COTS EQUIPMENT
Does One Size Fit All for Off-the-Shelf Computer Equipment?

Many hospitals use commercial off-the-shelf (COTS) computer equipment rather than components specifically designed for the health care setting. Some of these facilities allow COTS computer components to be used anywhere in the facility, including patient care areas. For example, such equipment may be placed in patient rooms as part of a hospital information system installation.

But does the use of COTS equipment near the patient create concerns about touch current or other safety issues that should prohibit its use? ECRI Institute doesn’t think so, if the proper precautions are taken.

For COTS computers and monitors used within the patient care vicinity — that is, the area extending 6 feet beyond the normal location of the bed or other patient support, and vertically 7 feet 6 inches above the floor — there are reasonable steps that can be taken to verify the equipment’s quality and safety so that it can be used without worry. For equipment that will not be used within the patient care vicinity, fewer precautions are required.

WHAT RELEVANT CODES AND AUTHORITIES SAY
Compliance with codes and the expectations of authorities could be an issue when deciding whether to allow COTS equipment in the patient care vicinity. Many hospitals look to agencies such as the Joint Commission or the National Fire Protection Association (NFPA) for guidance. Unfortunately, neither of these organizations nor any other certifying organizations or prevailing standards offer detailed recommendations on the use of COTS computer equipment.

**ECRI Institute Recommendations**

**VERIFY UL LISTING, AT MINIMUM**

Even for computers and monitors that will be used in the patient care vicinity, a facility need not limit its selections to equipment that complies with a medical device standard such as Underwriters Laboratories’ UL 60601-1 (Medical Electrical Equipment—Part 1: General Requirements for Safety) if not required to do so by local regulations.

Most COTS computer equipment is UL listed, not to the medical device requirements of UL 60601-1, but to other relevant UL standards (e.g., those covering IT or office equipment). While the latter standards may not be as rigorous as those for medical devices, they still provide some assurance of safety.

If a COTS device being considered is not listed to a medical device standard such as UL 60601-1, the facility should verify that the device has a UL or similar listing or mark that is appropriate for the general category of equipment.

**BE WARY OF RELYING ON MEDICAL/HOSPITAL-GRADE LABELING**

When selecting computer monitors and some other nonmedical devices, a hospital does not need to limit its selections to products designated as “medical grade” or “hospital grade.” No universal meaning exists for these terms, and neither term is defined in the 60601-1 standards or in NFPA 99. NFPA 99 does not require hospitals to use hospital-grade or medical-grade equipment, even for patient care.

Precisely what is meant by “medical grade” or “hospital grade” varies among suppliers. With some devices, the medical-grade or hospital-grade designation is used to indicate that the device addresses concerns covered by 60601-1 standards. But with other devices, these designations are not related to equipment safety but instead describe, for example, inclusion of performance features that the supplier considers appropriate for medical
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applications. As a result, a computer or monitor with such a designation may not necessarily offer any safety advantages over a commercial device.

A facility that does decide it prefers computer equipment with a medical-grade or hospital-grade designation should contact the supplier to verify whether the designation relates to the device’s safety.

VERIFY EQUIPMENT SAFETY
All COTS computers or monitors being considered for use in the patient care vicinity should be verified to be electrically safe. Further, such equipment should be assessed for other considerations that might be relevant in a medical environment, such as fluid resistance and instructions for cleaning and disinfection. More specific recommendations include:

1. Examining the Equipment
   Have health technology management personnel examine the equipment for overall quality and electrical safety.

2. Addressing Touch Current
   Several hospitals have expressed concern to ECRI Institute that COTS computer equipment may exceed the touch (leakage) current limits they apply to their medical devices, since COTS devices are subject to less stringent regulations than devices designed for medical use. ECRI believes that COTS equipment exceeding a facility’s maximum touch current can be used safely in the patient care vicinity, provided that the appropriate steps are taken and that precautions are applied when called for. The first step is to measure the device’s touch current. This measurement should be made before any redundant grounds are installed. If equipment touch current is 500 μA or less, the device meets international and U.S. standards and no measures to address touch current are needed.

THIS ARTICLE is based on an article that was posted on ECRI Institute’s membership website on December 24, 2014. The full article features additional ECRI perspectives and recommendations, more background and details on relevant standards, and more detailed guidance on addressing touch currents. The article is available on ECRI’s Health Devices System, Health Devices Gold, and SELECTplus member websites. To learn more about these programs or any other ECRI Institute service, visit www.ecri.org or call (610) 825-6000, ext. 5891.