Limited test report

REP032968-5TRFWL

Date of issue: April 26, 2024

Applicant:

Canary Medical

Product description:

Home Base Station

Model:

Canary HBS2

Product marketing name(s):

Canturio™

FCC ID:

2AYAJ-BS1

Specifications:

- FCC 47 CFR Part 95 Subpart I
  Medical Device Radio Communication Service

Lab and test locations

Company name	Nemko USA Inc.
Address	2210 Faraday Ave, Suite 150
City	Carlsbad
State	California
Postal code	92008
Country	USA
Telephone	+1 760 444 3500
Website	www.nemko.com
FCC Site Number	Test Firm Registration Number: 392943; Designation Number: US5058
ISED Test Site	2040B-3

Tested by	Martha Espinoza, Wireless Test Engineer
Reviewed by	James Cunningham, EMC/WL Manager
Review date	April 26, 2024
Reviewer signature	

Limits of responsibility

Note that the results contained in this report relate only to the items tested and were obtained in the period between the date of initial receipt of samples and the date of issue of the report.
This test report has been completed in accordance with the requirements of ISO/IEC 17025. All results contain in this report are within Nemko USA's ISO/IEC 17025 accreditation.
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Table of Contents

Section 1 Report summary

1.1 Test specifications

FCC 47 CFR Part 95 Subpart	Medical Device Radio Communication Service

1.2 Exclusions

The purpose of this testing was to spot-check the compliance of a host product using a certified radio module. Testing was limited to partial output power and spurious emissions measurements.

1.3 Statement of compliance

Testing was performed against all relevant requirements of the test standard(s).

Results obtained indicate that the product under test complies in full with the tested requirements as indicated by Section 1.2 above.

The test results relate only to the item(s) tested.

See “Section 2 Summary of test results” for full details.

1.4 Test report revision history

Table 1.4-1: *Test report revision history*

Revision #	Issue Date	Details of changes made to test report
REP032968-5TRFEMC	April 26, 2024	Original report issued

Section 2 Summary of test results

2.1 Sample information

Receipt date	25-Mar-24
Nemko sample ID number	REP032968

2.2 Testing period

Test start date	26-Mar-24
Test end date	01-Apr-24

2.3 Test results

Table 2.3-1: *FCC 47 CFR Part 15, Subpart B & C, general requirements*

Part	Test description	Verdict
§15.207(a)	Conducted limits	Not tested
§15.31(e)	Variation of power source	Not tested
§15.203	Antenna requirement	Not applicable[1]

Notes: [1]

Table 2.3-2: *FCC Part 95 Subpart I, Medical Device Radio Communications Service, test results*

Part	Test description	Verdict
§95.2565	Frequency Accuracy	Not tested
§95.2567(a)	Field strength of fundamental	Pass
§95.2573(a)	Emission Bandwidth (20 dB)	Not tested
§95.2579	Band Edges	Pass
§95.2579	Unwanted Emissions	Pass

Section 3 Equipment under test (EUT) details

3.1 Disclaimer

This section contains information provided by the applicant and has been utilized to support the test plan. Inaccurate information provided by the applicant can affect the validity of the results within this test report. Nemko accepts no responsibility for the information contained within this section and the impact it may have on the test plan and resulting measurements.

3.2 Applicant

Company name	Canary Medical
Address	2710 Loker Ave West, Suite 350
City	Carlsbad
State	CA
Postal/Zip code	92010
Country	United States

3.3 Manufacturer

Company name	Canary Medical
Address	2710 Loker Ave West, Suite 350
City	Carlsbad
State	CA
Postal/Zip code	92010
Country	United States

3.4 EUT information

Product name	Home Base Station
Model	Canary HBS2
Variant(s)	N/A
Serial number	01-00000021
Part number	N/A
Power requirements	5 VDC 0.1A Max
Description/theory of operation	Home Base Station that gathers information from an implant connected to a tibial plate of a knee replacement. The device connects to the internet and transfers data files to the cloud.
Operational frequencies	402 - 406 MHz
Software details	N/A

3.5 Transmitter Information

Frequency band	400 – 406 MHz
Transmitter type	N/A
Minimum frequency (MHz)	400
Maximum frequency (MHz)	406
Type of modulation	N/A
Data rate	N/A
Tested frequencies	400 – 406 MHz
Antenna type	Helical Wire
Antenna peak gain	1.7 dBi

3.6 EUT setup details

Table 3.6-1: *EUT sub assemblies*

Description	Brand name	Model/Part number	Serial number	Rev.
N/A	N/A	N/A	N/A	---

Table 3.6-2: *EUT interface ports*

Description	Qty.
USB Port	1

Table 3.6-3: *Support equipment*

Description	Brand name	Model/Part number	Serial number	Rev.
Knee sensor	Canary	N/A	N/A	---
Medical AC/DC Adapter	CUI INC	SWM6-5-NH-I38	190400831	---

Table 3.6-4: *Inter-connection cables*

Cable description	From	To	Length (m)
USB Cable	EUT	AC/DC Adapter	0.5

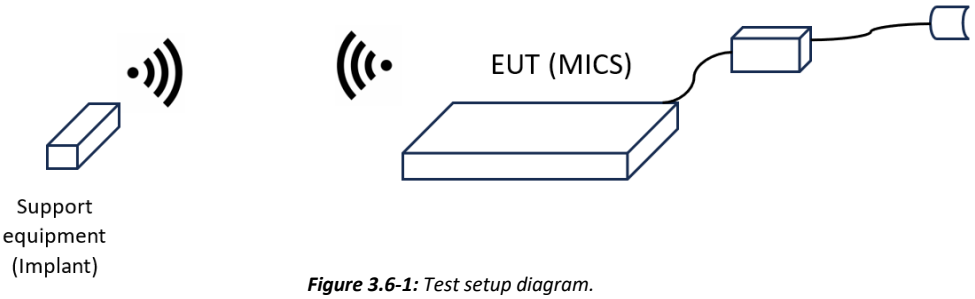

Figure 3.6-1: *Test setup diagram.*

Section 4 Engineering considerations

4.1 Modifications incorporated in the EUT

None.

