The presence of non-condensable gases (NCG) in a steam sterilization process is most difficult to detect and is one of the most frequent malfunctions in the daily practice. On the one hand already very small volumes of NCG are problematic – a tube of 1 m length and 2 mm diameter e.g. has a total inside volume of 3,14 ml only – on the other hand there is only a very small time frame in which the presence of NCG is critical during the come-up phase. At the beginning of the air removal phase NCG are noncritical – the following vacuum cycles transport them out of the chamber – and during the plateau phase NCG also do not cause any problems because during this time no steam condenses in the packages anymore and NCG cannot get inside of the packages and the instruments.

This information is already explaining the limitations of NCG detectors (also called inert gas detectors):

- An NCG detector system has to detect NCG volumes much less than 1 ml; if this is not the case, false-positive results are possible.
- The detectors integrate the NCG amount over the total cycle time, but the critical time frame is only the come-up phase, that means the time in which steam and with it the NCG volume quantitatively penetrates the hollow lumens. Integration over a longer period may result in false-negative results.

Besides these two issues mentioned above, further basic problems exist during use of such detectors.

- All NCG-detectors condense steam. The condensate is collected to detect NCG. This procedure – basically also described in EN 285 – has the disadvantage that not all kinds of NCG are detected. While nitrogen N_2 can reliably be detected forming gas bubbles, the detection of carbon dioxide CO_2 and oxygen O_2 is only rarely or even not possible because these NCG dissolve in the condensate and are therefore invisible. The detectors cannot detect them, because they are dissolved in water.
- The location in the chamber with the highest probability of NCG is near the door at the bottom. In this place most of the condensate is collected and also a PCD system with indicator should be placed there. However, NCG detectors make the gas sampling from different locations (i.e. steam supply pipe, any chamber location or drain). Presence or Absence of NCG in the pipe does not allow any conclusion about the situation in the packages and hollow devices.
- NCG detectors cannot be calibrated until a concentration of around 5% NCG in steam is present. In the current practice the calibration of the detectors is made in comparison to another test system. Some are calibrated using a Bowie-Dick cotton pack and check a temperature failure of 2°C inside the pack. Independent from the reference test there is always the problem that only comparable measurements can be made. Calibrating an NCG detector with absolute measurements – which would conform to calibration – is presently not possible until a very high NCG concentration (see above, approx. 5%) is reached. But EN 285 requires an NCG limit of 3,5 % NCG in the condensate, equal to 35 ml NCG in 1672 l steam, equivalent to about 0,0005 %, an extreme low concentration where NCG detectors cannot be calibrated.

GKE has carried out many tests about this subject. Actually, our research laboratories could not develop a satisfying solution of NCG detection by parametric release until now. This is the reason why we are currently still working with the combination of PCD and chemical indicator to securely fulfil the requirements for the proof of the presence or absence of NCG. GKE fulfils these requirements for example by the dimensioning of the tests (very small inner volume, therefore proof of much less than 1 ml NCG), by positioning the test at the most critical location in the chamber, by monitoring exclusively the critical time frame (steam consumption of the PCD during the come-up time – analogue to the instruments being sterilized) and provide a graduated test result (several indicator bars provide a graduated result not only a fail/pass information).

Where biological indicators are required to validate or monitor sterilization processes, GKE has developed special low volume self-contained biological indicators (SCBIs) which can be used in especially designed Bio-PCDs – the first method to simulate the hollow load Helix-PCD according EN 867-5 (new: EN ISO 11140-6) with an SCBI. In the past only BI strips could be used in Helix-PCDs.