Keywords
- steam sterilisation
- routine monitoring
- process challenge device
- Hollow A

Experience with a new routine monitoring system for steam sterilization processes standardized in EN 867-5 as Hollow A test system

A. Brusa, V. Rigobello, O. Mauriziano, A. Ospedaliera*

Introduction

During the last 15 years more and more complex surgical instrumentation have been implemented in hospitals. Most of them are sterilized in steam sterilization processes. In Italy many different kinds of steam sterilizers are used in hospitals. The processes differ mainly in their air removal and steam penetration capabilities.

We raised the question whether traditional test methods like the Bowie-Dick-Test according to EN 285, biological indicator strips according to EN 866-3, or chemical indicator strips according to EN 867-1 class D are still suitable to monitor the sterility of complex items – because penetration characteristics of porous loads like the Bowie-Dick-Test differ completely from those of hollow devices. Also chemical and biological indicator strips can monitor sterility only at the place were they are located. In hollow instruments the lumen is the most difficult place to be sterilized. The traditional test methods mentioned above are unable to test the sterility inside of hollow instruments.

In the European standard UNI-EN-867-5 a special process challenge device has been defined to test small sterilizers of type B according to EN 13060. This device represents a hollow lumen and can host a biological or chemical indicator at its most difficult penetration place. We used this device to monitor our steam sterilization batches in all departments of Mauriziano Hospital, in particular:

- Sterilization Plant of Turin Centre
- General Surgery
- Theatres of Turin Centre
- Cardiovascular Department Theatre of Turin Centre
- Odontostomatologia Ambulatory on Turin Centre
- Sterilization Plant of Candiolo Centre
- Theatres of Lanzo Centre
- Theatres of Valenza Centre

The test period went from August 2002 to November 2002; the test results are listed in table 1 with detailed explanations.

Materials and Methods

In the above mentioned seven departments steam sterilizers according to EN 285 have been used. All systems have sub-atmospheric fractionated vacuum cycles and all sterilizers are able to perform the batch monitoring test. All cycles have been monitored by a temperature-pressure-time recording system which is built into the sterilizers. Fail conditions of the sterilizers are recorded if the temperature-time-plateau-period is not met.

As a batch monitoring system we used a system of gke-mbH, Germany (article-no. 211-260 purchased from: SOVETA Srl, Via Cadorna, 37, 20017 RHO (MI)) which consists of a process challenge device of 1.5 m PTFE-tube with 2 mm inner diameter and 3 mm outside diameter with a capsule at the end hosting a chemical indicator (Fig. 1). The indicator shows a pass with an F_0 value of 15 min and the presence of steam. It shows a fail with an F_0 value of 15 min and the presence of air. It also shows a fail with an F_0 value < 15 min and the presence of steam. This system is validated with the test method of EN 867-4 to the reference process challenge device according to EN 867-5.

The batch monitoring system was placed on a tray at the bottom close to the sterilizer doors where we expect the highest concentration of non-condensable gases, if they are present. At the end of the process the batch monitoring indicator strip was taken out and attached to the documentation sheet.

Results

All sterilizers were monitored with a temperature-pressure-time recording system where we registered valid cycles according to physical parameters in comparison to the batch monitoring system (BC) according to EN 867-5.

In table 1, Line 1 shows the percentage of physical pass cycles and batch monitoring pass cycles.

Line 2 shows adequate physical pass cycles but batch monitoring fail cycles.

Line 3 shows adequate batch monitoring pass cycles and physical fail cycles.

Line 4 shows non-adequate physical and non-adequate batch monitoring cycles.

The results in line 2 were particularly astonishing for us, because here a lot of physical cycles show a pass but the batch monitoring cycles show non-condensable gases indicating insufficient steam penetration and therefore insufficient sterilization in about 10 % of all cases.

