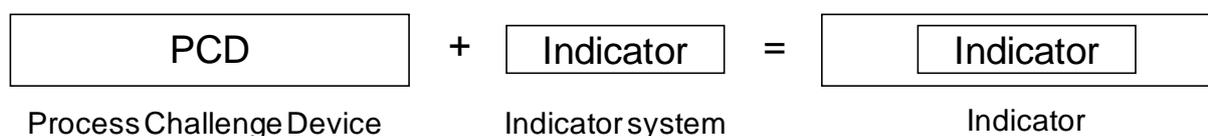


<i>gke</i> – Technical Information	TI 730-079-EN	
Which chemical indicators should be used in a Processes Challenge Device system (PCD; BMS; MDS)?	Version 03	
	Created by	30.10.2006 UK
	Changed by	02.09.2010 UK
	Checked by	02.09.2010 UK
	Released by	02.09.2010 UK
Page 1 of 1		

Chemical indicator systems consisting of a Process Challenge Device (PCD) with an indicator inside are calibrated always with an especially selected indicator.

EN ISO 11140-1 unfortunately uses descriptions that are different from habitual language use. The indicator strip – or i.e. using a BD cotton pack the indicator sheet – is called “indicator system” in the standard and an “indicator” is a PCD with an indicator strip inside (or a BD cotton pack with indicator sheet inside).



In event of non-availability of an original indicator strip where the validation has been carried out with, what happens, if any other Class D or Class 5 or 6 integrating indicator is used?

The sensitivity of a PCD depends on various factors. One is the free effective capsule volume determined by the capsule volume minus the volume of the indicator. The volume of the chemical indicator (CI) does not depend only on its outside dimensions, but also on the porosity of the carrier of the CI. For a user it is very difficult to produce another CI with exactly the same inner volume. Small volume differences of only 20-30 µl may heavily influence the indicator system’s sensitivity.

However more important is the CI-substrate-specification. A class 5 or 6 indicator has to show the critical parameters for a steam sterilization process according to EN ISO 11140-1: temperature, time and water (created by condensation). A class 5 or 6 indicator and a class 2 indicator may have identical stated values (SV) referring to the parameters above defined in the standard. However inside a PCD there is never steam or water or non condensable gases (NCG) only. In reality there is always a mixture of gases, even there is colour change of a CI or total kill of a biological indicator (BI). The so called partial pressure of NCG and steam influences the colour changing behaviour of a CI and is different for all CIs made by different manufacturers. The colour change characteristic is influenced by the partial pressure of steam and NCG but is not defined in any standard. As a consequence the change of a CI-substrate will change the sensitivity of a PCD-System, even if all hardware PCD components and the SV remain unchanged.

Even if exactly the same PCD is used with different CIs, remarkable sensitivity changes are observed, already reported by several publications. Therefore a class 2 indicator system, consisting of a PCD and a CI inside, should be always calibrated and used with the originally calibrated components. The new development of Medical Device Simulators (MDS) and Batch Monitoring Systems (BMS) for which standards are developed, take these phenomena into consideration.