SAR Test Report

FOR:

Manufacturer: ReliantHeart, Inc.
Model Number: CTL002
FCC ID: 2AB4ZCTL002

Test Report #: SAR_RELIA_004_15001_FCC-Rev1

Date of Report: Nov 3, 2015

A2LA Accredited
FCC Recognized

IC Recognized #
3462B-1

***CETECOM* Inc.**
411 Dixon Landing Road ◆ Milpitas, CA 95035 ◆ U.S.A.
Phone: + 1 (408) 586 6200 ◆ Fax: + 1 (408) 586 6299 ◆ E-mail: info@cetecomusa.com ◆ http://www.cetecom.com
CETECOM Inc. is a Delaware Corporation with Corporation number: 2905571

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1. Assessment

The following device was evaluated against the limits for general population uncontrolled exposure specified in FCC 2.1093 according to measurement procedures specified in FCC regulation as listed in chapter 5 and IEEE 1528:2013 and no deviations were ascertained during the course of the tests performed.

Manufacturer	Description	Model #
Reliant Heart Inc.	Controller for HeartAssist5 Left Ventricular Assist Device	CTL002

Responsible for Testing Laboratory:

Date	Section	Name	Signature
Nov 3, 2015	Compliance	Josie Sabado (Lab Manager)	

Responsible for the Report:

Date	Section	Name	Signature
Nov 3, 2015	Compliance	James Donnellan (Test Engineer)	James Donnellan — Digitally signed by James Donnellan DN: cn=James Donnellan, c=US, o=Cetecom Inc., ou=Compliance, email=james.donnellan@cetecom.com Date: 2015.11.04 11:13:51 -08'00'

The test results of this test report relate exclusively to the test item specified in Section 3.
CETECOM Inc. USA does not assume responsibility for any conclusions and generalizations drawn from the test results with regard to other specimens or samples of the type of the equipment represented by the test item. The test report may only be reproduced or published in full. Reproduction or publication of extracts from the report requires the prior written approval of CETECOM Inc. USA.

2. Administrative Data

2.1. Identification of the Testing Laboratory Issuing the SAR 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
Test Lab Manager	Josie Sabado
Responsible Project Manager	Cathy Palacios

2.2. Identification of the Client

Applicant's Name	Reliant Heart, Inc.
Street Address	8965 Interchange
City/Zip Code	Houston, TX 77054
Country	USA
Contact Person:	Branden Messarra
Phone No.	(713)-457-1474
Fax:	(713)-665-0963
e-mail:	BMessarra@reliantheart.com

2.3. Identification of the Manufacturer

Same as client

3. Equipment under Test (EUT)

3.1. General Specification of the Equipment under Test

Model No:	CTL002
FCC ID:	2AB4ZCTL002
Product Type:	Portable
Prototype/Production:	Pre-Production
RF Exposure Environment:	General / Uncontrolled
Dimensions:	Width: 85mm Height: 141mm Depth: 44mm
Exposure Conditions:	Body worn
Supported Radios:	GPRS/EGPRS, MS Class 10, Power Class 4/1, Mobile Class B WCDMA/HSDPA/HSUPA/HSPA+, Power Class 3, DL cat 14, UL cat 6 (5.7 Mbps uplink and QPSK)
Antenna Type:	Internal; Manufacturer stated max 2dBi
Battery Pack Operating Voltage Range:	9.0 - 14 Volts
Operating Temperature Range:	-10 °C to 40 °C
Power Back-Off Modes:	None
Date of Testing:	6-23-2015 to 6-24-2015, 10-2-2015

3.2. Technical Specification of Supported Radios

Signal Type	Duty Cycle	Type(s) of UL Modulation	Band	Uplink Transmit Frequency Range (MHz)	Measured Maximum Conducted Output Power (dBm)
GPRS	1 uplink timeslot: 12.5% 2 uplink timeslot: 25%	GMSK	850 MHz	824 – 849	32.4
			1900 MHz	1850 – 1910	29.0
WCDMA	100%	QPSK	FDD II	1850 - 1910	22.4
			FDD IV	1710 - 1755	22.6
			FDD V	824 – 849	23.2

