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CURRENT AND FUTURE NEEDS FOR COMPUTATIONAL METHODS FOR MEDICAL APPLICATIONS

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ABSTRACT

This paper describes deficiencies and requirements of computational methods for of medical devices. The focus will be on computational methods for safety and effectiveness evaluations of medical devices. The U.S. Food and Drug Administration (FDA) is the U.S. authority to approve medical devices. In the review process the manufacturer has to show the safety and effectiveness of the device. Therefore, FDA has a broad picture of what kind of computational methods should be used, or are not be used, for various medical devices. In recent years many manufacturers provided data based on computer simulations to show safety and effectiveness of their product. The submission of these applications is increasing over the last couple years. Unfortunately the reviews of these submissions have shown deficiencies; sometimes major deficiencies. On the other hand some applications would need computational methods to prove safety and effectiveness, but manufacturers are hesitating to use these methods. One example is RF or microwave ablation devices. The devices have been evaluated experimentally in saline or gel phantom material. The large change in temperature rise and the complexity of anatomical structures make an evaluation in static homogeneous phantom material questionable.

Sophisticated, commercially available software and cheaper hardware is one of the reasons for more usage of computational methods. 64 bit computers with several Giga Byte (GB) of memory and multiple processors are affordable even for small companies. Today computers are able to handle problems which could only be handled by supercomputers a few years ago. Modern simulation software with sophisticated Graphical User Interfaces (GUIs) often seems easy to use but without thorough understanding of the underlying method reliable evaluations are not guaranteed. Erroneous results for safety and effectiveness evaluations for medical devices can be fatal.

The complexity of computational methods shows a recent comparison involving 15 international distinguished groups for numerical dosimetry. The IEEE Standard Coordination Committee 34, Sub-Committee 2 developed a protocol to compare the Specific Anthropomorphic Mannequin (SAM) to two anatomical heads. All 15 groups used their own software and followed exactly the instructions given in the protocol. The results for the anatomical heads show differences up to a factor of 2. Although this example is not a medical application it makes the complexity of computational methods obvious, even if a standardized protocol is used. A factor of two for critical medical applications could be too much to be considered a reliable method to evaluate the safety and effectiveness of medical devices.

The paper focuses on four current topics for needs of computational methods: 1. Safety of active implantable medical devices (AIMD) in electromagnetic fields, 2. Safety of patients, medical personnel, and AIMDs in the Magnetic Resonance Imaging (MRI) environment, 3. Medical devices and wireless technology, and 4. Radiofrequency (RF) and microwave ablation devices. We discuss the requirements for computational methods and the need for standardization if computational methods should be successfully used for medical applications. Several very useful tools are currently available, but there is still a lot of development needed till computational methods are widely and correctly used for medical device evaluations. Some of the currently missing features of available software are: user-friendly GUIs, solvers for the bio-heat equation, low frequency solver for pulsed and sinusoidal waveforms, conformal meshing, subgrids, graded meshes, tissue specific results averaging (H, E, J, T, SAR), volume and surface averaging (H, E, J, T, SAR), optimized fast solvers, solvers able to handle very small structures, simultaneous simulation of high and low frequency excitation (pulsed and sinusoidal), multi processor capability, cluster capability, simulation of blood flow, temperature dependent dielectric properties, calculation of tissue damage for large temperature increase, accurate anatomical models, and import and export capabilities in standardized data formats.