

	Technical Information	730-171-EN		V05
	Existing EN ISO Standards for Type 2 indicator systems according EN ISO 11140-1	Created	08.04.2020	UK
		Changed	05.08.2021	KP
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The question has been raised which standards refer to the different GKE type 2 indicator systems.

The standard EN ISO 11140-1 defines the design of type 2 indicator systems, but does not specify their sensitivities.

Only three sterilizer standards contain specifications for so-called type tests which are testing the minimal performance requirements of sterilizers:

1. **BD-Test 7 kg cotton pack** according EN ISO 11140-4 and EN 285 to test European sterilizers
2. **BD-Test 4 kg cotton pack** according ISO 11140-5 and AAMI/ANSI ST 79 to test American sterilizers
3. **Helix test** according to EN 867-5 (will be replaced by EN ISO 11140-6) with a tube length of 1.5 m used in the sterilizer standards EN 285, EN 13060 Type B and EN 14180

Type 2 indicator systems (Process Challenge Device = PCD with indicator) to be used as batch monitoring systems (BMS) are not specified, but special requirements for BMS can be derived from the following standard EN ISO 14937: 8.6 which describes how to correctly select a PCD for BMS:

If PCDs are used as part of the establishment of the sterilization process their appropriateness shall be determined. PCDs shall present a challenge equivalent to or greater than at the position in product, where it has been determined that the sterilization conditions are most difficult to achieve.

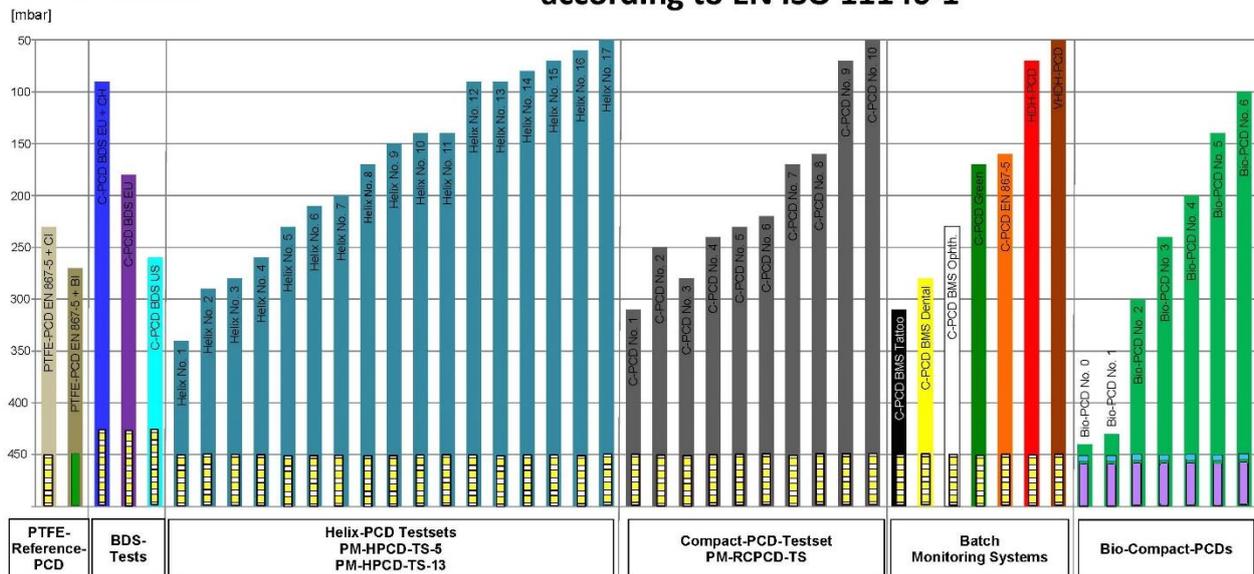
Therefore, in the validation standards EN ISO 17665-1 and EN ISO 14937 it is requested that special type 2 indicator systems according to EN ISO 11140-1 shall be used, if for example complex hollow devices are sterilized. The penetration characteristics of a BMS must be more difficult in comparison to the instruments inside the load configuration.

Therefore, the sensitivity of a PCD must be adjusted/calibrated to the most difficult load configuration. The below chart shows all the type 2 indicator systems manufactured by GKE. Length and diameter of different Compact- or Bio-Compact-PCDs do not describe their sensitivity since the patented design of the C-PCDs having a series connection of a large volume, a smaller volume and a tiny capsule volume amplifies the difficulty of air removal and steam penetration. Therefore, these dimensions do not provide any useful information for the end user. In order to avoid any misinterpretation of the PCD characteristics, no information about these dimensions is published.

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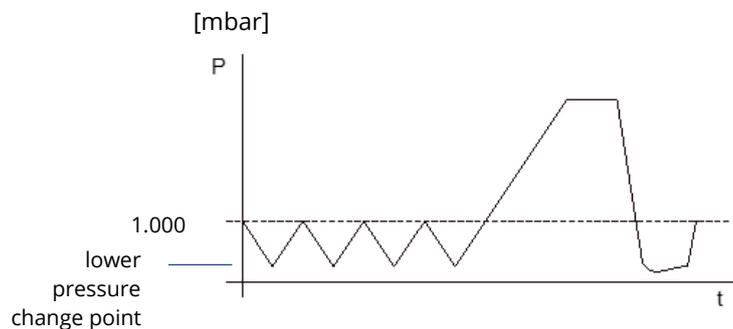
Sensitivity comparison of different *gke* type 2 indicator systems according to EN ISO 11140-1



The diagram shows the lower pressure change point where PCD results change from PASS to FAIL. The higher the bar the more difficult is the PCD to pass.

PCD Test procedure:

- steam test sterilizer according to EN ISO 18472 used
- for air removal: 4 vacuum pulses from various pressure change points (see chart above) to 1000 mbar
- 450 mbar/min pressure change rate
- sterilization conditions: 3.5 min at 134°C



To find the correct PCD for a specific sterilization process requires a validation of this PCD according to the GKE Technical Information TI 730-168.