



SAR Test Report

FOR:

Manufacturer: ReliantHeart, Inc.
Model Number: CTL001
FCC ID: 2AB4ZCTL001

Test Report #: SAR_RELIA_001_14001_FCC_Rev1

Date of Report: January 12, 2015



FCC Listed #:
A2LA Accredited

IC Recognized #
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Appendix A – Plots

Appendix B – Antenna location , Test Setup Photos

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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 1528:2003 and 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:

Jan 12, 2015 Compliance Franz Engert
(Manager of Compliance)

Date	Section	Name	Signature
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Responsible for the Report:

Jan 12, 2015 Compliance Josie Sabado
(Lab Manager)

Date	Section	Name	Signature
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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
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Test Lab Manager:	Josie Sabado
Responsible Project Leader:	Cathy Palacios

2.2. Identification of the Client

Applicant's Name:	ReliantHeart, Inc.
Street Address:	8965 Interchange
City/Zip Code	Houston, TX 77054
Country	USA
Contact Person:	Bryan E. Lynch or William Graham
Phone No.	(713)-412-3418 or (713)-457-1479 or (713)-457-1480
Fax:	(713)-665-0963
e-mail:	blynch@reliantheart.com or wgraham@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

Product Type:	Portable
Prototype/Production:	Pre-Production
RF Exposure Environment:	General / Uncontrolled
Dimensions:	Width: 85mm Height: 153mm Depth: 50mm
Exposure Conditions:	Body worn
Marketing Name:	HeartAssist5 LVAD Controller
Model No:	CTL001
FCC ID:	2AB4ZCTL001
Antenna Type:	Internal; Manufacturer stated max 2 dBi
Battery Pack Operating Voltage Range:	9.0 - 14 Volts
Operating Temperature Range:	-10 °C to 40 °C
Supported Radios:	GPRS, MS Class 12, Power Class 4/1, Mobile Class B
Power Back-Off Modes:	None
Date of Testing:	2-28-2014

3.2. Technical Specification of Supported Radios

Signal Type	Duty Cycle	Type(s) of Modulation	Band	Transmit Frequency Range (MHz)	Measured Maximum Conducted Output Power (dBm)
GPRS	1 uplink timeslot: 12.5%	GMSK	GSM 850	824.2 – 848.8	33.4
	2 uplink timeslots: 25%		PCS 1900	1850.2 – 1909.8	30.2
	3 uplink timeslots: 37.5%				
	4 uplink timeslots: 50%				

NOTES:

1. Bands are supported by the EUT, but outside of the scope of this test report.

3.3. Identification of the Equipment Under Test (EUT)

EUT #	IMEI	HW Version	SW Version
1	35323402659513003	C	1.0.13

3.4. 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

3.5. Maximum SAR values

Signal Type	Band	Exposure Condition	Measured 1g SAR	Maximum Scaled 1g SAR ¹
GPRS	850	Body Worn	0.170	0.240
GPRS	1900	Body Worn	0.335	0.473

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 1528:2003. The following KDB publications have additionally been applied:

447498 D01 V05R02 – Mobile and Portable Devices RF Exposure Procedures and Equipment Authorization Policies

865664 D01V01R03 – SAR Measurement Requirements for 100 MHz to 6 GHz

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

Phantom Requirements

For body-worn and other configurations a flat phantom shall be used which is comprised of material with electrical properties similar to the corresponding tissues.

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 resolution can also be tested using the functions in [IEEE 1528:2003] Annex E (see E.5.2). 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 -2 dB 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).

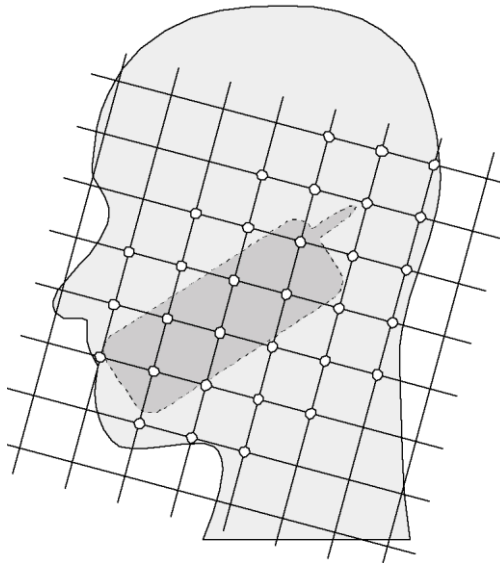


Figure 4 – Example of an area scan including the position of the handset. The scanned area (white dots) should be larger than the area projected by the handset and antenna.

