

	Technical Information	730-149-EN		V03
	Time period between end of process and incubation start (Holding Time of Biological Indicators)	Created	21.11.2017	HeK
		Changed	06.08.2021	KP
		Checked	06.08.2021	UK
		Released	06.08.2021	UK
File no.: 3.0				

Background Information:

Biological indicators (BI) are used to monitor sterilization processes. After sterilization the indicators have to be aseptically transferred into a growth medium or self-contained biological indicators (SCBI) have to be activated and incubated at defined temperatures.

The period of time between the end of the sterilization process and the start of incubation is referred to as the "holding time" of a BI in English-speaking countries, based on FDA documents. The holding time influences the incubation result depending on the sterilization process and spores used.

Influence of the holding time of a BI to monitor chemical low-temperature sterilization processes:

A long holding time has a very strong influence on the result of incubation. At the end of chemical low-temperature sterilization processes residues of sterilizing gases can remain in the packaging and the carrier material of the BIs. Examples are ethylene oxide, formaldehyde and hydrogen peroxide gases.

The residues of these sterilizing gases after sterilization continuously kill left alive spores in a BI, which would grow after immediate incubation of the BI, if direct transfer into the neutralizing growth medium would occur. In seldom cases a BI incubated directly after the end of the process can still show growth, but would no longer grow when the incubation is delayed.

The culture media for incubation of BI and SCBI for monitoring FO and VHPO sterilization processes contain special additives to immediately destroy the absorbed residual gases from the sterilisation process.

Recommendation at the beginning of the incubation:

When using BIs, it is always recommended to start incubation as quickly as possible after the sterilization process has been finished. For chemical low-temperature sterilization processes, this must be done with special consideration for personal safety. In thermal processes like as steam or dry heat, the beginning of the incubation can take place within 72 hours after the end of the sterilization process, without changing the result.