Abbott

Heartmate Flex

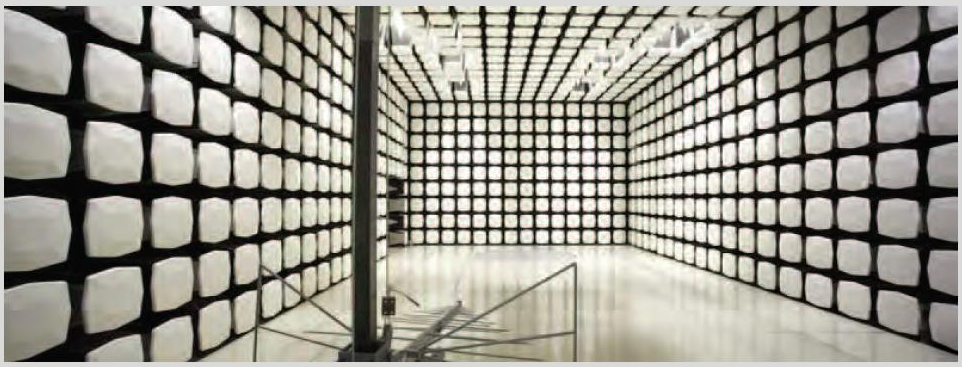
FCC 15.247:2025

RSS-247 Issue 3:2023

RSS-Gen Issue 5:2018+A1:2019+A2:2021

Bluetooth Radio

Report: STJM0361.0 Rev. 01, Issue Date: September 15, 2025



CERT #3310.04

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element
2023.04.17

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CERTIFICATE OF TEST

Last Date of Test: June 4, 2025
Abbott
EUT: Heartmate Flex

Radio Equipment Testing

Standards

Specification	Method
FCC 15.247:2025	ANSI C63.10:2020
RSS-247 Issue 3:2023	ANSI C63.10:2020
RSS-Gen Issue 5:2018+A1:2019+A2:2021	ANSI C63.10:2020

Guidance

FCC KDB 558074 v05r02:2019
Notice 2021 - CEB0001

Results

Test Description	Result	FCC Section(s)	RSS Section(s)	ANSI C63.10 Section(s)	Comments
Powerline Conducted Emissions	N/A	15.207	RSS-Gen 8.8	6.2	Not required to show compliance of the module in the host.
Duty Cycle	Pass	KDB 558074 - 6.0	RSS-Gen 3.2	11.6	
DTS Bandwidth (6 dB)	N/A	15.247(a)(2), KDB 558074 - 8.2	RSS-247 5.2(a)	11.8.2	Not required to show compliance of the module in the host.
Occupied Bandwidth (99%)	N/A	KDB 558074 - 2.1	RSS-Gen 6.7	6.9.3	
Output Power	Pass	15.247(b)(3), KDB 558074 - 8.3.1	RSS-247 5.4(d, f), RSS-Gen 6.12	11.9.1.1	
Equivalent Isotropic Radiated Power	N/A	15.247(b)(3), KDB 558074 - 8.3.1	RSS-247 5.4(d, f), RSS-Gen 6.12	11.9.1.1	Not required to show compliance of the module in the host.
Power Spectral Density	N/A	15.247(e), KDB 558074 -8.4	RSS-247 5.2(b)	11.10.2	
Band Edge Compliance	N/A	15.247(d), KDB 558074 -8.5	RSS-247 5.5	11.11	
Spurious Conducted Emissions	N/A	15.247(d), KDB 558074 -8.5	RSS-247 5.5	11.11	
Radiated Band Edge Emissions	N/A	15.247(d), KDB 558074 - 8.6, 8.7	RSS-247 5.5, RSS-Gen 6.13, 8.10	11.12.1, 11.13.2, 6.6	
Spurious Radiated Emissions	Pass	15.247(d), KDB 558074 - 8.6, 8.7	RSS-247 5.5, RSS-Gen 6.13, 8.10	11.12.1, 11.13.2, 6.4, 6.5, 6.6	

Product compliance is the responsibility of the client; therefore, the tests and equipment modes of operation represented in this report were agreed upon by the client, prior to testing. The results of this test pertain only to the sample(s) tested. The specific description is noted in each of the individual sections of the test report supporting this certificate of test. This report reflects only those tests from the referenced standards shown in the certificate of test. It does not include inspection or verification of labels, identification, marking or user information. As indicated in the Statement of Work sent with the quotation, Element's standard process is to always use the latest published version of the test methods even when earlier versions are cited in the test specification. Issuance of a purchase order was de facto acceptance of this approach. Otherwise, the client would have advised Element in writing of the specific version of the test methods they wanted applied to the subject testing.

CERTIFICATE OF TEST

Deviations From Test Standards

None

Approved By:

Johnny Candelas, Operations Manager
Signed for and on behalf of Element

Product compliance is the responsibility of the client; therefore, the tests and equipment modes of operation represented in this report were agreed upon by the client, prior to testing. The results of this test pertain only to the sample(s) tested. The specific description is noted in each of the individual sections of the test report supporting this certificate of test. This report reflects only those tests from the referenced standards shown in the certificate of test. It does not include inspection or verification of labels, identification, marking or user information. As indicated in the Statement of Work sent with the quotation, Element's standard process is to always use the latest published version of the test methods even when earlier versions are cited in the test specification. Issuance of a purchase order was de facto acceptance of this approach. Otherwise, the client would have advised Element in writing of the specific version of the test methods they wanted applied to the subject testing.

REVISION HISTORY

Revision Number	Description	Date (yyyy-mm-dd)	Page Number
01	Antenna type changed from PCB to "Chip antenna"	2025-09-15	13
	Power in the C5 test headers changed from "battery" to "110VAC/60Hz"	2025-09-15	18, 24

ACCREDITATIONS AND AUTHORIZATIONS

element
2025.02.07

United States

FCC - Designated by the FCC as a Telecommunications Certification Body (TCB). Certification chambers, Open Area Test Sites, and conducted measurement facilities are listed with the FCC.

A2LA - Each laboratory is accredited by A2LA to ISO / IEC 17025, and as a product certifier to ISO / IEC 17065 which allows Element to certify transmitters to FCC and IC specifications.

FDA - Recognized by the FDA as an Accreditation Scheme for Conformity Assessment (ASCA)-accredited testing laboratory for basic safety and essential performance.

Canada

ISED - Recognized by Innovation, Science and Economic Development Canada as a Certification Body (CB) and as a CAB for the acceptance of test data.

European Union

European Commission – Recognized as an EU Notified Body validated for the EMCD and RED Directives.

United Kingdom

BEIS – Recognized by the UK as an Approved Body under the UK Radio Equipment and UK EMC Regulations.

Australia/New Zealand

ACMA - Recognized by ACMA as a CAB for the acceptance of test data.

Korea

MSIT / RRA - Recognized by KCC's RRA as a CAB for the acceptance of test data.

Japan

VCCI - Associate Member of the VCCI. Conducted and radiated measurement facilities are registered.

Taiwan

BSMI – Recognized by BSMI as a CAB for the acceptance of test data.

NCC - Recognized by NCC as a CAB for the acceptance of test data.

Singapore

IDA – Recognized by IDA as a CAB for the acceptance of test data.

Israel

MOC – Recognized by MOC as a CAB for the acceptance of test data.

Hong Kong

OFCA – Recognized by OFCA as a CAB for the acceptance of test data.

SCOPE

For details on the Scopes of our Accreditations, please visit:

California Minnesota Oregon Washington

FACILITIES

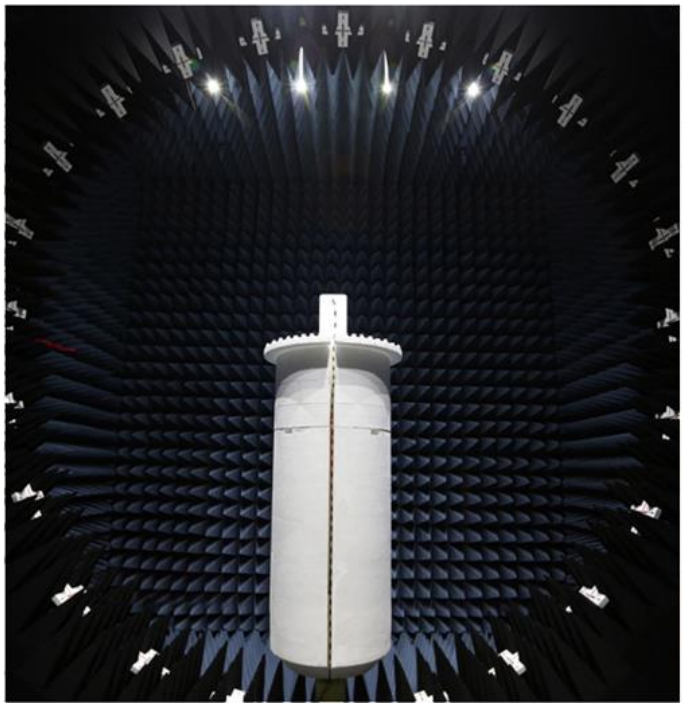
element
2025.01.03

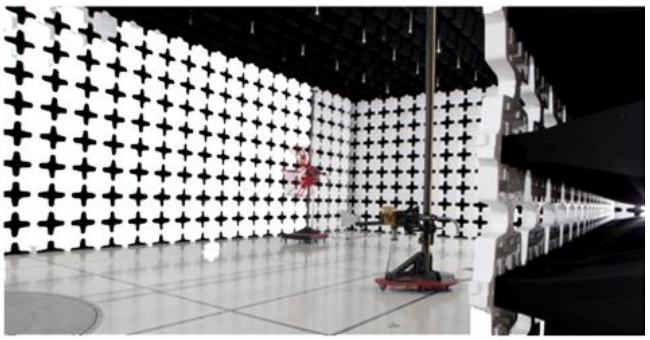
Testing was performed at the following location(s)

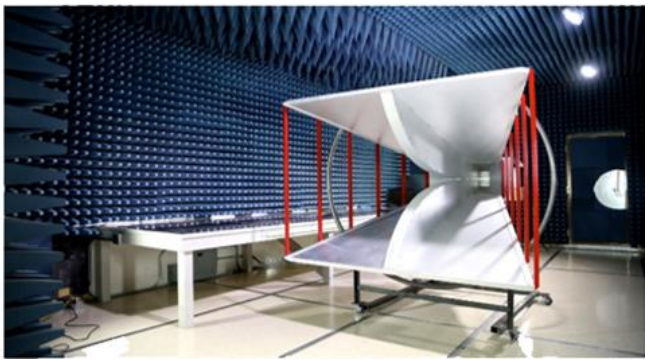
	Location	Labs (1)	Address	A2LA (2)	ISED (3)	BSMI (4)	VCCI (5)	CAB (6)	FDA (7)
☒	California	OC01-17	41 Tesla Irvine, CA 92618 (949) 861-8918	3310.04	2834B	SL2-IN-E-1154R	A-0029	US0158	TL-55
☐	Minnesota	MN01-11	9349 W Broadway Ave. Brooklyn Park, MN 55445 (612) 638-5136	3310.05	2834E	SL2-IN-E-1152R	A-0109	US0175	TL-57
☐	Oregon	EV01-12	6775 NE Evergreen Pkwy #400 Hillsboro, OR 97124 (503) 844-4066	3310.02	2834D	SL2-IN-E-1017	A-0108	US0017	TL-56
☐	Washington	NC01-05	19201 120th Ave NE Bothell, WA 98011 (425) 984-6600	3310.06	2834F	SL2-IN-E-1153R	A-0110	US0157	TL-67
☐	Offsite	N/A	See Product Description	N/A	N/A	N/A	N/A	N/A	N/A

See data sheets for specific labs

(1) The lab designations denote individual rooms within each location. (OC01, OC02, OC03, etc.)
(2) A2LA Certificate No.
(3) ISED Company No.
(4) BSMI No.
(5) VCCI Site Filing No.
(6) CAB Identifier. Recognized Phase I CAB for ISED, ACMA, BSMI, IDA, KCC/RRA, MOC, NCC, OFCA
(7) FDA ASCA No.







