Is the Steam o.k.? The Air Detector Knows the Answer

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In the international arena sterilisation of medical devices is being continually regulated by new standards , or existing standards are being revised as needed. This is particularly true in the case of the standards relating to steam sterilisation. International standard ISO 17665 "Sterilization of Health Care Products", which is presently available as a draft version, will soon replace European standard EN 554 regulating "Validation and routine monitoring for sterilisation with moist heat". The second edition of European standard 285 "Sterilisation – Steam sterilisers – Large sterilisers" will soon be published. Standard prEN 13060, which is completely new and applies to the same area but in this case to small sterilisers up to 60 litres, was recently put to a vote. Publication of this standard is soon expected. All three draft standards make reference to a device known as "air detector" which hitherto has elicited little attention in Germany or in other countries.

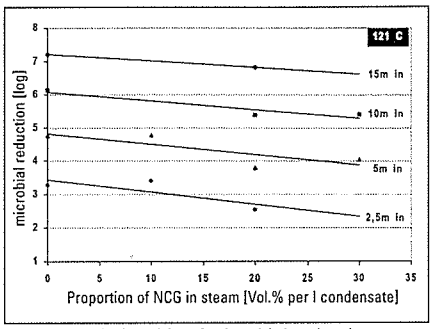

Fig. 1: Relationship of microbial reduction to proportion of non-condensable gases in the steam supply

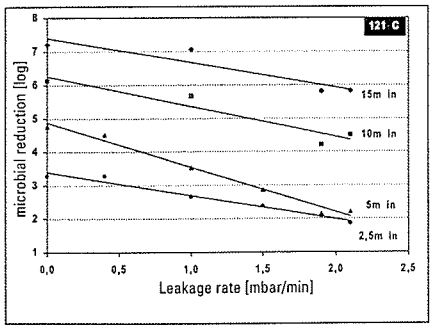

Fig. 2: Relationship of microbial reduction to chamber leakage rate

But just what is an air detector?

Before we answer this question, we must first of all consider the quality of steam as a sterilant. In this paper steam of a good quality is understood to mean a form of steam that contains no, or only minute quantities of, air or of other non-condensable gases. In this context non-condensable gases are understood to mean gases that do not condense under the conditions prevailing during steam sterilisation, i.e. they persist in a gaseous state under all the given circumstances, even if the steam condenses to liquid water.

The quality of the steam exerts a major effect on the outcome of a moist-heat sterilisation process. Even minute quantities of residual non-condensable gases in the steam (also formerly known as inert gases) can reduce the rate of microbial inactivation for certain microorganisms to an unacceptable level.

The steam in the steriliser chamber acts upon the surfaces of the supplies to be sterilised, producing the intended microbial inactivation on these items. The quality of the steam immediately unfolding on these surfaces is a function of myriad factors. First of all, the quality of the steam delivered to the goods undergoing sterilisation depends on the quality of the steam supply, but also on the residual air in the steriliser chamber following the air removal phase as well as on the gases being emitted from the supplies to be sterilised and on any leaks in the chamber, door seals, valves and pipes. Other influence factors may certainly be found. In the case of certain problem-prone items the non-condensable gases can even accumulate at critical sites (e.g. within laundry packages), thus possibly detracting from the quality of the steam at such locations.

Quantitative tests carried out with a size 669 steam steriliser (6 StUs, Steriliser units) demonstrated, for example, just how close is the relationship between microbial inactivation and the steam quality. To that effect, biological indicators with Bacillus stearothermophilus spores with a baseline count of $10^{8.21}$, $D_{121°C}$ 2.5 min were placed in the centre of a laundry package and exposed to steam sterilisation under variable experimental conditions. The laundry package was in conformance with the standard laundry package stipulated in EN 285, Chap. 26.1 and was composed of cotton towels (H x W x D = approx. 250 x 220 x 300 mm). The exposure times were 2,5, 5, 10 and 15 min with a sterilisation temperature of 121°C. Then the microbial reduction achieved in each case was evaluated and illustrated in Figs. 1 and 2.

