



Safety testing in healthcare robotics



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Executive Summary



The safety of robotically assisted surgical equipment and systems

From its first documented use nearly 30 years ago, robotics today is playing a major role in efforts to bring innovative patient treatments to the healthcare industry. Robotically assisted equipment and systems are now being widely used in advanced surgical procedures, helping to reduce complications and improve overall surgical outcomes.

The International Electrotechnical Commission (IEC) has now published a standard to address the specific performance and safety characteristics of robotically assisted equipment. The standard, IEC 80601-2-77, Medical Electrical Equipment – Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment, bridges an important gap in previously available medical device standards. Reflecting more than a decade of work by industry experts from around the world, IEC 80601-2-77 is expected to be adopted in the near future by regulatory authorities in most international medical markets for use in assessing the safety of advanced robotic systems and devices used in surgery.

In this UL white paper, we'll summarize the key aspects of this important standard and provide information on the anticipated adoption of the standard by regulators.



The state of robotics in healthcare

In late 1992, Dr. William Bargar, a California engineer-turned-orthopedic surgeon, conducted the first documented robotic surgery on a human. Using a complex, multipurpose robotically assisted surgical (RAS) system designed with his colleague and friend, Howard “Hap” Paul, and the aptly named Robodoc, Bargar drilled a cavity into the femur of a patient in order to accommodate the shape of the prosthesis that would be implanted as part of hip replacement surgery. Bargar would go on to conduct six more feasibility studies using his robotic system in human hip replacement procedures, and the original Robodoc prototype built by Bargar and Paul is now housed in the Smithsonian National Museum in Washington, D.C.¹

From that storied beginning, RAS systems and equipment have now found their way into a broad range of specialty surgical applications, including urology, gynecology, cardiology and, of course, orthopedics. Today, RAS systems and equipment are commonly employed in procedures such as gall-bladder removal, hysterectomies and prostatectomies. In addition to their ability to execute surgical procedures with extreme precision, thereby reducing the risk of surgical complications, the use of RAS equipment also offers important advantages to hospitals and healthcare systems, giving them the ability to attract patients interested in taking advantage of the most technologically advanced systems to address their healthcare issues.²

The global market for surgical robots currently stands at just under \$4 billion (U.S.) annually and is expected to increase to \$6.5 billion by the year 2023, a compound annual growth rate (CAGR) of over 10% during each of the next five years.³ Drivers for this growth are expected to include advancements in robotic technologies and as well as the application of RAS systems in more complex surgical procedures. These drivers, along with increased experience in using robotic technologies by physicians and healthcare professionals, will also fuel the more widespread adoption of RAS systems and equipment by hospitals and ambulatory surgical centers.

Safety issues with robotics in healthcare

The introduction of any new technology into an established process is likely to bring with it some degree of risk. For most electrical and electronic equipment and devices, risk assessments typically encompass electrical and mechanical considerations, as well as electromagnetic compatibility (EMC) and immunity. For equipment and devices that incorporate software or communications modules, a more expansive assessment of risk is necessary to address the unique safety and performance issues that these technologies introduce.

But, when it comes to robotic systems used in surgical procedures, the risk proposition becomes much more significant in importance. By design, RAS systems and equipment are intended for use in invasive surgical procedures, during which patients are potentially most vulnerable to physical harm. In such situations, even a minor failure in the performance of a RAS system could have catastrophic consequences, ranging from extended post-surgical recovery periods to serious injury and even death. Over the years, a number of studies have shown that RAS systems and equipment are generally safe to use and result in surgical outcomes comparable to or better than those obtained with conventional surgical techniques. For example, a study published in 2018 reviewed records for more than 5,600 robotically assisted surgeries conducted in seven different medical departments by 47 physicians at a university medical center in Seoul, South Korea, between 2008 and 2013. The study found that RAS system malfunctions and failures were observed in 185 cases (1.8% of the total), and that mortality occurred in just 12 cases (0.12%).⁴

A separate review of the Manufacturer and User Facility Device Experience (MAUDE) database maintained by the U.S. Food and Drug Administration (FDA) yielded similar results. According to that review, 10,624 adverse events related to robotic systems and equipment were reported during the period from 2000 to 2013, representing 0.6% of the estimated 1.745 million robotic procedures conducted during that period. Device malfunctions were identified in 8,061 of those reports (0.0046% of the total number of procedures), and mortality associated with the surgical procedure was noted in 144 (0.00008%) of the reports filed.⁵



At the same time, concerns regarding the safety of RAS systems and equipment continue to surface. In recent years, the FDA has received numerous reports of device malfunctions, such as robotic arms moving in unintended directions and device insulation disintegrating within patients during a surgical procedure. In other instances, some patients have reported burns and other thermal injuries directly resulting from robotically assisted surgical (RAS) procedures.⁶

There are many factors potentially associated with RAS system malfunctions and patient injuries, including insufficient operator training and lack of experience in effectively using such advanced equipment. However, the previously mentioned review of adverse reports posted to the FDA's MAUDE database concludes with the recommendation that "the adoption of advanced techniques in the design and operation of robotic surgical systems ... may reduce these preventable incidents in the future." For robotic device manufacturers, the challenge, and the opportunity is to embrace a new set of requirements specifically developed to address the unique risk profile for RAS systems and equipment.

