NOVEMBER | 20th | 2021

SYMPOSIUM **FACTSHEET**

THE IMPORTANCE OF LOW TEMPERATURE STERILIZATION VALIDATION & COMPLIANCE

SPEAKERS & TOPICS

Quality assurance through process verification

PATRICK TURNER,
BEAUMONT HOSPITAL, IRELAND

The science behind the BI/PCD

BENJAMIN FRYER,
ASP R&D

ISO13485 Compliance of full LTS process in the CSSD

WOUTER MEERT,
UZ LEUVEN, BELGIUM

21ST WORLD STERILIZATION CONGRESS

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Quality assurance through process verification

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DECONTAMINATION MANAGER FOR BEAUMONT HOSPITAL DUBLIN

There are a number of questions that we, as decontamination practitioners must ask ourselves:

- Do we have adequate instruction for reprocessing from the medical device manufacturer in accordance with ISO sterilization standards and ISO 13485 principles?
- Is there documented evidence that the Medical Device (MD) remains functional and safe for use after repeated reprocessing?
- Has the staff been adequately trained?
- Do we have the appropriate equipment's and consumables to meet instruction for reprocessing?

Comprehensive research is vital before medical devices are reprocessed for the first time.

Reprocessing of the medical device over time

Are the Cleaning parameters compatible with Manufacturer's instructions for reprocessing and have the chemicals used in the cleaning process of the MD been approved for use with the sterilisation process?

Has the staff demonstrated competency to reprocess the medical device; has been trained and certified per healthcare facility training policy?

Are the products that we are using to package the Medical Devices (MDs) compatible with the sterilization process and adapted to the device?

Is there a structure to collect customer feedback in line with ISO 13485?

“Staff training and equipment maintenance are essential component to producing a quality product .”

Monitoring and Measuring of the process

Is the validation of the reprocessing equipment recorded and critical parameters compared to commissioning data and is the trained staff, examined and certified as competent to reprocess the MDs as set out in the Manufacturers IFU and in compliance with the healthcare facility training policy?
Is there a facility to receive measure and report customer feedback in line with ISO 13485?

“Monitoring over time is key to producing a quality product.”

This presentation sets out to challenge the attendees, if they have considered all the aspects of the product that they intend to reprocess, before the start of processing. [DP2] Are we in compliance with the manufacturer’s specific instructions for reprocessing? When it is in place are we monitoring and measuring the process to ensure there is still compliance after set periods of time? Are we receiving and monitoring customer feedback to ensure we are producing a quality product still fit for purpose? Is the product still safe for use?

Take home messages:

- RESEARCH THE PRODUCT BEFORE PROCESSING
- AUDIT AND MONITOR THE PRODUCT DURING ITS REPROCESSING OVER TIME
- REVIEW THE DATA AND PROPOSE IMPROVEMENTS WERE APPLICABLE

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The science behind the BI/PCD

BENJAMIN FRYER

ASP R&D

BI & PCD according to the guidelines

There is an important functional difference between a Biological Indicator (BI) and a Process challenge device (PCD).

International relevant guidelines, such us ANSI/AAMI and ISO standards, defined the subtle difference what each BI/PCD configuration demonstrates relative to load sterilization.

Standards are consistent, PCDs must provide a challenge equal or greater than most difficult items routinely processed.

What is the relative resistance between the two configurations

A BI is only intended to demonstrate necessary conditions were met to achieve sterilization, it does not prove the load is sterile. So while a BI is very useful, it just proves the sterilizer is capable of sterilization, in other words a negative BI indicates the sterilizer capable of sterilizing the BI.

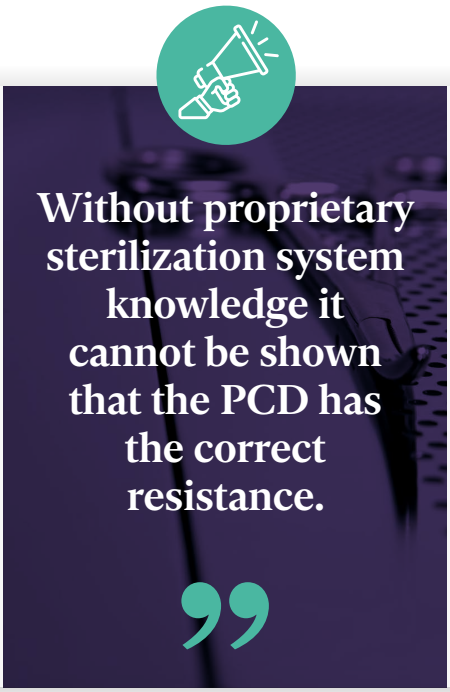
"A BI is only intended to demonstrate necessary conditions were met to achieve sterilization, it does not prove the product is sterile."

> **"(...) negative PCD result indicates that the sterilizer cycle was capable of achieving a 10^{-6} SAL with the worst-case load designed for that cycle."**

A PCD provides a greater challenge to the sterilization process than a BI. PCDs are designed to constitute a defined resistance to a sterilization process and are used to assess the performance of the process. In this case a negative PCD result indicates that the sterilizer cycle was capable of achieving a 10^{-6} SAL with the worst case product designed for that cycle.

