

	<b>Technical Information</b>	<b>730-037-EN</b>		<b>V04</b>
	<b>Monitoring of prion programs in steam sterilization processes at 134°C ≥ 18 min</b>	Created	17.08.2009	UK
		Changed	02.09.2021	KP
		Checked	02.09.2021	UK
		Released	02.09.2021	UK
<b>File no.: 1.1.4</b>				

To prevent potential disease transmission e. g. Creutzfeld-Jakob disease, which is transmitted by prions, in different countries (France, Switzerland, etc.) prion programs are used in steam sterilization programs at 134°C; 18 min.

Two important physical parameters have to be monitored in prion sterilization processes:

1. Temperature time window (134°C; ≥ 18 min)
2. Steam penetration inside instruments that have to be sterile.

GKE offers batch monitoring systems (BMS) consisting of a process challenge device (PCD) and an integrating indicator strip inside, called type 2 indicator systems according EN ISO 111401.

GKE PCDs are designed as hollow devices and simulate complex instruments. A chemical indicator strip is placed into the PCD and provides the information of steam penetration at the most difficult position inside of the sterilization load by changing its color to black. Additionally the color change assures that the temperature time window has been achieved.

Batch monitoring systems are able to detect non condensable gases (NCG) which easily accumulate in hollow instruments. Volumes below 1 ml are critical to prove successful sterilization in minimal invasive surgical (MIS) instruments.

The standard GKE batch monitoring systems consist of PCD and integrating indicator strips and monitor the common temperature-time-window of 121°C; 15 min ( $F_0 = 15$  min) or 134°C; 3 min where all traditional pathogenic germs are killed. The construction of the PCD proves steam penetration inside hollow instruments. Longer sterilization times up to 18 min can be recorded by the sterilizer itself.

However, some countries, e. g. Switzerland and France, exclusively require prion programs for all sterilization processes used. Therefore, GKE offers special indicator strips according to EN ISO 11140-1 type 6 (package monitoring) and type 2 indicator systems (consisting of PCD and indicator strip) that are designed for 134°C; 18 min.

GKE recommends to monitor steam sterilization processes with prion programs as follows:

1. GKE batch monitoring systems should be used to monitor sufficient air removal and steam penetration at the most difficult position inside of the sterilization load.
2. Physical data such as temperature and time should be recorded by the sterilizer.
3. If the sterilizer does not record the physical data or prion programs are exclusively used, the GKE chemical indicator for 134°C; 18 min inside the PCD should be used.

The Bowie-Dick-Test has a defined temperature-time standard (Stated Value = 134°C; 3.5 min) and does not require a special indicator for prion programs.