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ASP Advanced Sterilization Products

2024 WEBINAR SERIES #5

MEDICAL DEVICES BACK TO THE REPROCESSING: FUTURE

ISO 22441 - THE NEW STANDARD FOR H_2O_2 STERILIZATION

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2nd WEBINAR

DR. PHILIPPE DESTREZ:

01. ISO 22441: the first standard dedicated to H_2O_2 sterilization

SINCE ITS INTRODUCTION IN THE EARLY 1990S, HYDROGEN PEROXIDE (H_2O_2) LOW-TEMPERATURE STERILIZATION (LTS) HAS EMERGED AS THE PREFERRED METHOD ON HEALTHCARE FACILITIES, SURPASSING TRADITIONAL OPTIONS LIKE ETHYLENE OXIDE AND FORMALDEHYDE DUE TO THEIR TOXICITY AND PROTEIN-FIXING PROPERTIES.

H_2O_2 LTS PERMITS CONVENIENT AND SAFE TERMINAL STERILIZATION OF HEAT SENSITIVE CRITICAL DEVICES THAT WERE OFTEN ONLY HIGH-LEVEL DISINFECTED.

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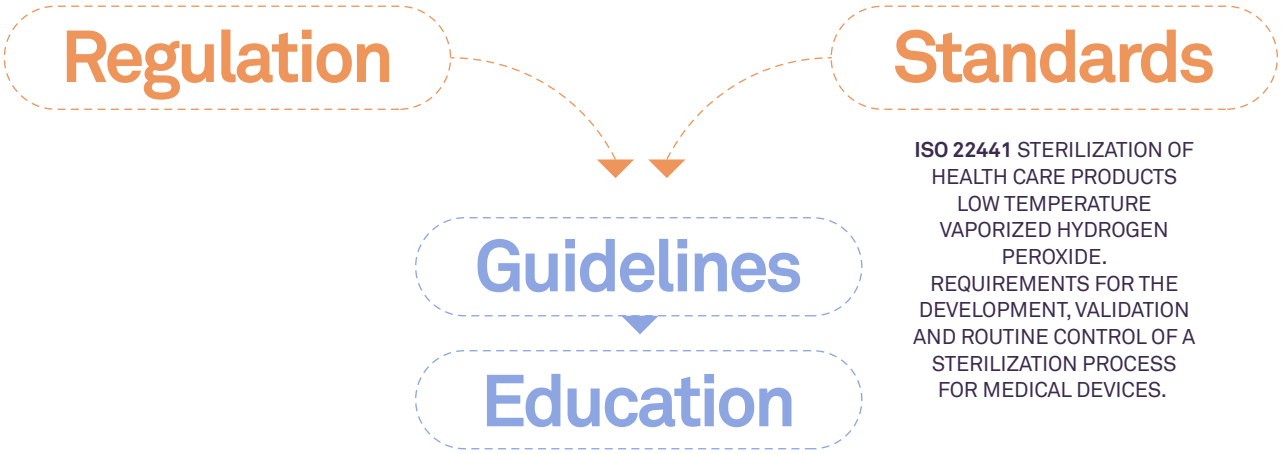
THE PUBLICATION OF **ISO 22441** MATERIALIZES THE SUCCESS OF H_2O_2 LTS. OTHER 2 STANDARDS FOR MANUFACTURERS OF H_2O_2 STERILIZERS (EN17180) AND H_2O_2 BACTERIOLOGICAL INDICATORS (ISO/AWI 11138-6) SHOULD BECOME AVAILABLE IN THE NEXT 2 YEARS.[1-3]

> **The publication of ISO 22441 materializes the growing success of H_2O_2 LTS.**

ISO 22441: H_2O_2 IS THE REFERENCE LTS MODALITY IN HEALTHCARE FACILITIES THROUGH THE WORLD.