MEASUREMENT UNCERTAINTY

element
MU 2025-03-26

Measurement Uncertainty

When a measurement is made, the result will be different from the true or theoretically correct value. The difference is the result of tolerances in the measurement system that cannot be completely eliminated. To the extent that technology allows us, it has been our aim to minimize this error. Measurement uncertainty is a statistical expression of measurement error qualified by a probability distribution.

A measurement uncertainty estimation reported is based on statistical analysis that was performed by the laboratory. The estimation is used to compare the measured result with its "true" or theoretically correct value. The expanded measurement uncertainty (k=2) can be found in the table below. A lab specific value may also be found in the applicable test description section. Our measurement data meets or exceeds the measurement uncertainty requirements of the applicable specification; therefore, the test data can be compared directly to the specification limit to determine compliance. The calculations for estimating measurement uncertainty are based upon ETSI TR 100 028 (or CISPR 16-4-2 as applicable) and are available upon request.

The following table represents the Measurement Uncertainty (MU) budgets for each of the tests that may be contained in this report.

Various Measurements

Test	All Labs (+/-)
Frequency Accuracy (%)	0.0007
Amplitude Accuracy (dB)	1.2
Conducted Power (dB)	1.2
Radiated Power via Substitution (dB)	0.7
Temperature (degrees C)	0.7
Humidity (% RH)	2.5
Voltage (AC) (%)	1
Voltage (DC) (%)	0.7
Near-field Measurement of E-Field (dB)	1.89
Near-field Measurement of H-Field (dB)	2.65

Field Strength Measurements (dB)

Range	OC10 (+/-)
10kHz-30MHz	1.8
30MHz-1GHz 3m	4.6
1GHz-6GHz	5
6GHz-40GHz	5.1

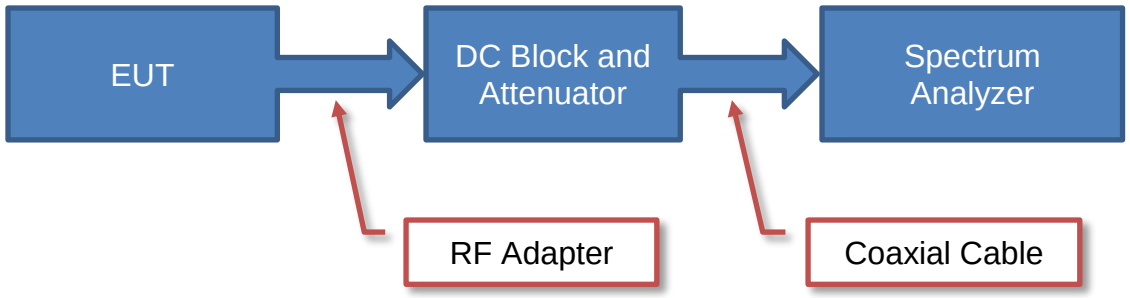
TEST SETUP BLOCK DIAGRAMS

Measurement Bandwidths

Frequency Range (MHz)	Peak Data (kHz)	Quasi-Peak Data (kHz)	Average Data (kHz)
0.01 - 0.15	1.0	0.2	0.2
0.15 - 30.0	10.0	9.0	9.0
30.0 - 1000	100.0	120.0	120.0
Above 1000	1000.0	N/A	1000.0

Unless otherwise stated, measurements were made using the bandwidths and detectors specified. No video filter was used.

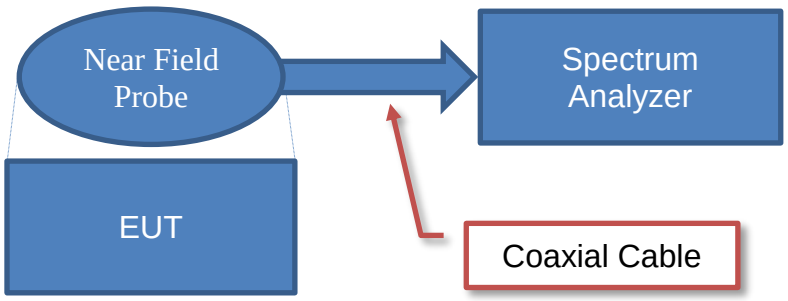
Antenna Port Conducted Measurements



Sample Calculation (logarithmic units)

Measured Value		Measured Level		Reference Level Offset
71.2	=	42.6	+	28.6

Near Field Test Fixture Measurements

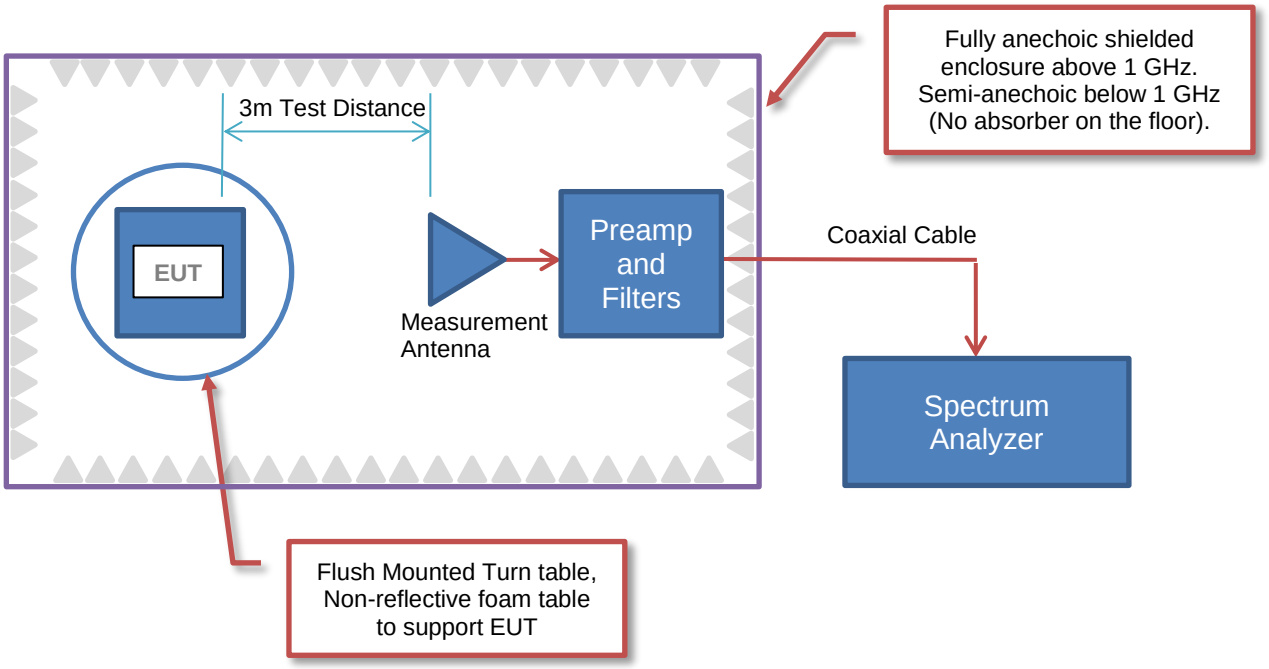


Sample Calculation (logarithmic units)

Measured Value		Measured Level		Reference Level Offset
71.2	=	42.6	+	28.6

TEST SETUP BLOCK DIAGRAMS

Emissions Measurements



Sample Calculation (logarithmic units)

Radiated Emissions:

Measured Level (Amplitude)		Factor: Antenna Factor		Factor: Cable Factor		Factor: Amplifier Gain		Distance Adjustment Factor		External Attenuation		Field Strength
42.6	+	28.6	+	3.1	-	40.8	+	0.0	+	0.0	=	**33.5**

Conducted Emissions:

Measured Level (Amplitude)		Factor: Transducer Factor		Factor: Cable Factor		External Attenuation		Adjusted Level
26.7	+	0.3	+	0.1	+	20.0	=	**47.1**

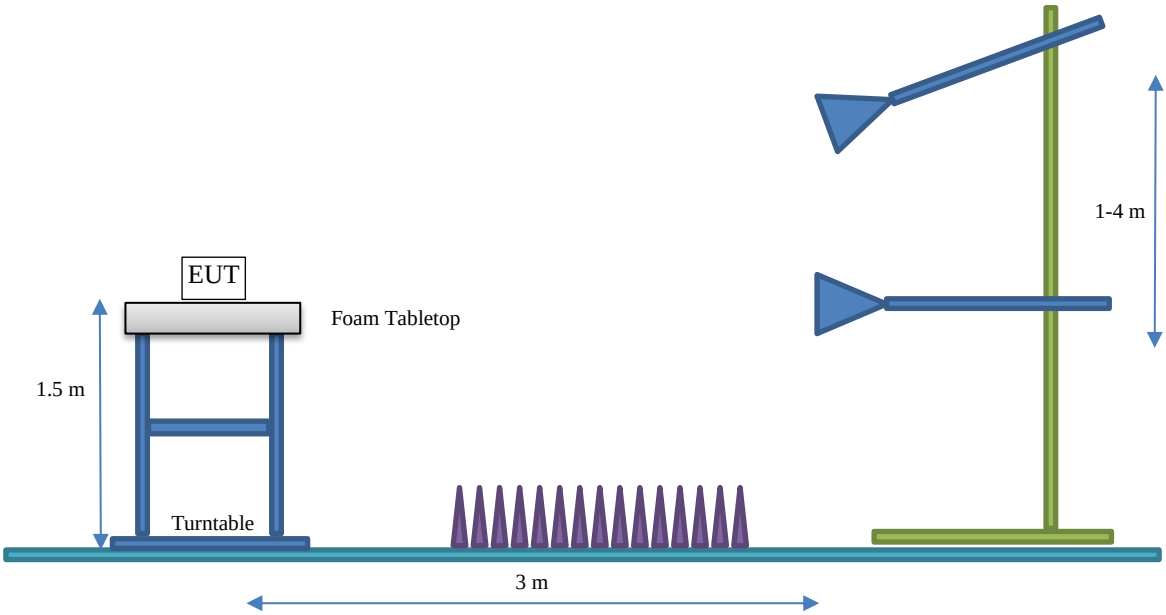
Radiated Power (ERP/EIRP) – Substitution Method:

Measured Level into Substitution Antenna (Amplitude dBm)		Substitution Antenna Factor (dBi)		EIRP to ERP (if applicable)		Measured power (dBm ERP/EIRP)
10.0	+	6.0	-	2.15	=	**13.9/16.0**

TEST SETUP BLOCK DIAGRAMS

Bore Sighting (>1GHz)

The diameter of the illumination area is the dimension of the line tangent to the EUT formed by 3 dB beamwidth of the measurement antenna at the measurement distance. At a 3 meter test distance, the diameter of the illumination area was 3.8 meters at 1 GHz and greater than 2.1 meters up to 6 GHz. Above 1 GHz, when required by the measurement standard, the antenna is pointed for both azimuth and elevation to maintain the receive antenna within the cone of radiation from the EUT. The specified measurement detectors were used for comparison of the emissions to the peak and average specification limits.



