

## AAMI Adopts International Standard to Replace HE74

AAMI and the American National Standards Institute (ANSI) voted in late October 2010 to adopt the international standard IEC 62366:2007 *Medical devices – Application of usability engineering to medical devices*. This document replaces the existing AAMI standard HE74 *Human factors design process for medical devices*.

IEC 62366 was developed by Joint Working Group (JWG) 4, Medical devices – General requirements for safety and essential performance – Usability, of Subcommittee (SC) 62A, Common aspects of electrical equipment used in medical practice. U.S. experts participated in its development.

The international standard describes a usability engineering process and provides guidance on how to implement and execute the process to provide safety in medical devices. It is intended to be useful not only for manufacturers of medical devices, but also for technical committees responsible for the preparation of particular medical device standards.

AAMI encourages its committees to harmonize their work with international standards to the extent possible. Upon review of IEC 62366:2007, the AAMI Human Factors Engineering Committee, which serves as the U.S. Technical Advisory sub-Group (sub-TAG) to JWG 4, decided to adopt it verbatim as a revision of ANSI/AAMI HE74:2001/(R)2009. ■

To order ANSI/AAMI/IEC 62366:2007, call (877) 249-8226 or visit <http://marketplace.aami.org>. Order code 62366, source code PB. List price \$120, AAMI member price \$60.

## FDA Highlights Pediatric Medical Device Adverse Events, Encourages Reporting

The U.S. Food and Drug Administration's (FDA's) Office of Pediatric Therapeutics and Medical Surveillance Network recently outlined major human factors issues with pediatric devices reported via KidNet, the pediatric subnetwork of the Medical Surveillance Network (MedSun). The information was featured in an article that appeared in *AAP News*, which is published by the American Academy of Pediatrics.

The agency reported on events involving cracked luer hubs of peripherally inserted central venous catheters. The adverse events, initially attributed to users over-tightening catheter connectors, were cited by the agency as an example of how human factors issues can cause unintended problems after a device is marketed. Ultimately, the manufacturer made design and material improvements to the luer hub to help it resist cracking.

Another example of an adverse event with pediatric devices involved a hospitalized toddler in a crib removing a medication syringe from an infusion pump. To correct the problem, the manufacturer designed a lockable plastic enclosure for medication syringes in the pump.

To help identify human factors issues and other problems, the agency encourages healthcare providers to report medical device adverse events to MedWatch or through MedSun. For more information, visit [www.fda.gov/Safety/MedWatch/HowToReport/default.htm](http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm). ■

## Misreading Letters, Numbers Spells Trouble

Did you know that more than 50% of letter-number errors come from just four basic mistakes?

- The letter “L” and the number “1”
- The letter “O” and the number “0”
- The letter “Z” and the number “2”
- The numbers “1” and “7.”

An article by the Institute for Safe Medication Practices (ISMP) reported on these common errors and others that occur frequently in both handwritten and computer-generated information.

It can be extremely dangerous to misread letters and numbers on medical devices, prescriptions, drug orders, and medical records. Medication orders, which often contain both letters and number, are especially prone to such mixups.

Strategies to reduce errors include using lower-case letters or mixed-case letters (which are easier to read) and encouraging block printing on lightly lined forms for handwritten orders. Symbolic differentiation is another way to reduce errors. For example, a zero written with a slash through it will distinguish it from the letter “O.” The numeral 7 and the letter Z can each be written with a bar through it to prevent confusion with similar-looking numbers. And, allowing adequate spacing between the drug name and dose is another way to reduce mistakes.

For a list of more than 20 commonly confused letters and numbers and more tips on how to reduce errors, see the article at <http://www.ismp.org/newsletters/acutecare/articles/20090702.asp>. ■