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Subatmospheric pressure air leakage testing of small-bore connectors and reservoir connectors using the ISO 80369 and ISO 18250 standards

The ISO 80369 and ISO 18250 series of standards were developed to prevent misconnection between various small-bore connectors and reservoir connectors used in healthcare applications. The standards prescribe performance requirements and the test methods used to determine conformance with the performance requirements.

The ISO 80369-20:2015 standard contains the test methods. The following standards contain the dimensional and performance requirements of the connectors:

- The ISO 80369-2 (FDIS 2018) standard is for small-bore connectors used in breathing systems and driving gases applications.
- The ISO 80369-6:2016 standard is for small-bore connectors for Neuraxial applications.
- The ISO 80369-7:2016 & 2021 standard is for small-bore connectors for intravascular or hypodermic applications, commonly referred to as “Luers with a 6% taper”.
- The ISO 18250-3:2018 standard is for connectors for reservoir delivery systems for healthcare applications - Enteral applications.
- The ISO 18250-8:2018 standard is for connectors for reservoir delivery systems for healthcare applications - Citrate-based anticoagulant solution for apheresis applications.

Clause 6.2 in ISO 80369-2, ISO 80369-6 and ISO 80369-7 as well as clause 6.3 in ISO 18250-3 and clause 5.7 in ISO 18250-8 require that these connectors be evaluated for subatmospheric pressure air leakage.

The allowable leakage limit is based on the change in pressure in the evacuated connector over a fixed time, and its volume. There are different application pressures, limits and application periods in each of the standards. Table 1 contains details about the limits and pressures to be applied.

In ISO 80369-6, ISO 80369-7 and ISO 18250-8, the limits in these standards require that the connectors shall not leak by more than 0,005 Pa m^3/s while being subjected to a subatmospheric pressure between 80 kPa and 88 kPa, over a specified hold period.

The required subatmospheric pressure means that the pressure applied to the sample has to be 80 kPa to 88 kPa below the ambient atmospheric pressure. This requirement raises a potential difficulty with the application of the standard.

Pressure reduction due to elevation

Standard atmospheric pressure at sea level (0 m) is 101.325 kPa. As elevation is increased the atmospheric pressure decreases (because there is less air pushing down at higher elevations). This is an approximately linear decrease at low altitudes, where the atmospheric pressure decreases at a rate of approximately 1.2 kPa per 100 metres.

At an elevation of 750m above sea level, atmospheric pressure is reduced to approximately:

101 - (1.2 x 750/100) = 92 kPa

At an elevation of 1,000m above sea level, atmospheric pressure is reduced to approximately:

101 - (1.2 x 1000/100) = 89 kPa.

At an elevation of 2,000m above sea level, atmospheric pressure is approximately:

101 - (1.2 x 2000/100) = 77 kPa.

Where the atmospheric pressure is less than 80 kPa it is impossible to create a pressure 80 kPa below this atmospheric pressure, because that implies a negative absolute pressure, and that in turn implies a negative number of air molecules.

Even at atmospheric pressures greater than 80 kPa (e.g. 82 kPa to 92 kPa), it is not practically possible to achieve 80 kPa below the atmospheric pressure because very expensive vacuum equipment and seals would be needed. The closer the actual atmospheric pressure is to 80 kPa the more difficult it is to reduce the pressure by 80 kPa.

Note that many websites quote an equivalent sea level pressure when giving readings of atmospheric pressure for various cities that are elevated. This equivalent pressure is meaningful to meteorologists, but does not reflect the actual air pressure experienced on the ground.

What the standards require

Where the application standard contains pressure requirements for a subatmospheric pressure of between 80 kPa and 88 kPa, it is not directly achievable above a certain elevation. From about 750 m above sea level, it is quite difficult to achieve without more specialised equipment.

The following table states the requirements of each of the part standards, including the application pressures, leakage limit, and which of the Enersol equipment model is required to carry out the test.

Table 1: Subatmospheric pressure requirements and limits

Standard	Limit (Pa m^3/s)	Pressure (below atmospheric pressure)	Equipment model required
ISO 80369-2 (DIS) - R1 connectors	0,00005	Between 3 kPa and 5 kPa	S78A
ISO 80369-2 (DIS) – R2 connectors	0,005	Between 35 kPa and 45 kPa	S78B
ISO 80369-6:2016	0,005	Between 80 kPa and 88 kPa	S78B or S78BH models
ISO 80369-7:2016	0,005	Between 80 kPa and 88 kPa	S78B or S78BH models
ISO 18250-3:2018	0,005	Between 4.0 kPa and 4.8 kPa	S78A
ISO 18250-8:2018	0,005	Between 80 kPa and 88 kPa	S78B or S78BH models

Please note that the S78B is suitable for locations up to 600 m above sea level. Where a laboratory is located 600 m to 900 m above sea level a different ejector can used in the S78B to improve vacuum at that elevation. Although a stronger air compressor is needed to operate the modified version of the S78B. The H models of are for laboratories at high elevations of 900m+ above sea level.

The Enersol Automated Subatmospheric-pressure air leakage testers

Enersol designed its original Automated Subatmospheric-pressure Air Leakage Tester, the "S78", for the test method in Annex D of the ISO 80369-20:2015 standard. It was developed to apply the pressure and limit requirements of ISO 80369-6:2016 and ISO 80369-7:2016.