PRODUCT DESCRIPTION

Client and Equipment under Test (EUT) Information

Company Name:	Abbott
Address:	23 Fourth Ave
City, State, Zip:	Burlington, MA 01803
Test Requested By:	Brian Marchionni
EUT:	Heartmate Flex
First Date of Test:	May 12, 2025
Last Date of Test:	June 4, 2025
Receipt Date of Samples:	May 12, 2025
Equipment Design Stage:	Production
Equipment Condition:	No Damage
Purchase Authorization:	Verified

Information Provided by the Party Requesting the Test

Functional Description of the EUT:
The HeartMate (HM) Flex System consists of several body-worn and stationary peripherals that provide and control power to the HM3 Left Ventricular Assist Device (LVAD).

Testing Objective:
To demonstrate compliance of the module in the host per KDB 996369 for the Bluetooth radio to FCC 15.247/RSS-247 requirements.

POWER SETTINGS AND ANTENNAS

The power settings, antenna gain value(s) and cable loss (if applicable) used for the testing contained in this report were provided by the customer and will affect the validity of the results. Element assumes no responsibility for the accuracy of this information. The power settings below reflect the maximum power that the EUT is allowed to transmit at during normal operation.

ANTENNA GAIN (dBi)

Type	Provided by:	Frequency Range (MHz)	Gain (dBi)
Chip Antenna	Silicon Labs	2400 – 2483.5	1.86

The EUT was tested using the power settings provided by the manufacturer which were based upon:

☒ Test software settings Software / firmware used for testing: BLE Application, v935-000.036.099-25120364-d

☐ Rated power settings

SETTINGS FOR ALL TESTS IN THIS REPORT

Modulation Types / Data Rates	Type	Channel	Position	Frequency (MHz)	Power Setting
BLE GFSK 1 Mbps	DTS	37	Low Channel	2402	-1 dBm
		18	Mid Channel	2442	-1 dBm
		39	High Channel	2480	-1 dBm

CONFIGURATIONS

Configuration STJM0361-5

Software/Firmware Running During Test	
Description	**Version**
HeartMate Flex Controller SW	030-000.009.002-b03de211
HeartMate Flex AC Power Supply SW	032-000.007.000-0961ae16-d
LVAD SW	6.3.2.0.41
BLE Application	935-000.036.099-25120364-d

EUT			
Description	**Manufacturer**	**Model/Part Number**	**Serial Number**
HeartMate Flex Controller	Abbott Medical	600222577	FNC-DV0054

Peripherals in Test Setup Boundary			
Description	**Manufacturer**	**Model/Part Number**	**Serial Number**
LVAD	Abbot Medical	1008969	MLP-011735
Endurance Loop	Abbott Medical	105912	100010456-003
HeartMate Flex AC Power Supply	Abbott Medical	600257318	PS-DV0098

Cables					
Cable Type	**Shield**	**Length (m)**	**Ferrite**	**Connection 1**	**Connection 2**
Drive Line Cable	No	120cm	No	HeartMate Flex Controller	LVAD
AC Power Cable	No	2m	Yes	AC Mains	HeartMate Flex AC Power Supply
HeartMate Flex AC Power Supply Cable	No	3m	Yes	HeartMate Flex AC Power Supply	HeartMate Flex Controller

CONFIGURATIONS

Configuration STJM0361-7

Software/Firmware Running During Test	
Description	**Version**
HeartMate Flex Controller SW	030-000.009.002-b03de211
BLE Application	935-000.036.099-25120364-d

EUT			
Description	**Manufacturer**	**Model/Part Number**	**Serial Number**
HeartMate Flex Controller	Abbott Medical	600222577	FNC-DV0054

Peripherals in Test Setup Boundary			
Description	**Manufacturer**	**Model/Part Number**	**Serial Number**
Discharge Fixture	Abbott Medical	10016301	309086

Cables					
Cable Type	**Shield**	**Length (m)**	**Ferrite**	**Connection 1**	**Connection 2**
Drive Line Cable	No	120cm	No	HeartMate Flex Controller	LVAD

MODIFICATIONS

Equipment Modifications

Item	Date	Test	Modification	Note	Disposition of EUT
1	2025-05-12	Spurious Radiated Emissions	Tested as delivered to test Station.	No EMI suppression devices were added or modified during this test.	EUT remained at Element following the test.
2	2025-05-13	Duty Cycle	Tested as delivered to test Station.	No EMI suppression devices were added or modified during this test.	EUT remained at Element following the test.
3	2025-05-13	Output Power	Tested as delivered to test Station.	No EMI suppression devices were added or modified during this test.	Scheduled testing was completed.

DUTY CYCLE

element
TbtTx 2023.12.06.3
WTD.2025.03.25.0

TEST DESCRIPTION

Testing was performed using the mode(s) of operation and configuration(s) noted within the report. The individuals and/or the organization requesting the test provided the modes, configurations and settings used to complete the evaluation. The actual test parameters are specified in the test data, this includes items such as investigated frequency range (scanned) and test levels. The testing methods and performance specifications, as well as the test site used for the evaluation are indicated in the test data.

The measurement was made using a direct connection between the RF output of the EUT and a spectrum analyzer.

The Duty Cycle (x) of the single channel operation of the radio as controlled by the provided test software was measured for each of the EUT operating modes.

There is no compliance requirement to be met by this test, so therefore no Pass / Fail criteria.

The measurements were made using a zero span on the spectrum analyzer to see the pulses in the time domain. The transmit power was set to its default maximum.

The duty cycle was calculated by dividing the transmission pulse duration (T) by the total period of a single on and total off time.

If the transmit duty cycle < 98 percent, burst gating may have been used during some of the other tests in this report to only take the measurement during the burst duration.

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Cal. Due
Analyzer - Spectrum Analyzer	Agilent	N9010A	AFJ	2025-03-03	2026-03-03
Block - DC	Fairview Microwave	SD3379	ANG	2024-10-03	2025-10-03
Attenuator	Fairview Microwave	SA18H-20	UAX	2024-07-11	2025-07-11
Cable	Element	None	OC5	2024-10-02	2025-10-02
Generator - Signal	Agilent	E8257D	TGU	2023-11-08	2026-11-08

DUTY CYCLE

element
TbtTx 2023.12.06.3
WTD.2025.03.25.0

EUT:	Heartmate Flex	Work Order:	STJM0361
Serial Number:	FNC-DV0054	Date:	2025-06-04
Customer:	Abbott	Temperature:	22.7°C
Attendees:	None	Relative Humidity:	55.8%
Customer Project:	None	Bar. Pressure (PMSL):	1012 mbar
Tested By:	Nolan De Ramos	Job Site:	OC13
Power:	110VAC/60Hz	Configuration:	STJM0361-5

COMMENTS

Heartmate Flex with LVAD

DEVIATIONS FROM TEST STANDARD

None

CONCLUSION

N/A

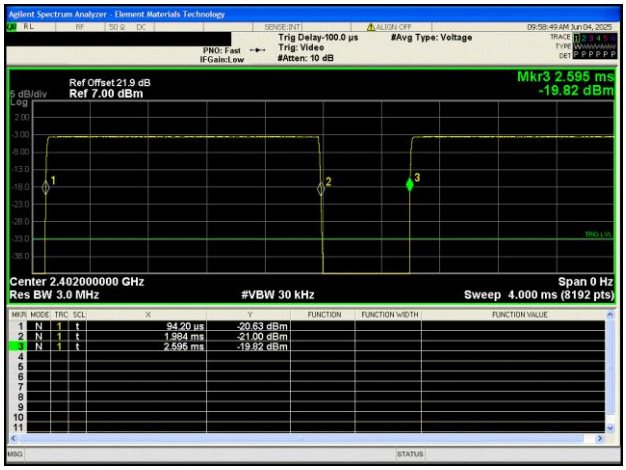
Tested By

TEST RESULTS

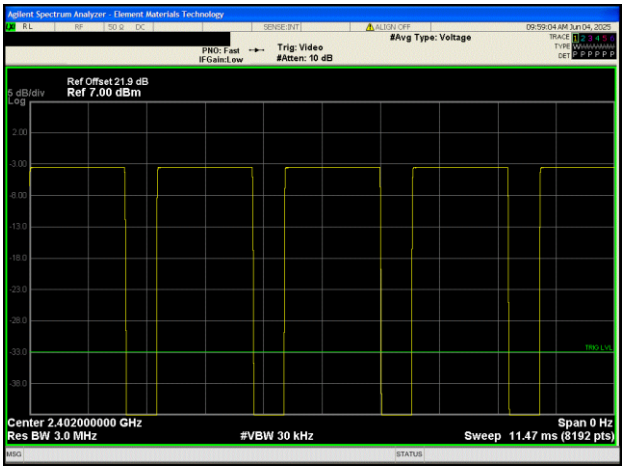
	Pulse Width	Period	Number of Pulses	Value (%)	Limit N/A ()	Results
BLE/GFSK 1 Mbps						
Low Channel, 2402 MHz	1.889 ms	2.5 ms	1	75.6	N/A	N/A
	N/A	N/A	5	N/A	N/A	N/A
Mid Channel, 2442 MHz	1.889 ms	2.501 ms	1	75.6	N/A	N/A
	N/A	N/A	5	N/A	N/A	N/A
High Channel, 2480 MHz	1.889 ms	2.501 ms	1	75.6	N/A	N/A
	N/A	N/A	5	N/A	N/A	N/A

DUTY CYCLE

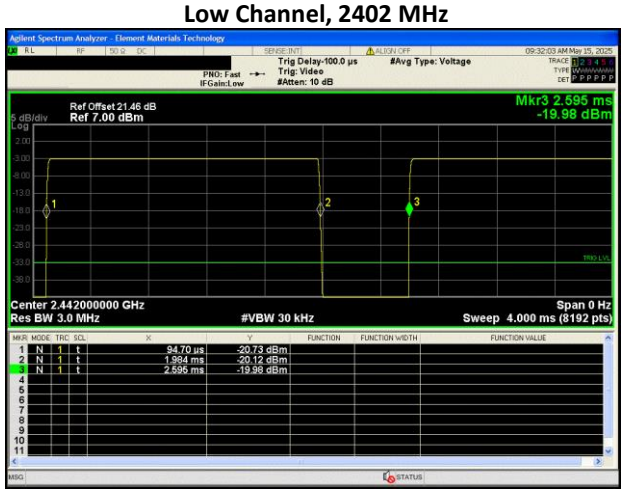
element
TbtTx 2023.12.06.3
WTD.2025.03.25.0



