3M℠ Health Care Academy

Driving to Zero: The Rationale for Every Load Monitoring Across Sterilization Modalities

Sarah Sholes Antonelli

MED-MedEd-CA-XXXX-2300055

Disclosure

- Name
- Title
- 3M Employee

Disclaimer

Important Information:

The content of this webinar is based on current United States information including regulations, standards, guidelines, and practices as of September 7, 2023.

Requirements in other countries may be different and US guidance may change in the future.

Always consult product *Instructions For Use* and follow local laws and regulations.

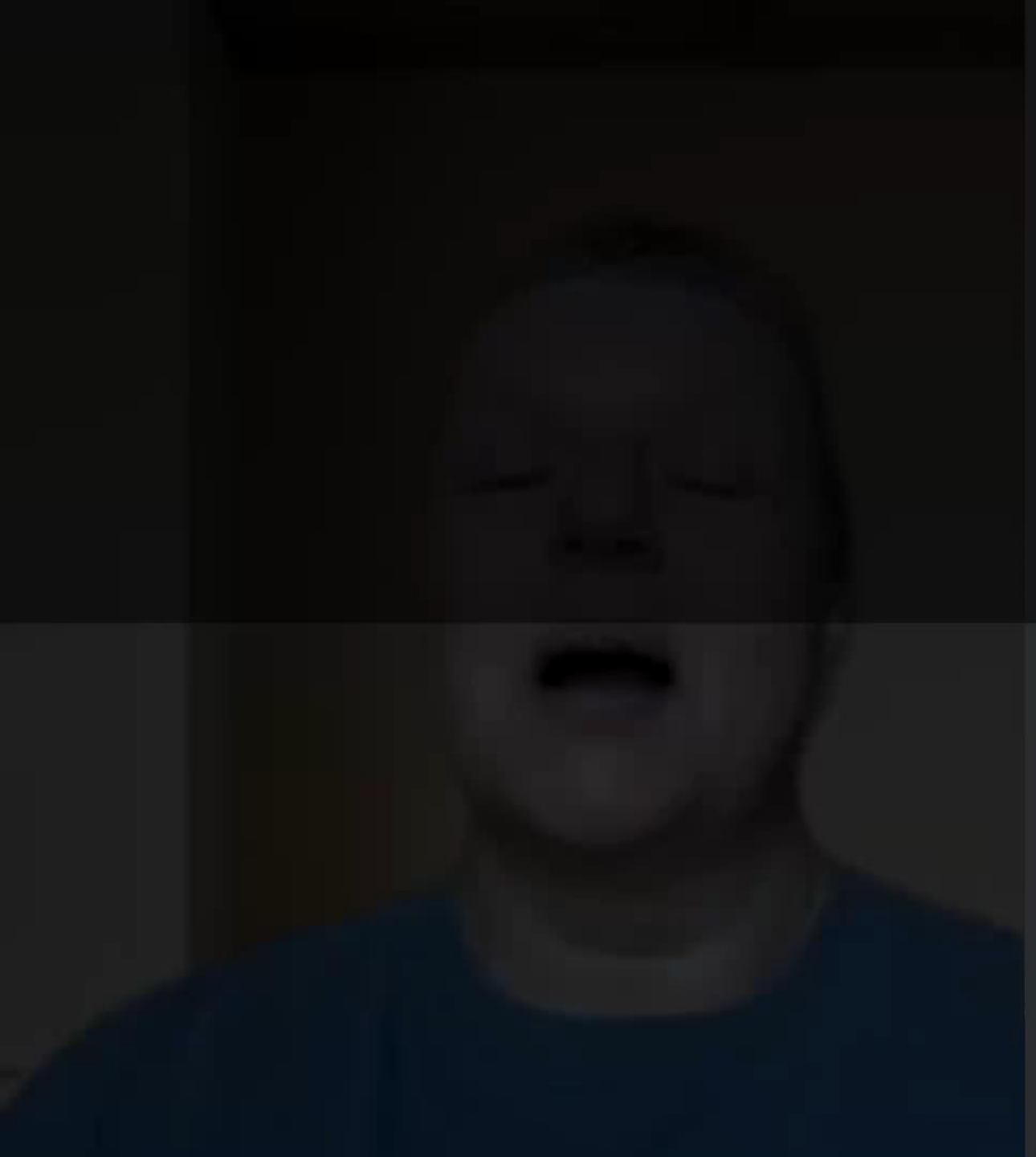
This presentation contains an overview of general information and should not be relied upon, in isolation, to make specific decisions.

Learning Objectives

1. Review the key risks of surgical infections
2. Differentiate the two primary modalities of sterilization: Steam and vaporized hydrogen peroxide (VH202)
3. Cite the relevant AORN, ANSI/AAMI, and CSA guidelines pertaining to quality assurance monitoring across modalities
4. Describe the technology behind the “king” of monitoring tools: The Biological Indicator (BI)
5. Explain the rationale for every load monitoring (ELM)

What is the current ELM practice at your facility?

- No ELM
- ELM steam only
- ELM VH2O2 only
- ELM steam and VH2O2



Risks of Surgical and Hospital Acquired Infections

What's In the Numbers?

Airline Industry Stats

- ≈1.1 billion passengers/year
- 1,139 crashes/year
- 349 deaths/year
- 1 in 1.2 million chance of being in a crash/year
- 1 in 11 million chance of dying in a crash/year

Fact check: is flying safe? | The Week UK

Klevens et al; Stanford Medicine Healthcare

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- 1 in 50 chance of getting SSI/year
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- $3.3 billion/year

