FCC Partial Scope Test Report

FOR:

Manufacturer: ReliantHeart, Inc.

Model: CTL001

Description: Controller for HeartAssist5 Left Ventricular Assist Device

FCC ID: 2AB4ZCTL001

47 CFR Part 2, 22, 24

TEST REPORT #: EMC_RELIA_001_14001_WWAN_Rev1
DATE: January 12, 2015

FCC listed:
A2LA Accredited

IC recognized #
3462B-1

CETECOM **Inc.**
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Table of Contents

1   <u>Assessment</u>

The following equipment, as detailed in section 3 of this test report, was evaluated against the applicable criteria specified in FCC CFR 47 Parts 2, 22, 24.
No deviations were ascertained during the course of the tests performed.

Company	Description	Model #
ReliantHeart, Inc.	Controller for HeartAssist5 Left Ventricular Assist Device	CTL001

Responsible for Testing Laboratory:

		Franz Engert	
January 12, 2015	Compliance	(Manager of Compliance)	
Date	**Section**	**Name**	**Signature**

Responsible for the Report:

		Josie Sabado	
January 12, 2015	Compliance	(Test Lab Manager)	
Date	**Section**	**Name**	**Signature**

2   Administrative Data

2.1   Identification of the Testing Laboratory Issuing the Test Report

Company Name:	CETECOM Inc.
Department:	Compliance
Address:	411 Dixon Landing Road Milpitas, CA 95035 U.S.A.
Telephone:	+1 (408) 586 6200
Fax:	+1 (408) 586 6299
Acting Test Lab Manager:	Franz Engert
Test Engineer:	Josie Sabado

2.2   Identification of the Client

Client Firm/Name:	RelianHeart, Inc.
Street Address:	8965 Interchange Drive
City/Zip Code	Houston, TX 77459
Country	USA
Contact Person:	Bryan E. Lynch or William Graham
Phone No.	713-412-3418 or 713-457-1479 or 713-457-1480
e-mail:	blynch@reliantheart.com or wgraham@reliantheart.com

2.3   Identification of the Manufacturer

Manufacturer's Name:	
Manufacturers Address:	Same as Client
City/Zip Code	
Country	

3   Equipment under Test (EUT)

3.1   Details of the Equipment under Test

Model No:	CTL001
Product Description:	Controller for HeartAssist5 Left Ventricular Assist Device
Hardware Revision[1] :	A C
Software Revision[1] :	PP1 1.0.13
FCC-ID:	2AB4ZCTL001
Integrated Module Information:	GPRS Data radio: Gemalto TC65i FCC ID: QIPTC65I
Frequency:	GSM 850: 824.2 – 848.8 MHz PCS 1900: 1850.2 – 1909.8 MHz
Type(s) of Modulation:	GMSK
Number of channels:	GSM850: 125 and PCS 1900: 300
Antenna Information:	Internal Isolated Magnetic Dipole Manufacturer Stated Max. Antenna Gain: 2 dBi
Power Supply:	Dedicated Lithium battery pack Rated Operating Voltage Range: 9 (Low) / 10.8 (Nom) / 14 (High)
Rated Operating Temperature Range:	-10°C to 40°C
Prototype / Production unit	Prototype

NOTES:

1.   See section 5.6 for hardware and software version differences.

3.2   Identification of the Equipment Under Test (EUT)

EUT #	IMEI Number	HW Version	SW Version
1	35323402659400003	A	PP1
2	35323402659513003	C	1.0.13

3.3   Identification of Accessory equipment

AE #	Type	Manufacturer	Part Number	Serial Number
1	Battery Pocket with Lithium ion battery #1	MicroMed	Li2025x-78C	110224D16A0492
2	Battery Pocket with Lithium ion battery #2	MicroMed	Li2025x-78C	110224D16A0504

4 Summary of Measurement Results

850 Band:

Test Specification	Test Case	Temperature and Voltage Conditions	Pass	Fail	NA	NP	Result
§2.1046 §22.913 (a) RSS132 4.4	RF Output Power	Nominal	■	□	□	□	Complies
§2.1055 §22.355 RSS132 4.3	Frequency Stability	Nominal	□	□	□	■	Note 1
§2.1049 §22.917(b) RSS132 4.2	Occupied Bandwidth	Nominal	□	□	□	■	Note 1
§2.1051 §22.917 RSS132 4.5	Band Edge Compliance	Nominal	□	□	□	■	Note 1
§2.1051 §22.917 RSS132 4.5	Conducted Spurious Emissions	Nominal	□	□	□	■	Note 1
§2.1053 §22.917 RSS132 4.5	Radiated Spurious Emissions	Nominal	■	□	□	□	Complies

Note: NA= Not Applicable; NP= Not Performed.
1. Conducted RF antenna port measurements are documented in a seperate test report. See section 5.5

1900 Band:

Test Specification	Test Case	Temperature and Voltage Conditions	Pass	Fail	NA	NP	Result
§2.1046 §24.232 (a) RSS133 6.4	RF Output Power	Nominal	■	☐	☐	☐	Complies
§2.1055 §24.235 RSS133 6.3	Frequency Stability	Nominal	☐	☐	☐	■	Note 1
§2.1049 §24.238(b) RSS133 6.2	Occupied Bandwidth	Nominal	☐	☐	☐	■	Note 1
§2.1051 §24.238 RSS133 6.5	Band Edge Compliance	Nominal	☐	☐	☐	■	Note 1
§2.1051 §24.238 RSS133 6.5	Conducted Spurious Emissions	Nominal	☐	☐	☐	■	Note 1
§2.1053 §24.238 RSS133 6.5	Radiated Spurious Emissions	Nominal	■	☐	☐	☐	Complies

Note: NA= Not Applicable; NP= Not Performed.

1. Conducted RF antenna port measurements are documented in a seperate test report. See section 5.5

5   Measurement Information

5.1   Dates of Testing

June 30, 2012 – July 5, 2012; January 10, 2014

5.2   Measurement Uncertainty

The following measurement uncertainties are applicable to the measurements described in this test report:
    Conducted power and emission measurements: +/- 0.5 dB
    Radiated power and emissions measurements: +/- 3.0 dB

5.3   Nominal EUT Conditions During Test

The following nominal EUT conditions were used during the course of testing, unless otherwise stated:
     EUT Voltage: 2 Li-ion battery packs

5.4   Nominal Environmental Conditions During Test

The following nominal environmental conditions were maintained during the course of testing, unless otherwise stated:
     Ambient Temperature: 20-25 °C
     Relative Humidity: 40-60%

5.5   Associated Test Reports
The EUT integrates a pre-certified module, Gemalto TC65i with FCC ID: QIPTC65I

Taking into account guidance from FCC KDB 996369 (modular approval) and where relevant test procedures did not change, conducted test results are leveraged from the conducted test report for the TC65i modem under FCC ID: QIPTC65I. For conducted measurements under, see test report numbers MDE_SIEM_0714_FCCb and MDE_SIEM_0714_FCCc issued by 7 Layers AGE dated 2008-06-23.

This test report contains full radiated testing as per FCC 22H/24E and RSS-132/133 and conducted power verification required per KDB 996369.

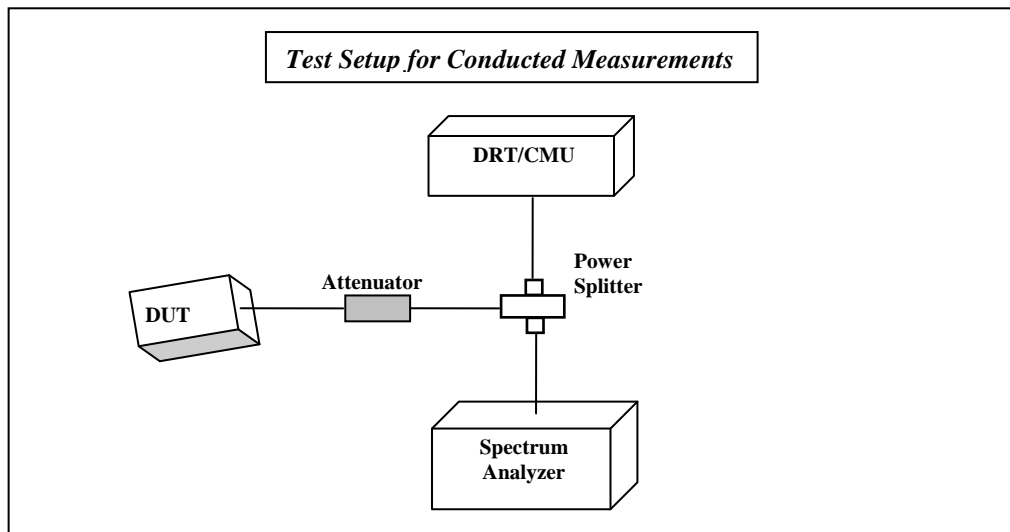### 5.6   Other Testing Notes:
1.   The different cellular operation modes of the EUT as required for testing are controlled through the link with the Digital Radio Communication Tester (R&S CMU200).
2.   The EUT is tested on the low, mid and high channel of each of the supported cellular operation modes, unless otherwise stated.
3.   During the course of testing, the cellular antenna was updated for better performance in a non-US band. EIRP measurements were performed on the hardware revision C to ensure compliance.

