



NEW ISO 80369 Small-Bore Connector Standards

There is a new standard in development known as ISO 80369, to minimize misconnections of small-bore connectors used in liquid and gas healthcare applications. Qosina carries thousands of stock components including small-bore connectors, and you may be affected by this new ISO 80369 standard. We would like to make you aware of the future changes and are happy to talk to you about your concerns and help plan for the implementation.

Why is there a new ISO standard being developed?

Small-bore connectors convey liquids or gases in a patient-care setting. Such connectors are used in IV Access, enteral feeding tubes, breathing systems, urinary catheters, and many other healthcare applications.

Patients often have multiple lines connected to them to deliver medicine and nutrients. Numerous devices and systems use the universal luer lock connector, which is a type of small-bore connector. A small-bore connector is defined as having an ID of less than 8.5 mm, and a luer is defined by the ISO 594-1 and ISO 594-2 standards as: "... a conical fitting with a 6% taper for syringes, needles, and certain other medical equipment."

Through this luer connector, a healthcare worker or patient could mistakenly connect one device used for one application, such as enteral nutrition, to another device used for another application such as intravenous therapy. These types of mistakes were highlighted in an FDA report from 2009 (AAMI News: Jan 2011: New Standard).

How does this affect you?

If you are currently using any small-bore connectors in a kit, set, or line, which drives gas or pressurized fluids to patients or are using luers in non-IV applications, this may impact you. This standard will involve some key changes from component suppliers, which may include designing new connectors or modifying existing connectors to meet the specifications in the new standard.

What does the ISO 80369 standard cover?

The new standard ISO 80369-1, approved in the fall of 2010, is for medical device manufacturers and gives guidance on how to create connectors for different applications to prevent accidental misconnections and how to prepare for the remaining standards in the series.

ISO 80369-1 specifies the general requirements for small-bore connectors, which convey liquids or gases in healthcare applications, and are part of medical devices intended for use with a patient. It also specifies the healthcare fields in which these small-bore connectors are intended to be used. It basically will provide the structure for risk mitigation, and how to validate the new design.

Each of the remaining standards in the series will focus on the specific healthcare fields, the clinical applications, and the design requirements for each connector which must be used in the related delivery systems.



ISO 80369-1 General Requirements and Overview		
ISO 80369-2 Breathing Systems and Driving Gases (Airway)	ISO 80369-3 Enteral and Gastric (Stomach)	ISO 80369-4 Urinary Collection (Urethra)
ISO 80369-5 Limb Cuff Inflation (Tourniquets and BP Cuffs)	ISO 80369-6 Neuraxial (Spine)	ISO 80369-7 Intravenous (Artery/Veins)*

***Note:** Section 7 will define the standard luer fitting. This section will replace the current ISO 594-1 and the ISO 594-2. No physical changes to the current luer specification are anticipated.

How can Qosina help you prepare for the new standards?

Qosina is actively researching the upcoming changes. We will be a resource for information and guidance and will modify tools or design new connectors to meet the new standards. Qosina will educate and support you on these matters, address your concerns, research your questions and come up with solutions based on your connector needs.

Contact Qosina, your OEM partner for over 30 years, we are ready for your questions and concerns. Once these standards become approved, we will continue to save you time and money by providing in-stock solutions based on the specific needs of your project.

Qosina is ISO 9001, ISO 14001 certified and will be prepared to follow the ISO 80369 standards once they are finalized. You can rely on Qosina to help with your concerns today.

Sincerely,

Stuart Herskovitz
President

Note: "This information is solely provided by Qosina based on research done through the AAMI and ISO websites. These notes have not been endorsed or approved by AAMI or ISO and should not be used to make specific business decisions."

For additional information to ISO 80369 please see http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=45976