



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

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Disclosure

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Learning objectives

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

DRIVING TO ZERO!



2009 Book of the year Award by the American College of Healthcare Executives.

Healthcare can learn from aviation that safety shouldn't depend solely on the assumption that a process worked.

“Perfect safety...doesn't mean eliminating all mistakes. It means structuring a system that expects and safely deals with mistakes.”

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

<https://www.theweek.co.uk/97155/fact-check-is-flying-safe> [Accessed: March 27, 2023]

Healthcare Industry Stats

- ≈38 million surgeries/year
- 157,500 SSIs/year
- 8,200 SSI deaths/year
- 1 in 250 chance of getting SSI/year
- ≈1 in 5,000 chance of dying from SSI/year
- \$3.3 billion/year

Klevens et al; Bicket et al; Rezaei et al

Expertise and Experience Dose Not Eliminate Human Error



What is the goal of sterilization?

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

Steam sterilization goal = VH202 sterilization goal



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



Vaporized hydrogen peroxide sterilization (VH2O2)

Advantages

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



Limitations

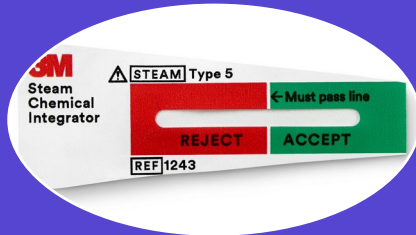
- Technique Sensitive
- Materials compatibility
- Adaptability
- Penetrability
- Organic material resistance
- Toxic

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

Sterilization process monitoring tools



Physical
Monitors



Chemical
Indicators



Biological
Indicators

Assurance of sterility

Monitoring tools do not indicate everything was successful, they indicate something went wrong. Stop, notify, and evaluate

Each monitoring tool provides a different role in assurance of sterility. Each monitoring tool is important part of the monitoring.

CYCLE START AT 7:46:32
ON 9/21/21

CYCLE COUNT 23582
OPERATOR
STERILIZER UAC 01
SERIAL # 0301708-01

STER TEMP = 273.0F
CONTROL TEMP = 275.0F
STER TIME = 5 MIN
DRY TIME = 45 MIN

TIME	T	F	Unit	Pa
7:46:54A	125.9	0.2F		
7:47:55A	223.4	10.7F		
7:49:15A	178.6	13.1U		
7:50:51A	265.2	26.0F		
7:52:56A	197.7	17.0A		
7:53:46A	265.6	26.1P		
7:55:34A	201.9	15.7U		
7:56:48A	265.1	26.0F		
7:58:38A	263.0	15.9U		
8:02:27A	273.8	31.2F		
8:03:27A	275.0	31.2F		
8:04:27A	274.7	31.7F		
8:05:27A	274.7	31.2F		
8:06:27A	274.6	31.2F		
8:07:27A	274.6	31.2F		
8:08:23A	221.2	3.6P		
8:53:24A	154.1	28.4U		
8:55:08A	142.7	2.8U		

LOAD 092183

TEMP MAX=275.7F
TEMP MIN=273.0F

CONDITION = 0:15:33
STERILIZE = 0:05:00
EXHAUST = 0:47:14
TOTAL CYCLE = 1:08:14

PRINTOUT CHECKED BY: *Shelley*

= READY TO USE =

* NOT READY 9150156A
READ OPEN



Types of sterilization monitoring tools:

- **Physical Monitors** = Evidence of sterilizer time and temperature performance
- **Chemical Indicators** = Evidence of exposure to specified process conditions.
- **Biological Indicators** = Strongest direct evidence of process lethality

CYCLE START AT 7:46:32
ON 9/21/21

CYCLE COUNT 23582
OPERATOR
STERILIZER VAC 01
SERIAL # 0301708-01

STER TEMP = 273.0F
CONTROL TEMP = 275.0F
STER TIME = 5 MIN
DRY TIME = 45 MIN

TIME	T = F	Unit	Pa
7:46:54A	125.9	0.2F	
7:47:55A	223.4	10.7F	
7:49:15A	178.6	13.1F	
7:50:51A	265.2	26.0F	
7:52:55A	197.7	17.0A	
7:53:46A	265.6	26.1F	
7:55:34A	201.9	13.7U	
7:56:48A	265.1	26.0F	
7:58:30A	203.0	13.9U	
8:02:27A	273.8	31.2F	
8:03:27A	275.0	31.2F	
8:04:27A	274.7	31.7F	
8:05:27A	274.7	31.5F	
8:06:27A	274.6	31.5F	
8:07:27A	274.6	31.5F	
8:08:23A	221.2	3.6F	
8:53:24A	154.1	28.4U	
8:55:08A	142.7	2.0U	

LOAD 092183

TEMP MAX=275.7F
TEMP MIN=273.0F

CONDITION = 0:15:33
STERILIZE = 0:05:00
EXHAUST = 0:47:14
TOTAL CYCLE = 1:08:14

PRINTOUT CHECKED BY:
Shelby

= READY TO USE =

* NOT READY 9:55:15A
READ OPEN



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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