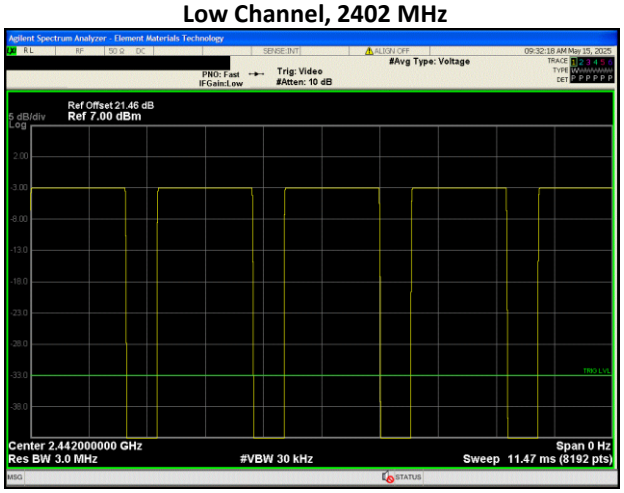
BLE/GFSK 1 Mbps
Low Channel, 2402 MHz



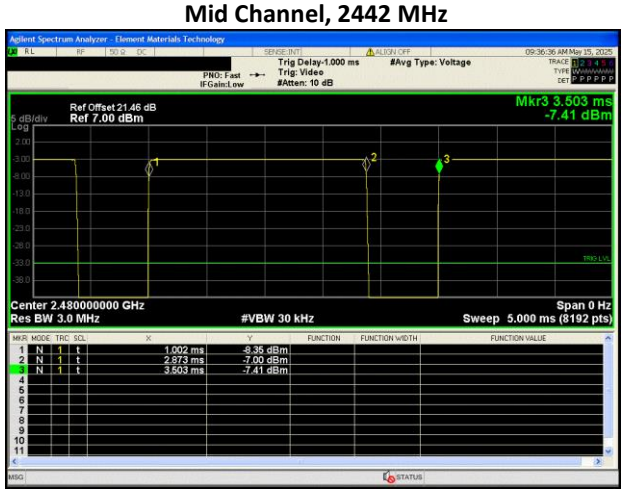
BLE/GFSK 1 Mbps
Low Channel, 2402 MHz



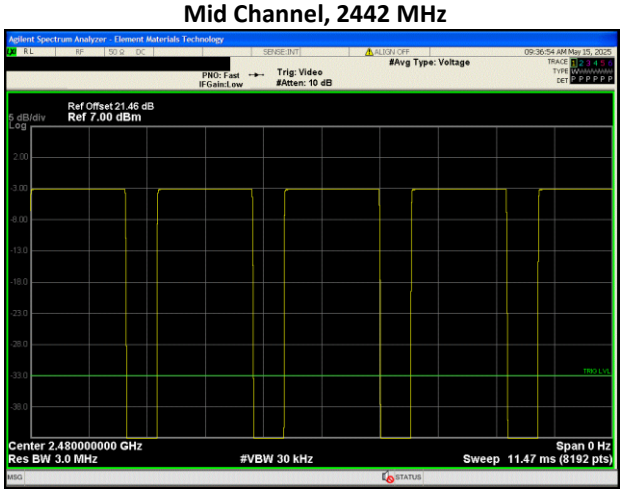
BLE/GFSK 1 Mbps
Mid Channel, 2442 MHz



BLE/GFSK 1 Mbps
Mid Channel, 2442 MHz



BLE/GFSK 1 Mbps
High Channel, 2480 MHz



BLE/GFSK 1 Mbps
High Channel, 2480 MHz

DUTY CYCLE

element
TbtTx 2023.12.06.3
WTD.2025.03.25.0

TEST DESCRIPTION

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The duty cycle was calculated by dividing the transmission pulse duration (T) by the total period of a single on and total off time.

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TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Cal. Due
Analyzer - Spectrum Analyzer	Agilent	N9010A	AFJ	2025-03-03	2026-03-03
Block - DC	Fairview Microwave	SD3379	ANG	2024-10-03	2025-10-03
Attenuator	Fairview Microwave	SA18H-20	UAX	2024-07-11	2025-07-11
Cable	Element	None	OC5	2024-10-02	2025-10-02
Generator - Signal	Agilent	E8257D	TGU	2023-11-08	2026-11-08

DUTY CYCLE

element
TbtTx 2023.12.06.3
WTD.2025.03.25.0

EUT:	Heartmate Flex	Work Order:	STJM0361
Serial Number:	FNC-DV0054	Date:	2025-05-15
Customer:	Abbott	Temperature:	22.6°C
Attendees:	Michelle George	Relative Humidity:	55.8%
Customer Project:	None	Bar. Pressure (PMSL):	1012 mbar
Tested By:	Nolan De Ramos	Job Site:	OC13
Power:	Battery	Configuration:	STJM0361-7

COMMENTS

Heartmate Flex with Discharge Fixture

DEVIATIONS FROM TEST STANDARD

None

CONCLUSION

N/A

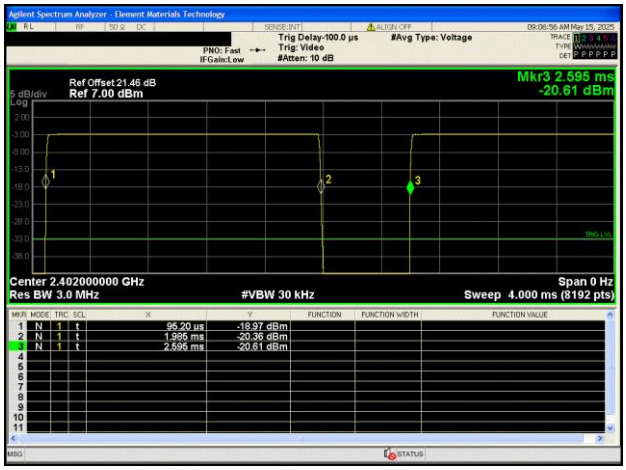
Tested By

TEST RESULTS

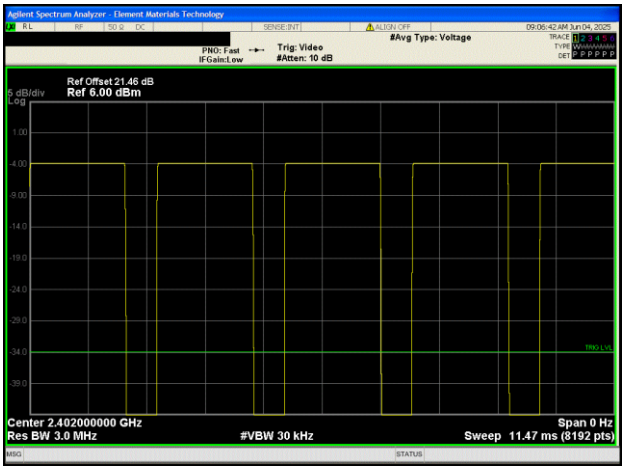
	Pulse Width	Period	Number of Pulses	Value (%)	Limit N/A	Results
BLE/GFSK 1 Mbps						
Low Channel, 2402 MHz	1.89 ms	2.5 ms	1	75.6	N/A	N/A
	N/A	N/A	5	N/A	N/A	N/A
Mid Channel, 2442 MHz	1.889 ms	2.5 ms	1	75.6	N/A	N/A
	N/A	N/A	5	N/A	N/A	N/A
High Channel, 2480 MHz	1.871 ms	2.501 ms	1	74.8	N/A	N/A
	N/A	N/A	5	N/A	N/A	N/A

DUTY CYCLE

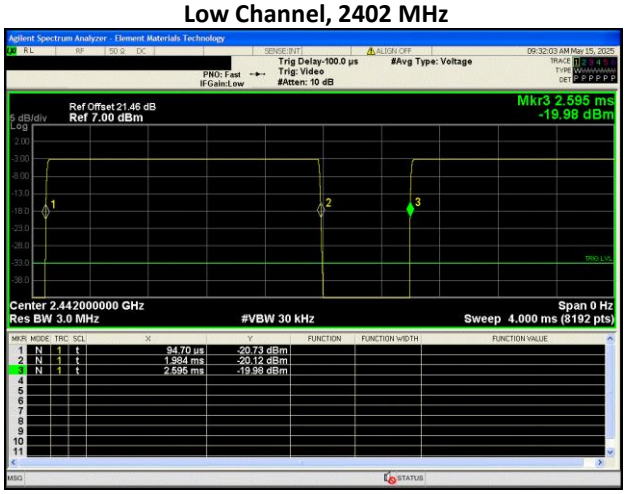
element
TbtTx 2023.12.06.3
WTD.2025.03.25.0