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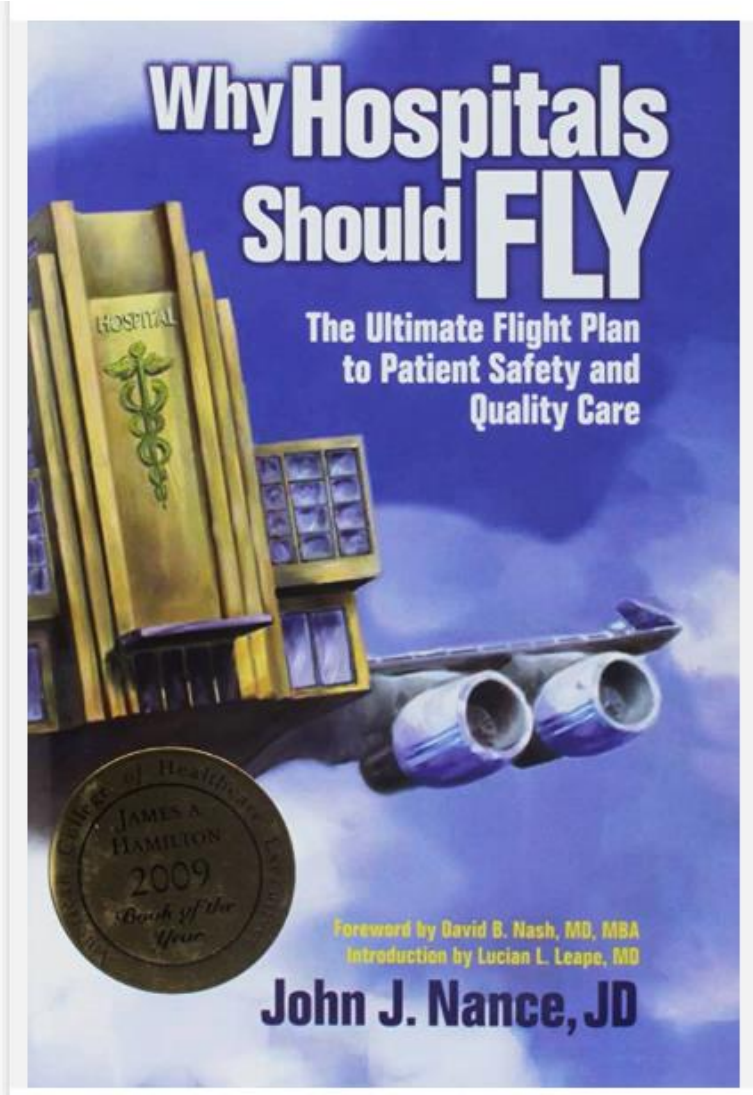
DRIVING TO ZERO!



John Nance book applies safety lessons learned in the airline industry to the healthcare industry

Steam vs. VH2O2 Sterilization

What is the Goal of Sterilization?

ISO 11139:2018 Sterilization of health care products — *Vocabulary of terms used in sterilization and related equipment and process standards*

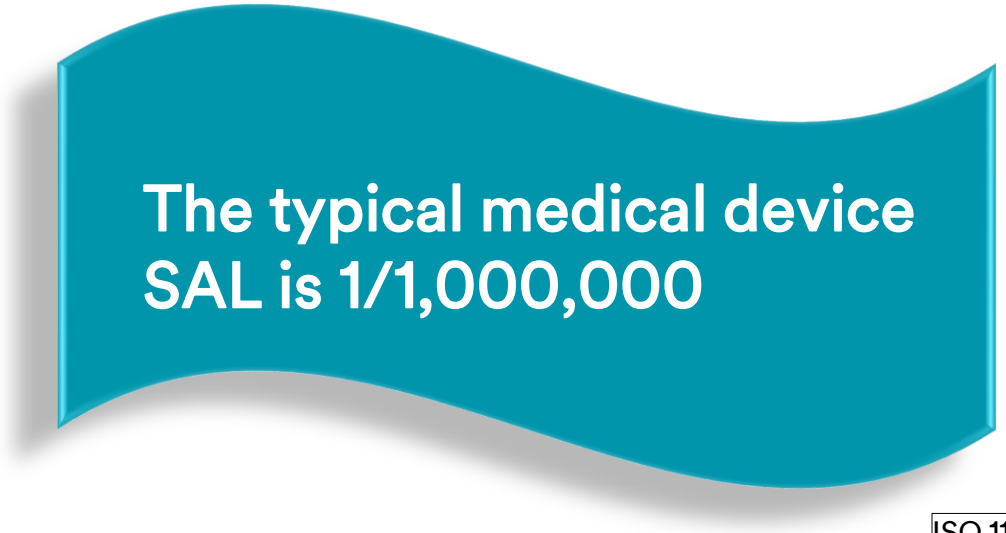
Sterilization: Validated process used to render product free from viable microorganisms

Steam sterilization goal = VH202 sterilization goal

Defining the Goal of Sterilization . . .

Sterility Assurance Level (SAL)

"probability of a single viable microorganism occurring on an item after sterilization"



ISO 11139: *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*. 2018.

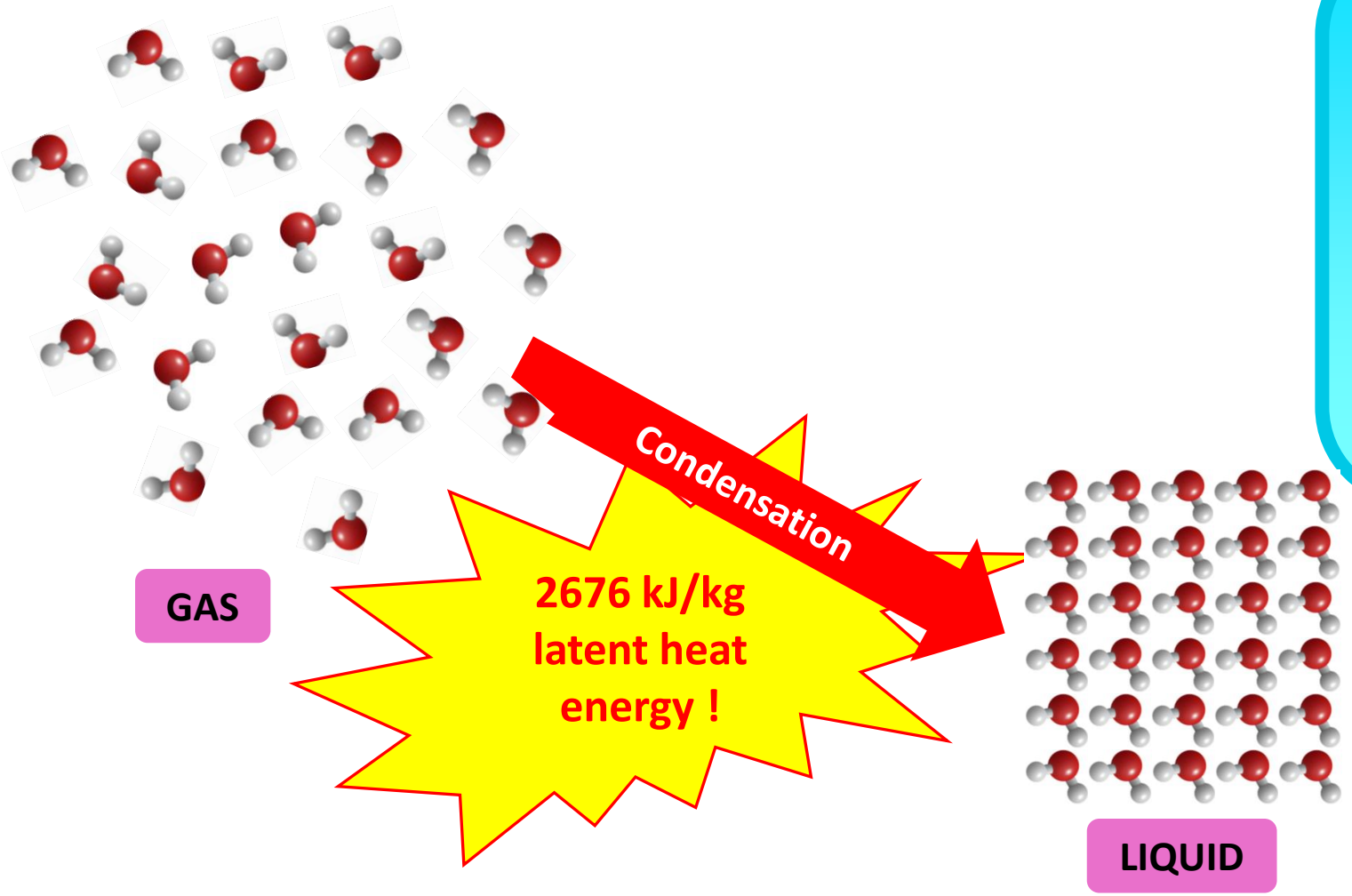
Steam Sterilization

Approximately 85% of medical device sterilization in healthcare facilities is achieved with saturated steam under pressure