About IEC 80601-2-77

The publication of IEC 80601-2-77 represents the culmination of efforts that began in October 2009. At that time, a Working Group (WG) of the International Organization for Standardization (ISO) was developing a new standard to address specific requirements for personal care robots. During the WG's deliberations, it became evident that a separate standards development effort might be required to address the unique aspects of medical devices using robotic technology, resulting in the formation of separate Study Group (SG) on medical care robots.

Over the ensuing years, synergies between the ISO SG's efforts and those of an IEC WG focused on medical electrical equipment eventually resulted in the formation of a Joint Working Group (JWG) in 2015. The JWG quickly determined the need to develop particular requirements specifically applicable to robotically assisted surgical equipment (RASE) and robotically assisted surgical systems (RASS). That decision ultimately led to the development of IEC 80601-2-77, as well as its companion standard, IEC 80601-2-78, which applies to medical robots used for rehabilitation, assessment, compensation or alleviation purposes.

IEC 80601-2-77 defines RASE and RASS as "medical electrical equipment (or "system," in the case of RASS) that incorporates PEMS (programmable electrical medical systems) actuated mechanism intended to facilitate the placement or manipulation of robotic surgical instrument(s)." As a particular standard under the IEC structure, IEC 80601-2-77 serves to address the unique aspects of RAS systems and equipment that are not sufficiently covered in general standards applicable to medical electrical (ME) equipment (in this case, IEC 60601-1:2005/AMD1:2012). In effect, IEC 80601-2-77 adds, replaces or amends specific requirements contained in the general standards or collateral standards as they apply to RAS systems and equipment.



A summary of IEC 80601-2-77 requirements

The key requirements of IEC 80601-2-77 that are now specifically applicable to RAS systems and equipment fall under the categories listed in the following sections.

Definitions

A number of new definitions have been included in IEC 80601-2-77 (Clause 201.3), several of which signal increased attention to features and conditions unique to RAS systems and equipment. The most significant additions include:

- **Interaction conditions** – Interaction conditions are conditions that apply to help ensure basic safety when a RAS system or equipment is used concurrently with multiple instruments or with applied parts of other ME equipment.
- **Interface conditions** – Interface conditions are defined as conditions that apply to help ensure the basic safety of any functional connection between a RAS system or equipment and any other ME equipment or non-ME equipment in the robotic surgical configuration.
- **Mechanical interface** – A mechanical interface is a mounting surface integral to a RAS system or equipment that allows for the attachment of accessories, components or parts that are manipulated by the RAS system.

General requirements

- **Essential performance** – The standard specifies “essential performance” requirements (Subclause 201.4.3) intended to help ensure that the device poses no unacceptable risk to a patient if information essential to perform surgery is degraded, or if motion control of the device has performance degradation.
- **Risk assessment for parts** – IEC 80601-1-77 provides additional guidance on the risk assessment (Subclause 201.4.6) applicable to medical electrical equipment or system parts that come in contact with a patient. According to the guidance on this requirement in Annex AA (“Particular Guidance and Rationale”) of the standard, a risk assessment of a RAS system or equipment should consider that patients undergoing surgery with a RAS system or equipment are typically anaesthetized and therefore may not be able to perceive or respond to negative stimulus. The risk assessment should also consider possible issues that could arise during normal use or reasonably foreseeable misuse from contact between equipment parts when robotic surgical instruments are attached.



Electrical hazards

- **Protective earthing of moving parts** – This requirement (Subclause 201.8.6) stipulates that any protective earth connection used on a moving part must remain reliable during the expected service life of the RAS system or equipment.
- **Creepages and clearances** – In Subclause 201.8.9.1.1, IEC 80601-2-77 allows for creepage distances and air clearance to be reduced in robotic surgical instruments to better accommodate parts with small dimensions, as long as the risk management process demonstrates adequate safety. This subclause also expressly references the requirements of Subclause 8.5.1.3 of IEC 60601-1, mandating that two means of operator protection (MOOP), pollution degree 1, must be met.



