

New AAMI Committee Tackles Home Use Device Challenges

AAMI has created a new home healthcare committee called Medical Devices and Systems in Home Care Applications to tackle home healthcare issues, which complements the U.S. Food and Drug Administration's (FDA) initiative.

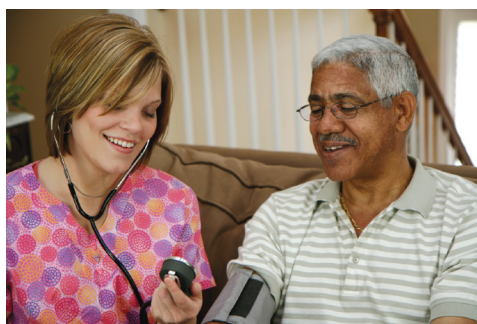
The committee may undertake projects such as contributing to the new international standard IEC 60601-1-11, which focuses on home care applications of medical equipment. "The standard will raise the bar for healthcare devices specifically intended to be used in the home environment in terms of safety of construction and installation, electromagnetic isolation, and safety when in use," says committee co-chair Denny Treu, vice president of research for NxStage Medical, a Lawrence, MA, based manufacturer of the only FDA-cleared home dialysis system marketed today. "I think a major focus of the committee's work will be in the area of human factors and risk management."

Treu says the FDA initiative will augment the committee's efforts. "There is a good long history of the FDA

and AAMI working well together and making sure that patient safety is taken into account, while addressing the needs of the manufacturers as well," he says.

Committee member Steve Wilcox, PhD, founder and principal of Design Science Consulting in Philadelphia, says AAMI's new home healthcare committee can provide "in-depth information to help device manufacturers meet FDA's requirements in the home healthcare arena."

Other committee members say the FDA initiative will help to draw much-needed attention to the issue. "In the past, efforts for assuring the safe use of home medical equipment have been overseen by home health companies' accrediting bodies. It is very appropriate for the FDA to create better regulations, guidelines, and education from the manufacturer's perspective," says Byron L. Jacobs, CBET, a biomedical equipment technician with Sanford USD Medical Center in South Dakota. "This initiative will need to be clear cut, definitive, and enforceable if it is to have any true effect on things." ■



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