# A case study of steam penetration monitoring indicates the necessity of Every Load Monitoring of steam sterilization processes

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# A case study of steam penetration monitoring indicates the necessity of Every Load Monitoring of steam sterilization processes

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## Summary
With the growing number of surgical instruments with cavities, e.g. narrow channels, it is important that steam penetration in surgical instruments is sufficient to ensure sterilization conditions on inner surfaces in every process. Recent literature demonstrates that measuring only temperature and pressure is insufficient to ensure these conditions. Using an Electronic Test System (ETS model 4108 3M™) the steam penetration capacities of the steam sterilization processes in the Central Sterile Supply Department (CSSD) of the Heilig Hart Ziekenhuis in Leuven (Belgium) were monitored from April 2009 to June 2015 with a daily steam penetration test, as required in the standard ISO 17665 part 1. In the period from January 2015 to June 2015 a steam penetration was performed additionally in every load.
The ETS was chosen as steam penetration test because it can be used in every process, regardless the duration of the plateau period. Apart from this, it was the only commercially available steam penetration test that quantities steam penetration, making quantitative analyses of the acquired data possible.
The results demonstrate a wide range in steam penetration between the individual processes when every load monitoring is performed. In some cases (approximately 1%) sterilization conditions are even jeopardizing because the large amount of None Condensable Gases (NCGs) prevented saturated steam sterilization conditions. Combined with the possibility to reduce operational costs, monitoring the steam penetration in every process of these CSSD sterilizers indicates the necessity of Every Load Monitoring of steam sterilization processes.

## Introduction
Steam sterilization is an essential step in the reprocessing of surgical instruments. In the literature steam sterilization conditions are specified (1). These conditions are saturated steam at a specified temperature for a given time, e.g. saturated steam at 134 °C for 3 minutes. With the growing number of Minimal Invasive Surgeries (MISs) more instruments contain "inner" surfaces. On these inner surfaces the specified steam sterilization conditions have to be established as well. Hence, the steam penetration capacities of each individual process become more important. Literature demonstrates that "parametric release" based on pressure and temperature measurements is insufficient to ensure steam sterilisation conditions (2). However, steam quality measurements according to the EN285 (3) performed during validation activities (not reported here), indicated that during a production day the steam quality may vary. In this perspective this means the absence of saturated steam or the presence of NCGs. This indicates that also the steam penetration capacities of a steam sterilization process may vary over a production day. This suggests that Every Load Monitoring (ELM) based on measurements of temperature and saturation of steam is essential to ensure steam sterilization conditions as specified in the literature (1). To investigate this point we assessed – as a case study – if the steam penetration capacities of the three steam sterilizers located in the CSSD of the Heilig Hart Hospital in Leuven (Belgium) were adequate to ensure steam sterilization conditions on all (inner and outer) surfaces.

KEY WORDS
- steam sterilization
- monitoring
- steam
- penetration
- trends

The presence of non-saturated steam is generally caused by the presence of NCGs. The three main causes of presence of NCGs are, in random order:
- insufficient air removal (during the conditioning phase of a process),
- NCGs in the supplied steam, and,
- leaks in the sterilizer (this includes the hardware connected to the sterilizer, e.g. vacuum-pump and steam supply).

Insufficient air removal may lead to insufficient steam penetration. Standards specify performance requirements, accuracies and procedures for steam penetration tests (3 – 5). The test has to be performed once a day before starting the production with an empty chamber that is only loaded with

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one steam penetration test. The argument for an empty chamber is that the load may influence the result. For example, a heavy load with artificial materials, e.g. plastics, will need larger amounts of steam to reach the sterilization temperature than an empty load or a light metal load of needles. In case the supplied steam contains (small) amounts of NCGs these NCGs will accumulate in the sterilizer chamber and may lead to less steam penetration. The reason is that steam that condenses reduces over 1600 times in volume at 134 °C. This condensation would mean that the pressure in the chamber would decrease. To prevent de-pressurization more steam has to be supplied to keep or increase the aimed pressure. At the same time the present NCGs cannot condense and will therefore stay in the chamber or even in the load. With the new supplied steam more NCGs can be introduced in the chamber and load. This may result in accumulation of NCGs in the chamber and load, and jeopardize saturated steam sterilization conditions. Obviously, the more NCGs are present in the supplied steam the sooner saturated steam sterilization conditions (1) are jeopardized.

