3M℠ Health Care Academy

Are They Really That Different?

A Comparative Analysis of Steam vs Hydrogen Peroxide Sterilization in Healthcare Today

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Disclosure

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Disclaimer

Important Information:

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

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

Examine the goal of sterilization and how sterilization is assured in healthcare facilities

Compare differences between steam sterilization and vaporized hydrogen peroxide (VH2O2) sterilization

Discuss differences between FDA guidelines, ANSI/AAMI and ISO standards, and AORN recommendations for steam and vaporized hydrogen peroxide (VH2O2) monitoring tools

Review chemical indicators (CIs) cleared by the U.S. FDA for monitoring vaporized hydrogen peroxide (VH2O2) sterilization in healthcare facilities

Examine the Goal of Sterilization and How Sterilization is Assured in Healthcare Facilities

Polling Question Number 1

What is the goal of sterilization ?

a) Kill everything

b) Inactivate some microorganisms

c) Render product free from viable microorganisms

d) Assure organisms are dead on devices

e) Different goal depending on the product

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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.*

"Validated process used to render product free from viable microorganisms".

The goal of steam sterilization = same goal of VH2O2 sterilization

How Do We Prove a Device is Sterile ?

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

Sterilization process is expressed in terms of probability. This can be a very low number; it can never be zero.

There is no practical way to prove any device is sterile in a healthcare facility!

Polling Question Number 2

If we cannot prove sterility, what can we do?

a) Validate processes in the hospital

b) Implement assurance of sterility program

c) Allow Joint Commission audits

d) Follow requirements U.S. FDA has established for hospitals

e) Recognize HSPA mission for healthcare

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Polling Question Number 2

If we cannot prove sterility, what can we do ?

- Assurance of sterility is the industry concept for sterilization since we can never prove sterilization (cannot prove a negative state).
- We do not validate processes in the hospital, but we can verify or qualify (different definitions).
- We allow and want accreditation surveys of our facility so we can receive payments from Centers for Medicare & Medicaid Services (CMS).
- U.S. FDA does not regulate hospitals. U.S. FDA regulates device manufacturers.
- We should recognize HSPA mission for healthcare, but the mission is not the alternate to proving sterility.

If We Cannot Prove Sterility, What Can We Do ?

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

Assurance of sterility

Qualitative concept comprising <u>all activities</u> that <u>provide confidence</u> that product is sterile

AAMI ST79:2017 Section 13 Process monitoring, testing, and quality control

Polling Question Number 3

What activities comprise assurance of sterility?

a) Monitoring of mechanical cleaning equipment

b) Product identification and traceability

c) Physical, chemical, & biological monitoring

d) Preventative maintenance of sterilizers

e) All the above

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d) Preventative maintenance of sterilizers

e) All the above 

What is Assurance of Sterility in a Healthcare Facility ?

ANSI/AAMI ST79:2017 Section 13 *Process monitoring, testing, and quality control. The assurance of sterility for reusable instrumentation requires…*

- Monitoring of mechanical cleaning equipment;
- Product identification and traceability;
- Physical, chemical, & biological monitoring
- Residual air (Bowie-Dick type) testing of dynamic-air-removal sterilizers;
- Periodic product quality assurance;

Monitoring tools do not indicate everything was successful, they indicate something went wrong.

