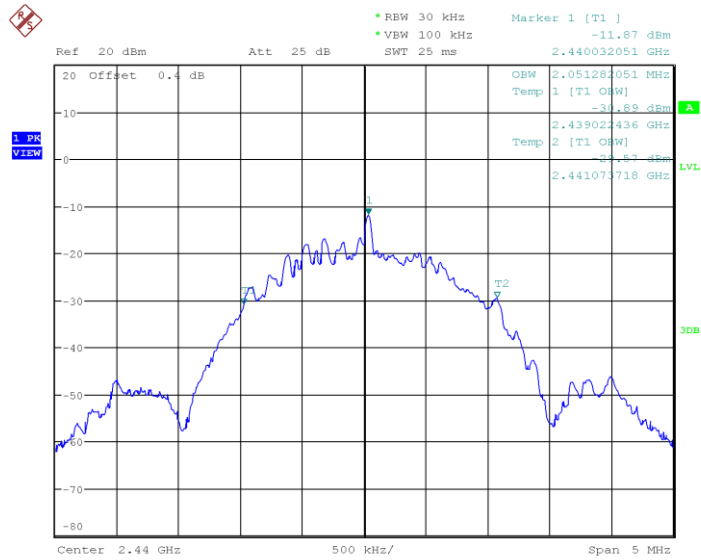


Figure 17: 2440MHz, 2Mbps, 99% Bandwidth

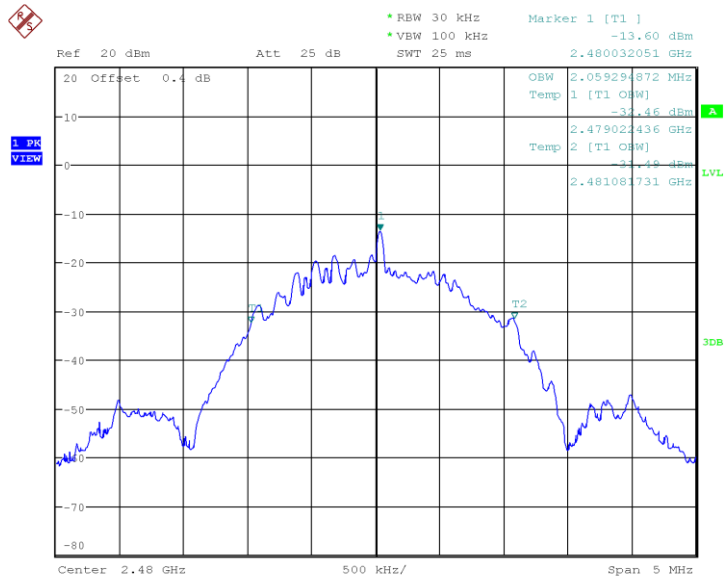


Figure 18: 2480MHz, 2Mbps, 99% Bandwidth

### 4.3 Peak Power Spectral Density

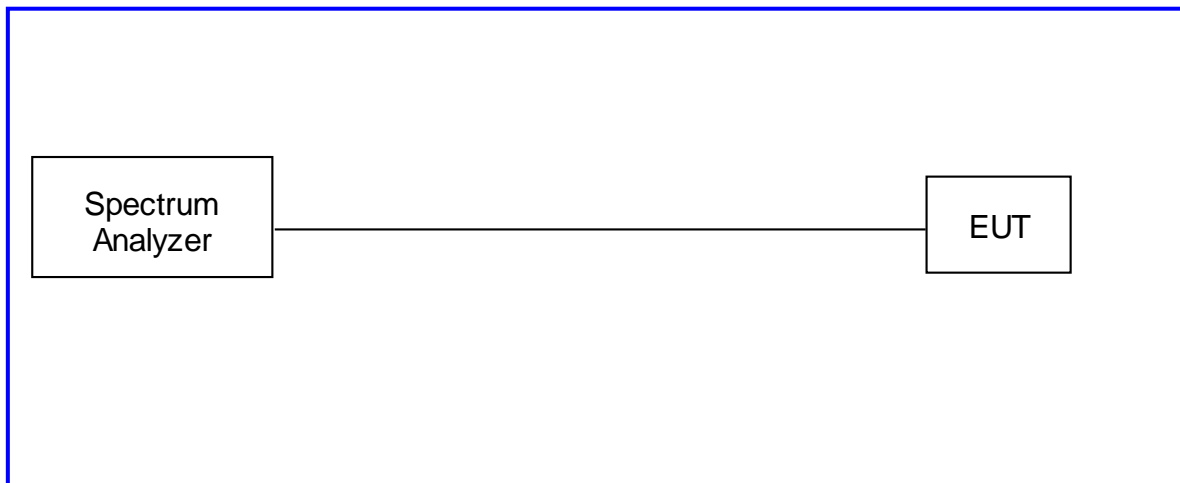
*According to the CFR47 Part 15.247 (e) and RSS 247 Sect.5.2 (b), the power spectral density conducted from the intentional radiator to the antenna shall not be greater than 8 dBm in any 3 kHz band during any time interval of continuous transmission.*

#### 4.3.1 Test Method

The conducted method was used to measure the channel power output per ANSI C63.10-2013 Section 11.10.2. The measurement was performed with modulation per CFR47 Part 15.247 (e) and RSS 247 Sect.5.2 (b). The worst findings were conducted on 3 channels in each operating frequency range of 2402 MHz to 2480 MHz.

Method PKPSD of “KDB 558074 – DTS Measurement Guidance v04” was used.

#### 4.3.2 Test Setup: (Conducted)



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### 4.3.3 Results

As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

**Table 4: Peak Power Spectral Density – Test Results**

| <b>Test Date:</b> November 02, 2022          |                         | <b>Test By:</b> Rachana Khanduri    |                  |             |
|--|-------------------------|-------------------------------------|------------------|-------------|
| <b>Test Method:</b> Conducted Measurements   |                         | <b>Power Setting:</b> -8 dBm        |                  |             |
| <b>Antenna Type:</b> Patch                   |                         | <b>Max. Antenna Gain:</b> -10.1 dBi |                  |             |
| <b>Ambient Temp.:</b> 21 °C                  |                         | <b>Relative Humidity:</b> 37%       |                  |             |
| Bluetooth LE – Peak Power Spectral Density   |                         |                                     |                  |             |
| Data Rate                                    | Operating Channel (MHz) | Total PSD [dBm/kHz]                 | Limit [dBm/3kHz] | Margin [dB] |
| 1Mbps  | 2402                    | -24.35                              | 8.0dBm /3kHz     | -32.35      |
|  | 2440                    | -24.81                              | 8.0dBm /3kHz     | -32.81      |
|  | 2480                    | -26.66                              | 8.0dBm /3kHz     | -34.66      |
| 2Mbps  | 2402                    | -26.75                              | 8.0dBm /3kHz     | -34.75      |
|  | 2440                    | -27.19                              | 8.0dBm /3kHz     | -35.19      |
|  | 2480                    | -28.90                              | 8.0dBm /3kHz     | -36.90      |
| Note: The highest PSD was observed at 1 Mbps |                         |                                     |                  |             |

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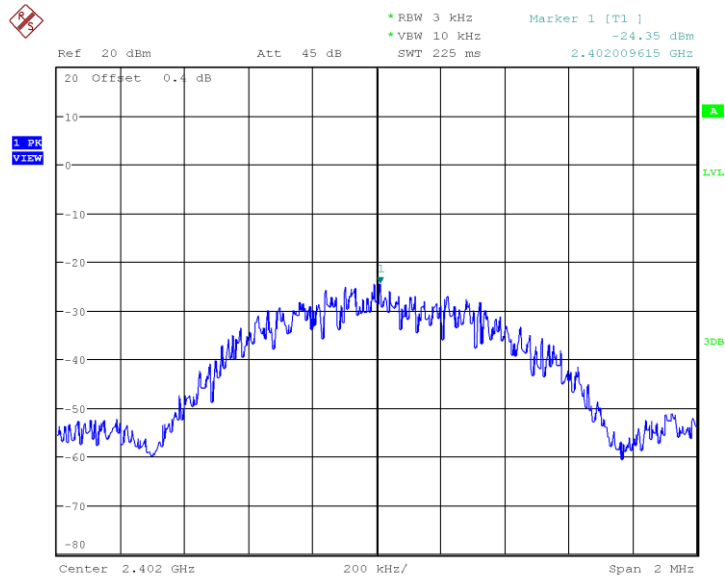


Figure 19: 2402 MHz, 1Mbps, PSD

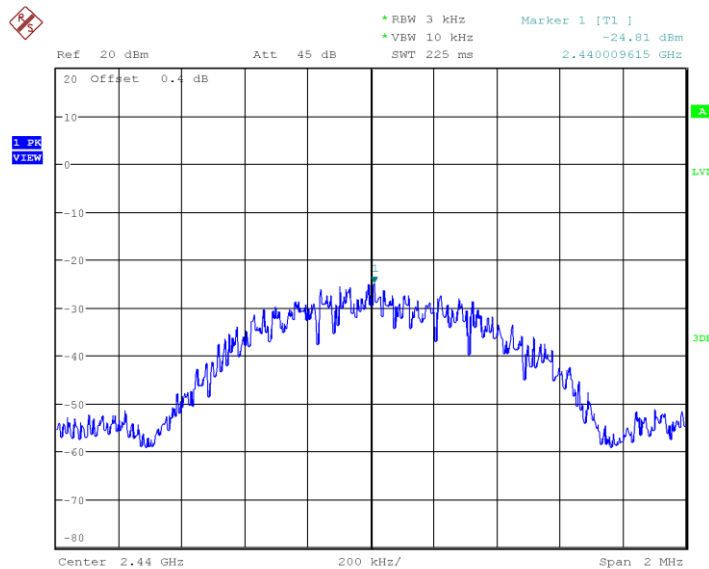


Figure 20: 2440 MHz, 1Mbps, PSD

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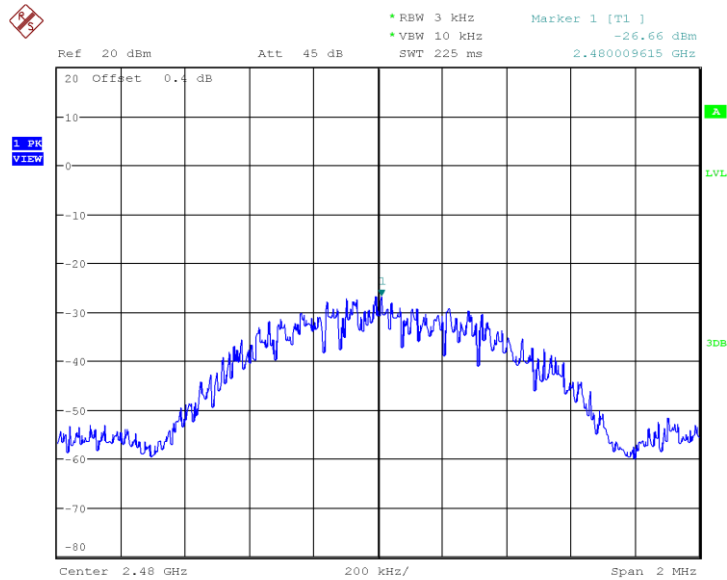


Figure 21: 2480MHz, 1Mbps, PSD

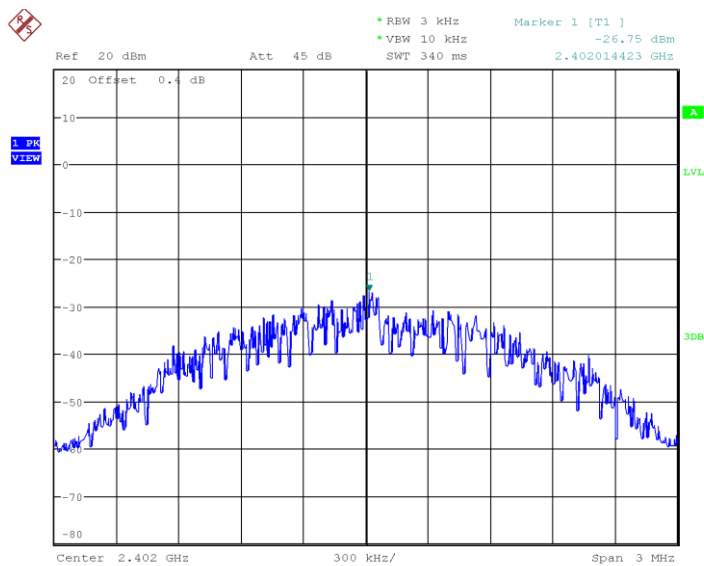


Figure 22: 2402 MHz, 2Mbps, PSD

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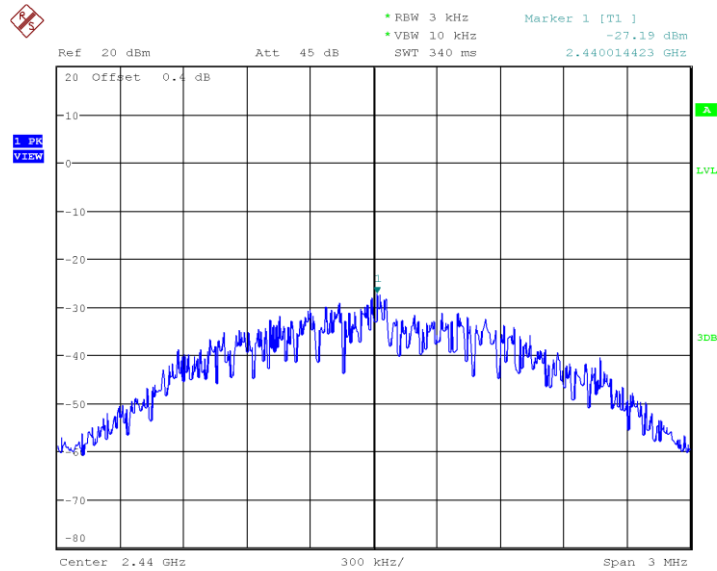