In this respect it is important to realize that although in the literature (1) and the standards (3) small amounts of NCGs are tolerated for steam sterilisation processes, saturated steam is specified as water in the gas aggregation state in the absence of any other gas (1, 3, 6). This implies that at locations where NCGs accumulate saturated steam cannot be present.

Condensation will take place as long as the load is colder than the steam. Because of energy loss of a sterilizer and its load, the sterilizer will demand steam from the start of the process until the end of the sterilization phase (plateau period [3]). When one stands next to a running sterilizer the sound of the steam valves opening and closing can be permanently heard indicating that steam is supplied to the sterilizer chamber (and the sterilizer's jacket). Especially loads with a large heat capacity will need a large amount of steam during a steam sterilization process. In case of the presence of NCGs in the steam supplied to the sterilizer, these will accumulate in the chamber, as described above.

The presence of leaks in the sterilizer (including the hardware connected to the sterilizer, is not monitored when only pressure (*p*) and temperature (*T*) are measured in the sterilizer chamber (2). Next to the fact that NCGs may be introduced by the supplied steam, a steam sterilizer contains components that can breakdown unexpectedly and an unnoticed malfunction may occur during any process. For example a leak in a valve, gasket or vacuum pump (2).

In the CSSD of the Heilig Hart Hospital the steam penetration test procedure is respected and performed daily during the period of data acquisition, April 2009 to June 2015. Next to this procedure, in the period from January 2015 to June 2015, a steam penetration test was performed in every load that was processed.

## Material and methods

From April 2009 to June 2015 a steam penetration test was performed each day before starting production on the 3 steam sterilizers of the Central Sterile Supply Department of the Heilig Hart Hospital in Leuven (Belgium). Additional to the daily steam penetration test, over the period January 2015 to June 2015 in every process of the sterilizer a steam penetration test was part of the load. The combination of sterilizer, process, load, loading pattern and wrapping was not changed during the reported period. The sterilizers fulfilled the applicable requirements in the standards (3, 5). To ensure this the sterilizers were and are validated periodically as specified in these standards. This case study is not meant to judge the sterilizer. Therefore disclosing the brand and type of the sterilizers would not have added value. Only the process at 134 °C for 3 minutes was included in this study.

The conditions for surface steam sterilization are specified in the literature (1). Based on these conditions the minimum requirements for the steam penetration test are specified in the standards (4). The steam penetration test checks the steam penetration and, once established, if these conditions are kept for the specified time. Consequently, in each process the steam penetration has to meet the specified minimum requirements. This could be translated as having a pass of the steam penetration test to release the load, regardless the load or the moment in time of performing a test. The steam penetration test used was the Electronic Test System (ETS 4108, 3M™ Neuss, Germany). This device was selected for several reasons addressed hereafter.

The ETS fulfils the performance qualifications for steam penetration tests as specified in the applicable standard ISO 11140 part 4 (4). Also this device is discussed and explained in the literature (2, 7, 8). An ETS can be used for 400 cycles. After these cycles the ETS has to be replaced by a new one. Within this period the ETS does not have to be calibrated or maintained in any way. Each ETS is certified and calibrated to the requirement performance of the ISO 11140 part 4 (4), exchanging an ETS by another ETS will therefore not influence the results.