NOTES:

3.3. Identification of the Equipment Under Test (EUT)

EUT #	Serial Number	HW Version	SW Version
1	00070	M10022 Rev H	2.4.433

3.4. Identification of Accessory equipment

AE #	Type	Manufacturer	Model / PN	Serial Number
1	Battery Pocket	Reliant Heart	M10036	029901
2	Battery Pocket	Reliant Heart	M10036	029935
3	LVAD Lithium Ion Battery	Reliant Heart	Li202SX-7800	-
4	LVAD Lithium Ion Battery	Reliant Heart	Li202SX-7800	-

3.5. Maximum SAR values

Equipment Class	Exposure Condition	Signal /Band	Measured 1g SAR (W/kg)	Maximum Rated 1g SAR[1] (W/kg)
PCT	Body Worn	GPRS 850	0.585	0.676

NOTES:
1. Measured 1g SAR scaled to manufacturer stated output power upper tolerance limit.

4. Subject of Investigation

The objective of the measurements done by CETECOM Inc. was the dosimetric assessment of the EUT described in section 3. The tests were performed in configurations for devices operated next to a person's body. The examinations were carried out with the dosimetric assessment system DASY52 described in Section 6.

4.1. The IEEE Standard C95.1 and the FCC Exposure Criteria

The limits are set by CFR 47 FCC rule parts 1.1307 and 2.1093, following the recommendations in IEEE C95.1-1999 (ANSI/IEEE C95.1-1999), "IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz."

4.2. SAR Limit

In this report the comparison between the exposure limits and the SAR data is made using the spatial peak SAR.

Having in mind a worst case consideration, the SAR limit is valid for uncontrolled environment and portable transmitters. The SAR values have to be averaged over a mass of 1g (SAR_{1g}) with the shape of a cube.

Standard	Exposure Condition	Average SAR (W/kg)	Mass Average (g)
FCC CFR 47 Part 2.1093 (d)(2)	Partial-Body	1.6	1

5. Measurement Procedure

The Federal Communications Commission (FCC) requires routine dosimetric assessment of mobile telecom-communications devices, either by laboratory measurement techniques or by computational modeling, prior to equipment authorization or use. The measurement procedure shall be performed according to IEEE 1528:2013. The following KDB publications have additionally been applied:

447498 D01 V05 – General RF Exposure Guidance
865664 D01V01 – SAR measurement 100 MHz to 6 GHz
941225 D01 V02 – SAR Measurement Procedures for 3G Devices
941225 D03 V01 – Recommended SAR Test Reduction Procedures for GSM/GPRS/EDGE

5.1. General Requirements

SAR evaluation was performed in a laboratory with an environment which avoids influence on SAR measurements by ambient EM sources and any reflection from the environment itself. The ambient temperature was in the range of 20°C to 26°C and 30-70% humidity. Simulating liquid temperature did not deviate more than +/- 2°C throughout SAR evaluation.

5.2. Body-worn and Other Configurations

Test Position
The body-worn configurations shall be tested with the supplied accessories (belt-clips, holsters, etc.) attached to the device in normal use configuration. Devices with a headset output shall be tested with a connected headset.

Test to be Performed
For purpose of determining test requirements, accessories may be divided into two categories: those that do not contain metallic components and those that do. For multiple accessories that do not contain metallic components, the device may be tested only with that accessory which provides the closest spacing to the body. For multiple accessories that contain metallic components, the device must be tested with each accessory that contains a unique metallic component. If multiple accessories share an identical metallic component, only the accessory that provides the closest spacing to the body must be tested. If the manufacturer provides none body-worn accessories a separation distance of 1.5 cm between the back of the device and the flat phantom is recommended. Other separation distances may be used, but they shall not exceed 2.5 cm. In these cases, the device may use body-worn accessories that provide a separation distance greater than that tested for the device provided however that the accessory contains no metallic components.

For devices with retractable antenna the SAR test shall be performed with the antenna fully extended and fully retracted. Other factors that may affect the exposure shall also be tested. For example, optional antennas or optional battery packs which may significantly change the volume, lengths, flip open/closed, etc. of the device, or any other accessories which might have the potential to considerably increase the peak spatial-average SAR value.