Figure 23: 2440 MHz, 2Mbps, PSD

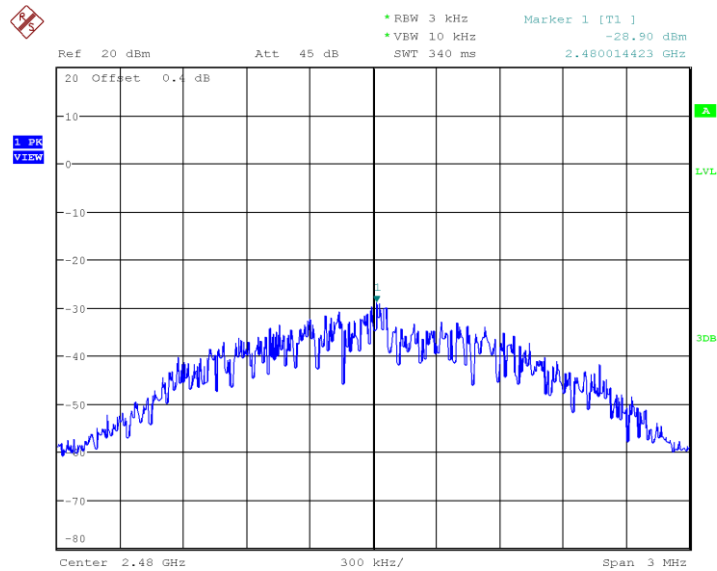


Figure 24: 2480MHz, 2Mbps, PSD



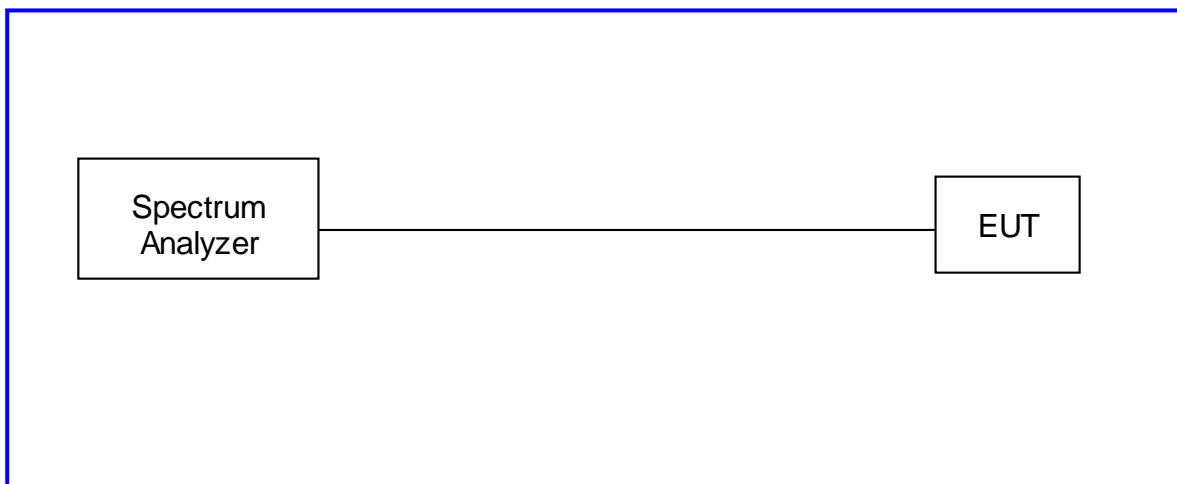
#### 4.4 Out of Band Emissions: Non-Restricted Bands

*Transmitter spurious emissions are emissions outside the frequency range of the equipment when the equipment is in transmitting mode; per requirement of CFR47 15.205, 15.209, 15.247(d), RSS-247 Sect. 5.5, RSS-GEN Sect. 8.9 and 8.10.*

##### 4.4.1 Test Method

Conducted measurements per ANSI C63.10-2013 Sections 6.10, 11.11, 14.3.3 were used to measure the undesirable emission requirement in non-restricted bands. The measurement was performed with modulation. The measurement was conducted from 30MHz to 26.5GHz on 3 channels in each mode on the EUT. Band edge tests were conducted on the low and high channel of each mode. The worst case measurement of each mode is recorded in this report.

##### 4.4.2 Test Setup: (Conducted)



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#### 4.4.3 Results

As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

**Table 5: Emissions at the Band-Edge – Test Results**

| <b>Test Date:</b> October 31, 2022  |           |                   | <b>Test By:</b> Rachana Khanduri    |                   |                     |         |
|---|-----------|-------------------|-------------------------------------|-------------------|---------------------|---------|
| <b>Test Method:</b> Conducted Measurements  |           |                   | <b>Power Setting:</b> -8 dBm        |                   |                     |         |
| <b>Antenna Type:</b> Patch  |           |                   | <b>Max. Antenna Gain:</b> -10.1 dBi |                   |                     |         |
| <b>Ambient Temp.:</b> 21 °C   |           |                   | <b>Relative Humidity:</b> 37%       |                   |                     |         |
| Bluetooth LE – Emissions at the Band-Edge   |           |                   |                                     |                   |                     |         |
| Data Rate   | Band Edge | Center Freq (MHz) | Out of Band Level (dBm)             | 20dBc Level (dBm) | Measured Freq (MHz) | Results |
| 1Mbps   | Low       | 2402              | -40.97                              | -28.94            | 2400.0              | Pass    |
|   | High      | 2480              | -41.12                              | -31.09            | 2483.5              | Pass    |
| 2Mbps   | Low       | 2402              | -38.35                              | -29.01            | 2400.0              | Pass    |
|   | High      | 2480              | -41.91                              | -31.13            | 2483.5              | Pass    |
| <b>Note:</b> dBc is defined as the level below the main carrier.<br>The band-edge level must be lower than the 20dBc level. |           |                   |                                     |                   |                     |         |

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### 4.4.3.1 Band Edge - conducted

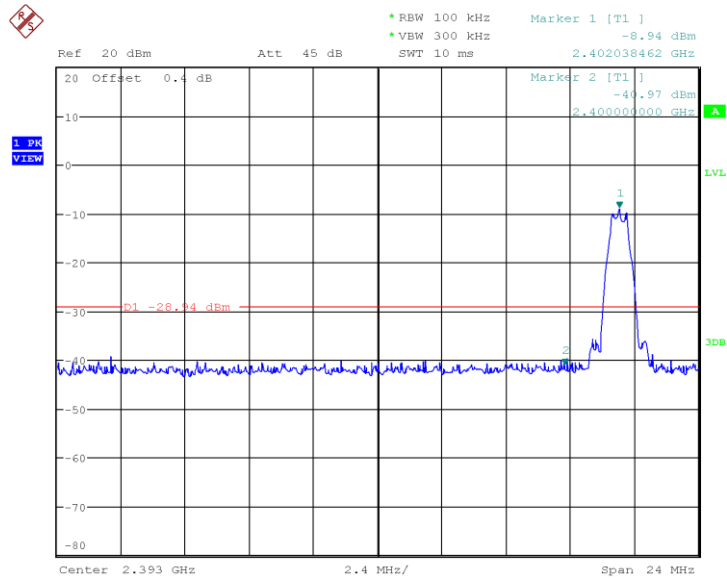


Figure 25: 2402MHz, 1Mbps, Lower Band Edge

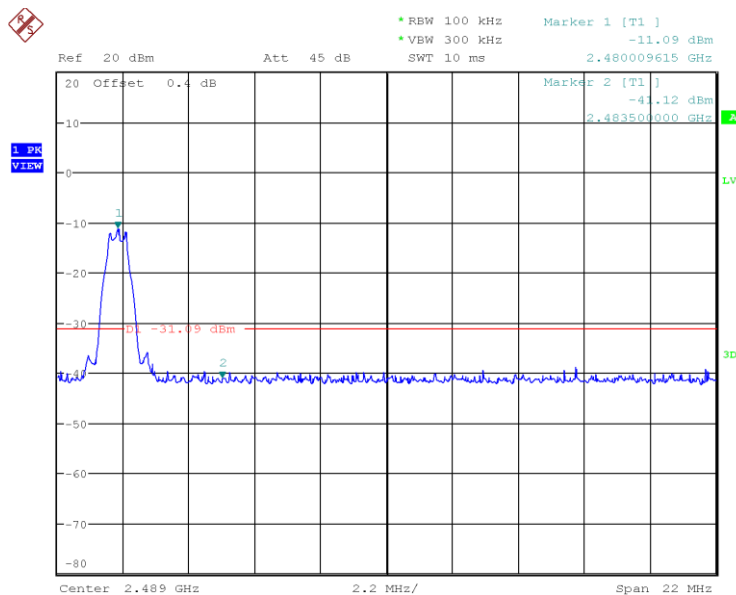


Figure 26: 2480MHz, 1Mbps Upper Band Edge

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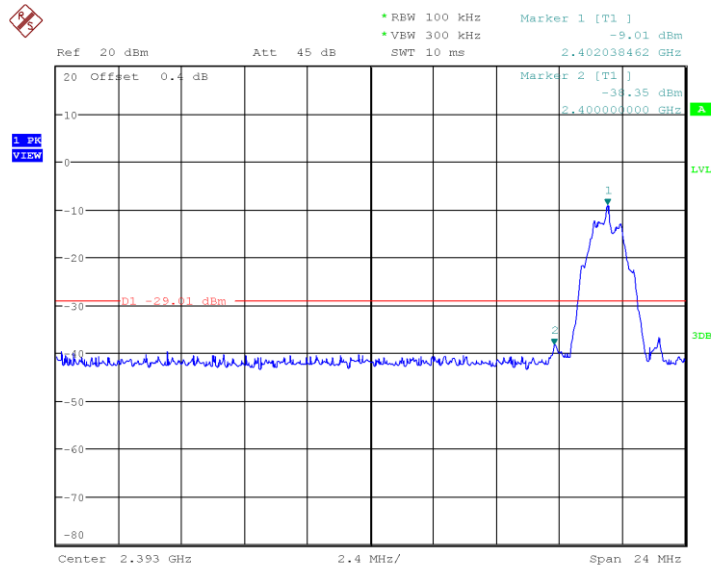


