# Safety of Surgical Robots and IEC 80601-2-77: The First International Standard for Surgical Robots

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*Abstract: A new standard IEC 80601-2-77 will be issued to establish safety requirements for surgical robots under regulatory control. A new term Robotically Assisted Surgical Equipment (RASE) is introduced to cover a wide variety of mechanical structures, control algorithms, human-machine interface and intended surgical procedures. This article is to introduce the key ideas of this standard, the scope, to what extent this standard will be applicable and some of the specific requirements. The future of surgical robot safety, including the emerging autonomy is also mentioned.*

*Keywords: robot safety; medical device safety; invasiveness; robotically assisted surgical equipment; autonomy*

## 1 Introduction

IEC (the International Electrotechnical Commission) and ISO (International Organization for Standardization) are currently preparing to publish a new safety standard for surgical robots, IEC 80601-2-77. It is expected to be issued in 2019. Since it is the first safety standard, particularly applicable to surgical robots, and it is expected to be a mandatory requirement in many nations and regions, knowing it will benefit study and development of surgical robots. This paper will provide the key ideas of this standard, the extent of the scope, and some of requirements. Though the author is appointed as the project leader of the joint working group (JWG 35) for this development, this paper does not represent the opinion of the working group, IEC or ISO. Correspondingly, this paper is written based on the draft of the standard.

# 2    Robot Safety and Safety of Medical Robots

Before discussing the standard for surgical robots, we review robot safety in Section 2.1 followed by safety of medical robots in Section 2.2.

## 2.1    Safety of (Traditional) Robots and Personal Care Robots

Here we define 'medical robot' as 'robot intended to be used as a medical device[1]'. Safety of medical robots can be divided into two parts, robot safety and medical device safety.

Robot safety is mainly related to mechanical hazards that a moving robot can pose. Such hazards include the collision between the robot and human, or the robot and other items including the robot itself. Other typical mechanical hazards are the trapping, crushing, shearing, pinching, and/or entanglement by the robot. The real baseline is that these hazards can occur under the hazardous situations including the unintended movement, the uncontrolled trajectory/speed, which the movement goes off from the expected one. Such situations can be critical when the safeguard functions do not work as expected or the human operators who are in charge of monitoring do not react properly.

These hazards and hazardous situations can commonly happen in many types of machines at home, in factory, in commerce and transportation, etc. In particular, factory machines mostly intend to realize automation. Uninterrupted and fast movement has been pursued and hazards enlarged. Factory safety has traditionally kept hazardous machines separated from human by covering or placing such machines in the work cells.

The same principle was applied to industrial robots. ISO 10218:1992, the initial issue of the safety standard for industrial robots (current latest issue is ISO 10218-1:2011) rigorously required the separation principle. Although it was revised to allow human-robot cooperative maneuver under certain restrictions, the separation principle is still valid.

However, certain robot applications intended robots to co-work with human, including service robots, personal care robots, and medical robots. In such cases the separation principle could not maintain. ISO 13482:2014 "Safety requirements for personal care robots" was the first standard for personal care robots. This standard assumes that a robot works with a human in its vicinity or in contact with the robot. Considering the nature of personal care robots, which are usually less powerful, less bulky than industrial robots and the intended use is often not for

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[1]     Medical robot is defined as "**robot** intended to be used as **medical electrical equipment** or **medical electrical system**" in IEC TR 60601-4-1. **Medical electrical equipment/systems** are terms roughly correspond to 'active medical devices and systems using electric energy.'

automation, this standard allows alternative risk mitigation measures other than the separation, such as reducing speed near human, etc.

When the discussion to develop ISO 13482 started in 2006, it was also recognized that medical robots could also apply similar risk mitigation measures. But it was concluded that medical robots should be covered by their own dedicated standards rather than the one for personal care robots, as medical robots need to address the medical device safety as well as the robot safety.

## 2.2    Safety of Medical Robots as Medical Devices

Medical robots are medical devices by definition. Medical robot safety is certainly different from the safety of other robots mainly in the following aspects.

- Patient safety: Patients are considered as lay persons - knowledge, education and training regarding the safety cannot be assumed. They are often vulnerable. In some cases, including surgery, they are anesthetized so that they cannot react to escape from hazards.

- Medical staff as contributors for safety: they are not lay persons. They can be assumed to receive training to use medical robots. This may increase the effectiveness of safety information as a risk mitigation measure. However, they are not experts of robotics and mechanical engineering.

