Effects of Non-Condensable Gases (NCGs) on Steam Sterilisation Processes

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Introduction

The dangers posed by non-condensable gases (NCGs) in steam sterilisation processes have long been underestimated. Biological indicators, or the best chemical indicators on the market, do not signal the presence of a NCG content of up to 10% in a sterilisation process so long as there is mixing of steam and NCGs in the sterilisation chamber.

Already back in 1963, Bowie and Dick (1) demonstrated that steam/NCG mixtures could prove dangerous if steam resulting from condensation is being consumed on the sterile supplies and the NCGs enclosed in this steam are able to accumulate present in the form of closed packages.

If the NCGs are unable to mix again with steam within closed packages containing instruments, in porous laundry packages or within lumened devices, these quantities of gas will accumulate and prevent steam penetration into these areas, thus also preventing the build-up of heat and entry of water which are prerequisites for successful sterilisation.

Relatively large volumes of steam are consumed in sterilisation processes for heating (sterilisation) supplies (approx. 300 – 400 l per 10 kg materials under normal conditions). Conversely, the steam decreases its volume by a factor of 1,000 on condensing to water. This means that one litter of steam produces around 1 ml of condensate which represents a realistic value, which if exceeded will lead to quantifiable problems.

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To curtail this risk many steriliser manufacturers therefore use steam instead of air. The use of steam means that the service life of the door seals is shortened and that, accordingly, the maintenance intervals are also shorter.

4. Steam Pipes and steam generators become filled with air or NCGs if they are not used over a period of time. Before using the sterilisation system again, steam generators and pipes must first be rinsed out with steam. In the hospital setting this rinsing task is performed mainly by running an empty load to heat the steriliser. The ensuing Bowie-Dick test is then run to check that air has been successfully removed from the pipes. If the BD test is negative on the first attempt, the next attempt will generally be successful. Therefore a BD test programme of e.g. 134 °C, 3.5 min is generally stipulated for large sterilisers.

Small sterilisers with an integrated steam generator face less risk because they are not hampered by long pipelines. Hence the recently published standard...
regulating small sterilisers,

EN 13060, does not stipulate a BD
test for small sterilisers.

5. The most critical source of problems is
NGCs that are carried into the sterilisa-
tion process with the steam. These NGCs
are formed during steam generation be-
cause of:

- Air dissolved in the water that is ex-
  pelled when the water is heated. In
  the case of raw water containing iron
  and manganese, air is often introduced
  into external water-processing systems
to precipitate these metals as oxides.
What remains then is water with a high
content of dissolved air.

- Hydrogen carbonate salts dissolved in
  the feedwater which when heated dis-
  integrate to carbonate salts (limescale)
  and give off carbon dioxide (CO2) as a
  NCG.
The water should be demineralised and de-
gassed before being fed into the steam
generator.

While more than 90% of dissolved
salts are removed from the raw water by
means of reverse osmosis (RO) desalina-
tion systems, gases such as CO2 and air
pass quantitatively through the RO mem-
branes. The latter are thus not sufficient
for feedwater processing, so for this rea-
son mixed-bed ion exchangers still have
not to be used to remove at least the CO2 but
not the dissolved air.

The best way to remove NGCs is to
preconnect a degassing facility that heats
the water to 90 – 100°C before it is fed in-
to the steam generator. No thermal ener-
gy is lost here because the water contin-
ues being heated later.

Therefore the presence of any NGCs
in the steam plays a critical role in sterili-
sation process since with each episode of
discontinued feeding of water into the
steam generator, a NCG peak is formed in
the steam a short time later. Hence the
NCG concentration in the steam is not
constant over time, rather NCG peaks oc-
cur after feeding water into the steam
generator. In a hospital setting where a
central steam supply facility with a high
steam consumption rate, e.g. for the
kitchen or laundry, is used such peaks oc-
cur only at certain times.

The method outlined in standard EN
285 can be used to measure (2) NGCs.

For a long time now discussions have
focused on what NCG concentrations pose
a danger to the steam sterilisation process.
Here there is no absolute answer as this
will depend greatly on the loading pattern.
Minimal loads in a large steriliser are more
critical because any residual quantities of
NGCs in the steriliser will be fully taken up
by the minimal load, whereas the same
residual quantity of NGCs is better distri-
buted in a full load, and is thus less criti-
cal for the individual load (small load ef-
effect = SLE). The SLE is manifested only
in the case of those causes listed above
in Points 1 – 4. This does not apply if NGCs
are present in the steam (Point 5).

