

<i>gke</i> – Technical Information	TI 730-096-EN	
Requirements for routine monitoring in steam sterilization processes according to EN ISO 17665-1	Version 02	
	Created by	02.10.2009 JM
	Changed by	25.06.2013 JM
	Checked by	26.06.2013 UK
	Released by	26.06.2013 UK
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The sterilizing process must be validated before initial start up, after each major repair, after a certain amount of sterilization cycles or a certain period according to the Medical Device Directive (MDD) and local laws or directives. A validated method proves that the intended result is always reached under the same conditions. The standard EN ISO 17665-1 describes validation and routine monitoring of steam sterilization processes. This standard describes the methods of a validation and how a successful sterilization can be permanently controlled and monitored. A validated process remains efficient if it is reproducible on a day-to-day basis.

EN ISO 17665-1 contains well-defined information for the functionality check of the sterilizer (IQ, OQ) as well as for monitoring of each batch:

1. Functionality check of the sterilizer after start-up:

In section 12 (Maintaining process effectiveness) it says literally in 12.1.6: **„If the sterilization process relies on the removal of air from the sterilizer chamber in order to achieve rapid and even penetration of steam into the sterilizer load, a steam penetration test shall be carried out each day after start-up.“**

This standard requires that a functionality check for the sterilizer before start-up is mandatory to prove air removal and steam penetration. The standard EN ISO 17665-1 does not define which test system has to be used for routine monitoring. Therefore the type tests described in EN 285 (BD-Test and hollow load test according to EN 867-5) are commonly used. *gke* offers a test device that combines both requirements of EN 285 (BD-Test) and EN 867-5 (Hollow load test) in one test system.

A correctly working sterilizer is never a proof that all goods are sterilized successfully in the production cycles. Therefore a load adapted monitoring system shall be used in all cycles.

2. Routine monitoring

EN ISO 17665-1 specifically requires routine monitoring according to the load configuration for each batch which is described in this standard e.g.:

- In section 10 (Routine monitoring and control) it says literally in **10.1. „Routine monitoring and control shall be performed on each operating cycle.“**
- In Paragraph **10.3.** under point d) the term **„steam penetration“** is mentioned. Therefore steam penetration is technically a critical parameter according to the standard and has to be monitored. If this proof is not available, the batch cannot be released.

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- In Section 11. (Product release from sterilization): „**Procedures for the review of records and product release from the sterilization process shall be specified. The procedure(s) shall define the requirements (see 9.5.2 and 10.3 as appropriate) for designating a sterilization process as conforming. If a requirement is not met, product shall be designated as nonconforming and handled in accordance with 4.4.**”

Therefore all batches have to be re-sterilized if the parameter “steam penetration” is not met. Sufficient steam penetration has to be proved in each batch.

A proof of steam penetration inside of hollow instruments can be secured by using a process challenge device (PCD) with a chemical indicator inside with higher air removal characteristics than the goods that have to be sterilized. This test can be used for batch monitoring in each cycle and is a so-called Batch Monitoring System = BMS.

To assure that the BMS is more difficult regarding air removal as the load, a validation of the BMS using the methods of DIN 58921 has to be carried out in an accredited microbiological laboratory for this specific task.

Additional information:

In EN ISO 17665-1 the term „if applicable“ is often mentioned in connection with air removal and steam penetration. This term is misleading and gives the reason that routine monitoring is voluntary if the sterilizer is not working steady. This statement is not correct. The authors of this standard use the term „if applicable“ for special cases whereas air removal or steam penetration may not be necessary, e.g. liquid sterilization. In this case water already exists and steam condensation is not necessary only heat supply. Therefore steam penetration tests are not necessary if only liquids are sterilized. A steam penetration test is essential if hollow devices are sterilized.

Modern sterilizers are often equipped with detectors for non condensable gases (NCG) to measure NCG in steam. The steam is removed e.g. from the steam pipe or different area and feed to the detector. A NCG-detector is no substitution for a batch monitoring system because the detector can only measure the steam quality and air removal within the sterilizer but no air removal or steam penetration in the instruments (see our technical information TI-730-084). Furthermore the validation standard (see above) specifically requires the proof of steam penetration inside of hollow devices. Steam penetration should not be mixed up with steam quality and the measurement of both cannot be compared. Sufficient steam quality cannot proof, if air and NCGs inside hollow devices have been removed successfully.