IEC 60601 & IEC 60512

15 MINUTES TO UNDERSTAND CRITICAL INTERNATIONAL STANDARDS FOR BRINGING MEDICAL DEVICES TO MARKET

Summary: The need for International Standards regulating the design of electrical, electronic and related technologies is paramount to the safety and market acceptance of electrical products worldwide. Compliance to Internal Standards IEC 60601 and IEC 60512 are a necessary requirement for the commercialization of electrical medical equipment in many countries. However, compliance and testing waters can be tricky to navigate. This paper outlines the structure of IEC 60601 and IEC 60512 and discusses how, with an experienced engineering team, your organization can achieve compliance and prepare your medical device for market success.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL STANDARDS ARE BORN

Not long after the inception of electricity, the need for standards became clear. With advancements in electrical design happening at break-neck speed, electrical engineers across the world began to see the need for closer collaboration to standardize terminology, testing and safety. While the 19th century had been the era of electrotechnical innovation, there was an urgency for consolidation and standardization to provide clarity for engineers, manufactures and consumers.

Founded in 1906, the IEC (International Electrotechnical Commission) is the world's leading organization for the preparation and publication of International Standards for all electrical, electronic and related technologies. IEC provides a platform to companies, industries and governments for meeting, discussing and developing the International Standards they require. Close to 20,000 experts from industry, commerce, government, test and research labs, academia and consumer groups participate in IEC Standardization work.

INTERNATIONAL STANDARDS PROVIDE SAFETY, PROMOTE TRADE

The beauty of standardization is thousands of engineers have already done the heavy lifting. Through experience, trial and error, they've already figured out the best, most efficient way to improve design, engineering, production, installation and certification. As a result, international standards allow organizations to streamline production and facilitate quality control to provide safe, reliable products anywhere in the world.

Reduce Barriers to Trade

As international standards reflect the best in industry, research, and consumer regulations worldwide, adherence to IEC standards allows companies to trade their products on an international scale with greater ease. Products can be built using IEC CA (Conformity Assessment) Systems to accelerate market access in many countries. IEC CA Systems greatly simplify the global certification process by reducing the number of steps required to obtain certification at the national level. This reduces trade barriers caused by different national certification criteria as IEC CA Systems provide a standardized approach to testing and certification.