Figure 27: 2402MHz, 2Mbps, Lower Band Edge

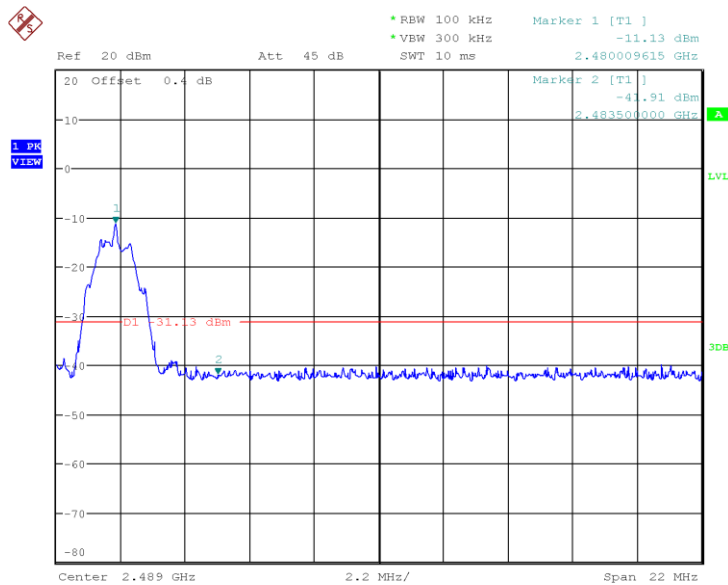


Figure 28: 2480MHz, 2Mbps Upper Band Edge

### 4.4.3.2 Conducted Spurious

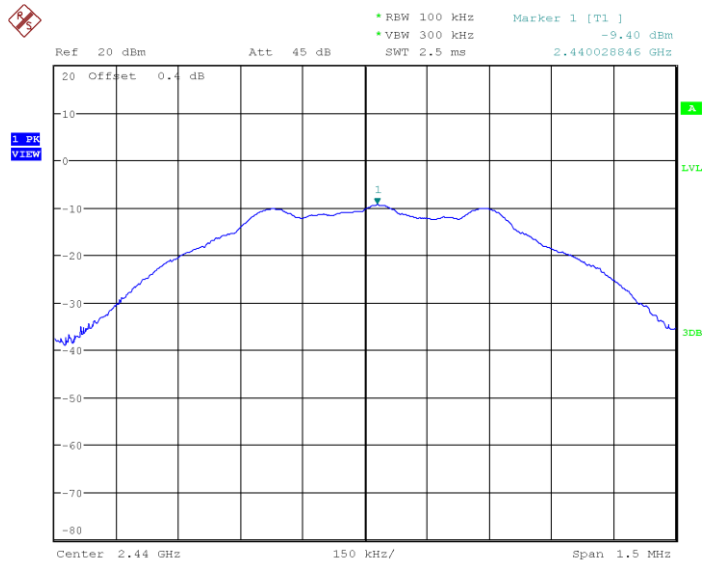


Figure 29: 1Mbps Ref Measurement

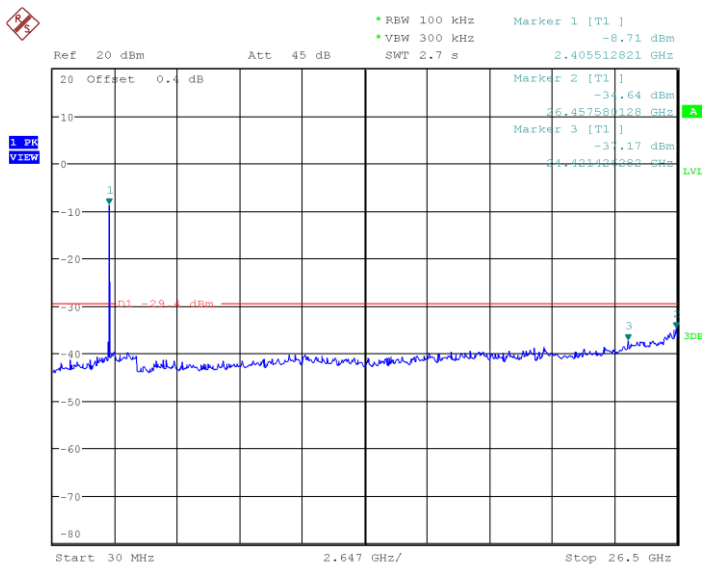


Figure 30: Conducted Emissions, 2402 MHz, 1Mbps

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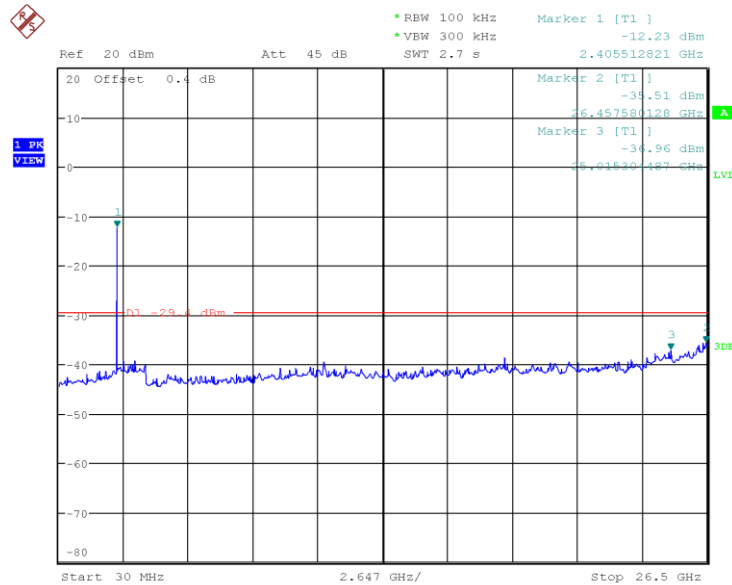


Figure 31: Conducted Emissions, 2440 MHz, 1Mbps

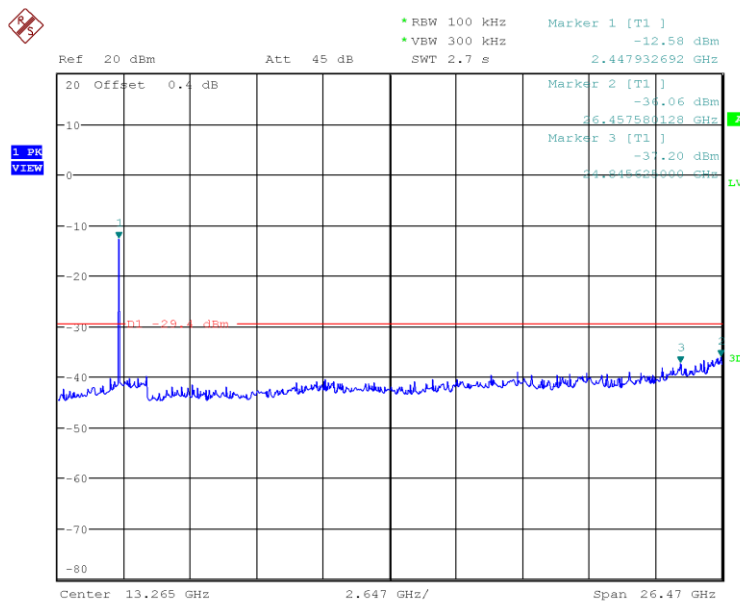


Figure 32: Conducted Emissions, 2480 MHz, 1Mbps

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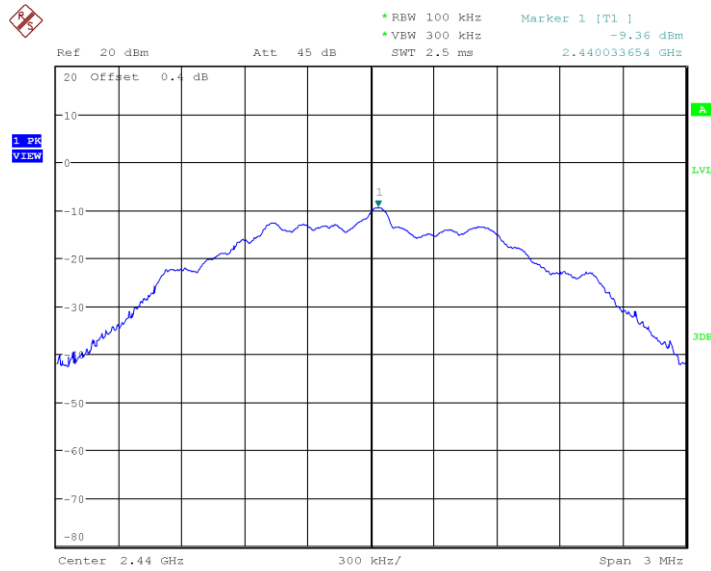


Figure 33: 2Mbps Ref Measurement

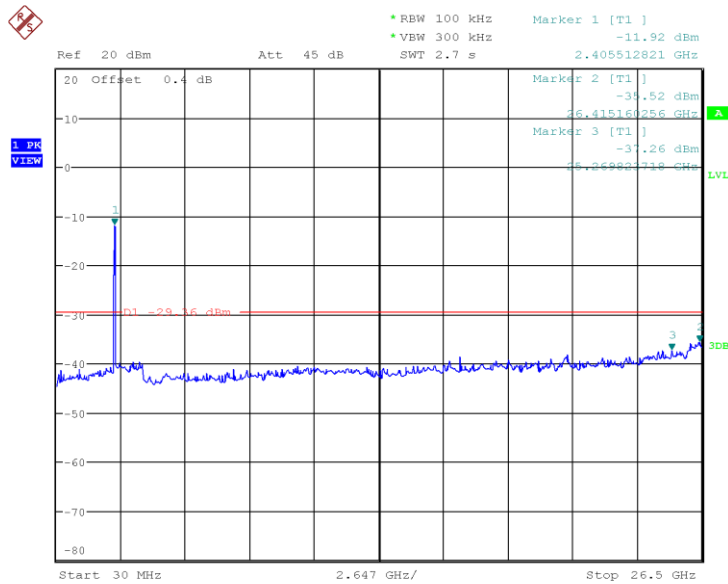


Figure 34: Conducted Emissions, 2402 MHz, 2Mbps

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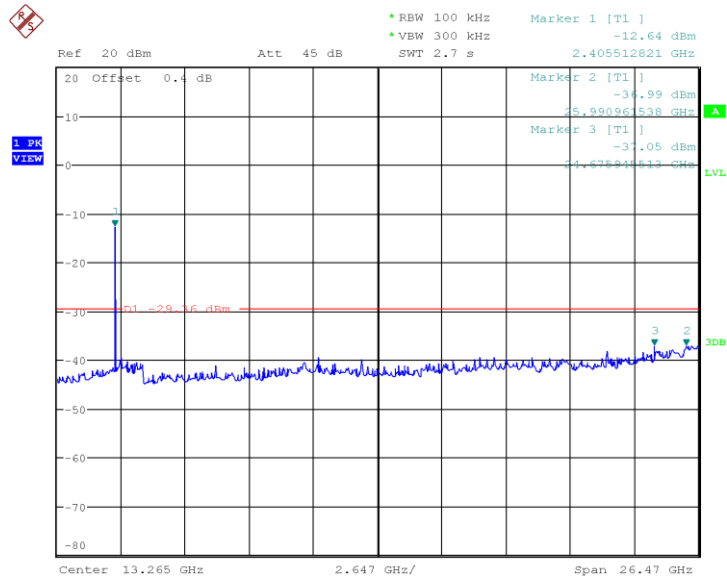


Figure 35: Conducted Emissions, 2440 MHz, 2Mbps

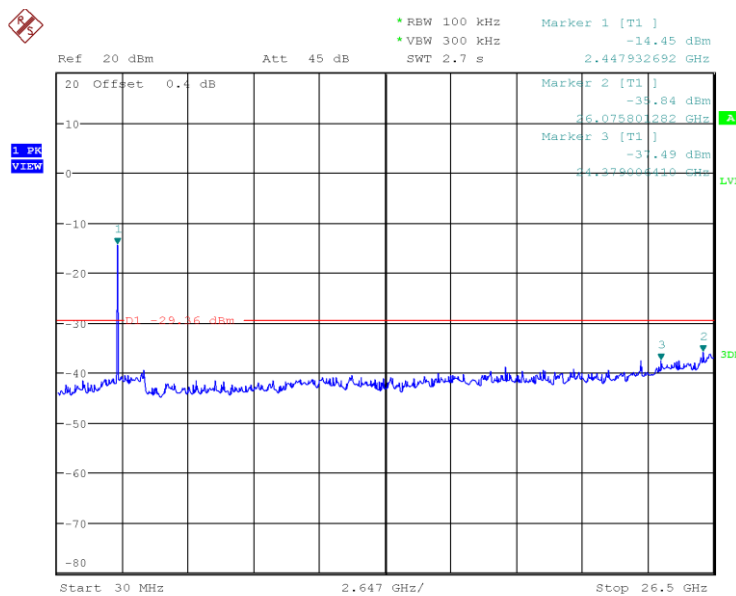


Figure 36: Conducted Emissions, 2480 MHz, 2Mbps



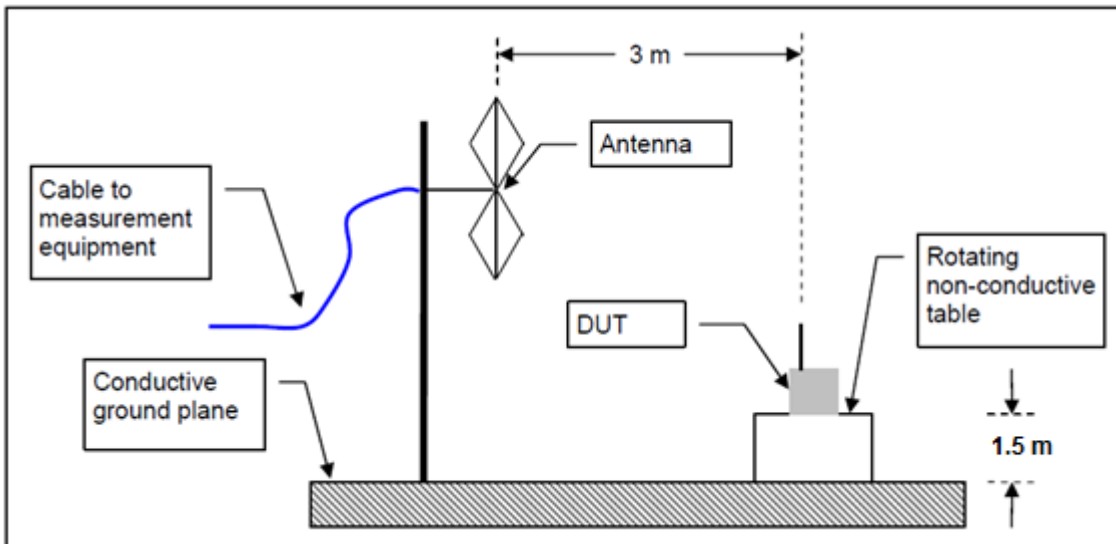
#### 4.1 Out of Band Emissions: Restricted Band Edge

Transmitter spurious emissions are emissions outside the frequency range of the equipment when the equipment is in transmitting mode; per requirement of CFR47 15.205, 15.209, 15.247(d), RSS-247 Sect. 5.5, RSS-GEN Sect. 8.9 and 8.10.

##### 4.1.1 Test Method

Radiated measurements per ANSI C63.10-2013 Section 6.10.5 were used to measure the undesirable emission requirement in restricted bands. Peak points were found and RMS Average was taken for each point found. The measurement was performed with modulation. This test was conducted on low and high channels in BLE mode on the EUT. The worst case 1Mbps measurement of each channel is recorded in this report. All channels were tested at highest power settings. RBW is set to 1MHz, VBW is set to 3MHz.

##### 4.1.2 Test Setup



The DUT was stimulated by manufacturer provided test software that is not available to the end user.