Stop, notify, and evaluate

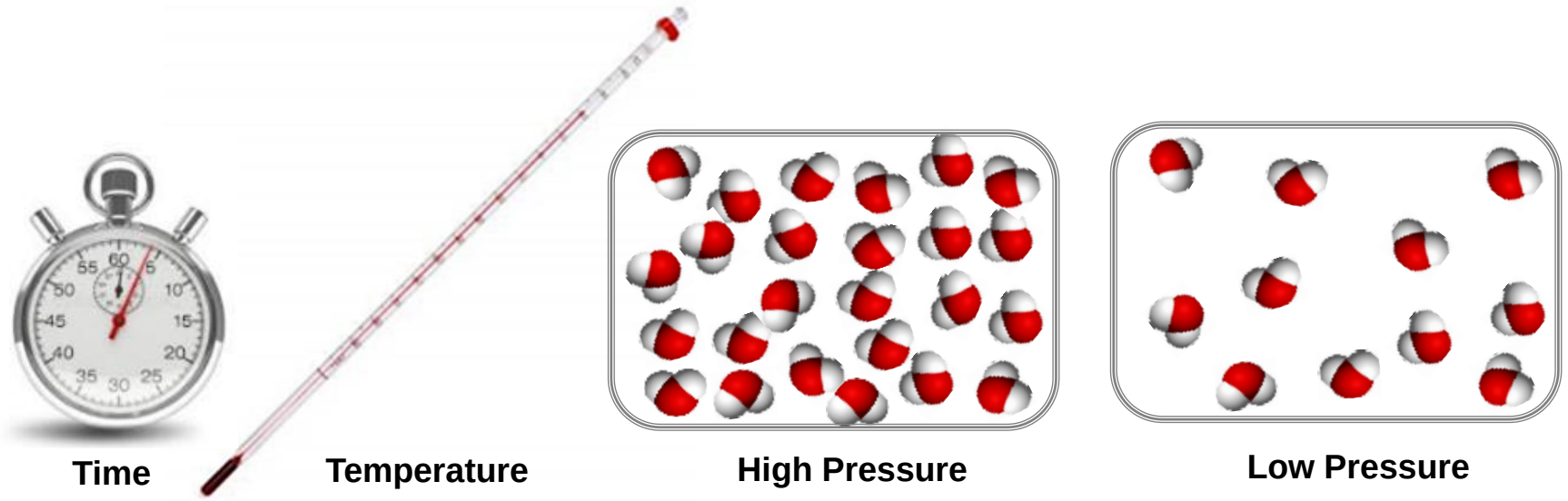
Plus, much more !

Distinct and Different Roles in Assurance of Sterility

Physical Monitors

Physical monitors verify that the (physical) parameters of the sterilization cycle have been met.

Most parameters for success established by the sterilizer manufacturer.



STERRAD∗ 100S STERILIZER # 073202
04-05526-8-001A 10-31-08
DAILY CYCLE # 3
TOTAL MACHINE CYCLES 7632
THU 07/28/16 11:48:27 AM
Vacuum Stage Press = 397 mtorr
18 min 38 sec
Injection Stage Press = 8.11 torr
6 min 2 sec
Diffusion Stage Press ⟩15 torr
2 min 0 sec
Plasma Stage Press = 507 mtorr
6 min 14 sec
Injection Stage Press = 8.37 torr
6 min 1 sec
Diffusion Stage Press ⟩15 torr
2 min 0 sec
Plasma Stage Press = 495 mtorr
6 min 6 sec
Vent Stage
PROCESS COMPLETE 12:35:29 PM
47 min 2 sec

Validated by:_____

Biological Indicator:_____
NUMBER OF CYCLES AVAILABLE = 1
CASSETTE EXPIRATION DATE: 02/17
∗ Trademark

Injection Stage Pressure # 1

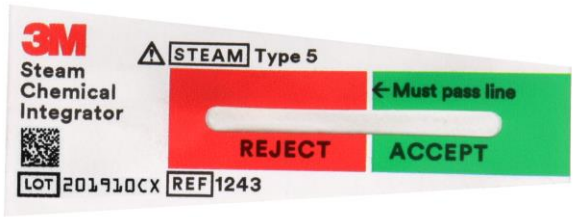
Injection Stage Pressure # 2

ANSI/AAMI ST79:2017 *Section 13.5.1 and AAMI ST58:2013 Section 9.5.1*

Distinct and Different Roles in Assurance of Sterility

Chemical Indicators (CIs)

Chemical indicators verify that one or more conditions necessary for sterilization have been achieved within the package and/or at a specific location within the load.

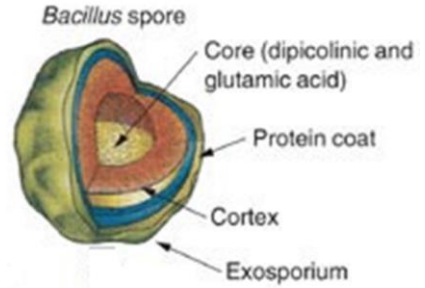


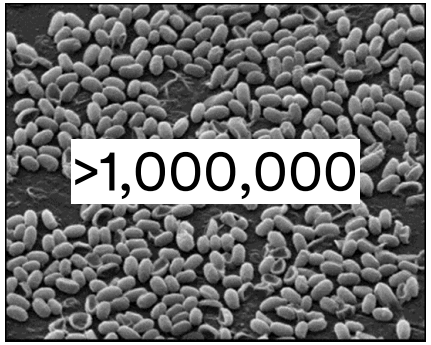
ANSI/AAMI ST79:2017 *Section 13.5.2 and AAMI ST58:2013 Section 9.5.3*

Distinct and Different Roles in Assurance of Sterility

Biological Indicators (BIs)

Biological indicators verify that the conditions at a location within the load were adequate to kill a population of microorganisms resistant to the sterilization process and demonstrate the lethality of the sterilization process.