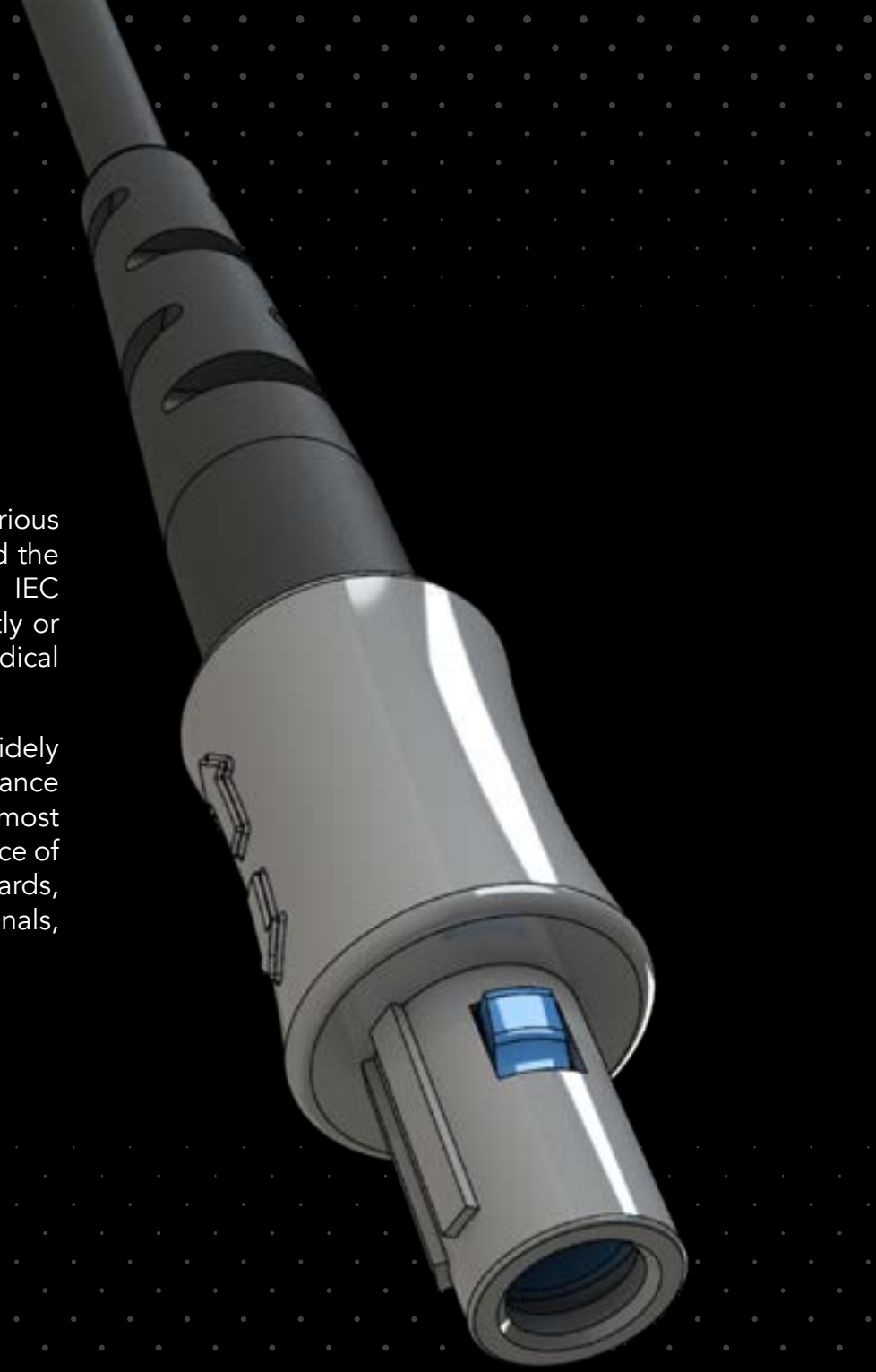
Ensures Safety and Reassures Consumers

IEC standards protect the public from all kinds of hazards associated with electrical and electronic products, equipment and systems. Consumers can be confident that electrical and electronic products are safe to use, energy efficient and environmentally friendly and perform to expectations.

IEC 60601: SAFELY CONNECTING TO MEDICAL EQUIPMENT

No power, signal interruptions or inadvertent application of injurious electrical energy can prove disastrous for patients, doctors and the device maker. To govern the design of medical equipment, IEC has produced a standard to control all aspects of safety directly or indirectly relating to the handling, use or connection to, of medical equipment. This standard is referenced as IEC 60601.

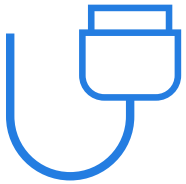
The general standard of the IEC 60601 series provides a widely accepted benchmark for medical electrical equipment. Compliance with IEC 60601-1 is viewed as the de facto requirement for most markets as it applies to the basic safety and essential performance of medical electrical equipment. By adhering to IEC 60601 standards, interconnects can reliably provide critical digital and analog signals, data, power and more to medical devices.



UNDERSTANDING THE IEC 60601 STANDARD SERIES

Since its first publication in 1977, IEC 60601 have been updated and restructured, and now encompass the general standard, about 10 collateral standards, and about 60 particular standards.

The IEC 60601 standards series consists of four distinct parts. The IEC 60601-1 base standard is the core of the series and a part of the 60601–1 grouping (base and collateral). The 60601–2 grouping includes particular device-specific standards, and the 60601–3 grouping includes performance and device-specific standards.



Base Standard

IEC 60601-1 covers all the general requirements for electrical medical (or electromedical) products.