In 9 cases the cycle was stopped (see line 3) by the sterilization program, but before opening the door the sterilizer kept the temperature of 96 – 120 °C for about 30 min. Therefore, the required F_0 value

* Dr. Artemio Brusa, Via Febo 14, 10133 Torino, Italy, E-Mail: abrusa@asl102.to.it

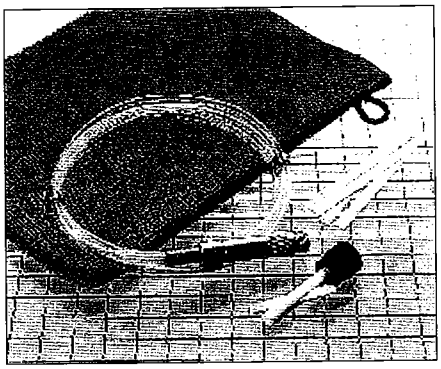

Fig. 1: Process challenge device

of 15 min was nevertheless achieved, thus allowing a pass according to UNI-EN 554 which also triggers a pass of the batch monitoring system if air removal and steam penetration is achieved.

Conclusions

We have had many discussions with sterilizer manufacturers who defended their current technology and claimed that the batch monitoring system used was too sensitive. But what is the reason for those failures?

The failure of the cycles is caused by inadequate penetration of the steam into hollow devices. Reasons for this can be manifold:

1. insufficient air removal
2. leaks during the vacuum phase in fractionated vacuum machines
3. non-condensable gases in the steam supply or
4. leaks of pneumatically driven door seals

We noticed that about 10 % of the total amount of cycles carried out failed in total steam penetration but gave a pass by parametric release. We noticed that the biggest amount of fails was generated in one hospital with centralized steam supply where the steam supply created quite different failure percentages in the different departments.

The recently published test from RIVM in the Netherlands (1) with a similar batch monitoring system came to very similar conclusions. With those results it is absolutely necessary to adapt the sterilization procedures and their monitoring systems according to the complexity of the instruments.

Consequences for our hospitals

Our hygienic commission has decided to change the procedures for monitoring steam sterilization processes. We will check temperature and time parameters and in addition use a batch monitoring system with the following advantages:

- It is not necessary anymore to place a single chemical indicator in each pack.
- The information about the success of the sterilization process in available immediately at the end of the process.
- At the end of the process all relevant information is available to the authorized person releasing the batch.
- The sterilization technician can identify immediately whether each pack of the batch is sterile and can be distributed for use.
- The theatre staff can receive the material in complete security: it is not necessary for them to open the packs to verify whether the process has had a positive result.
- The price-benefit-ratio is excellent compared to the single package monitoring.
- It is less stressful to check the batch documentation than to check the documentation of each individual pack.
- The adhesive indicators simplify the documentation collection. ❄

References

[1] A.C.P. de Bruijn, A. Van Drongelen: The Relevance of the Bowie and Dick Test in Hospital Sterilization. Zentr Steril 2003; 11 (5): 319–328.

Table 1: Results of the gke Batch Control System tested from 1st August to 15th November 2002

Mauriziano	Turin				IRCC Candiolo	Lanzo	Valenza
Department	Sterilisation Department	General Surgery	Cardiova Scular Surgery	Odontostoma Tologia Ambulatory	Sterilisation Plant	Theatres	Theatres
Adequate B.C. Valid Cycle	1023 (98.6 %)	431 (91.1 %)	1338 (90.7 %)	200 (91.7 %)	211 (98.6 %)	669 (98.2 %)	236 (86.4 %)
Non Adequate B.C. Valid Cycle	3 (0.3 %)	42[1] (8.9 %)	137[2] (9.3 %)	18[3] (8.3 %)		12 (1.8 %)	37[4] (13.6 %)
Adequate B.C. Non Valid Cycle	9[5] (0.8 %)				2 (0.9 %)		
Non Adequate B.C. Non Valid Cycle	2 (0.3 %)				1 (0.5 %)		
Total B.C. Cycles	1037 (100 %)	473 (100 %)	1475 (100 %)	218 (100 %)	214 (100 %)	681 (100 %)	273 (100 %)

All Autoclaves have been monitored according the standards UNI EN 554.

[1] Demineralised water; the non adequate B.C. were concomitant to the alarm for substituting the salts bottles.

[2] The sterilisation activity was stopped owing to maintenance.

[3] The autoclave maintenance concern explained the non adequate B.C. as a consequence of a low steam quality and proposed a better demineralisation machine.

[4] The autoclave maintenance concern was called.

[5] The cycle was stopped because of a low temperature in the pre-sterilisation period. The alarmed machine stops the cycle and keeps the physical values, temperature (range 120–96 °C) and pressure (bar range 0,90–1) for 30 minutes, resulting in an achieved F_0-value of 15 min minimum, causing the B.C. pass.