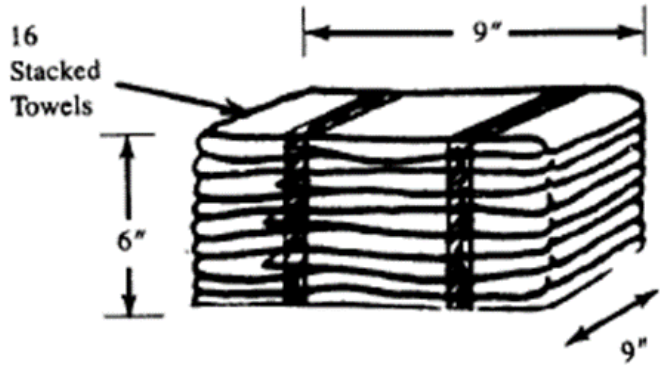


ANSI/AAMI ST79:2017 *Section 13.5.3.1 and AAMI ST58:2013 Section 9.5.4.1*

Distinct and Different Roles in Assurance of Sterility

Process Challenge Device (PCDs)

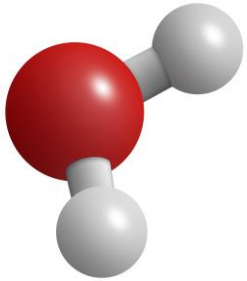
A PCD is a device used to assess the effective performance of a sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult-to-sterilize item routinely processed.



ANSI/AAMI ST79:2017 *Section 13.5.3.1 and AAMI ST58:2013 Section 9.5.4.1*

Compare Differences Between Steam Sterilization and VH2O2 Sterilization

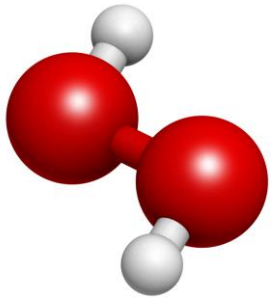
Steam and VH2O2 Sterilization in Healthcare



H2O molecule

Steam Sterilization:

Saturated steam under pressure, for a specified exposure time and at a specified temperature, as the sterilizing agent.



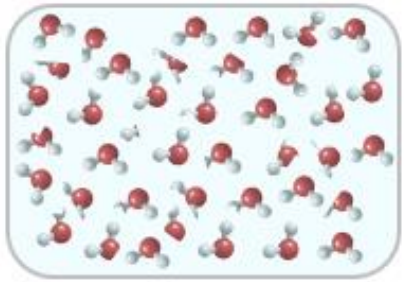
H2O2 molecule

VH2O2 Sterilization:
Chemical sterilization, process using a chemical agent (VH2O2), designed to render a product free of viable microorganisms.

Process Variables (Critical Variables)

Steam Sterilization

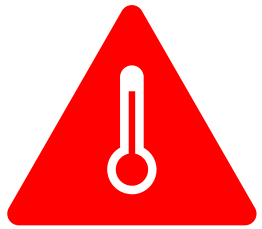
Temperature



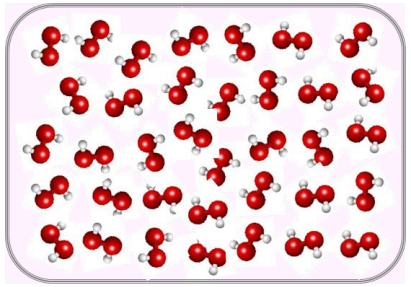
Steam

Time

VH2O2 Sterilization



Temperature



Hydrogen Peroxide Concentration

Time

...changes alter effectiveness...