4.2 Technical judgement

None.

4.3 Deviations from laboratory test procedures

None.

Section 5 Test conditions

5.1 Atmospheric conditions

Temperature	15–30 °C
Relative humidity	20–75 %
Air pressure	86–106 kPa

When it is impracticable to carry out tests under these conditions, a note to this effect stating the ambient temperature and relative humidity during the tests shall be recorded and stated.

5.2 Power supply range

The normal test voltage for equipment to be connected to the mains shall be the nominal mains voltage. For the purpose of the present document, the nominal voltage shall be the declared voltage, or any of the declared voltages ±5 %, for which the equipment was designed.

Section 6 Measurement uncertainty

6.1 Uncertainty of measurement

Nemko USA Inc. has calculated measurement uncertainty and is documented in EMC/MUC/001 "Uncertainty in EMC measurements." Measurement uncertainty was calculated using the methods described in CISPR 16-4-2 Specification for radio disturbance and immunity measuring apparatus and methods – Part 4-2: Uncertainties, statistics, and limit modelling – Measurement instrumentation uncertainty. The expression of Uncertainty in EMC testing. Measurement uncertainty calculations assume a coverage factor of K=2 with 95% certainty.

Table 6.1-1: *Measurement uncertainty calculations*

Measurement		**U_{cispr} dB**	**U_{lab} dB**
Conducted disturbance at AC mains and other port power using a V-AMN	9 kHz to 150 kHz	3.8	2.9
	150 kHz to 30 MHz	3.4	2.3
Conducted disturbance at telecommunication port using AAN	150 kHz to 30 MHz	5.0	4.3
Conducted disturbance at telecommunication port using CVP	150 kHz to 30 MHz	3.9	2.9
Conducted disturbance at telecommunication port using CP	150 kHz to 30 MHz	2.9	1.4
Conducted disturbance at telecommunication port using CP and CVP	150 kHz to 30 MHz	4.0	3.1
Radiated disturbance (electric field strength in a SAC)	30 MHz to 1 GHz	6.3	5.5
Radiated disturbance (electric field strength in a FAR)	1 GHz to 6 GHz	5.2	4.7
Radiated disturbance (electric field strength in a FAR)	6 GHz to 18 GHz	5.5	5.0

Notes: Compliance assessment:

If U_{lab} is less than or equal to U_{cispr} then:

- compliance is deemed to occur is no measured disturbance level exceeds the disturbance limit;
- non-compliance is deemed to occur if any measured disturbance level exceeds the disturbance limit

If U_{lab} is greater than U_{cispr} then:

- compliance is deemed to occur is no measured disturbance level, increased by (U_{lab} - U_{cispr}), exceeds the disturbance limit;
- non-compliance is deemed to occur if any measured disturbance level, increased by (U_{lab} - U_{cispr}), exceeds the disturbance limit

V-AMN: V type artificial mains network
AAN: Asymmetric artificial network
CP: Current probe
CVP: Capacitive voltage probe
SAC: Semi-anechoic chamber
FAR: Fully anechoic room

Section 7 Test equipment

7.1 Test equipment list

Table 7.1-1: *Test Equipment List*

Equipment	Manufacturer	Model no.	Asset no.	Cal cycle	Next cal.
EMI Receiver	Rohde & Schwarz	ESU 40	E1121	1 year	Aug 23, 2024
System Controller	Sunol Systems	SC104V	E1191	NCR	NCR
Bilog Antenna	Schaffner	CBL 6111D	1763	2 years	April 02, 2024
Antenna, DRWG	EMCO	3115	0529	NCR	NCR
Horn Antenna	ETS Lindgren	3117 PA	E1139	2 years	Jan 11, 2026

Notes: NCR: no calibration required

7.2 Test software list

Table 7.2-1: *Test Software*

Manufacturer	Details
Rohde & Schwarz	EMC 32 V10.60.15 (radiated emissions)

Section 8 Testing data

8.1 Maximum peak output power

8.1.1 References and limits

FCC Part 95 → Subpart I → 95.2567 (a)
Each MedRadio transmitter type must be designed such that the MedRadio equivalent isotropically radiated power (M-EIRP) does not exceed the limits in this section. Compliance with these limits must be determined as set forth in §95.2569.

(a) Transmitters subject to frequency monitoring—401-406 MHz. For MedRadio transmitters that are not excepted under §95.2559(b) from the frequency monitoring requirements of §95.2559(a):

(1) The M-EIRP within any 300 kHz bandwidth within the 402-405 MHz band must not exceed 25 microwatts.

8.1.2 Test summary

Verdict	Pass		
Test date	April 1, 2024	Temperature	20 °C
Test engineer	Martha Espinoza, Wireless Test Engineer	Air pressure	1004 mbar
Test location	☐ Wireless bench ☒ Other: 3M Chamber	Relative humidity	52 %

8.1.3 Notes

Testing was performed with the transmitter operating on normal operation mode. This is a radiated test. There is no access to the conducted port.

The spectrum was searched in the band: 400 – 406 MHz.

The spectral plots within this section have been corrected with all relevant transducer factors.