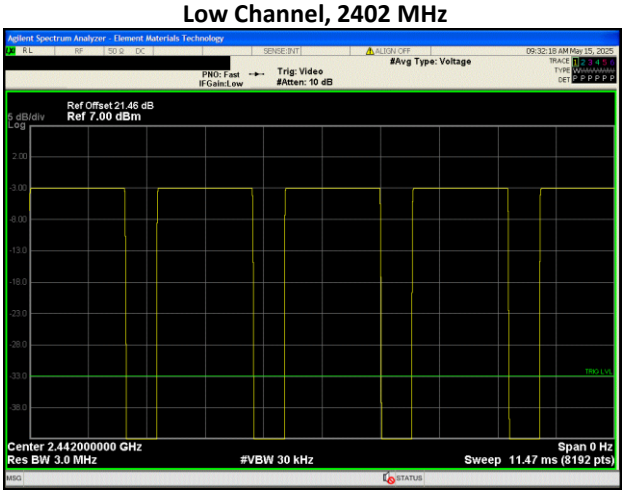
BLE/GFSK 1 Mbps
Low Channel, 2402 MHz



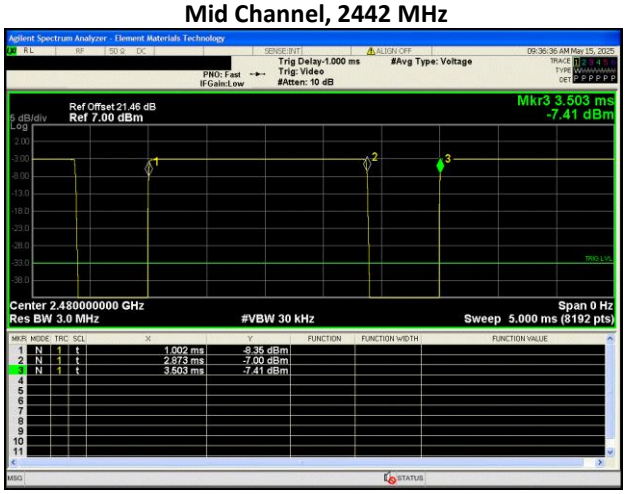
BLE/GFSK 1 Mbps
Low Channel, 2402 MHz



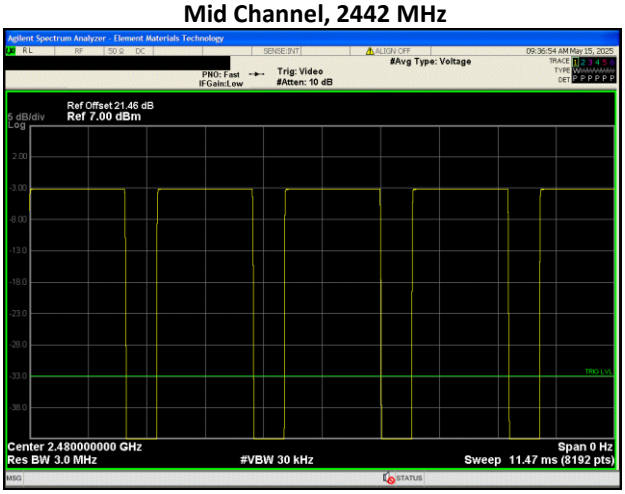
BLE/GFSK 1 Mbps
Mid Channel, 2442 MHz



BLE/GFSK 1 Mbps
Mid Channel, 2442 MHz



BLE/GFSK 1 Mbps
High Channel, 2480 MHz



BLE/GFSK 1 Mbps
High Channel, 2480 MHz

OUTPUT POWER

element
TbtTx 2023.12.06.3
WTD.2025.03.25.0

TEST DESCRIPTION

Testing was performed using the mode(s) of operation and configuration(s) noted within the report. The individuals and/or the organization requesting the test provided the modes, configurations and settings used to complete the evaluation. The actual test parameters are specified in the test data, this includes items such as investigated frequency range (scanned) and test levels. The testing methods and performance specifications, as well as the test site used for the evaluation are indicated in the test data.

The measurement was made using a direct connection between the RF output of the EUT and a spectrum analyzer.

The transmit frequency was set to the required channels in each band. The transmit power was set to its default maximum.

Prior to measuring peak transmit power the DTS bandwidth (B) was measured.

The method found in ANSI C63.10:2020 Section 11.9.1.1 was used because the RBW on the analyzer was greater than the DTS Bandwidth of the radio.

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Cal. Due
Analyzer - Spectrum Analyzer	Agilent	N9010A	AFJ	2025-03-03	2026-03-03
Block - DC	Fairview Microwave	SD3379	ANG	2024-10-03	2025-10-03
Attenuator	Fairview Microwave	SA18H-20	UAX	2024-07-11	2025-07-11
Cable	Element	None	OC5	2024-10-02	2025-10-02
Generator - Signal	Agilent	E8257D	TGU	2023-11-08	2026-11-08
Meter - Power	ETS-Lindgren	7002-008	SRU	2024-08-27	2025-08-27

OUTPUT POWER

element
TbtTx 2023.12.06.3
WTD.2025.03.25.0

EUT:	Heartmate Flex	Work Order:	STJM0361
Serial Number:	FNC-DV0054	Date:	2025-06-04
Customer:	Abbott	Temperature:	22.7°C
Attendees:	None	Relative Humidity:	55.8%
Customer Project:	None	Bar. Pressure (PMSL):	1012 mbar
Tested By:	Nolan De Ramos	Job Site:	OC13
Power:	110VAC/60Hz	Configuration:	STJM0361-5

COMMENTS

Heartmate Flex with LVAD

DEVIATIONS FROM TEST STANDARD

None

CONCLUSION

Pass

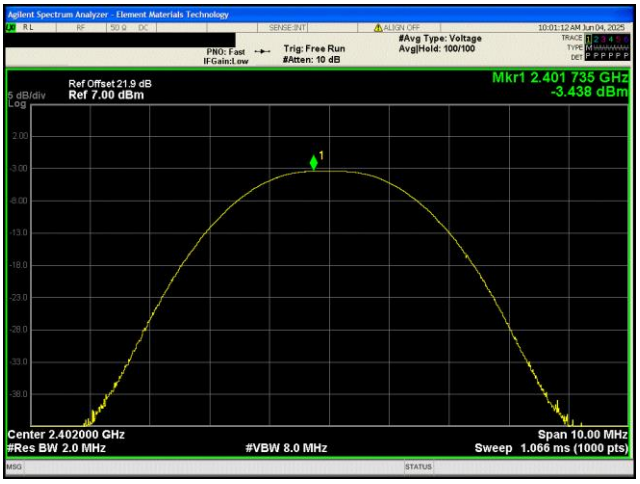
Tested By

TEST RESULTS

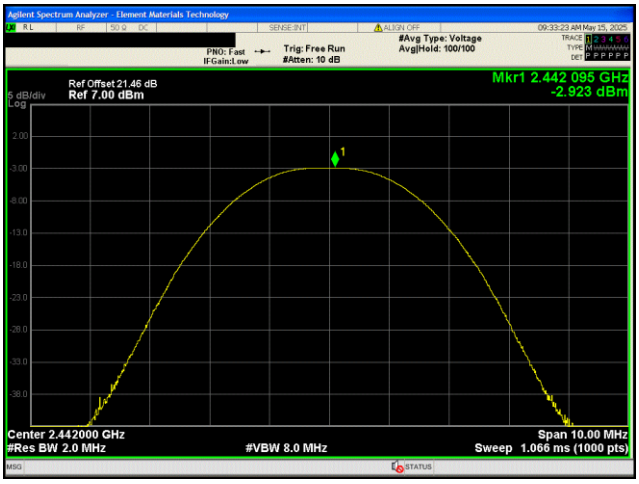
	Out Pwr (dBm)	Limit (dBm)	Result
BLE/GFSK 1 Mbps			
Low Channel, 2402 MHz	-3.438	30	Pass
Mid Channel, 2442 MHz	-3.576	30	Pass
High Channel, 2480 MHz	-3.617	30	Pass

OUTPUT POWER

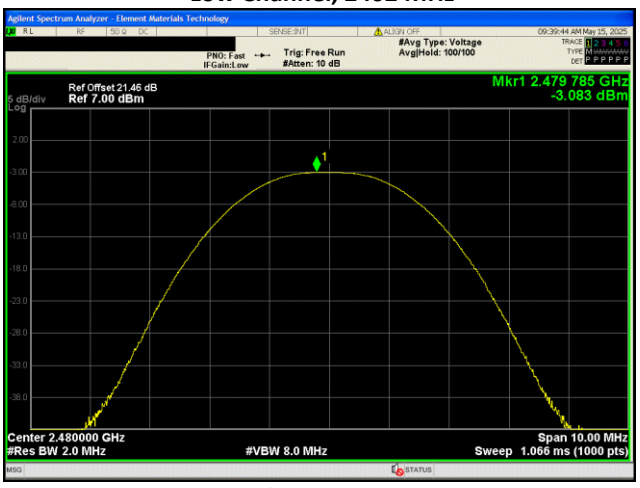
element
TbtTx 2023.12.06.3
WTD.2025.03.25.0



BLE/GFSK 1 Mbps
Low Channel, 2402 MHz



BLE/GFSK 1 Mbps
Mid Channel, 2442 MHz



BLE/GFSK 1 Mbps
High Channel, 2480 MHz

OUTPUT POWER

element
TbtTx 2023.12.06.3
WTD.2025.03.25.0

TEST DESCRIPTION

Testing was performed using the mode(s) of operation and configuration(s) noted within the report. The individuals and/or the organization requesting the test provided the modes, configurations and settings used to complete the evaluation. The actual test parameters are specified in the test data, this includes items such as investigated frequency range (scanned) and test levels. The testing methods and performance specifications, as well as the test site used for the evaluation are indicated in the test data.

The measurement was made using a direct connection between the RF output of the EUT and a spectrum analyzer.

The transmit frequency was set to the required channels in each band. The transmit power was set to its default maximum.

Prior to measuring peak transmit power the DTS bandwidth (B) was measured.

The method found in ANSI C63.10:2020 Section 11.9.1.1 was used because the RBW on the analyzer was greater than the DTS Bandwidth of the radio.

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Cal. Due
Analyzer - Spectrum Analyzer	Agilent	N9010A	AFJ	2025-03-03	2026-03-03
Block - DC	Fairview Microwave	SD3379	ANG	2024-10-03	2025-10-03
Attenuator	Fairview Microwave	SA18H-20	UAX	2024-07-11	2025-07-11
Cable	Element	None	OC5	2024-10-02	2025-10-02
Generator - Signal	Agilent	E8257D	TGU	2023-11-08	2026-11-08
Meter - Power	ETS-Lindgren	7002-008	SRU	2024-08-27	2025-08-27

OUTPUT POWER

element
TbtTx 2023.12.06.3
WTD.2025.03.25.0

EUT:	Heartmate Flex	Work Order:	STJM0361
Serial Number:	FNC-DV0054	Date:	2025-05-15
Customer:	Abbott	Temperature:	22.7°C
Attendees:	Michelle George	Relative Humidity:	55.8%
Customer Project:	None	Bar. Pressure (PMSL):	1012 mbar
Tested By:	Nolan De Ramos	Job Site:	OC13
Power:	Battery	Configuration:	STJM0361-7

COMMENTS

Heartmate Flex with Discharge Fixture

DEVIATIONS FROM TEST STANDARD

None

CONCLUSION

Pass

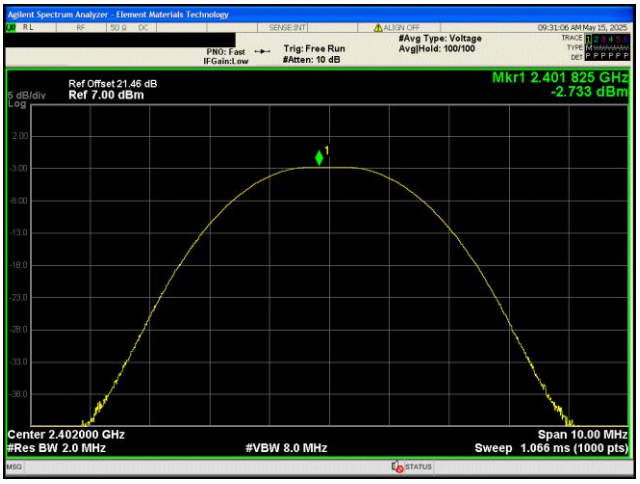
Tested By

TEST RESULTS

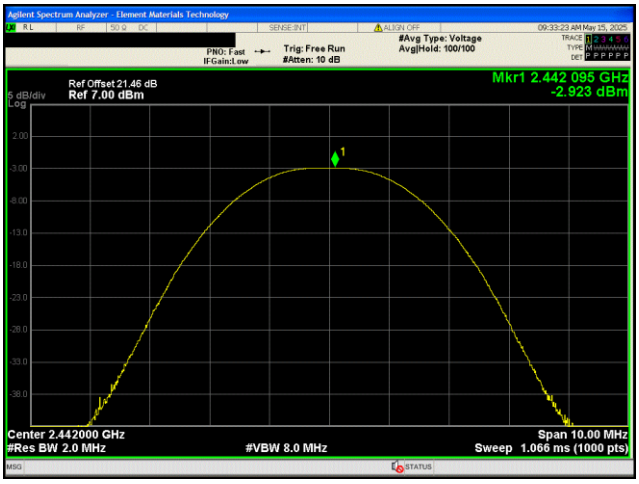
	Out Pwr (dBm)	Limit (dBm)	Result
BLE/GFSK 1 Mbps			
Low Channel, 2402 MHz	-2.733	30	Pass
Mid Channel, 2442 MHz	-2.923	30	Pass
High Channel, 2480 MHz	-3.083	30	Pass

