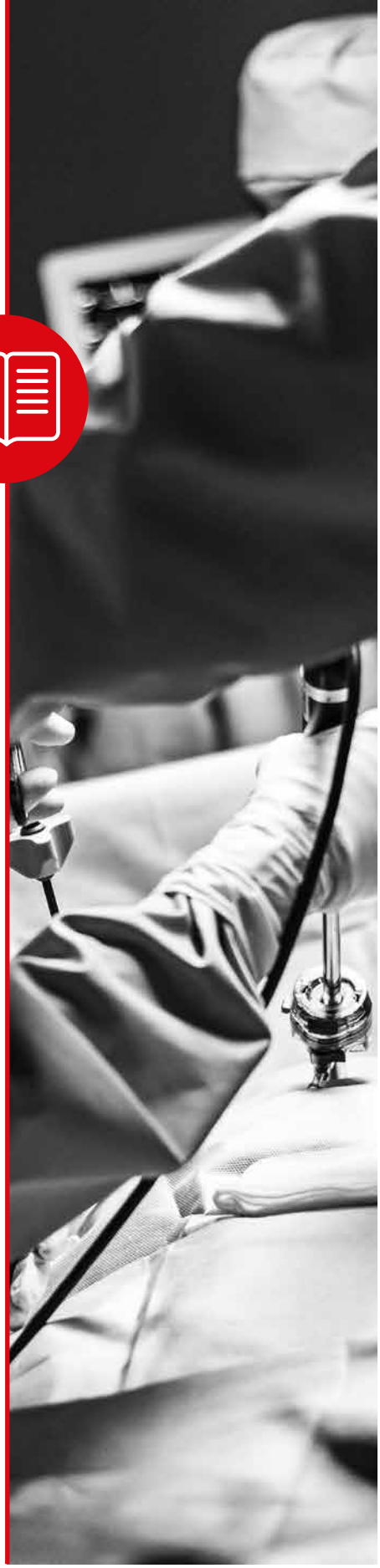
WHITE PAPER

MANAGING RISK IN MEDICAL CONNECTORS

EDITION 1.2 | FEBRUARY 2018



fischer® CONNECTORS

REIMAGINING CONNECTIVITY TOGETHER

MANAGING RISK IN MEDICAL CONNECTORS

FDA IMPLEMENTATION OF IEC 60601-1 ELEVATES THE RESPONSIBILITIES OF DEVICE DEVELOPERS TO NEW LEVELS

This paper was written to educate those involved with the design and manufacture of medical devices about some important changes that have been enacted by the FDA. Understanding the implications of these new regulations will enable manufacturers to adjust their business plans and adapt accordingly. In short, manufacturers now bear responsibility for conducting risk management processes in compliance with applicable standards. It is our belief that working with qualified suppliers will improve a manufacturers' ability to comply with these new quality systems and risk management requirements and help them maintain their competitive edge.

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Patrick Kinyanjui is a Senior Engineer at Fischer Connectors Inc., an ISO 13485:2016 certified supplier with a nearly 60-year history of working with medical product manufacturers to develop and produce innovative electronic connectors and cabling for use in medical applications. He has extensive experience in electro-mechanical design and manufacturing. He has been in the connector and cable industry for over 10 years, working with a wide range of military and medical companies to determine the best connector and cable solution for their particular applications.

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INTRODUCTION

The FDA has implemented a challenging new standard that affects all medical device manufacturers seeking to market medical electrical equipment in the United States. This article provides an overview of the foundations and evolution of medical device regulation, leading up to a discussion of the new philosophy encompassed by the 3rd edition of the International Electrotechnical Commission's general standard for assessing the safety of medical devices, IEC 60601-1.

1. A NEW ERA FOR MEDICAL DEVICES

Every day, medical device manufacturers are getting better and better at managing risk. They know they have to. Changes have been introduced into international regulatory schemes that impact device design all the way down to the component level. Perhaps the most fundamental and wide-ranging of these has been the emergence and adoption of formal risk management methodologies as an integral part of the regulatory process.

ISO 14971, Application of Risk Management to Medical Devices, is acknowledged as the international standard for applying the principles of risk management to the realm of medical devices. It has become an essential tool for satisfying regulatory requirements in most major markets, including the US, Australia, Canada, the EU, and Japan. It has also been formally recognized by the FDA as a means of conducting risk management activities and documenting their results.