IMAGE SOURCE : https://www.freepik.com/free-ai-image/people-hanging-out-with-robot_132310043.htm#fromView=search&page=1&position=22&uuid=e4c82f61-d5d0-4d80-af5d-13d0d74507bd

STANDARDS, GUIDELINES AND REGULATION:



Source: 1. Courtesy of Philippe Destrez, Scientific Director ASP, Strasbourg - France

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

ISO 22441 IS A STERILIZATION PROCESS STANDARD FOR H_2O_2 LTS. IT COVERS ALL TASKS THAT CONTRIBUTES TO THE SAFE STERILIZATION OF MEDICAL DEVICES FROM EARLY DEVELOPMENT STAGES BY THE STERILIZER MANUFACTURER TO DAILY OPERATIONS BY THE HEALTHCARE FACILITY.

ISO 22441 HENCE CONTAINS REQUIREMENTS APPLICABLE TO THE STERILIZER MANUFACTURER, FOR STERILIZATION DEPARTMENTS BUT ALSO FOR MEDICAL DEVICE MANUFACTURERS.[4]

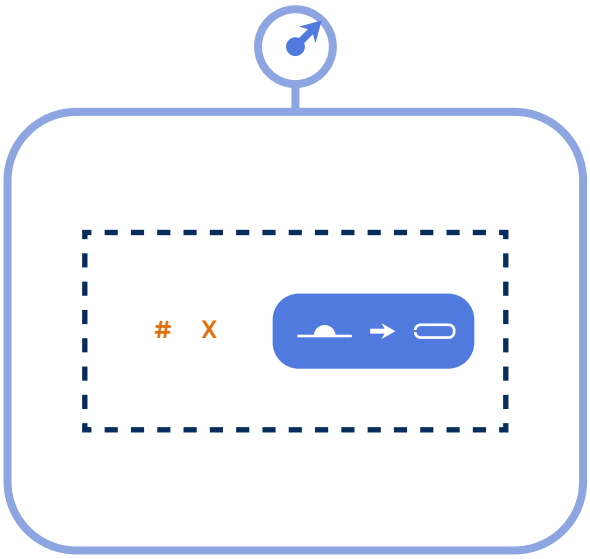
> ISO 22441 applies to sterilizer manufacturers, medical device manufacturers and healthcare facilities.

03. Partnership between medical device manufacturer and sterilizer manufacturer is key

MEDICAL DEVICE MANUFACTURERS MUST PROVIDE INSTRUCTIONS FOR REPROCESSING AND VALIDATE THE CLEANING PROCESS AND STERILIZATION CYCLES THAT THEY RECOMMEND.

GIVEN THE GROWING COMPLEXITY OF HEAT SENSITIVE MINIMALLY INVASIVE SURGERY DEVICE, VALIDATION MEANS STERILITY TESTS ON REAL DEVICES AND IN MOST CHALLENGING LOCATION IN THESE DEVICES. IT IS ALSO VERIFIED THAT THE DEVICE REMAINS FULLY FUNCTIONAL AFTER REPEATED REPROCESSING.

AS H_2O_2 CYCLES ARE SPECIFIC, STERILITY AND FUNCTIONALITY TESTS ARE OFTEN PERFORMED IN PARTNERSHIP WITH STERILIZER MANUFACTURERS.[5,6]



A NEW NORM: ISO 22441 VALIDATION:
MICROBIOLOGICAL PQ = 1 + 2 + 3 + 4 + 5 + 6

1. FOR EACH CYCLE
2. MOST CHALLENGING DEVICE WITH INOCULUM OR BI AT MOST DIFFICULT POSITION TO STERILIZE
   OR
   PCD (BI PCD) SHOWN TO BE EQUIVALENT
   NUMBER AND LOCATION ACCORDING TO MANUFACTURER GUIDANCE
3. IN PACKAGING
4. AT MOST CHALLENGING LOCATION IN MOST CHALLENGING LOAD
5. CYCLE PARAMETERS: AT LEAST P, T°C, T, VH_2O_2 (DIRECTLY OR INDIRECTY) WITHIN SPECIFIED TOLERANCE

Source:18 Courtesy of Philippe Destrez – R&D ASP: ISO 22441:2022 – Fig.6 Performance Qualification
Image: 5, Courtesy of Philippe Destrez – Advanced Sterilization Products – Research & Development

Complexity of minimally invasive heat sensitive medical device require thorough validation.

ALL H_2O_2 CYCLES ARE NOT EQUIVALENT.

