ZENTRAL STERILISATION 5

Keywords
- steam sterilisation
- BD-Test
- dataloggers

Verification of BD Test in the CSSD*

Results based on practical tests with 27 sterilisers in different hospitals

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This paper presents a novel method of multi-dimensional representation of the parameters pressure, temperature and time. A steam penetration test (Bowie-Dick test) provides no information on the time course. Using a BD datalogger (e.g. ebro Electronic, Ingolstadt, Germany) these parameters of the BD test can be documented; inert gases cannot, however, be documented. Hence any faults that cannot be detected by means of the device documentation alone can be recognised at an early stage.

Introduction

In the circuit traversed by sterile processing of medical devices, the sterilisation step represents an area that is clearly regulated by standards compared to the other steps such as e g. cleaning. One of the most important daily functional checks conducted for any steam steriliser is the steam penetration test (Bowie-Dick (BD) test). Using a chemical indicator, proof is furnished each morning on commencing operation that condensing steam reaches all surfaces of the reference load (BD test), something that is possible only after a sufficient amount of air has been removed. The standard test pack (EN 285) or indicators (DIN EN 867) with the following parameters are used in the test

- Sterilisation time 3 5 (15) minutes (± 5 s)
- Sterilisation temperature 134 °C /121 °C (– 0/+1.5 °C)
- Proportion of inert gases < 3.5 vol.%

Indicators meeting these specifications comply with DIN EN 867classe B (ISO 11140 class 2).

The putative safety documented by the CSSD with the BD test is an important determinant when it comes to using steam sterilisers and hence also for the use of sterile instruments.

The BD test must be evaluated immediately in order to release the steriliser A uniform change in colour signals a positive BD test. The BD test must be reproducible

But many years of experience show that reproducibility is questionable. Hence a negative result means that the respective steriliser is not released even if a repeat BD test had been positive. Due to safety reasons, such cases give rise to operational constraints with attendant servicing costs.

Material and Method

The aim of this investigation was not to check the indicators for the BD test pack but rather to furnish proof that the steriliser had complied with the specified parameters; this is a precondition for successful employment of the BD test. Tests were conducted with the same procedure as that employed in daily routine operation. The proportion of inert gases was not measured.

The parameters of the Bowie-Dick test programme entailing in total 27 hospital sterilisers were checked with a BD logger (figure 1, ebro Electronic, Ingolstadt, Germany). This logger is a precision measuring instrument, needing no mains connection, which records in the sterilisation chamber – at a measuring frequency that can be programmed to different frequencies (at least 1 s) – the parameters pressure, temperature and time. After extraction via a read-out device, these data are processed and saved in a PC, independently of the device documentation

Fig. 1 BD logger

Results

The measurements conducted for 26 sterilisers showed that the process parameters of the BD test kit corresponding to the standard specifications were not observed. Only one steriliser met the aforementioned process parameters time and temperature.

In addition to the deviations noted in respect of time (> 30 s) and of temperature (> 4 °C), faults were also detected in the steam supply. The BD test indicators thus do not provide any insights.

Discussion

Based on the premise that newly installed sterilisers should comply with the specifications, the question arises as to how deviations of this magnitude can occur One

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reason may be the slow response of the sterilisers' own electronics. But deviations on this scale should have been precluded by servicing and repairing the sterilisers.

Enquiries made in the respective departments revealed that, faced with problems emanating from the BD test, the after-sales service often expressed doubts about the BD test itself – sterilisers of other manufacture were proposed or the steriliser was "adapted" to the BD test. Accordingly, it was possible to detect compensation times of 2 minutes, which is not recorded in the device documentation. The problem was likewise "eliminated" by temperatures above 140 °C.

Often it is not possible to control old sterilisers properly, but since stocks are protected the expensive sterilisers are not replaced. In some of these sterilisers the BD test is run in the full programme with a maximum of 20 minutes hold time, with large leaks in gaskets and valves being hardly detected.