The standard EN285 (3) specifies that the plateau period consists of an equilibration time immediately followed by a holding period. The equilibration time is defined as the period which elapses between the attainment of the sterilization temperature at the reference measurement point and the attainment of the sterilization temperature at all points within the load (3). The holding period is defined as the period for which the temperatures at the reference measurement point and at all points within the load are continuously within the sterilization temperature band (3). According to the same standard the equilibration time shall not exceed 15 s for sterilizer chambers up to 800 l usable space and 30 s for larger sterilizer chambers. Consequently, the equilibration time in a process could vary from 0 to 30 s. Many commercially available steam penetration tests specify an exposure at 134 °C for 3.5 minutes, that is, 30 s of equilibration time and 180 s of holding time, adding up to 210 s or 3.5 minutes. A steam penetration test process on a sterilizer may have to be adopted to the time specifications of the used steam penetration test. However, the results of the physical measurements of the ETS are not influenced by the duration of the plateau period time. Roughly, the analysis of the ETS can be divided in two parts: the steam penetration during the conditioning phase of the process (7) and that during the actual exposure time. If the conditions for one of these parts are not fulfilled the ETS will generate a BD value (see below) lower than or equal to 0 and indicate a fail process. Still, each ETS fulfils the performance requirements of the ISO 11140-4 (4, 8). As mentioned above, the equilibration time in production processes, and hence in our case study, may vary from 0 to 30 s. As indicated above, many ink based steam penetration tests specify the exposure period e.g., 134 °C for 3.5 minutes. When the time is longer than the specified time the test becomes less critical, or even, the result does cannot be used as a steam penetration test because the test is not used as intended. Consequently, a steam sterilization process has to be adapted to appreciate the 3.5 minutes to meet the intended us of an ink based steam penetration test. By measuring the exposure time, as the ETS does, this limitation is overcome.

A further advantage of using the ETS was that it calculates a so called dimensionless Bowie and Dick (BD) value. When this value is less than or equal to 0 (BD ≤ 0), the steam penetration test result is a fail. When the BD value is higher than 0 (BD > 0) the result is a pass. This dimensionless BD value of the ETS is based on the performance criteria as defined in the standard ISO 11140 part 4 (4). The maximum difference in de BD value between the ETSs is less than 20. Although the pass limit is 0, the higher the BD value, the better the steam penetration of a process. The principle of the ETS measurements are addressed in the literature (7, 8). The quantified steam penetration results make it possible to analyse the data and find tendencies in the steam penetration capacities of a sterilizer. No other steam penetration test was found in the market that had the possibility to quantify the steam penetration.

Before using an ETS, the core temperature of this device has to be equal to or lower than 35 °C. When only performing one steam penetration test a day one ETS per sterilizer would be sufficient, although a "spare" ETS would be helpful in case a second steam penetration test had to be performed. During the period that ELM was performed on the sterilizers, more ETSs were necessary to facilitate cool-down time between uses of the same ETS. After use in a process the conditions of the CSSD an ETS took approximately 2 hours to cool down to below 35 °C. Given the intensity of use of the steam sterilizers it appeared to be necessary and sufficient to use four ETSs during the period of ELM in the three monitored steam sterilizers (approximately January 2015 to June 2015).

During each test (steam penetration test and ELM), an ETS was positioned in the centre of the lowest level (a plane of 940 × 610 mm) of the loading cart of the sterilizer. This was approximately 70 mm from the sterilizer bottom. At the start of the ELM period it was expected to experience practical difficulties, that the volume of the ETS would influence the loading pattern and might reduce the sterilization volume of instruments. However, such difficulties were not experienced by the staff of the CSSD. Consequently, the loading procedures did not have to be adapted and sterilization volumes were not affected.

## Results

In table 1 a summary of the BD values per sterilizer and per period (from April 2009 to June 2015) is presented. Figure 1 displays the details of the period January 2014 to July 2015. In the figure the moments of maintenance of the sterilizer are indicated by vertical black lines. The corresponding moment in time (the date) is indicated at the horizontal axis. During the period January 2015 to June 2015 an ETS was included in every process.

A closer inspection of the results in table 1 and figure 1 of the mandatory daily steam penetration test (5) (first test of the day) and the steam penetration test in every load (following tests of the day) indicate a large difference in the mean value and standard deviations (STD) in each period. The STD, also defined as the amount of variation around the mean value of a dataset, indicates the variation or spread in the measured values. The row labelled "grand total" in the table 1 represents all values (including "first test of the day" and "following tests of the day") of one sterilizer over the full period of monitoring. The mean and the STD of the grand totals of the three sterilizers (table 1) appear to be comparable, approximately 300 and 150, respectively. The number of fail steam penetration processes (first test of the day) for the three sterilisers amount to 1.4, 0.8 and 1.8%, respectively. When only the "following tests of the day" are taken into consideration the BD values and STDs are approximately 400 and 190. This indicates that with loads the mean BD values are higher while the STDs, the variation in BD values, is 30 (BD value units) larger. The number of fail production steam penetration processes (following tests of the day ) for the three sterilizers amount to 2.6, 1.2 and 3.3 %, respectively.