- Invisible and insensible hazards: Some hazards, such as electric shock, toxicity of material, infection of microbe, radiation, etc., are invisible and insensible for human. When such hazards are found, they can be often already unacceptable in terms of safety. Preventing, minimizing or informing users about risks from such hazards are responsibility of manufacturers.

- Invasiveness: Surgical robots are invasive. It is a most significant difference from any other robots. Invasiveness can escalate the risk level. An adverse event that is not harmful at outside patient body can be fatal if it occurs inside patient's body.

A significant difference on the safety concerns between medical device and other products can be found in the requirements of the electric shock prevention. The medical electrical equipment standard IEC 60601-1 requires the leak current of the order of milli- to micro- ampere, whilst other safety standards set the allowance in the voltage of the order of 10 V.

# 3   Defining 'Surgical Robots'

Before discussing the standard for surgical robots, it is necessary to clarify the boundary of surgical robots for the purpose of the standard. In Section 3.1 we discuss possible factors that can define the boundary of surgical robots. Section 3.2 describes common aspects discussed in Section 3.1.

## 3.1    Boundary of 'Surgical Robots'

Probably robot-assisted minimally invasive surgery (RAMIS) is the most known and typical application of surgical robots. The most famous surgical robot for RAMIS is the da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA, USA). Although there have been several revisions of the da Vinci Surgical System in its history over 20 years, all of these are the master-slave manipulators that are totally controlled by the surgeon, in other words, the operator is in the control loop [1]. The system has a limited ability to optimize the movement such as the tremor cancellation, yet it has no automated or intelligent trajectory generation and motion control.

Computer-integrated surgery (CIS) is another well studied application of surgical robots. A typical example of CIS system is ROBODOC (currently renamed as TSolution One Surgical System by THINK Surgical Inc., Fremont, CA, USA) for orthopedic surgery. CIS uses digitized information about the patient's anatomy obtained from medical images. The trajectory is generated from the 3D information. The operator approves the trajectory then monitors the system correctly works.

Surgical robots have wide variety of mechanical structures, control algorithm, human-machine interface and intended surgical procedures [2]. JWG 35 initially investigated which types of medical devices should be covered by the standard to write, as well as what types of medical devices should be excluded. Most of the medical devices described in [2] are at the center of the definition, some are at the boundary, some are out of the boundary. Finding the boundary is not a trivial question. The meanings of terms 'surgical' and 'robot' are vague and understood differently by medical experts or stakeholders.

1) Term 'surgery'

Term surgery is differently used in different medical disciplines. A World Health Organization (WHO) document contains a working definition of surgery as "procedure conducted in the operating room involving the incision, excision, manipulation or suturing of tissue which usually requires regional or general anesthesia or profound sedation to control pain [3]". This definition was adopted in this standard with modification. Medical procedures on the boundary of surgery can be:

-   Medical treatments referred as intervention, e.g., vascular intervention

- Radiological treatments referred as radiosurgery

- Treatments by laser, ultrasound and other modes of physical energy

- Orthopedic treatments done without instruments, such as repositioning fractured bone or shoulder dislocation

- Invasive procedures not for treatment, such as biopsy

- Dental treatments by dentists

- Invasive cosmetic procedures, e.g., hair implantation [2], tattooing

2) Term 'robot'

Robot is defined as "programmed actuated mechanism with a degree of autonomy, moving within its environment, to perform intended tasks"[2]. This definition is based on general perception about robot, that includes i) mechanisms mimicking arms, fingers, legs, or other human body parts, and/or ii) something intelligent that controls adaptive motion. The term 'a degree of autonomy' is not defined in ISO 8373. We will discuss this term in Section 6.

Table 1

Modes of surgical invasiveness

| Modes of invasiveness | Examples |
|---|---|
| 1) Energy only administered through the surface of patient body (no incision) | - radiosurgery<br>- focused ultrasound<br>- shoulder relocation |
| 2) Invasion into patient body from the surface of patient body | - open surgeries<br>- bone fixation using screws<br>- bone milling<br>- laparoscopic surgery (minimally invasive surgery)<br>- vascular intervention |
| 3) Energy administered via the inner surface of natural orifice | - focused ultrasound via endoscope |
| 4) Invasion into patient body via the inner surface of natural orifice | - endomucosal resection (EMR)<br>- dental milling |

3) Robots used in surgery are not always surgical robots

Medical devices that fall into the definition of robot certainly exist in modern surgeries; for instance, robot-shape actuated operating table [ 4 ], robotized microscope [5], etc. However, these two are usually not considered as surgical robots. These are not surgical instruments, and do not have an invasive part.

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[2] It is a working definition by ISO TC 299 which will be adopted in the future revision of ISO 8373.