As a result of new standards now in place globally, manufacturers are looking closer at the risks of using every component and material used in their device, and documenting those risks for FDA inspection. This new standard has altered product selection methods and requirements of medical device developers, the professionals who are most often responsible for identifying electronic components — including connectors and cabling.

2. FDA AND CE MARKING: RISK-BASED DEVICE CLASSIFICATION

Through the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act, the United States became the first nation to establish a distinct regulatory regime for medical devices and diagnostics [1]. From the very beginning, U.S. regulations acknowledged differences in the type and level of risk represented by various medical technologies, and required FDA's Center for Devices and Radiological Health (CDRH) to shape the regulatory processes for permitting devices to enter the marketplace in accordance with the risk of the device in use. The general outline of that scheme is shown here:

- Class I is associated with the lowest risk devices, for which the agency requires compliance with general controls that include standards for manufacturing, labeling, postmarket surveillance, and adverse event reporting. Most Class I devices do not undergo any formal FDA review prior to being marketed.

- Class II devices carry potentially higher risk, for which general controls are considered insufficient. These devices are associated with special controls, which may include a declaration of conformity with internationally accepted performance standards. Class II devices also generally require FDA clearance, which is obtained via a premarket notification (510(k)) submission demonstrating the substantial equivalence of the new device to a specified predicate device already on the market.

- Class III devices are those judged to pose the highest potential risk. Implantable devices, some diagnostic devices, and monitoring devices fall under Class III. These devices may sustain or support life or may carry a high risk of adverse events. The types of controls used for Class I and Class II devices are considered insufficient to demonstrate safety and efficacy; therefore, most Class III devices require FDA premarket approval (PMA) prior to being released. Approval via the PMA pathway typically requires clinical data demonstrating the safety and efficacy of the device for specified clinical applications in its intended patient population.

In the European Union, medical products are regulated through three 'new approach' directives that were enacted during the 1990s[2, 3, 4]. To receive the CE mark that permits entry to the European market, products must satisfy the 'essential requirements' established by the applicable directive. Like the FDA's classification system, the CE marking system also relies on a risk-stratified approach, applying such criteria as the duration of body contact, invasive character, use of an energy source, effect on the central circulation or nervous system, or diagnostic impact, to determine the level of risk associated with a particular device.

3. THE NEXT BIG THING: QUALITY SYSTEMS

Closely related to the use of risk-based assessments for premarket review was the gradual adoption of a quality systems approach for regulating the full life cycle of medical products, in both the United States and Europe. Shown here are some of the key milestones in this process, the fullest expression of which is the ISO 13485, the internationally recognized quality systems standard for medical device manufacturers[5].

- FDA Current Good Manufacturing Practices Regulation (CGMP): Prescribed the facilities, methods, and controls to be used in the manufacture, packaging, and storage of medical devices[6].

- Quality Management Systems — Requirements (ISO 9001): Established an internationally recognized standard for certifying a company's quality management system[7].

- FDA Quality System Regulation (1996): Incorporated the quality systems approach of ISO 9001 into FDA regulation[8].

- Medical Devices: Quality Management Systems — Requirements for Regulatory Purposes (ISO 13485): Established requirements for a comprehensive quality management system specific to the design and manufacture of medical devices[9].

Certification to ISO 13485 is the first step toward meeting the EU's CE marking requirements, and under some circumstances can also be used to satisfy some FDA requirements. Benefits of ISO 13485 certification include improved operations, more-consistent processes, enhanced market expansion capability, and a strengthened competitive position. To extend their quality systems compliance, many medical device manufacturers request that their suppliers also become ISO 13485 certified.

4. RISK MANAGEMENT

Over the past decade, many changes have been introduced to national and international regulatory schemes. But perhaps the most fundamental and wide-ranging of these has been the emergence and adoption of formal risk management methodologies as an integral part of the regulatory process. ISO 14971, Application of Risk Management to Medical Devices, is acknowledged as the only international standard for applying the principles of risk management to the realm of medical devices [10]. It has become an essential tool for satisfying regulatory requirements in most major markets, including Australia, Canada, the EU, and Japan. It has also been formally recognized by the FDA as a means of conducting risk management activities and documenting their results.