5.7   Measurement Method:
Testing is performed according to the guidelines provided in *FCC publication (KDB) 971168 D01 Power Meas License Digital Systems v02r01: Measurement Guidance for Certification of Licensed Digital Transmitters7, June 2013* and according to relevant parts of TIA-603C 2004 as detailed below.

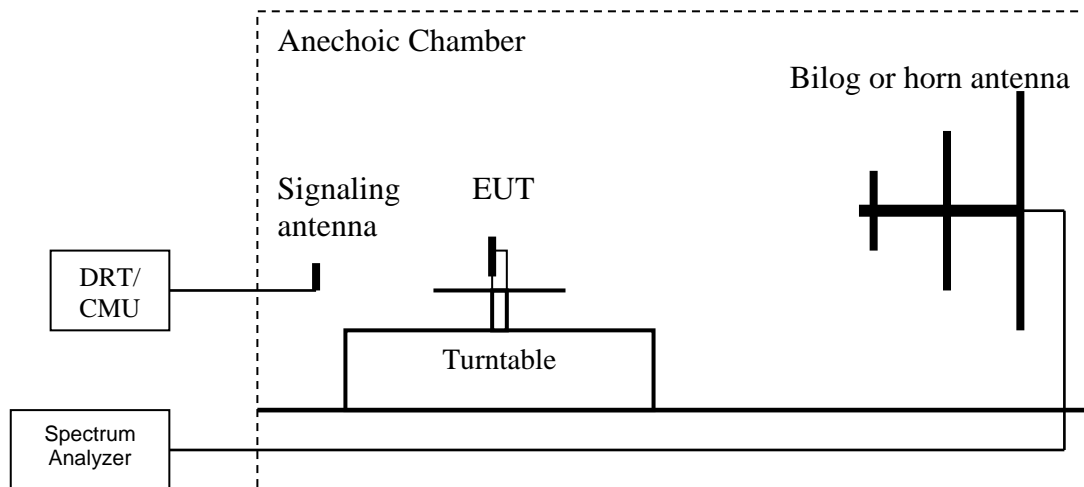## 5.8 RF Antenna Port Conducted Measurement Procedure

Ref: TIA-603C 2004 2.2.1

Test Setup for Conducted Measurements

1. Connect the equipment as shown in the above diagram. A Digital Radio Communication Tester (DRT: R&S CMU200 here) is used to enable the EUT to transmit and to measure the output power.
2. Adjust the settings of the CMU200 to set the EUT to its maximum power at the required channel.
3. Record the Peak and Average Output power level measured by the CMU200.
4. Correct the measured level for all losses in the RF path.
5. Measurements are to be performed with the EUT set to the low, middle and high channel of each frequency band and for all types of modulation schemes.
   a. GMSK mode measurements are performed in GSM 1 uplink slot configuration.

5.9   Radiated Measurement Procedure

Ref: TIA-603C 2004 -2.2.17.2 Effective Radiated Power (ERP) or Effective Isotropic Radiated Power (EIRP)

1. Connect the equipment as shown in the above diagram with the EUT's antenna in center of the turn table.
2. Adjust the settings of the Digital Radio Communication Tester (DRT) to set the EUT to its maximum power at the required channel.
3. Set the spectrum analyzer to the channel frequency and to required settings: peak detector, max hold trace, RBW>OBW, VBW= RBW, sweep time auto couple, span > 2x RBW.
4. Rotate the EUT 360°. Record the peak level in dBm (**LVL**).
5. Replace the EUT with a vertically polarized half wave dipole or known gain antenna. The center of the antenna should be at the same location as the center of the EUT's antenna.
6. Connect the antenna to a signal generator with known output power and record the path loss in dB (**LOSS**). **LOSS** = Generator Output Power (dBm) − Analyzer reading (dBm).
7. Determine the ERP using the following equation:
   ERP (dBm) = **LVL** (dBm) + **LOSS** (dB)
8. Determine the EIRP using the following equation:
   EIRP (dBm) = **ERP** (dBm) + 2.14 (dB)
9. Measurements are to be performed with the EUT set to the low, middle and high channel of each frequency band.
10. Radiated emission measurements were made in GMSK mode.

Note: Steps 5 and 6 above are performed prior to testing and **LOSS** is recorded by test software. Steps 3, 4, 7 and 8 above are performed with test software.

All radiated test data in this report shows the worst case emissions for H/V measurement antenna polarizations and for all three orthogonal orientations of the EUT.

Unless mentioned otherwise, the emission signals above the limit line in the plots are from the carrier.

5.10 Sample Calculations for Radiated Measurements

The measurement on the Spectrum Analyzer is used as a basis for the Substitution procedure.
The EUT is replaced with a Signal Generator and an antenna. The setting on the Signal Generator is varied until the Spectrum Analyzer displays the original reading. EIRP is calculated as-

EIRP (dBm) = Signal Generator setting (dBm) - Cable Loss (dB) + Antenna Gain (dBi)

Example:

Frequency (MHz)	Measured SA (dBμV)	Signal Generator setting (dBm)	Antenna Gain (dBi)	Dipole Gain (dBd)	Cable Loss (dB)	EIRP (dBm)
1000	95.5	24.5	6.5	0	3.5	27.5

6   Measurement Results

6.1   RF Power Output

6.1.1   References

FCC 2.1046: RF power output.

Power output shall be measured at the RF output terminals when the transmitter is adjusted in accordance with the tune-up procedure to give the values of current and voltage on circuit elements as specified. The electrical characteristics of the radio frequency load attached to the output terminals when this test is made shall be stated.

6.1.2   Limits:

FCC 22.913 (a) Effective radiated power limits.

The effective radiated power (ERP) of mobile transmitters must not exceed 7 Watts.

FCC 24.232 (b)(c) Power limits.

(b) Mobile/portable stations are limited to 2 Watts effective isotropic radiated power (EIRP).
(c) Peak transmit power must be measured over any interval of continuous transmission using instrumentation calibrated in terms of an rms equivalent voltage. The measurement results shall be properly adjusted for any limitations, such as detector response times, limited resolution bandwidth capability when compared to the emission bandwidth, sensitivity, etc., so as to obtain a true peak measurement over the full bandwidth of the channel.

6.1.3   Spectrum Analyzer Settings:

	E(I)RP
Resolution Bandwidth	5 MHz
Video Bandwidth	5 MHz
Detector	Peak
Trace Mode	Max Hold
Sweep Time	Auto

6.1.4   Testing Notes

Hardware version C used for E(I)RP measurements. Hardware version A used for conducted power measurements.

6.1.5 Test Results

Frequency (MHz)	Measured Peak Output Power from module's test report (dBm)	Conducted Peak Output Power (dBm)	Peak ERP / EIRP (dBm)
850 GMSK			
824.2	32.7	32.5	**30.5 / 32.6**
836.6	32.7	32.5	**30.3 / 32.4**
848.8	32.7	32.5	**31.1 / 33.2**
1900 GMSK			
1850.2	29.8	29.8	**28.6**
1880	29.9	29.7	**28.8**
1909.8	29.6	29.6	**28.3**

6.1.6 Measurement Verdict

Peak output power from module certification test report has been compared to the measured peak conducted power from the EUT.