In the first experiment (see Fig. 1) different volumes of air, 0, 10, 20 and 30%, were mixed with the steam supply in the steriliser. The % specifications refer to the volumetric proportion of air vs the liquid condensate of the steam. As expected, the reduction factors achieved declined in line with an increasing proportion of non-condensable gases.

In the second experiment (see Fig. 2) using a dosing facility chamber leaks were created with different leakage rates of between 0 and 2.1 mbar/min. Here, too, as expected the reduction factor declined in line with an increasing leakage rate.

It is therefore important to check that all is in order with the steam for each load. At this juncture the air detector comes into play – it monitors the steam quality. If the quality of the steam in the chamber is inadequate, thus suggesting that sterilisation cannot be properly conducted, the air detector signals this and prematurely aborts the sterilisation process.

It is therefore important to realise that air, as well as other gases, are heavier

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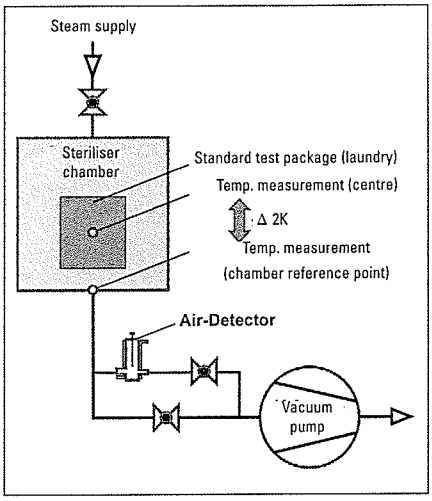


Fig. 3: Installation site of air detector in steriliser/positioning of standard test package as per EN 285

than steam when subjected to the conditions prevailing in steam sterilisation. This means that non-condensable gases tend to accumulate at the bottom of the chamber or in the chamber drain. It is therefore advisable to place the air detector at this site so as to provide for inert gas monitoring at the most critical site in the steriliser chamber (see Fig. 3).

Functional Principle of the Air Detector

There are various types of air detectors, differing not only in respect of their technical design but also as regards their measuring principle (weight or differential pressure measurement, counting method, temperature measurement, etc.). The air detectors, which were primarily developed in the United Kingdom, are thus available in manifold designs and it is in some respects very hard to distinguish between them. However, in general the air detector consists of a small vessel within which the steam flowing out of the chamber briefly dwells so as to undergo partial condensation. This procedure ensures that the non-condensable gases in the steam are chiefly accumulated in the air detector. Subsequently, a reference value corresponding to the proportion of these gases in the steam mixture is calculated in accordance with the respective measuring principle of the air detector, i.e. based on weight or differential pressure measurement, counting method or temperature measurement, etc. This reference value is thus a figure that reflects the weight, or it is a pressure value, meter reading or a temperature.

Figure 4 shows two process curves typical of steam sterilisation, i.e. a temperature and a pressure curve. Both curves are based on the measured values obtained at the reference measuring point of the sterilisation chamber (see Fig. 3). All modern steam sterilisers that conform to European standard EN 285 operate according to what is known as the "pulsed vacuum method". Using this principle the steriliser chamber is repeatedly evacuated from the beginning of the process and then filled once again with steam. This phase is known as the "air removal phase". During this phase the pressure prevailing within the chamber generally assumes negative values, i.e. is lower than the ambient pressure (see Fig. 4). During the air removal phase air is removed from the chamber, on the one hand, while, on the other hand, a high rate of steam penetration is achieved for the supplies to be sterilised, even on poorly accessible surfaces (e.g. within lumens and laundry packages). Hence the quality of the steam generated on the surfaces of the supplies, and accordingly a successful sterilisation outcome, is determined by the effectiveness of the air removal phase.

Following the air removal phase the chamber pressure rises above the ambient pressure. By virtue of the fact that as from this point in time positive pressure conditions prevail within the chamber, any leaks in the system will have no further implications. For this reason, exactly when the chamber pressure curve is at the 0-mbar line a single measurement is conducted with the air detector, while at the same time a decision is taken as to whether the air removal phase just completed has been successful or not and whether the steam within the chamber is in order or not.