Collateral Standards

Standards numbered IEC 60601-1-x contain horizontal issues that may deal with many different types of medical devices. IEC 60601-1-2 is an example of a collateral standard, and it encompasses electromagnetic compatibility (EMC) issues of electrical medical devices. A standard on the horizon in this category is IEC 60601-1-6, which deals with human factors (usability) issues.

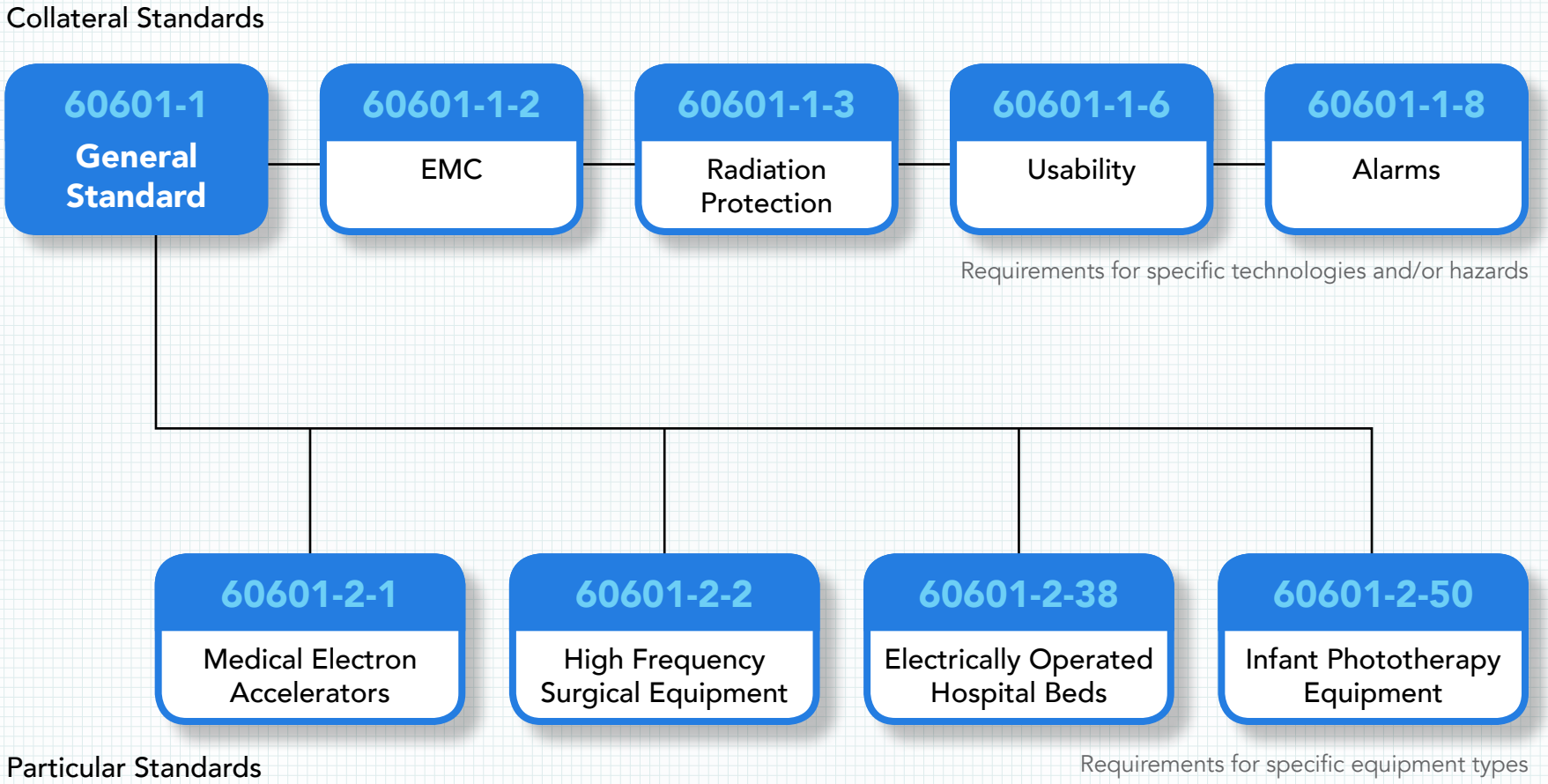
Particular Standards

Standards numbered IEC 60601-2-x lay out requirements for a specific type of medical device. IEC 60601-2-2 is the particular standard for high-frequency surgical devices. Particular standards can amend, modify, and/or supersede part of the requirements specified in IEC 60601-1.