4) Modes of invasiveness

Invasiveness of surgeries differ by surgeries. Table 1 shows the various modes of surgical invasiveness considering the boundary applications listed previously. The resulting 'boundary' set in this standard will be discussed in Section 4.3.

## 3.2    Common Safety Aspects of Surgical Robots

Although possible applications of robotic technology can be broad, JWG 35 identified two common characteristics in terms of the safety.

1)    Surgical robots are to hold and/or maneuver different types of tools attached to the end of robotic body. In robotics term, the tools are the end effectors. For surgical robots, the tools are surgical instruments. Surgical instruments can be forceps, mono- and bi-polar blade, milling drill, endoscope, laser fiber, ultrasound transducer, etc. Robotic body facilitates placement and manipulation of the surgical instruments. Surgical instruments are usually detachable for the purpose of tool exchange and sterilization.

2)    Surgical robots are used with other medical devices. Electrical, thermal, mechanical and other functional connections between the robot and these devices, intended or unintended, can occur by collision or contact between them. Such functional connections can be sources of hazards, even though such devices individually satisfy necessary risk mitigation measures.

# 4    Structure of IEC 80601-2-77

IEC 80601-2-77 is being developed under a joint effort of IEC and ISO, where IEC technical committee (TC) 62 is for medical electrical equipment and ISO TC 299 is for robotics. The joint working group (JWG) 35 was organized in 2015 as a liaison group of the both organizations. It will be a part of IEC 60601 safety standards series, because when a surgical robot is marketed, it is regulated as a medical electrical equipment rather than a robot in most of nations and regions. This standard is written as the differences from IEC 60601-1 general standard for safety of medical electrical equipment.

Since IEC 60601-1 refers to ISO 14971 risk management standard for medical device, the risk management process for surgical robot is also harmonized to ISO 14971.

## 4.1    Issues Covered by IEC 80601-2-77

Based on these considerations, this standard covers the following issues:

−    Issues related to robot movement e.g., quality of motion control, emergency management

−    Issues related to electrical and other functional connections with other objects in the patient environment, that can generate and transfer harmful energy e.g., leak current, excessive heat

−    Issues related to the effect of unintended collision with other objects such as robot itself, surgical instruments, other medical devices, patient body and medical staff working nearby the robot

−    Other general requirements to the robot hardware and software, e.g., structural strength, the biological safety, the usability engineering, software integrity, etc.

Surgical instruments and other medical devices usually have own safety standards to follow. Hence this standard uses these other standards to cover of the safety of these parts. For instance, endoscopic equipment is covered by IEC 60601-2-18, high frequency (HF) surgical equipment by IEC 60601-2-2, ultrasound imaging equipment by IEC 60601-2-37, etc.

## 4.2    Key Definitions

The key definitions of this standard are the following two terms. Bold types represent defined terms in this standard and IEC 60601-1.

**Robotically assisted surgical equipment, RASE**

**Medical electrical equipment** that incorporates **PEMS**[3] actuated mechanism intended to facilitate the placement or manipulation of **robotic surgical instrument**

**Robotic surgical instrument**

**Invasive device** with **applied part**, intended to be manipulated by **RASE** to perform tasks in **surgery**

A new term **RASE** was introduced. This standard intentionally avoids using the term surgical robot from a few reasons, mainly to avoid possible confusion and to emphasize that it is to assist surgeons, not to replace them by automation. The definition does not refer to specific mechanical structures, means of actuation, nor the control algorithms.

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[3] programmable electrical medical system

## 4.3   Scope

The definition of robotic surgical instrument limits the scope of this standard to invasive devices. The following cases are not considered as invasive;

- Cases that energy only is administered to the patient, such as percutaneous high intensity ultrasound [6], bone fracture relocation device attached to the skin surface [7], robotic radiotherapy equipment [8].

- Cases that are not intended to touch the patient body, such as frameless stereotactic device to display the orientation of the target [9].

Therefore, robots with such devices are not in the scope of this standard. The same device can be in the scope when they are incorporated in or connected to the invasive part. For example, if a high intensity ultrasound transducer is attached to a robotic endoscope to be inserted into patient's body, or if a bone fracture relocation device is attached to the patient by invasive screws [10], they are considered as within the scope of this standard.

