

# Standards Navigator Subscriptions

## **Medical Device Standards Updates**

**Direct Access to SoftwareCPR<sup>®</sup> Experts  
involved in Standards work**

**Provision of publicly available draft standards  
for comment**

**Access to SoftwareCPR<sup>®</sup> standards navigator  
documents and templates**

**Notification of new standards work items**

**Some of the Medical Device and Software  
Standards Covered:**

- IEC 60601-1 series
- ISO 13485 and ISO 14971
- IEC 62366
- IEC 62304 amendment and second edition
- IEC 80002-1 and AAMI Software Safety and Assurance TIR
- IEC 80001-1 and related Health IT standards
- General Software and Systems Engineering Standards

**...Turn for details**



**Standards and guidance** used by regulators of medical device and health information software as well as general software and systems engineering standards are rapidly changing. The ability to quickly create and change software applications challenges the existing medical device regulatory framework. New approaches are being considered and new standards and guidance will play a significant role. How can you keep up with what has changed, let alone understand what is coming in the near future? To help you navigate the coming changes in standards and guidance, SoftwareCPR<sup>®</sup> is offering a new subscription service.

SoftwareCPR<sup>®</sup> Standards Navigator gives you expert insight into the meetings and discussions that create US and International standards for medical devices in general and software and health information applications in particular.

**Standards Navigator Subscription (\$5000/year)**

- Quarterly reports on medical device software, risk management, and health information technology standards and guidance that are being developed or modified as well as web based Q&A with our standards experts each of whom has personally participated in standards development.
- Special SoftwareCPR<sup>®</sup> Standards Navigator documents and information, which contain the current status of all pertinent medical device software and health information technology standards and guidance, including any new software standard or guidance that has been approved to begin development.
- A single user subscription to the SoftwareCPR<sup>®</sup> medical device software regulatory and safety website

**SoftwareCPR<sup>®</sup> participates** in major US and international standards development organizations. SoftwareCPR<sup>®</sup> partners have chaired the work on standards such as IEC 62304, AAMI TIR32, IEC 80001-1 and others. SoftwareCPR<sup>®</sup> understands not only what standards are currently approved, but what will be changing in the future. SoftwareCPR<sup>®</sup> Standards Navigator gives you the benefits of this extensive experience and participation led personally by Sherman Eagles and Alan Kusnitz.

**Standards Navigator PLUS Subscription (\$9800/year) as above plus:**

- Up to 16 hours per year of off-site software standards-related consulting or training by SoftwareCPR<sup>®</sup>. This will be tailored to your preferences and could include, for example, periodic telecons, document or procedure review and feedback, or online training.
- Monthly updates with analysis
- Draft standards for comment as they become available
- Real time Alerts when changes to software standards and guidance are being discussed that you have identified as being of particular interest to you
- Announcements of new medical device and health information technology software standards and guidance when they are proposed – before they are started