If the air removal phase has not been a success, the process is immediately aborted. This is done at exactly the time point at which the proportion of non-condensable gases measured in the air detector exceeds a specified threshold value. The threshold value, e.g. weight count, pressure value, meter reading, temperature limit value, is set at the time of adjusting the air detector.

How Is the Air Detector Adjusted or Calibrated?

Calibration merely verifies to what extent a particular requirement is being met (in this case the requirements set out in European standard EN 285). To that effect,

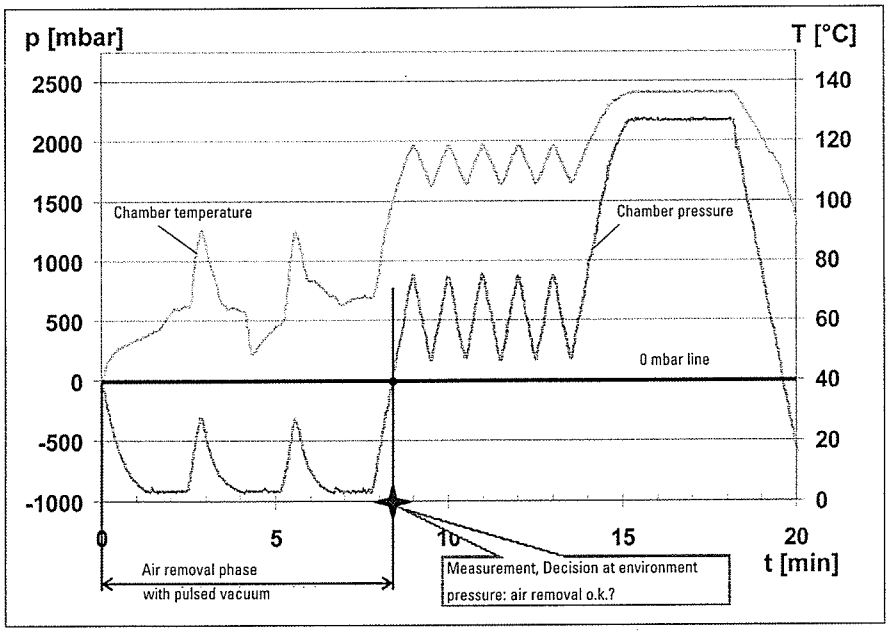


Fig. 4: Steam sterilisation process curves

a reference measurement (comparison) is carried out to establish whether the stipulated limit values are being complied with or exceeded and whether the air detector is correctly set or not.

Calibration of the air detector, i.e. verification of its functional capabilities, is effected at regular intervals. This is mainly done at the time of on-site revalidation of the steam steriliser processes. Calibration of the air detector for a steam steriliser comprises 4 procedural steps:

1. Set a leakage rate of just below 10 mbar/min
2. Start the sterilisation programme
3. Check whether the air detector signals a fault
4. Check whether the temperature difference in the standard test package is less than 2 K

If the air detector passes this test (calibration) one can be assured that the requirements set out in EN 285, Chap. 21 will be met during the ensuing routine operation.

Adjustment means setting or aligning the air detector such that any subsequent undesirable deviations that could compromise a successful sterilisation outcome are detected. Adjustment – as opposed to calibration – thus always calls for a technical intervention to ensure that the system is brought to a permanent setting.

If calibration has been successful there is no need for adjustment. This is a tremendous advantage in practical terms because calibration can be conducted essentially more easily and more quickly than an adjustment. When adjusting the air detector artificial leaks are generated to deliberately introduce air into the steriliser chamber. This is done with a dosing facility as per EN 285, Chap. 26.9 (e.g. orifice, needle valve, etc.). As per the requirements of EN 285, Chap. 21, the air detector must signal a fault if

- the set leakage rate is more than 10 mbar/min or
- at the beginning of the sterilisation time the temperature in the centre of the standard laundry test package differs by more than 2 K from the chamber temperature (see Fig. 3).

The air detector threshold value (weight count, pressure value, meter reading, temperature limit value, etc.) is set such that a fault is signalled in the event of a chamber leakage rate just beneath 10 mbar/min. Hence the first of the two aforementioned requirements is met.

