Quite often there are discussions with a service engineer of a sterilizer manufacturer (very often with Getinge) if a sterilizer will not pass (anymore) a selected type 2 indicator system (PCD) with a defined air removal/steam penetration characteristic. The service engineer recommends to use a PCD or BDS pack of the sterilizer manufacturer and then the problem will be solved.

When a type test (e. g. BD- or helix-test) to test the sterilizer or an indicator system type 2 for continuous batch monitoring is selected, 3 different requirements have to match:

1. **What is the capability of a sterilizer for air removal and steam penetration?**

   This depends on the number and type of air removal cycles, steam quality depending on water quality, leaks, etc.
   Sterilizer companies have different programs with different air removal and steam penetration potential. In the last years they are under pressure and try to minimize the total cycle time where they also minimize the time for the air removal cycles using lower pressure difference per cycle etc.

2. **Requirement of air removal and steam penetration of the load to be sterilized**

   Solid instruments are easy to sterilize, however, lumen instruments like arthroscopic instruments are much more difficult to sterilize inside such lumens.

3. **PCD sensitivity for air removal and steam penetration**

   GKE has different versions which should be selected for validation and batch monitoring to be more difficult to pass than the worst-case load configuration (see no. 2).

There can be always a PCD (no. 3) selected, which can pass a sterilizer, if the PCD is easy enough to pass. However, this will not assure sterility of the load (no. 2), if the penetration characteristic of 3 is easier in comparison to 2. Therefore a PCD (no. 3) must be selected which is more difficult than the worst-case area of the load (no. 2). If the correct PCD is passing, the sterilizer program (no. 1) can be easily tested. If most of the time a pass but sometimes a fail is detected, it is an indication that the sterilizer is not running reproducibly from cycle to cycle. If the sterilizer gets always a fail, the PCD may be too difficult to pass and may be too difficult to simulate the worst-case load configuration (no. 2) or the PCD is correct and the sterilizer program is not good enough for air removal and steam penetration of the load.

To check if the PCD is simulating the worst-case load configuration (no. 2) a validation procedure has to be carried out with biological indicators at the worst-case location of the load. If indicator strips don't fit into a lumen instrument, a direct inoculation with biological indicator suspension has to be carried out for the validation procedure.