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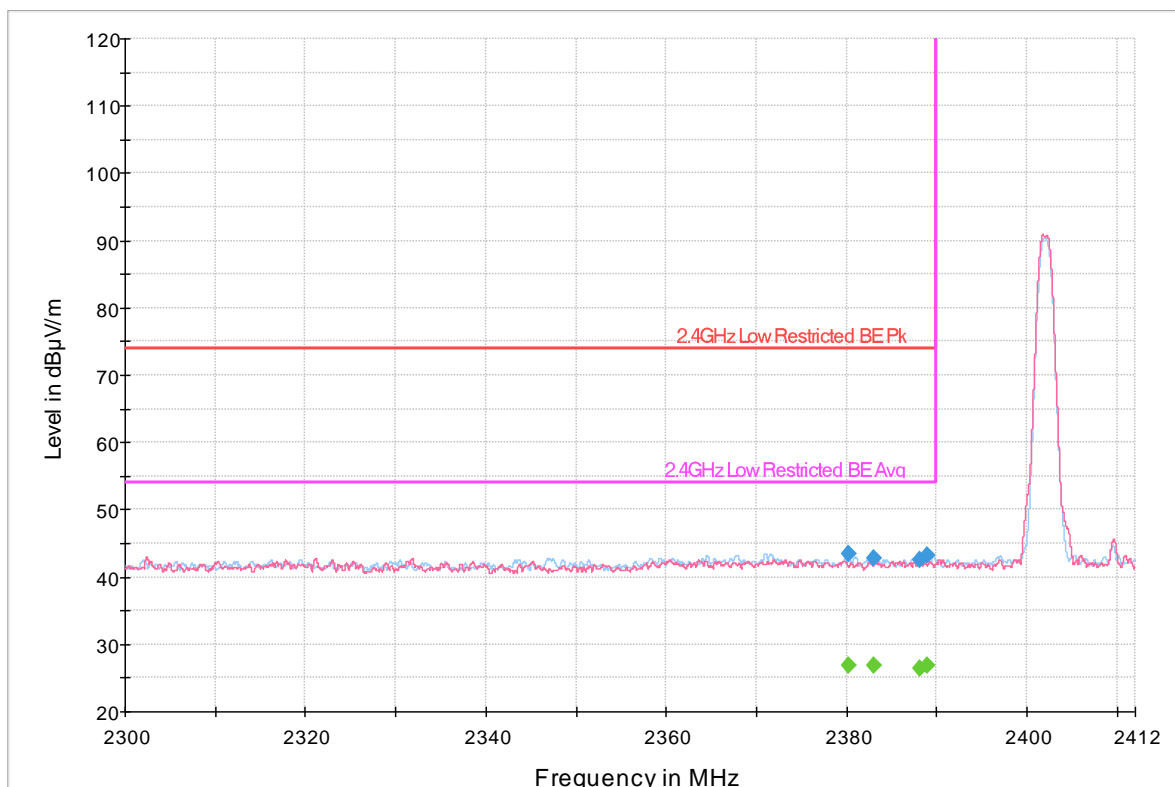
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Prüfbericht-Nr.:

### 4.1.3 Test Results

|  |
|--|
| <b>Test Conditions:</b> Radiated Measurement, Normal Temperature and Voltage |
| <b>Antenna Type:</b> Patch   |
| <b>Power Setting:</b> -8dBm  |
| <b>Max. Antenna Gain:</b> -10.1dBi   |
| <b>Test Performed by:</b> Rachana Khanduri                                   |

| Frequency (MHz) | MaxPeak (dBµV/m) | Average (dBµV/m) | Limit (dBµV/m) | Margin (dB) | Bandwidth (kHz) | Height (cm) | Pol | Azimuth (deg) | Corr. (dB/m) |
|-----------------|------------------|------------------|----------------|-------------|-----------------|-------------|-----|---------------|--------------|
| 2380.259200     | 43.40            | ---              | 74.00          | 30.60       | 1000.000        | 123.0       | H   | 125.0         | -3.2         |
| 2380.259200     | ---              | 26.89            | 54.00          | 27.11       | 1000.000        | 123.0       | H   | 125.0         | -3.2         |
| 2383.036800     | 42.69            | ---              | 74.00          | 31.31       | 1000.000        | 105.0       | H   | 52.0          | -3.1         |
| 2383.036800     | ---              | 26.88            | 54.00          | 27.12       | 1000.000        | 105.0       | H   | 52.0          | -3.1         |
| 2388.177600     | 42.64            | ---              | 74.00          | 31.36       | 1000.000        | 194.0       | V   | 59.0          | -3.5         |
| 2388.177600     | ---              | 26.52            | 54.00          | 27.48       | 1000.000        | 194.0       | V   | 59.0          | -3.5         |
| 2388.928000     | 43.13            | ---              | 74.00          | 30.87       | 1000.000        | 250.0       | H   | 28.0          | -3.1         |
| 2388.928000     | ---              | 26.88            | 54.00          | 27.12       | 1000.000        | 250.0       | H   | 28.0          | -3.1         |



— Preview Result 1H-PK+     
 — 2.4GHz Low Restricted BE Avg     
 — Preview Result 1V-PK+     
 ◆ Final\_Result PK+     
 ◆ 2.4GHz Low Restricted BE Pk     
 ◆ Final\_Result AVG

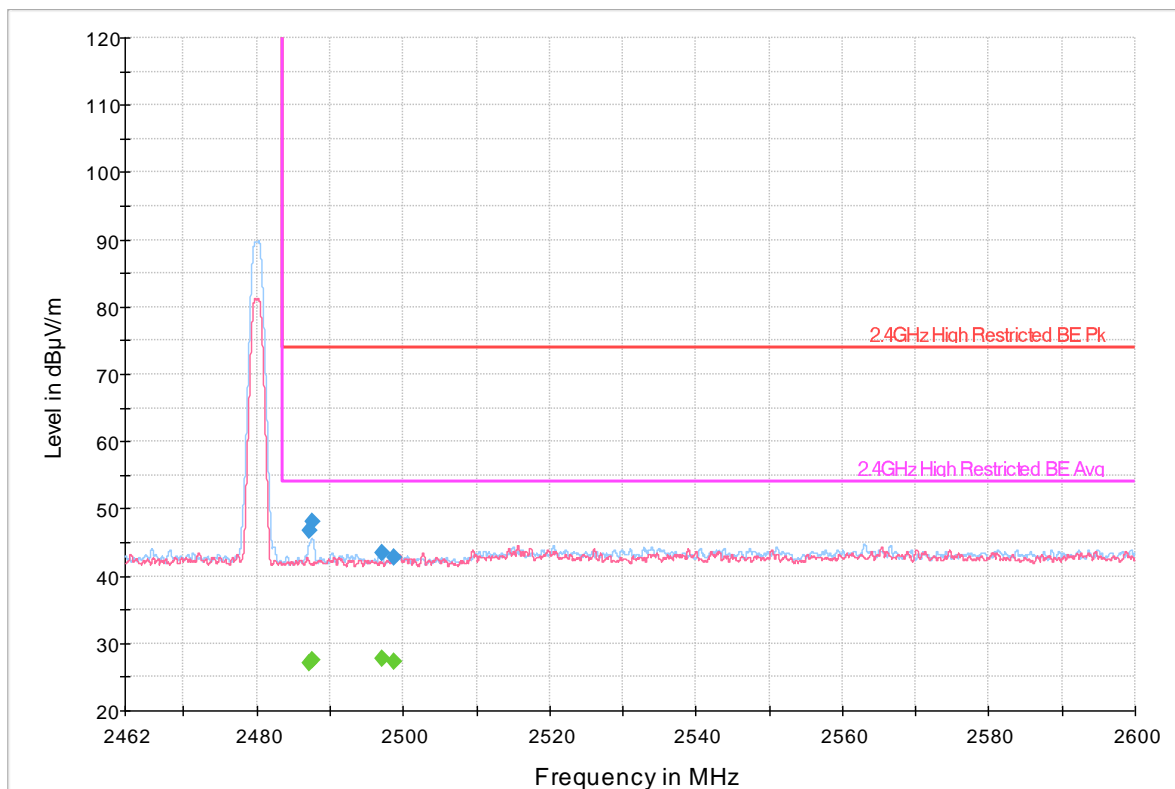
Figure 37: Restricted Band Edge, Low, 2402MHz, 1 Mbps

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Prüfbericht-Nr.:

| Frequency (MHz) | MaxPeak (dBµV/m) | Average (dBµV/m) | Limit (dBµV/m) | Margin (dB) | Bandwidth (kHz) | Height (cm) | Pol | Azimuth (deg) | Corr. (dB/m) |
|-----------------|------------------|------------------|----------------|-------------|-----------------|-------------|-----|---------------|--------------|
| 2487.088400     | ---              | 27.15            | 54.00          | 26.85       | 1000.000        | 250.0       | V   | 270.0         | -3.3         |
| 2487.088400     | 46.78            | ---              | 74.00          | 27.22       | 1000.000        | 250.0       | V   | 270.0         | -3.3         |
| 2487.530000     | 48.16            | ---              | 74.00          | 25.85       | 1000.000        | 100.0       | H   | 57.0          | -2.9         |
| 2487.530000     | ---              | 27.56            | 54.00          | 26.44       | 1000.000        | 100.0       | H   | 57.0          | -2.9         |
| 2497.038200     | ---              | 27.74            | 54.00          | 26.26       | 1000.000        | 106.0       | H   | 180.0         | -2.9         |
| 2497.038200     | 43.34            | ---              | 74.00          | 30.66       | 1000.000        | 106.0       | H   | 180.0         | -2.9         |
| 2498.639000     | 42.83            | ---              | 74.00          | 31.17       | 1000.000        | 104.0       | V   | 254.0         | -3.3         |
| 2498.639000     | ---              | 27.36            | 54.00          | 26.64       | 1000.000        | 104.0       | V   | 254.0         | -3.3         |



— Preview Result 1H-PK+     
 — 2.4GHz High Restricted BE Avg     
 — Preview Result 1V-PK+     
 ◆ Final\_Result PK+     
 — 2.4GHz High Restricted BE Pk     
 ◆ Final\_Result AVG

Figure 38: Restricted Band Edge, High, 2480MHz, 1 Mbps

## 4.2 Transmitter Spurious Emissions

Transmitter spurious emissions are emissions outside the frequency range of the equipment when the equipment is in transmit mode; per requirement of CFR47 15.205, 15.209, 15.247(d), RSS 247 Sect.5.5, RSS-GEN Sect. 8.9 and 8.10.

### 4.2.1 Test Methodology

#### 4.2.1.1 Preliminary Test

A test program that controls instrumentation and data logging was used to automate the preliminary RF emission test procedure. The frequency range of interest was divided into sub-ranges to yield a frequency resolution of approximately 120 kHz and provide a reading at each frequency for no more than 12° of turntable rotation. For each frequency sub-range the turntable was rotated 360° while peak emission data was recorded and measured over the frequency range of interest in horizontal and vertical antenna polarization's.

Preliminary emission profile testing was performed inside the anechoic chamber. The EUT was placed on a 1.0m x 1.5m non-conductive table 80cm (<1 GHz) and 150cm (>1 GHz) above the floor. The EUT was positioned as shown in the setup photographs. The receiving antenna was placed at a distance of 3m at a fixed height of 1m. Measurement equipment was located outside of the chamber. A video camera was placed inside the chamber to view the EUT.

Pre-scans were performed to determine the worst data rate / chains.

#### 4.2.1.2 Final Test

For each frequency measured, the peak emission was maximized by manipulating the receiving antenna from 1 to 4 meters above the ground plane and placing it at the position that produced the maximum signal strength reading. The turntable was then rotated through 360° while observing the peak signal and placing the EUT at the position that produced maximum radiation. The six highest emissions relative to the limit were measured unless such emissions were more than 20 dB below the limit. If less than six emissions are within 20 dB of the limit, than the noise level of the receiver is measured at frequencies where emissions are expected. Multiples of all oscillator and microprocessor frequencies were also checked.

Final testing was performed on an NSA compliant test site. The EUT was placed on a 1.0m x 1.5m non-conductive table 80cm (<1 GHz) and 150cm (>1 GHz) above the ground plane. The placement of EUT and cables were the same as for preliminary testing and is shown in the setup photographs.

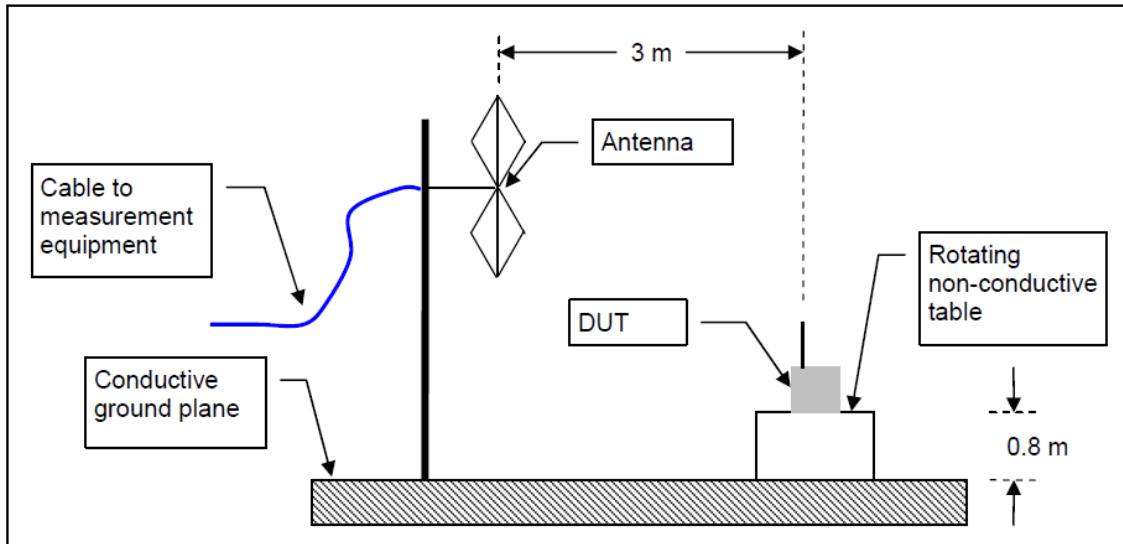
#### 4.2.1.3 Deviations

None.

