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1. Purpose

The purpose of this report is to document the results of design verification.

<table>
<tr><td>Design being verified:</td><td>ENG-300200-000B – Final Assembly, Medium, RE, A2E16
ENG-300200-100A – Final Assembly, Large, Right Eye, A2E16
ENG-300200-200C – Final Assembly, Medium, LE, A2E16
ENG-300200-300A – Final Assembly, Large, Left Eye, A2E16
ENG-300200-450F – Final Assembly, OR Coil, A2E16</td></tr>
<tr><td>Requirements and Specification(s) being verified :</td><td>DES-A2E16-0002 Rev. H:
DIS 3.4.10.1
The forward telemetry at 3.156 MHz and backward telemetry at 473 and 490 kHz shall comply with the General Public Exposure limits listed in Table 3 as determined by REC 1999/519/EC. [EN 50364:2010 Clause 4.1]
<table>
<tr><td>Quantity</td><td>Forward Telemetry Limit (3.156 MHz)</td><td>Backward Telemetry Limit (473,490 kHz)</td></tr>
<tr><td>Current Density</td><td>6312 mA/m^2</td><td>946, 980 mA/m^2</td></tr>
<tr><td>Whole Body Average SAR</td><td colspan="2">0.08 W/kg</td></tr>
<tr><td>Localized SAR (head and trunk)</td><td colspan="2">2 W/kg</td></tr>
<tr><td>Localized SAR (limbs)</td><td colspan="2">4 W/kg</td></tr>
<tr><td>Contact and Limb Current</td><td colspan="2">20 mA</td></tr>
</table>
DIR 3.4.14
The Eyewear shall comply with applicable clauses of RSS-Gen, General Requirements for Compliance of Radio Apparatus
DES-A2E16-0007 Rev. D:
DIS 3.4.10.1
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</table>
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</table>

	Contact and Limb Current | 20 mA ***DIR 3.4.12*** **The OR Coil shall comply with applicable clauses of RSS-Gen, General Requirements for Compliance of Radio Apparatus**		
Method of Verification (Select all that apply):	☐ **Testing**	**Protocol ID:**	**Rev:**
	☒ **Simulation**		
	☒ **Analysis**		
	☐ **Inspection**		
	☐ **Compilation of relevant scientific literature**		
	☐ **Comparison of a design to a previous product having an established history of successful use**		
	☐ **Other - Explain:**		
Date(s) the verification was performed / completed:	**July 2018**		
Performed at:	☐ **Second Sight** ☐ **Testing lab** ☒ **Academic Researcher**		
Name(s) of individual(s) / testing lab performing the verification – List below:			
Gianluca Lazzi, PhD / Keck School of Medicine, University of Southern California			

2. Summary

Using voxelized 3D part models of the components constituting the A2E16 Eyewear, a simulation for the specific absorption rate (SAR) using a cubical voxel resolution of 0.25mm^3 was conducted to ensure that the device meets all applicable rules and regulations. Based on the simulation and analysis results, the A2E16 Eyewear (ENG-300200-000B, ENG-300200-100A, ENG-300200-200C, and ENG-300200-300A), in addition to the A2E16 OR Coil Assembly (ENG-300200-450F), meet the design input requirements and specifications listed above within *Section 1. Purpose*.

Due to the test methods and acceptance criteria for the design input specifications verified within this report being controlled by a published standard, there is no associated SSMP released protocol corresponding to this verification report.

3. Associated Documents

DES-A2E16-0002 Rev. H – Design Input and Traceability, Eyewear, A2E16

DES-A2E16-0007 Rev. D – Design Input and Traceability, OR Coil, A2E16

DES-A2E16-0032 Rev. C – Fault Tree Analysis / Risk Management, Argus2s System

SOP 4.2.4.3 Rev. D – Good Record Keeping Practices

SOP 7.3.5 Rev. G – Design Verification

SOP 8.1.2 Rev. G – Statistical Technique

4. Results

4.1. Test and control articles: For the purposes of this simulation, a unique 3D CAD assembly, for which the constitutive component CAD files can be found within Appendix I Item A, was prepared consisting of the Argus2s Eyewear (ENG-300200-000B) paired to an Argus II LX HDE implant (ENG-292200-000C), and positioned within a reference head model created from anthropometric data and supplemented with coil positioning metrics provided by SSMP. Material specifications were also provided to ensure that each component was correctly characterized within the simulation. Since the RF electronics are identical for all four variants of the Eyewear, in addition to the OR Coil Assembly, the same 3D model was used to simulate all device variants within the product family.