ISO 11140-1:2014

Process Variables (Critical Variables)

Chemical or physical attribute within…a sterilization process, changes in which can

… *alter its effectiveness.*

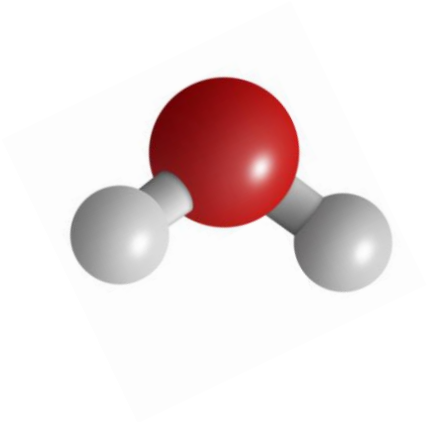
Examples: Time, temperature, pressure, concentration, humidity, wavelength

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

Steam and VH2O2 Sterilization - Significant Differences

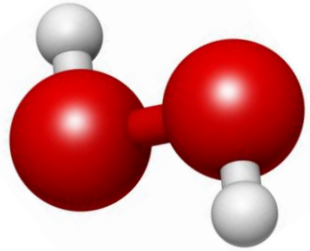
Steam Sterilization:

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



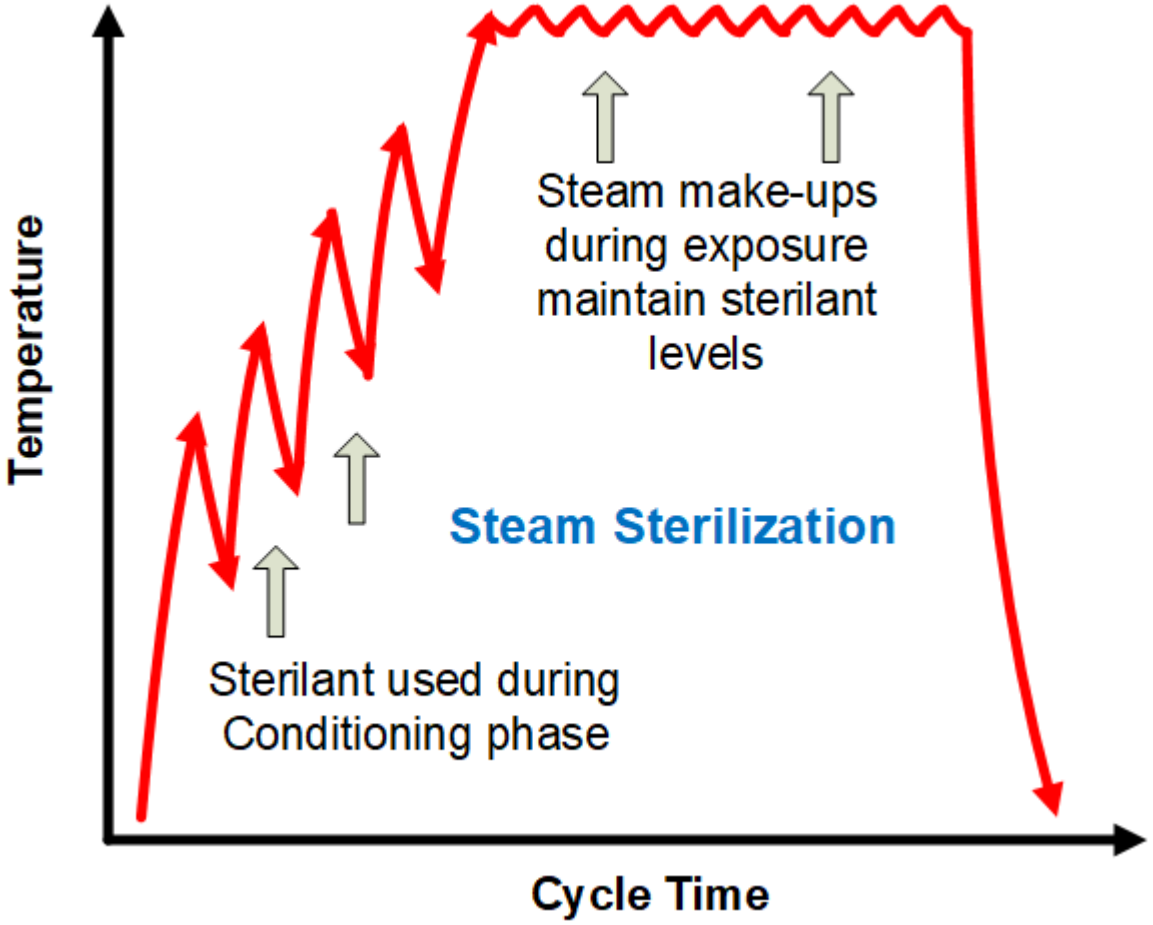
VH2O2 Sterilization:

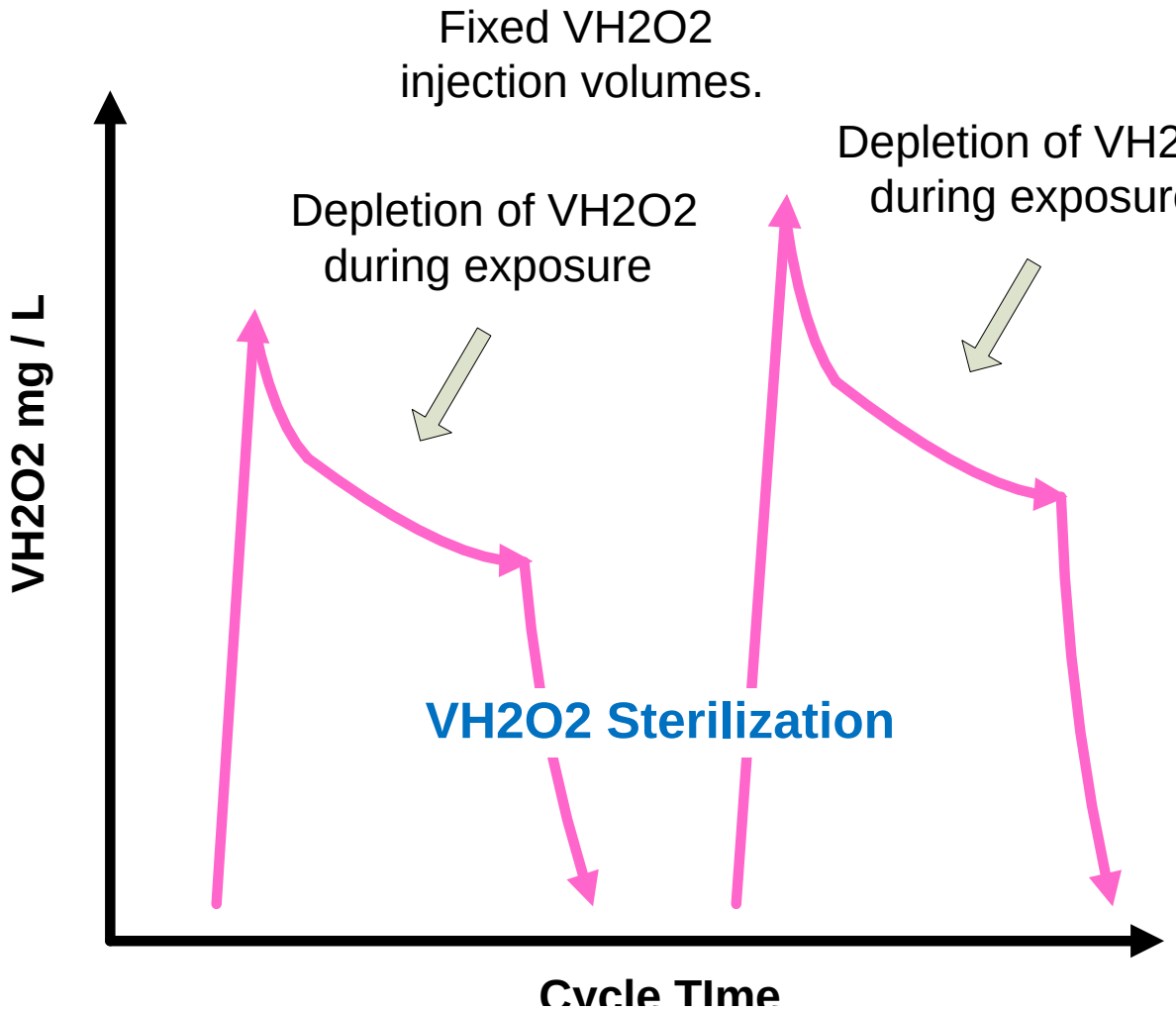
1. Sterilant not used in conditioning phase.*
2. Fixed amount of sterilant (VH2O2) during exposure phase (no sterilant make-ups).**
3. VH2O2 is naturally an unstable molecule (depletes readily during exposure).
4. Method is technique sensitive.