OUTPUT POWER

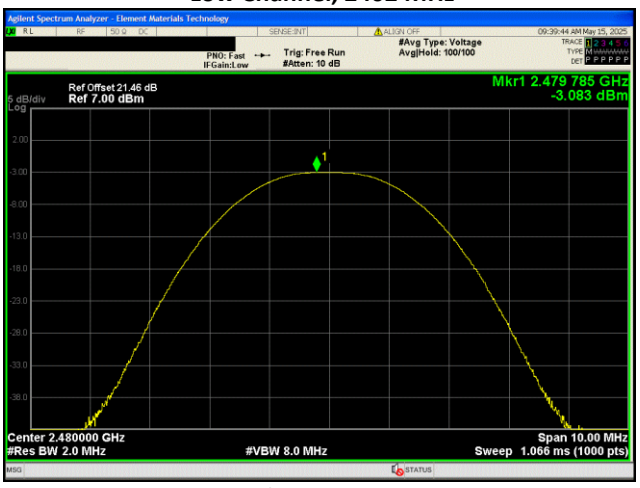
element
TbtTx 2023.12.06.3
WTD.2025.03.25.0



BLE/GFSK 1 Mbps
Low Channel, 2402 MHz



BLE/GFSK 1 Mbps
Mid Channel, 2442 MHz



BLE/GFSK 1 Mbps
High Channel, 2480 MHz

SPURIOUS RADIATED EMISSIONS

element
WTD.2025.03.25.0
EmiR5 2024.05.24.5
PSA-ESCI 2024.11.22.0

TEST DESCRIPTION

The highest gain antenna of each type to be used with the EUT was tested. The EUT was configured for the required transmit frequencies and the modes as showed in the data sheets.

For each configuration, the spectrum was scanned throughout the specified range as part of the exploratory investigation of the emissions. A reference preview scan (pre-scan) is included in the report. Final measurements on individual emissions were then made and included in this test report.

The individual emissions from the EUT were maximized by rotating the EUT on a turntable, adjusting the position of the EUT and EUT antenna in three orthogonal axis if required, and adjusting the measurement antenna height and polarization (per ANSI C63.10). A preamp and high pass filter (and notch filter) were used for this test in order to provide sufficient measurement sensitivity.

Measurements were made with the required detectors and annotated on the data for each individual point using the following annotation:

QP = Quasi-Peak Detector
PK = Peak Detector
AV = RMS Detector

Measurements were made to satisfy the specific requirements of the test specification for out of band emissions as well as the restricted band requirements.

If there are no detectable emissions above the noise floor, the data included may show noise floor measurements for reference only.

Measurements within 2 MHz of the allowable band may have been taken using the integration method from ANSI C63.10 clause 11.13.3. This procedure uses the channel power feature of the spectrum analyzer to integrate the power of the emission within a 1 MHz bandwidth.

Where the radio test software does not provide for a duty cycle at continuous transmit conditions (> 98%) and the RMS (power average) measurements were made across the on and off times of the EUT transmissions, a duty cycle correction is added to the measurements using the formula of 10*log(1/dc).

TEST EQUIPMENT

Description	Manufacturer	Model	ID	Last Cal.	Cal. Due
Analyzer - Spectrum Analyzer	Agilent	E4440A	AFA	2025-03-20	2027-03-20
Antenna - Loop	EMCO	6502	AZB	2023-09-06	2025-09-06
Antenna - Biconilog	Teseq	CBL 6141A	AYE	2023-08-08	2025-08-08
Antenna - Double Ridge	ETS Lindgren	3115	AIR	2024-07-23	2026-07-23
Antenna - Standard Gain	ETS Lindgren	3160-07	AHR	2024-12-03	2025-12-03
Antenna - Standard Gain	ETS Lindgren	3160-08	AHT	2024-12-03	2025-12-03
Antenna - Standard Gain	ETS Lindgren	3160-09	AHN	2024-12-03	2025-12-03
Cable	Northwest EMC	10kHz-1GHz RE Cables	OCH	2025-05-01	2026-05-01
Cable	Northwest EMC	1-8GHz RE Cables	OCJ	2025-04-30	2026-04-30
Cable	Northwest EMC	8-18GHz RE Cables	OCO	2025-03-18	2026-03-18
Cable	Northwest EMC	18-26GHz RE Cables	OCK	2024-12-10	2025-12-10
Amplifier - Pre-Amplifier	Miteq	AM-1402	AOZ	2025-05-01	2026-05-01
Amplifier - Pre-Amplifier	Cernex	CBL01084020-xx	PAX	2025-04-30	2026-04-30
Amplifier - Pre-Amplifier	Miteq	AMF-6F-08001200-30-10P	AOE	2025-03-18	2026-03-18
Amplifier - Pre-Amplifier	Miteq	AMF-6F-12001800-30-10P	AOF	2025-03-18	2026-03-18
Amplifier - Pre-Amplifier	Miteq	AMF-6F-18002650-25-10P	AOI	2024-12-10	2025-12-10
Attenuator	Fairview Microwave	SA18H-20	TKQ	2025-05-01	2026-05-01
Filter - Low Pass	Micro-Tronics	LPM50004	LFT	2024-12-17	2025-12-17

SPURIOUS RADIATED EMISSIONS

element
WTD.2025.03.25.0
EmiR5 2024.05.24.5
PSA-ESCI 2024.11.22.0

FREQUENCY RANGE INVESTIGATED

9 kHz TO 26.5 GHz

POWER INVESTIGATED

110VAC/60Hz

CONFIGURATIONS INVESTIGATED

STJM0361-5

MODES INVESTIGATED

Transmitting Bluetooth Low Energy: 2402, 2442, and 2480 MHz. Data Rate: 1 Mbps. Output Power Setting: -1 dBm

SPURIOUS RADIATED EMISSIONS

element
WTD.2025.03.25.0
EmiR5 2024.05.24.5
PSA-ESCI 2024.11.22.0

EUT:	Heartmate Flex	Work Order:	STJM0361
Serial Number:	FNC-DV0054	Date:	2025-05-12
Customer:	Abbott	Temperature:	23.8°C
Attendees:	Michelle George	Relative Humidity:	49.4%
Customer Project:	None	Bar. Pressure (PMSL):	1014 mb
Tested By:	Nolan De Ramos	Job Site:	OC10
Power:	110VAC/60Hz	Configuration:	STJM0361-5

TEST PARAMETERS

Run #:	146	Test Distance (m):	3	Ant. Height(s) (m):	1 to 4(m)

COMMENTS

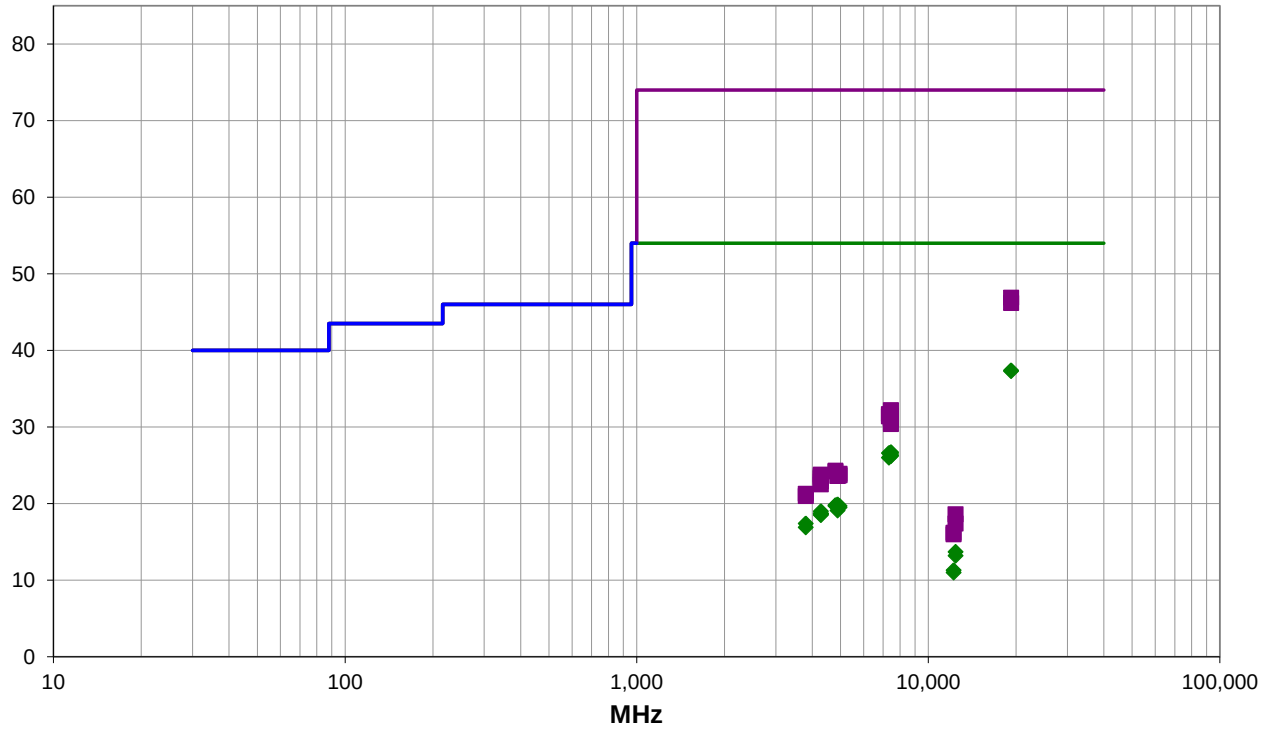
None

EUT OPERATING MODES

Transmitting Bluetooth Low Energy: 2402, 2442, and 2480 MHz. Data Rate: 1 Mbps. Output Power Setting: -1 dBm

