



Technical Information

730-128-EN

V04

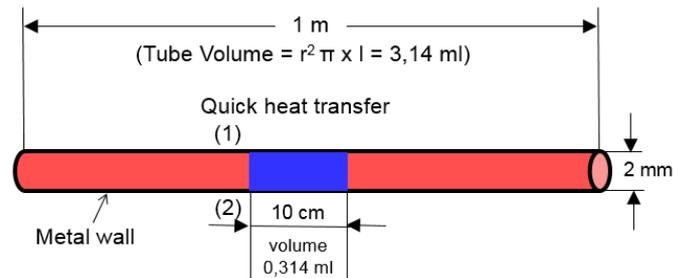
The hollow PCD sensitivity depends heavily on the indicator capsule volume

Created	20.08.2014	JM
Changed	06.08.2021	KP
Checked	06.08.2021	UK
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Already small amounts of non-condensable gases (NCG), like air, block the penetration of the sterilant into hollow devices, e.g. MIS instruments or tubes. This is not only valid for steam sterilization processes but also for low temperature sterilization processes, e.g. with formaldehyde or hydrogen peroxide.

In a tube of 1 m length and 2 mm diameter already about 0.3 ml NCG can be the reason that a section of 10 cm inside the tube remains unsterile (see drawing).



Calculation of the tube volume. Already far below than 1 ml NCG can block sterilant penetration of a tube section of several cm.

Unsterile conditions in the instruments themselves cannot be detected during routine operation. Therefore hollow load tests are used, consisting of a PCD (Process Challenge Device) and inserted indicator strips.

In EN 867-5 (new: EN ISO 11140-6) a hollow load test, the so-called „helix-test“, is described:



Colour change of the inserted indicator strip with complete and insufficient steam penetration.



Complete steam penetration



Insufficient steam penetration

The hollow load test according EN 867-5 (new: EN ISO 11140-6) can detect very small NCG amounts, because the indicator capsule has an extreme small inner volume of only 0.283 ml. Therefore already an NCG amount of far below 1 ml – as well as in a real hollow instrument – strongly blocks the steam penetration so that the inserted chemical indicator does not reach its end point colour on all indicator bars.

PCDs with a too large indicator capsule cannot determine such small NCG amounts.

Actually, there are PCDs on the market with indicator capsule volumes of 15 ml up to 50 ml. The capsules of these tests are therefore partly more than hundred times larger than the NCG amount to be detected.



Examples for PCDs with extreme large capsules to host the indicator strip.

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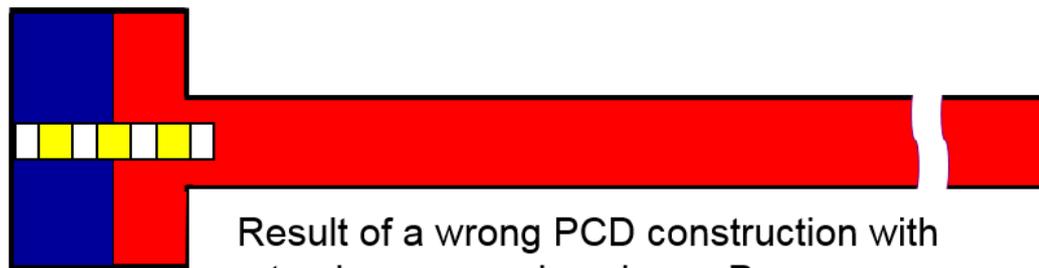
PCDs with such large indicator capsules therefore have a faulty design because of their geometry and are completely insensitive for NCG amounts of less than 1 ml. The reason is derived from the physical gas law. The two drawings below show that after a single identical vacuum cycle steam or another sterilizing agent can not reach the indicator due to the remaining amount of residual air at a small indicator capsule volume (ICV). If a large ICV is used, steam or the sterilizing agent will partially penetrate the capsule at the first pressure pulse, mix with the air and causing a colour change of the indicator. However, this PCD does not represent a tube or MIS instrument and should not be used as a test PCD.



After a vacuum cycle of 100 mbar steam feeding (1000 mbar) under identical test conditions:



Result of a correct PCD construction: Fail



Result of a wrong PCD construction with a too large capsule volume: Pass



air (1 bar)



steam (1 bar)