ACTIVE IMPLANTABLE MEDICAL DEVICES
EVALUATION & TESTING REQUIREMENTS

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INTRODUCTION

Active implantable medical devices (AIMDs) are complex products subject to rigorous regulatory standards by authorities across the globe. With both implantable and non-implantable factors, as well as EMC and wireless considerations, manufacturers have a lengthy list of standards to know and to which they must comply. It is important to know which standards and requirements apply to a given product and to consider them throughout the production process to get a compliant, marketable product to the industry quickly and efficiently.

This paper provides an overview of the various requirements for AIMDs, and explores the benefits of conducting all testing simultaneously, throughout the design and production process.
AIMDs: AN OVERVIEW

AIMDs are medical devices that: 1) rely on a source of electrical energy or any source of power for functioning, other than what is directly generated by the human body or gravity; and 2) are totally or partially introduced inside the human body and then remain in place. There is a wide range of AIMDs used in modern medicine, including such items as pacemakers, defibrillators, implantable infusion pumps, cochlear implants and neurostimulators.

Given their nature, AIMDs are one of the highest risk categories of medical devices. As such, they are subject to stringent regulatory controls and standards that must be met before they can enter the marketplace. These regulations apply to multiple aspects of the AIMD and its various components.

Most AIMDs consist of both the non-implantable supporting equipment—such as battery packs, implant kits, software applications and controllers—as well as the implantable device that is inserted into the body. Both the non-implantable and implantable components require testing and evaluation to medical regulatory standards. For many devices, electromagnetic compatibility (EMC) and wireless considerations must also be taken into account. It is important for manufacturers to be familiar with these aspects and the requirements for each.
IMPLANTABLE DEVICE TESTING

The ISO 14708 and EN 45502 family of standards, “Implants for Surgery – Active Implantable Medical Devices,” applies to the implantable device itself. The standard has seven parts. Devices will not necessarily need to comply with the entirety of this standard. Compliance will depend on the product type, as certain sections only apply to certain types of products. For example, one part is specific to pacemakers, while another is for infusion pumps.

The seven parts of the ISO14708 standard are:

- **Part 1.** This specifies the general requirements for AIMDs to deliver basic assurance of safety for patients and users. It includes the obligations for product marking and information/documentation that manufacturers must provide to patients and users to minimize possible risks related to product misuse.
- **Part 2.** This part covers specific safety and assurance, marking and packaging requirements for cardiac pacemakers.
- **Part 3.** This part covers requirements for implantable neurostimulators, or devices intended for electrical stimulation of the central or peripheral nervous system.
- **Part 4.** This part applies to specific requirements for implantable infusion pumps, devices intended to deliver medicinal substances to site-specific locations within the human body. It covers safety requirements that need to be illustrated via type testing of samples.
- **Part 5.** This part applies to circulatory support devices. It specifies type tests, animal studies and clinical evaluation requirements required to illustrate compliance with the standard.
- **Part 6.** This part addresses specific requirements for AIMDs intended to treat tachyarrhythmia, including implantable defibrillators.
- **Part 7.** This part specifies requirements applicable to AIMDs intended to treat hearing impairment via electrical stimulation of the auditory pathways, also known as cochlear implant systems. It includes type test specifications for these products.

The EN45502 family has a general standard and three particular standards, they are:

- **EN45502-1** General requirements for safety, marking and for information to be provided by the manufacturer
- **EN45502-2-1** Particular requirements for active implantable medical devices intended to treat Bradyarrhythmia (Cardiac Pacemakers)
- **EN45502-2-2** Particular requirements for active implantable medical devices intended to treat Tachyarrhythmia (includes implantable defibrillators)
- **EN45502-2-3** Particular requirements for cochlear and auditory brainstem implant system.

The requirements of ISO14708 parts 2-7 or the particular standards of EN45502 supplement or modify those of Part 1. The requirements of each part take priority over those of Part 1, as they indicate requirements, procedures and methods specific to their product type.

