

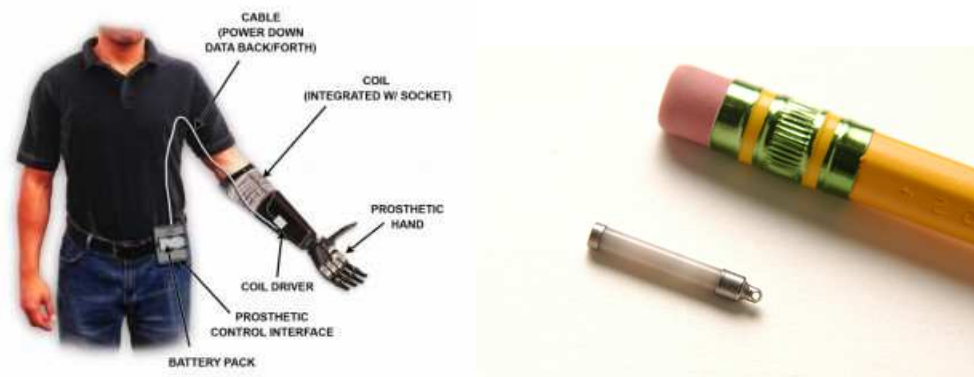
EXHIBIT 1

DESCRIPTION OF PROPOSED EXPERIMENTAL OPERATIONS

Pursuant to Section 5.71 of the Commission's rules,¹ the Alfred Mann Foundation for Scientific Research ("AMF"), a nonprofit research corporation devoted to development of advanced medical products, requests a two-year license for conventional experimental operation of wireless implantable myoelectric sensor ("IMES") devices. The requested experimental license will allow AMF to test and develop its first-generation IMES system in an ongoing clinical trial with three patients at the Walter Reed National Military Medical Center in Bethesda, Maryland.²

AMF's IMES system is a wireless prosthesis control system designed to address a shortcoming of commercially available prosthetic devices that use two-point, body-worn electromyographic ("EMG") sensors (*i.e.*, placed on the skin): these body-worn EMG sensors may pick up signals from more than one muscle at a time and thus can degrade performance of the prosthesis and frustrate its user. In contrast, the IMES system consists of (i) multiple implanted sensors (Model No. 720-10006-003) that transmit signals for controlling a prosthesis, enabling greater and more accurate degrees of stable control; (ii) an external radiofrequency ("RF") coil (Model No. ASY-00041-001) that provides the conduit for power to and communications with the implanted sensors; and (iii) a controller (Model No. ASY-00044-001) that transmits power and configuration data to, and receives EMG data from, the implanted sensors.

Figure 1: IMES System



The IMES system uses tiny sensors implanted directly into the muscles to ensure accurate, reliable collection of EMG data, facilitating intuitive, direct user control of the robotic prosthetic limb. The EMG signals are transmitted wirelessly from the muscles to

¹ See 47 C.F.R. § 5.71.

² Concurrently with this filing, AMF is submitting an application for an experimental special temporary authorization to test and develop its first-generation IMES system in the clinical trial at the Walter Reed National Military Medical Center.

the controller via an RF coil that wraps around the residual limb where the sensors are implanted. The controller then interprets the EMG signals and commands the prosthesis to perform the intended movement.

The IMES system operates on the nominal 121 kHz frequency for both data and power transmissions, in compliance with applicable emissions limits specified under Sections 15.209 and 18.305(b) of the Commission's rules, 47 C.F.R. §§ 15.209, 18.305(b). The RF technical parameters of the IMES system are further specified in the accompanying Form 442.

During normal and other modes of operation (*e.g.*, fitting and surgical modes), the IMES system transmits and receives data communications at 121 kHz. During the start-up mode lasting less than one second, however, the IMES controller and coil transmit data in the 94.6 - 157.4 kHz band to configure the implanted sensors, thus resulting in non-spurious emissions in the 90 - 110 kHz band, which is restricted under Section 15.205(a) of the Commission's rules.³

The Commission has waived Section 15.205(a) to permit wireless medical device operations in the 90 - 110 kHz restricted band.⁴ Thus, AMF's proposed experimental operations in the 90 - 110 kHz restricted band – limited only to the start-up mode lasting less than one second – are consistent with Commission precedent allowing other wireless medical device operations in the same restricted band. Moreover, consistent with Section 5.3(i) of the Commission's rules,⁵ grant of the requested experimental license will allow AMF to test and develop innovative wireless medical devices, paving the way for future versions that will offer substantial health benefits for countless amputees in the United States and, in particular, returning injured warfighters.

³ See 47 C.F.R. § 15.205(a).

⁴ See *Respironics, Inc. and Boston Scientific Corporation*, 21 FCC Rcd 13450, ¶ 1 (OET 2006) (finding that waivers “will afford medical patients the important health benefits provided by the Respironics and Boston Scientific devices for which there currently are no reasonable alternatives and would not contravene the underlying purposes of our rules for unlicensed devices”); *Boston Scientific Corporation*, 26 FCC Rcd 11405, ¶ 10 n.13 (OET 2011) (extending term of waiver grant and noting that the federal government's radionavigation LORAN-C operations in the 90 - 110 kHz restricted band have been discontinued).

⁵ See 47 C.F.R. § 5.3(i).