Since the publication of the ISO 80369-6 and ISO 80369-7 standards in 2016, other standards requiring the same test are in development or have been developed and published. The requirements of the newer standards including ISO 18250-3, ISO 18250-8 and ISO 80369-2 were reviewed by Enersol's Engineers and new models were developed to cover the various requirements. In 2021, a new edition of ISO 803697 was published and a new edition of ISO 80369-20 is underway. The former has not affected Enersol's equipment models but the latter will, as there are changes in Annex D that permit the laboratory to use a different application period (time). Enersol's S78B (standard model), S78A (variant) and S78BH (variant) will eventually ship with a feature to allow the user to choose the application period (time in seconds).

There are several pressure and limit requirements overall, and Enersol makes equipment for all of these requirements.

All the Enersol subatmospheric pressure air leakage tester models achieve a pressure below atmospheric pressure by ejecting air from the sample (and system). As described in this white paper, the ability to achieve a subatmospheric-pressure of between 80 kPa and 88 kPa below atmospheric pressure is only possible where the atmospheric pressure at the test location is greater. For these higher elevations, the H models are required.

Model S78A

The model "S78A" is specifically for ISO 80369-2 (DIS) for RESP-125 (R1) connectors and the connectors of ISO 18250-3:2018. This model has two pressure ranges that it can apply, one in the range of 3 kPa to 5 kPa below atmospheric pressure, and the other is 4.0 kPa to 4.8 kPa below atmospheric pressure. There are different limits it can apply, too, in-keeping with the requirements of the two standards.

Model S78B

The model "S78B" is the standard model. It is suited for laboratories that intend to test connectors in ISO 80369-6:2016, ISO 80369-7:2016 & 2021 as well as ISO 80369-2 (DIS) RESP-6000 (R2) connectors. It is also used for ISO 18250-8:2018 reservoir connectors. This model has two pressure ranges that it can apply, one in the range of 35 kPa to 45 kPa below atmospheric pressure, and the other is 80 kPa to 88 kPa below atmospheric pressure.

On request, the S78B model can be supplied with a stronger ejector when the laboratory is in a location 600 m to 900 m above sea level.

Models for higher elevations (S78BH)

The high elevation variants of the Enersol subatmospheric pressure air leakage testers have been developed for laboratories where 80 kPa to 88 kPa below atmospheric pressure is difficult to achieve.

The S78BH is the high elevation model that is directly comparable to model S78B as it applies the same subatmospheric pressures, with the same pass/fail limit requirements as the S78B.

For most locations the pressure range of 35 kPa to 45 kPa below atmospheric pressure is more easily achieved, so the S78B is suitable in those locations (up to 900 m above sea level). The S78BH is needed where the laboratory is located more than 900 m above sea level due to the nature of applying 80 kPa to 88 kPa below atmospheric pressure.

The high elevation models include the same test system as the S78B, with a similar control unit, though the H models also include a pressurising system and chamber. This is used to create an artificial atmospheric pressure inside that is high enough for the 80 kPa to 88 kPa test to be carried out.

The pressurising system and chamber - why Increase the pressure?

The requirement to increase the pressure surrounding the sample and pressure measuring device stems from two requirements;

Firstly, to enable a physical reduction of 80 kPa requires a starting atmosphere that is above 80 kPa.

Secondly, to raise the pressure outside the sample to approximate the air pressure at sea level, will enable tests to be performed at elevated laboratories to mimic those performed at sea level.

How has Enersol achieved this?

Enersol has designed a chamber for the sample under test and enclosed the pressure transducer in the same atmosphere. The pressure inside is being raised by about 20 kPa (2.9 psi) to 25kPa (3.63 psi). The actual rise can be adjusted to allow close approximation to standard pressure. This allows laboratories at higher elevations to create a higher atmospheric pressure inside the test system, from which a subatmospheric pressure of 80 kPa to 88 kPa, can be applied.

Are the results from the Enersol S78BH equipment meaningful?

The results are effective as they allow the test to be performed by removing 80 kPa to 88 kPa.

The starting pressure is raised marginally via a precision regulator, thus increasing the pressure surrounding the specimen to be tested and the pressure measuring device to a pressure that would be experienced at sea level. After the environment surround the sample has stabilised the pressure inside the sample is reduced to between 80 kPa and 88 kPa below this.

Pressure/Elevation effect on leakage rate

The leakage rate as defined in the standards is directly proportional to the pressure drop during the test, for any given test setup.

This in turn depends on the initial pressure on the high-pressure side, the density of the air and the size of the hole. The air density is, in turn, a function of pressure. Applied to leakage through a small hole, this leads to an almost linear relationship, i.e., if the pressure is 10% higher, we expect a leak rate to increase by about 10%, if 20% higher, we expect the leak rate will be about 20% higher. Conversely with reduced pressure if the pressure is 10% lower the leak rate will also be 10% lower. The result of the test is thus elevation-dependent unless the high side pressure is controlled to a fixed value.

This issue is in addition to the ability to create the necessary vacuum to do the test.

End.