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STANDARD ALIGNMENT AND HARMONIZATION

The standards for implantable devices align and harmonize with other standards, meaning the evaluation, testing and report structure is the same for both sets of standards. As a result, it is possible for one set of reports to cover all required standards.

The following alignments and harmonization occur within ISO 14708 for AIMDs:

- ISO 14708-1:2014 and EN 45502-1:2015 are harmonized with each other

There are some differences between the harmonized standards that should be noted:

- ISO 14708-1 and IEC 60601-1 reference ISO and IEC standards
- EN 45502-1 and EN 60601-1 reference ISO and EN standards
NON-IMPLANTABLE COMPONENT TESTING

Under ISO 14708 for AIMDs, non-implantable supporting equipment must be evaluated to the specifications set by the International Electrotechnical Commission (IEC) regarding electrical safety and performance. These are found within two IEC standards, IEC 60601 and IEC 62304. The following standards apply to the non-implantable components of AIMDs:

- IEC 60601-1. This standard covers general requirements for basic safety and essential performance of medical electrical equipment.
- IEC 60601-1-2. This subsection of the main standard for medical electrical equipment is specific for EMC to ensure a device’s safety and performance in proximity to other electrical products.
- IEC 60601-1-6. This collateral standard and sections of IEC 62366 are required which covers the application of usability engineering to medical devices.
- IEC 60601-1-11. This collateral standard covers requirements for medical electrical equipment and medical electrical systems used in the home-healthcare environment and should be used for any device intended for home use.
- IEC 60601-1-12: A collateral standard that covers equipment intended for use in an emergency medical services environment.
- IEC 62304. This standard specifies life cycle requirements for the development of medical software and software used within medical devices. It includes provisions for risk management, maintenance and configuration.
- Other IEC60601 particular standards may apply if the non-implantable equipment performs other medical purposes such as the monitoring of the patient’s vital signs.

Some implants require specialized active medical equipment that is only used during the implant process. This equipment is also subject to the requirements of IEC 60601-1, but is often overlooked and could delay approval if not part of the original evaluation.
EMC & WIRELESS EVALUATIONS

Many new AIMDs systems use wireless interfaces that require additional testing. Like any medical device, AIMDs are expected to maintain basic safety and essential performance without interfering with other equipment in their vicinity or the intended electromagnetic (EM) environment. The intent is to make sure the device will maintain the EM equilibrium condition that exists when equipment is performing its designed functions, without causing or suffering unacceptable degradation due to electromagnetic interference (EMI).

Emission is not usually a problem for most AIMDs because they use less power. Also, because they are implanted inside the body, emissions are attenuated by the body tissue. AIMDs are subject to limited EM disturbance tests compared to medical devices that are external to the body and fall into the scope of IEC 60601. However, AIMDs are subject to more severe levels of EM disturbance than the collateral 60601-1-2 standard because of their portability and exposure to dense EM environments due to growing radio frequency (RF) and wireless devices.

**EMC**

As mentioned previously, the ISO 14708 and EN 45502 family has a general standard that all AIMDs are required to meet, as well as particular standards for specific devices. The manufacturer’s risk management process may also determine other requirements beyond the scope of the standards that are required as well.

Clause 27 of all parts of ISO 14708 deals with tests to determine the effects of EMI on an AIMD. The intent is to verify that the implantable parts of an AIMD do not result in an unacceptable risk when they become susceptible to EM fields. Examples of these risks include damage, heating, or local increase of induced electrical current density within the patient.

Some AIMDs like cardio vascular implants are highly sensitive devices, and it is difficult to make them immune to commonly encountered EM environments. In these kinds of cases, the intent of the test is not just to make sure the AIMD is immune to EMD, but to also have an insight on its susceptibility threshold and address it so the user and doctors are aware of the risks associated with using the AIMD near this type of interference. Susceptibility is the inability of a system to perform without degradation in the presence of an EMD; immunity is the ability of a system to perform without degradation in the presence of an EMD.