5.3. Procedure for assessing the peak spatial-average SAR

Step 1: Power reference measurement:

Prior to the SAR test, a local SAR measurement should be taken at a user-selected spatial reference point to monitor power variations during testing.

Step 2: Area scan

The measurement procedures for evaluating SAR associated with wireless handsets typically start with a coarse measurement grid in order to determine the approximate location of the local peak SAR values. This is referred to as the "area scan" procedure. The SAR distribution is scanned along the inside surface of typically half of the head of the phantom but at least larger than the areas projected (normal to the phantom's surface) by the handset and antenna. An example grid is given in Figure 4. The distance between the measured points and phantom surface should be less than 8 mm, and should remain constant (variation less than ± 1 mm) during the entire scan in order to determine the locations of the local peak SAR with sufficient precision. The distance between the measurement points should enable the detection of the location of local maximum with an accuracy of better than half the linear dimension of the tissue cube after interpolation. The approximate locations of the peak SARs should be determined from area scan. Since a given amplitude local peak with steep gradients may produce lower spatial-average SAR than slightly lower amplitude peaks with less steep gradients, it is necessary to evaluate the other peaks as well. However, since the spatial gradients of local SAR peaks are a function of wavelength inside the tissue simulating liquid and incident magnetic field strength, it is not necessary to evaluate peaks that are less than –2dB of the local maximum. Two-dimensional spline algorithms [Press, et al, 1996], [Brishoual, 2001] are typically used to determine the peaks and gradients within the scanned area. If the peak is closer than one-half of the linear dimension of the 1 g or 10 g tissue cube to the scan border, the measurement area should be enlarged if possible, e.g., by tilting the probe or the phantom (see Figure 5).

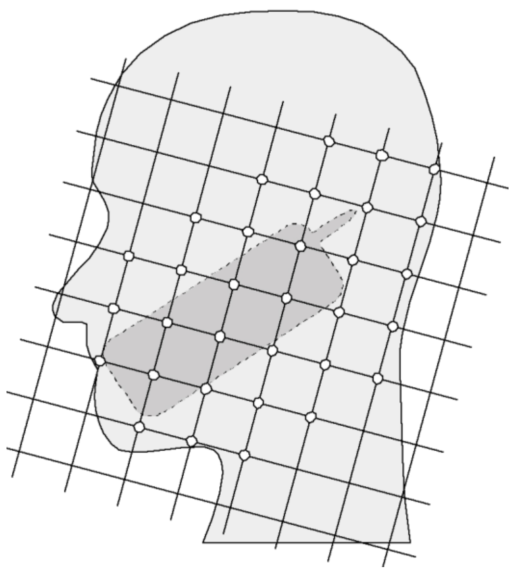


Figure 4 – Example of an area scan including the position of the handset. The scanned area (white dots) should be larger than the area projected by the handset and antenna.

The SPEAG DASY SAR system uses a mechanical sensor detection to find the phantom surface. To decrease test time, the DASY software allows the operator to choose an option where the SAR probe will reuse measurement locations from a previous identical area scan. With this option enabled, the DASY system will not use mechanical sensor detection to find the phantom surface. Locations of each measurement point of the area scan is taken at the same locations as an identical area scan if one is available. Area scans that reused location of measurement points is noted in the result plots under DASY Configuration > Sensor-Surface.

Step 3: Zoom scan

In order to assess the peak spatial SAR values averaged over a 1 g and 10 g cube, fine resolution volume scans, called "zoom scans", are performed at the peak SAR locations determined during the “area scan.” The zoom scan volume should have at least 1.5 times the linear dimension of either a 1 g or a 10 g tissue cube for whichever peak spatial-average SAR is being evaluated. The peak local SAR locations that were determined in the area scan (interpolated value) should be on the centerline of the zoom scans. The centerline is the line that is normal to the surface and in the center of the volume scan. If this is not possible, the zoom scan can be shifted but not by more than half the dimension of the 1 g or a 10 g tissue cube.