In one case the indicator sheet did not at all undergo a change in colour. For the indicators that did change colour a test was run manually for 3.5 minutes, and this produced different results. While some were in order, other results warranted closure and repair of the steriliser system.

In one steriliser the BD test was run for 2.5 minutes, producing a good result. Why the device was set to this time is not known.

Poor steam supply was documented for some sterilisers. For example, 3 sterilisers were connected to one steam supply pipe (connection to the steam mains in the building). During operation the sterilisers competed for steam, thus slowing down the process for 8 minutes and, in turn, causing the temperature to drop in some cases to below 120 °C.

Even if our survey is only marginally representative, then a shocking deviation by the actual parameters from those legally prescribed must be noted. To what extent a successful sterilisation performance can be achieved under these circumstances is questionable.

The state of hospital sterilisers is certainly often in need of improvement. Apparently the CSSD continues to be banished to the basement and forgotten. People remember this department only when supplies are interrupted due to a breakdown in operations. Only then is remedial action considered.

Furthermore, the results of the investigations described here point to a questionable after-sales service. Should one be led to believe that the after-sales firms are not aware of the important role these sterilisers play in patient safety?

Based on our experience, the BD test is also handled in a very casual manner in many departments, as demonstrated by the following examples described by users who had participated in training courses:

For instance, on Saturdays no BD test was carried out, just because it was Saturday. A further example shows that as a routine measure the BD test was omitted when staff were on call, even if the sterilisers had not been in operation for many hours. In another case while the BD test was run, it was evaluated only later in the