PCD process resistance vs the peroxide dose in a low temperature hydrogen peroxide system.

The design of a low temperature sterilization (LTS) PCD requires detailed, proprietary knowledge of how the LTS cycle was designed, the biological model used to develop the cycle and an understanding of the critical inputs to control the LTS system. Without this proprietary sterilization system knowledge it cannot be shown that the PCD has the correct resistance.



Use of a PCD or a BI/PCD provides a higher standard of care than a BI. It is likely that there will be an increasing trend of the use of PCDs for LTS sterilization due to the higher standard of care they provide.

- ANSI/AAMI AND ISO STANDARDS DEFINE THE DIFFERENCES BETWEEN BI ON WHAT EACH CONFIGURATION DEMONSTRATES RELATIVE TO LOAD STERILIZATION.
- A BI IS USED ONLY DEMONSTRATE NECESSARY CONDITIONS WERE MET TO ACHIEVE STERILIZATION.
- A PCD IS BETTER THAN BI BECAUSE IT CAN BE USED TO ASSESS PROCESS PERFORMANCE.
- STANDARDS ARE CONSISTENT, PCDS MUST PROVIDE A CHALLENGE EQUAL OR GREATER THAN MOST DIFFICULT ITEMS ROUTINELY PROCESSED.
- DESIGNING A PCD WITH THE CORRECT RESISTANCE REQUIRES PROPRIETARY KNOWLEDGE OF THE LTS SYSTEM IT IS USED IN.

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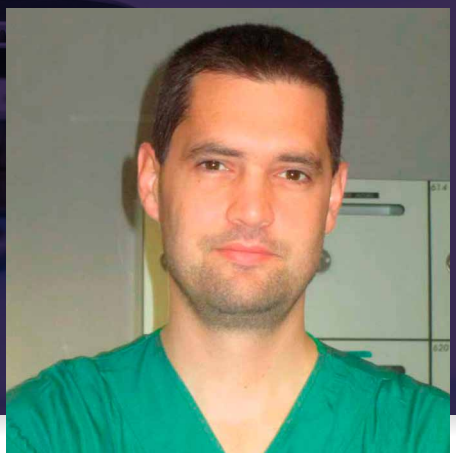
ISO13485 Compliance of full LTS process in the CSSD



WOUTER MEERT

UZ LEUVEN, BELGIUM

An EN ISO 13485 certificated CSSD

How do you make sure that every product leaves CSSD with all sterility assurance requirements and a timely manner? This to guarantee patient safety. You need to find the balance between quantity and quality. The best way is using a quality system that guides you through the whole process. **ISO 13485 possesses all the tools to create a secured process and organize continuous analysis and improvement.** Developing your department on the foundation of ISO 13485 help frame the organization, state of the art infrastructure and environmental control, a QMS structure not only on paper but in daily operational practice. Improvement is based on customer feedback, audits and data analyses. Off course this is not possible without a highly trained staff.

> **The ISO 13485 possesses all the tools to create a stabile process and keeps you continuously analyzing and improving.**

Integration of hydrogen peroxide as a standard process in your CSSD

In the present times it's almost unthinkable to run a CSSD without a low temperature sterilization method. **Hydrogen peroxide has been integrated as a standard sterilization process within the present CSSD.** Is the hydrogen peroxide process compatible within an ISO 13485 setting?

The hydrogen peroxide process is described by QMS. Of course, validation and maintenance are controlled by the auditor every time at each of his visits. To prove the quality off your end product the system requires process control. In our setting with the STERRAD™ 100NX Velocity BI, Access software and our traceability system TraCSA makes sure this part is covered. Every process within the CSSD needs to be handled by trained staff. On collaboration with ASP all new employees receive a theory session and afterwards hands on training on the floor by experienced colleagues. A final important aspect is confirming the compatibility of instruments with the hydrogen peroxide process. Within the ISO 13485 you need to prove you have confirmed this by using the IFU in our case the STERRAD™ sterility guide.

“Hydrogen peroxide has been integrated as a standard sterilization process within the present CSSD.”

Every CSSD wants to deliver a high quality product to guarantee patient safety. ISO 13485 helps to achieve that goal. Hydrogen peroxide sterilization has taken his place in daily operational activity within the CSSD. Due to the availability of all the necessary process parameters and surrounding support of the manufactures it can perfectly be built into an ISO 13485 CSSD environment.

Take home messages:

- INTRODUCING AN ISO 13485 QUALITY SYSTEM: ORGANIZE AND OPTIMIZE YOUR CSSD PROCESS FLOW.
- LOW TEMP STERILIZATION BY HYDROGEN PEROXIDE BECAME A STANDARD IN THE REPROCESSING OF MEDICAL DEVICES. TAKE THE OPPORTUNITY TO CREATE A QUALITATIVE PROCESS IN YOUR CSSD BASED ON THE ISO 13485.

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