The second requirement is generally met by the fact that modern steam sterilisers use (i.e. are set to) a sterilisation process that ensures that even in the event of a leakage rate of 10 mbar/min the temperature in the centre of the standard test package at the beginning of the sterilisation time differs by less than 2 K from the chamber temperature.

Advantages of the Air Detector

The air detector is a technical device used to detect air. The use of such a device reflects the general trend towards widespread automation of medical device processing in hospitals, including the sterilisation procedures. This is because, in the course of everyday routine working practices, it is important to continually achieve the same production results with minimum investment and to verify this in a timely manner. To that effect, the sterilisation processes are validated from the outset (generally on an annual basis) and during the ensuing routine operations the parameters that could compromise a successful sterilisation outcome are automatically checked and documented for each sterilisation load for compliance with values within a specified tolerance range. If a parameter is not being maintained within its specified tolerance range, the sterilisation process is automatically aborted. As from now, the steriliser will not consume any further energy or media (resources) and a fault message will be generated.

The actual value obtained for the air detector threshold value is not decisive, because it depends in the individual case on myriad factors (installation site, process, equipment geometry, etc.). But what is decisive is that the air detector is calibrated at the time of validation of the sterilisation process (see above) and that the threshold value is used for automatic verification during subsequent, repetitive routine operations.

This procedural approach confers the following advantages:

- Enhanced patient safety since every load is verified
- Avoidance of the faulty operation or misdiagnosis associated with some indicators or manual test systems (e.g. B & D test)
- Quicker throughput
- Automated documentation
- Less investment for training
- Lower operating costs.

In addition to the advantages cited, it must be pointed out that the air detector test merely "accompanies" each sterilisation load and calls for no additional test procedure such as the Bowie & Dick test carried out each morning. The chances that non-condensable gases will be detected by a single daily indicator test are at any rate low.

The air detector test obviates the need for the unproductive procedural steps, expensive manpower time and extra energy costs that would come hand in hand with running any additional test loads. ✦

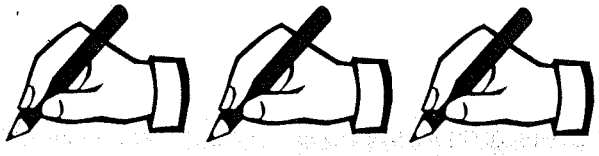
References

ISO/CD 17665.2: 3.1 Air detector, 10. Routine monitoring and control;

prEN 285: 8.3.4 Air detector, 19 Air detector tests;

prEN 13060: 4.8.2.4.

LETTERS



Air Detector

Remarks on: P. Eifler: Is the Steam o.k.? The Air Detector Knows the Answer. Zentr Steril 2004; 12 (4): 279–280.

Dr. U. Kaiser, c/o gke-mbH
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It is good of you to have addressed the problematic issue of non-condensable gases (NCGs) in steam. It is indeed true that NCGs pose major potential risks for the steam sterilisation process, relating not only to insufficient air removal and leakages but also to aperiodic peaks of NCGs during steam generation. The risks posed will vary greatly depending on the timepoint at which the NCGs occur in the sterilisation process:

1 Occurrence at the beginning of the fractionated vacuum phase

The risk arising here is slight because the ensuing evacuation cycles will remove the NCGs once again.

2 During the come-up time

In this case large volumes of steam flow into the packages to be sterilised in order to heat them, while at the same time introducing the NCGs into the packaging. The large steam volumes condense to a small volume of condensate. Hence the NCGs become concentrated within the packaging and within lumened instruments, giving rise to dangerous pockets of NCGs.

3 Entry during the plateau sterilisation phase

At this timepoint no further steam is needed to heat the instruments, hence the steam no longer penetrates into the packaging or instruments and is therefore at this timepoint not critical as far as the sterilisation outcome is concerned.

If the air detector signals the presence of NCG peaks, can this lead to a critical or non-critical sterilisation outcome. What can be said about this?

