
	Technical Information	730-075-EN		V01
	Can built-in detectors replace the use of a Process Challenge Device (PCD)?	Erstellt	04.04.2022	UK
		Änderung		KP
		Prüfung	04.04.2022	UK
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Ablage-Nr.: 1.0				

Some steam sterilizers are equipped with a so-called "inert gas detector". These systems are sometimes sold with the argument that further controls are obsolete when such a detector is installed.

This statement is technically not correct. The detector systems have by far not the air removal and sterilizer gas penetration sensitivity of hollow load test systems and reach their technical limits with the following arguments:

1. Hollow instruments have extremely small internal volumes. For example, a tube of 1 m length and 2 mm inner diameter has an internal volume of only 3.14 ml. If about 10 cm of the length of this tube is filled with air or with another non-condensable gas (NCG), this is a critical volume of only about 0.3 ml. For the detection of such small amounts of NCG, which are already critical for narrow lumen instruments, NCG detectors cannot provide information whether NCG is present in the hollow device.
2. The presence of NCG in the steam is only critical during the come-up time. During this phase, and only during this phase, the steam enters the packages and lumens and, if it contains NCG, would carry them into the packages or instruments. To monitor the temporal correlation between an NCG peak and the come-up time, measurement in a hollow device itself is necessary. Of course sensors of a detector system are located somewhere in the sterilizer equipment, but not in the packs or instruments themselves. Therefore the sensors cannot monitor if there is actually steam in the specific instrument.
3. Many detector systems integrate the amount of NCG over time, i.e. they show at the end of the process how much NCG was totally measured, but they cannot show at which time the NCG peaks occurred. However, this is of particular importance (see point 2) because the presence of NCG is critical only during the come-up time.
4. The measuring methods of the detectors are often based on condensing steam and measuring the amounts of NCG in the condensate, e.g. by collecting NCG bubbles in one place or by light barriers that generate a signal when an NCG bubble crosses the light beam. However, as soon as water vapor is condensed, CO₂, one of the most frequent NCGs in the condensate, immediately dissolves again and is therefore not measurable by the detector system. For these reasons, the additional use of an "inert gas detector" is possible, but the devices are not able to replace a hollow load test system due to their design and their mode of operation, as they cannot provide information about the agglomeration of NCG in hollow systems or hollow instruments. This is only possible by measuring in the hollow devices themselves or by using a batch monitoring system that simulates the most difficult load and has been validated accordingly before. The standard EN ISO 17665-1 for the validation and monitoring of steam sterilization processes requires both monitoring of pressure and temperature as well as successful steam penetration with a suitable Process Challenge Device (PCD) that simulates the most difficult to sterilize parts of the load.

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5. Inert gas detectors cannot be calibrated because reference concentrations of NCG quantities in the steam cannot be represented reproducibly. There are only indirect calibration methods possible, for example, an inert gas detector can simulate a porous cotton pack (see EN ISO 11140-4). Larger amounts of NCG of 50 - 200 ml must be accumulated in it, far too much to guarantee the safe sterilization of hollow devices.