Table 2

Scope applicability of robotic systems

| Modes of invasiveness | | Scope | Examples (mentioned in [2] otherwise indicated) |
|---|---|---|---|
| 0) | No robotic surgical instrument attached to actuated mechanism, or no applied part exists | No | - robotized microscope [5] [a]<br>- scrub nurse robot [b]<br>- NavioPFS [c]<br>- ROSA, Neuromate [9] [d] |
| 1) | Energy only administered to surface of patient body (no incision) | No | - Cyberknife [e]<br>- fracture relocation device [7] [f] |
| 2) | Invasion into patient body from surface of patient body | Yes | - Artas<br>- bone fixation using screws [11]<br>- ROBODOC, MAKO<br>- da Vinci Surgical System<br>- CorPath, Sensei |
| 3) | Energy administered via inner surface of natural orifice | Yes | (not realized) |
| 4) | Invasion into patient body via inner surface of natural orifice | Yes | - Neocis dental robot [4]<br>- robotic endoscopic tools for EMR (not realized) |

a: Robot without a surgical instrument.

b: Robot with a surgical instrument, lacking an applied part.

c: An applied part intelligently controlled, but lacking placement or manipulation by actuated mechanism.

    d: Robot with a surgical instrument, lacking an applied part. However, if the manufacturer wants, this standard is applicable, because the pointer tip enters the surgical field and it can accidentally hit or touch the patient.

    e: Energy only administered, covered by IEC 60601-2-68.

    f: Attached to the skin without incision.

Scope applicability of some systems in [2] and other literature are shown in Table 2, with classification based on the modes of invasiveness in Table 1.

# 5   Safety Requirements

**Essential performance** is a requirement of the performance which is necessary to achieve the safety. This standard describes the following requirements as the RASE's essential performance.

- To ensure there is no unacceptable risk if information essential to perform surgery is degraded (information integrity).

- To ensure there is no unacceptable risk if motion control of the robotic surgical instrument has performance degradation (integrity of motion control).

Figure 1 illustrates the relation of these essential performance requirements. These are considered as a loop of interaction between the surgeon and patient, where the RASE acts as the interface between them. In actual implementation, the essential performance requirements will vary by implementation. However, these are considered as common in typical RASE surgeries.

The requirement of integrity of motion control can be different by the types of robot control. As discussed in Section 2.1, mechanical hazards can occur when there is hazardous situation including:

- Unintended movement initiated

- Trajectory goes off from the expected one, or the speed is out of control

- Safeguard functions do not work or the human operators who are in charge of monitoring do not react properly.

In case of RAMIS systems, operators are responsible of continuously monitoring the movement, and the RASE is responsible to stop quickly when an operator requested.
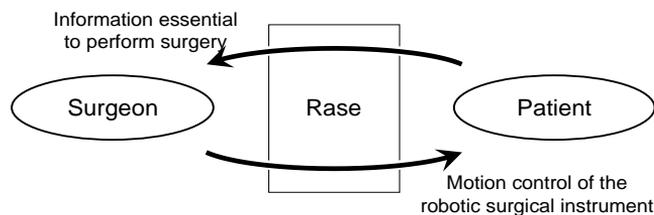
Figure 1

Example of the essential performance of RASE

Some of major particular requirements in this standard are

- Conditions to constitute the 'continuous activation' (the main surgeon continuously monitors the movement of the RASE and reacts to reduce the risk when a hazardous situation is expected) is extended to allow other persons (e.g., the assistant surgeon or nurses) can also take the role of monitoring and reacting. IEC 60601-1 allows the continuous activation as a risk control measure against the trapping zone hazards. However, in case of endoscopic surgery, the main surgeon needs to concentrate on watching the endoscopic view and he/she cannot watch the robot's movement outside the patient body. Other staff can monitor and react to the hazardous situation outside the patient body.

- Interaction between surgical instruments (including those of RASE itself) shall be considered in the risk management. In particular, HF surgical equipment can be eventually hazardous by the capacitive coupling leakage and electromagnetic disturbance to the robot control system.

- Narrow size robotic surgical instruments can be allowed under certain condition. IEC 60601-1 requires keeping the minimum creepage distance and air clearances between conductive parts within several millimeters. Following this requirement can end up the size of surgical instruments impractically large for endoscopic surgery. This standard allows a risk management may relax the requirement to enable thin surgical instruments.

- If an equipment drape, the drape to cover a RASE for sterilization and other purposes, is necessary, its effects shall be considered in the risk management. Such drape may be used to maintain the sterility, including prevention of the contamination by liquid entering the sterile field. The drape should be durable against mechanical movement. Also, side effects of the drape should be considered, for example, the temperature of RASE can escalate when covered by the drape.

- Attachment of robotic surgical instruments and RASE, by means of **mechanical interface**, shall be tested so that the strength of fixation is appropriate. Design of mechanical interface is one of the critical engineering

points. Figure 2 illustrates relationship between surgical instruments and the robot body by means of mechanical interface.

