Sterile Barrier Association

Guidance in the use of Seal Strength Test EN 868-5, Annex D

Round Robin Tests have shown that seal strength measurements using the method outlined in EN 868-5 Annex D may show significant differences in the resulting values even if the same sample specimens are tested and the test method is followed as described.

It has been found out that the following circumstances are of influence on the results and thus that the standard requirements should be strictly adhered to.

- Test equipment setting: the separating speed must be kept exactly at 200mm / min.

- The specimen's tail must not be supported: depending on the materials, supporting or not supporting the specimen's tail can influence the measurement and the results significantly.

- Test equipment setting: the frequency of measurements and the number of data documented and used for the calculation of peak- and average values of the seal strength is of importance. For example, a measuring frequency of 50 hz will deliver for a 10mm wide seal a number of approx. 150 units of value whereas equipment using 1 khz will deliver 3000 units of value.

it is important that these factors are taken into consideration when comparing test results from various laboratories, when validating test methods or when correlating methods and values.

Sterile Barrier Association, 9 Brockley Acres,
Eastcombe, Stroud, Gloucestershire GL6 7DU
Tel/Fax 01452 771 225, mailto:director.general@sterilebarrier.org
Website: www.sterilebarrier.org