It might be expected that after maintenance the steam penetration capacities (BD values) would be better (higher) than before the maintenance and also that over time the penetration capacities would reduce. In this respect, one should note that the mean values in table 1 indicate that maintenance does not automatically imply an increased BD value. In some cases the mean BD

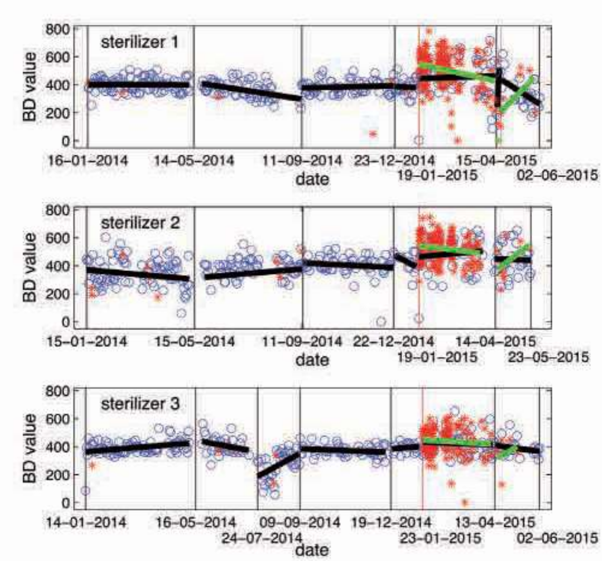


**Fig. 1: Bowie and Dick (BD) values in the period from January 2014 to July 2015 for the three steam sterilizers in this case study. In the graphs the BD values from steam penetration tests according to the standards (3 – 5) ("first test of the day") are represented by the blue circles. The red asterisks represent all following BD values on a day ("following tests of the day"). The moments of maintenance are represented by the black vertical lines. The corresponding time (date) is presented on the horizontal axis. The red vertical lines indicate the moment after which an ETS was included in every process, from January 2015 to July 2015. The bold black lines through the data are trend lines for the specific period of steam penetration tests (3). The bold green lines are the trend lines of the BD values used in processes with loads. To make the figure easier to read the range of y-axis is chosen from -50 to 820, consequently BD values lower than -50 are not presented but can be found table 1.**

Table 1: Bowie and Dick (BD) values from 14-04-2009 to 02-06-2015 per sterilizer and period. The BD value is dimensionless. A BD value smaller than or equal to 0 (BD ≤ 0) is a fail. A value larger than 0 (BD > 0) a pass. The higher the BD value the better the steam penetration. These criteria meet the performance requirements for steam penetration tests in the standards (4, 8).

