

	Technical Information	730-049-EN		V03
	The temperature-time window of GKE chemical indicators used in all GKE Bowie-Dick-Simulation Tests and batch monitoring system	Created	16.02.2004	UK
		Changed	02.09.2021	KP
		Checked	02.09.2021	UK
		Released	02.09.2021	UK
File no.: 2.0				

The GKE Bowie-Dick Simulation Test and GKE Batch Monitoring Systems consist of a Process Challenge Device (PCD) with a chemical indicator inside to monitor non-condensable gases (NCG) which result from insufficient air removal, leaks in the sterilizer during the vacuum phase, NCG in steam and/or from pneumatic leaking door seals. Additionally, all chemical indicators inside of the PCD verify the temperature-time window of the steam sterilization process.

Those chemical indicator systems fulfil the requirements according to EN ISO 11140-1 type 2. They exclusively react in presence of steam or steam condensate from yellow to black. They do not change to black under dry heat conditions.

Depending on the temperature-time window in the presence of steam the chemical indicators react as follows:

121°C, $F_{(0)} = 10$ min no colour change to black

121°C; $F_{(0)} \geq 15$ min colour change to black

134°C, = 1 min no colour change to black

134°C, ≥ 3 min colour change to black

There is no problem to extend the above temperature-time window. The indicators will always change to black if steam is present and the minimum temperature-time window is met.

Even long sterilization cycles without presence of steam will not allow the indicator to change to black and simulate a pass. The colour always remains brown, if no longer sterilization times above 10 min at 132-137°C are carried out. Above temperature-time windows are adequate to achieve sufficient sterilization power according to the standard EN ISO 17665-1. Therefore a longer duration time for pure sterilization purposes ($F_{(0)} > 15$ min) is not required for standard products from a sterility point of view.

If longer sterilization times are required because of higher bioburdens or special pathogenic species, like prions, the most precise detection is to monitor the temperature time curve given by the recording system of the sterilizer. However, this information does not allow any information about the presence of dangerous NCG.