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Is the helix-test a batch monitoring system?

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The helix test is described in the standard EN 867-5 (new: EN ISO 11140-6) consisting of a 1.5 m Teflon tube closed at one end with a Teflon capsule containing a biological indicator. It is used as a so-called type test to test the technical air removal specifications of small table top sterilizers according to EN 13060 Type B and large sterilizers according to EN 285. Also, the helix test is used after start of small table top sterilizers as a replacement of a Bowie-Dick-Test as a functional test of the sterilizer after heating up in an empty chamber, since the original BD cotton pack is too large to fit in table top sterilizers.

A batch monitoring system is sterilized together with the load to check if air removal and steam penetration guarantees sterility of the load. Therefore, the batch monitoring system used must have more difficult air removal characteristics than the load.

GKE offers the helix test, but it can only represent a simple load. Only in exceptional cases it suitable for batch monitoring. It should therefore only be used as a type test for steam sterilizers and as a start-up test in the empty chamber of a sterilizer in the morning.

GKE offers a range of batch monitoring systems with more difficult air removal characteristics representing normal loads and loads with difficult air removal characteristics. This ensures safe sterilization as long as the PCD system is correctly selected to represent the load.

These GKE Type 2 PCD systems according to EN ISO 11140-1 can not only be used in steam sterilization processes but also in all low temperature (EO, LTSF or VHPO) sterilization processes.