

	Technical Information	730-055-EN		V05
	Changes of EN 285 for large sterilizers – integration of the helix PCD as a mandatory test	Created	05.11.2004	UK
		Changed	02.09.2021	KP
		Checked	02.09.2021	UK
		Released	02.09.2021	UK
File no.: 0.3 + 1.1				

GKE has already published¹ in 2001, that the performance of air removal and steam penetration using the original BD-Test, based on a 7 kg cotton pack, is not always able to detect fails in hollow devices. While the original BD-tests or other porous simulation tests may show a pass result in the same programs, tubes and hollow devices show fail results in several air removal programs. The same results appeared in a consolidated laboratory test, which a working group of the above-mentioned committee has been carried out.

The reason depends on a different sensitivity of the BD-test and hollow devices. While the original BD-test detects non condensable gases (NCG) above 100 ml inside of the packs, an amount < 1 ml of NCG blocks the steam penetration in hollow instruments already.

To prove the sterilization of tubes, hollow instruments and minimal invasive surgical (MIS) instruments, EN 285 requires a hollow load test in addition to the BD-test. The helix test (hollow load test) according to EN 867-5 (new EN ISO 11140-6) has been selected, which is already used as a test for small steam sterilizers according to EN 13060 type B. This modification of EN 285 has been implemented beginning of 2008.

The GKE batch monitoring system conforms to the hollow load helix test according to EN 867-5 and is able to detect amounts ≤ 0.1 ml of NCG in hollow instruments assuring sterilization inside of hollow devices.

GKE developed a BD-test on a hollow device basis, which accomplishes both mandatory functions above. The GKE PCDs (Helix- und Compact-PCD[®]s) can cover both functions by using one test. The GKE BD-Test may be more sensitive compared to porous BD-tests on the market depending on the air removal program used.

¹ Gömann, Kaiser, Menzel: Air Removal from Porous and Hollow Goods using Different Steam Sterilization Processes., Zentr. Steril 2001; 9 (3): 182-186