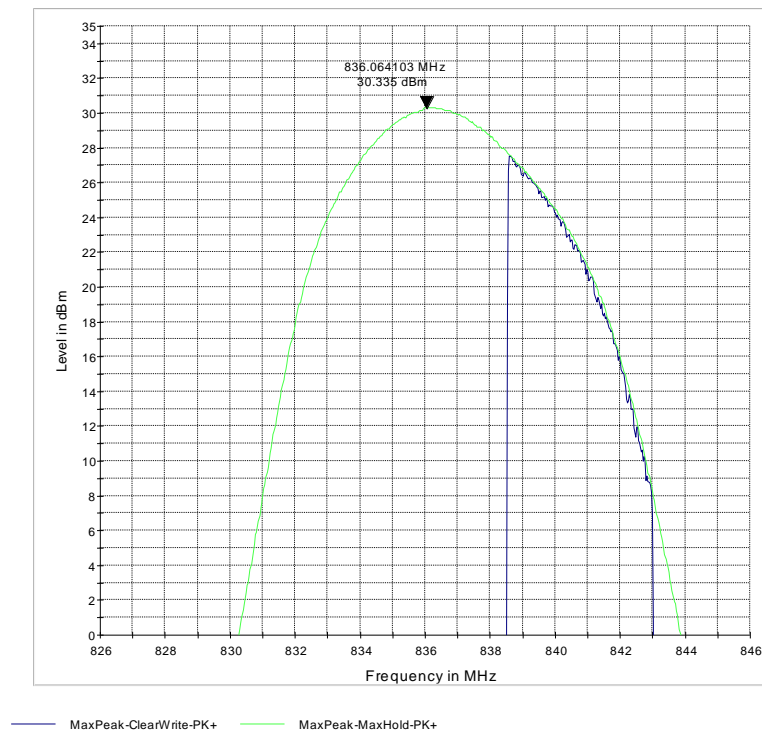All results within manufacturer tolerance and measurement uncertainty.
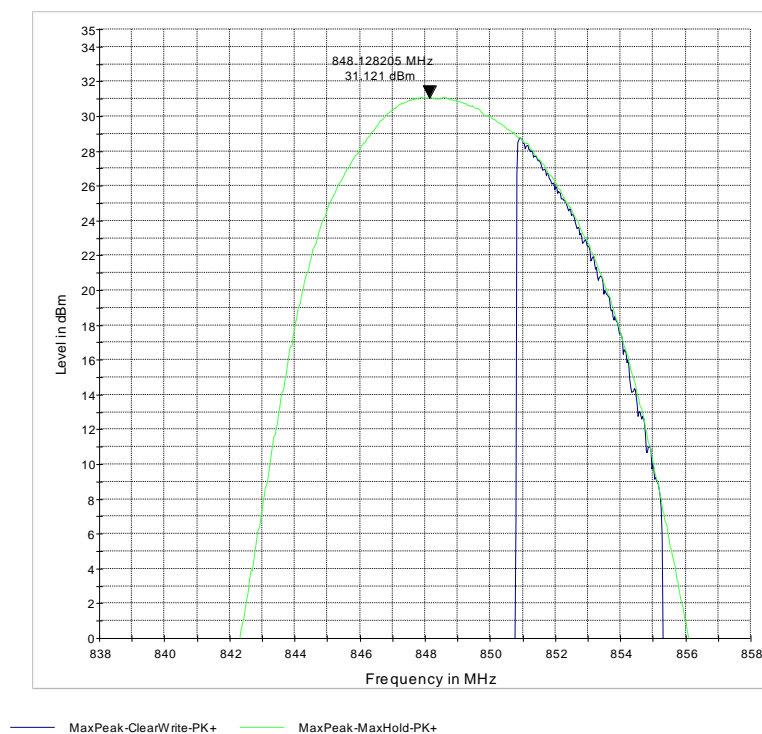
Pass

6.1.7   Test Plots

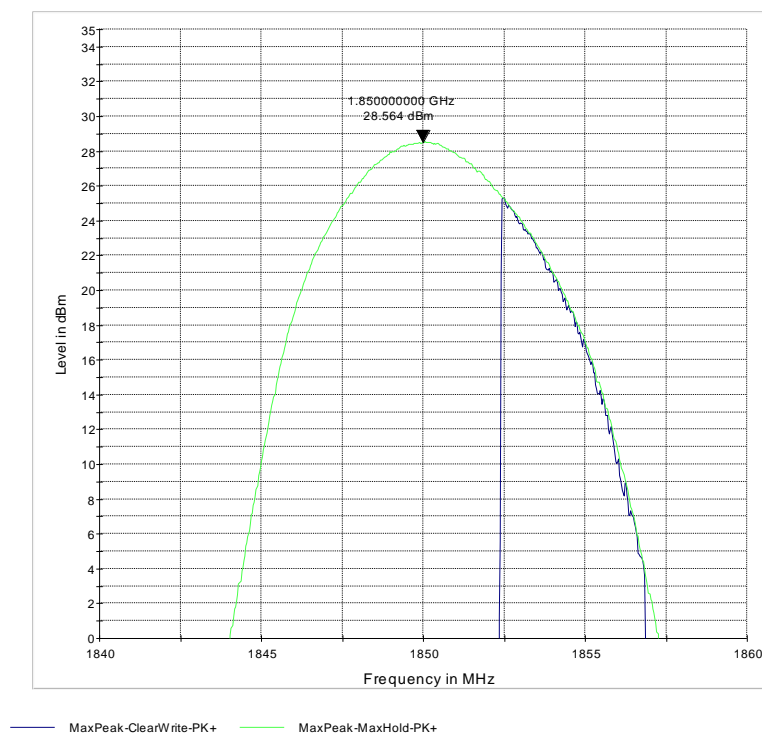**ERP (GSM 850) CHANNEL 128**

ERP (GSM 850) CHANNEL 190

ERP (GSM 850) CHANNEL 251

EIRP (PCS-1900) CHANNEL 512
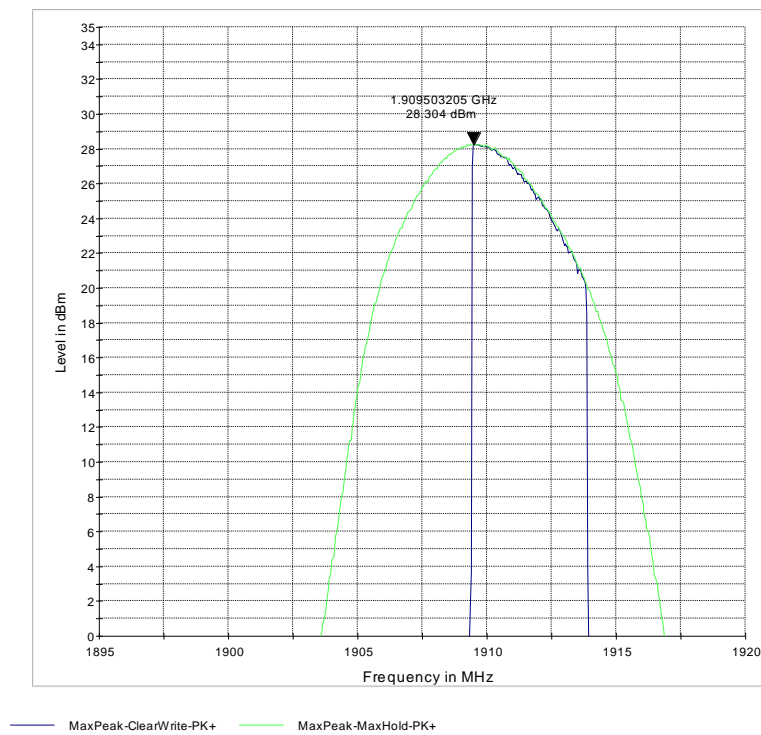
1.850000000 GHz
28.564 dBm

Level in dBm

Frequency in MHz

MaxPeak-ClearWrite-PK+   MaxPeak-MaxHold-PK+

EIRP (PCS-1900) CHANNEL 661

1.879647436 GHz
28.813 dBm

Level in dBm

Frequency in MHz

MaxPeak-ClearWrite-PK+   MaxPeak-MaxHold-PK+

EIRP (PCS-1900) CHANNEL 810

6.2   Emissions Radiated

6.2.1   References

FCC 2.1053: Field strength of spurious radiation.

Measurements shall be made to detect spurious emissions that may be radiated directly from the cabinet, control circuits, power leads or intermediate circuit elements under normal conditions of installation and operation. Curves or equivalent data shall be supplied showing the magnitude of each harmonic and other spurious emission.

6.2.2   Limits:

(a) *Out of band emissions*. The power of any emission outside of the authorized operating frequency ranges must be attenuated below the transmitting power (P) by a factor of at least $43 + 10 \log(P)$ dB.

6.2.2.1   Emission limitations

Measurement procedure. Compliance with these provisions is based on the use of measurement instrumentation employing a resolution bandwidth of 100 kHz or greater. In the 1 MHz bands immediately outside and adjacent to the frequency block a resolution bandwidth of at least one percent of the emission bandwidth of the fundamental emission of the transmitter may be employed. A narrower resolution bandwidth is permitted in all cases to improve measurement accuracy provided the measured power is integrated over the full required measurement bandwidth (*i.e.* 100 kHz of 1 percent of emission bandwidth, as specified). The emission bandwidth is defined as the width of the signal between two points, one below the carrier center frequency and one above the carrier center frequency, outside of which all emissions are attenuated at least 26 dB below the transmitter power.

6.2.3   Testing Notes

Radiated Emissions performed on hardware version A.

