



TECHNICAL TIP

FROM ISO 594 TO ISO 80369: MAKING SENSE OF THE LATEST LUER REQUIREMENTS

With the release of a new ISO 80369-7 standard for Luer connectors, many medical device manufacturers are now striving to achieve compliance with both new and legacy connectors.

Bearing little resemblance to ISO 594-1/-2, the new ISO 80369-7 may be confusing and ambiguous with regard to exactly what is needed to comply. Therefore, it is worth distilling the primary areas of interest for those ready to test their product.



The following requirements from ISO 80369-7 are the most important to adhere to for achieving compliance:

- Dimensional and Non-Interconnectability Requirements
- Luer Connector Material Requirements
- Performance Testing

1. Dimensional and Non-Interconnectability Requirements

ISO 80369-7 has introduced the requirement that connectors must have dimensional characteristics that prevent the incorrect mating of the Luer connector with other liquid and gas medical connectors. These dimensional requirements vary based on the type of connector (i.e. male luer slip connector, female luer slip connector, etc.).

The simplest and most cost-effective way to comply with this requirement is to design and manufacture the connector within the prescribed geometries and tolerances detailed in the standard. The alternative is a lengthy and complex non-interconnectability study involving multiple connector mating tests.

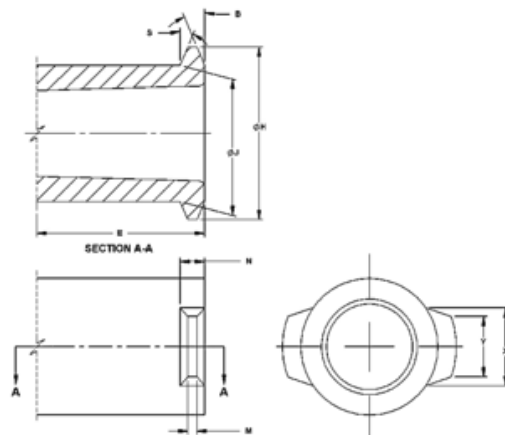
A manufacturer should begin by updating the part drawings to reflect the ISO 80369-7 requirements.

There are several additional characteristics that were not outlined in the old ISO 594 standards. As a result, injection mold changes may be required to meet these new tolerances.

Next, a sample group of manufactured parts then should be measured to ensure they are within specification. Although not an explicit requirement, it would be worthwhile to consider dimensional stability of the part after sterilization and over time. A post-aging dimensional study using sterilized parts is by far the most common approach.

Our Test Services can support in the following areas:

- 2D/3D CAD model compliance reviews, drawing updates and assessment reports
- Touch probe dimensional verification tests and reports
- Part scanning, reverse engineering and 2D/3D CAD modeling of legacy parts



FOR MORE INFORMATION

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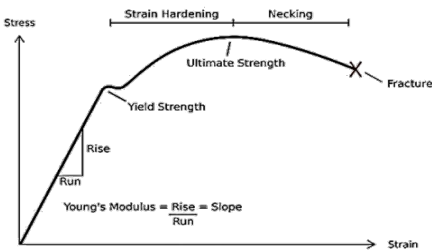


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2. Luer Connector Material Requirements

Connectors must now be manufactured from a material with a nominal modulus of elasticity (Young's Modulus) either in flexure or in tension greater than 700 MPa.



Compliance must be verified by tests described in ASTM D638-14 (tension) or ASTM D790-15e2 (flexure). The material vendor should be able to provide material data sheets to confirm this.

3. Performance Testing

Connectors must now be manufactured from a material with a nominal modulus of elasticity (Young's Modulus) either in flexure or in tension greater than 700 MPa.

As with ISO 594, connectors are required to undergo performance testing. However, compliance with legacy test methods is not sufficient to comply with the new performance test requirements outlined in ISO 80369-7.

There have been some updates to the test methods and a notable absence of the Gauging and the Ease of Assembly tests. An option is now available to perform Fluid Leakage by employing a new, recommended Pressure Decay method.

A summary of the required tests are as follows:

1. Fluid Leakage (Leakage by Pressure Decay Method). Compliance is checked by applying the tests of ISO 80369-20:2015, Annex B or Positive Pressure Liquid Leakage Method. Compliance is checked by applying the tests of ISO 80369-20:2015, Annex C)

2. Sub-Atmospheric Pressure Air Leakage. Compliance is checked by applying the tests of ISO 80369-20:2015, Annex D
3. Stress Cracking. Compliance is checked by applying the tests of ISO 80369-20:2015, Annex E followed by either Fluid Leakage tests
4. Resistance to Separation from Axial Load. Compliance is checked by applying the tests of ISO 80369-20:2015, Annex F
5. Resistance to Separation from Unscrewing (Luer Lock only). Compliance is checked by applying the tests of ISO 80369-20:2015, Annex G
6. Resistance to Overriding (Luer Lock only). Compliance is checked by applying the tests of ISO 80369-20:2015, Annex G

Summary

Despite the differences between ISO 80369-7 and its predecessor, the new standard is poised to serve as the go-to international standard for Luer testing and compliance. Our own interpretation of some of the complex language has been built on many rounds of reading and testing, and we have therefore developed a familiarity with its step-by-step logic.

The good news about ISO 80369-7 is that it completely supplants ISO 594-1/-2, and thus fulfills its requirements, which means device engineers need not worry about reverting to the old standard in certain situations.

It would be important to also review and consider the annexes of ISO 80369-7 in relation to usability, application-specific suggested attributes, and design verification and validation activities.

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