

Instructions for Interpreting the Inert Gas Value of 3.5 % in DIN EN 285

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

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A sterilisation process can be deemed sufficiently effective only if the intended sterilisation action can be reproduced on all surfaces of the items being sterilised. Whether this is the case will depend on a number of influence variables. These include:

1. The process sequence (pressure and temperature values, pulsed vacuum procedures, pressure gradients).
2. The properties of the objects being sterilised (easily accessible surfaces; porous goods, hollow devices) and of the packaging.
3. The quality of the operating materials.

As regards the operating materials, the quality of the steam and its content of non-condensable gases constitute the most important variables.

Hence if one wishes to check a steriliser or the process being conducted in it

in order to establish whether the sterilisation conditions are being met on all surfaces of the goods, one can do so only for defined goods (e.g. in the standard, these are test loads) and for a specified steam quality.

The 3.5% value is a "limit value" given in the standard (an upper value for non-condensable gases) at which the steriliser must still achieve its "standardised performance", which is measured for all test loads.

The 3.5% value was defined after gathering extensive experience. In general no problems have occurred in the past during tests on complying with this "limit value".

However, one cannot infer from this that steam with high quantities of non-condensable gases are generally unsuitable or that compliance with this limit value will guarantee that the process will

prove suitable for sterilisation of all articles.

This can be proven only during validation which takes account of all the variables exerting an influence in any individual case.

A special problem encountered when assessing the steam quality derives from the fact that in many steam networks or steam generators the content of non-condensable gases fluctuates greatly, with major episodes of overshooting being also observed for brief periods. Since the adverse effects of such episodes of overshooting depend to a large extent on the time point at which they occur in the process cycle (they are particularly undesirable during the come-up time), it is important to assess the temporal constancy of the steam quality. ♦