| Start date | First test of the day | | | | | | Following tests of the day | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Sterilizer 1** | **n** | **mean** | **STD** | **min** | **max** | **BD≤0** | **n** | **mean** | **STD** | **min** | **max** | **BD≤0** |
| 27-04-2009 | 1247 | 260 | 151 | –1132 | 530 | 22 | 42 | 46 | 406 | –1094 | 368 | 6 |
| 16-01-2014 | 87 | 401 | 49 | 254 | 506 | 0 | 2 | 381 | 46 | 348 | 413 | 0 |
| 23-05-2014 | 62 | 364 | 57 | 230 | 478 | 0 | 1 | 312 | – | – | – | – |
| 11-09-2014 | 63 | 384 | 48 | 314 | 498 | 0 | 2 | 235 | 263 | 49 | 421 | 0 |
| 23-12-2014 | 21 | 384 | 58 | 279 | 512 | 0 | 1 | 354 | – | – | – | – |
| 19-01-2015 | 57 | 453 | 132 | 5 | 714 | 0 | 170 | 510 | 123 | 0 | 782 | 0 |
| 15-04-2015 | 3 | 380 | 171 | 184 | 494 | 0 | 2 | 350 | 318 | 125 | 575 | 0 |
| 20-04-2015 | 27 | 338 | 105 | 169 | 620 | 00 | 9 | 291 | 168 | 101 | 524 | 0 |
| **Total** | 1567 | 285 | 149 | –1132 | 714 | 22 | 229 | 229 | 275 | -1094 | 782 | 6 |
| **Grand total** | 1796 | 302 | 176 | –1132 | 782 | 28 | (from 27-04-2009 to 02-06-2015) | | | | | |
| | | | | | | | | | | | | |
| **Sterilizer 2** | **n** | **mean** | **STD** | **min** | **max** | **BD≤0** | **n** | **mean** | **STD** | **min** | **max** | **BD≤0** |
| 27-04-2009 | 1228 | 286 | 112 | –1111 | 623 | 8 | 56 | 229 | 125 | –21 | 466 | 3 |
| 15-01-2014 | 83 | 338 | 161 | –817 | 602 | 1 | 6 | 296 | 296 | 175 | 475 | 0 |
| 15-05-2014 | 67 | 347 | 216 | –842 | 552 | 2 | 3 | 418 | 418 | 316 | 504 | 0 |
| 11-09-2014 | 59 | 403 | 74 | 0 | 519 | 1 | 1 | 398 | 398 | – | – | 0 |
| 22-12-2014 | 13 | 422 | 67 | 261 | 500 | 0 | 0 | – | – | – | – | – |
| 19-01-2015 | 49 | 483 | 124 | 25 | 653 | 0 | 172 | 524 | 524 | 288 | 745 | 0 |
| 14-04-2015 | 32 | 444 | 108 | 247 | 652 | 0 | 12 | 434 | 434 | 231 | 620 | 0 |
| **Total** | 1531 | 307 | 130 | –1111 | 653 | 12 | 250 | 446 | 159 | –21 | 745 | 3 |
| **Grand total** | 1781 | 327 | 143 | –1111 | 745 | 15 | (from 27-04-2009 to 23-05-2015) | | | | | |
| | | | | | | | | | | | | |
| **Sterilizer 3** | **n** | **mean** | **STD** | **min** | **max** | **BD≤0** | **n** | **mean** | **STD** | **min** | **max** | **BD≤0** |
| 14-04-2009 | 1205 | 259 | 161 | –1105 | 546 | 28 | 51 | 214 | 135 | –71 | 506 | 6 |
| 14-01-2014 | 82 | 393 | 54 | 85 | 530 | 0 | 1 | 267 | – | – | – | – |
| 16-05-2014 | 33 | 408 | 61 | 270 | 565 | 0 | 3 | 388 | 22 | 373 | 414 | 0 |
| 24-07-2014 | 37 | 268 | 94 | 59 | 409 | 0 | 2 | 237 | 141 | 137 | 336 | 0 |
| 09-09-2014 | 52 | 372 | 39 | 282 | 459 | 0 | 0 | – | – | – | – | – |
| 19-12-2014 | 19 | 393 | 33 | 334 | 444 | 0 | 0 | – | – | – | – | – |
| 23-01-2015 | 56 | 423 | 80 | 290 | 655 | 0 | 146 | 439 | 92 | 0 | 611 | 1 |
| 13-04-2015 | 27 | 389 | 54 | 309 | 555 | 0 | 6 | 356 | 118 | 129 | 452 | 0 |
| **Total** | 1511 | 284 | 156 | –1105 | 655 | 28 | 209 | 378 | 146 | –71 | 611 | 7 |
| **Grand total** | 1720 | 296 | 157 | –1105 | 655 | 35 | (from 14-04-2009 to 02-06-2015) | | | | | |

*The start of a period is given in the row with the data. The end of the period is presented in the following row. The last period end is given in the "grand total". "Grand total" includes the data from all steam penetration tests ("first test of the day" and "following tests of the day") during the indicated time period. The columns labelled "first test of the day" is the mandatory daily steam penetration test (5). The columns labelled "following tests of the day" represent the BD values of the ETS included in a process with a load. "n" represents the number of tests, "mean" the mean (average) value of these tests, "max" the maximum BD value, "min" the minimum BD value and "BD ≤ 0" the number of processes with a BD value lower than or equal to zero. Because the data is normal distributed also the standard deviation ("STD", the amount of variation) is calculated and presented.*

value (and hence steam penetration) became lower after maintenance. This can be recognized in figure 1, as well. For sterilizer 1 the BD value was judged too low (184) after maintenance on 15-04-2015. After an extra maintenance on 20-04-2015 an "average" BD value was generated again (approximately 300, see table 1 and figure 1).