The 25 microwatt limit must be transformed to dBµV/m to get a radiated limit. Following equations are used with this end:

$$PD = \frac{ERP}{4\pi d^2}$$

$$Electric\ field\ strengh\ (v/m) = \sqrt{(PD)(Z_o Vacumm)}$$

$$Electric\ field\ strengh\ (dB\mu v/m) = 20Log(Electric\ field\ strengh\ in\ v/m) + 120$$

$$Electric\ field\ limit = 81.38\ db\mu v/m$$

Where:
PD = Power Density (Watts/m^2)
ERP = Radiated power in Watts
d = Distance in meters

8.1.4 Setup details

EUT power input during test	Enclosure port
EUT setup configuration	☒ Table-top ☐ Floor standing ☐ Other:

Receiver/spectrum analyzer settings:

Resolution bandwidth	300 kHz
Video bandwidth	1 MHz
Detector mode	Peak (preview measurements) Peak (final measurements)

8.1.5 Test data

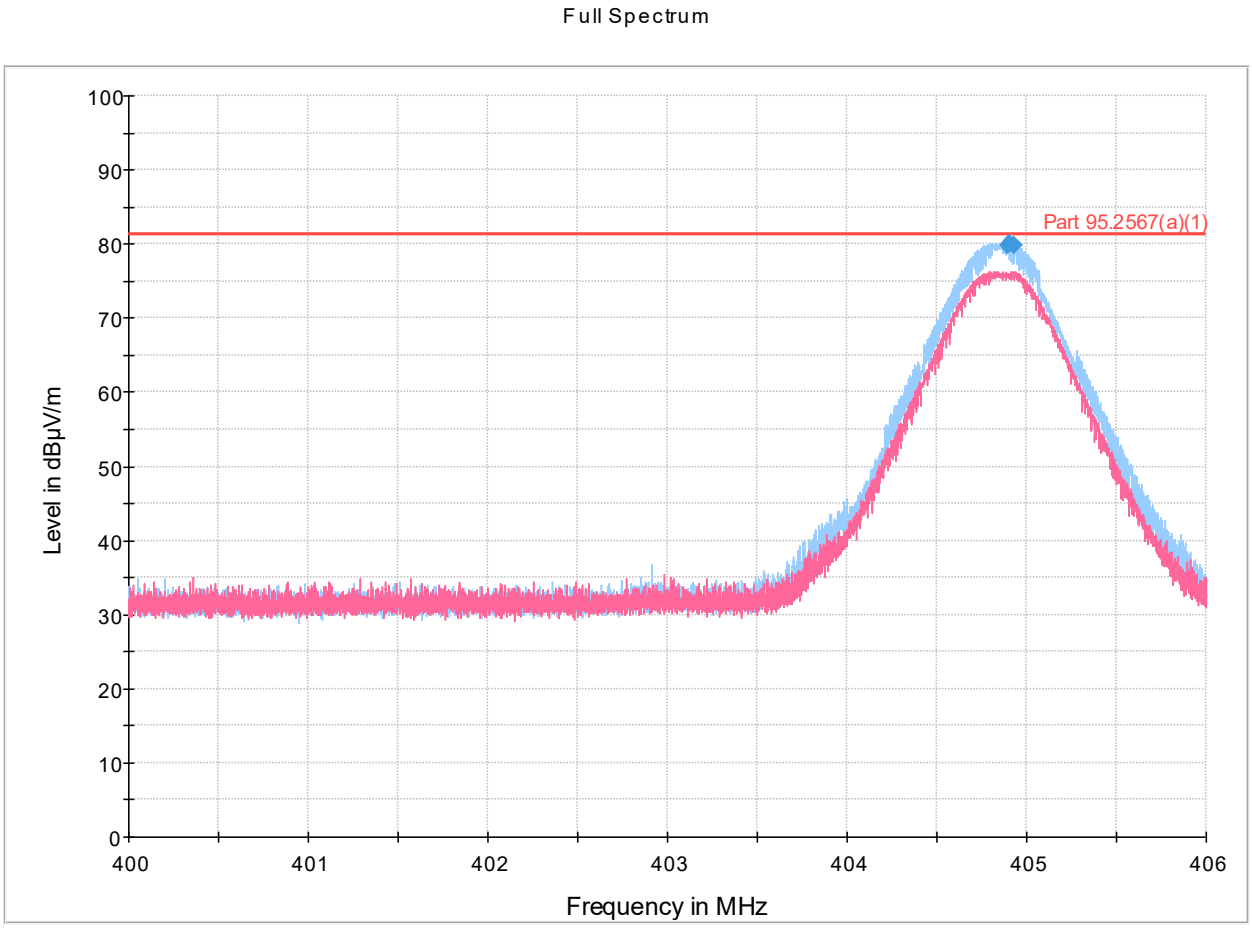

Figure 8.1-1: *Radiated emissions spectral plot (400 MHz - 406 MHz)*

Table 8.1-1*: Radiated emissions results*

Frequency (MHz)	MaxPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)
404.897000	79.85	81.38	1.53	5000.0	300.000	246.0	H	137.0	24.4
404.900600	80.10	81.38	1.28	5000.0	300.000	100.0	H	139.0	24.4
404.930400	79.92	81.38	1.46	5000.0	300.000	245.0	H	136.0	24.4

Notes:
[1] Field strength (dBµV/m) = receiver/spectrum analyzer value (dBµV) + correction factor (dB)
[2] Correction factors = antenna factor ACF (dB) + cable loss (dB)
[3] Emissions that were continuously present for a minimum of 1 second and occurred more than once for every 15 seconds observation period were considered valid emissions. The maximum value of valid emissions has been recorded.

8.2 Spurious emissions

8.2.1 References and limits

FCC Part 95 → Subpart I → 95.2579
Unwanted emission field strength limits and attenuation requirements apply to each MedRadio transmitter type, as set forth in this section and part 2.

(a) Field strength limits. The field strengths of unwanted emissions from each MedRadio transmitter type, measured at a distance of 3 meters, must not exceed the field strength limits shown in the table in this paragraph for the indicated frequency ranges, if the frequencies of these emissions are:

(1) More than 250 kHz outside of the 402-405 MHz band (for devices designed to operate in the 402-405 MHz band);

.