- Fast
- Highly effective
- Reliable
- Relatively low cost
- Easy to use
- Readily available
- Technology well understood
- No toxicity or hazardous residues

CDC Guideline for Sterilization and Disinfection in Healthcare Facilities (2008) Steam Sterilization | Disinfection & Sterilization Guidelines | Guidelines Library | Infection Control | CDC; Common industry knowledge

Steam Sterilization Kills with Latent Heat



Steam condensation on surfaces releases latent heat (energy) that damages and destroys large biochemical molecules required for life

PHYSICAL POUNDING!

McDonnell, Gerald. *Block's Disinfection, Sterilization, and Preservation*. Available from: Wolters Kluwer, (6th Edition). Wolters Kluwer Health, 2020

Vaporized Hydrogen Peroxide Sterilization (VH2O2)

Advantages

- High efficacy
- Rapid activity
- Cost effectiveness
- Monitoring capability

Limitations

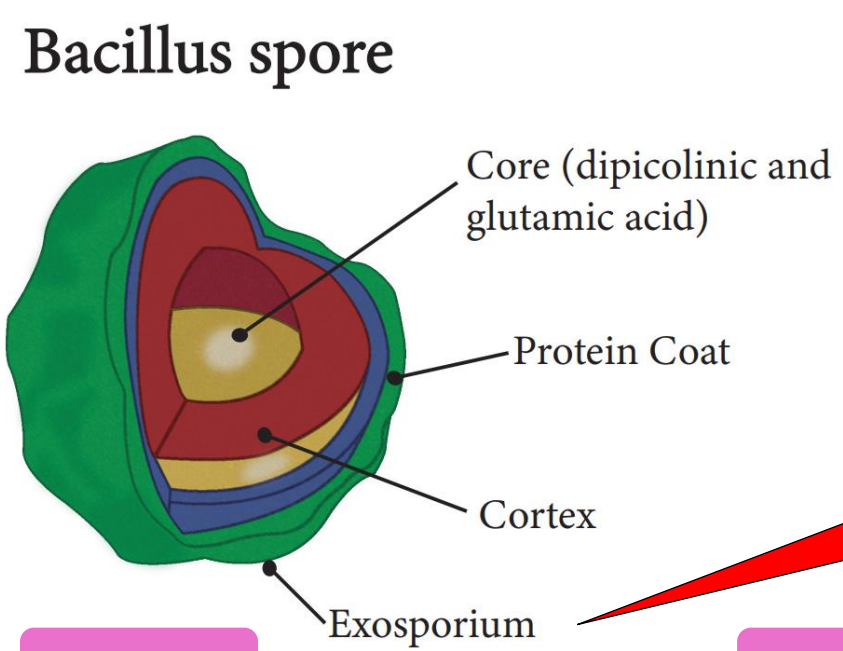
- Technique Sensitive
- Materials compatibility
- Adaptability
- Penetrability
- Organic material resistance
- Toxic

Schneider, M.S. New Technologies for Disinfection and Sterilization. Published in Disinfection, Sterilization and Antisepsis from: Principles, Practices, Challenges, and New Research, edited by William Rutala. Published by the Association for Professionals in Infection Control and Epidemiology, Inc, Washington, DC, 2003. www.apic.org

Hydrogen Peroxide Kills by Oxidation

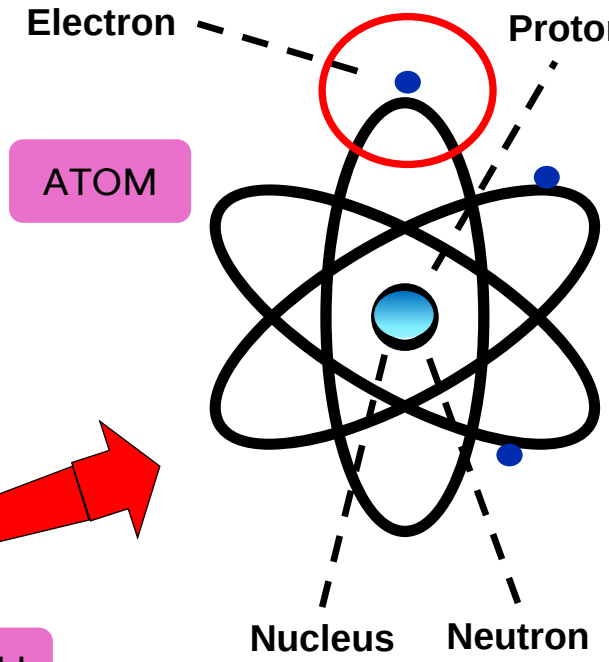
Oxidation occurs when an atom <u>LOSES</u> electrons

The atom is the basic building block for molecules

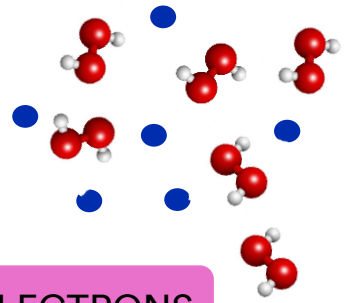


BACTERIA

CELL WALL



ATOM



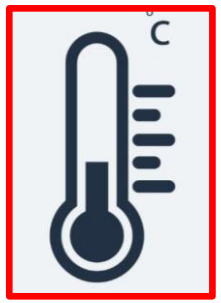
ELECTRONS

CHEMICALLY RIPPED APART!