The dangers posed by the NCG con-
centrations in the steam vary greatly for the
different sterile supplies:

1. NCGs are not at all critical for open
   trays with solid, unwrapped instru-
   ments because convection provides
   for mixing of the NCG with the steam.
   Hence such a load can also be reliably
   sterilised in sterilisers using gravita-
   tional or flow methods.

2. High NCG concentrations are always
critical for trays containing wrapped
   solid instruments irrespective of the
   porosity of the packaging. This is be-
   cause no convection takes place and
   the amount of NCGs accumulating
   within the packaging as a result of
   steam condensation will not be dis-
   tributed. The NCGs can escape only
   by means of slow diffusion through the
   packaging. This is explains why longer
   sterilisation times are selected for
   processes with poor air removal: to re-
   move the air rather than to kill the
   microbes. But a longer sterilisation time
   is not effective for voluminous porous
   items and lumened (hollow) devices
   under such conditions.

3. As the volume of a package increases,
   porous articles such as laundry pack-
   ages, surgical towels or swabs impede
   convection. For a long time it was be-
   lieved that it was large porous pack-
   ages that were the main cause of pro-
   blems in sterilisation processes. There-
   fore even today European standard EN
   285 uses a 7-kg laundry package as a
   BD test package to simulate a worst-
case scenario for air removal and steam
penetration test. From standard tests
described in the test standard EN 867-
4 one notes that this laundry package
signals errors in the steam sterilisation
process when the quantity of NCGs
reaches approx. 150 – 250 ml.

4. Narrow-lumened (hollow) devices such
   as minimally invasive surgical (MIS) in-
   struments, catheters and tubes have
   very small lumens depending on their
design, and these lumens are also heat-
ed by steam. If NGCs are present they
will also be carried into such lumens
and have no means of mixing once again
with the steam through convec-
tion. A tube with a 2 mm internal di-
diameter and 1 m length has an interval
volume of only 3.14 ml. If 10 cm of this
internal volume is occupied by NGCs,
the remaining volume will only be 0.31
ml. This demonstrates how even NCG
quantities of well below 1 ml can be ab-
солute critical for lumened devices.

A study conducted by Prof. von Eiff of
University of Münster in hospitals in North
Rhine Westphalia and Lower Saxony
revealed that, in particular, 40% of hollow in-
struments released for use were not ster-
ile (4). One reason for such problems is
that the classic biological and/or well-in-
tegrated chemical indicators can attest to
the sterility of supplies only at those lo-
cations at which they are positioned. But
in general these indicators cannot be
placed at those sites within the instru-
ment which are most difficult to access,
thus the established practice of using
such indicators is not suitable for provid-
ing insights into the sterility of lumened
deves.

Implications for Validation and
Routine Monitoring

Various publications (2) have revealed
the standard BD test is not able to detect NCG
quantities below 50 ml. These NCG quan-
tities are too high by a factor of 100 as far
as lumened devices are concerned. Euro-
pean standard EN 867-5 describes a hol-
low device system "Hollow A" that is ca-
pable of detecting NCG quantities of well
below 1 ml. This is a tube model with a 1.5
m PTFE tube with an internal diameter of
2 mm and a PTFE terminal capsule with
Since the NCG concentrations change for each load, if hollow devices are being sterilised, hollow PCDs should also be used instead of the porous BD test to furnish proof of the effectiveness of the process, not only on commencing operations but also for all loads.

In the revised draft to European Standard EN 285 for large sterilisers for the health sector, which had been in force for 10 years, The European Standardisation Commission has included, in addition to the BD test system, the Hollow A test from European standard EN 867-5 for the type test in order to ensure that the respective steriliser type can sterilise the intricate devices currently used in the health sector.

To measure the critical NCG quantities for hollow devices there is at present no technical means other than to use a suitable process challenge device (PCD) able to measure the minute NCG quantities. Their sensitivity must be adapted to the loading pattern. The "Hollow A" PCD described in EN 867-5 is representative of a large portion of the instruments currently used in the health sector, but not of all supplies undergoing sterilisation. When validating steam sterilisation processes it must be ensured that the PCDs employed present a greater challenge to steam penetration than do the intricate devices contained in a load.