ENERSOL
SERVING THE GLOBAL MEDICAL DEVICE INDUSTRY

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Determining the internal volume for the ISO80369-20 leakage methods, pressure decay and subatmospheric pressure air leakage.

The ISO 80369-20 standard contains two leakage test methods that use formulas to calculate the leakage rate. These formulas (in Annex B and Annex D) contain a number of components of which one is an internal volume (v). This must be determined.

The definition of volume in the standard differs slightly between the two annexes, and is ambiguous. Enersol's interpretation of the volume is that it includes all the parts of the system that are pressurised or evacuated. No method is given in the standard for calculating the volume, which must be reported in the test report, and is used in the calculation to calculate the leakage rate.

This document is intended as a guide to the components used in the determination of the internal volume under test, including possible methods for measuring or calculating the volumes.

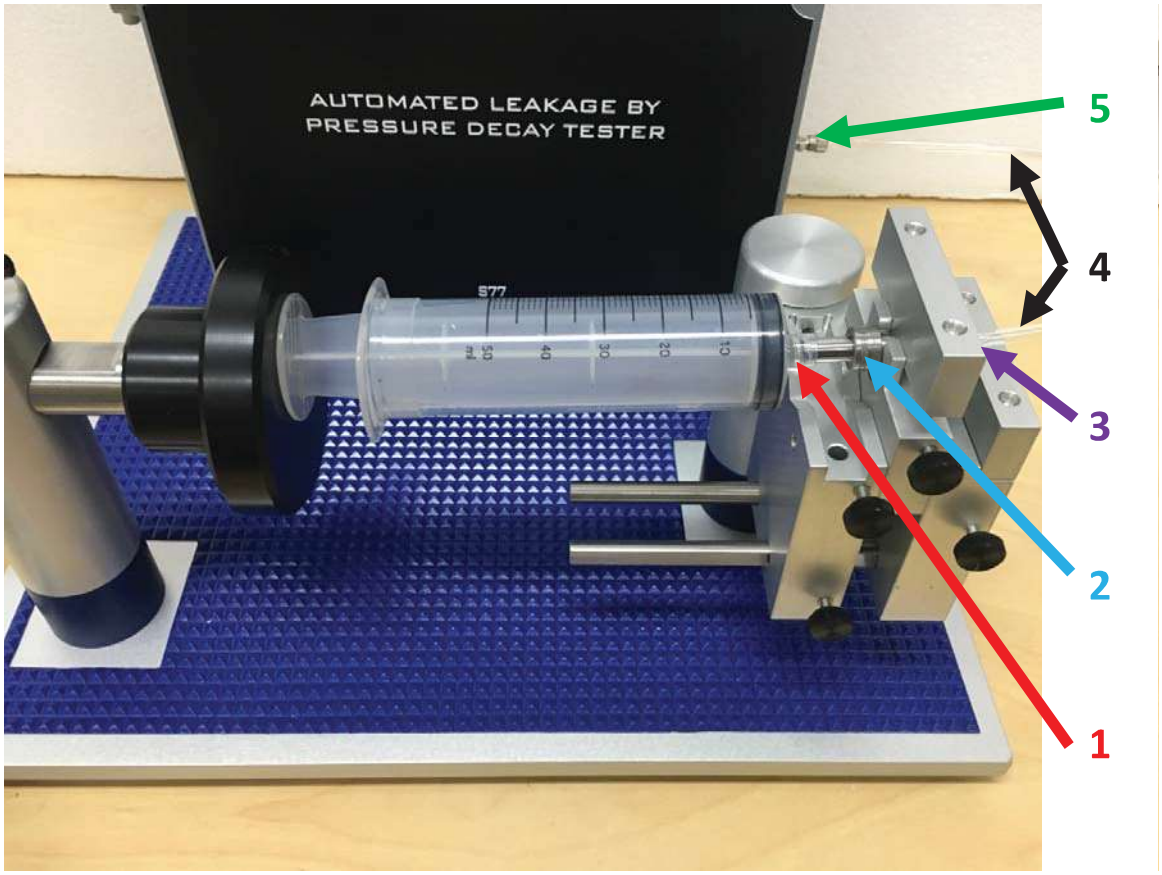
Determination of the internal volume

Enersol has calculated the internal volume of its testing equipment. This is pre-programmed into the software of the Enersol Automated Leakage by Pressure Decay Tester, and Enersol Automated Subatmospheric Pressure Air Leakage Tester.