When a patient with an AIMD, along with its non-implantable peripheral device, goes outside of the controlled clinical environment, he is exposed to general expected EM environments. The tests outlined in the ISO and EN standards for AIMDs verify that the AIMD maintains basic safety and continues to provide essential performance in the presence of the expected EM disturbance a device can be exposed to during its normal use.
Clause 27 of the ISO standard includes tests verifying protection from static magnetic fields, test verifying protection from AC magnetic fields of 10 Hz to 30 MHz, and tests verifying protection from EM fields of 30 MHz – 450 MHz and 450 MHz – 3 GHz. The test levels for these evaluations are derived from International Commission on Non-Ionizing Radiation Protection (ICNIRP) guidance for the general public. The newer versions of particular standards for ISO 14708 place an emphasis on risk management and risk analysis to be done by the manufacturer. Each function of the implantable device that can affect performance should be tested in a scenario that is critical from patient outcome based on risk, placing a lot of responsibility on the shoulders of the manufacturer.

The standard expects and requires disclosure, explanation, and justification from the manufacturer for any unintended behavioral responses during testing. These types of responses are expected to be temporary and to end at the cessation of testing. Test labs are expected to make accurate notes on behavioral responses of the AIMD during testing. Permanent changes in performance due to these tests, outside of specification, are not allowed.

Wireless

AIMDs can have wireless technologies such as Bluetooth, WiFi, wireless induction charging, and RFID chips. Ensuring the wireless safety of AIMDs is important in helping to ensure the devices’ safety and performance. As with any wireless devices, AIMDs are subject to standards and requirements regarding coexistence, security and functionality. The governing bodies for these considerations vary by geography, but in many cases, wireless considerations will bring additional regulatory bodies into play.

In the U.S., the FDA provides guidance regarding wireless medical devices. This guidance highlights and discusses RF wireless technology considerations that can influence the safe and effective use of medical devices. These considerations include the selection of wireless technology, quality of service, coexistence, security, and EMC.

Selection of wireless technology should be based on the ability to:

- Function properly in intended environments where other RF wireless technologies will likely be located.
- Provide correct, secure and timely transmission of medical data to ensure safe operation, especially for medical devices that perform critical functions like life-sustaining activities.
**Wireless Quality of Service**

Wireless quality of service (QoS) of a medical device is different and more important than QoS of a cellular telephone network. The performance criteria acceptable for voice communications might not be sufficient for medical purposes.

**Wireless Coexistence**

A key factor affecting a wireless medical device’s performance is the limited amount of RF spectrum available, which can result in potential competition among wireless technologies for simultaneous access to the same spectrum. To address this issue, the FDA recommends that manufacturers address their device’s environmental specifications and needs, including:

- Associated sources of EMD expected in the environments of the medical device
- Co-channel and adjacent channel interference from medical devices and other users of the RF band.

If the wireless medical device is expected to be used in proximity to other RF wireless in-band (i.e., the same or nearby RF frequency) sources, the FDA recommends addressing such risks through testing for coexistence of the device wireless system in the presence of the number and type of in-band sources expected to be in proximity to the device.

**Security of Wireless Signals and Data**

Security of RF wireless technology is a means to prevent unauthorized access to patient data or hospital networks and to ensure that information and data received by a device are intended for that device. Authentication and wireless encryption play vital roles in an effective wireless security scheme.
EMC of the Wireless Technology

The FDA recommends that EMC be an integral part of the development, design, testing and performance of RF wireless medical devices. This should include consideration of applicable telecommunications standards and regulations and the potential for device RF emissions that might cause EMI with other equipment. In addition, RF wireless technology (by itself and in conjunction with the medical device) needs to meet applicable requirements from the Federal Communications Commission (FCC).