6.2.4   Radiated out of band emissions results on EUT- Transmit Mode:

6.2.4.1   Test Results Transmitter Spurious Emission GSM850:

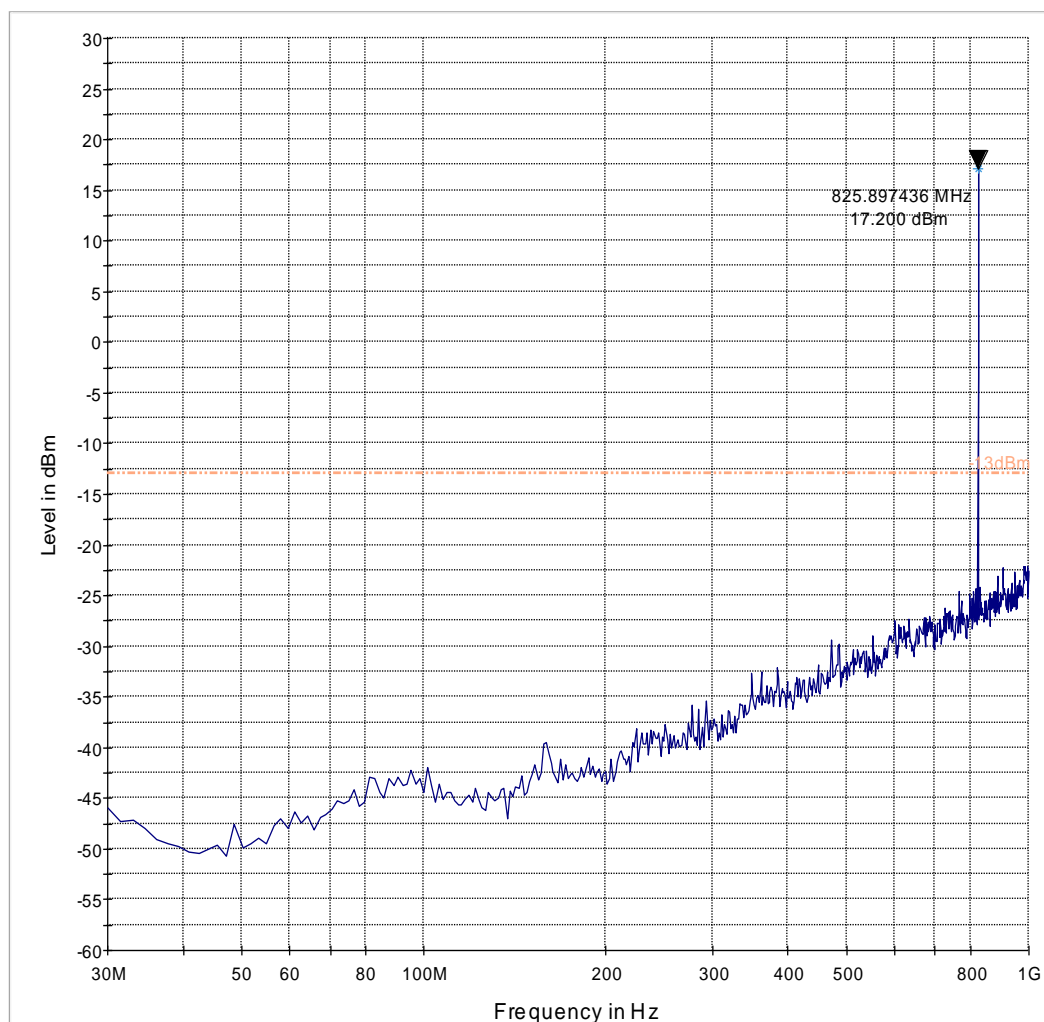| Harmonic	Tx ch-128 Freq. (MHz)	Level (dBm)	Tx ch-190 Freq. (MHz)	Level (dBm)	Tx ch-251 Freq. (MHz)	Level (dBm)
1	824.2	-	836.6	-	848.8	-
2	1648.4	-42	1673.2	-41	1697.6	-45
3	2472.6	-50	2509.8	-48	2546.4	-47.5
4	3296.8	-50	3346.4	-53	3395.2	NF
5	4121	-49	4183	-52	4244	NF
6	4945.2	NF	5019.6	NF	5092.8	NF
7	5769.4	NF	5856.2	NF	5941.6	NF
8	6593.6	NF	6692.8	NF	6790.4	NF
9	7417.8	NF	7529.4	NF	7639.2	NF
10	8242	NF	8366	NF	8488	NF
NF = Noise Floor						

6.2.4.2   Measurement Verdict
Pass

Legend for the plots:

———— -13dBm.LimitLine
———— Preview Result
＊ Data Reduction Result
◆ Final Measurement Result

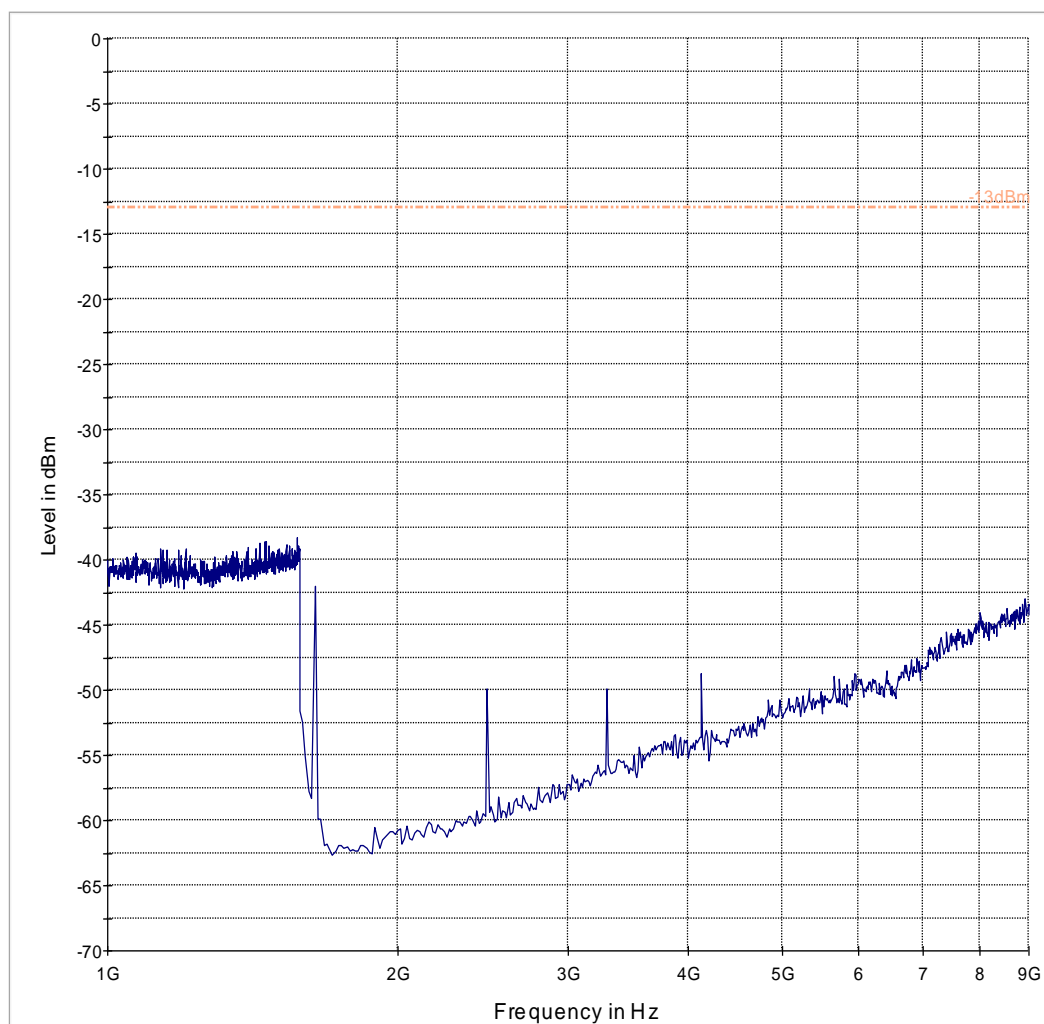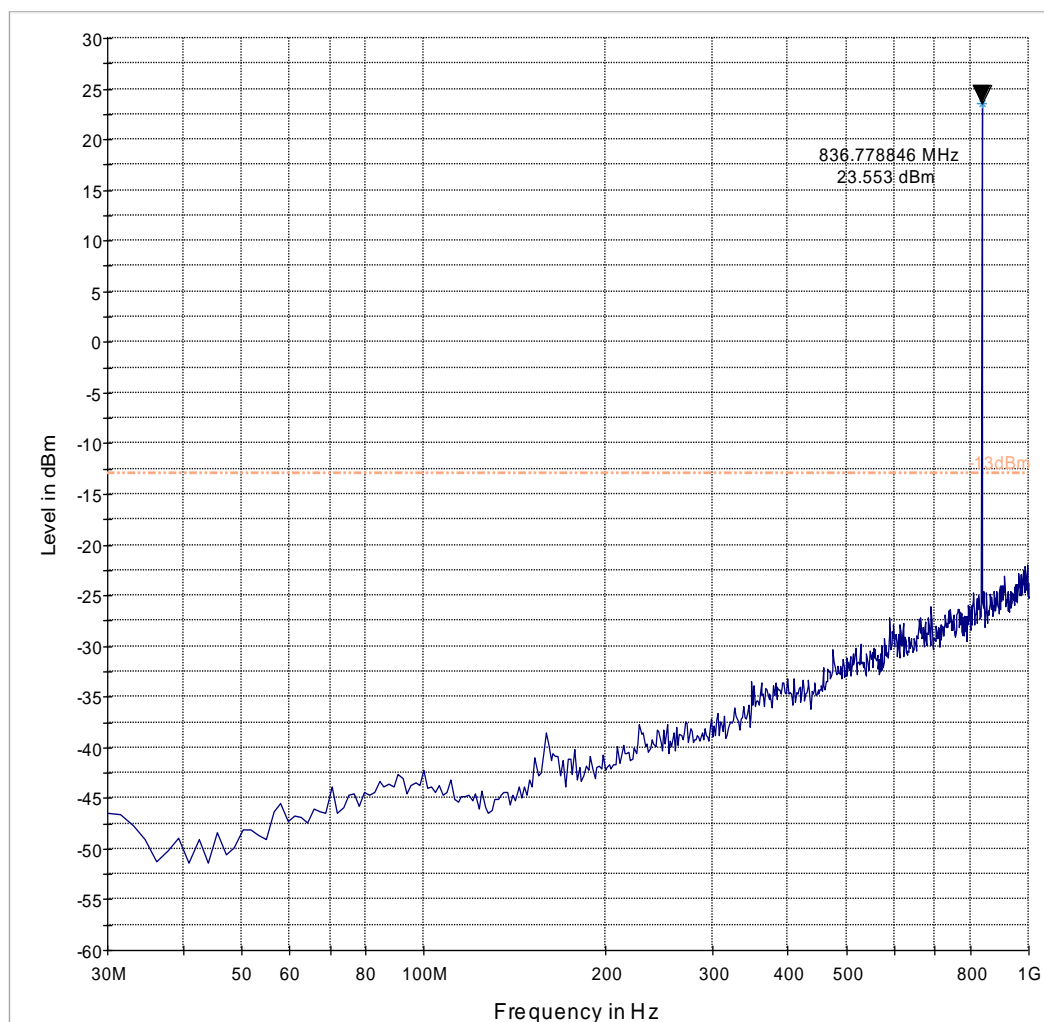## Radiated Spurious Emissions (GSM-850) Tx: Low Channel
Test results 30M-1GHz
Emission signal above the limit line in the plots is from the Carrier.