Frequency range (MHz)	**Field strength (µV/m)**
30-88	100
88-216	150
216-960	200
960 and above	500

Note to table in paragraph (a)(5): At the boundaries between frequency ranges, the tighter limit (lower field strength) applies. Below 1 GHz, field strength is measured using a CISPR quasi-peak detector. Above 1 GHz, field strength is measured using an average detector with a minimum reference bandwidth of 1 MHz. See also part 2, subpart J of this chapter.

(b) Harmonic emissions. Radiated unwanted emissions from a MedRadio transmitter type must be measured to at least the tenth harmonic of the highest fundamental frequency emitted.

(c) Attenuation requirements, 402-405 MHz. For MedRadio transmitter types designed to operate in the 402-405 MHz band, unwanted emissions must be attenuated below the maximum permitted transmitter output power by at least:

(1) 20 dB, on any frequency within the 402-405 MHz band that is more than 150 kHz away from the center frequency of the occupied bandwidth;
g) Measurements. Compliance with the limits in paragraphs (c), (d), and (e) of this section is based on the use of measurement instrumentation using a peak detector function with an instrument reference bandwidth approximately equal to 1.0 percent of the emission bandwidth of the device under measurement.

8.2.2 Test summary

Verdict	Pass		
Test date	April 1, 2024	Temperature	20 °C
Test engineer	Martha Espinoza, Wireless Test Engineer	Air pressure	1004 mbar
Test location	☐ Wireless bench (conducted tests) ☐ 10 m semi-anechoic chamber (radiated tests) ☒ 3 m semi-anechoic chamber (radiated tests) ☐ Other:	Relative humidity	52 %

8.2.3 Notes

Testing was performed with the transmitter operating on normal operation mode (spot check). This is a radiated test. There is no access to the conducted port.

The spectrum was searched from 30 MHz to 5 GHz (above the 10th harmonic of the highest transmit frequency).

The spectral plots within this section have been corrected with all relevant transducer factors.

8.2.4 Setup details

EUT power input during test	Enclosure port
EUT setup configuration	☒ Table-top ☐ Floor standing ☐ Other:

Receiver settings for radiated measurements below 1 GHz:

Resolution bandwidth	120 kHz
Video bandwidth	300 kHz
Detector mode	Peak (preview measurements) Quasi-Peak (final measurements)

Receiver settings for radiated measurements above 1 GHz:

Resolution bandwidth	1 MHz
Video bandwidth	3 MHz
Detector mode	Peak (preview measurements) Peak and average (final measurements)

Receiver settings for radiated measurements within restricted bands:

Resolution bandwidth	10 kHz
Video bandwidth	30 kHz
Detector mode	Peak (preview measurements) Peak and average (final measurements)

8.2.5 Test data

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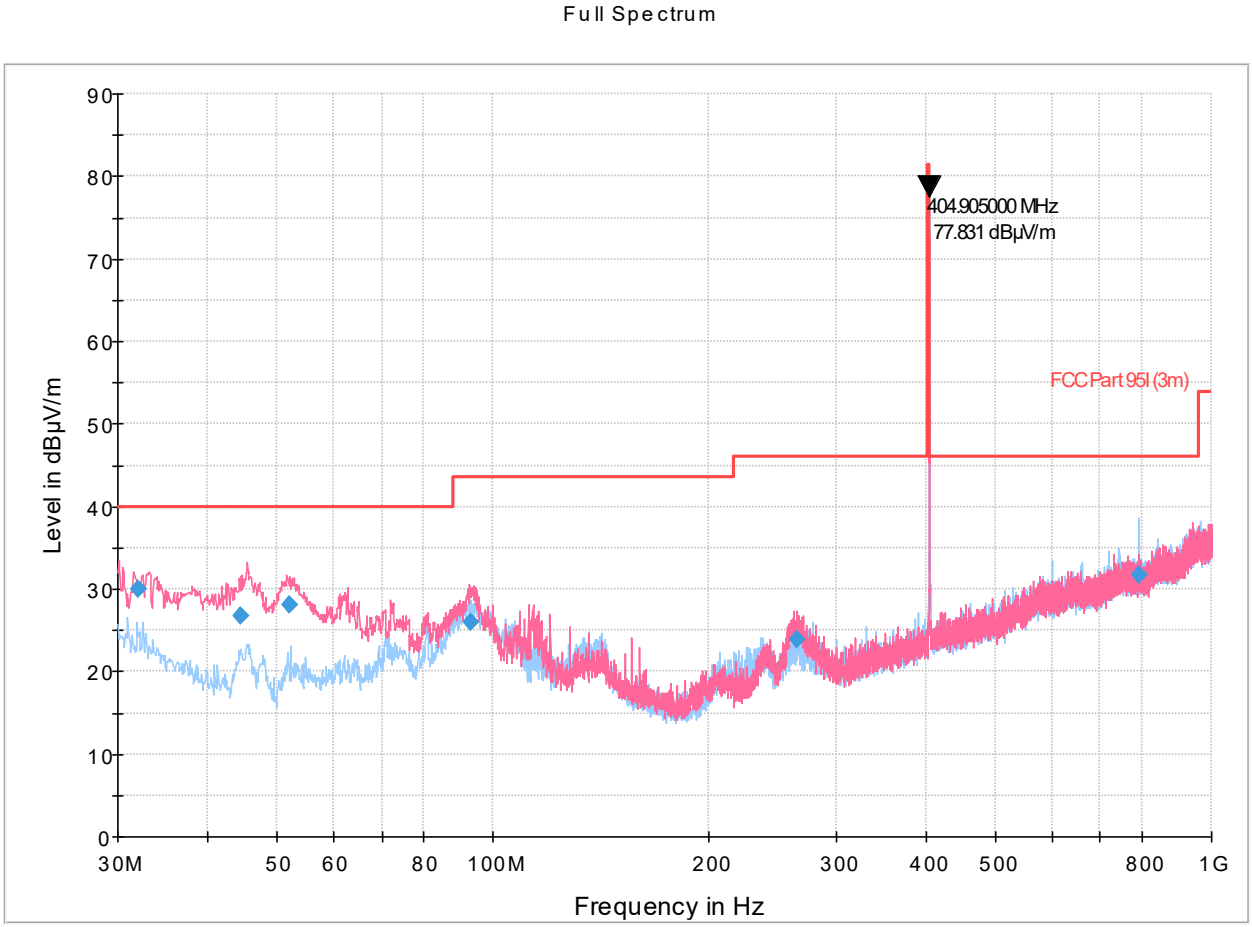