The maximum spatial-average SAR is determined by a numerical analysis of the SAR values obtained in the volume of the zoom scan, whereby interpolation (between measured points) and extrapolation (between surface and closest measured points) routines should be applied. A 3-D-spline algorithm [Press, et al, 1996], [Kreyszig, 1983], [Brishoual, 2001] can be used for interpolation and a trapezoidal algorithm for the integration (averaging). Scan resolutions of larger than 2 mm can be used provided the uncertainty is evaluated according to E (see E.5).

In some areas of the phantom, such as the jaw and upper head region, the angle of the probe with respect to the line normal to the surface might become large, e.g., at angles larger than ± 30º (see Figure 5), which may increase the boundary effect to an unacceptable level. In these cases, a change in the orientation of the probe and/or the phantom is recommended during the zoom scan so that the angle between the probe housing tube and the line normal to the surface is significantly reduced (<30º).

Step 4: Power reference measurement

The local SAR should be measured at exactly the same location as in Step 1. The absolute value of the measurement drift (the difference between the SAR measured in Step 4 and Step 1) should be recorded in the uncertainty budget. It is recommended that the drift be kept within ± 5%. If this is not possible, even with repeat testing, additional information may be used to demonstrate the power stability during the test. Power reference measurements can be taken after each zoom scan, if more than one zoom scan is needed. However, the drift should always be referred to the initial state with fully charged battery.

5.4. Determination of the largest peak spatial-average SAR

In order to determine the largest value of the peak spatial-average SAR of a handset, all device positions, configurations and operational modes should be tested for each frequency band according to steps 1 to 3 below.

Step 1: The tests of 6.4 should be conducted at the channel that is closest to the center of the transmit frequency band (*fc*) for:

a) all device positions (cheek and tilt, for both left and right sides of the SAM phantom,
b) all configurations for each device position in (a), e.g. antenna extended and retracted, and
c) all operational modes for each device position in (a) and configuration in (b) in each frequency band, e.g. analog and digital.

If more than three frequencies need to be tested, (i.e., Nc > 3), then all frequencies, configurations and modes must be tested for all of the above positions.

Step 2: For the condition providing highest spatial peak SAR determined in Step 1 conduct all tests of 6.4 at all other test frequencies, e.g. lowest and highest frequencies. In addition, for all other conditions (device position, configuration and operational mode) where the spatial peak SAR value determined in Step 1 is within 3dB of the applicable SAR limit, it is recommended that all other test frequencies should be tested as well.

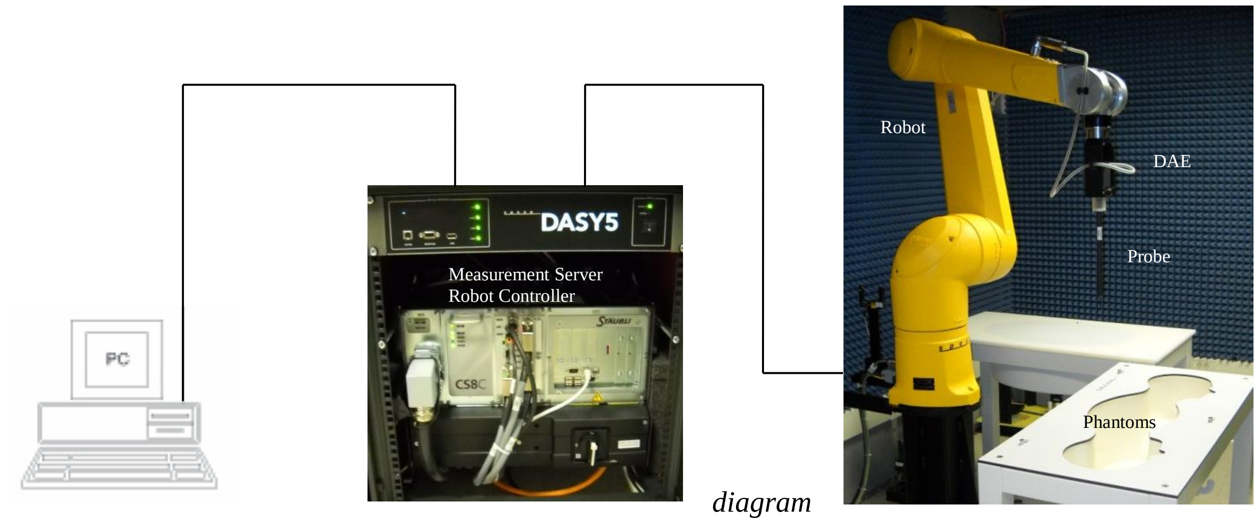
Step 3: Examine all data to determine the largest value of the peak spatial-average SAR found in Steps 1 to 2.