Performance Standards

Standards numbered IEC 60601-3-x lay out performance requirements for specific types of devices.

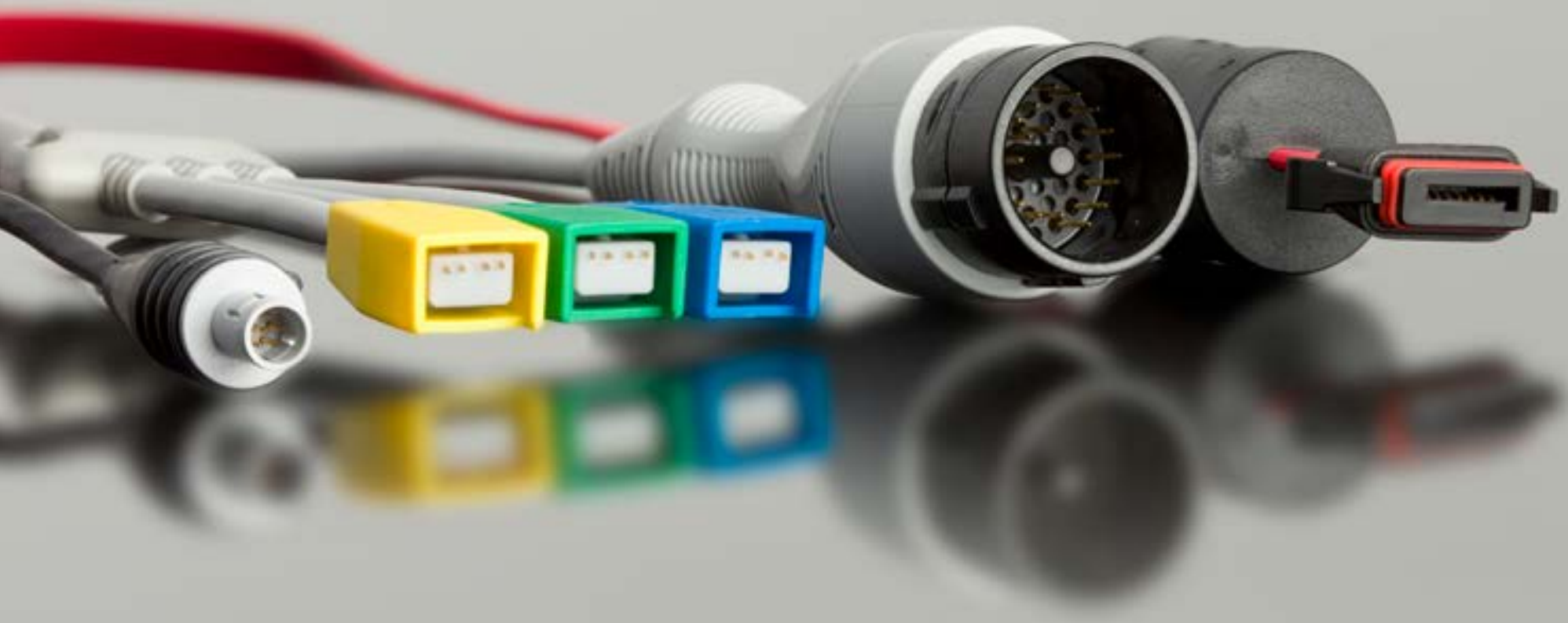
IEC 60601-1, COLLATERALS, PARTICULARS



WORKING TOGETHER TO ENSURE IEC 60601 COMPLIANCE

A successful outcome for a medical device interconnect requires ongoing collaboration and communication between the manufacturer and the device supplier. At the beginning of every project, ATL engineers trained in the requirements of IEC 60601 meet with the customer's engineering and regulatory personnel to review details of their device and how it is employed by the clinician in its indicated use.

