

<i>gke</i> - Technical Information	TI 730-041-EN	
Monitoring Low Temperature Formaldehyde (LTSF) Sterilization Processes with Biological Indicators	Version 04	
	Created by	09.03.2006 JG
	Changed by	07.03.2013 UK
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The resistance of the indicators should be determined in a Resistometer with a gas atmosphere created by a formalin solution, characteristic for LTSF sterilization processes. A publication of the *gke* application laboratory demonstrated that this kind of resistance determination can cause big failures (see Gömann, J., Kaiser, U., Menzel, R.: Reaction Kinetics of LTSF- Sterilization Processes. Central Steril. 2000, 8 (5): 290-293. These test conditions are not reproducible to determine the resistance of indicators. Therefore the publication proposed to test instead in the gas phase in a formalin solution and directly afterwards to neutralize the absorbed formaldehyde adhering on the indicator. This publication is available on the *gke* website (www.gke.eu).

The Standard EN ISO 11138-5:2005 requesting *Geob. stearrowthermophilus* spore strips with a minimum population of 10^5 CFU/strip. The resistance has to be determined in 1-M formalin solution at 60°C. The $D_{60^\circ\text{C}}$ -value has to be at least 6 minutes, the standard EN ISO 25424 for the validation of LTSF-processes requires an F(Bio)-value of 30-36 minutes at 60°C.

For sterilization monitoring the indicators are placed inside the load at locations difficult to penetrate. If hollow devices are sterilized, the use of a process challenge device (PCD) according EN 867-5 is mandatory. This standard will be replaced by EN ISO 11140-6. After sterilization the BI has to be removed from the LTSF sterilization process and incubated as follows:

1. To inactivate remaining absorbed formaldehyde, the spore strips have to be aseptically transferred in a test tube with 10 ml sterile filtrated 2 % $\text{Na}_2\text{SO}_3\text{-H}_2\text{O}$ solution, briefly shaken and left at room temperature for 10 minutes.
2. Afterwards the spore strips have to be aseptically transferred in a CaSO-liquid medium and heat shocked in a tightly closed test tube at 90°C for 60 minutes.
3. Using this growth medium, the spore strips have to be incubated afterwards for at least 5 days at 55-58°C as usually and have to be checked for growth every day.

For further details about resistance determination with sodium sulphite please check above mentioned publication and/or the European and International standard EN ISO 11138-5.

To circumvent the complex neutralization with Na_2SO_3 and heat shock treatment afterwards, *gke* offers a self-contained biological indicator (SCBI) that can be incubated by the user without a microbiological laboratory. The SCBIs for Low Temperature Steam Formaldehyde (LTSF) sterilization processes contain in the growth medium substances, decomposing remaining absorbed formaldehyde, so that the pretreatment with Na_2SO_3 according to EN ISO 11138-5 is not required anymore

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and the results can be obtained much faster. The SCBIs have also been designed to be used inside a *gke Steri-Record*[®] Bio-Compact Process Challenge Device (Bio-C-PCD[®]) number 4 simulating a hollow load test according to EN 867-5. Furthermore the corresponding incubator is available as well.

Also in the LTSF sterilizer standard EN 14180 the PCD "Hollow load" according to EN 867-5 is used as a type test to check the penetration characteristics of LTSF sterilizers. It is mentioned in the standard, that the PCD should be made of plastic. Recent tests showed that stainless steel PCDs, which are more stable, don't have any influence on the test result, since the LTSF sterilizers themselves are made of stainless steel. Therefore *gke* offers all Helix- or Compact-PCD capsules for LTSF processes made of stainless steel.

Biological indicators and accessories necessary for monitoring formaldehyde sterilization processes are available from *gke* under the following article numbers:

1. Self-contained biological indicators (SCBI) and spore strips to test formaldehyde sterilization processes:

Art.-No.*	Quantity/ pack	Product Code	Cap colour	Population
325-601	10	B-F-MBP-10-6	Yellow	10 ⁶
325-605	50			
330-501	100	B-S-F-SS-10-5	-	10 ⁵

2. Incubator:

Art.-No.*	Product Code	Description/ Application
610-110	I-57	Incubator with incubation temperature of 57°C to incubate <i>G. Stearothermophilus</i> biological indicators
610-113	I-AB-MBP	Aluminum block for incubator for all <i>gke Steri-Record</i> [®] SCBIs

3. Process Challenge Devices (PCD):

Art.-No.*	Product Code	PCD- Version	Description
300-014	B-PM-OCPD-4	Oval	Complies with Hollow Load Test according to EN 867-5
300-019	B-PM-RCPD-4	Round	
213-260	C-F-PM-HPCD-KIT	Helix	Starter kit with Hollow load helix test according to EN 867-5 with 100 integrating indicator strips

***Notice:** On all *gke*-packages, an additional letter code has been added to the 6-digit article number. The additional letter code refers to the language and/or customized version. It is only added on the outside label, the inside of the pack is identical to the article numbers in the above table. All articles with the same 6-digit number have the same specifications.

Our application laboratory will assist you with any further questions.