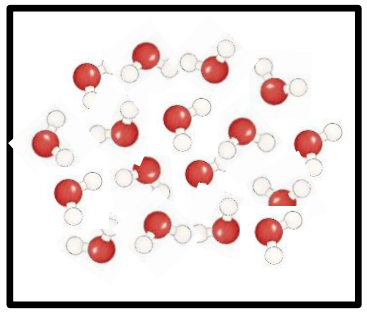
[What Is Oxidation? Definition and Example (thoughtco.com)]

Process Variables (Critical Variables)

Steam Sterilization

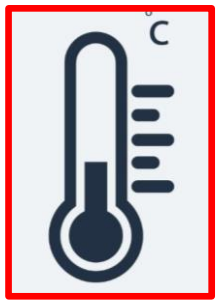


Temperature

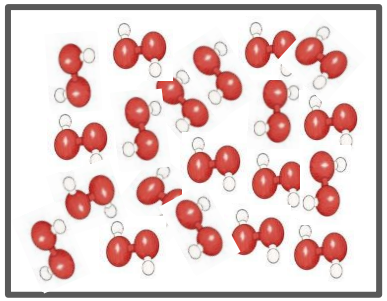


Steam

VH2O2 Sterilization



Temperature



Hydrogen Peroxide Concentration

Time

...changes alter effectiveness...

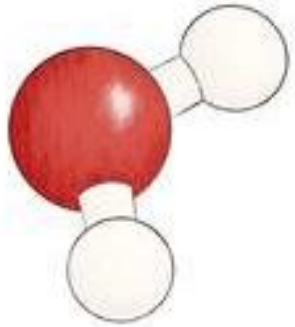
Time

ISO 11140-1:2014 *Sterilization of healthcare products – Chemical indicators – Part 1: general requirements*
ISO 11139:2018, *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*

Steam vs. VH2O2 Sterilization Differences

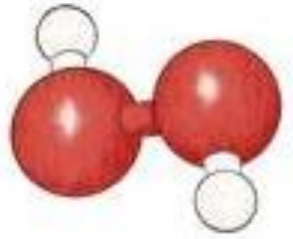
Steam Sterilization:

- Sterilant used during conditioning phase
- Sterilant (steam) make-ups during exposure phase
- More robust than VH2O2



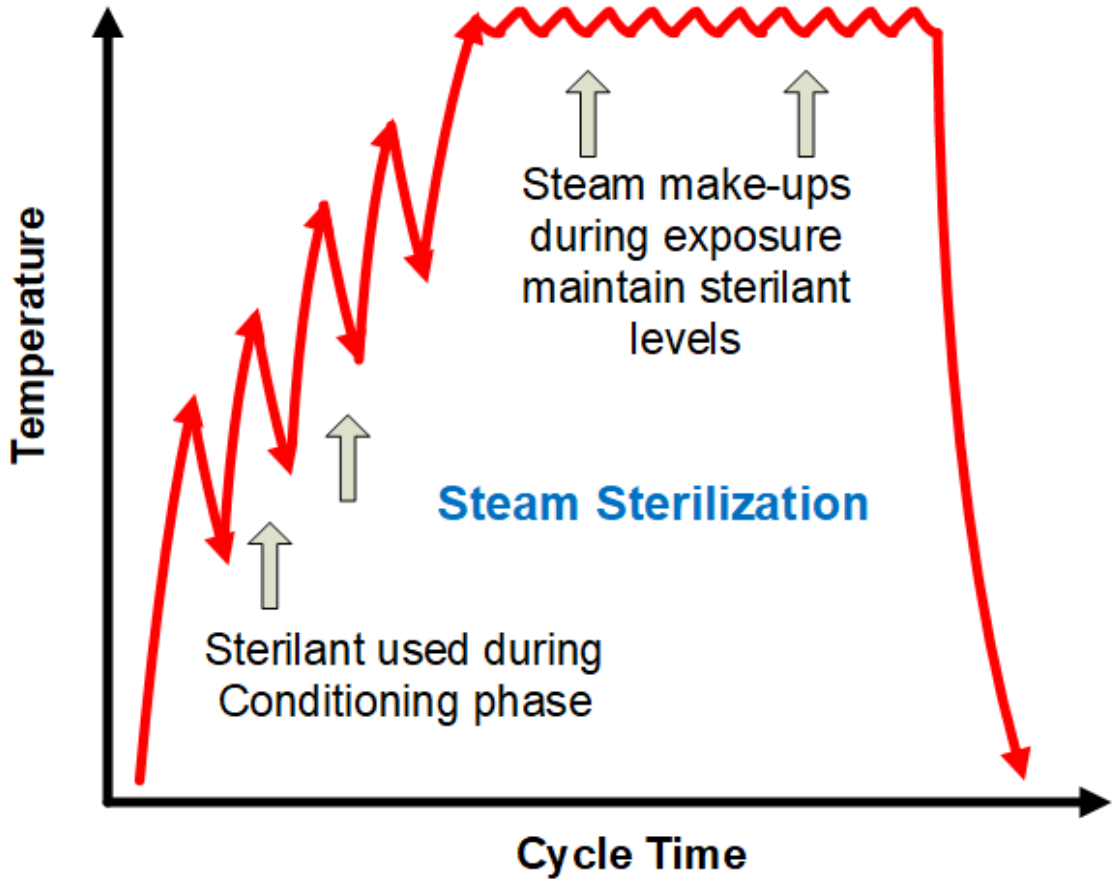
VH2O2 Sterilization:

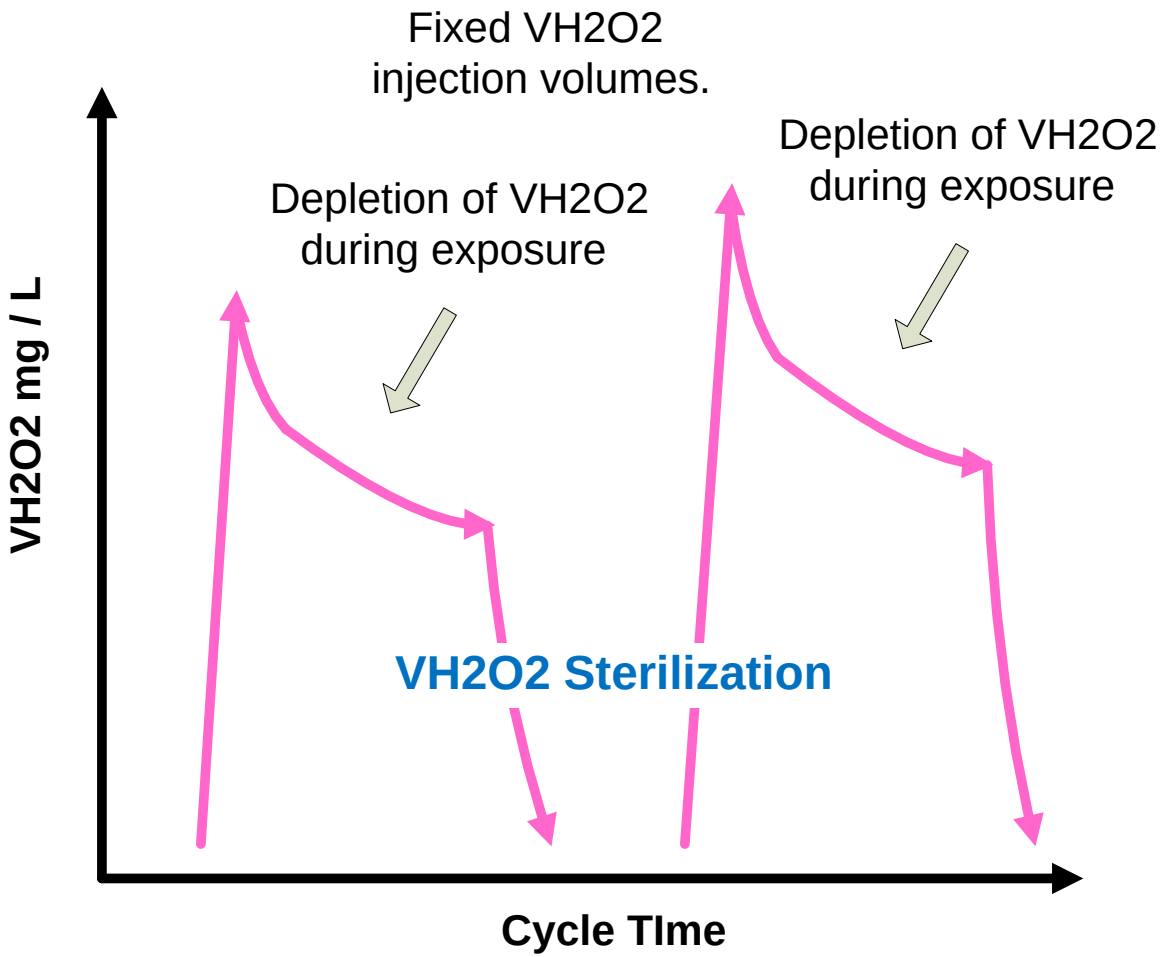
- Sterilant not used in conditioning phase
- Fixed amount of sterilant (VH2O2) during exposure phase (no sterilant make-ups)
- VH2O2 is naturally an unstable molecule (depletes readily during exposure)
- Method is technique sensitive