Keeping in mind the converging regulatory trends of quality systems management and risk management that are already affecting the world of medical devices, we can now turn our attention to IEC 60601-1, the latest expression of these trends, which has already become mandatory in the EU and Canada, and is in the process of being implemented worldwide.

5. IEC 60601-1: THE NEW APPROACH

The International Electrotechnical Commission (Geneva) first published its series of technical standards for the safety and effectiveness of medical electrical equipment in 1977. Since then, the IEC 60601 standards have been updated and restructured, and now encompass the general standard, about 10 collateral standards, and about 60 particular standards.

The general standard of the IEC 60601 series — Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1) — provides a widely accepted benchmark for medical electrical equipment [11]. Many companies view compliance with IEC 60601-1 as a de facto requirement for most markets. This cornerstone document applies to the basic safety and essential performance of medical electrical equipment, and addresses many of the risks associated with such equipment. The standard is complex, multifaceted, and sometimes confusing, but not overwhelming.

[1] *Medical Device Amendments of 1976.*

[2] *Active Implantable Medical Devices Directive (1990).*

[3] *Medical Devices Directive (1993).*

[4] *In Vitro Diagnostics Directive (1998).*

[5] *Medical Devices: Quality Management Systems — Requirements for Regulatory Purposes (ISO 13485).*

[6] *FDA Good Manufacturing Practices Regulation (1978).*

[7] *Quality Management Systems — Requirements (ISO 9001).*

[8] *FDA Quality System Regulation (1996).*

[9] *Medical Devices: Quality Management Systems — Requirements for Regulatory Purposes (ISO 13485).*

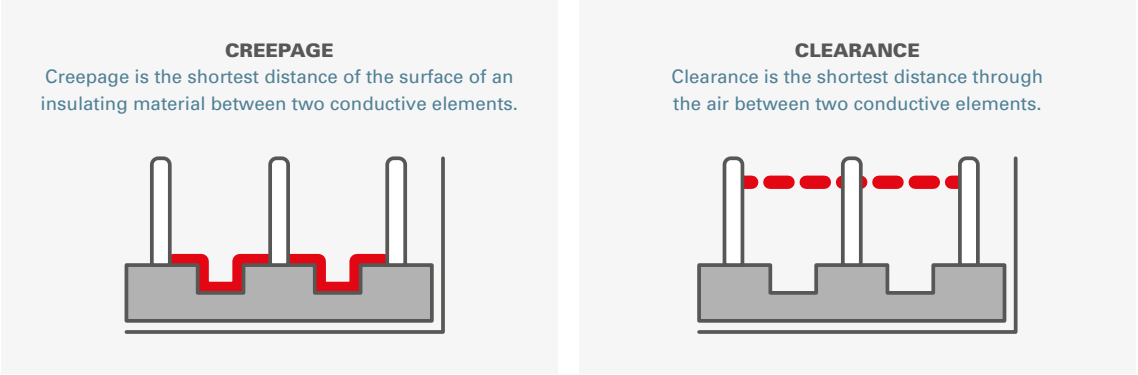
[10] *Application of Risk Management to Medical Devices (ISO 14971).*

[11] *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1).*

By far the biggest change that is brought about by the latest edition of IEC 60601-1 is the philosophical shift to a risk management approach, bringing the standard into alignment with the industry's broad regulatory trends over the past decade. Manufacturers experience this shift in some of the following ways:

- A product's essential performance characteristics must be examined in relation to criteria needed to avoid unacceptable risk.
- The manufacturer's process for complying with IEC 60601-1 must itself be in compliance with ISO 14971.
- A risk management file is required for every product.