CYCLE START AT 7:46:32A
ON 9/21/21

CYCLE COUNT 23582
OPERATOR
STERILIZER VAC 01
SERIAL # 0301708-01

STER TEMP = 273.0F
CONTROL TEMP = 275.0F
STER TIME = 5 MIN
DRY TIME = 45 MIN

	TIME	T= F	U=inhPa P=psia
C	7:46:54A	125.9	0.2P
C	7:47:55A	223.4	10.7P
C	7:49:15A	178.6	13.1U
C	7:50:51A	265.2	26.0P
C	7:52:36A	197.7	13.8U
C	7:53:46A	265.6	26.1P
C	7:55:34A	201.9	13.7U
C	7:56:40A	265.1	26.0P
C	7:58:30A	203.0	13.9U
S	8:02:27A	273.8	31.2P
S	8:03:27A	275.0	31.5P
S	8:04:27A	274.7	31.7P
S	8:05:27A	274.7	31.5P
S	8:06:27A	274.6	31.5P
E	8:07:27A	274.6	31.5P
E	8:08:23A	221.2	3.6P
E	8:53:24A	154.1	28.4U
Z	8:55:08A	142.7	2.0U

LOAD 092103

TEMP MAX=275.7F
TEMP MIN=273.0F

CONDITION = 0:15:33
STERILIZE = 0:05:00
EXHAUST = 0:47:41
TOTAL CYCLE = 1:08:14

PRINTOUT CHECKED BY:
Shelly

=====

= READY TO UNLOAD =

=====

* NOT READY 8:56:56A
DOOR OPEN

Special equipment tests – Type 2

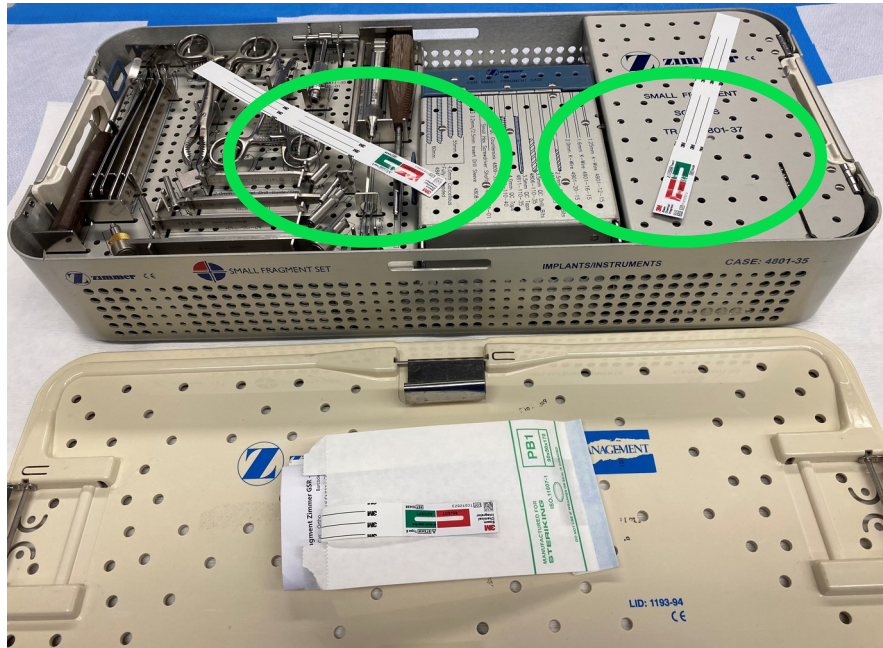
- Bowie-Dick Test:
 - Pre-vacuum Steam Sterilizers
- Daily test to ensure the vacuum system is working properly



Internal steam chemical indicators (CI)

Place a chemical indicator inside every package

- Can be Type 3, 4, 5, or 6 but **preferably** a Type 5 or Type 6 CI

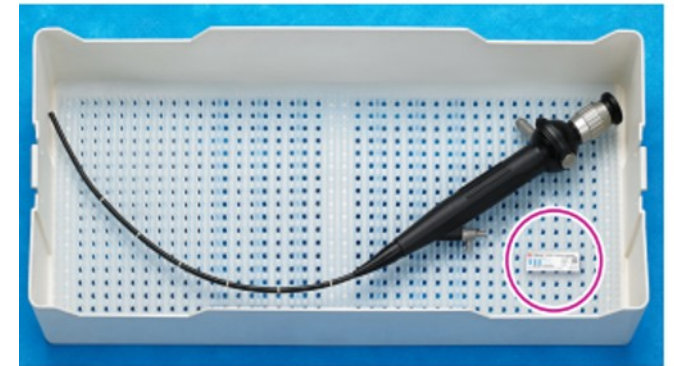


ANSI/AAMI ST79:2017/(R)2022; *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*. Section 13.5.2.2.2

VH2O2 internal chemical indicators (CI)

Internal CI placed inside every package, tray, containment device, cassette, instrument tray

- Using chemical indicators: "...the CI should be placed in that area of the package, tray, or containment device that creates the greatest challenge to sterilant penetration..."
- Annex J: "The use of multivariable chemical indicators...provides more information about the process as compared to sterilization process indicators..."



