P2725.1

Submitter Email: jlibove@ultraviewcorp.com
Type of Project: New IEEE Standard
PAR Request Date: 13-Dec-2017
PAR Approval Date: 15-Feb-2018
PAR Expiration Date: 31-Dec-2022
Status: PAR for a New IEEE Standard

1.1 Project Number: P2725.1
1.2 Type of Document: Standard
1.3 Life Cycle: Full Use

2.1 Title: Standard for Microwave Structural, Vascular or Functional Medical Imaging Device Safety

3.1 Working Group: Standard for Microwave Structural, Vascular or Functional Medical Imaging Device Safety (EMB/Stds Com/Microwave Imager Safety)
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None

3.2 Sponsoring Society and Committee: IEEE Engineering in Medicine and Biology Society/Standards Committee (EMB/Stds Com)
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None

4.1 Type of Ballot: Individual
4.2 Expected Date of submission of draft to the IEEE-SA for Initial Sponsor Ballot: 03/2019
4.3 Projected Completion Date for Submittal to RevCom
Note: Usual minimum time between initial sponsor ballot and submission to Revcom is 6 months.: 02/2020

5.1 Approximate number of people expected to be actively involved in the development of this project: 25
5.2 Scope: This standard specifies the area(s) of intended usage, electromagnetic and electrical safety and electromagnetic compatibility (EMC) requirements for microwave medical imaging systems and brain machine interface (BMI) devices.

5.3 Is the completion of this standard dependent upon the completion of another standard: No
5.4 Purpose: The purpose of this standard is:

* To specify the maximum allowable exposure of radio frequency (RF) energy to which the device exposes the human body and to further specify required means within the device to continually monitor such energy emission and to automatically shut down the device in the event these limits are exceeded.

*To specify the electrical safety requirements, to ensure that in the event of any single-point failure, the device does not expose the subject to leakage currents exceeding a specified existing limit that is established as safe, such as the electrical safety parameters specified in IEC -60601.

*To specify the electromagnetic compatibility (EMC) requirements of the device, to prevent interference with communications, and to prevent unintended transmission of patient data due to RF leakage.

*In addition to the creation and approval of human safety and EMC requirements documents, this standard also defines the assurance program for evaluating and certifying products against those requirements.

5.5 Need for the Project: Medical imaging systems that can be produced at lower cost and in a portable format than conventional large imaging systems could provide potentially life-saving benefits, by screening for tumors, aneurysms and other vascular malformations, and emboli. Said portable imaging systems could further enable wearable brain machine interfaces (BMIs) which could potentially be used for neuroprosthetics and for direct brain-to-machine communications that could bypass the need for, or exceed the capabilities of, conventional methods of communications such as speech and writing.

5.6 Stakeholders for the Standard: Government and Regulatory Bodies, Device Manufacturers, Healthcare Facilitators, Application Developers, Medical Researchers, Social Networking Providers and Consumers.

Intellectual Property
6.1.a. Is the Sponsor aware of any copyright permissions needed for this project?: Yes
If yes please explain: This specification shall incorporate, by reference, C95.7-2014 - IEEE Recommended Practice for Radio Frequency Safety Programs, 3 kHz to 300 GHz https://standards.ieee.org/findstds/standard/C95.7-2014.html

This specification shall further incorporate, by reference, IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.

6.1.b. Is the Sponsor aware of possible registration activity related to this project?: No

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7.1 Are there other standards or projects with a similar scope?: Yes
If Yes please explain: C95.7-2014 - IEEE Recommended Practice for Radio Frequency Safety Programs, 3 kHz to 300 GHz

The C95.7 specification covers allowable radio frequency exposure to the human body, in the same frequency ranges utilized by the subject devices.

IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. Several subsections in this specification cover electrical safety requirements for medical devices.

IEC 60601-1-2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Collatoral Standard: Electromagnetic Compatibility, covers RF emission limits for medical devices.

and answer the following
Sponsor Organization: ---
Project/Standard Number: ---
Project/Standard Date:
Project/Standard Title: ---
7.2 Joint Development
Is it the intent to develop this document jointly with another organization?: No

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8.1 Additional Explanatory Notes: Item 7.1 specifies that the RF exposure safety limits in C95.7-2014 (IEEE Recommended Practice for Radio Frequency Safety Programs, 3 kHz to 300 GHz) be adopted. Microwave energy covers the 300MHz through 300GHz subset of this frequency range. Hence, medical imaging radar, of the type used herein for a brain imager or BMI generally emits and utilizes energy between 10MHz and 20GHz, and thereby is classified as both a general RF emitter as well as a microwave emitter.

Regarding Item 5.4, the EMC requirement alone does not ensure data security, but provides the benefit of reducing RF emissions that might otherwise convey/broadcast patient/subject neural information. This specification does not provide for encryption or other added data security measures that may be required to ensure privacy of patient/subject data.

Regarding Item 5.5, Justifications for commencing the project at the current research stage, prior to commercial product deployment are:
1) At least one commercial microwave structural brain imaging device is undergoing field testing. It is anticipated that additional structural and vascular imaging prototypes will begin clinical trials within the next year, and functional microwave imagers and BMIs for neuroprosthetics and internal speech decoding could follow within 2-3 years.

2) Microwave imaging has the potential to be safer than established imaging methods (e.g. MRI/fMRI), if an initial specification ensures that the energy the patient/subject receives from it is lower than that absorbed from an MRI or cellular phones, and if this is consistently ensured from the outset by requiring that emitted energy be continuously self-monitored in real time, with provision for automatic shutdown upon any failure.