Reference #s from reference slides: 4, 6, 11-12, 18, 21-22

Graphic Representation of Sterilant During Cycle

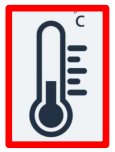
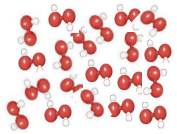




See References 1, 4, 6, 11-12, and 18

VH2O2 is considered a relatively unstable molecule

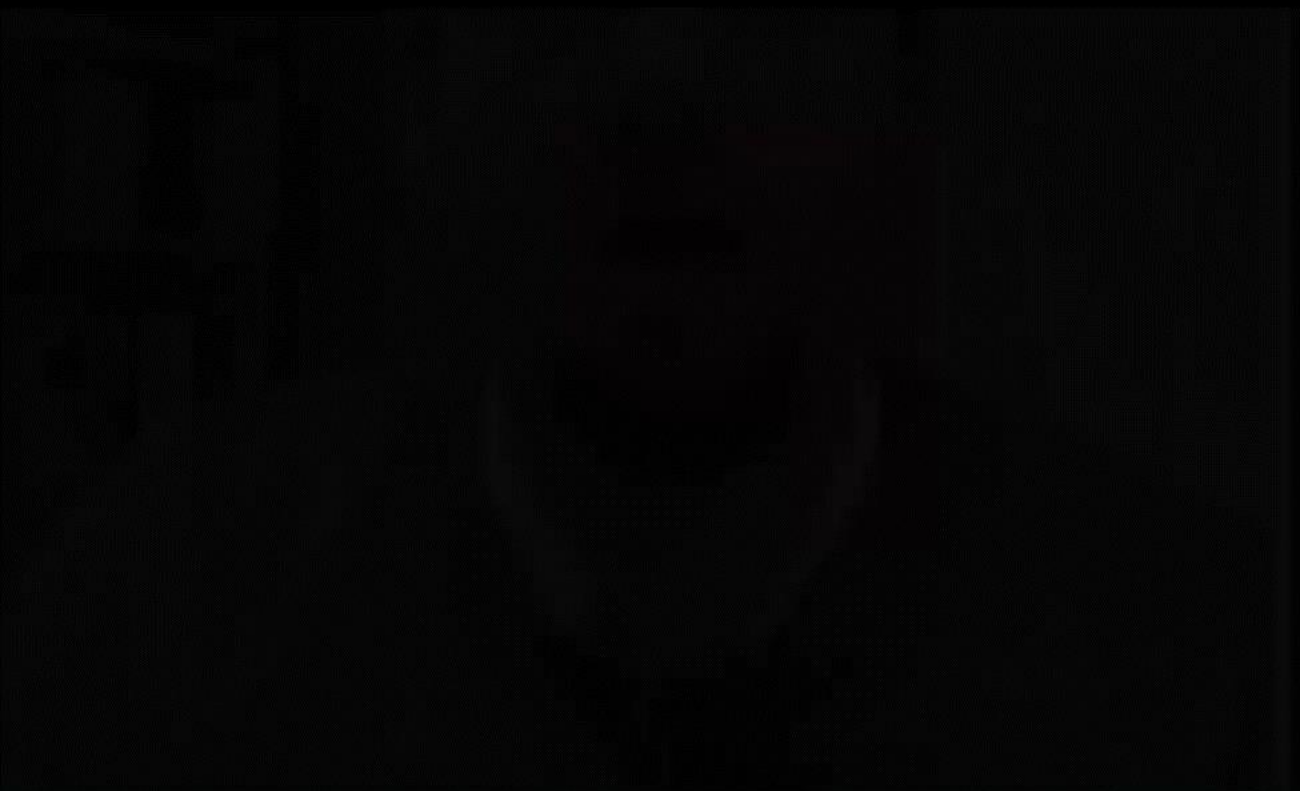
Steam vs VH2O2 Summary

Variables	Steam*	VH2O2**
 Process Temperature	designed for inside pack temp close to sterilizer printout	lower inside pack
 Sterilant	designed for sterilant inside pack close to sterilizer printout	lower inside pack
 Exposure Time	designed for consistent exposure temperature and sterilant with addition of steam in conditioning	conditions vary during exposure time
 Packaging Type	less impact	more impact

VH2O2 sterilization processes:

- Are technique sensitive; the user can have a significant impact on the outcome of the process
- Quality monitoring tools; physical, chemical, and biological may fail independently in the same cycle
- Understanding the role of each quality tool is critical