The EMC collateral standard contains an exemption from the EM immunity provisions in the “exclusion band” (passband) where the medical device’s RF wireless receiver or transmitter operates. Consequently, such standards do not adequately address whether the wireless communications will operate properly in the presence of in-band EMD (e.g., other RF emissions overlapping the frequency band utilized by the medical device wireless signals). Therefore, wireless communication should be actively transmitting while testing for susceptibility during all EMC immunity testing.

In the EU AIMDs are regulated under the Medical Device Directive and the Active Implantable Medical Device Directive. Outside the US and EU, countries generally adopt international EMC standards or amended versions thereof.

The most common sources for wireless requirements are the IEC and CISPR. These regulations cover output power, effective radiated power, occupied bandwidth, power spectral density, spurious emissions, frequency stability and specific absorption rate (SAR). These considerations ensure the AIMD’s safety and performance not only as it interacts with other devices, but also as it functions within the body.
BENEFITS OF SIMULTANEOUS TESTING

Evaluating the implantable and non-implantable equipment simultaneously has several advantages, including savings in time and costs. Simultaneous testing allows for economies of scale as both testing types have requirements around risk management, software, usability and references to each other. For example, ISO14708-1 requires the application of risk management according to ISO14971, software development according to IEC62304 and usability according to IEC62366. These same standards are also required for the non-implantable equipment. In addition, ISO14708 reference many of the requirements in IEC 60601-1 for the non-implantable support equipment.

Reports that reference each other eliminate the need for duplicate evaluations, resulting in cost and time savings. Concurrent evaluations also offer reduced costs and faster time to market by having one approved body handle and coordinate all evaluation efforts.

With this approach, one team of engineers can become familiar with the equipment or system and produce a single, highly organized report package that contains much of the information necessary for the FDA or notified body to properly review both the active implantable device and the non-implantable supporting medical equipment.

Evaluation time can be reduced by evaluating the non-implantable equipment and the implantable equipment concurrently, while also conducting EMC and wireless evaluations. References between reports can be made and a single point of contact for both the external equipment and implantable parts can be established.

Without having to duplicate efforts, the FDA or notified body can quickly and efficiently review all relevant data for a potentially faster approval and release into the market.
INTERTEK SOLUTIONS

Intertek offers an extensive history of electrical testing, backed by industry experts who are familiar with the standards and requirements for AIMDs. Intertek’s solutions include testing and certification, plus evaluations for non-implantable components, the implantable device and Wireless and EMC evaluations. Our full range of AIMD services include:

**Non-Implantable Equipment**
- Evaluated utilizing the standard procedures for:
  - IEC 60601-1
  - IEC 60601-1-2
  - IEC 60601-1-6, Includes sections of IEC62366
  - IEC 60601-1-11
  - IEC 62304
- Intertek will provide checklists to the manufacturer for each standard evaluated to help reduce evaluation time and provide the opportunity to discover and correct issues before the evaluation begins.

**Implantable Devices**
- Evaluations to the requirements set forth in the ISO 14708 and EN 45502 family of standards
- A checklist is provided to the manufacturer, including a column for each clause that can be used to indicate which requirements can be addressed or tested by Intertek, as well as information the manufacturer needs to provide to complete the clause, including samples, packaging, data, risk assessment or rational.
- Providing a range of subcontractors to complete testing not able to be completed at an Intertek lab or by the manufacturer.
- Test reports that follow a familiar format for auditors and are produced by a certified test lab carry some weight towards the validity and completeness of the product evaluation.

**EMC and Wireless**
With a global network of EMC testing labs, Intertek provides the capacity, proximity and engineering resources to streamline EMC compliance testing. We hold a long list of EMC accreditations from around the world. We offer both open and fully sheltered sites, fully anechoic and semi-anechoic chambers, with site size ranging from 3 meters to 10 meters.

**Accreditations**
In 2018, Intertek became the first independent lab in North America accredited for end-to-end evaluation of both implantable and non-implantable medical devices.
Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 44,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers’ operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

FOR MORE INFORMATION

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