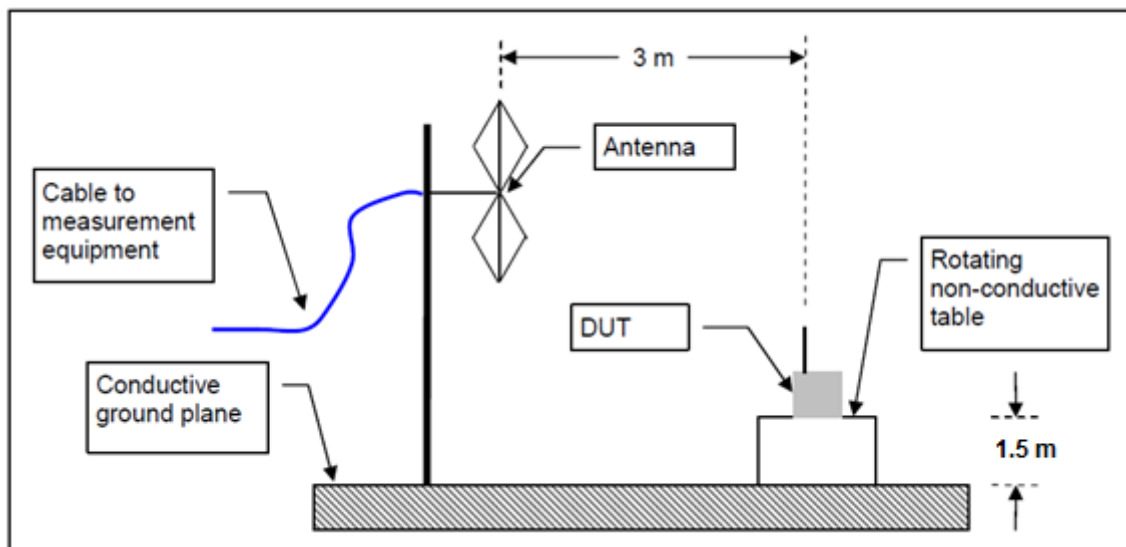
#### 4.2.2 Test Setup:

All tests were conducted at full power on low, middle, and high channels. The DUT was stimulated by manufacturer provided test software that is not available to the end user.

#### 30MHz-1GHz



#### 1-26.5GHz



### 4.2.3 Transmitter Spurious Emission Limit

The spurious emissions of the transmitter shall not exceed the values in CFR47 Part 15.205, 15.209: 2015 and RSS Gen Sect. 8.9 and 8.10: 2014.

| Frequency (MHz)  | Field strength<br>(microvolts/meter) | Measurement<br>distance<br>(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                                   |

### 4.2.4 Test Results

The final measurement data was taken under the worst case operating modes, configurations, and/or cable positions. It also reflects the results including any modifications and/or special accessories listed in Sections 1.4 and test plan.

Frequencies below 30MHz and above 18GHz were investigated and no emissions were found above the noise floor. Both horizontal and vertical polarities were investigated. The results show only the worst case.

As originally tested, the EUT was found to be compliant to the requirements of the test standard(s).

Note: The 2.4 GHz notch filter was used to protect the front end of the pre-amp.

4.2.4.1 Measurement Results:

| Frequency (MHz) | QuasiPeak (dBµV/m) | Limit (dBµV/m) | Margin (dB) | Meas. Time (ms) | Bandwidth (kHz) | Height (cm) | Pol | Azimuth (deg) | Corr. (dB/m) |
|-----------------|--------------------|----------------|-------------|-----------------|-----------------|-------------|-----|---------------|--------------|
| 48.049550       | 24.25              | 40.00          | 15.75       | 10000.0         | 120.000         | 100.0       | V   | 95.0          | -9.8         |
| 143.673600      | 28.31              | 43.52          | 15.21       | 10000.0         | 120.000         | 154.0       | H   | 212.0         | -16.3        |
| 168.022850      | 37.27              | 43.52          | 6.25        | 10000.0         | 120.000         | 104.0       | H   | 215.0         | -15.0        |
| 192.046000      | 36.89              | 43.52          | 6.63        | 10000.0         | 120.000         | 100.0       | H   | 215.0         | -13.4        |
| 503.626800      | 28.25              | 46.02          | 17.77       | 10000.0         | 120.000         | 100.0       | V   | 170.0         | -5.9         |
| 836.355100      | 23.29              | 46.02          | 22.73       | 10000.0         | 120.000         | 100.0       | V   | 167.0         | -1.7         |

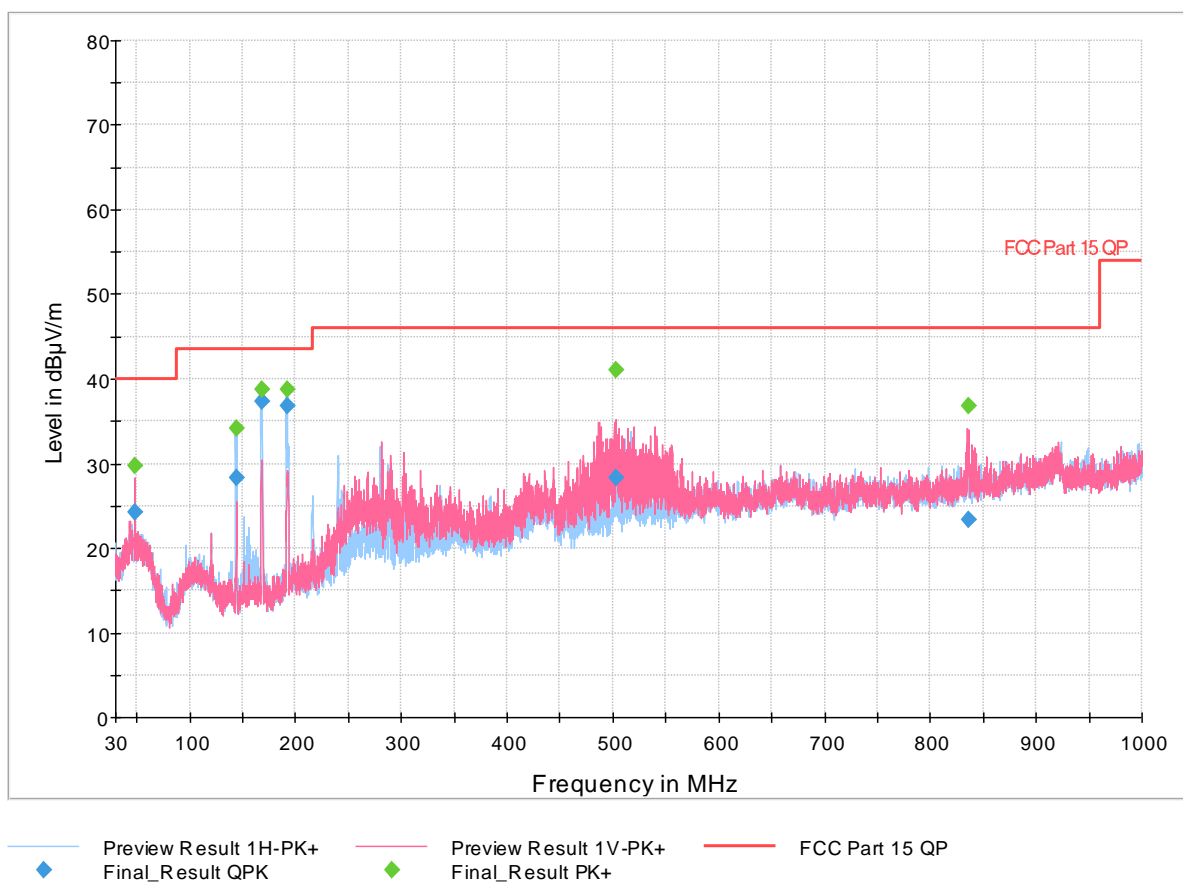


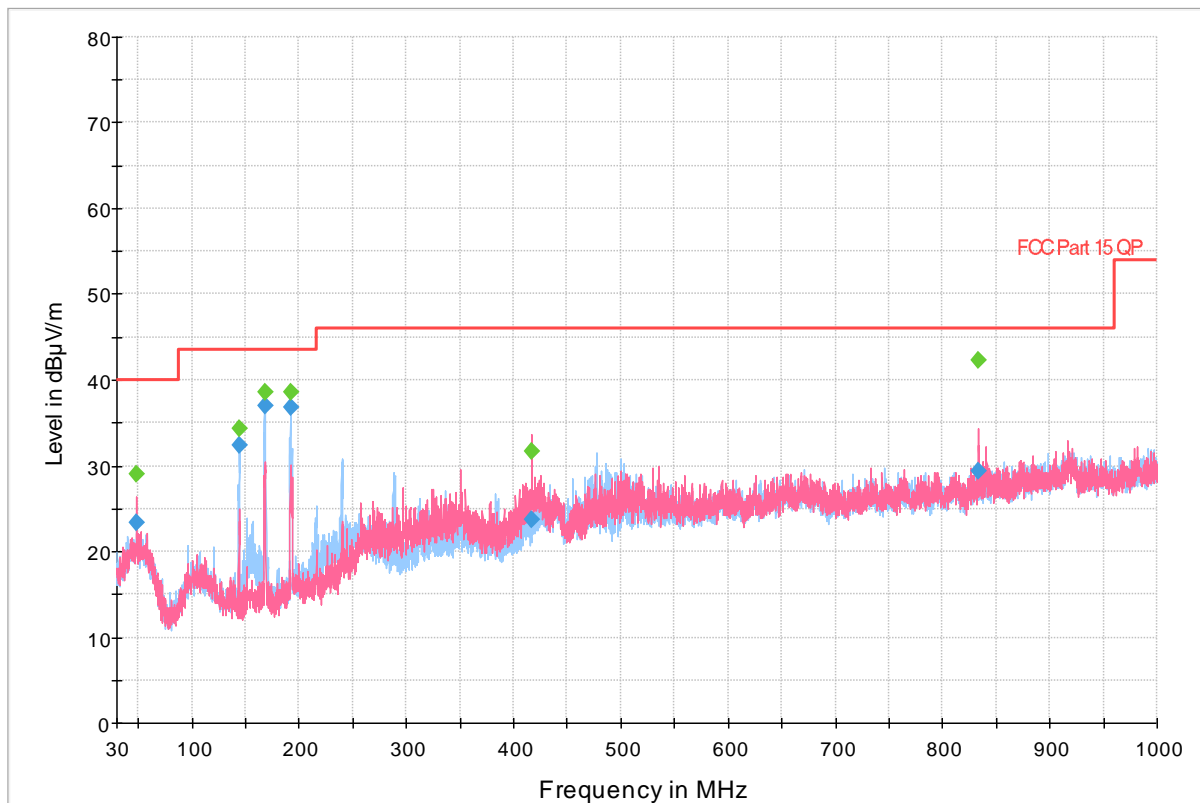
Figure 39: Radiated Spurious Emissions 30MHz – 1GHz, 2402MHz, 1Mbps

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Prüfbericht-Nr.:

| Frequency (MHz) | QuasiPeak (dBµV/m) | Limit (dBµV/m) | Margin (dB) | Meas. Time (ms) | Bandwidth (kHz) | Height (cm) | Pol | Azimuth (deg) | Corr. (dB/m) |
|-----------------|--------------------|----------------|-------------|-----------------|-----------------|-------------|-----|---------------|--------------|
| 48.160400       | 23.34              | 40.00          | 16.66       | 10000.0         | 120.000         | 100.0       | V   | 287.0         | -9.9         |
| 143.994200      | 32.44              | 43.52          | 11.08       | 10000.0         | 120.000         | 150.0       | H   | 210.0         | -16.4        |
| 168.377950      | 37.01              | 43.52          | 6.51        | 10000.0         | 120.000         | 105.0       | H   | 214.0         | -15.0        |
| 191.891600      | 36.76              | 43.52          | 6.76        | 10000.0         | 120.000         | 100.0       | H   | 221.0         | -13.4        |
| 416.971300      | 23.64              | 46.02          | 22.38       | 10000.0         | 120.000         | 105.0       | V   | 172.0         | -8.2         |
| 833.895000      | 29.36              | 46.02          | 16.66       | 10000.0         | 120.000         | 100.0       | V   | 187.0         | -1.7         |



◆ Preview Result 1H-PK+ Final\_Result QPK    
 ◆ Preview Result 1V-PK+ Final\_Result PK+    
 — FCC Part 15 QP