Figure 8.2-1: *Radiated emissions spectral plot (30 MHz - 1 GHz)*

Table 8.2-1*: Radiated emissions results*

Frequency (MHz)	QuasiPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)
31.992000	29.99	40.00	10.01	5000.0	120.000	104.0	V	0.0	24.1
44.566000	26.79	40.00	13.21	5000.0	120.000	100.0	V	216.0	16.6
52.093000	28.07	40.00	11.93	5000.0	120.000	107.0	V	0.0	13.8
92.879000	26.07	43.50	17.43	5000.0	120.000	113.0	V	169.0	15.6
265.197000	23.81	46.00	22.19	5000.0	120.000	104.0	V	205.0	21.7
792.592000	31.71	46.00	14.29	5000.0	120.000	291.0	H	116.0	31.9

Notes: [1] Field strength (dBµV/m) = receiver/spectrum analyzer value (dBµV) + correction factor (dB)
[2] Correction factors = antenna factor ACF (dB) + cable loss (dB)
[3] Emissions that were continuously present for a minimum of 1 second and occurred more than once for every 15 seconds observation period were considered valid emissions. The maximum value of valid emissions has been recorded.

Full Spectrum

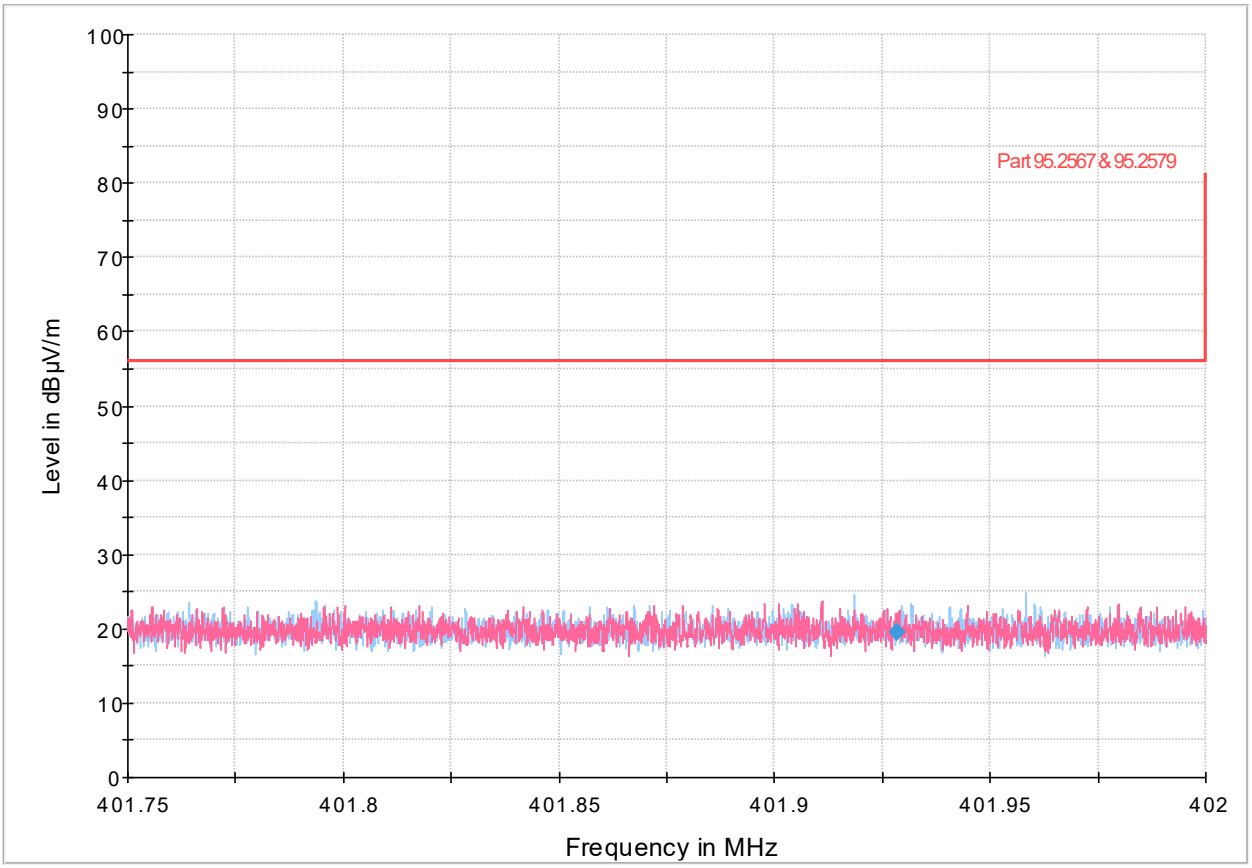

Figure 8.2-2: *Radiated emissions spectral plot (401.75 MHz - 402 MHz)*

Table 8.2-2*: Radiated emissions results*

Frequency (MHz)	MaxPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)
401.928300	19.61	56.00	36.39	5000.0	10.000	183.0	H	201.0	24.3

Notes:
[1] Field strength (dBµV/m) = receiver/spectrum analyzer value (dBµV) + correction factor (dB)
[2] Correction factors = antenna factor ACF (dB) + cable loss (dB)
[3] Emissions that were continuously present for a minimum of 1 second and occurred more than once for every 15 seconds observation period were considered valid emissions. The maximum value of valid emissions has been recorded.