ANSI/AAMI ST58:2024; *Chemical sterilization and high-level disinfection in health care facilities*. Section 8.6.4.2; Annex I.3.j

Biological Indicators

1. Biological Indicators (BIs)

- The only monitoring tool that directly measures the lethality/killing power of the sterilization process
- Provide direct proof that sterilization kills resistant microorganisms

2. How They Work

- Contain highly resistant bacterial spores:
 - *Geobacillus stearothermophilus* (steam, hydrogen peroxide)
 - *Bacillus atrophaeus* (ethylene oxide)
- Destruction confirms effective sterilization conditions

3. Why They Matter

- Verify achievement of Sterility Assurance Level 10^{-6} (1 in 1,000,000 survival risk)
- Negative results = strong assurance instruments are safe for patient use
- Act as worst-case challenge within the load using a **process challenge device (PCD)**



Guidelines addressing quality assurance monitoring

Regulatory and Professional Recommendations for Monitoring

Regulatory

Centers for Medicare & Medicaid Services / Center for Disease Control



Evidence - Based

Association of Operating Room Nurses (AORN)



Consensus Standards

Association for the Advancement of Medical Instrumentation (AAMI)





Center for Disease Control

CDC Recommendations:

Use mechanical, chemical, and biological indicators to monitor sterilization effectiveness.

Monitor every load with internal and external **CI**s

CIs indicate exposure to sterilization conditions but do not prove sterilization occurred.

CIs should complement; not replace **BI**s.

BIs are the only process indicators that directly monitor the lethality of a sterilization process.

Use **BI**s at least weekly and for every implant load; quarantine implants until BI results are negative whenever possible.

STEAM Sterilization Monitoring

Monitoring Element	CMS Hospital Infection Control Surveyor Worksheet / CMS State Operations Manual	AAMI ST/79	AORN 2026 Guidelines
Physical monitoring	Monitor sterilization parameters	Monitor time, temperature & pressure for every load	Routine monitoring of sterilization parameters
Chemical indicators	CI with sterilization loads	External and internal CIs as appropriate	External and internal CIs
Biological indicators	At least weekly for each sterilizer	Weekly; preferably daily	Weekly; preferably daily
Implant loads	BI with every implant load	BI/PCD with every implant load	BI with every implant load
Dynamic-air-removal	Air-removal testing each day of use	Bowie-Dick testing daily before first processed load	Routine efficacy testing per applicable guidance

VH2O2 Sterilization Monitoring

Organization	VH ₂ O ₂ monitoring guidance
CMS	No VH₂O₂-specific monitoring frequency identified. CMS has general sterilization-monitoring expectations, including CI monitoring every load and BI monitoring at least weekly for each sterilizer and with implant loads.
AAMI ST58:2024	BI in an appropriate PCD/quality monitoring device for each cycle type, every day the sterilizer is in use; preferably every load.
AORN	Routine sterilizer efficacy monitoring every day the sterilizer is used for each cycle type; preferably every load.

Standardize Monitoring for Sterility Assurance

Steam Sterilization

BI monitoring standard **weekly, preferably daily** and every load with an implant



Vaporized Hydrogen Peroxide Sterilization

BI monitoring **daily preferably every load**



Standardization or 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.”

High-reliability healthcare systems build in **redundancy, standardized processes, communication, and mechanisms for detecting failure before harm reaches the patient.**

Back to the numbers

Healthcare Industry Stats

- $\approx$ 48 million surgeries/year
- 157,500 SSIs/year
- 8,200 SSI deaths/year
- 1 in 250 chance of getting SSI
- $\approx$ 1 in 5,000 chance of dying from SSI
- \$3.3 billion/year



Every Load Monitoring (ELM) Rational

Patient Safety & Raising Standards

- ✓ Safety shouldn't depend solely on the assumption that a process worked.
- ✓ Expertise and experience Dose Not eliminate human error.
- ✓ 85% of medical devices are sterilized using steam and the BI standard is weekly preferable daily.
- ✓ VH202 is used to sterilize fewer and less invasive devices, and the BI standard is daily preferably every load.
- ✓ Ensure compliance with patient safety guidelines by going over and above basic guidelines (implants are required to be monitored every time).
- ✓ Every load monitoring provides the same level of care to each, and every patient served by the facility.
- ✓ Standardization eliminates sterilization failure recalls.

Thank you

Sterilization Education Hosted by
Monique Jelks



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