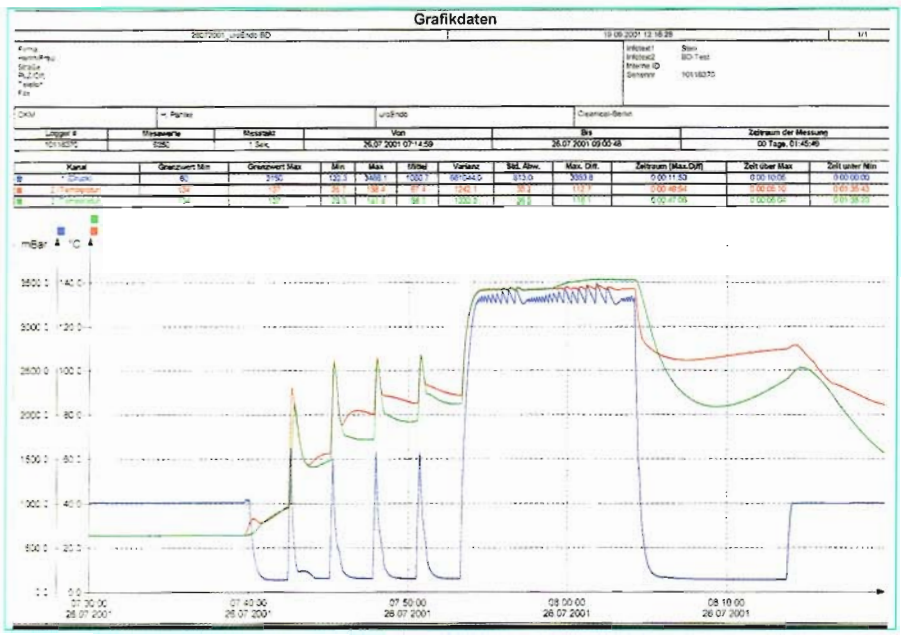

Fig. 2 10 min hold time with considerable overheating

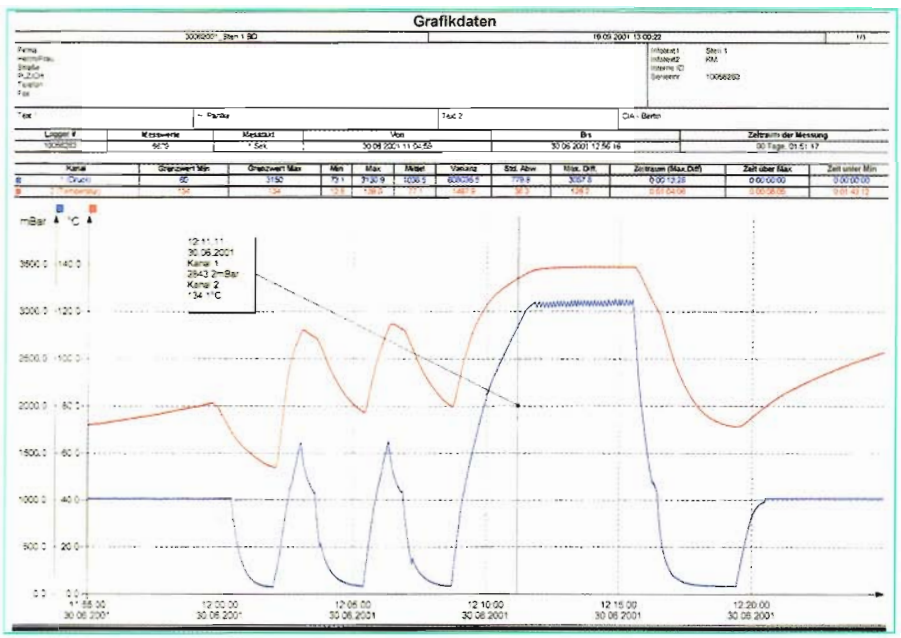

Fig. 3 Temperature > 134 °C for over 4 min

course of the day (as were the batch checks), meanwhile of course routine operation was allowed to continue, with sterile (or non-sterile) trays being handed out. In view of such practices, one must ask why this test is used at all?

A ridiculously sounding argument has also been put forward, stating that the use of loggers is not legally permitted in Germany. This is claimed despite the fact that, using a datalogger, the repair service can directly check the new settings in respect of the requisite specification.

Unfortunately, to date only very few CSSDs are equipped with a datalogger system. Hence the incorrect settings detected here are not being signalled. Errors that cannot be detected alone on the basis of the device documentation of the BD test can be picked up at an early stage with dataloggers.

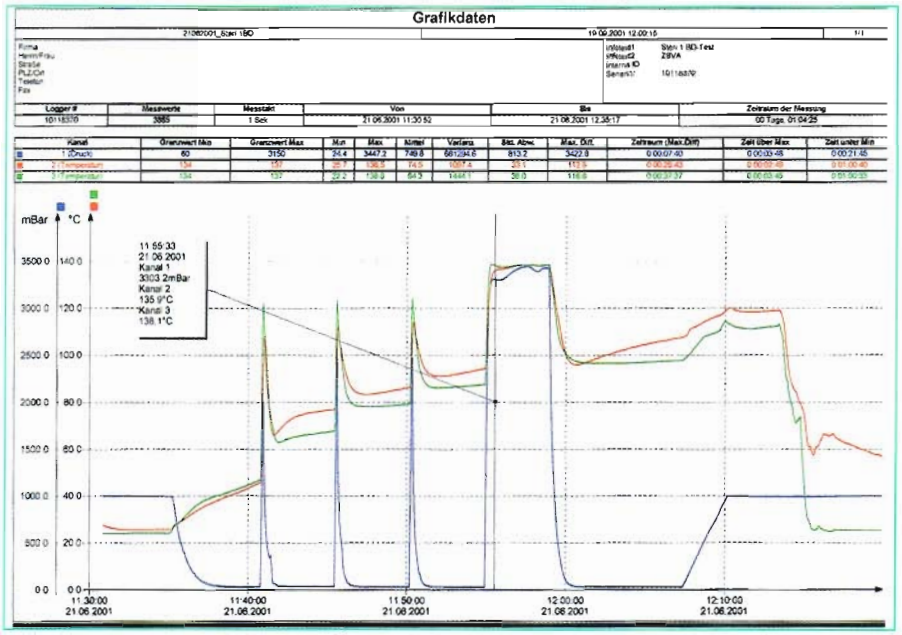

Fig. 4 5 min holdt time, temperature > 136 °C; 4 times vacuum for 5 min; total BD test time 35 min