Full Spectrum

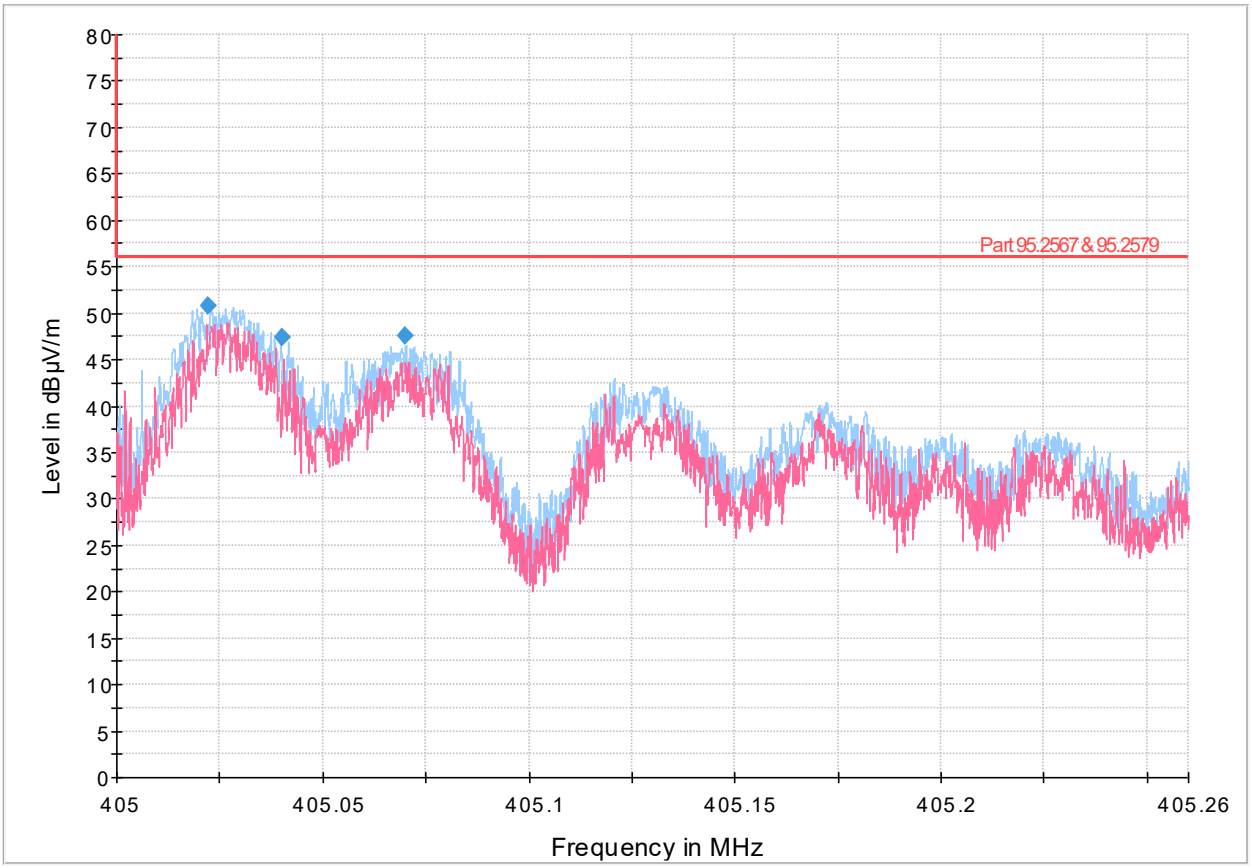

Figure 8.2-3: *Radiated emissions spectral plot (405 MHz - 405.26 MHz)*

Table 8.2-3*: Radiated emissions results*

Frequency (MHz)	MaxPeak (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)
405.022172	50.79	56.00	5.21	5000.0	10.000	245.0	H	132.0	24.4
405.040000	47.44	56.00	8.56	5000.0	10.000	246.0	H	137.0	24.4
405.070064	47.58	56.00	8.42	5000.0	10.000	100.0	H	149.0	24.4

Notes:
[1] Field strength (dBµV/m) = receiver/spectrum analyzer value (dBµV) + correction factor (dB)
[2] Correction factors = antenna factor ACF (dB) + cable loss (dB)
[3] Emissions that were continuously present for a minimum of 1 second and occurred more than once for every 15 seconds observation period were considered valid emissions. The maximum value of valid emissions has been recorded.