In figure 1 linear trend lines are presented. Inspection of these trend lines shows that results of the steam penetration tests may become better (larger BD value) during a period, such as in sterilizer 2 during the period 15-05-2014 to 11-09-2014 and in sterilizer 3 during the period 24-07-2014 to 09-09-2014, after a less successful maintenance. Amongst other possibilities this might be caused by wearing out of the vacuum pump of the sterilizer. A bad vacuum pump could result in a slower pumping of the gas mix out of the sterilizer chamber. This yields more time for diffusion, resulting in a better steam penetration. On the process registration (print out) it was possible to recognise the lengthened process time.

The results of ELM are also presented in figure 1 for the period from approximately January 2015 to June 2015. As mentioned above, the mean BD values of ELM are higher and their variation seems larger. Comparing the values of the period with and without ELM indicates that the load influences the steam penetration capacities of a process. When steam is required in a process and the steam contains (even small) amounts of NCGs, more NCGs will accumulate in the sterilizer. Hence, the steam penetration decreases.

## Discussion

Approximately 1% of the mandatory daily steam penetration tests (5) generate a fail result (4). After maintenance the steam penetration does not always perform better than before maintenance. Also, the linear trend lines of BD values indicate that results may or may not improve over time. These observations already demonstrate the added value of the daily steam penetration test. Especially a steam penetration test that quantifies the steam penetration adds value to the test because data can be analysed and trends can be recognised.

When the requirements for steam penetration tests (4) are applied for ELM, the mean BD value (steam penetration) becomes better than for the load with only a steam penetration test. In contrast, the variation in BD values increases. Amongst other reasons, the better mean BD value of the ELM results may be caused by the warming up of the sterilizer and its hardware. During the night time the sterilizers and hardware were not used and cooled down. In this time NCGs may accumulate in the sterilizer and its hardware, e.g., the steam supply system. During the warming up of the sterilizers in the morning these NCGs are "washed out" of the sterilizer and its hardware. Furthermore, the larger variations in the ELM BD values may be caused by the kind of load that is processed (e.g. weight of load, type of materials), by wearing out of the mechanical components (e.g. the vacuum pump), or by variations in the steam supplied to the sterilizer. In case of heavy loads the amount of accumulating NCGs may be so large that steam sterilisation conditions as specified in the literature (1) may be jeopardized. In this case study this may have happened in sterilizer 1 in up to 2.6%, in sterilizer 2 in up to 1.2 % and in sterilizer 3 in up to 3.3.% of the processes. Finally, it has to be considered that steam sterilizers have various components that may break down unexpectedly and unnoticed (e.g. leaks in gaskets, vacuum-pump or valves). This indicates that ELM is a necessity.

It has to be considered that because the measurement of only pressure and temperature is not sufficient to ensure saturated steam (2) more precautions have to be taken to ensure sterilisation. If only $p$ and $T$ are measured, loads assumed to be sterile may be released while they were not exposed to sterilization conditions and used on patients. Obviously, this may lead to a risk for patients and staff and additional costs for treatment. This indicates that ELM of the essential steam sterilization parameters (saturation of steam and temperature) is a necessity.

The results of steam penetration tests could be used to check the quality of maintenance and to identify trends (figure 1). Possibly, these results could be used to extend the period before maintenance of the sterilizer, reducing costs for the hospital. Overall it has to be concluded that the wide variation in steam penetration between processes may jeopardise steam sterilisation conditions. This makes monitoring of the essential parameters for steam sterilization – saturated steam, temperature and time (1, 2) – a necessity. Together with the possible cost reductions for maintenance and an increased safety for patients and staff the present results indicate that monitoring of steam penetration in every load has an added value for the sterilizers in this case study. Likely, similar advantages can be demonstrated for other sterilizers, as well.

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## Competing interests

At the time of data acquisition for this study, J.P.C.M. van Doornmalen was employed by 3M Deutschland GmbH, Infection Prevention Division,

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