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Test results 1GHz-9GHz

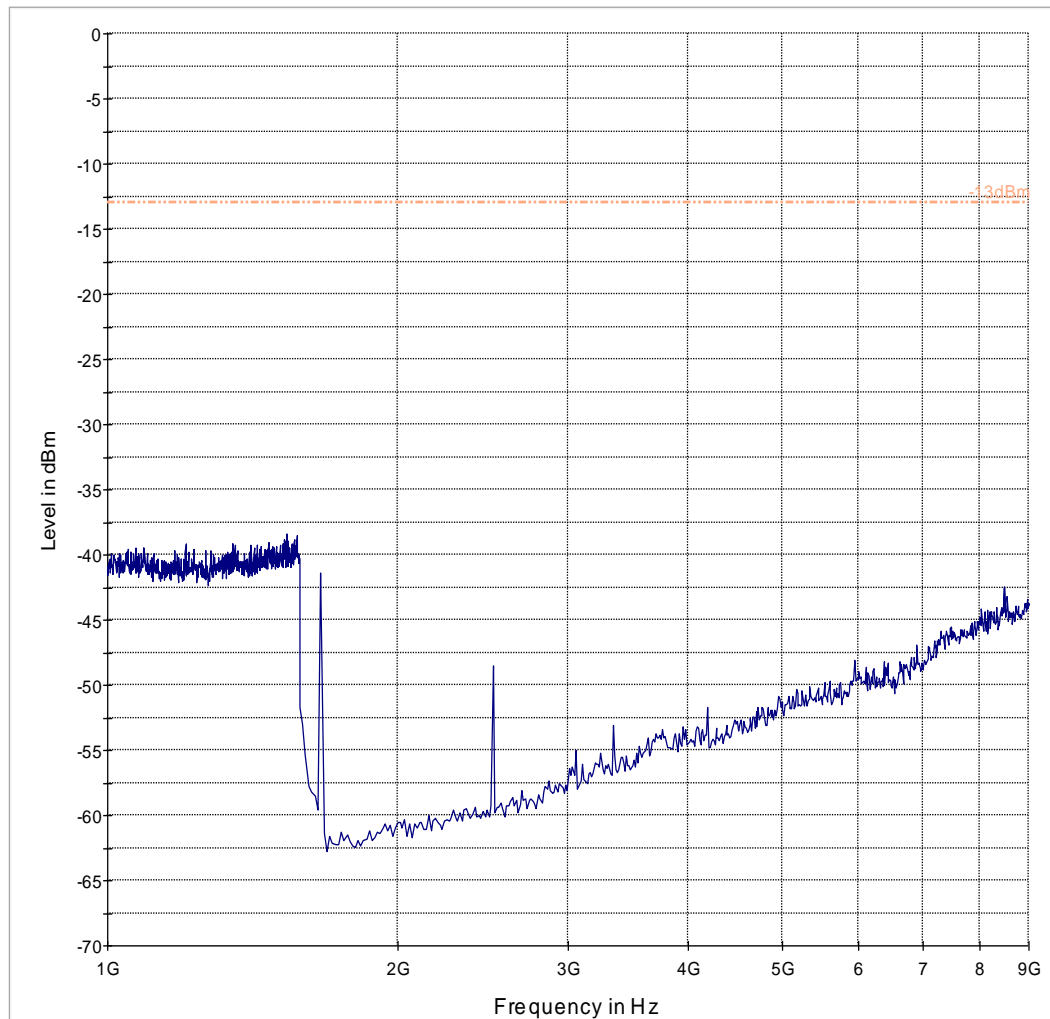## Radiated Spurious Emissions (GSM-850) Tx: Mid Channel
Test results 30M-1GHz
Emission signal above the limit line in the plots is from the Carrier.
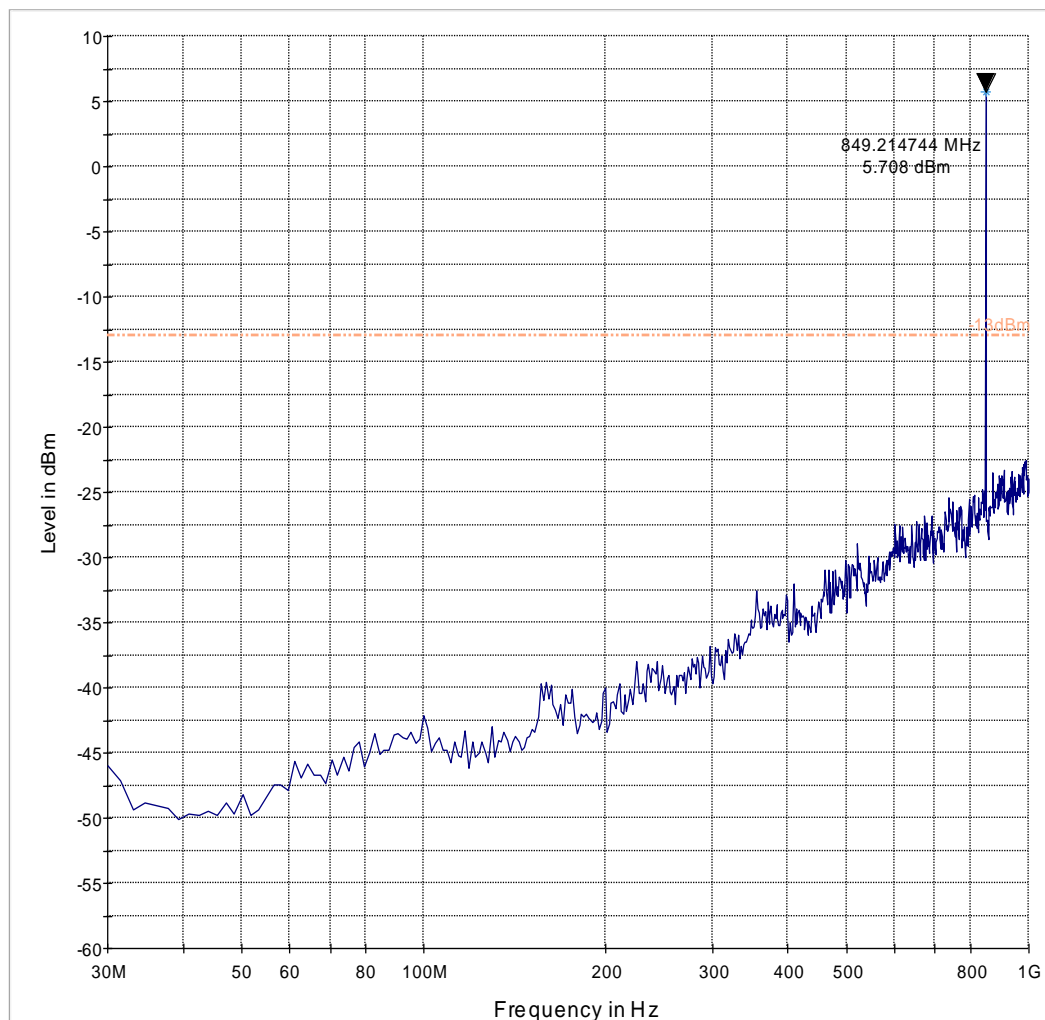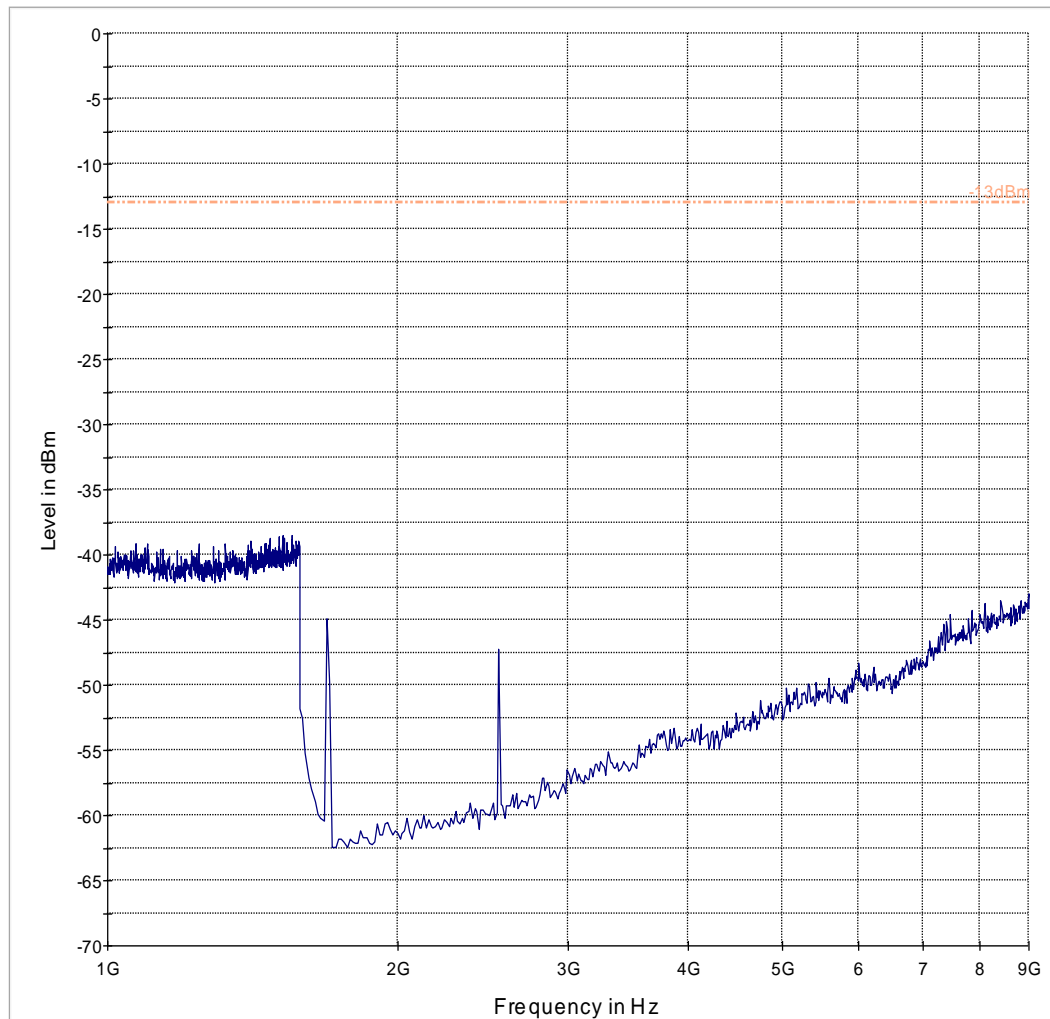
Test results 1GHz-9GHz