DEVIATIONS FROM TEST STANDARD

None



Run #: 146 ■ PK ◆ AV ● QP

SPURIOUS RADIATED EMISSIONS

element
WTD.2025.03.25.0
EmiR5 2024.05.24.5
PSA-ESCI 2024.11.22.0

RESULTS - Run #146

(MHz)	Amplitude (dBuV)	Factor (dB/m)	Antenna Height (meters)	Azimuth (degrees)	Duty Cycle Correction Factor (dB)	External Attenuation (dB)	Polarity/ Transducer Type	Detector	Distance Adjustment (dB)	Adjusted (dBuV/m)	Spec. Limit (dBuV/m)	Compared to Spec. (dB)	Comments
19216.980	36.6	-0.4	1.5	36.0	1.2	0.0	Horz	AV	0.0	37.4	54.0	-16.6	Tx 2480 MHz, 1 Mbps, EUT on Side
19217.530	36.5	-0.4	1.5	126.0	1.2	0.0	Vert	AV	0.0	37.3	54.0	-16.7	Tx 2480 MHz, 1 Mbps, EUT on Side
19216.050	47.3	-0.4	1.5	36.0	0.0	0.0	Horz	PK	0.0	46.9	74.0	-27.1	Tx 2480 MHz, 1 Mbps, EUT on Side
7439.996	18.8	6.7	1.3	178.0	1.2	0.0	Vert	AV	0.0	26.7	54.0	-27.3	Tx 2480 MHz, 1 Mbps, EUT on Side
7439.998	18.8	6.7	2.8	5.0	1.2	0.0	Horz	AV	0.0	26.7	54.0	-27.3	Tx 2480 MHz, 1 Mbps, EUT on Side
7326.001	18.9	6.5	1.0	82.0	1.2	0.0	Horz	AV	0.0	26.6	54.0	-27.4	Tx 2442 MHz, 1 Mbps, EUT on Side
7440.003	18.6	6.7	3.5	328.0	1.2	0.0	Horz	AV	0.0	26.5	54.0	-27.5	Tx 2480 MHz, 1 Mbps, EUT Vert
7440.001	18.4	6.7	1.0	17.0	1.2	0.0	Vert	AV	0.0	26.3	54.0	-27.7	Tx 2480 MHz, 1 Mbps, EUT Horz
7440.002	18.4	6.7	1.0	202.0	1.2	0.0	Horz	AV	0.0	26.3	54.0	-27.7	Tx 2480 MHz, 1 Mbps, EUT Horz
19217.940	46.6	-0.4	1.5	126.0	0.0	0.0	Vert	PK	0.0	46.2	74.0	-27.8	Tx 2480 MHz, 1 Mbps, EUT on Side
7440.004	18.3	6.7	2.3	257.0	1.2	0.0	Vert	AV	0.0	26.2	54.0	-27.8	Tx 2480 MHz, 1 Mbps, EUT Vert
7325.996	18.3	6.5	1.0	184.0	1.2	0.0	Vert	AV	0.0	26.0	54.0	-28.0	Tx 2442 MHz, 1 Mbps, EUT on Side
4883.998	22.5	-3.8	1.8	127.0	1.2	0.0	Vert	AV	0.0	19.9	54.0	-34.1	Tx 2442 MHz, 1 Mbps, EUT on Side
4804.002	22.6	-4.0	1.0	177.0	1.2	0.0	Horz	AV	0.0	19.8	54.0	-34.2	Tx 2402 MHz, 1 Mbps, EUT on Side
4803.999	22.5	-4.0	1.0	333.0	1.2	0.0	Vert	AV	0.0	19.7	54.0	-34.3	Tx 2402 MHz, 1 Mbps, EUT on Side
4960.004	22.1	-3.6	1.0	0.0	1.2	0.0	Vert	AV	0.0	19.7	54.0	-34.3	Tx 2480 MHz, 1 Mbps, EUT on Side
4959.995	21.9	-3.6	1.0	211.0	1.2	0.0	Horz	AV	0.0	19.5	54.0	-34.5	Tx 2480 MHz, 1 Mbps, EUT on Side
4883.999	21.7	-3.8	3.1	269.0	1.2	0.0	Horz	AV	0.0	19.1	54.0	-34.9	Tx 2442 MHz, 1 Mbps, EUT on Side
4280.000	23.1	-5.3	1.2	306.0	1.2	0.0	Horz	AV	0.0	19.0	54.0	-35.0	Tx 2480 MHz, 1 Mbps, EUT Horz
4279.999	22.8	-5.3	4.0	351.0	1.2	0.0	Vert	AV	0.0	18.7	54.0	-35.3	Tx 2480 MHz, 1 Mbps, EUT Horz
4279.999	22.8	-5.3	1.5	16.0	1.2	0.0	Vert	AV	0.0	18.7	54.0	-35.3	Tx 2480 MHz, 1 Mbps, EUT on Side
4279.999	22.8	-5.3	1.5	153.0	1.2	0.0	Vert	AV	0.0	18.7	54.0	-35.3	Tx 2480 MHz, 1 Mbps, EUT Vert
4280.004	22.7	-5.3	1.5	360.0	1.2	0.0	Horz	AV	0.0	18.6	54.0	-35.4	Tx 2480 MHz, 1 Mbps, EUT Vert
4280.004	22.6	-5.3	3.5	173.0	1.2	0.0	Horz	AV	0.0	18.5	54.0	-35.5	Tx 2480 MHz, 1 Mbps, EUT on Side
3797.999	22.4	-6.2	1.5	20.0	1.2	0.0	Horz	AV	0.0	17.4	54.0	-36.6	Tx 2480 MHz, 1 Mbps, EUT on Side
3797.997	21.9	-6.2	1.5	345.0	1.2	0.0	Vert	AV	0.0	16.9	54.0	-37.1	Tx 2480 MHz, 1 Mbps, EUT on Side
12400.000	14.1	-1.6	1.0	242.0	1.2	0.0	Horz	AV	0.0	13.7	54.0	-40.3	Tx 2480 MHz, 1 Mbps, EUT on Side
12400.000	13.6	-1.6	1.0	340.0	1.2	0.0	Vert	AV	0.0	13.2	54.0	-40.8	Tx 2480 MHz, 1 Mbps, EUT on Side
7440.002	25.5	6.7	2.8	5.0	0.0	0.0	Horz	PK	0.0	32.2	74.0	-41.8	Tx 2480 MHz, 1 Mbps, EUT on Side
7325.998	25.2	6.5	1.0	82.0	0.0	0.0	Horz	PK	0.0	31.7	74.0	-42.3	Tx 2442 MHz, 1 Mbps, EUT on Side
7440.000	24.8	6.7	3.5	328.0	0.0	0.0	Horz	PK	0.0	31.5	74.0	-42.5	Tx 2480 MHz, 1 Mbps, EUT Vert
7325.997	24.9	6.5	1.0	184.0	0.0	0.0	Vert	PK	0.0	31.4	74.0	-42.6	Tx 2442 MHz, 1 Mbps, EUT on Side
12210.000	13.3	-3.2	1.7	171.0	1.2	0.0	Vert	AV	0.0	11.3	54.0	-42.7	Tx 2442 MHz, 1 Mbps, EUT on Side
7439.997	24.5	6.7	1.0	17.0	0.0	0.0	Vert	PK	0.0	31.2	74.0	-42.8	Tx 2480 MHz, 1 Mbps, EUT Horz
7439.996	24.4	6.7	2.3	257.0	0.0	0.0	Vert	PK	0.0	31.1	74.0	-42.9	Tx 2480 MHz, 1 Mbps, EUT Vert
7440.002	24.3	6.7	1.3	178.0	0.0	0.0	Vert	PK	0.0	31.0	74.0	-43.0	Tx 2480 MHz, 1 Mbps, EUT on Side
12210.000	13.0	-3.2	1.0	204.0	1.2	0.0	Horz	AV	0.0	11.0	54.0	-43.0	Tx 2442 MHz, 1 Mbps, EUT on Side
7439.996	23.7	6.7	1.0	202.0	0.0	0.0	Horz	PK	0.0	30.4	74.0	-43.6	Tx 2480 MHz, 1 Mbps, EUT Horz
4803.998	28.3	-4.0	1.0	177.0	0.0	0.0	Horz	PK	0.0	24.3	74.0	-49.7	Tx 2402 MHz, 1 Mbps, EUT on Side
4803.997	28.2	-4.0	1.0	333.0	0.0	0.0	Vert	PK	0.0	24.2	74.0	-49.8	Tx 2402 MHz, 1 Mbps, EUT on Side

SPURIOUS RADIATED EMISSIONS

element
WTD.2025.03.25.0
EmiR5 2024.05.24.5
PSA-ESCI 2024.11.22.0

(MHz)	Amplitude (dBuV)	Factor (dB/m)	Antenna Height (meters)	Azimuth (degrees)	Duty Cycle Correction Factor (dB)	External Attenuation (dB)	Polarity/ Transducer Type	Detector	Distance Adjustment (dB)	Adjusted (dBuV/m)	Spec. Limit (dBuV/m)	Compared to Spec. (dB)	Comments
4959.998	27.5	-3.6	1.0	211.0	0.0	0.0	Horz	PK	0.0	23.9	74.0	-50.1	Tx 2480 MHz, 1 Mbps, EUT on Side
4280.002	29.1	-5.3	1.5	153.0	0.0	0.0	Vert	PK	0.0	23.8	74.0	-50.2	Tx 2480 MHz, 1 Mbps, EUT Vert
4959.996	27.3	-3.6	1.0	0.0	0.0	0.0	Vert	PK	0.0	23.7	74.0	-50.3	Tx 2480 MHz, 1 Mbps, EUT on Side
4280.003	28.9	-5.3	1.2	306.0	0.0	0.0	Horz	PK	0.0	23.6	74.0	-50.4	Tx 2480 MHz, 1 Mbps, EUT Horz
4883.995	27.4	-3.8	1.8	127.0	0.0	0.0	Vert	PK	0.0	23.6	74.0	-50.4	Tx 2442 MHz, 1 Mbps, EUT on Side
4883.996	27.4	-3.8	3.1	269.0	0.0	0.0	Horz	PK	0.0	23.6	74.0	-50.4	Tx 2442 MHz, 1 Mbps, EUT on Side
4279.999	28.7	-5.3	1.5	360.0	0.0	0.0	Horz	PK	0.0	23.4	74.0	-50.6	Tx 2480 MHz, 1 Mbps, EUT Vert
4279.996	28.6	-5.3	3.5	173.0	0.0	0.0	Horz	PK	0.0	23.3	74.0	-50.7	Tx 2480 MHz, 1 Mbps, EUT on Side
4279.998	28.2	-5.3	4.0	351.0	0.0	0.0	Vert	PK	0.0	22.9	74.0	-51.1	Tx 2480 MHz, 1 Mbps, EUT Horz
4279.995	27.8	-5.3	1.5	16.0	0.0	0.0	Vert	PK	0.0	22.5	74.0	-51.5	Tx 2480 MHz, 1 Mbps, EUT Vert
3798.005	27.5	-6.2	1.5	20.0	0.0	0.0	Horz	PK	0.0	21.3	74.0	-52.7	Tx 2480 MHz, 1 Mbps, EUT on Side
3798.005	27.2	-6.2	1.5	345.0	0.0	0.0	Vert	PK	0.0	21.0	74.0	-53.0	Tx 2480 MHz, 1 Mbps, EUT on Side
12400.000	20.2	-1.6	1.0	242.0	0.0	0.0	Horz	PK	0.0	18.6	74.0	-55.4	Tx 2480 MHz, 1 Mbps, EUT on Side
12400.000	19.0	-1.6	1.0	340.0	0.0	0.0	Vert	PK	0.0	17.4	74.0	-56.6	Tx 2480 MHz, 1 Mbps, EUT on Side
12210.000	19.4	-3.2	1.0	204.0	0.0	0.0	Horz	PK	0.0	16.2	74.0	-57.8	Tx 2442 MHz, 1 Mbps, EUT on Side
12210.000	19.2	-3.2	1.7	171.0	0.0	0.0	Vert	PK	0.0	16.0	74.0	-58.0	Tx 2442 MHz, 1 Mbps, EUT on Side