This team determines and agrees upon a list of the relevant sections of IEC 60601. The ATL engineering team's expertise in specification requirements, and years of experience designing to IEC standards, create an IEC 60601-compliant interconnect system.



SPECIFICATION ATTAINMENT PLAN KEY TO COMPLIANCE

ATL's commitment to its customers goes beyond just checking the box when it comes to compliance. Our "engineer-to-engineer" relationship ensures that the engineering teams have a deep understanding of the use case of each product designed, and therefore a comprehensive plan to produce successful results.

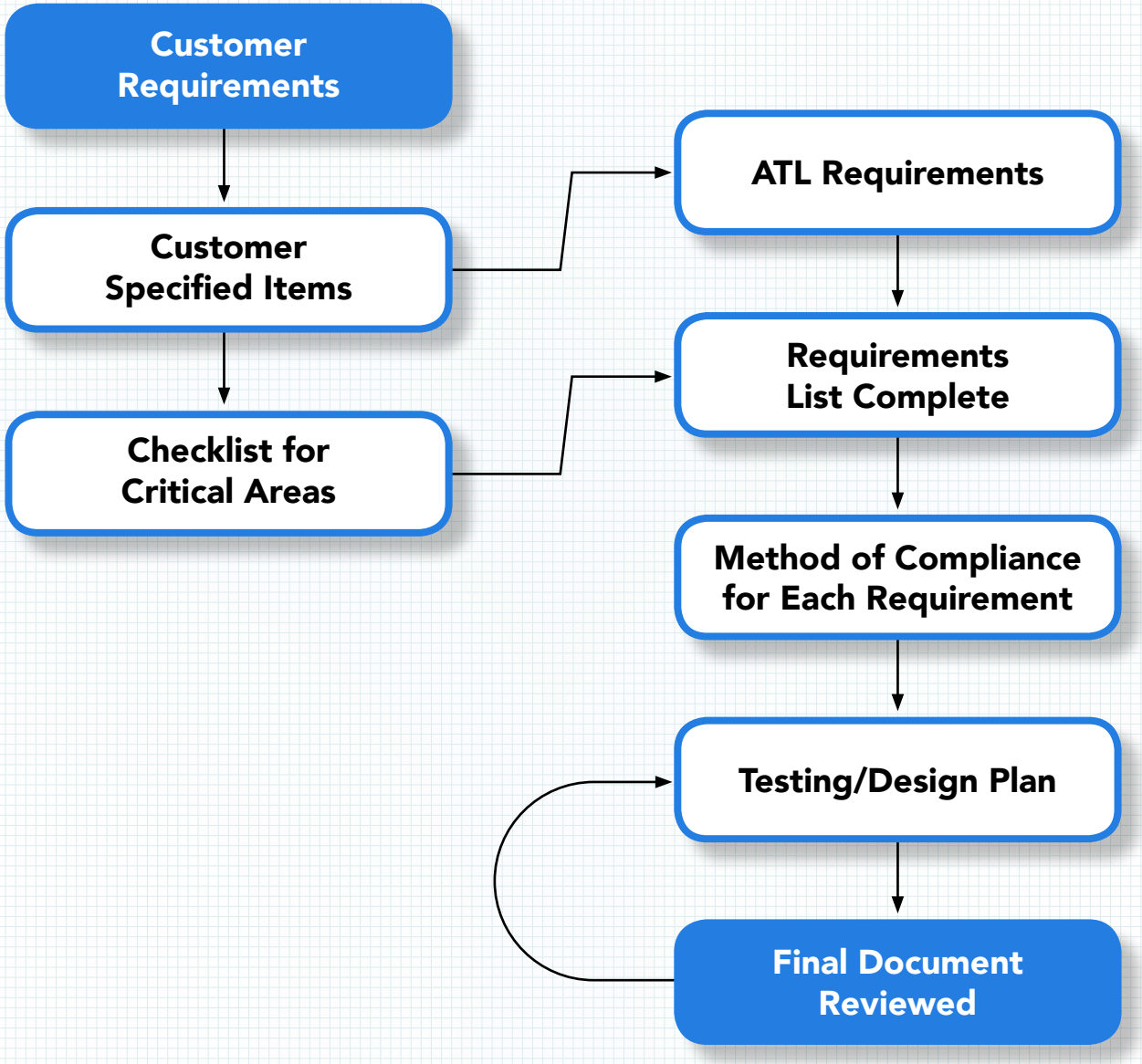
ATL created a process called the Specification Attainment Plan (SAP). The SAP is a document that lists all known customer product requirements and specifications, including the planned method to ensure that those requirements are met. The SAP creation process begins with the customer's set of requirements. These may be in the form of a detailed specification or they may all be captured on an engineering drawing of the product.