6. The Measurement System

6.1. Robot system specification

The SAR measurement system being used is the SPEAG DASY52 system, which consists of a Stäubli TX90XL 6-axis robot arm and CS8c controller, SPEAG SAR Probe, Data Acquisition Electronics, and SAM Twin Phantom. The robot is used to articulate the probe to programmed positions inside the phantom to obtain the SAR readings from the EUT.

The system is controlled remotely from a PC, which contains the software to control the robot and data acquisition equipment. The software also displays the data obtained from test scans.



Schematic diagram of the SAR measurement system

In operation, the system first does an area (2D) scan at a fixed depth within the liquid from the inside wall of the phantom. When the maximum SAR point has been found, the system will then carry out a 3D scan centered at that point to determine volume averaged SAR level.

6.2. Isotropic E-Field Probe for Dosimetric Measurements

The probes are constructed using three orthogonal dipole sensors arranged on an interlocking, triangular prism core. The probes have built-in shielding against static charges and are contained within a PEEK cylindrical enclosure material at the tip. Probe calibration is described in the probe's calibration certificate.

6.3. Data Acquisition Electronics

The DAE contains a signal amplifier, multiplexer, 16bit A/D converter and control logic. It uses an optical link for communication with the DASY5 system. The DAE has a dynamic range of -100 to 300 mV. It also contains a two step probe touch detector for mechanical surface detection and emergency robot stop.

6.4. Phantoms

The Twin SAM V4.0 Phantom is designed to specifications defined in IEEE 1528 and IEC/EN 62209-1. It enables the dosimetric evaluation of left and right hand phone usage as well as body mounted usage at the flat phantom region. The material shell thickness is 2mm +/- 0.2 mm at the flat section and 6mm +/- 0.2 mm at the ear reference point. The relative permativity is 3.5 +/- 0.5 and the loss tangent is ≤ 0.05 for frequencies ≤ 6 GHz.

Additionally, the Oval Flat ELI V4.0 Phantom is designed to specification defined in IEEE 1528 and IEC/EN 62209-2. It enables the dosimetric evaluation of body mounted usage. The material thickness is 2mm +/- 0.2 mm. For frequencies ≤ 6 GHz, the relative permativity is 4 +/- 1 and the loss tangent is ≤ 0.05. The bottom plate is 600 x 400 mm elliptical shape with a depth of 190 mm.

6.5. Interpolation and Extrapolation schemes

The interpolation, extrapolation and maximum search routines are all based on the modifed Quadratic Shepard's method. The interpolation scheme combines a least-square fitted function method and a weighted average method which are the two basic types of computational interpolation and approximation. The routines construct a once-continuously differentiable function that interpolates the measurement values.

7. Test Results Summary

7.1. Conducted Average Output Power

Measurement uncertainty for conducted measurements is ±0.5dB.
Tolerance Limits are from Telit Power Tune up procedure for HE910 Product Family.
Code 30378NT11098A Dated 24/05/2012

850 Band – (E)GPRS
Average power measured using a Rhode and Schwarz CMU 200.

	Number of Uplink Timeslots	Modulation	Channel / Frequency [MHz]						Burst Average Upper Power Tolerance Limit
			128 / 824.2		190 / 836.6		251 / 848.8		
			Measured Burst Average Power [dBm]	Calculated Time Average Power [dBm]	Measured Burst Average Power [dBm]	Calculated Time Average Power [dBm]	Measured Burst Average Power [dBm]	Calculated Time Average Power [dBm]	
GPRS	1	GMSK	32.4	23.4	32.4	23.4	32.3	23.3	33
	2		32.4	26.4	32.4	26.4	32.3	26.3	33
EGPRS	1	GMSK	32.2	23.2	32.2	23.2	32.4	23.4	33
	2		32.2	26.2	32.2	26.2	32.4	26.4	33
	1	8PSK	26.5	17.5	26.6	17.6	26.8	17.8	-
	2		26.5	20.5	26.6	20.6	26.8	20.8	-

PCS 1900 Band - (E)GPRS
Average power measured using a Rhode and Schwarz CMU 200.