Figure 40: Radiated Spurious Emissions 30MHz – 1GHz, 2440MHz, 1Mbps

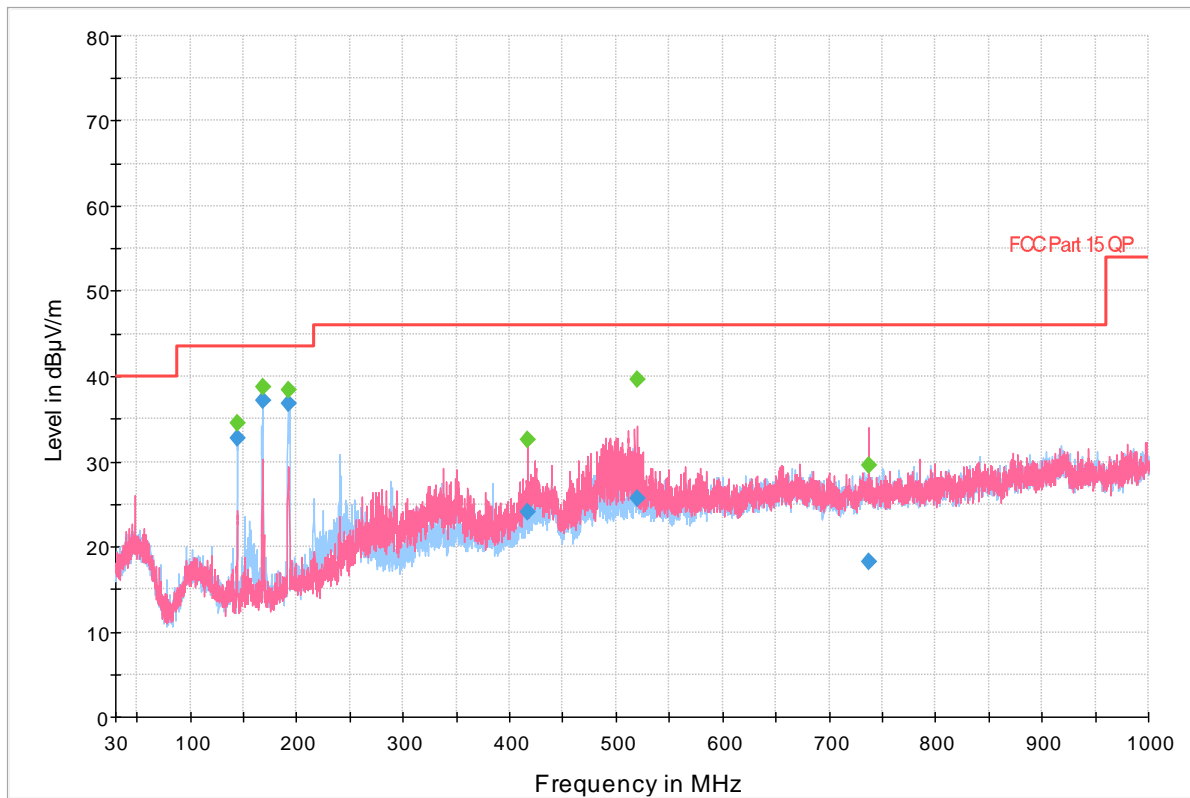


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Prüfbericht-Nr.:

| Frequency (MHz) | QuasiPeak (dBµV/m) | Limit (dBµV/m) | Margin (dB) | Meas. Time (ms) | Bandwidth (kHz) | Height (cm) | Pol | Azimuth (deg) | Corr. (dB/m) |
|-----------------|--------------------|----------------|-------------|-----------------|-----------------|-------------|-----|---------------|--------------|
| 144.157150      | 32.66              | 43.52          | 10.86       | 10000.0         | 120.000         | 150.0       | H   | 207.0         | -16.4        |
| 168.086950      | 37.15              | 43.52          | 6.37        | 10000.0         | 120.000         | 103.0       | H   | 223.0         | -15.0        |
| 192.130900      | 36.74              | 43.52          | 6.78        | 10000.0         | 120.000         | 103.0       | H   | 227.0         | -13.4        |
| 416.827700      | 24.01              | 46.02          | 22.01       | 10000.0         | 120.000         | 105.0       | V   | 216.0         | -8.2         |
| 519.613650      | 25.62              | 46.02          | 20.40       | 10000.0         | 120.000         | 100.0       | V   | 164.0         | -5.6         |
| 737.624300      | 18.31              | 46.02          | 27.71       | 10000.0         | 120.000         | 244.0       | V   | 33.0          | -2.3         |



◆ Preview Result 1H-PK+      ◆ Preview Result 1V-PK+      — FCC Part 15 QP  
◆ Final\_Result QPK              ◆ Final\_Result PK+

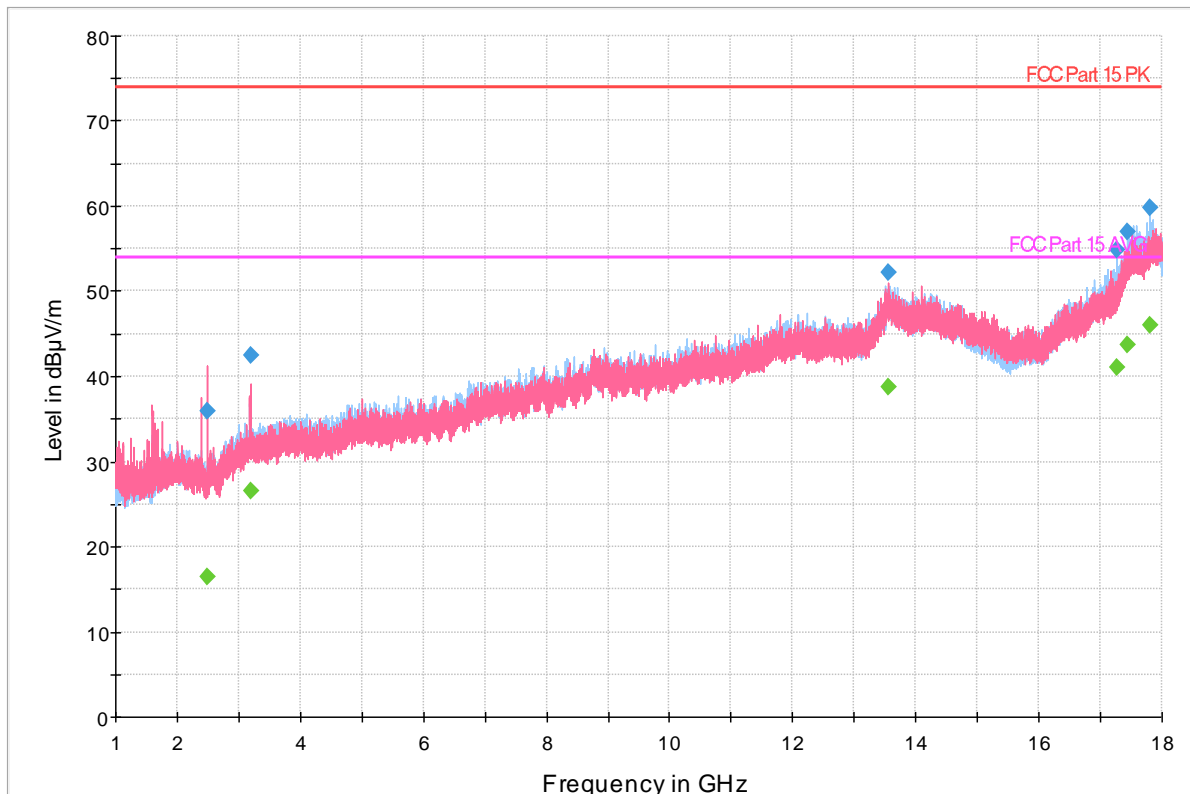
Figure 41: Radiated Spurious Emissions 30MHz – 1GHz, 2480MHz, 1Mbps

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Prüfbericht-Nr.:

| Frequency (MHz) | MaxPeak (dBµV/m) | Average (dBµV/m) | Limit (dBµV/m) | Margin (dB) | Bandwidth (kHz) | Height (cm) | Pol | Azimuth (deg) | Corr. (dB/m) |
|-----------------|------------------|------------------|----------------|-------------|-----------------|-------------|-----|---------------|--------------|
| 2479.675000     | ---              | 16.46            | 54.00          | 37.54       | 1000.000        | 154.0       | V   | 133.0         | -3.5         |
| 2479.675000     | 35.93            | ---              | 74.00          | 38.07       | 1000.000        | 154.0       | V   | 133.0         | -3.5         |
| 3192.500000     | ---              | 26.54            | 54.00          | 27.46       | 1000.000        | 150.0       | V   | 212.0         | -0.4         |
| 3192.500000     | 42.45            | ---              | 74.00          | 31.55       | 1000.000        | 150.0       | V   | 212.0         | -0.4         |
| 13551.000000    | 52.25            | ---              | 74.00          | 21.75       | 1000.000        | 100.0       | V   | 339.0         | 18.1         |
| 13551.000000    | ---              | 38.81            | 54.00          | 15.19       | 1000.000        | 100.0       | V   | 339.0         | 18.1         |
| 17267.500000    | 54.90            | ---              | 74.00          | 19.10       | 1000.000        | 150.0       | H   | 95.0          | 22.4         |
| 17267.500000    | ---              | 41.01            | 54.00          | 12.99       | 1000.000        | 150.0       | H   | 95.0          | 22.4         |
| 17435.783000    | 57.07            | ---              | 74.00          | 16.93       | 1000.000        | 250.0       | H   | 71.0          | 23.8         |
| 17435.783000    | ---              | 43.63            | 54.00          | 10.37       | 1000.000        | 250.0       | H   | 71.0          | 23.8         |
| 17798.821000    | 59.77            | ---              | 74.00          | 14.23       | 1000.000        | 250.0       | H   | 19.0          | 26.5         |
| 17798.821000    | ---              | 45.98            | 54.00          | 8.02        | 1000.000        | 250.0       | H   | 19.0          | 26.5         |



— Preview Result 1H-PK+     — Preview Result 1V-PK+     — FCC Part 15 PK  
— FCC Part 15 AVG     ◆ Final\_Result PK+     ◆ Final\_Result AVG

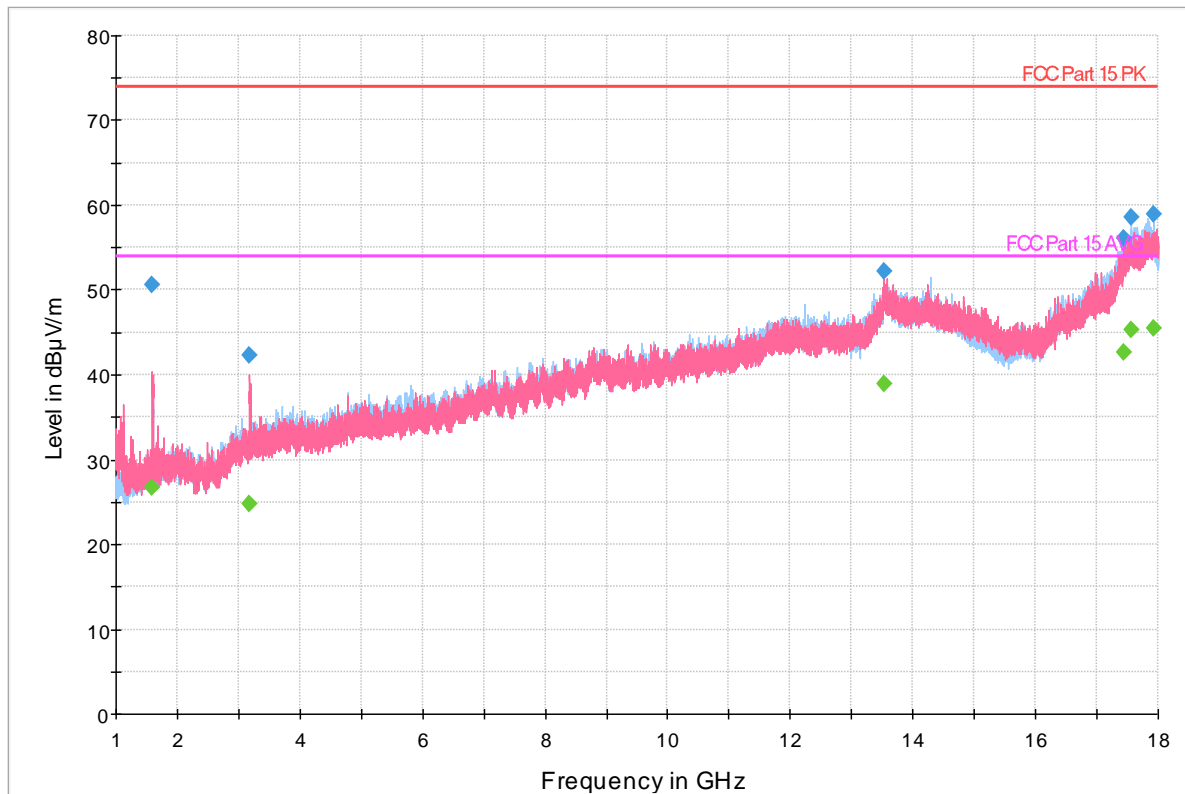
Figure 42: Radiated Spurious Emissions 1GHz - 18GHz, 2402MHz, 1Mbps

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Prüfbericht-Nr.:

| Frequency (MHz) | MaxPeak (dBµV/m) | Average (dBµV/m) | Limit (dBµV/m) | Margin (dB) | Bandwidth (kHz) | Height (cm) | Pol | Azimuth (deg) | Corr. (dB/m) |
|-----------------|------------------|------------------|----------------|-------------|-----------------|-------------|-----|---------------|--------------|
| 1596.180000     | 50.57            | ---              | 74.00          | 23.43       | 1000.000        | 154.0       | V   | 239.0         | -6.5         |
| 1596.180000     | ---              | 26.76            | 54.00          | 27.24       | 1000.000        | 154.0       | V   | 239.0         | -6.5         |
| 3185.839000     | 42.25            | ---              | 74.00          | 31.75       | 1000.000        | 250.0       | V   | 207.0         | -0.4         |
| 3185.839000     | ---              | 24.78            | 54.00          | 29.22       | 1000.000        | 250.0       | V   | 207.0         | -0.4         |
| 13520.815971    | 52.22            | ---              | 74.00          | 21.78       | 1000.000        | 235.0       | V   | 22.0          | 18.0         |
| 13520.815971    | ---              | 38.88            | 54.00          | 15.12       | 1000.000        | 235.0       | V   | 22.0          | 18.0         |
| 17441.645000    | 56.04            | ---              | 74.00          | 17.96       | 1000.000        | 104.0       | V   | 240.0         | 23.0         |
| 17441.645000    | ---              | 42.67            | 54.00          | 11.33       | 1000.000        | 104.0       | V   | 240.0         | 23.0         |
| 17567.358971    | ---              | 45.31            | 54.00          | 8.69        | 1000.000        | 104.0       | H   | 203.0         | 25.0         |
| 17567.358971    | 58.64            | ---              | 74.00          | 15.36       | 1000.000        | 104.0       | H   | 203.0         | 25.0         |
| 17936.999029    | ---              | 45.47            | 54.00          | 8.53        | 1000.000        | 250.0       | H   | 52.0          | 26.3         |
| 17936.999029    | 58.93            | ---              | 74.00          | 15.07       | 1000.000        | 250.0       | H   | 52.0          | 26.3         |