Radiated Spurious Emissions (GSM-850) Tx: High Channel
Test results 30M-1GHz

Emission signal above the limit line in the plots is from the Carrier.

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Test results 1GHz-9GHz

6.2.4.3 Test Results Transmitter Spurious Emission PCS-1900:

Harmonic	Tx ch-512 Freq.(MHz)	Level (dBm)	Tx ch-661 Freq. (MHz)	Level (dBm)	Tx ch-810 Freq. (MHz)	Level (dBm)
1	1850.2	-	1880.0	-	1909.8	-
2	3700.4	-48	3760	-50	3819.6	-47.5
3	5550.6	NF	5640	NF	5729.4	NF
4	7400.8	NF	7520	NF	7639.2	-42.5
5	9251	NF	9400	NF	9549	NF
6	11101.2	NF	11280	NF	11458.8	NF
7	12951.4	NF	13160	NF	13368.6	NF
8	14801.6	NF	15040	NF	15278.4	NF
9	16651.8	NF	16920	NF	17188.2	NF
10	18502	NF	18800	NF	19098	NF
NF = Noise Floor						

6.2.4.4 Measurement Verdict
Pass

Legend for the plots:

———	-13dBm.LimitLine
———	Preview Result
*	Data Reduction Result
◆	Final Measurement Result

Radiated Spurious Emissions (GSM-1900) Tx: Low Channel
Test results 1GHz-18GHz
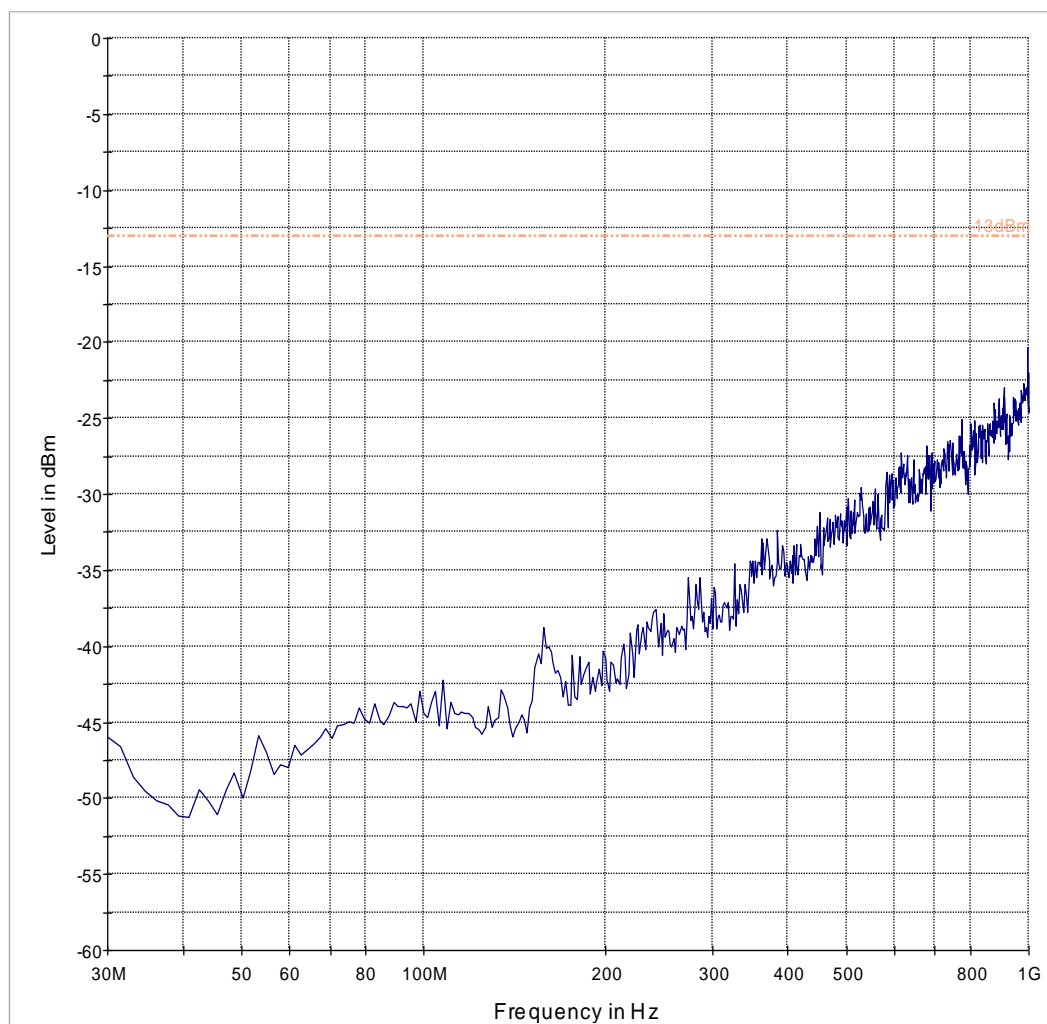Emission signal above the limit line in the plots is from the Carrier.