	Number of Uplink Timeslots	Modulation	Channel / Frequency [MHz]						Burst Average Upper Power Tolerance Limit
			512 / 1850.2		661 / 1880		810 / 1909.8		
			Measured Burst Average Power [dBm]	Calculated Time Average Power [dBm]	Measured Burst Average Power [dBm]	Calculated Time Average Power [dBm]	Measured Burst Average Power [dBm]	Calculated Time Average Power [dBm]	
GPRS	1	GMSK	28.9	19.9	28.9	19.9	28.8	19.8	30
	2		28.9	22.9	29.0	23.0	28.8	22.8	30
EGPRS	1	GMSK	28.9	19.9	29.0	20.0	28.8	19.8	30
	2		28.9	22.9	28.9	22.9	28.8	22.8	30
	1	8PSK	25.1	16.1	25.2	16.2	25.1	16.1	-
	2		25.2	19.2	25.2	19.2	25.1	19.1	-

WCDMA
Average power measured using a Rhode and Schwarz CMU 200.

Band	Channel	Frequency [MHz]	Average Power [dBm]	Upper Power Tolerance Limit
			12.2kbps RMC	
FDD II	9262	1852.4	22.2	23.5
	9400	1880	22.4	23.5
	9538	1907.6	22.1	23.5
FDD IV	1312	1712.4	22.5	23.5
	1413	1732.6	22.6	23.5
	1513	1752.6	22.3	23.5
FDD V	4132	826.4	23.2	23.5
	4183	836.6	23.2	23.5
	4233	846.6	23.0	23.5

HSDPA
Settings are according to FCC KDB 941225 D01, "SAR Measurement Procedures for 3G Devices" section "Release 5 HSDPA Data Devices"
Average power measured using a Rhode and Schwarz CMU 200. Reference Rhode and Schwarz application note 1CM72: Operation Guide for HSDPA Test Setup according to 3GPP TS 34.121, section 2.2.

Band	Channel	Frequency [MHz]	Average Power [dBm]			
			Sub-test 1	Sub-test 2	Sub-test 3	Sub-test 4
WCDMA FDD II	9262	1852.4	22.1	22.1	21.7	21.5
	9400	1880	22.2	22.1	21.9	21.6
	9538	1907.6	21.8	21.8	21.6	21.3
WCDMA FDD IV	1312	1712.4	22.3	22.2	22.0	21.7
	1413	1732.6	22.3	22.3	22.1	21.8
	1513	1752.6	21.9	21.9	21.7	21.4
WCDMA FDD V	4132	826.4	23.0	23.0	22.7	22.5
	4183	836.6	23.0	23.0	22.7	22.4
	4233	846.6	22.7	22.7	22.5	22.2

HSUPA

Settings are according to FCC KDB 941225 D01, "SAR Measurement Procedures for 3G Devices" section "Release 6 HSPA Data Devices"
Average power measured using a Rhode and Schwarz CMU 200. Reference Rhode and Schwarz application note 1CM73: Operation Guide for HSUPA Test Setup according to 3GPP TS 34.121, section 2.1 and 2.2.

