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23RD WORLD BARCELONA STERILIZATION CONGRESS

wfhss World Federation for Hospital Sterilisation Sciences

SYMPOSIUM **FACTSHEET**

"H_2O_2 STERILIZATION: STANDARDS, PHYSICS, MEDICAL DEVICES AND PRACTICE."

NOVEMBER | 17th | 2022

THE PHYSICS OF H_2O_2 STERILIZATION

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ISO 22441 AND FUTURE H_2O_2 STANDARDS

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PROCESS VALIDATION & MEDICAL DEVICES QUALIFICATION IN PRACTICE

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Intro

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SYMPOSIUM **FACTSHEET**

Since its creation by ASP in the early 1990's, H_2O_2 Low Temperature Sterilization (LTS) has come a long way. It became the indisputable reference low temperature sterilization modalities for hospitals across the world. As the number of sterilizer manufacturers attracted by the technology and applications of H_2O_2 LTS keeps growing, time had come to develop dedicated international standards. After several years of intense and rich debates, ISO 22441 was published and will progressively take the place 14937.

We will take a walk through ISO 22441, remind the core principles common to ISO 14937 and ISO 22441 and explain on the additional information and clarification brought by ISO 22441. Although H_2O_2 LTS has reached maturity, there is still a lot to be said on the H_2O_2 sterilization science. We will dive in the intimate physics of H_2O_2 interaction with surfaces and germs. Time will then come to conclude with the implementation of ISO 22441 and sterilization science in everyday practice.

HAVING THIS IN MIND, **ASP** CONDUCTED AN **ASP SYMPOSIUM** DURING THE 23RD WORLD STERILIZATION CONGRESS, IN ORDER TO CLARIFY THE NEW ISO 22441, THE REQUISITES OF H_2O_2 LTS TECHNOLOGY AND HOW WE CAN PUT IT ON PRACTICE DAILY BASIS. THE SYMPOSIUM COUNTED WITH THE FOLLOWING 3 LECTURES:

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Exploring the intimacy of sterilization.

Sterilization processes are commonly characterized by variables such as pressure, temperature, time, concentration of the sterilizing agent. Measures are made at chamber or load level i.e. at some distance from germs. With adequate safety margin and validation, this is good enough to guarantee that conditions for sterility are met within the load. However, understanding the intimacy of sterilization implies a closer look to phenomena such as adsorption and condensation, occurring at germ level.

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> MEASURING VARIABLES AT CHAMBER OR LOAD LEVEL ARE **SUFFICIENT TO CONTROL STERILIZATION PROCESS** BUT **NOT ENOUGH TO UNDERSTAND THEM.**

Observing sterilization at germ level.

Physics and microbiology

ASP advanced research brought together world-renowned condensation physicists and microbiologists. Studies were performed at atmospheric pressure and low concentration H_2O_2 to obtain a slow motion of phenomena that are too fast in a sterilizer chamber.

Sophisticated scientific equipment and installations were used to monitor condensation, H_2O_2 concentration, temperature, relative humidity, inactivation kinetics and even film the interaction between H_2O_2 and germs.

ATMOSPHERIC PRESSURE AND LOW CONCENTRATION H_2O_2 FOR AN OBSERVATION OF STERILIZATION IN SLOW MOTION.

"For the first time, inactivation of germs was filmed with high magnification cameras."

"when, well controlled, H_2O_2 is so powerful that even prion cannot resist."

Confirming the rapid and powerful action of H_2O_2

Of course, conditions prevailing in sterilizer chambers at high concentration and under vacuum are different but laws of physics allow parallels and correlations can be made.
Results confirm that inactivation kinetics is optimal in the early stage of exposure when adsorption and the first layers of condensation bring the highest concentration of sterilization agent at inoculum interface. In some conditions even prion does not resist to the power of H_2O_2.

INACTIVATION STARTS AS SOON AS THE **GERMS** ARE **EXPOSED TO H_2O_2.**

Take home messages:

- PHYSICS AND MICROBIOLOGY TO EXPLORE THE INTIMACY OF H_2O_2 STERILIZATION AT GERM LEVEL.
- H_2O_2 INACTIVATION KINETICS IS FAST AND POWERFUL,

  BUT ....
- STERILIZATION IS MORE THAN p, T°C, VH2O2 cc,

  AND ....
- THEORY CANNOT YET REPLACE TESTS ON DEVICES OF INCREASING GEOMETRIC AND MATERIAL DIVERSITIES.