04. The role of the healthcare facility

VALIDATION OF STERILIZATION PROCESSES ENSURE THAT ALL DOCUMENTATION AND CERTIFICATE WERE PROVIDED, THAT THE STERILIZER IS PROPERLY INSTALLED, OPERATIONAL, AND ABLE TO ACHIEVE CONDITIONS FOR STERILITY. ON SITE, PERFORMANCE QUALIFICATION (PQ) IS PERFORMED WITH WORST CASE LOAD AND BACTERIOLOGICAL INDICATORS. AS DETERMINATION OF AN H_2O_2 WORST CASE LOAD IS NOT EASY, CHALLENGE TEST PACK ARE MADE AVAILABLE. BI MIGHT BE REPLACED BY BI PCD THAT SIMULATE THE MOST COMPLEX DEVICES APPROVED FOR REPROCESSING.
FOR ROUTINE CONTROL AND MONITORING FAST READOUT BIS OR BI PCD SUPPORT PROCESS PARAMETER CONTROLS.[6,7]

BI-PCD CONFIRM WITHIN MINUTES THAT CONDITIONS FOR STERILITY ARE MET AT THE HEART OF THE MOST COMPLEX DEVICES.

Performance qualification is performed with worst case load and preferably BI PCDs.

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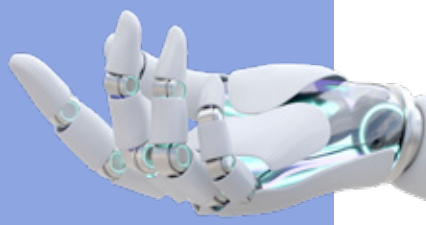
DR. PHILIPPE DESTREZ:

1. New ISO 22441 international standards materializes the success of H_2O_2 LTS;
2. Sterilization Process standards is applicable to sterilizer Manufacturers but also to Medical Device Manufacturers and healthcare facilities;
3. Partnership between sterilizer manufacturers and manufacturers of medical devices is key to overcome the growing material and geometrical complexity of modern heat sensitive devices;
4. Validation and control routine and monitoring can be performed with fast readout BI PCD that confirm withing minutes that conditions for sterility are met at the heart of the most complex medical devices.

Take home messages



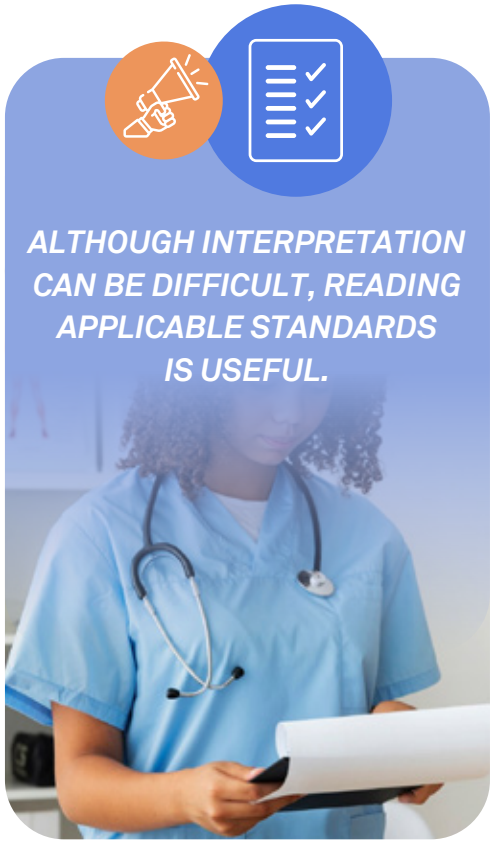
MR. WOUTER MEERT:

01. ISO 22441: the first standard dedicated to H_2O_2 sterilization

AN **ISO 13485** CERTIFIED CSSD IS OBLIGATED TO SHOW THE AUDITOR THEY HAVE A SYSTEM TO VERIFY IF NEW STANDARDS ARE AVAILABLE AND HOW THEY MAY IMPACT CURRENT PROCESS FLOWS.[8]

HAVING A MEMBERSHIP OF A STANDARDS ORGANIZATION IS ONE METHOD OF RECEIVING UPDATES AND COPIES OF STANDARDS. PROFESSIONAL ORGANIZATIONS, SUCH AS THE WFHSS OR NATIONAL SOCIETIES AND STERILIZER MANUFACTURERS, ARE USEFUL FOR UNDERSTANDING THEIR PRACTICAL IMPLICATIONS.