— Preview Result 1H-PK+    
 — Preview Result 1V-PK+    
 — FCC Part 15 PK  
— FCC Part 15 AVG    
 ◆ Final\_Result PK+    
 ◆ Final\_Result AVG

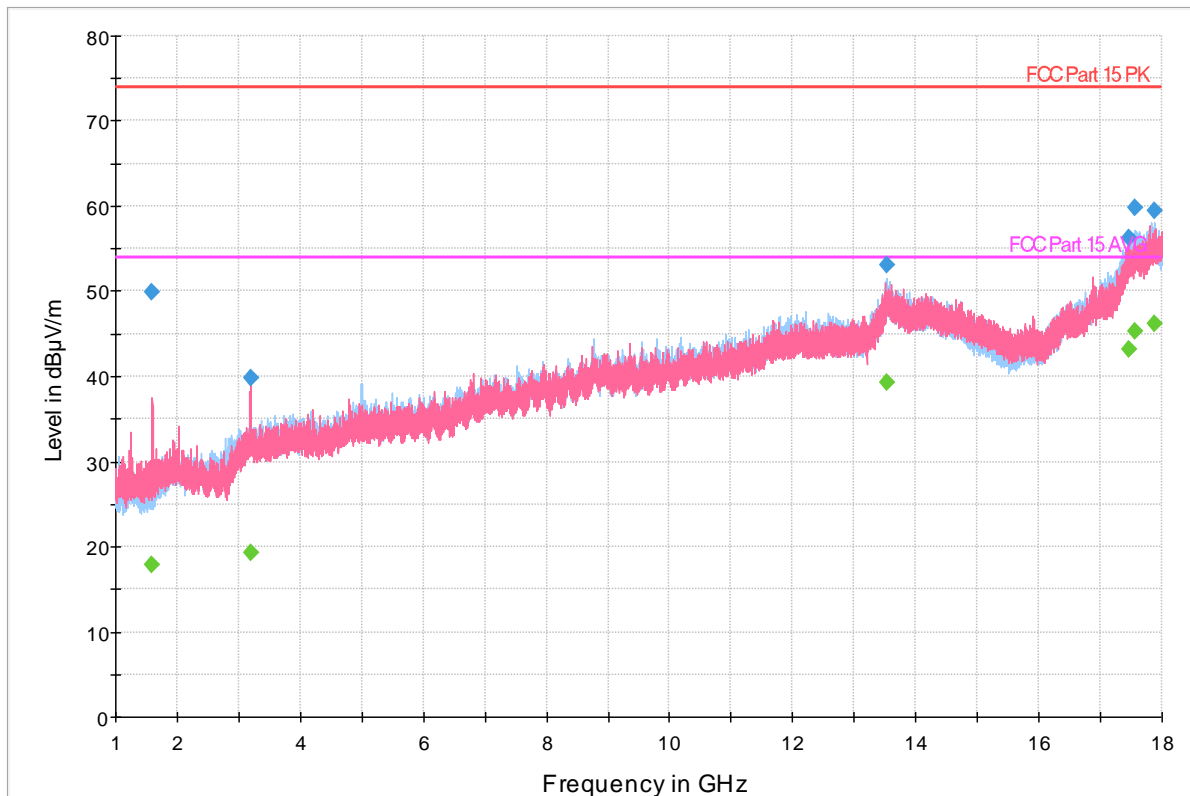
Figure 43: Radiated Spurious Emissions 1GHz - 18GHz, 2440MHz, 1Mbps

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Prüfbericht-Nr.:

| Frequency (MHz) | MaxPeak (dBµV/m) | Average (dBµV/m) | Limit (dBµV/m) | Margin (dB) | Bandwidth (kHz) | Height (cm) | Pol | Azimuth (deg) | Corr. (dB/m) |
|-----------------|------------------|------------------|----------------|-------------|-----------------|-------------|-----|---------------|--------------|
| 1598.031000     | ---              | 17.79            | 54.00          | 36.21       | 1000.000        | 103.0       | V   | 195.0         | -6.5         |
| 1598.031000     | 49.90            | ---              | 74.00          | 24.10       | 1000.000        | 103.0       | V   | 195.0         | -6.5         |
| 3189.386971     | 39.76            | ---              | 74.00          | 34.24       | 1000.000        | 103.0       | V   | 234.0         | -0.4         |
| 3189.386971     | ---              | 19.24            | 54.00          | 34.76       | 1000.000        | 103.0       | V   | 234.0         | -0.4         |
| 13529.248000    | 53.11            | ---              | 74.00          | 20.89       | 1000.000        | 100.0       | H   | 209.0         | 18.2         |
| 13529.248000    | ---              | 39.32            | 54.00          | 14.68       | 1000.000        | 100.0       | H   | 209.0         | 18.2         |
| 17454.023000    | ---              | 43.15            | 54.00          | 10.85       | 1000.000        | 100.0       | V   | 58.0          | 23.1         |
| 17454.023000    | 56.29            | ---              | 74.00          | 17.71       | 1000.000        | 100.0       | V   | 58.0          | 23.1         |
| 17565.131000    | 59.74            | ---              | 74.00          | 14.26       | 1000.000        | 150.0       | H   | 288.0         | 25.0         |
| 17565.131000    | ---              | 45.35            | 54.00          | 8.65        | 1000.000        | 150.0       | H   | 288.0         | 25.0         |
| 17873.484029    | 59.46            | ---              | 74.00          | 14.54       | 1000.000        | 155.0       | H   | -1.0          | 26.8         |
| 17873.484029    | ---              | 46.16            | 54.00          | 7.84        | 1000.000        | 155.0       | H   | -1.0          | 26.8         |



— Preview Result 1H-PK+    
 — Preview Result 1V-PK+    
 — FCC Part 15 PK  
— FCC Part 15 AVG    
 ◆ Final\_Result PK+    
 ◆ Final\_Result AVG

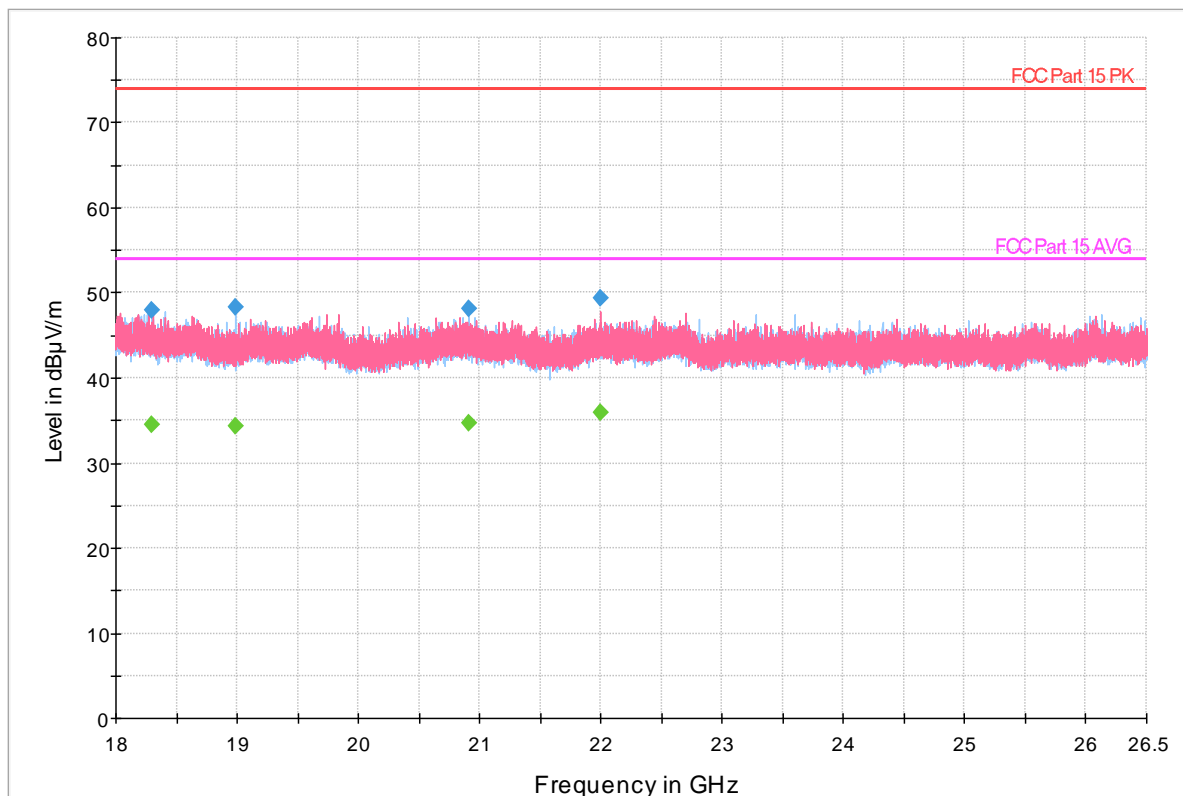
Figure 44: Radiated Spurious Emissions 1GHz - 18GHz, 2480MHz, 1Mbps

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Prüfbericht-Nr.:

| Frequency (MHz) | MaxPeak (dBµV/m) | Average (dBµV/m) | Limit (dBµV/m) | Margin (dB) | Bandwidth (kHz) | Height (cm) | Pol | Azimuth (deg) | Corr. (dB/m) |
|-----------------|------------------|------------------|----------------|-------------|-----------------|-------------|-----|---------------|--------------|
| 18298.042971    | 47.92            | ---              | 74.00          | 26.08       | 1000.000        | 106.0       | H   | 205.0         | -2.7         |
| 18298.042971    | ---              | 34.54            | 54.00          | 19.46       | 1000.000        | 106.0       | H   | 205.0         | -2.7         |
| 18984.250000    | ---              | 34.27            | 54.00          | 19.73       | 1000.000        | 103.0       | H   | 164.0         | -1.8         |
| 18984.250000    | 48.34            | ---              | 74.00          | 25.66       | 1000.000        | 103.0       | H   | 164.0         | -1.8         |
| 20907.000000    | 48.06            | ---              | 74.00          | 25.94       | 1000.000        | 100.0       | H   | 158.0         | 0.5          |
| 20907.000000    | ---              | 34.68            | 54.00          | 19.32       | 1000.000        | 100.0       | H   | 158.0         | 0.5          |
| 22000.372029    | ---              | 35.95            | 54.00          | 18.05       | 1000.000        | 100.0       | V   | 214.0         | 0.8          |
| 22000.372029    | 49.46            | ---              | 74.00          | 24.54       | 1000.000        | 100.0       | V   | 214.0         | 0.8          |



— Preview Result 1H-PK+     — Preview Result 1V-PK+     — FCC Part 15 PK  
— FCC Part 15 AVG     ◆ Final\_Result PK+     ◆ Final\_Result AVG

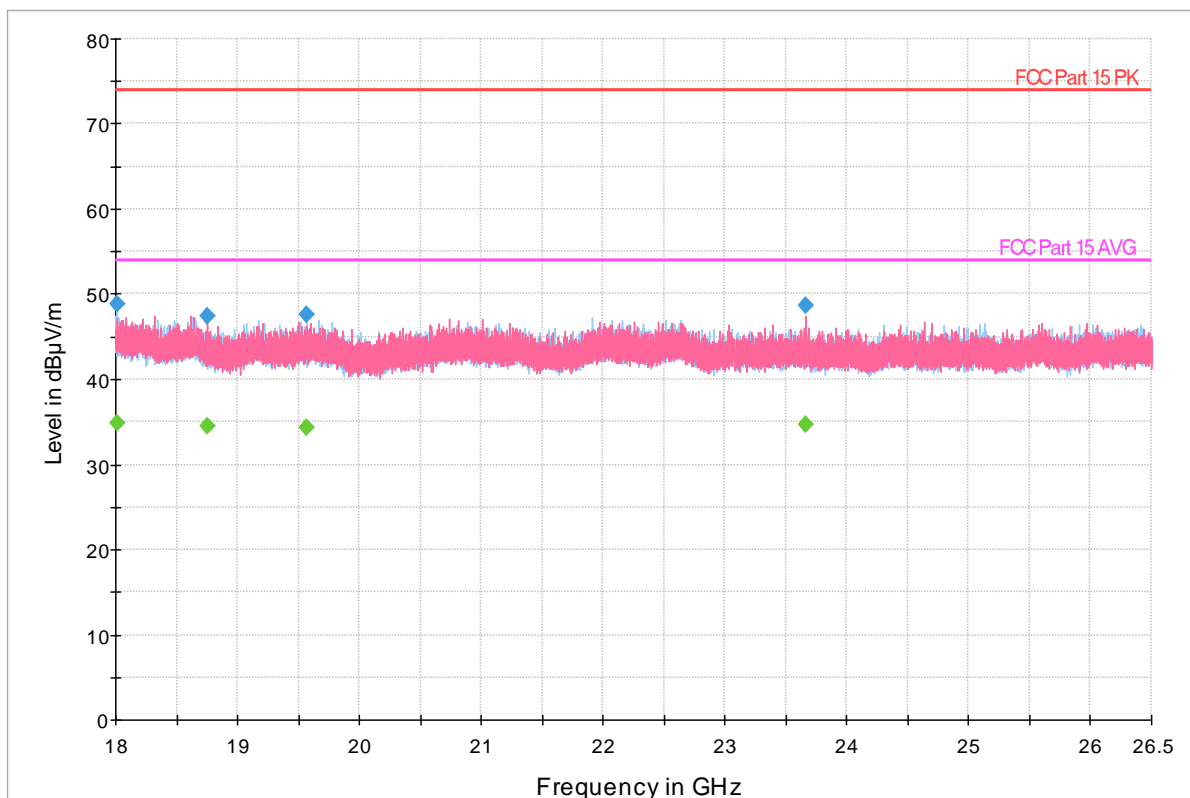
Figure 45: Radiated Spurious Emissions 18GHz – 26.5GHz, 2402MHz, 1Mbps