ATL engineers dissect the customer's requirements and list each requirement individually in the first column of the SAP document. These are identified as customer specified items. A checklist is then used to make certain requirements have been determined for every critical area (safety requirements, sterilization methods, biocompatibility, etc.). If the customer specified requirements are complete, then the requirements list is done.

Typically, the customer overlooks some aspects that should be governed by specifications. In this case, ATL adds requirements which are identified as "ATL requirements". With the requirements list complete, a "method of compliance" is specified for each individual requirement. The "method of compliance" is the detailed design approach planned to be used to assure meeting the specified requirement.

In addition, a method for verifying the success of the design approach is also specified. This is often testing, but can also be calculations or equivalency to another existing product using the same feature. The final document is reviewed by the ATL/customer team and used to drive the design details and testing.

SPECIFICATION ATTAINMENT PLAN



IEC 60512 PROVIDES RIGOROUS TESTING

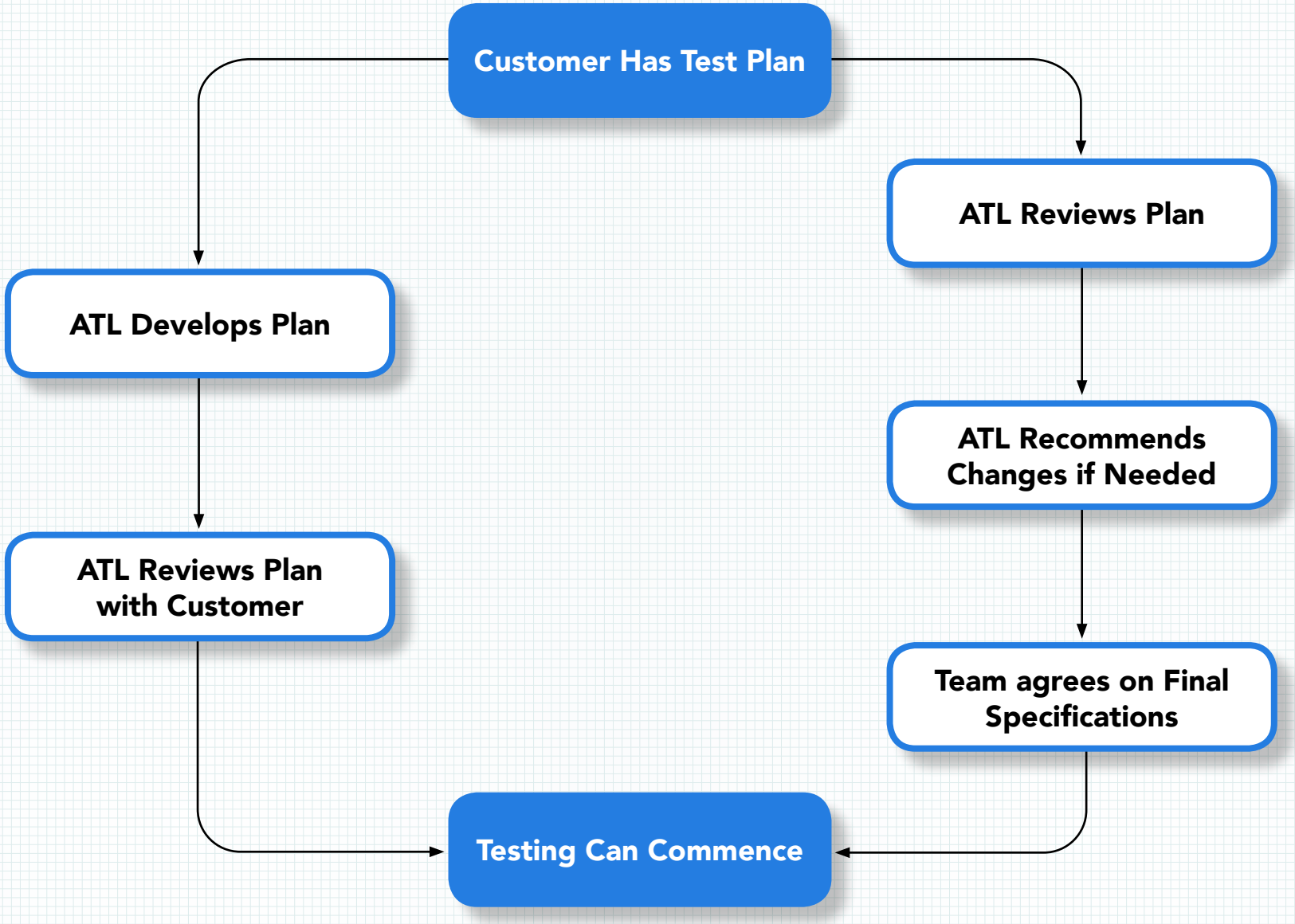
IEC 60512 is a set of industry standard test methods applicable to verifying the performance of electrical connectors. By employing these consistent, standardized test methods, testing can be duplicated by the customer or other third parties without variable results that might otherwise occur with inconsistent methods.