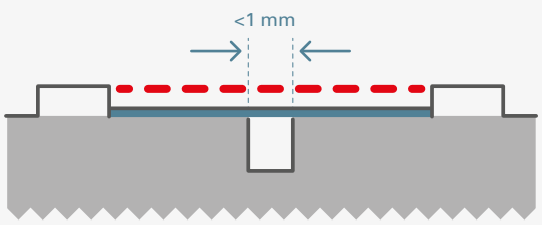
In addition to adopting a risk management approach to device development, the 3rd edition of IEC 60601-1 also revises technical requirements in areas ranging from mechanical hazards such as crushing or instability to the application of alarm systems. Virtually every one of the standard's sections incorporates subsections that have special importance for the field of medical connectors 12. An example of the standard's new and important technical requirements for connectors can be seen if we drill down even further. Illustrated here are the standard's definitions and new requirements for creepage distance and air clearance (Subsection 8.9), which are essential for distinguishing the means of patient protection (MOPP) from the means of operator protection (MOOP) required for a particular device.



Adapted from IEC 60664-1, definition 1.3.2.

To comply with the requirements of the new edition of IEC 60601-1, manufacturers need to assess how creepage and air clearance in their connectors affects the risks associated with their products. And to accomplish that, developers first need to know how creepage and air clearance are properly measured. Shown here are a couple examples from the IEC rules that are used to clarify the way that creepage and air clearance are measured under the new requirements of IEC 60601-1 (3rd ed.). Here you see that when the gap is less than 1 mm, both creepage distance and air clearance are measured point-to-point, as if the gap didn't exist. If the gap is equal to or greater than 1mm, air clearance is still measured across the gap, but creepage must be measured along the contour of the groove.

EXAMPLE 1



IEC 2405/05

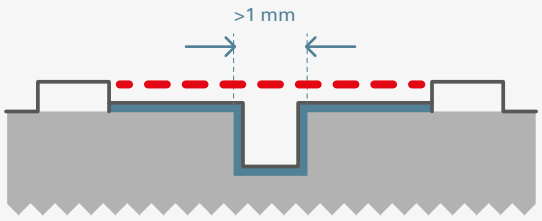
Condition

Path under consideration includes a parallel- or converging-sided groove of any depth with a width less than 1mm

Rule

Creepage Distance and Air Clearance are measured directly across the groove as shown.

EXAMPLE 2



IEC 2407/05

Condition

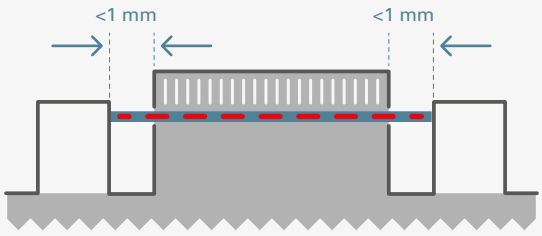
Path under consideration includes a parallel-sided groove of any depth and equal to or more than 1mm.

Rule

Air Clearance is in the 'line of sight' distance. Creepage Distance path follows the contour of the groove.

Here's another example, showing an application for uncemented joints, where both creepage and air clearance are measured by line of sight.

EXAMPLE 3



IEC 2410/05

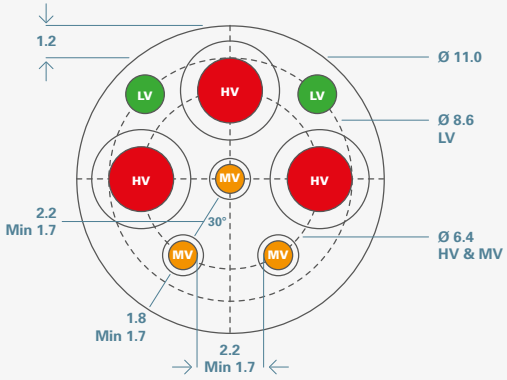
Condition

Path under consideration includes an uncemented joint with grooves less than 1mm wide on each side.

Rule

Creepage Distance and Air Clearance are in the 'line of sight' distance shown.

When product developers understand the rules in the new edition of IEC 60601-1 regarding creepage and air clearance, they can readily specify connectors that comply with technical requirements, satisfy the essential performance characteristics required for their device, and eliminate unacceptable risks related to the use of the device. The variable voltage and signal requirements shown here are typical of many connectors.



FISCHER CONNECTORS CAN SUPPLY SUCH A DESIGN FROM ITS CORE 104 OR ULTIMATE SERIES OF CONNECTORS.