Band	Channel	Frequency [MHz]	Average Power [dBm]				
			Sub-test 1	Sub-test 2	Sub-test 3	Sub-test 4	Sub-test 5
WCDMA FDD II	9262	1852.4	21.2	19.1	19.4	19.1	20.8
	9400	1880	21.2	19.1	19.5	19.3	21.2
	9538	1907.6	20.9	18.8	19.2	19.0	20.9
WCDMA FDD IV	1312	1712.4	20.3	18.8	19.7	19.5	21.0
	1413	1732.6	21.4	19.4	19.7	19.5	21.5
	1513	1752.6	21.1	18.9	19.3	19.1	21.1
WCDMA FDD V	4132	826.4	22.1	19.9	20.3	20.2	21.7
	4183	836.6	22.0	19.9	20.3	20.1	22.0
	4233	846.6	21.8	19.7	20.0	19.9	21.8

7.2. Test Positions and Configurations

Exposure Condition	Distance	Position	Positioning Photo (Appendix B)
Body SAR (Elliptical Phantom)	Touch	Back	Photo 1
Body SAR (SAM Phantom)	Touch	Back	Photo 2

For 850/1900 bands, the uplink timeslot configuration with the highest source-based time-averaged output power is used for full SAR evaluation for body exposure positions.
Spot check measurements for other uplink timeslot configurations are performed on the position with the highest measured SAR value to when the SAR value is more than 3 dB below the limit.
EGRPS mode is not tested because the output power is lower than GPRS.

7.3. SAR Results for Body

Band	Operation Mode	Channel	Frequency (MHz)	Position	Measured SAR 1g (W/kg)	Reported Scaled SAR 1g (W/kg)	Results (Appendix A)
1900	**2 Uplink Timeslot**	**661**	**1880**	Back	0.288	0.359	Plot 1
FDD II	**12.2kbps RMC**	**9400**	**1880**	Back	0.325	0.415	Plot 2
FDD IV	**12.2kbps RMC**	**1413**	**1732.6**	Back	0.312	0.383	Plot 3
850	**2 Uplink Timeslot**	**190**	**836.6**	Back	0.585	0.676	Plot 4
FDD V	**12.2kbps RMC**	**4183**	**836.6**	Back	0.25	0.270	Plot 5

NOTES:
1. Measured SAR values are scaled up to the manufacturer's stated output power.
2. Configurations with multiple SAR values have at least one peak SAR within 2 dB of the primary peak.

7.4. Dipole verification

Prior to formal testing at each frequency a system verification was performed in accordance with IEEE 1528. The 1 Watt reference SAR value is taken from the SPEAG dipole calibration report as required by FCC KDB 450824 D01. All of the testing described in this report was performed within 24 hours of the system verification. The following results were obtained:

Date	Liquid Type	Frequency (MHz)	CW input at dipole feed (Watts)	1g SAR (W/kg)[1]	1 Watt reference SAR value (W/kg)	Difference reference SAR value to normalized SAR	Results (Appendix A)
6/23/2015	MSL	835	1	9.69	9.3	4.2%	Plot 6
6/24/2015	MSL	1750	1	34.4	37.7	-8.8%	Plot 7
6/23/2015	MSL	1900	1	36.7	40.2	-8.7%	Plot 8
11/2/2015	MSL	835	1	9.01	9.3	-3.1%	Plot 9

8. References

1. [IEEE 1999] IEEE Std C95.1-1999: IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz, Inst. of Electrical and Electronics Engineers, Inc., December 1998.

2. [IEEE 2013] IEEE Std 1528-2013: IEEE Recommended Practice for Determining the Peak Spatial-Average Specific Absorption Rate (SAR) in the Human Head From Wireless Communications Devices: Measurement Techniques. Inst. of Electrical and Electronics Engineers, Inc., June 2013.

3. [NIST 1994] NIST: Guidelines for Evaluating and Expressing the Uncertainty of NIST Measurement Results, Technical Note 1297 (TN1297), United States Department of Commerce Technology Administration, National Institute of Standards and Technology, September 1994.

4. [FCC 20XX] Various FCC KDB Publications,
< http://transition.fcc.gov/oet/ea/eameasurements.html#sar>

9. Report History

Date	Report Name	– Changes to Report	Report prepared by
Jul 21, 2015	SAR_RELIA_004_15001_FCC	Inital Release	J. Donnellan
Nov 3, 2015	SAR_RELIA_004_15001_FCC-Rev1	TCB Review updates. Updated Results. Replaces previous test report number.	J. Donnellan