Safety Assessment of a Cortical Implant for the Restoration of Vision to the Blind

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The Argus II is a retinal prosthesis system developed to restore vision to the blind. Initial clinical tests for this device were carried out over a decade ago. Since then, the device has been approved for implantation in several countries and hundreds of people are benefitting from it. The Argus II consists on an external camera, external processing unit, implanted neurostimulator and a telemetry link. Visual information is captured by the external camera and sent to the processing unit. The processed information is sent to the neurostimulator via the telemetry link: the neurostimulator then converts this information into electrical pulses that are applied to the retina, which results in the patient perceiving an image.

Despite its initial success, the Argus II can restore some form of vision only to a subset of blind patients. In fact, only patients suffering from some form of retinal degeneration can potentially benefit from it. Because of this, a new visual prosthesis is currently under development: The Orion 1. The Orion 1 system moves the neural stimulation from the retina to the visual cortex, eliminating altogether the need to stimulate the retina and significantly broadening the number of patients who can be good candidates for receiving and benefiting from the implant. The Orion 1 components perform functions similar to those of the Argus II, with the primary difference being the target neural tissue to be stimulated.

In this work, we present models and methods used to verify the electromagnetic and thermal safety assessment of the current version of the Orion 1 system, extending our observation to cortical implants in general. Custom Finite-Difference Time-Domain (FDTD) and Bio-Heat solvers are used to compute the distribution of the electromagnetic fields, induced currents, and resulting temperature increase in the tissue. Our preliminary findings show that the Orion 1 system is capable of delivering the required amount of power to the cortical stimulator while meeting IEEE and ICNIRP guidelines. The visible human male is used to carry out the safety analysis presented in this work. These findings have broader application to a wider range of cortical neuroprosthetics.