The specific parameters selected for each test are tailored to the requirements of the application. For example, a single use connector will be tested to a lower number for "mating cycle life" than a long-life reusable connector. The usage profile of the connector, coupled with the organization's expertise in connector design and development, guides the engineer in selecting the appropriate parameters for each standardized test. The SAP is used to assure each requirement is recognized and addressed with specific design and testing details.

When mapping out a testing program, it is vital for the interconnect manufacturer's engineering team to work closely with the customer as the customer may have a thorough test program already defined. In this case, ATL reviews the customer's test program and recommends additions or changes if the testing is incomplete or inadequate.

With ATL's experience in designing interconnect devices for many medical applications, customers depend on our expertise to make recommendations and search for potential shortcomings in testing. A final specification is agreed by the ATL/customer team and testing commences. In other cases, the customer has no test plan and looks to ATL to apply its expertise to create the test plan. In this latter case, ATL develops the plan and reviews it with the customer. Once approved by the customer, the testing can commence.

WORKING WITH CUSTOMERS TO CREATE A TEST PROGRAM



BENEFITS OF IN-HOUSE TESTING

The ability to test connectors in-house to comply with IEC 60512 provides a number of benefits. First, without the need to outsource testing, ATL is able to complete tests in a timely, efficient manner. This efficiency translates into dollars saved and a faster time to market. Second, with testing conducted in-house by ATL engineers, if a problem does arise, they are able to quickly identify potential causes of the problem, since they've been involved in the entire lifecycle of the product.

PARTNERING FOR SUCCESS

Achieving IEC 60601 compliance and the associated IEC 60512 testing is no easy feat. The complexities involved in bringing a medical device to market requires an experienced partner. ATL's custom connector and cable design, and understanding of market and end-user expectations, helps us offer customized engineered solutions to help you build a successful medical device.

NEED HELP WITH IEC 60601 OR 60512?

Please email marketing@atltechnology.com and refernce the "60601 eBook." We will get you to the right people.

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Dan Porter is a mechanical engineer specializing in product development. Dan has an invention patent for a medical device/connector to his name. He holds a bachelor's degree in mechanical engineering from BYU with a master's in product development