Full Spectrum

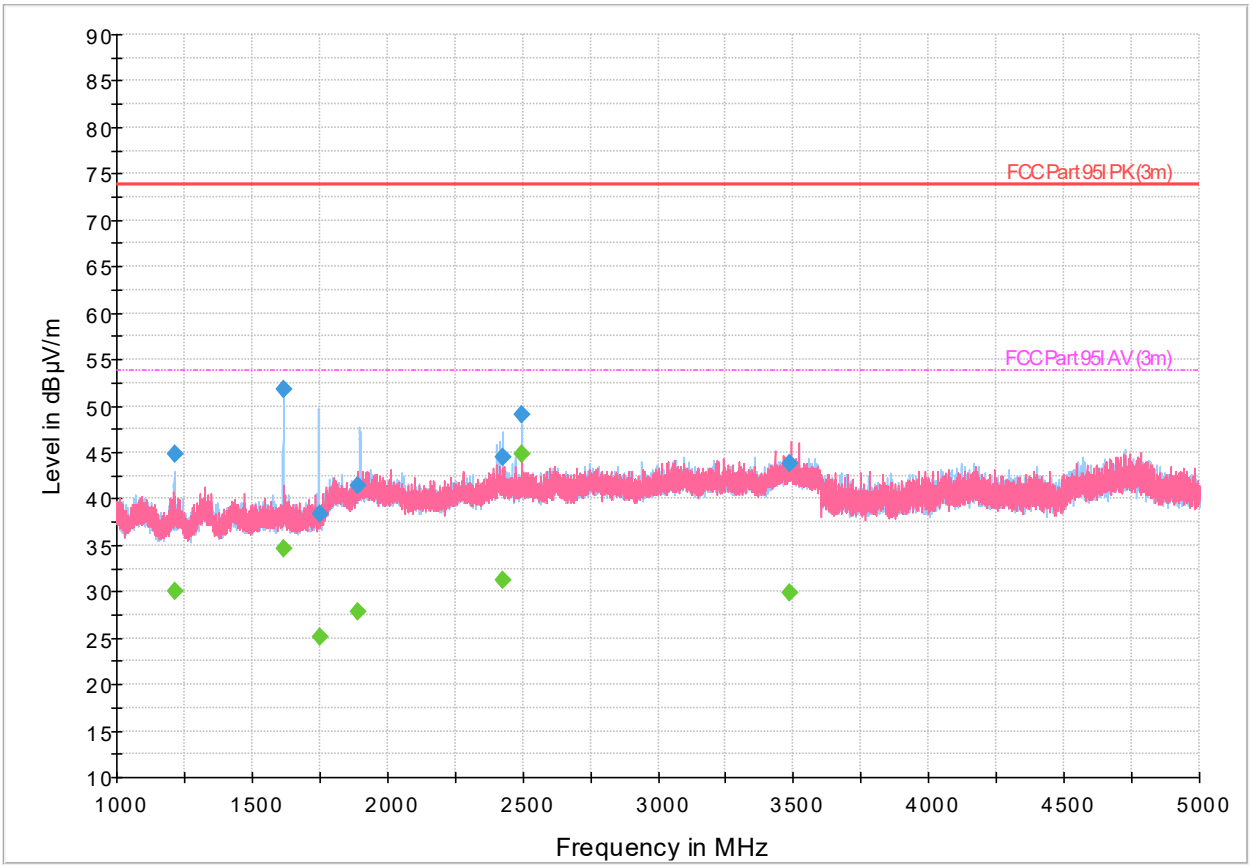

Figure 8.2-4: *Radiated emissions spectral plot (1 GHz - 5 GHz)*

Table 8.2-4*: Radiated emissions results*

Frequency (MHz)	MaxPeak (dBµV/m)	CAverage (dBµV/m)	Limit (dBµV/m)	Margin (dB)	Meas. Time (ms)	Bandwidth (kHz)	Height (cm)	Pol	Azimuth (deg)	Corr. (dB/m)
1212.666667	---	30.04	53.90	23.86	5000.0	1000.000	141.0	H	43.0	-11.1
1212.666667	44.86	---	73.90	29.04	5000.0	1000.000	141.0	H	43.0	-11.1
1616.711111	---	34.61	53.90	19.29	5000.0	1000.000	143.0	H	238.0	-9.4
1616.711111	51.77	---	73.90	22.13	5000.0	1000.000	143.0	H	238.0	-9.4
1751.511111	---	25.10	53.90	28.80	5000.0	1000.000	391.0	H	125.0	-8.6
1751.511111	38.42	---	73.90	35.48	5000.0	1000.000	391.0	H	125.0	-8.6
1890.711111	---	27.84	53.90	26.06	5000.0	1000.000	210.0	H	0.0	-6.0
1890.711111	41.43	---	73.90	32.47	5000.0	1000.000	210.0	H	0.0	-6.0
2424.088889	44.45	---	73.90	29.45	5000.0	1000.000	209.0	H	53.0	-4.1
2424.088889	---	31.25	53.90	22.65	5000.0	1000.000	209.0	H	53.0	-4.1
2496.177778	49.10	---	73.90	24.80	5000.0	1000.000	110.0	H	42.0	-4.0
2496.177778	---	44.86	53.90	9.04	5000.0	1000.000	110.0	H	42.0	-4.0
3487.777778	---	29.87	53.90	24.03	5000.0	1000.000	235.0	V	294.0	-0.8
3487.777778	43.76	---	73.90	30.14	5000.0	1000.000	235.0	V	294.0	-0.8

Notes: [1] Field strength (dBµV/m) = receiver/spectrum analyzer value (dBµV) + correction factor (dB)
[2] Correction factors = antenna factor ACF (dB) + cable loss (dB)
[3] Emissions that were continuously present for a minimum of 1 second and occurred more than once for every 15 seconds observation period were considered valid emissions. The maximum value of valid emissions has been recorded.