4.2. Results and analysis: Appendix I lists all raw data files and reference reports attached within EtQ. Analysis of the finite difference time domain (FDTD) method can be found in [1]. D-H FDTD is considered state-of-the-art and has been used previously by SSMP for analysis of a retinal prosthesis system[2] and cortical prosthesis system[3]. For this simulation, two different scenarios were investigated: (1) the coils parallel and offset at a distance of 28mm, representing the current "worst-case" scenario, and (2) the external coils misaligned to the implant coil at an angle of 25º and offset at a distance of 18mm for the "tilted" scenario. The results for both scenarios are provided in Tables 4.2.1 through 4.2.4, below.

4.3. The nominal output power fed to the forward telemetry coil (measured at 20 mm coil separation) was 0.56 W, and the worst-case output power fed to the forward telemetry coil (measured at 28 mm coil separation) was 0.75 W.

Table 4.2.1: SAR induced in the human head (current worst-case scenario)

Quantity	FDTD Simulation Result	Forward Telemetry Limit	Forward Telemetry Limit (Canada RSS-102)	Result
Maximum averaged 1 gram SAR	**0.006 W/kg**	**1.6 W/kg**	**1.6 W/kg**	**Passed**
Maximum averaged 10 gram SAR	**0.003 W/kg**	**2 W/kg**	**N/A**	**Passed**

[1] D. Sullivan, *Electromagnetic simulation using the FDTD method*, 1st ed. New York, N.Y.: IEEE Press, 2000.
[2] V. Singh et al, "Specific Absorption Rate and Current Densities in the Human Eye and Head Induced by the Telemetry Link of a Dual-Unit Epiretinal Prosthesis", *IEEE Transactions on Antennas and Propagation*, pp.3110-3118, 2009.
[3] P. Kosta et al, "Electromagnetic Safety Assessment of a Cortical Implant for Vision Restoration," *IEEE Journal of Electromagnetics, RF and Microwaves in Medicine and Biology*, vol. 2, no. 1, pp. 56-63, March 2018.

Table 4.2.2: Maximum current densities induced in the human head (current worst-case scenario)

Maximum Current density (A/m^2) averaged over 1 cm^2 area	FDTD Simulation Result	Forward Telemetry Limit	Result
Avg Jx	**0.613 A/m^2**	6.3 A/m^2	**Passed**
Avg Jy	**0.804 A/m^2**	6.3 A/m^2	**Passed**
Avg Jz	**1.433 A/m^2**	6.3 A/m^2	**Passed**

Table 4.2.3: SAR induced in the human head ("tilted" external coil scenario)

Quantity	FDTD Simulation Result	Forward Telemetry Limit	Forward Telemetry Limit (Canada RSS-102)	Result
Maximum averaged 1 gram SAR	**0.019 W/kg**	**1.6 W/kg**	**1.6 W/kg**	**Passed**
Maximum averaged 10 gram SAR	**0.008 W/kg**	**2 W/kg**	**N/A**	**Passed**

Table 4.2.4: Maximum current densities induced in the human head ("tilted" external coil scenario)

Maximum Current density (A/m^2) averaged over 1 cm^2 area	FDTD Simulation Result	Forward Telemetry Limit	Result
Avg Jx	**1.14 A/m^2**	6.3 A/m^2	**Passed**
Avg Jy	**1.50 A/m^2**	6.3 A/m^2	**Passed**
Avg Jz	**2.51 A/m^2**	6.3 A/m^2	**Passed**

Due to the localized nature and low power of the RF field in the A2E16 Glasses and OR Coil Assembly, in addition to the fact that the hand (for limb currents) is not required to hold the RF transmitter in place during use, contact and limb currents are negligible and considered not applicable. Additionally, the back telemetry signal is not considered for current density, due to the extremely low power (less than 100µW) output by the implant.

4.4. Deviations: No deviations

4.5. Pass/Fail Status: all PASS

5. Conclusion

It is concluded, based on the simulated results and accompanying analysis provided by the University of Southern California in the *Second Sight A2E16 System Multi-Coil Telemetry Link Electromagnetic Safety Assessment (07/25/2018)*, that the A2E16 Eyewear (ENG-300200-000B, ENG-300200-100A, ENG-300200-200C, and ENG-300200-300A) and OR Coil Assembly (ENG-300200-450F) comply with the General Public Exposure limits as determined by REC 1999/519/EC and RSS-Gen, and therefore meet the design input requirements and specifications listed above within *Section 1. Purpose*.

6. Appendix I – EtQ Attachments

A. *A2E16 SAR Fine Simulation File Repository – May 2018.zip* – contains the associated referenced simulation data files used for simulation and report creation

SecondSight_A2E16_07_25_2018_USC_V4.pdf – Second Sight A2E16 System Multi-Coil Telemetry Link Electromagnetic Safety Assess