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ISO 22441 AND FUTURE H_2O_2 STANDARDS.

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ISO 22441: the first standard dedicated to H_2O_2 sterilization

Since its publication in 2000 and amendment in 2009 in ISO 14937 is the international standards applicable to low temperature H_2O_2 sterilization processes. ISO 14937 also serves as the framework for all existing and future sterilization processes. The quality of ISO 14937 and the ease of H_2O_2 LTS to meet sterilization assurance level did not create an urgent need for a dedicated standard. However, as applications of H_2O_2 LTS are constantly broadening and success attracts more manufacturers across the world, a need appeared to remind the key principles of ISO 14937 and explain how they apply to H_2O_2 LTS.

> APPLICATIONS OF H_2O_2 STERILIZATION ARE **CONSTANTLY BROADENING.**

ISO 22441: remind ISO 14937 principles and explain how they apply to H_2O_2 LTS.

A safe and efficient H_2O_2 LTS process requires the implication of Medical device manufacturers and sterilizers manufacturers to support hospital sterilization departments.

Contributions of medical devices manufacturers, sterilizers manufacturers and healthcare facilities.

Interpretation of sterilization standards can be challenging for end-users. 2 reasons are that normative requirements must apply to domains with significant differences and standards cannot assign responsibilities in place of regulators.

A focus on typical responsibility assignments in healthcare facility domain helps clarify the contributions of hospital, medical device and sterilizers manufacturers to a safe and efficient H_2O_2 LTS process.

> STANDARD CAN BE CHALLENGING TO UNDERSTAND.

Partnership between medical device manufacturer and sterilizer manufacturer is key.

Low temperature sterilization was invented for critical devices that cannot be reprocessed by steam. In hospitals, H_2O_2 LTS rapidly took the place of Ethylene Oxide and formaldehyde.
More than steam however H_2O_2 must deals with the growing material and geometric complexity of medical devices.
Regulation, ISO 14937 and now ISO 22441 reminds the need for partnership between Medical Device and sterilizer manufacturers to ensure that medical device can be sterilized and remain fully functional after repeated reprocessing.

H_2O_2 STERILIZATION MUST ADAPT TO THE GROWING MATERIAL AND GEOMETRIC COMPLEXITY OF MODERN MEDICAL DEVICE.

"Partnership between medical devices manufacturers and H_2O_2 sterilizer manufacturers is key to ensure that devices can be sterilized and remain functional after repeated reprocessing."

The role of the healthcare facility

Validation and routine controls of sterilization processes ensure that the sterilizer is properly installed and operational, that adequate documentation and procedures are available, and that efficacy is maintained over time.
Research has created a new generation of fast read-out process challenge devices with biological indicators to support performance qualification and routine controls. Under the condition that they are carefully designed to mimic real devices, BI-PCD confirm within minutes that conditions for sterilization are met at the heart of the most complex medical devices.

"BI-PCD confirm within minutes that conditions for sterility are met at the heart of the most complex devices."

A NEW GENERATION OF BIOLOGICAL SENSORS.

Take home messages:

- NEW ISO 22441 STANDARDS REMINDS ISO 14937 PRINCIPLES AND EXPLAIN HOW THEY APPLY TO H_2O_2 LTS.
- A SAFE AND EFFICIENT H_2O_2 LTS PROCESS REQUIRES THE IMPLICATION OF MEDICAL DEVICE MANUFACTURERS AND STERILIZERS MANUFACTURERS TO SUPPORT HOSPITAL STERILIZATION DEPARTMENTS.
- PARTNERSHIP BETWEEN STERILIZER MANUFACTURERS AND MANUFACTURERS OF MEDICAL DEVICES IS KEY TO OVERCOME THE GROWING MATERIAL AND GEOMETRICAL COMPLEXITY OF MODERN HEAT SENSITIVE DEVICES.
- PROGRESSES OF SCIENCES HAVE ALLOWED THE EMERGENCE OF NEW BIOLOGICAL SENSORS THAT CONFIRM WITHING MINUTES THAT CONDITIONS FOR STERILITY ARE MET AT THE HEART OF THE MOST COMPLEX MEDICAL DEVICES.