You calibrate the inert gas detector by using the original BD test pack as per EN 285 and set a leakage rate that exceeds the 2K temperature range, while the detector is to signal a fault only either if the leakage rate is more than 10 mB/min or the 2K temperature range is exceeded. Since it is very difficult to carry out calibration in

ZENTRAL STERILISATION 5

the requisite concentration range, this is surely an acceptable method if one assumes that the BD laundry package serves as a reference for a worst-case scenario.

Measurements conducted by the Ad Hoc Group of the TC 102 WG 2 + 3 Standardisation Committee, which revised European standard 285, have demonstrated that the BD test is not suitable for all lumened instruments or MIS instruments. It is under discussion to incorporate the hollow device process challenge device (PCD) Hollow A as specified in EN 867-5 as an additional type test into standard EN 285. Whereas the BD test needs approx. 100 – 200 ml NCGs to exceed the 2K temperature range, volumes of less than 1 ml NCG are already critical for an MIS instrument, since this volume covers large surfaces within an MIS instrument, which then cannot be properly sterilised. This means that the inert gas concentrations that are hazardous for MIS instruments are more than 100-fold smaller that than those applicable to the BD laundry package, representing solid and porous instruments. Can the air detector measure NCG concentrations that are smaller by even two orders of magnitude?

Non-condensable gases are composed of air and primarily CO_2. The CO_2 is generated by decomposition of hydrogen carbonate salts when water is heated, provided that the salts have not been previously removed by means of an appropriate water treatment procedure. As is well known, there is outgasing of CO_2 and air on heating the feedwater. However, CO_2 dissolves once again on coming into contact with water and gives rise to carbon dioxide (aerated water) at low temperatures. In the air detector steam condenses and, in the presence of NCGs, a two-phase mixture is formed, composed of water and gas bubbles. The gas bubbles are used to measure NCGs. Whereas the air dissolves in the condensate only very slowly, a large portion of the gaseous CO_2 immediately dissolves in water. The greater the pH value, the faster will this dissolve. Hence a large proportion of the CO_2 disappears, thus eluding detection. Can you give any information on the order of magnitude of the detectable CO_2 proportion?

We would be grateful if you could please respond to these queries. Knowing the possibilities and limitations of an air detector is surely in the interest of all users of such a system. ✦

Author's Reply

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While discussing the air detector, Dr. Kaiser makes reference to the timepoint at which inert gases occur, to the measurement sensitivity of hollow devices and to detection of CO_2. Indeed, these points merit discussion when focusing on steam sterilisation. However, the use of the air detector tends to be based on a pragmatic approach: the air detector simulates a medical device which, due to its geometry and cooling properties, hampers steam penetration. To reinforce this effect, the air detector is placed at the most critical site within the steriliser which harbours the highest portion of non-condensable gases. It is checked, and reset, for proper functioning at the time of validation. At this juncture it must be borne in mind that routine validation of the sterilisation process at annual intervals has become an established practice in hospitals in the meantime. When carrying out testing within the framework of validation, thermoelectric measurements are performed in the medical devices – as in the air detector. Here observance of the delta 2K criterion plays a pivotal role because the temperature difference measured is a good measure of steam penetration, which is of paramount importance. Since at the time of adjustment (calibration), the air detector correlates with this measure on using the BD test package (checked) (see European standard EN 285) and it simulates a difficult-to-sterilise medical device, its "Go or no go" signal is decisive in respect of steam penetration. This is all the more true in view of the fact that this test is not conducted once annually or daily but for each and every sterilisation load. For routine operation the air detector is a robust test system that conforms to EN 285.However, the Ad Hoc Group of the TC 102, WG 2 + 3 Standardisation Committee, of EN 285, has acknowledged that the BD test is not necessarily representative of hollow device systems. This fact will probably lead to a tightening of EN 285 in that a special hollow device test system will be introduced (Hollow A). However, this does not at all impinge of the use of the air detector. Standardisation institutes and industry have a joint task: technology and standards must be tailored to each other. Without anticipating future events, it is conceivable that the air detector will be equipped in the form of a Hollow A device as outlined in EN 867-5. This would assure a direct correlation between the air detector and MIS hollow devices, endowed with corresponding sensitivity. But we must first of all await further developments and amendments to EN 285 which has just been revised. ✦