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 $\pm 30^\circ$ (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 ($<30^\circ$).

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 $\pm 5\%$. 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 (f_c) 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., $N_c > 3$), 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 well¹.

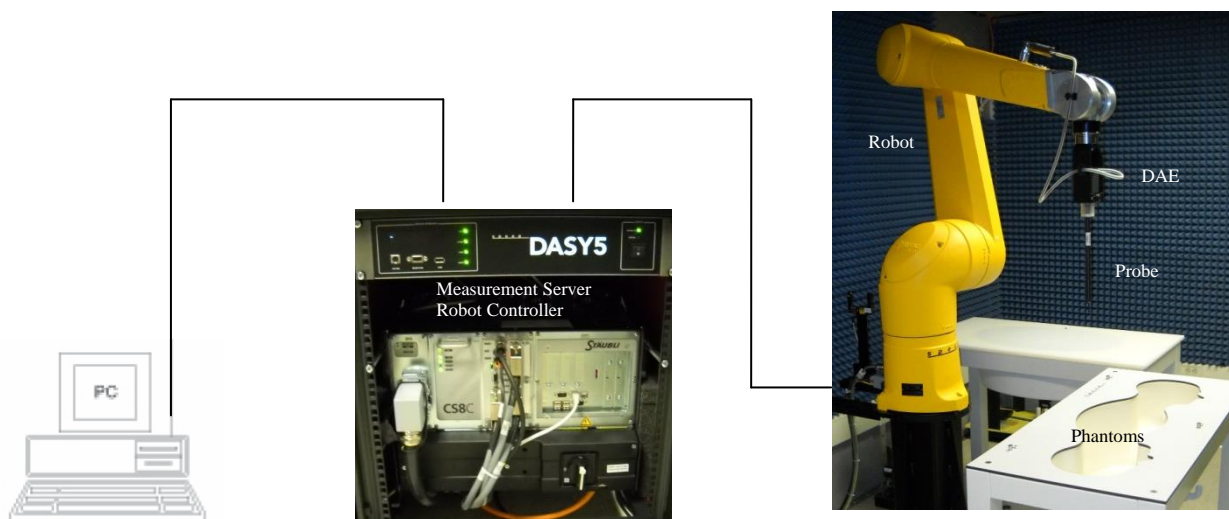
Step 3: Examine all data to determine the largest value of the peak spatial-average SAR found in Steps 1 to 2.

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.

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.

6.5. Interpolation and Extrapolation schemes

The interpolation, extrapolation and maximum search routines are all based on the modified 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. Uncertainty Assessment

The uncertainty values for components specified were evaluated according to the procedures of *IEEE 1528-2003*, *NIST 1297 1994 edition* and *ISO Guide to the Expression of Uncertainty in Measurements (GUM)*.