*common industry knowledge
**Reference: Slide 19

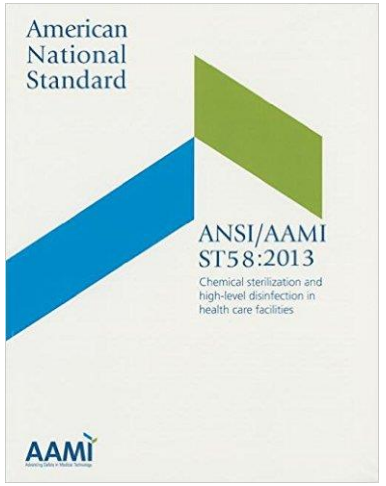


Guidelines Addressing Quality Assurance Monitoring

Standards and Guidelines for Monitoring Steam & Vaporized Hydrogen Peroxide

Reference Documents

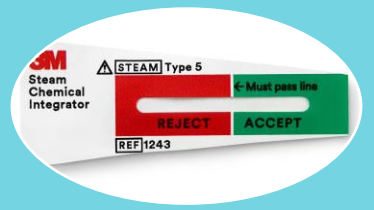
- ANSI/AAMI ST58:2013 – "*Chemical sterilization and high-level disinfection in health care facilities*"
- ANSI/AAMI ST79:2017 – "*Comprehensive guide to steam sterilization and sterility assurance in health care facilities*"
- AORN – "*Guidelines for Perioperative Practice: Sterilization*" 2023 Edition
- CSA Z314:23 "*Canadian medical device reprocessing in all health care settings*"



Images used with permission from ANSI/AAMI

Sterilization Process Monitoring Tools

Physical Monitors



Chemical Indicators

Biological Indicators

Physical Monitors

Physical monitor checked for every cycle to verify correct cycle was selected and cycle parameters were met

“Sterilizers that do not have recording devices should not be used, with the exception of sterilizers used together with accessory recording devices or printouts.”

ANSI/AAMI ST79:2017, Section 13.5.1

Chemical Indicators for Sterilization Monitoring

Devices used to monitor the presence or attainment of one or more of the parameters required for a satisfactory sterilization process, or used in specific tests of sterilization equipment

Primary Applications

1. Exposure Indicators (outside every pack)
2. Internal Chemical Indicators (inside every pack)
3. Sterilizer Test Indicators

ANSI/AAMI/ISO 11140-1:2014
ANSI/AAMI ST79:2017 Section 13.5.2
ANSI/AAMI ST58:2013 (R2018) Section 9.5.3

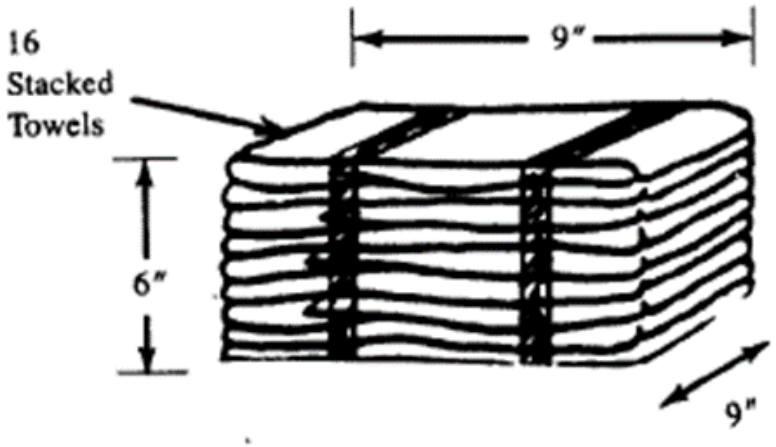
Biological Indicators for Sterilization Monitoring

- Test systems containing viable microorganisms providing a specified resistance to a specified sterilization process
- The only monitoring tool that directly measures the **lethality/killing power** of the sterilization process

ISO 11139:2018, 3.29

Process Challenge Devices (PCDs)

A PCD is a device used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult-to-sterilize item routinely processed.



ANSI/AAMI ST79:2017 *Section 13.5.3.1 and ANSI/AAMI ST58:2013 Section 9.5.4.1;*
Image used with permission from AAMI

Process Challenge Devices (PCDs)

Steam ✓

ANSI/AAMI ST79:2017
Example… BI test pack 16 towel pack

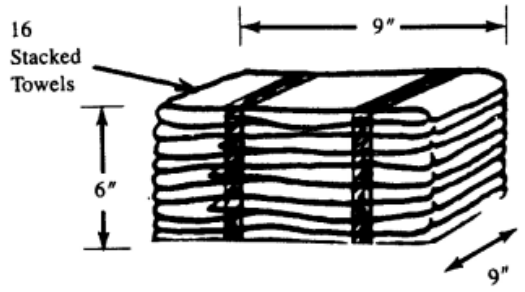


Figure 8—Preparation of the 16 towel PCD (BI challenge test pack)

VH2O2

ANSI/AAMI ST58:2013
No example

At this time, there are no guidelines on how health care personnel can create a universal BI PCD for VH2O2 sterilization processes.

Images used with permission from ANSI/AAMI

Process Challenge Devices (PCDs)

Steam

Common commercially available BI PCD example

VH2O2

Commonly used BI quality monitoring methods per IFU

BIs in pouch or bare BI

U.S. FDA clearance required for process challenge device or test pack.

U.S. FDA 510(k)'s Summary under the "design type" should include *test pack configuration* or *process challenge device* and should be in Indications for Use in IFU.

Routine Efficacy Monitoring with a BI PCD

Frequency of Monitoring with a BI PCD: Weekly, preferably daily

Sterilizers larger than 2 cubic feet

- AAMI 16 towel pack or commercially available disposable, FDA cleared BI PCD
- Commercially PCDs recommended for dynamic-air removal
- Full load on bottom shelf over drain
- Each cycle type should be tested
- Each load containing an implant

ANSI/AAMI ST79:2017, Sections 13.7,1, 13.7.2

VH2O2 Sterilizer Monitoring Recommended Biological Indicator (BI) Usage

- ***9.5.4.1 General considerations***

  "…Biological indicators are intended to demonstrate whether the conditions were adequate to achieve sterilization."

- ***9.5.4.3 Frequency of use…***
  - *"A PCD with the appropriate BI should also be used at* ***least daily, but preferably in every sterilization cycle*** *(see 9.5.4.5)"*
  - *Each load containing implantable.."*

ANSI/AAMI ST58:2013 (R2018), Section 9.5.4.3

Routine BI Sterilizer Efficacy Monitoring: Steam and VH2O2 Sterilizers

Modality	ANSI/AAMI	AORN	CSA
Steam Sterilizers	PCD with BI weekly, preferably daily and with every implant load	PCD with BI weekly, preferably daily and with every implant load	PCD with BI at least daily and with every implant load
Vaporized Hydrogen Peroxide	PCD with BI daily but preferably every cycle	PCD with BI used at least each day the sterilized is used, but preferably in every sterilization cycle	PCD with BI at least daily and with every implant load

ANSI/AAMI/ST79:2017, ANSI/AAMI/ST58:2013, AORN Sterilization– 2022, CSA Z314:23,

Sterilization Failure Recall

"If the cause of the failure is not immediately identified, then load should be quarantined, all loads back to the last negative BI should be recalled. Items in these loads should be retrieved, if possible and reprocessed (see 13.7.5.2) The sterilizer in question should be taken out of service until the cause of the failure is identified and corrected."