CONCLUSION
Pass

Tested By

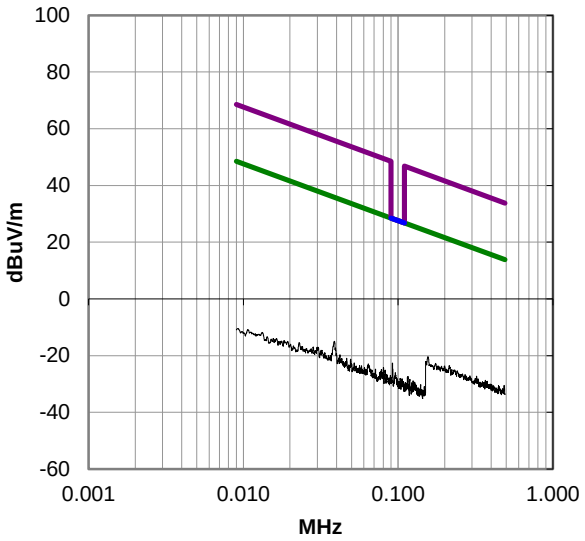
SPURIOUS RADIATED EMISSIONS

element
WTD.2025.03.25.0
EmiR5 2024.05.24.5
PSA-ESCI 2024.11.22.0

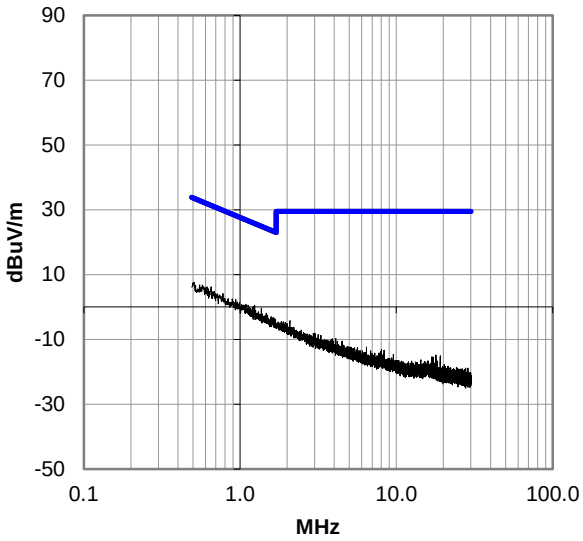
PRESCAN DATA

Radiated spurious emissions from the EUT are initially reviewed with Pre-scans (Preview scans). Pre-scans are performed, with the EUT transmitting on the lowest applicable data rate, for both vertical and horizontal polarizations. The Pre-scan plots below are shown with a peak detector and RBW for the following frequency ranges: 9 kHz RBW (< 30 MHz); 120 kHz RBW (30 - 1000 MHz); 1 MHz RBW (> 1 GHz). In the case where unintentional emissions are observed, an ambient or idle pre-scan with the radio off, will be shown for comparison.

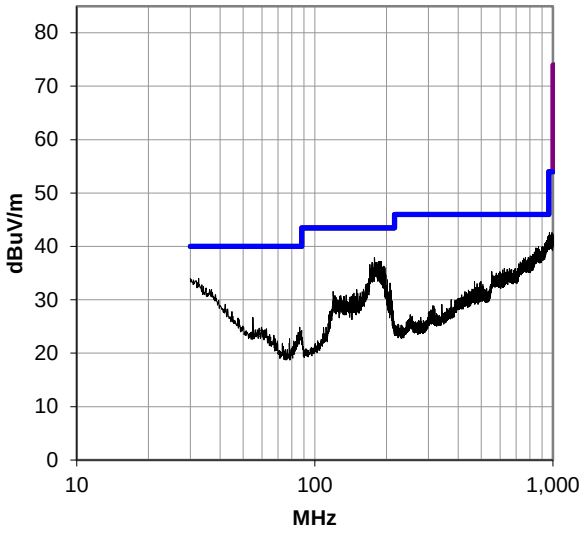
0.009-0.49 MHz, Run 8



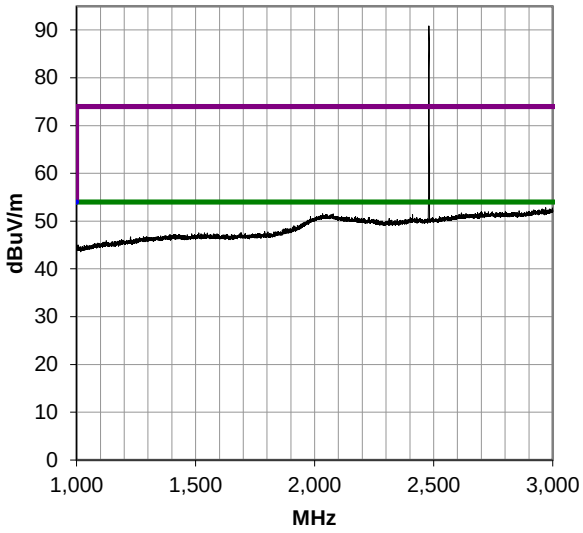
0.49-30 MHz, Run 9



30-1000 MHz, Run 5



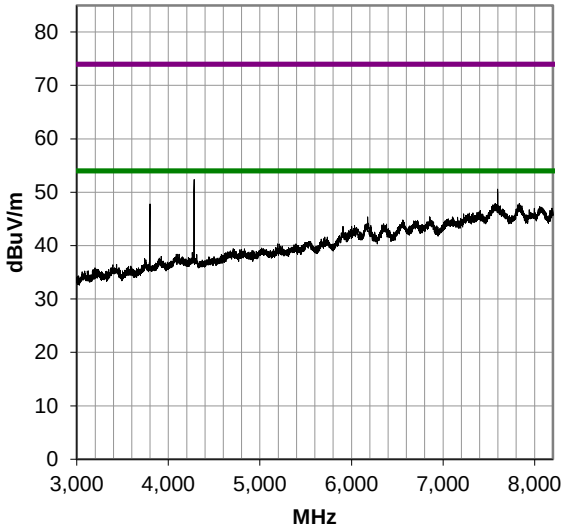
1000-3000 MHz, Run 142



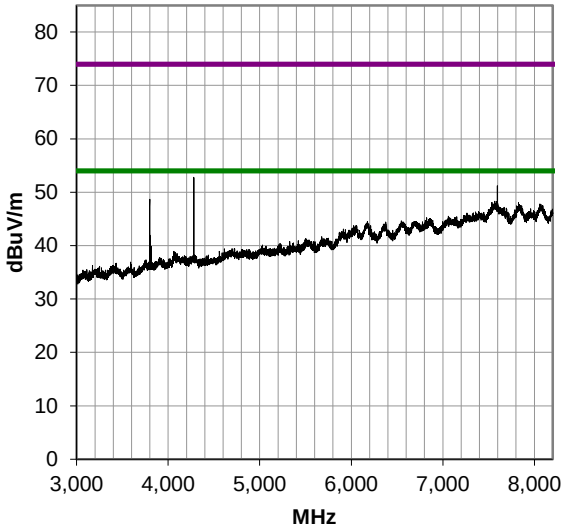
SPURIOUS RADIATED EMISSIONS

element
WTD.2025.03.25.0
EmiR5 2024.05.24.5
PSA-ESCI 2024.11.22.0

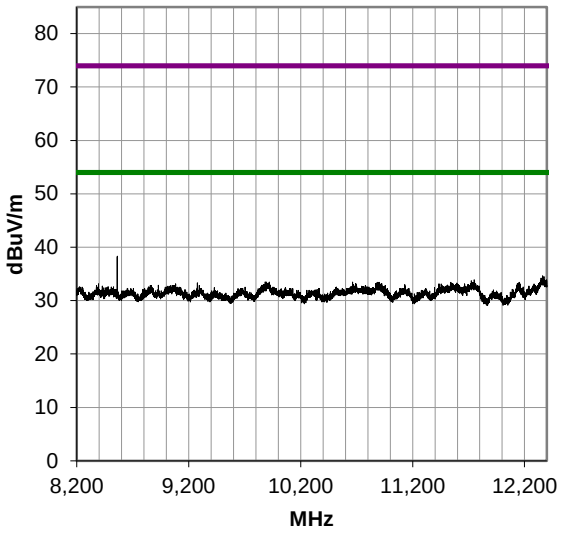
3000-8200 MHz, Run 143



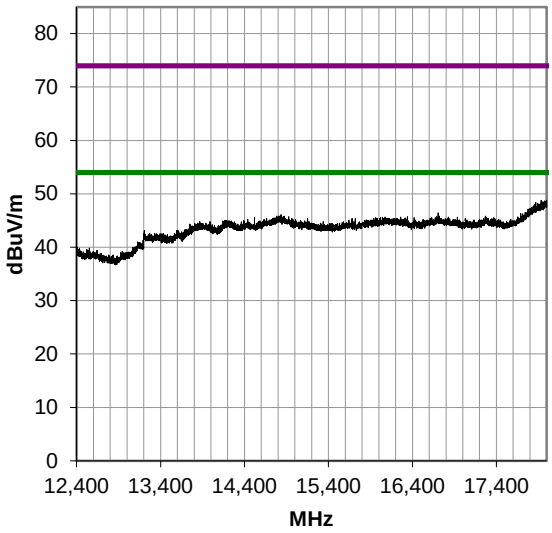
3000-8200 MHz, Run 146 (RADIO OFF)



8200-12400 MHz, Run 144

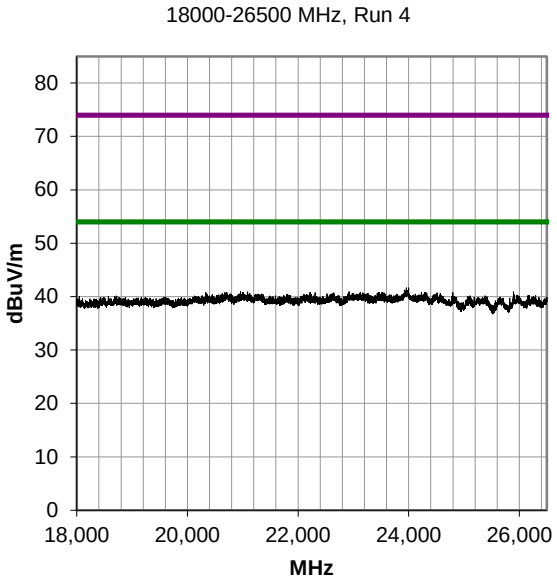


12400-18000 MHz, Run 145



SPURIOUS RADIATED EMISSIONS

element
WTD.2025.03.25.0
EmiR5 2024.05.24.5
PSA-ESCI 2024.11.22.0



End of Test Report