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| Frequency (MHz) | MaxPeak (dBµV/m) | Average (dBµV/m) | Limit (dBµV/m) | Margin (dB) | Bandwidth (kHz) | Height (cm) | Pol | Azimuth (deg) | Corr. (dB/m) |
|-----------------|------------------|------------------|----------------|-------------|-----------------|-------------|-----|---------------|--------------|
| 18016.532000    | 48.93            | ---              | 74.00          | 25.07       | 1000.000        | 105.0       | H   | 225.0         | -3.2         |
| 18016.532000    | ---              | 34.86            | 54.00          | 19.14       | 1000.000        | 105.0       | H   | 225.0         | -3.2         |
| 18753.099971    | 47.40            | ---              | 74.00          | 26.60       | 1000.000        | 105.0       | V   | 265.0         | -2.2         |
| 18753.099971    | ---              | 34.52            | 54.00          | 19.48       | 1000.000        | 105.0       | V   | 265.0         | -2.2         |
| 19563.066000    | ---              | 34.26            | 54.00          | 19.74       | 1000.000        | 100.0       | H   | 146.0         | -1.0         |
| 19563.066000    | 47.55            | ---              | 74.00          | 26.45       | 1000.000        | 100.0       | H   | 146.0         | -1.0         |
| 23664.827029    | ---              | 34.69            | 54.00          | 19.31       | 1000.000        | 155.0       | V   | 230.0         | 1.5          |
| 23664.827029    | 48.72            | ---              | 74.00          | 25.28       | 1000.000        | 155.0       | V   | 230.0         | 1.5          |



— Preview Result 1H-PK+     — Preview Result 1V-PK+     — FCC Part 15 PK  
— FCC Part 15 AVG     ◆ Final\_Result PK+     ◆ Final\_Result AVG

Figure 46: Radiated Spurious Emissions 18GHz – 26.5GHz, 2480MHz, 1Mbps

### 4.3 AC Conducted Emissions

Testing was performed in accordance with ANSI C63.10: 2013. These test methods are listed under the laboratory's A2LA Scope of Accreditation.

This test measures the levels emanating from the EUT's AC input port, thus evaluating the potential for the EUT to cause radio frequency interference to other electronic devices.

The AC conducted emissions of equipment under test shall not exceed the values in CFR47 Part 15.207: 2021 and RSS Gen: 2019 Sect. 8.8.

#### 4.3.1 Test Methodology

A test program that controls instrumentation and data logging was used to automate the AC Power Line Conducted emission test procedure. The frequency range of interest was divided into sub-ranges such as to yield a frequency resolution of 9 kHz. Each phase and neutral of the AC power line were measured with respect to ground. Measurements were performed using a set of 50 $\mu$ H/ 50 $\Omega$  LISNs.

The setup photographs clearly identify which site was used. The vertical ground plane used in the semi-anechoic chamber is a 2m x 2m solid aluminum frame and panel, and it is bonded to the horizontal ground plane.

In the case of tabletop equipment, the EUT is placed on a 1.0m x 1.5m non-conductive table 80cm above the ground plane and 40cm from a vertical ground reference plane. The rear of the EUT was positioned flush with the backside of the table and directly over the LISNs. The power and I/O cables were routed over the edge of the table and bundled approximately 40cm from the ground plane. Support equipment was powered from a separate LISN.

##### 4.3.1.1 Deviations

There were no deviations from this test methodology.

#### 4.3.2 Test Results

Test is not applicable since the EUT is DC powered by a battery.

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## 5 Test Equipment Use List

### 5.1 Equipment List

| Equipment                   | Manufacturer                 | Model #                  | Serial/Inst #     | Last Cal<br>mm/dd/yyyy | Next Cal<br>mm/dd/yyyy |
|-----------------------------|------------------------------|--------------------------|-------------------|------------------------|------------------------|
| Analyzer/EMI Receiver       | Rohde & Schwarz              | ESW, 2Hz-44GHz           | 5000-03280-0025   | 03/06/2022             | 03/06/2023             |
| Trilog Antenna              | Schwarzbeck;<br>Huber+Suhner | VULB 9163                | 01218:<br>111218A | 07/08/2022             | 07/08/2024             |
| Preamplifier, 30MHz – 8 GHz | Rohde & Schwarz              | TS-PR8                   | 102352            | 03/14/2022             | 03/14/2023             |
| Horn, 1-18GHz               | EMCO                         | 3115                     | 9402-4226         | 07/29/2021             | 07/29/2023             |
| Preamplifier, 1-18GHz       | Rohde & Schwarz              | TS-PR18                  | 3545.7008.03      | 02/23/2022             | 02/23/2023             |
| Horn, 18-40GHz              | Rohde & Schwarz              | 180-442-KF               | 132596-01         | 04/17/2022             | 06/17/2023             |
| Preamplifier, 18 – 40GHz    | Rohde & Schwarz              | TS-PR1840                | 100067            | 04/04/2022             | 04/04/2023             |
| Spectrum Analyzer           | Rohde & Schwarz              | FSU26.5                  | 200050            | 03/05/2022             | 03/05/2023             |
| 1.6 GHz Low Pass Filter     | K&L Microwave                | 8L120-X1600-0/09135-0249 | UA691-35          | N/A (See Note)         |                        |
| 2.4GHz Band Pass Filter     | Micro-Tronics                | BRM50702                 | 009               | N/A (See Note)         |                        |

Note: Equipment is characterized before use.



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## 6 EMC Test Plan

### 6.1 Introduction

This section provides a description of the Equipment Under Test (EUT), configurations, operating conditions, and performance acceptance criteria. It is an overview of information provided by the manufacturer (information supplied by the customer and can affect the validity of results) so that the test laboratory may perform the requested testing.

### 6.2 Customer

The information in the following tables is required, as it should appear in the final test report.

Table 6 – Customer Information

|                         |                                     |
|-------------------------|-------------------------------------|
| <b>Company Name</b>     | Otsuka America Pharmaceutical, Inc. |
| <b>Address</b>          | 3956 Point Eden Way                 |
| <b>City, State, Zip</b> | Hayward, CA 94545                   |
| <b>Country</b>          | U.S.A.                              |

Table 7 – Contact Information

|               |  |
|---------------|--|
| <b>Name</b>   | Jim Hutchison  |
| <b>E-mail</b> | <a href="mailto:jim.hutchison@otsuka-us.com">jim.hutchison@otsuka-us.com</a> |
| <b>Phone</b>  | (650) 394-6316   |

### 6.3 Equipment Under Test (EUT)

The information provided in the following table should be listed as it should appear in the final report. For those products that have only a model name, list the model number as *non-applicable* and vice-versa.

Table 8 – EUT Designation

|                            |   |
|----------------------------|---|
| <b>Product Name</b>        | Otsuka Patch  |
| <b>Model No.</b>           | D-Tect  |
| <b>Product Description</b> | The Patch device is a component of the Core Medical Device (CMD) that gathers ingestion, physiological and behavioral metrics from a user. This data is then transmitted to a BLE-enabled gateway device. The data can be accessed by external applications for further processing or displayed directly to a user via a display. |

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### 6.3.1 Product Specifications

The information provided in the following table should be listed as it should appear in the final report.

Table 9 – EUT Specifications\*

| EUT Specification   |   |
|---|---|
| DC Power Input  | 2.9VDC  |
| Environment   | Indoor/Outdoor  |
| Operating Temperature Range:  | +5 to +40 degrees C   |
| Multiple Feeds:   | <input type="checkbox"/> Yes and how many<br><input checked="" type="checkbox"/> No   |
| Product Marketing Name (PMN)  | Otsuka Patch  |
| Hardware Version Identification Number (HVIN)   | DT3.0   |
| Firmware Version Identification Number (FVIN)   | FIRMWARE_VERSION,17,v0.1.4.0 GIT:733  |
| Operating Mode  | Bluetooth Low Energy  |
| Transmitter Frequency Band  | 2402 to 2480 MHz  |
| Power Setting @ Operating Channel   | -8 dBm (max)  |
| Antenna Type  | Patch Antenna   |
| Antenna Gain (dBi)  | -10.1 dBi   |
| Modulation Type   | <input type="checkbox"/> AM <input type="checkbox"/> FM <input type="checkbox"/> DSSS <input type="checkbox"/> OFDM<br><input checked="" type="checkbox"/> Other describe: GFSK |
| Date Rate   | 1 Mbps and 2 Mbps   |
| TX/RX Chain (s)   | 1   |
| Directional Gain Type   | <input checked="" type="checkbox"/> Uncorrelated <input checked="" type="checkbox"/> No Beam-Forming<br><input type="checkbox"/> Other describe:                                |
| Type of Equipment   | <input checked="" type="checkbox"/> Table Top <input type="checkbox"/> Wall-mount <input type="checkbox"/> Floor standing cabinet<br><input type="checkbox"/> Other:            |
| Note: *All EUT specifications are provided by the manufacturer or the TUV direct customer. Information supplied by the customer and can affect the validity of results. |   |

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Table 10: Antenna Information

| Number | Antenna Type | Description | Max Gain (dBi) |
|--------|--------------|-------------|----------------|
| 1      | Patch        | Internal    | -10.1          |

Table 11: Interface Specifications

| Interface Type | Cabled with what type of cable? | Is the cable shielded?       | Maximum potential length of the cable?            | Metallic (M), Coax (C), Fiber (F), or Not Applicable? |
|----------------|---------------------------------|------------------------------|---|---|
| USB Cable      | 6 pin connector                 | <input type="checkbox"/> Yes | <input checked="" type="checkbox"/> Metric: <3.0m | <input checked="" type="checkbox"/> N/A               |

Note: Cable required for EUT configuration for regulatory test mode. 6pin to USB cable not utilized within final product. EUT powered by battery during test.

Table 12: Accessory Equipment

| Equipment | Manufacturer | Model | Serial | Comment |
|-----------|--------------|-------|--------|---------|
| N/A       | N/A          | N/A   | N/A    | N/A     |

**Note:** None.

Table 13: Ancillary Equipment (used for test purposes only)

| Equipment | Manufacturer | Model | Serial  | Used for   |
|-----------|--------------|-------|---------|--|
| Laptop    | Dell XPS     | P91F  | H6WKBK3 | Setup EUT operating channels via USB connection to EUT |

**Note:** None.

### 6.3.2 Configuration(s)

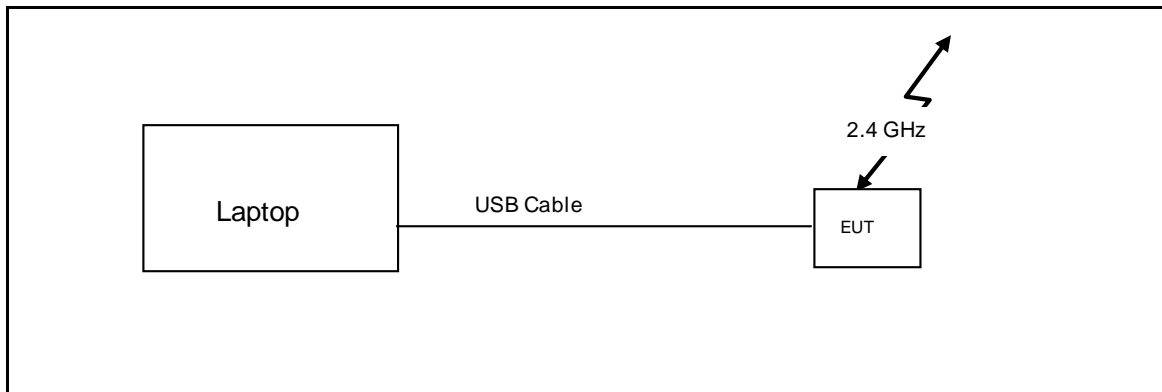


Figure 47: Block Diagram of EUT Setup - Radiated

- Note:** 1. The EUT was connected to the USB Port of the supporting laptop for configuration and control.  
 2. SMA cable was in place of the antenna for conducted measurement test purposes only.

Table 14: Description of Sample used for Testing

| Device                        | Sample Model Number | Configuration    | Used For  |
|-------------------------------|---------------------|------------------|---|
| Otsuka Patch<br>Model: D-Tect | 00196               | Radiated Sample  | Radiated Emissions,<br>Radiated Band Edge                           |
|                               | 00182               | Conducted Sample | Transmit Power, Occupied<br>Bandwidth, Out of Band<br>Emission, PSD |

Table 15: Description of Test Configuration used for Radiated Measurement.

| Device   | Antenna | Mode                 | Setup Description |
|--|---------|----------------------|-------------------|
| Otsuka Patch<br>Model: D-Tect                                    | Patch   | Transmit/<br>Receive | EUT Flat          |
| <b>Note:</b> EUT was tested on its X-Axis as this was worse case |         |                      |                   |

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#### 6.4 Test Specifications

The information provided in the following table should be provided as you would like the product to be evaluated if different from the requirements of the standard.

Table 16 - Test Specifications

| Emissions and Immunity   |             |
|--------------------------|-------------|
| Standard                 | Requirement |
| CFR 47 Part 15.247: 2022 | All         |
| RSS 247 Issue 2, 2017    | All         |

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**--- Ende des Prüfberichts / End of Test Report ---**