

Sterilization - recent changes to EN285 and EN ISO 15882

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Objectives

- EN 285 the standard
- Routine Monitoring and type tests what are they?
- How often are they conducted?
- EN ISO 15882 - general conditions
- Changes to the classification of indicators
- Process challenge devices
- Conclusion



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EN 285

- **EN 285 is formally titled EN285 – Sterilization – Steam sterilizers – Large sterilizers, and is the European harmonised standard for large steam sterilizers.**
- Large' is defined as having a useable chamber volume that can accommodate a single sterilization module (300 mm x 300 mm x 600 mm), hence having a chamber volume greater than approximately 60 litres.

When was EN285 Published ?

- It was originally published in 1996. As part of the normal review process of standards, EN 285 was revised and published in 2006.
- An amendment was proposed to EN 285 soon after the 2006 version was finalised. This was published as EN 285:2006+A1:2008.

What tests are required to conform to EN 285?

EN 285:2006+A1:2008 has a table (table 4) that lists the tests that are required in order to qualify a sterilizer to EN 285, which are described as either ‘type tests’ or ‘works tests’.

What is a Type Test

EN 285 (clause 3.38) defines a type test as a 'series of checks and tests for a **particular design of sterilizer** to demonstrate compliance with the requirements of this European Standard'.

What is a Works Test

EN 285 (clause 3.43) defines a works test as a ‘series of tests performed at the manufacturer’s works to demonstrate that **each sterilizer** will comply with its specification’.

What did the amendment change within EN 285?

- EN 285:1996 specified a series of tests to be conducted in order to qualify a sterilizer one of these tests was the rubber load test.
- The Rubber Load test was specified as a type test.
- The revised EN 285:2006+A1:2008 changed from a rubber load type test to a hollow load type test.
- This change was as a result of a multi-laboratory study that showed that the rubber load test was not sufficiently sensitive and would be improved by implementing the hollow load test.

What is the rubber load test?

A type test involving lengths of rubber tubing with biological indicators inserted within the bore of the rubber tubing at predetermined locations.

What is the hollow load test?

A type test involving the hollow load process challenge device (PCD) as specified in EN 867-5 with a chemical indicator at the terminal end of the PCD.

What are the implications of this change?

Sterilizer manufacturers who conduct the type testing for each design of their sterilizer will have to use the hollow load test in place of the rubber load test.

In the context of the standard what is a Bowie and Dick test ?

The Bowie Dick test is a daily steam penetration test that is performed at the commencement of each day that the steam sterilizer is used. It is a requirement of EN ISO 17665-1 to perform this test.

So is a Hollow Lumen test the same as a Bowie and Dick test ?

No - The hollow load test is a type test specified in EN 285:2006+A1:2008. It is not intended to be used other than as a type test by the sterilizer manufacturer. The Bowie Dick test is a test that is intended to be performed daily by the end user.

EN ISO 15882 2008

Sterilization of Healthcare products – Chemical Indicators – Guidance for selection use and interpretation of results -

EN ISO 15882

- All EU member countries are bound to give this Standard a national standard status by March 2009 and any conflicting National standards should be withdrawn.
- EN ISO 15882 provides guidance on the use of indicators as described in the ISO 11140 series of standards - ISO 11140 specifies the performance requirements of chemical indicators and is intended mainly for the use of manufacturers of chemical indicators

Section 3 - General requirements

3.2 states that the value of the information provided by a chemical indicator is dependent on the class of indicator , number and location of indicators – being representative of conditions throughout the load or the chamber.

3.7 Class 3,4,5 and 6 all require one or more Stated Values or SV's these are based on the outcomes of testing undertaken in a resistometer by the manufacturer.

Resistometers – EN ISO 15882

- Hospital sterilizers typically do not have the same response characteristics or accuracy of exposure conditions as resistometers it is very difficult for the user to replicate the manufacturers label claims.
- Therefore it is suggested that third party independent laboratories with resistometers are used to verify manufacturers claims.

EN ISO 15882 - classes of indicators

Classifications of indicators

Class 1 – as per 11140 -1 – Process indicator

Class 2 - as per 11140 -1 – indicator for use in a specific test
– Bowie Dick test sheet, Alternative BD test, indicator used in any PCD.

Class 3 – as per 11140 -1 Single Parameter

Class 4 – as per 11140 -1

Class 5 - as per 11140 – 1 – however it must be highlighted that a class 5 now in EN ISO 15882 is required to have 3 SV's at 135 C, 121 C and one in between.

Classes of Indicators

Class 4 – as per 11140 -1

Class 5 - as per 11140 – 1 – however it must be highlighted that a class 5 now in ENISO 15882 is required to have 3 SV's at 135 C, 121 C and one in between. This generally results in the moving line indicators

Class 6

- Shall be designed to react to ALL critical variables for specified sterilization cycles.
- The tolerances for class 6 shown in table 4 “ *are the most stringent of the different classes of chemical indicators. These test conditions can only be achieved in a resistometer and are virtually impossible to reproduce in a hospital sterilizer.* “
- Emulating indicators can therefore “ *offer a high level of assurance in demonstrating that the critical parameters of a specified cycle have been met* “

Indicators for use in Process Challenge devices – EN ISO 15882 6.4

- Process Challenge devices have been developed to represent a penetration challenge to the sterilization process.
- There is no PCD that can be used for all sterilizer types and sterilization procedures.
- The performance of the PCD is the combined effect of the chemical indicator and the PCD components.

EN ISO 15882 PCD's 6.4 cont

- *“ most commercially available PCD's are designed to assess the penetration of a reference load. Attention must be drawn to the fact that these PCD challenge the process and do not represent the sterilization load.*
- Different products, eg. Hollow loads (beakers tubing etc) porous loads (linen, dressings, textiles) and non porous loads (solid and surgical instruments) can be represented by different PCD's

In conclusion

Changes to these standards are intended to ensure greater clarity of requirements in the context of a modern decontamination facility, to reflect the technical advances made in the industry and ultimately to provide the greatest possible protection to the hospital, the healthcare workers and most importantly to the patients themselves.

Please get copies of these standards ...read these standards ..know these standards - others, like me should not be telling you how to interpret these standards, you should be questioning us