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A new norm: ISO 22441

A ISO 13485 certified CSSD is obligated to show the auditor they have a system to verify if new norms are available and how they impact the current process flow. Basically every CSSD needs to address this method. By taking a subscription with an normative organisation (CEN) you will always be informed. Having the norm is not the same as understanding its impact. For this information, professional organizations, like WFHSS, or the national groups together with manufacturers can help you to understand its importance.

> PROFESSIONAL ORGANIZATIONS, LIKE WFHSS, OR THE NATIONAL GROUPS TOGETHER WITH MANUFACTURERS CAN HELP YOU TO UNDERSTAND ITS IMPORTANCE.

Having the norm on paper is not the same as understanding its impact.

Decide together with your manufacturer which parameters are used to release your loads.

ISO 22441: releasing loads

Hydrogen peroxide was captured within the ISO EN 14937. It was always difficult to determine the "critical" parameters to release your loads. In most of the cases you looked at the print-out and normally it says "cycle completed" our "cycle successful". In this new norm you will see that the word critical does not exist. Only the variables are named: pressure, temperature, time and H_2O_2 concentration. Where it seems logical that H_2O_2 concentration feels like the most important the manufacturer decides which combination of variables gives you certainty about your sterilization process. Is the new norm telling us something about using CI's or BI's to release loads?

> ONLY THE VARIABLES PRESSURE, TEMPERATURE, TIME AND H_2O_2 CONCENTRATION.

ISO 22441: validation

Validation is and stays one of the basics in assuring the stability of your sterilization process. ISO 22441 does not change a lot in the way how to perform the validation. It is similar as the ISO 14937. This means IQ, OQ and PQ. And needs to be repeated yearly and after major repairs, this for every operating cycle. Important to take in account is that you need to find out your worst case scenario for every performed operational cycle. This by using you most challenging device our a specific designed PCD.

ISO 22441 DOES NOT CHANGE A LOT IN THE WAY HOW TO PERFORM THE VALIDATION.

"Take your time designing your own worst case scenario to perform the validation."

ISO 22441: instrument compatibility Buying a new hydrogen peroxide sterilizer

The new MDR 745-2017, applicable from May 2021, pushed a shock through the medical device landscape. Manufactures are working really hard to make sure everything gets certified on time. On the other hand certain product lines are abandoned. When talking about sterilization, manufacturers know need to perform very strict cleaning, disinfection and sterilization validations. With the new ISO 22441 validating an instrument for hydrogen peroxide becomes more clear. You can validate a process not a combination with an specific hydrogen peroxide sterilizer. As a footnote, what if I want to buy an new hydrogen peroxide sterilizer. For now there not yet an published norm for H_2O_2 sterilizers (EN 17180). From the moment the ISO 22441 is acknowledged within your normative institute you can use it for a tender. The manufacturer needs to comply to the process as described. On the other hand you can keep using ISO 14937 also. It's best to describe both of them in your tender.

WITH THE NEW ISO 22441 VALIDATING AN INSTRUMENT FOR HYDROGEN PEROXIDE BECOMES MORE CLEAR. YOU CAN VALIDATE A PROCESS NOT A COMBINATION WITH AN SPECIFIC HYDROGEN PEROXIDE STERILIZER.

"Use both ISO 22441 and ISO 14937 in your future tenders until the EN 17180 is published."

Take home messages:

- FIND FOR YOURSELF THE WAY TO UNDERSTAND THE CONTENT AND IMPACT OF THE NEW ISO 22441 NORM ON YOUR CSSD.
- USE THE NEW VARIABLES PRESSURE, TIME, TEMPERATURE AND H2O2 CONCENTRATION TOGETHER, IF NECESSARY, WITH BI, PREFERABLY WITH BI/PCD, CI TO DEFINE YOUR LOAD RELEASES.
- DEFINING A WELL THOUGHT OUT WORST CASE (BI/PCD AND CHALLENGE PACK) FOR YOUR HYDROGEN PEROXIDE CYCLE VALIDATIONS BUILDS IN MORE SAFETY IN THE PROCESS.
- ISO 22441 WILL HELP YOU TO SAFELY CONNECT NEW MEDICAL DEVICES WITH YOUR HYDROGEN PEROXIDE STERILIZATION PROCESS.

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