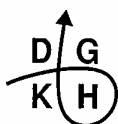


The Problems Arising from Non-Condensable Gases (NCGs) in Steam Sterilisation Processes with a Pulsed Vacuum Procedure

Practical tips from the Sterilisation Section of the German Society for Hospital Hygiene – DGKH e.V.



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Non-condensable gases (NCGs) such as air and/or CO₂ in the sterilisation steam can greatly jeopardise the effectiveness of steam-sterilisation processes under certain conditions. These gases are found in steam for different reasons:

- The drinking water used in the steam generator or in the preconnected water-conditioning unit may contain large quantities of dissolved air. This may result from the deferrisation and demanganising occurring following artificial introduction of air.
- Storage of demineralised water in an open (aerated) tank can lead to dissolution of air and CO₂ until a state of equilibrium is established vis-à-vis the atmosphere.
- Steam generation systems, which are designed for general use (heating, kitchens, laundries) often fail to produce steam of a quality suited to sterilisation.
- Removal of steam quantities that vary greatly over a period of time together with discontinuous supply of the steam generators result in major fluctuations in the NCGs.
- Gas leakage from door seals, pipes or vents in the presence of a vacuum.
- Residual air in the chamber if this has not been adequately removed prior to sterilisation.
- Air can imperceptibly enter the sterilisation chamber from a door seal that is under pneumatic control, if this seal is damaged. This source of danger for NCGs is, of course, precluded in the case of seals with pressure monitoring or seals operated by water or steam.
- When the steriliser is placed in operation, air is still to be found as a rule in

the steam generator, in the pipelines and in the chamber double sheath. This air will have entered the steriliser when it was cooling down and can now enter the sterilisation steam if special measures are not taken to remove the air content (by running an empty load).

If water is allowed to remain in contact with air for a sufficiently long period of time, the water will become saturated with air (1 l water can dissolve between 25 – 30 ml air at room temperature and atmospheric pressure). On heating, CO₂ will be cleaved from any hydrogen carbonates present.

A certain amount of oxygen consumption takes place in the drinking water network (e.g. oxidation with iron, biofilm), just as CO₂ is released through respiration (e.g. biofilm).

Small quantities of NCGs in the steam are non-critical for the respective process so long as the steam can mix with the NCGs and this mixture can reach all surfaces to be sterilised.

To heat the goods undergoing sterilisation, steam quantities determined by the mass and the specific heat of the goods are needed (typical values 300 – 400 l steam for 10 kg goods). In the presence of NCGs these large steam volumes introduce dangerous quantities of gases into the goods and their packaging. Whereas the steam condenses to water on the surfaces of the items being sterilised, these gases are retained, trapped within the goods and packaging where they form dry air pockets that in particular jeopardise the sterilisation of packed, porous or hollow medical devices. The lethality effect of dry gases is greatly reduced compared with that of steam at a similar temperature.

The quantity levels at which NCGs become critical depend on the respective goods. For example, a Bowie-Dick 7 kg laundry pack signals an error by means of an inserted indicator sheet or by growth of inserted biological indicators, if 150 – 200 ml air has accumulated within the pack. A tube with an internal diameter of 2 mm and 1 m in length has a total internal volume of only 3.14 ml. Already 0.314 ml NCG will block 10 cm of the tube length to steam condensation, thus preventing effective sterilisation at this location.

Due to the high steam consumption at the time of heating the goods from room temperature to the sterilisation temperature, such quantities of NCGs accumulate despite the fact that the NCG concentration in the steam is small, thus endangering safe sterilisation.

Therefore the content of NCGs is an important quality feature for the sterilisation steam.

The limit value of 3.5% specified for NCGs in DIN EN 285 serves to assess the performance of sterilisation processes for standardised sterilisation goods. The NCG quantities that can be tolerated in practice must be elucidated in the course of process validation (note: practical tips from the DGKH regarding the interpretation of the 3.5% value in DIN EN 285, see below).

To be viewed particularly critical, because they cannot be easily detected, are what are known as NCG peaks from the

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steam generator. These appear irregularly and thus may affect only the outcome of certain loads. This problem arises both in steam generators directly assigned to the steriliser and in central steam generators to which several sterilisers or other steam consumers are connected.

As regards these NCG peaks it is not only their magnitude and duration but also the time point at which they occur that have implications for the process sequence. Whereas NCGs arising within the come-up time can enter the goods with the steam and remain there, the occurrence of NCG peaks at the beginning of the

air-removal phase is of less significance, because the ensuing pulsed vacuum procedures will provide for adequate air removal. No new steam enters the goods during the sterilisation period itself because the sterilisation temperature has already been reached. Hence NCG peaks are non-critical during this phase of the process.

For this reason it is recommended that other control mechanisms be used in addition to the daily B&D test; these should be designed to provide information on the air removal and steam penetration for each load.

It is advisable to monitor and record pressure and temperature over time in order to be able to verify these important sterilisation parameters. But these data alone are not geared to detect NCGs. Non-condensable gases in the steam will increase the overall pressure in accordance with their partial pressure. The overall pressure will therefore be above the pressure of the saturated steam curve. However, the concentrations of NCGs that can endanger sterilisation are so minute that they cannot be detected with conventional measurement technology. ♦