	Technical Information	730-070-EN		V02
	Are there PCDs suitable for certain sterilizers/autoclaves?	Created	27.03.2006	UK
		Changed	02.09.2021	KP
		Checked	02.09.2021	UK
		Released	02.09.2021	UK
		File no.: 0.3		

GKE manufactures test systems to monitor sterilization processes, each consisting of a PCD with corresponding indicator strips. These systems, which are available both as Bowie-Dick simulation tests (BDS) and for batch monitoring, react very sensitively due to their construction as hollow PCDs and can indicate incomplete air removal even with slight variations in process quality.

If problems are detected when using GKE test systems, where the technical reason is not immediately obvious, it is often argued that GKE PCDs are "too sensitive" for the sterilizer or that the selected system is "not suitable for this sterilizer".

This argumentation is factually not correct, because it is in general not possible to assign sterilizer type and PCD.

The sterilization processes programmed in a sterilizer must be suitable for the instruments including their packaging and the entire load. This is checked during process validation. Then the suitable PCD is selected, which is not based on the sterilizer, but exclusively on the requirements of the load on the sterilization process. A PCD must ensure that it simulates the most difficult sterilization condition of a batch, so that it can be concluded from a successfully passed batch monitoring test that all goods have been successfully sterilized.

GKE offers different test systems to monitor sterilization batches, each consisting of a Compact-PCD® with an outside plastic housing and a stainless steel insert sealed with a capsule to hold the indicator, and corresponding indicator strips.

Under the condition that the test system has higher requirements for air removal than the most difficult load to sterilize, it reliably monitors the successful air removal or steam penetration and therefore the sterilization of complex hollow systems and their packaging.

Both large sterilizers according to EN 285 and small sterilizers of class B according to EN ISO 13060 must, as a minimum requirement, pass a hollow load test (so-called type test), which is described in the standard EN 867-5 or new in EN ISO 11140-6. This steriliser type test may be suitable as a batch monitoring system if it has higher requirements on the air removal performance than the load.

However, there are many loads - especially in the hospital area - that have higher demands and therefore need to be monitored with a "more difficult" test than described in the standard. Loads that are easier to sterilize - e.g. in the area of private medical practices - can also be monitored with "easier" tests than described in the standard.

A batch monitoring system is therefore a test that must always be "suitable for the load" and which must never be selected "to suit the sterilizer".

Of course, this test must also be passed by the sterilizer. If this is not the case, the process conditions of the sterilizer must be improved. However, this should already have been clarified during validation. If this is not the case, a new validation is required.