> **Professional organizations, such as WFHSS or the national societies and sterilizer manufacturers, are helpful to understand practical implications of standards.**



ALTHOUGH INTERPRETATION CAN BE DIFFICULT, READING APPLICABLE STANDARDS IS USEFUL.

IMAGE SOURCE: https://www.freepik.com/free-photo/female-doctor-taking-notes-clipboard_12892240.htm#fromView=search&page=5&position=33&uuid=d9a7f05e-37a6-4eb8-93d0-c61c66237aec

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COMPLIANCE TO ISO 22441 PROCESS STANDARD

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Sterilizer, BI and CI, packaging manufacturers

FOR COMPLIANCE TO APPLICABLE PARAGRAPHS OF ISO 22441 AND/OR OTHER STANDARDS

+

Medical device manufacturer

IN PARTNERSHIP WITH STERILIZER MANUFACTURER FOR STERILITY AND COMPATIBILITY EVALUATION OF MEDICAL DEVICES

+

Healthcare facility

FOR THE DEFINITION OF LOAD ACCORDING TO IFUS, SUPERVISION OF VALIDATION, ROUTINE CONTROL, LOAD RELEASE AND MAINTENANCE OF PROCESS EFFECTIVENESS

&

Applicable guidelines and regulation

FOR EXAMPLE FOR USE OF BI , BI PCD OR CI

Source: 1. courtesy of Philippe Destrez, Scientific Director ASP, Strasbourg - France

02. ISO 22441: Load Release

CONDITIONS FOR RELEASE OF LOADS REPROCESSED IN A H_2O_2 LOW TEMPERATURE STERILIZER WERE ALREADY DESCRIBED BY **ISO 14937**.[9] **ISO 22441** SPECIFIES THE VARIABLES THAT MUST BE MEASURED: PRESSURE, TEMPERATURE, TIME AND VAPORIZED H_2O_2 CONCENTRATION. LIKE FOR ALL CHEMICAL STERILIZATION PROCESSES, THE LATTER IS KEY. CYCLES PARAMETERS RANGES (I.E. VARIABLES VALUES RANGE) ARE DEFINED BY THE STERILIZER MANUFACTURER. **ISO 22441** REMINDS THAT BIOLOGICAL INDICATORS (BI) AND CHEMICAL INDICATORS (CI) MUST COMPLY WITH APPLICABLE STANDARDS BUT MODALITIES OF USES CYCLE ARE DEFINED BY USERS, GUIDELINES OR REGULATORS.[10-12]

STERILIZER MANUFACTURER SPECIFY CYCLE PARAMETERS NEED TO BE USED TO RELEASE YOUR LOADS.

> **ISO 22441 specifies variables to be measured: pressure, temperature, time and H_2O_2 concentration.**

03. ISO 22441: Process Validation

VALIDATION IS KEY TO ENSURE THE STABILITY OF THE STERILIZATION PROCESS. **ISO 22441**[1] REQUIREMENTS ARE CLOSE TO ISO 14937.[9] REQUALIFICATION IS COMMONLY REPEATED ANNUALLY AND AFTER MAJOR REPAIRS AND/OR RELOCATION. PERFORMANCE QUALIFICATION IS PERFORMED WITH THE WORST-CASE LOAD AND DEVICE OR MORE PRACTICALLY WITH A CHALLENGE TEST PACK AND A REPRESENTATIVE PROCESS CHALLENGE DEVICE (PCD).[7]

ISO 22441 validation requirements are based on ISO 14937 principles not changing a lot in the way how to perform the validation.

PERFORMANCE QUALIFICATION IS PERFORMED WITH THE WORST-CASE LOAD AND DEVICE OR MORE PRACTICALLY WITH A CHALLENGE TEST PACK AND A REPRESENTATIVE PROCESS CHALLENGE DEVICE (PCD).