This standard does not include the following requirements:

- Requirements to robotic surgical instruments that have own particular standards such as a HF surgical equipment or an endoscope

- Testing methods of mechanical performance, e.g., the accuracy and the repeatability

- Requirements specific to image guidance

- Requirements specific to RASE with some autonomy

Autonomous surgical robots, or surgical robots with artificial intelligence, are recent topics [12, 13], although we need more experience before introducing requirements in a mandatory standard.
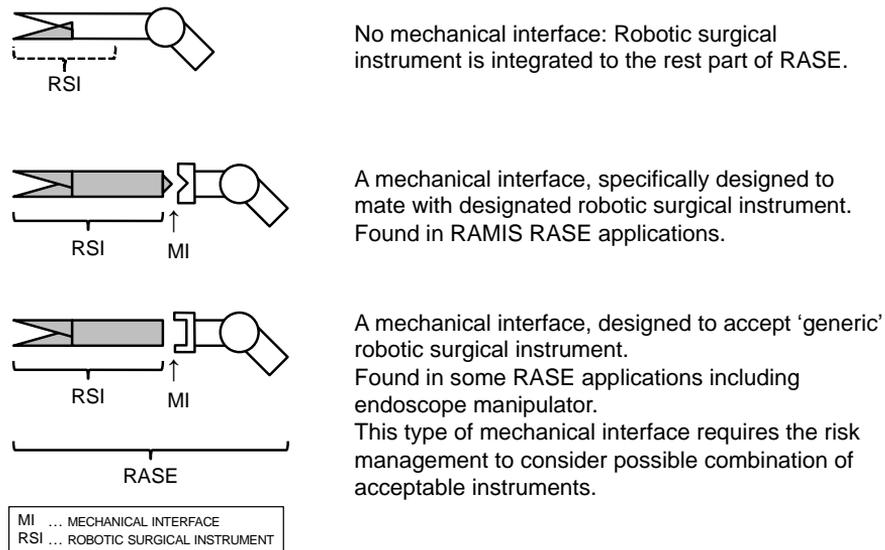


Figure 2

Types of mechanical interface

# 6   Future of RASE – Real Surgical 'Robot'?

RASE is not a robot if autonomy is the essential characteristics of robot. However, applications of machine learning technology to surgical procedures are under the horizon.

A technical report, which is not a mandatory document, IEC TR 60601-4-1 was published in May 2017 [16]. It is the first ISO and IEC document about autonomy of medical electrical equipment and systems. This technical report mainly provides the following:

- The definition of terms autonomy, degree of autonomy (DoA)

- Three methods of estimation of DoA

- Relationship between DoA and risk, basic safety, and essential performance;

- Usability engineering considerations for medical electrical equipment with higher DoA

- Operator's situation awareness

- Examples of DoA in medical electrical equipment, estimation of DoA, and risk assessment

The technical report does *not* provide the following:

- Risk level determined by DoA

- Conversion of DoA classified by one method to another

One of this technical report's most important message is that the degree of autonomy is not linked to the degree of the risk: the higher DoA does not necessarily mean the higher risk, and the lower DoA does not necessarily mean the lower risk. Another finding of the technical note is the fact that DoA does not introduce a new hazard, but it can introduce new sources of hazardous situation. Motivations and benefits to adopt DoA can be various; DoA may be applied to improve the usability of a medical device – but DoA can unintentionally complicate the scenarios resulting in new hazardous situations, such as *loss of operator's situation awareness*. Aviation industry already experienced fatal accidents related to the loss of situation awareness. Medical device industry can face this issue when the DoA goes high, possibly by introduction of artificial intelligence.

**Conclusion**

A new standard IEC 80601-2-77 will be published in 2019. It is a particular standard of IEC 60601-1 series, safety standard for medical electrical equipment. Safety requirements are introduced with respect to both the robot safety and the medical device safety. The robot safety is mainly about the mechanical hazards and the medical device safety is mainly about the patient safety, invisible and insensible hazards, and the risk management of invasiveness.

The scope of this standard is also derived from these safety concerns. Invasiveness is the most significant difference of surgical robot from other robots. This paper classified several examples of surgical robot systems by the mode of invasiveness if they are within the scope or not. Conversely, the variation of surgical

instruments, the mechanical structures, the means of actuation, the control algorithms, or the intended surgical procedures are not the determinant of the scope.

Although the degree of autonomy, that characterizes robots being intelligent, and the situation awareness are not included in the current revision, these will be key concerns in this field in the future.

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