The tables of creepage and air clearance values provided in the 3rd edition of IEC 60601-1 are complex, so developers should work closely with their supplier to make sure they are designing not only for function, but for compliance. Qualified component suppliers should work continuously with developers to make sure they have the proper specifications for their connectors and cables. But it remains the manufacturers' responsibility to define the essential performance requirements and related technical specifications for their products so that the risk assessment profile is accurate 13.

Another example of the standard's technical requirements important for connectors and cabling can be seen in the subsections of Section 6: Classification of medical electrical equipment and medical electrical systems, which provide requirements for sterilization methods (Subsection 6.4). Engineers should be able to provide manufacturers with detailed guidance about these methods as well as a range of options suitable for a variety of medical device applications.

Sterilization Methods

Method	Most Common	Notes	Applications
High Temperature	Steam Autoclave	High Pressure: 15-30 psi Short sterilization time: 3-30 min. cycle	Most surgical equipment: hand pieces, remotes, etc.
Chemical	Ethylene Oxide (EtO)	Low temperature (50-60°C Longer cycle time Very hazardous to staff	Heat or moisture sensitive devices Must be Tyvek packaged (or equivalent) Disposable/plastic devices, single use instruments
	Sterrad	Low temperature H2O2 plasma (45-50°C)	Heat-sensitive equipment: e.g. endoscopic instruments
	Steris	Low temperature Uses proprietary sterilant formulation Processing time: ~12min.	Heat-sensitive equipment: e.g. endoscopic instruments
	CidexOPA	High-level disinfectant	Surgical cameras (endoscopes)
Radiation	Gamma	Low temperature, high sterilization time Usually performed after packaging	Plastic or tubing products

6. CONCLUSION

In today's increasingly IT-enabled and interoperable world of medical devices, electrical connectors are playing a vital role in advancing product capabilities. They are also an important element that must be addressed whenever a manufacturer develops a risk assessment profile for a new or updated device.

Worldwide trends in medical device regulation favor the convergence of risk stratification, quality systems, and risk management approaches. Manufacturers will bear responsibility for conducting risk management processes in compliance with applicable standards. Working with qualified suppliers will facilitate manufacturers' compliance with quality systems and risk management requirements.

APPENDIX 1 - GENERAL REQUIREMENTS

The general standard of the IEC 60601 series — Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1) — applies to the basic safety and essential performance of medical electrical equipment and medical electrical systems. Major sections of the standard are as follows:

1. Scope, object, and related standards
2. Normative references
3. Terminology and definitions
4. General requirements
5. General requirements for testing ME equipment
6. Classification of ME equipment and ME systems
7. ME equipment identification, marking, and documents
8. Protection against electrical hazards from ME equipment
9. Protection against mechanical hazards of ME equipment and ME systems
10. Protection against unwanted and excessive radiation hazards
11. Protection against excessive temperatures and other hazards
12. Accuracy of controls and instruments and protection against hazardous outputs
13. Hazardous situations and fault conditions
14. Programmable electrical medical systems 15. Construction of ME equipment
16. ME systems
17. Electromagnetic compatibility of ME equipment and ME systems

APPENDIX 2 - DEFINING CONNECTOR SPECIFICATIONS

Following is a list of the types of technical information that manufacturers should be prepared to provide to their connector and assembly partner. Filling in as many of these blanks as possible — even before contacting the connector specialist — can facilitate design and selection of appropriate connectors and cabling, and help to speed the manufacturer's development processes.

1. Number of contacts needed
2. Voltage and current ratings of each contact
3. Known creepage and air clearance requirements for each contact
4. Environmental requirements (wipe down or sterilization requirements)
5. Material requirements and use (metal versus plastic, reusable versus disposable)
6. Tests to be performed on the completed assembly
7. Cable requirements for signal (twisted pairs or coax) and power (high AWG)

ABOUT FISCHER CONNECTORS

Fischer Connectors has been designing, manufacturing and distributing high-performance connectors and cable assembly solutions for more than 60 years. Known for their reliability, precision and resistance to demanding and harsh environments, Fischer Connectors' products are commonly used in fields requiring faultless quality, such as medical equipment, industrial instrumentation, measuring and testing devices, broadcast, telecommunication and military forces worldwide.

Primary design and manufacturing facilities are located in Saint-Prex, Switzerland, with subsidiaries and distributors located worldwide.

Fischer® CONNECTORS

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