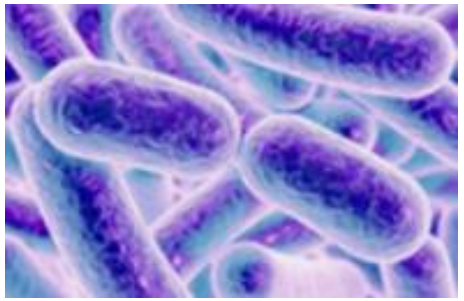
ANSI/AAMI ST 79:2017, Section 13.7.5

“Monitoring each sterilization load with a biological monitor increases patient safety which should be the at the top of everyone’s list.”

Lana L. Haecherl CBSPDT, CRCST
Director Surgical Support
Regional SPD Education & Development

Biological Indicator Technology and Standards

Key BI Performance Parameters



Population (number of test organisms)

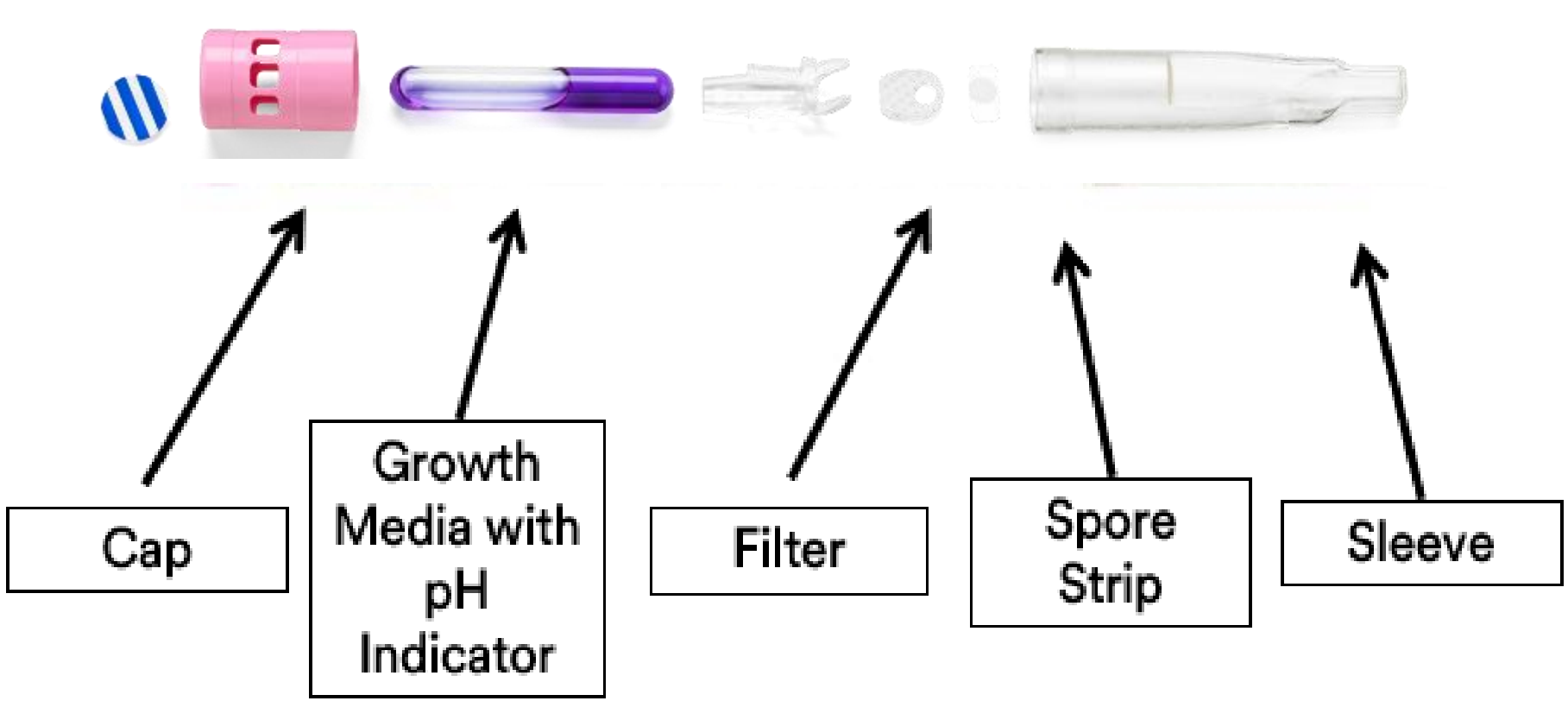
- Number of organisms that must be killed to get a negative BI
- The more organisms, the longer it takes to inactive the BI
- Measured by distributing the spores on plates and counting
- Expressed in exponents (e.g., 10^6 = 1,000,000)

D-value (resistance)

- A measure of how resistant the organisms are to the process (how hard to kill)
- Measured as the time to reduce the population by 90%
- Expressed in time units (usually minutes)

ISO 11138-1:2017, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

Self-Contained Biological Indicators



Biological Indicator Incubation

Process for providing the spores in the biological indicator with the perfect conditions to support the growth of the organisms

- Nutrients (food)
- Optimal temperature
- Optimal pH

The incubation conditions are designed to be able to recover a very small number of organisms that remain alive in the biological indicator after exposure to the sterilization process, if there is a sterilization process failure.

Brock, T.D., & Madigan M. T. (1991) *Biology Of Microorganisms* (6th Ed). Englewood Cliffs, New Jersey: Prentice Hall

Biological Indicator Incubation Time

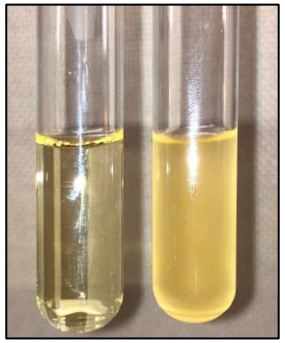
Biological indicator incubation time is the time required to make a final determination that the BI is negative

If the biological indicator turns positive at any point, the test is complete and appropriate action must be taken.

"An incubation period is commonly recognized to be 7 days for established sterilization processes . . ."

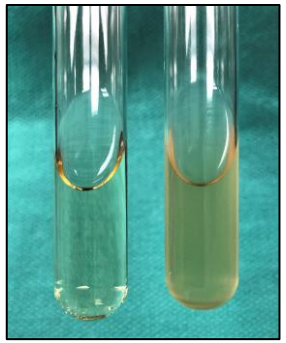
ISO 11138-8:2021, *Sterilization of health care products — Biological indicators — Part 8: Method for validation of a reduced incubation time for a biological indicator*

Positive Biological Indicator “Signals”



Turbidity

Bacterial cells scatter light



Media Color Change

pH shift caused by metabolic by-products

Fluorescence

Fluorescent response generated by metabolic enzyme action

Brock, T.D., & Madigan M. T. (1991) *Biology Of Microorganisms* (6th Ed). Englewood Cliffs, New Jersey: Prentice Hall

Explain the Rationale for Every Load Monitoring (ELM)

Back to the Numbers

Healthcare Industry Stats

- ≈48 million surgeries/year
- 274,000 SSIs/year
- 8,200 SSI deaths/year
- 1 in 50 chance of getting SSI
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- $3.3 billion/year

Klevens et al; Stanford Medicine Healthcare

The Human Impact

Sterilization is Complex

- Healthcare environment is not static
- Aging infrastructure, sterilizers & instrumentation
- To err is HUMAN

Why Do Every Load Monitoring (ELM) ?