Mechanical hazards

- **Other risk control measures** – Other risk control measures required by IEC 80601-2-77 (Subclause 201.9.2.2.4.4) require that moving parts, when in motion and within reach of people, shall not present an unacceptable risk. In addition, risk control applicable to mechanical hazards must include a second risk control measure (such as an emergency stopping device). Otherwise, the RAS system or equipment will be considered Single Fault Safe.
- **Continuous activation** – This requirement (Subclause 201.9.2.2.5) stipulates that movement of a RAS system or equipment or any of its parts is possible only by the continuous activation of the control by the operator, and that an additional operator that has access to the deactivation of movement at all times can be acceptable. This requirement also stipulates the availability of second risk control measure, which may be an emergency stop or a RASE protective stop.
- **Speed of movement** – Manufacturers of RAS systems or equipment are required to consider the device's speed of movement in the context of all other RAS-related movement, both inside and outside of the patient (Subclause 201.9.2.2.6).
- **Release of patient** – This requirement (Subclause 201.9.2.5) mandates that RAS systems and equipment provide the means to release a patient quickly and safely under multiple scenarios, including a breakdown of the equipment, the loss of power, the activation of a risk control measure, or emergency stopping initiated by the operator.
- **Support systems** – IEC 80601-2-77 requires that the construction of the support, suspension or actuation system of RAS systems or equipment be designed to support the total anticipated load in accordance with Table 21 in IEC 60601-1 (Subclause 201.9.8.1).
- **RASE protective stop functions** – Any protective stop functions integrated into RAS systems or equipment must reduce risk to an acceptable level and prevent the automatic resumption of operation unless it does not lead to unacceptable risk (Subclause 201.9.2.101).
- **Person colliding with RASE** – This requirement (Subclause 201.9.101) stipulates that the risk management process include the accidental collision with the devices by a person when a robotic surgical instrument is in or in proximity to a patient.
- **Mechanical strength** – This requirement (Subclause 201.15.3) requires the inclusions of assessments regarding the mechanical strength of robotic surgical instruments in the risk management process.

IEC 80601-2-77 includes a number of informative annexes that provide additional details on the specific requirements discussed in this section.

Status of IEC 80601-2-77 with regulatory authorities

IEC 80601-2-77 was officially published by the IEC in early July 2019. As of this writing (August 2019), a clear timeframe has not yet emerged for incorporating the standard's requirements into the regulatory schemes of countries with major medical device markets. However, it is likely that standards development bodies in the U.S., Canada, Japan, Europe and other countries will move quickly to approve national versions of IEC 80601-2-77, thereby facilitating the eventual adoption of the requirements of the standard by national regulators. The adoption of a version of the standard in the European Union (EU) is likely to take longer, due to a backlog in standards awaiting review under the EU's new Medical Device Regulation (MDR) and In-Vitro Diagnostic Device Regulation (IVDR).

At the same time, the development of IEC 80601-2-77 involved extensive collaboration over an extended period between regulators, medical device experts and industry representatives from countries around the world, including all of the key medical device markets. As such, there is already a widespread general awareness regarding the requirements of the standard among industry professionals. Even though regulatory approval in accordance with the requirements of IEC 80601-2-77 may not be required for some time, this general awareness of the standard is likely to facilitate the rapid acceptance of its requirements among many RAS systems and equipment manufacturers, who will consider the requirements of IEC 80601-2-77 in the development of new RAS systems and equipment. In an increasingly dynamic market, IEC 80601-2-77-compliant RAS systems and equipment will likely enjoy an important competitive advantage.



Summary and Conclusion



The introduction of IEC 80601-2-77 fills an important gap in the requirements applicable to RAS systems and equipment by addressing the unique characteristics and safety considerations applicable to these innovative devices. RAS systems and equipment that have been evaluated for compliance with the requirements of the standard will now represent the state-of-the-art in the safety of robotic surgical technologies and are likely to contribute to further reductions in the instances of device malfunction or patient injury. Further, RAS systems and equipment that have been IEC 80601-2-77 certified will help provide assurances to both healthcare providers and patients that the RAS system or equipment being used has been evaluated in accordance with the most rigorous requirements currently available.

UL's technical team has extensive expertise in medical device safety and has been actively involved in the development of medical device standards, including IEC 80601-2-77. UL is also a leading National Certification Body (NCB) under the International Electrotechnical Commission for Electrical Equipment (IECEE) CB Scheme for Medical Equipment, and a CB test report and certification issued by UL can greatly facilitate recognition by regulatory approval authorities in IECEE member countries.

For more information about UL's testing and certification services and the challenges of IEC 80601-2-77, email medical.inquiry@ul.com or visit UL.com/healthcare.

End Notes

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