7.1. Measurement Uncertainty Budget According to IEEE 1528:2003

<i>a</i>	<i>b</i>	<i>c</i>	<i>d</i>	<i>e = f(d,k)</i>	<i>f</i>	<i>g = c x f / e</i>	<i>k</i>
Uncertainty Component	Sec.	Tol. (± %)	Prob. Dist.	Div.	<i>c_i</i> (1-g)	1-g <i>u_i</i> (±%)	<i>v_i</i>
Measurement System							
Probe Calibration	E2.1	5.5	N	1	1	5.5	∞
Axial Isotropy	E2.2	4.7	R	√3	0.7	1.9	∞
Hemispherical Isotropy	E2.2	9.6	R	√3	0.7	3.9	∞
Boundary Effect	E2.3	1.0	R	√3	1	0.6	∞
Linearity	E2.4	4.7	R	√3	1	2.7	∞
System Detection Limits	E2.5	1.0	R	√3	1	0.6	∞
Readout Electronics	E2.6	0.3	N	1	1	0.3	∞
Response Time	E2.7	0.8	R	√3	1	0.5	∞
Integration Time	E2.8	2.6	R	√3	1	1.5	∞
RF Ambient Noise	E6.1	3.0	R	√3	1	1.7	∞
RF Ambient Reflections	E6.1	3.0	R	√3	1	1.7	∞
Probe Positioner Mechanical Tolerance	E6.2	0.4	R	√3	1	0.2	∞
Probe Positioning with respect to Phantom Shell	E6.3	2.9	R	√3	1	1.7	∞
Extrapolation, interpolation and Integration Algorithms for Max. SAR Evaluation	E5.2	1.0	R	√3	1	0.6	∞
Test sample Related							
Test Sample Positioning	E4.2	2.9	N	1	1	2.9	145
Device Holder Uncertainty	E4.1	3.6	N	1	1	3.6	5
Output Power Variation - SAR drift measurement	6.6.2	5.0	R	√3	1	2.9	∞
Phantom and Tissue Parameters							
Phantom Uncertainty (shape and thickness tolerances)	E3.1	4.0	R	√3	1	2.3	∞
Liquid Conductivity Target - tolerance	E3.2	5.0	R	√3	0.7	1.8	∞
Liquid Conductivity - measurement uncertainty	E3.3	2.5	N	1	0.7	1.6	∞
Liquid Permittivity Target tolerance	E3.2	5.0	R	√3	0.6	1.7	∞
Liquid Permittivity - measurement uncertainty	E3.3	2.5	N	1	0.6	1.5	∞
Combined Standard Uncertainty			RSS			± 10.7%	
Expanded Uncertainty (95% CONFIDENCE INTERVAL)			<i>k</i> = 2.00705			± 21.4%	

8. Test results summary

8.1. Conducted Average Output Power

Measurement uncertainty for conducted measurements is $\pm 0.5\text{dB}$

GSM 850 Band – 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	33.18	24.18	33.3	24.3	33.4	24.4	35
	2		31.4	25.4	31.5	25.5	31.6	25.6	33
	3		29.6	25.35	29.7	25.45	29.8	25.55	31
	4		27.8	24.8	27.9	24.9	28	25	29

PCS 1900 Band - 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	30.2	21.2	30.1	21.1	29.9	20.9	32
	2		28.5	22.5	28.5	22.5	28.2	22.2	30
	3		26.9	22.65	26.8	22.55	26.4	22.15	28
	4		25.2	22.2	25.1	22.1	24.8	21.8	26

8.2. Test Positions and Configurations

Exposure Condition	Distance	Position	Positioning Photo (Appendix B)
Body SAR	0 mm	Back	Photo 1

If the SAR value on the middle channel was more than 3dB below the limit, high and low channels were not evaluated.

For GSM 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 when the SAR value is more than 3 dB below the limit.

8.3. SAR Results for Body

Band	Operation Mode	Channel	Frequency (MHz)	Position	SAR 1g (W/kg)	Scaled SAR 1g (W/kg) ¹	Results (Appendix A)
GPRS 850	4 Uplink Timeslots	190	836.6	Back	0.335	0.473	Plot 1
GPRS 1900	4 Uplink Timeslots	661	1880	Back	0.17	0.240	Plot 2

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.

8.5. 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)
2/28/2014	MSL	835	1	9.28	9.55	-2.8%	Plot 3
2/28/2014	MSL	1900	1	37	40.3	-8.1%	Plot 4

9. 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 2003] IEEE Std 1528-2003: 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., December 2003.
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> >

10. Report History

Date	Report Number – Changes to Report	Report prepared by
June 2, 2014	SAR_RELIA_001_14001_FCC 1. First Version	J. Sabado
January 12, 2015	SAR_RELIA_001_14001_FCC_Rev1 1. Sections 3.1, 3.2, 3.4, 8.1 Updated 2. Replaces previous test report number	J. Donnellan