- Focus on Patient Safety
- Reduce Risks
- Raise Standards
- Manage Department Reputation
- Standardize Practice

Why Do ELM?

Patient Safety & Raising Standards

- World of the SPD department revolves around providing sterile equipment - which ensures patient safety
- Easier to ensure compliance with patient safety guidelines by going over and above basic guidelines
  - Guidelines state implants should be quarantined until a BI result is known
- When you monitor every load, you provide the same level of care to each, and every patient served by the facility

ANSI/AAMI ST79:2017, Table 3

Why Do ELM?

Manage the Reputation of the Hospital

- When a load is recalled, the impact is felt throughout the facility
- Recalls require staff time to notify parties, investigate, review records & recall loads back to the last negative BI, re-process instruments & write reports
- Every load monitoring means **only one** load is involved, minimizing the impact and protecting the reputation of the department and the facility

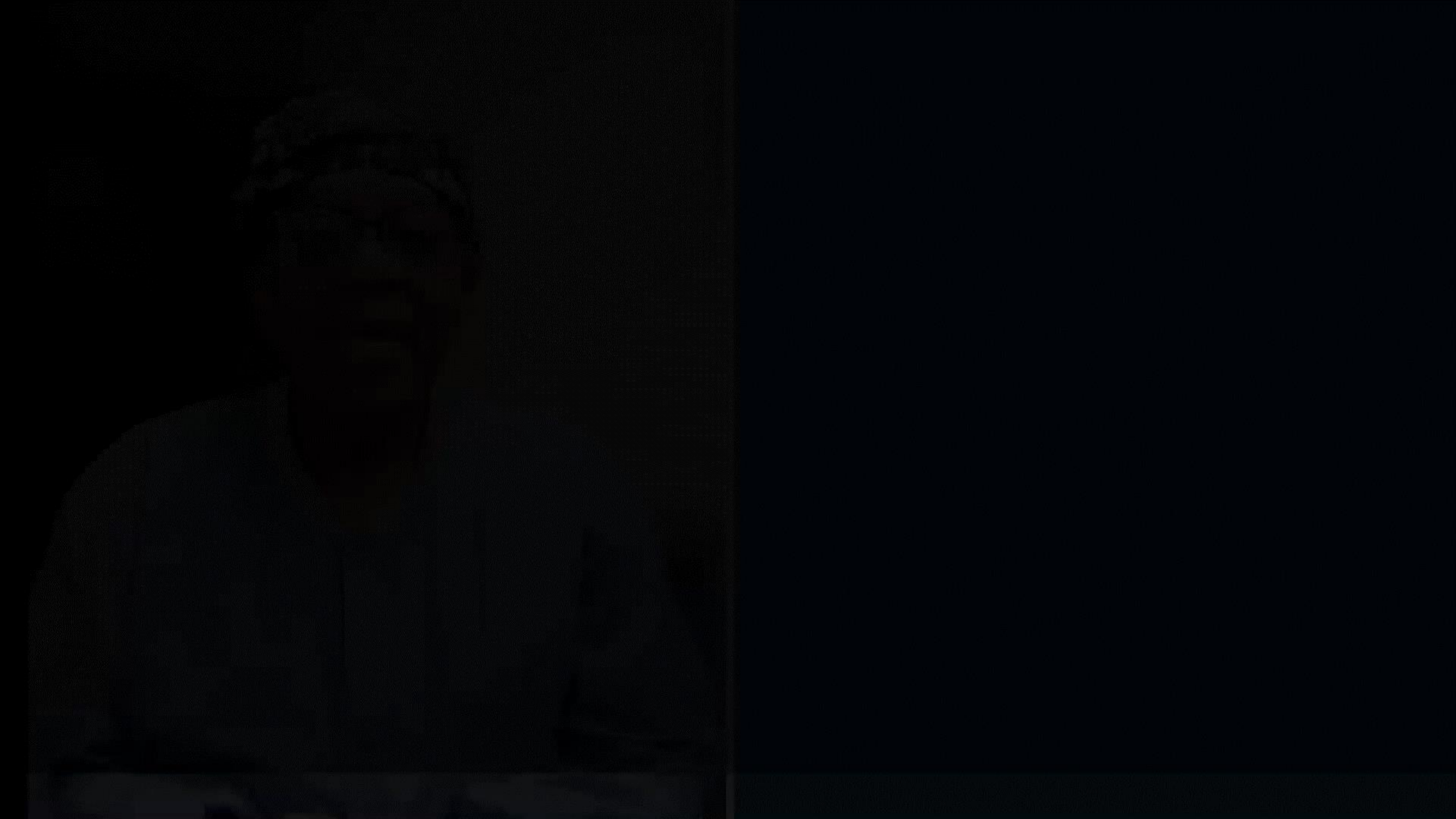
Why Do ELM?

Standardizes Training & Practice

- Allows the SPD Manager to streamline workflow, simplify training and reduce the opportunity for human error
  - Leads to consistent/standardized practice –follow the same process for every load
- Reduces the risk of failing to properly monitor an implant load
- Simplifies/shortens the training process in a department where turnover & staff shortages are a problem or travelers are often used

"It boils down to patient safety in every aspect of our sterilization process. ELM allows us to say the parameters were met and the BI test completes our monitoring of that process. ELM every load, every tray, every patient."

Sharon Greene-Golden, BA, CRCST, CER, FCS, SME
Manager OR Inventory & Sterile Processing
HSPA Past President



“You can raise the bar, or you can wait for others to raise the bar, but the bar is getting raised regardless.”

-Seth Godin

Used with permission by Seth Godin

References:

1. 3M Document EM-05-692858
2. Association for the Advancement of Medical Instrumentation. *Chemical sterilization and high-level disinfection in healthcare facilities.* ANSI/AAMI ST58:2013. Arlington, VA. 2013
3. Association for the Advancement of Medical Instrumentation. *Comprehensive guide to steam sterilization and sterility assurance in health care facilities.* ANSI/AAMI ST79:2017. Arlington, VA. 2017.
4. Association for the Advancement of Medical Instrumentation. *Compatibility of materials subject to sterilization.* ANSI/AAMI TIR17:2017,
5. Association of periOperative Registered Nurses. *Guidelines for Perioperative Practice* 2022 Edition. Denver, CO. © 2022 AORN Inc.- *Guideline for Sterilization*
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Thanks

Questions?