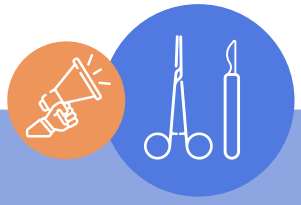
04. Medical Device (MD) compatibility and purchase of a new hydrogen peroxide (H_2O_2) sterilizer

THE NEW MDR 745-2017, APPLICABLE FROM MAY 2021, SIGNIFICANTLY CHANGED THE MEDICAL DEVICE LANDSCAPE. PRESSURE ON MEDICAL DEVICES MANUFACTURES (TO DEFINED AND VALIDATE REPROCESSING INSTRUCTIONS WAS INCREASED.[13]

WITH THE NEW **ISO 22441** STANDARD VALIDATING AN INSTRUMENT FOR HYDROGEN PEROXIDE BECOMES MORE CLEAR. ISO 22441 CLARIFIES WHAT IS EXPECTED FROM MDM.[9]

AS A FOOTNOTE, WHAT IF I WANT TO BUY A NEW HYDROGEN PEROXIDE STERILIZER?

AT THE MOMENT, THE STANDARD SPECIFYING MINIMUM FEATURES AND LEVEL OF PERFORMANCES TO BE PROVIDED BY H_2O_2 STERILIZERS (PREN 17180) IS STILL IN DEVELOPMENT **ISO 22441** HOWEVER CONTAINS KEY REQUIREMENTS AND CAN BE USED, AS WELL THE **ISO 14937**, FOR TENDERS SPECIFICATIONS.[6,9,13,14]



USE BOTH ISO 22441 AND ISO 14937 IS YOUR FUTURE TENDERS UNTIL THE EN 17180 IS PUBLISHED.

With the new ISO 22441 validating an instrument for hydrogen peroxide becomes more clear. ISO 22441 clarifies what is expected from MDM.

ISO 22441: INSTRUMENT COMPATIBILITY
BUYING A NEW HYDROGEN PEROXIDE STERILIZER

- MDR 2017-745
- IFU's
- General process validation instead of sterilizer specific

Source:20. Courtesy of Philippe Destrez – R&D ASP – ISO 22441 – Annex E.4

MR. WOUTER MEERT

Take home messages

1. Find for yourself the way to understand the content and impact of the new ISO 22441 norm on your CSSD
2. Use the new variables pressure, time, temperature and H_2O_2 concentration together if necessary with BI our CI to define your load releases
3. Defining a well thought out worst case for your hydrogen peroxide cycle validations builds in more safety in the process.
4. ISO 22441 will help you to safely connect new medical devices with your hydrogen peroxide sterilization process

References:

1. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html) 2. prEN 17180 Sterilizers for medical purposes - Low temperature vaporized hydrogen peroxide sterilizers - Requirements and testing (https://standardsdevelopment.bsigroup.com/projects/2017-02491#/section) 3. ISO/CD 11138-6 - Sterilization of health care products — Biological indicators, Part 6: Biological indicators for hydrogen peroxide sterilization processes (https://www.iso.org/standard/88921.html) 4. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Introduction, pag. vi, vii 5. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Paragraph: 4. Quality Management System, pag. 10-11; 6. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Paragraph: 8. Process definition, pag. 16-17; 7. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Paragraph: 9. Process validation, pag. 17-21 8. ISO 13485:2016 - Medical devices — Quality management systems — Requirements for regulatory purposes (https://www.iso.org/standard/59752.html) 9. ISO 14937:2009 - Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/59752.html) 10. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Paragraph: 6. Process & equipment characterization , pag. 13-15; 11. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Paragraph: 10. Routine control, pag. 21-22; 11. Load release, pag. 22 12. ISO 22441:2022 ISO 22441:2022 - Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (https://www.iso.org/standard/73214.html), Paragraph: 11. Load release, pag. 22 13. 2017/745 - EN - Medical Device Regulation - EUR-Lex (https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745) 14. prEN 17180 Sterilizers for medical purposes - Low temperature vaporized hydrogen peroxide sterilizers - Requirements and testing (https://standardsdevelopment.bsigroup.com/projects/2017-02491#/section)

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