Radiated Spurious Emissions (GSM-1900) Tx: Mid Channel
Test results 30M-1GHz
Worst case representation for all channels in this band.

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Test results 1GHz-18GHz

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Radiated Spurious Emissions (GSM-1900) Tx: High Channel
Test results 1GHz-18GHz
Emission signal above the limit line in the plots is from the Carrier.

---   -13dBm   ——— Preview Result 1-PK+

Test results 18GHz-19.1GHz Tx: Mid Channel
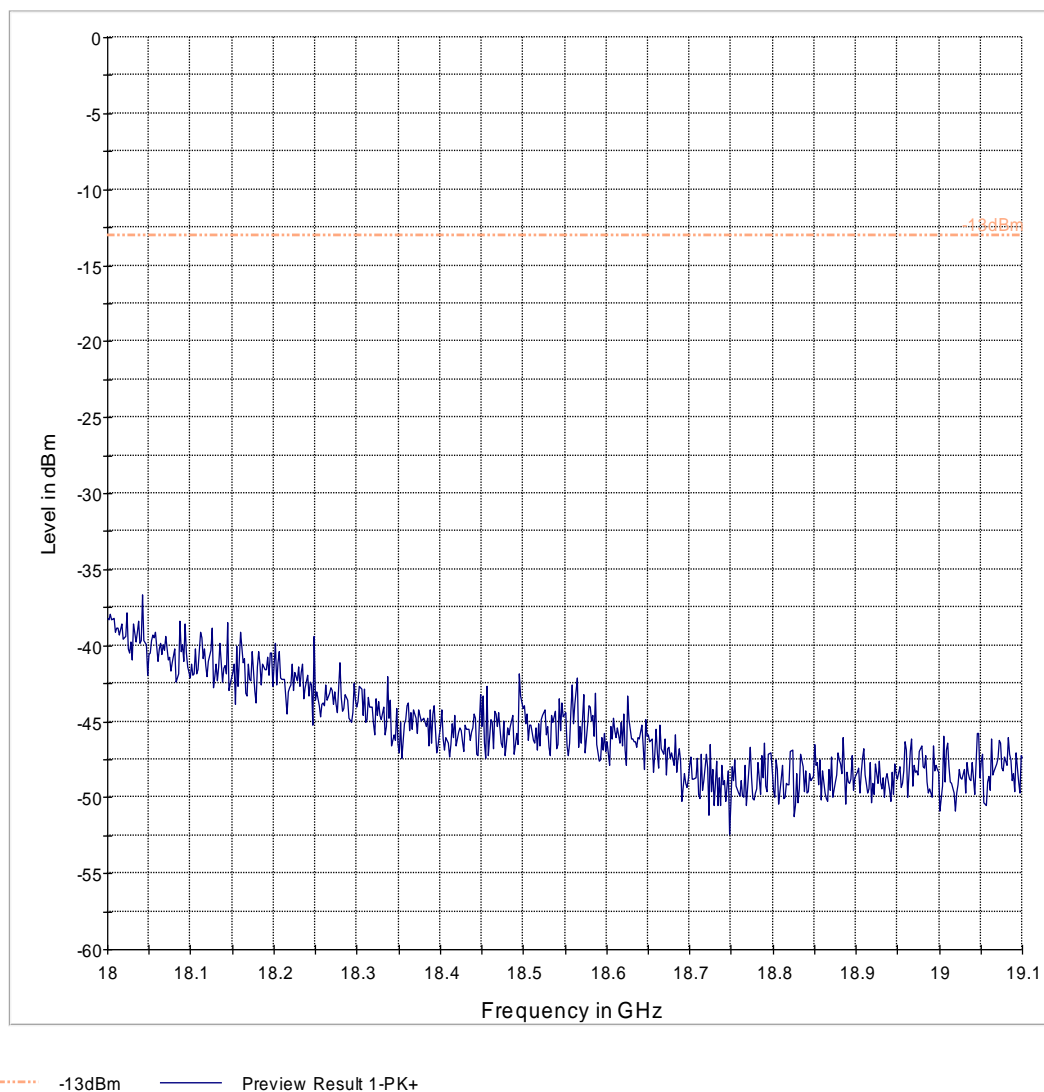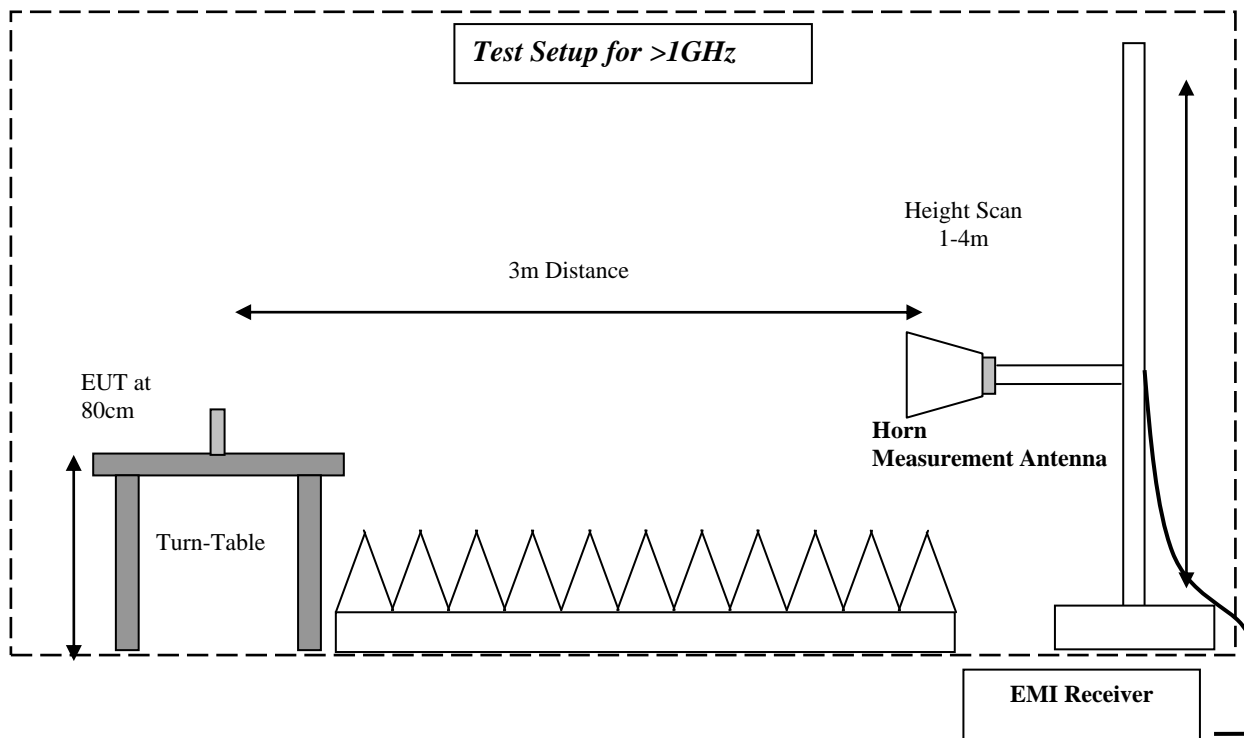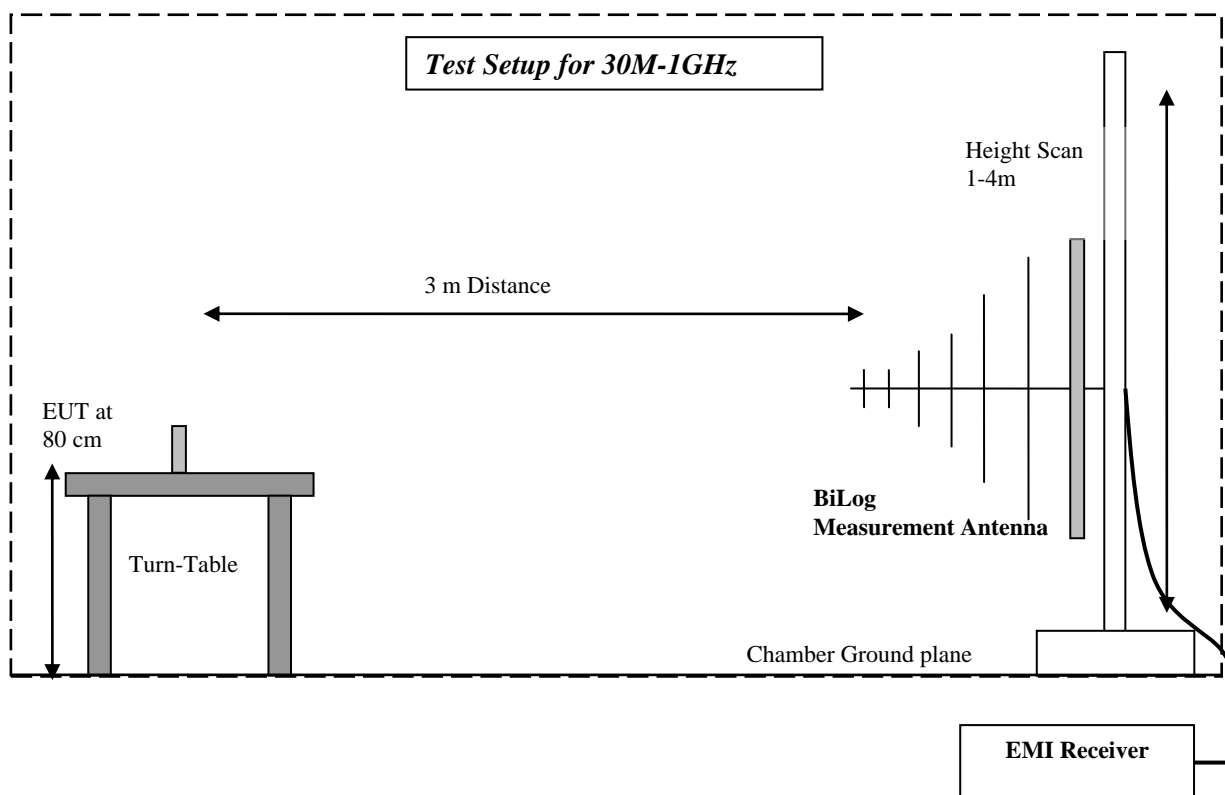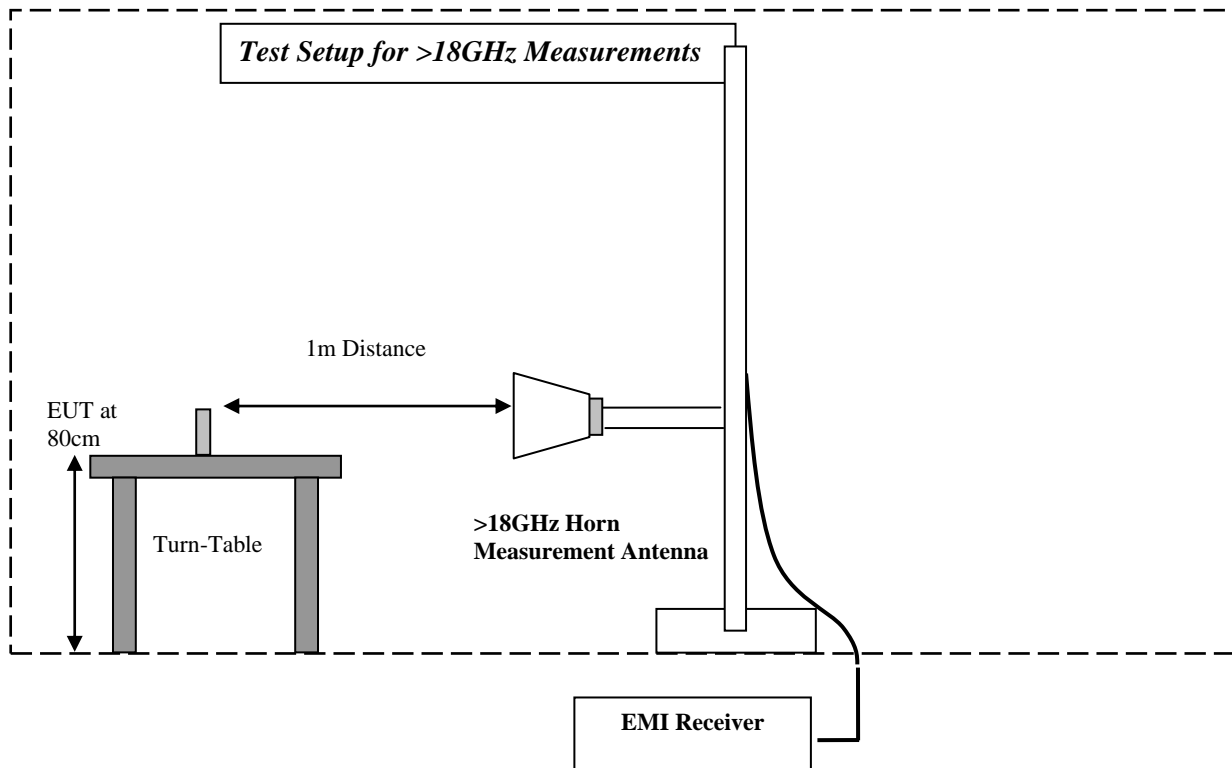
Worst case representation for all channels in this band.