During the set-up of a test the technician enters the volume of the remainder of the test assembly. This is the combined internal volume which includes:

1. The sample being tested
2. The reference connector
3. The hose connector fitted to the end of the reference connector
4. The tube connecting to the testing machine
5. The connector joining the tube to the test machine

Example set up testing a small-bore connector using the Automated Leakage by Pressure Decay Tester:



In this example the small-bore connector under test is on the end of a syringe. The volume of space inside the small-bore connector (and syringe) that will be under test (1) must be determined, along with reference connector (2), Festo fitting (3 (sitting out of view behind the grip)), hose (4) and connector (5) to the test equipment.

One way to calculate internal volume of each component is to use CAD dimensions, and modelling. If all the internal dimensions of all components are known then this is one method that can be used to calculate the internal volume under test. Although this appears simple in principle, one must take into account all of the connections where one component can take up space within another.

Another way to determine the internal volume of a component is by measuring the volume of water it will hold. This can be carried out by weighing the components, then filling them with water and re-weighing, then using calculations to determine the internal volume. The volumes of individual components are added together and subtractions are made for any overlapping parts.

A combination of these methods may be needed to determine the internal volumes for testing purposes.

Example:

First calculate the combined volume of the test port hose connector, and the hose. These have relatively simple, known interior shape. When using this method, this is volume (A) in this example.

Weigh the assembled reference connector, then fill it with water and re-weigh. Work out the volume, using the density of water. This is done after assembly of the sample with the reference connector with its Festo quickstar connector fitted. Ensure the sample is blocked, if required, to prevent leakage. Block the sample with the same plug or cap that will be used during the test. When using this method, this is volume (B) in this example.

Add the volume of the components (A) and (B) together and subtract the overlap between the end of the hose and inside of the Festo quickstar connector.

The calculated volume of these components is the volume the user must enter into the Enersol S77 or S78/S78H when carrying out a test. The equipment will automatically add the internal volume of the equipment to the volume entered by the technician, and use this total internal volume in its calculation of the leakage rate. The total volume under test will appear on-screen at the end of the test.

Considerations

In any volume determination one needs to consider that the sample under test may fit into, or onto, the reference connector, and take up part of its volume, and similarly that other connections in the system will be done in the same way (eg the Festo quickstar fitting which screws into the reference connector, and the hose which inserts into the Festo quickstar connector). Where one component goes into another, there may also be empty space inside the socket. This should be factored in. Also, CAD drawings do not accurately indicate the volume of threaded portion of reference connectors.

The components

Test sample, reference connector and hose fitting (components 1, 2 and 3)

The test sample is an unknown component and its volume has to be determined by the lab carrying out the test. One can use CAD information, or the water method when assembled with the components 2 and 3, as described earlier in this document.

Enersol reference connectors are made in accordance with the requirements of ISO 80369-# or ISO 18250-#, or similar. Where # is the actual part standard, e.g. ISO 80369-7. The reference connectors are supplied with the Enersol hex handle and an internal M5 thread. On the end of the reference connectors used for leakage is a Festo quickstar fitting. This is used for connecting to 4mm hoses, such as the test hose supplied with Enersol test equipment.

While it may be possible to calculate an internal volume of the reference connectors using CAD dimensions and modelling, there are a number of factors that make it complicated to do so. This includes the thread in which the Festo quickstar connector is inserted. It may or may not reach the full depth of the tapped thread in the handle of the reference connector. There is also the critical end of the reference connector, which is connected to the test sample. Connections differ and thus the overlapping of components may not always be the same. In any case, allowance must be made for the overlap.

As CAD drawings are available for the Festo Quickstar fittings, they can in principle be separated from the reference connectors, but then the volume of the threaded part of the reference connector would need to be subtracted from any volume determined by the water method.

Test hose and connector (components 4 and 5)

The Enersol equipment are supplied with a test hose, and connector for connecting to the equipment. The test hose is a particular length, typically 400mm for most equipment, and 600mm for the Automated Subatmospheric Pressure Air Leakage Tester for high elevations.

The hose is typically supplied with a label specifying the length. The length specified is the length of hose influencing the internal volume under test (thus excludes the overlap where it is connected onto the metal connector). The internal diameter of the hose is typically 2.1 mm.

Attached to one end of the test hose is a metal connector, which connects to the port on the Enersol equipment. Its internal volume can be calculated using the CAD dimensions supplied by the manufacturer.