

- **Limitation of Human Exposure to Electromagnetic Fields**

Specification: The forward telemetry at 3.156 MHz and backward telemetry at 473 and 490 kHz shall comply with the General Public Exposure limits listed below as determined by REC 1999/519/EC. [EN 50364:2001 Clause 4.1] [rf26][or26] and FCC 2.1093(d)(2)

Quantity	Forward Telemetry Limit (3.156 MHz)	Backward Telemetry Limit (473,490 kHz)
Current Density	6312 mA/m ²	946, 980 mA/m ²
Whole Body Average SAR	0.08 W/kg	
Localized SAR (head and trunk)	1.6 W/kg	
Localized SAR (limbs)	4 W/kg	
Contact and Limb Current	20 mA	

Analysis: A peer-reviewed paper has been published studying the specific absorption ratio (SAR) and current density of the Argus II RF link. The paper, 'Specific Absorption Rate and Current Densities in the Human Eye and Head Induced by the Telemetry Link of an Epiretinal Prosthesis' [1] (see attached), calculated specific absorption ratio for the system over various frequencies between 2 and 10 MHz and at a peak coil current of 620 mA. The Argus II System being analyzed herein uses a carrier frequency of 3.156 MHz and a peak coil current of up to 980 mA in some conditions.

A justification showing that the Argus II System is still within specifications for SAR and current density given the specific carrier frequency and peak coil current, based on [1], is included as an attachment also.

Due to the localized nature and low power of the RF field in the Argus II Glasses and Argus II OR Coil, 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 extreme low power (less than 100 uW) output by the implant.

References:

1. V.Singh et.al, "Specific Absorption Rate and Current Densities in the Human Eye and Head Induced by the Telemetry Link of an Epiretinal Prosthesis", IEEE Transactions on Antennas and Propagation, vol.57, No.10, October 2009, pp 3110 – 3117.