7   Test Equipment and Ancillaries used for tests

Instrument/Ancillary	Model	Manufacturer	Serial No.	Cal Date	Cal Interval
Radio Communication Tester	CMU 200	Rohde & Schwarz	101821	May 2011	2 Years
Radio Communication Tester	CMU 200	Rohde & Schwarz	101821	May 2013	2 Years
EMI Receiver/Analyzer	ESIB 40	Rohde & Schwarz	100107	May 2011	2 Years
EMI Receiver/Analyzer	ESU 40	Rohde & Schwarz	100251	May 2012	1 Year
EMI Receiver/Analyzer	ESU 40	Rohde & Schwarz	100251	Sept 2013	2 Year
Spectrum Analyzer	FSU	Rohde & Schwarz	200302	May 2011	2 Years
Spectrum Analyzer	FSU	Rohde & Schwarz	200302	May 2013	2 Years
Biconilog Antenna	3141	EMCO	0005-1186	Apr 2012	3 years
Horn Antenna (1-18GHz)	3115	ETS	00035111	Apr 2012	3 years
Horn Antenna (18-40GHz)	3116	ETS	00070497	Sep 2011	3 years
Communication Antenna	IBP5-900/1940	Kathrein	n/a	n/a	n/a
High Pass Filter	5HC2700	Trilithic Inc.	9926013	Part of system calibration	
High Pass Filter	4HC1600	Trilithic Inc.	9922307	Part of system calibration	
6GHz High Pass Filter	HPM50106	Microtronics	001	Part of system calibration	
Pre-Amplifier	JS4-00102600	Miteq	00616	Part of system calibration	
Power Smart Sensor	R&S	NRP-Z81	100161	May 2011	2 Years
Power Smart Sensor	R&S	NRP-Z81	100161	May 2013	2 Years
Multimeter	MM200	Klein	N/A	Apr 2011	2 Years
Multimeter	MM200	Klein	N/A	Apr 2013	2 Years
Temp Hum Logger	TM320	Dickson	03280063	Mar 2012	2 Year
Temp Hum Logger	TM325	Dickson	5285354	Mar 2012	2 Year

8   Test Setup Diagrams:

Test Setup for 30M-1GHz

Height Scan
1-4m

3 m Distance

EUT at
80 cm

**BiLog
Measurement Antenna**

Turn-Table

Chamber Ground plane

EMI Receiver

Test Setup for >1GHz

Height Scan
1-4m

3m Distance

EUT at
80cm

**Horn
Measurement Antenna**

Turn-Table

EMI Receiver

Test Setup for >18GHz Measurements

1m Distance

EUT at
80cm

Turn-Table

**>18GHz Horn
Measurement Antenna**

EMI Receiver

9   Revision History

Date	Report Name – Changes to report	Report prepared by
June 2, 2014	EMC_RELIA_001_14001_WWAN 1. First Version	J. Sabado

January 12, 2015	EMC_RELIA_001_14001_WWAN_Rev1
	   1. Removed IC reference on cover page
	   2. Updated section 3.1, 5.6, 5.9, 6.2.2
	   3. Replaces previous test report number
		J. Sabado