Section 9 Photos

9.1 Test setup photos

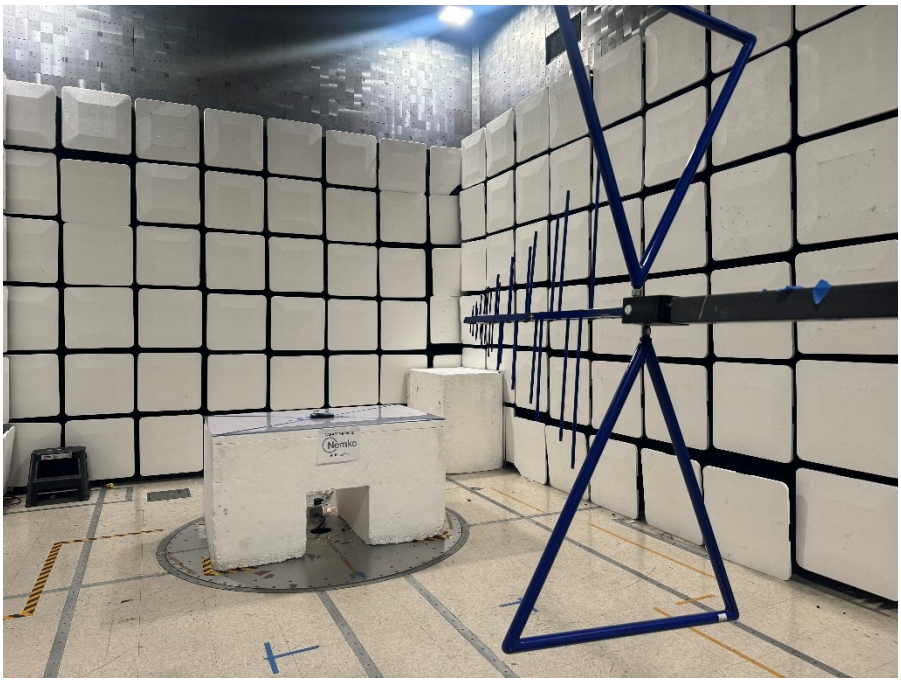

Figure 9.1-1: *Radiated emissions setup (0.030 – 1 GHz): Front view photo.*

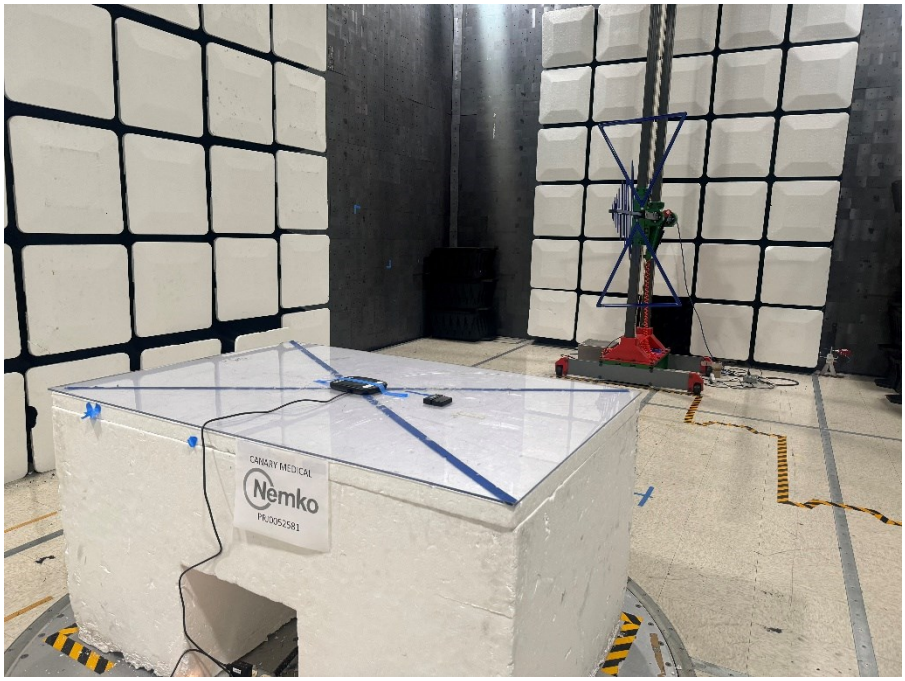

Figure 9.1-2: *Radiated emissions setup (0.030 – 1 GHz): Rear view photo.*

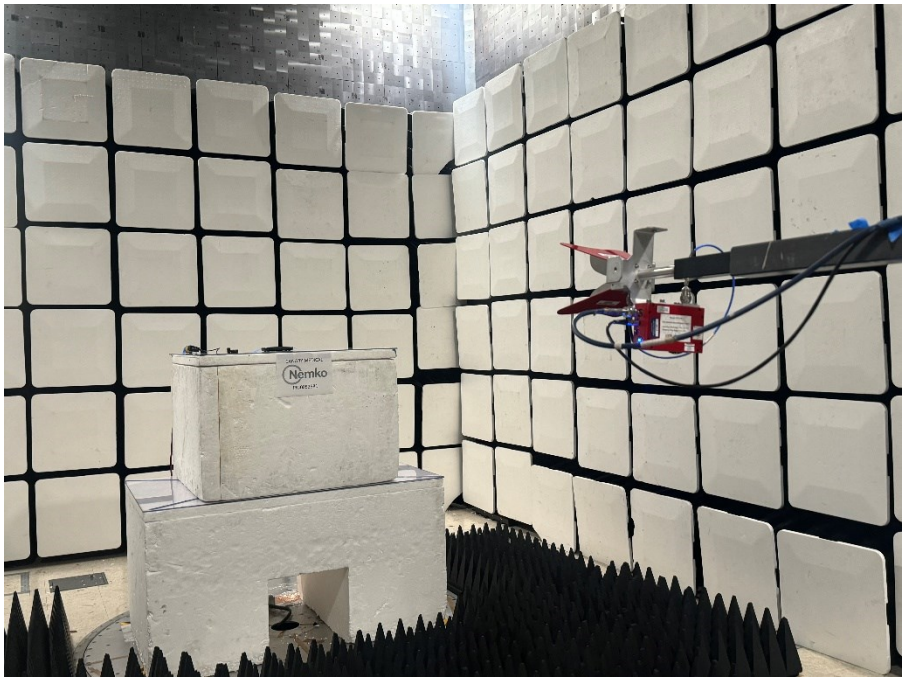

Figure 9.1-2: *Radiated emissions setup (1 – 5 GHz): Front view photo.*

Figure 9.1-3: *Radiated emissions setup (1 - 5 GHz): Rear view photo.*

9.2 EUT photos

Figure 9.2-1: *Front view photo.*

Figure 9.2-2: *Rear view photo.*

Figure 9.2-3: *Top view photo.*

Figure 9.2-4: *Bottom view photo.*

End of test report