*The newest STERIS V-PRO s2 and 60 have a VH2O2 prime injection
** STRYKER® Sterizone VP4 and Sterilucent® HC80 TT have limited dynamic injections

Representation of Sterilant During Exposure





VH2O2 is considered a relatively unstable molecule

Polling Question Number 4

Which statements are TRUE?

a) Steam is considered more robust than VH2O2.

b) VH2O2 concentration is stable during exposure.

c) VH2O2 sterilization has make-ups during exposure.

d) All the above.

Polling Question Number 4

Which statements are TRUE?

a) Steam is more robust than VH2O2.

b) VH2O2 concentration is stable during exposure.

c) VH2O2 sterilization has make-ups during exposure.

d) All the above.

Polling Question Number 5

Under normal routine VH2O2 processing conditions in healthcare, which is closer to truth?

a) Temperature inside a pack is cooler than reported cycle printout.

b) Temperature inside a pack is close to temp reported cycle printout.

c) I am not sure.

Polling Question Number 5

Under normal routine VH2O2 processing conditions in healthcare, which is closer to truth?

a) Temperature inside a pack is cooler than reported cycle printout. 

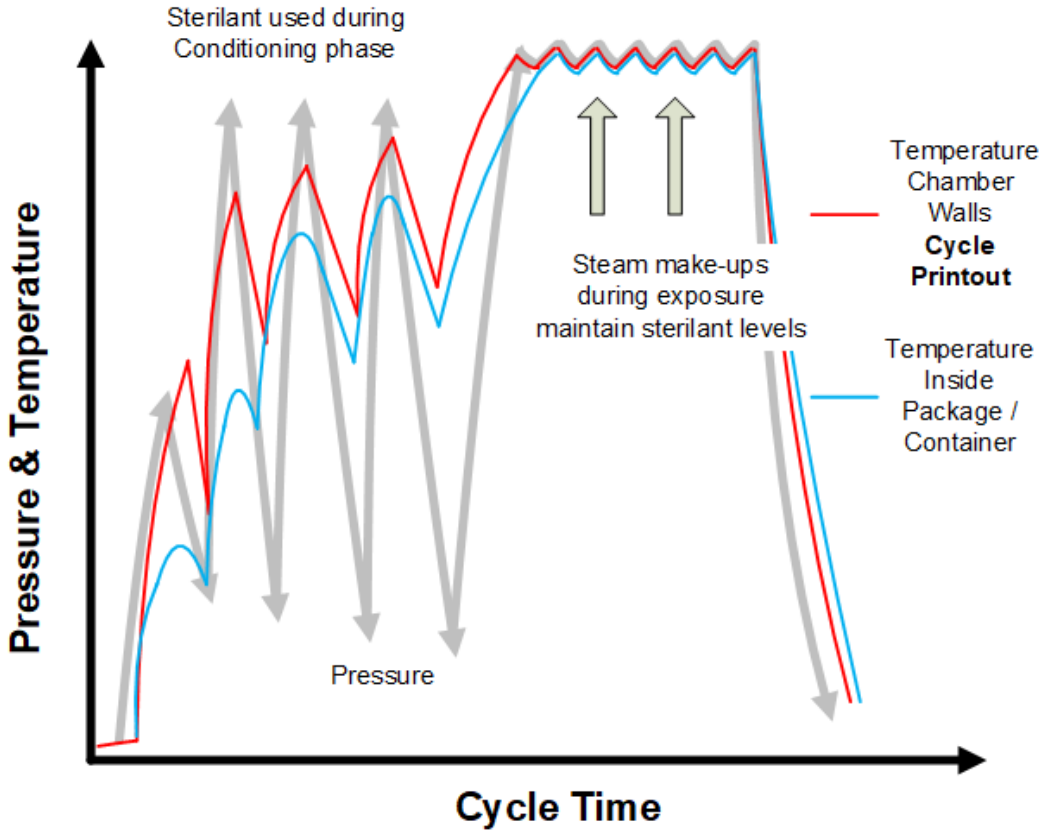
b) Temperature inside a pack is close to temp reported cycle printout.

c) I am not sure.

Steam Temperature Process Variable and Location

Process designed for temperature to be uniform throughout the loaded chamber.*

Process designed for temperature inside a pack to be comparable to reported on cycle printout.*



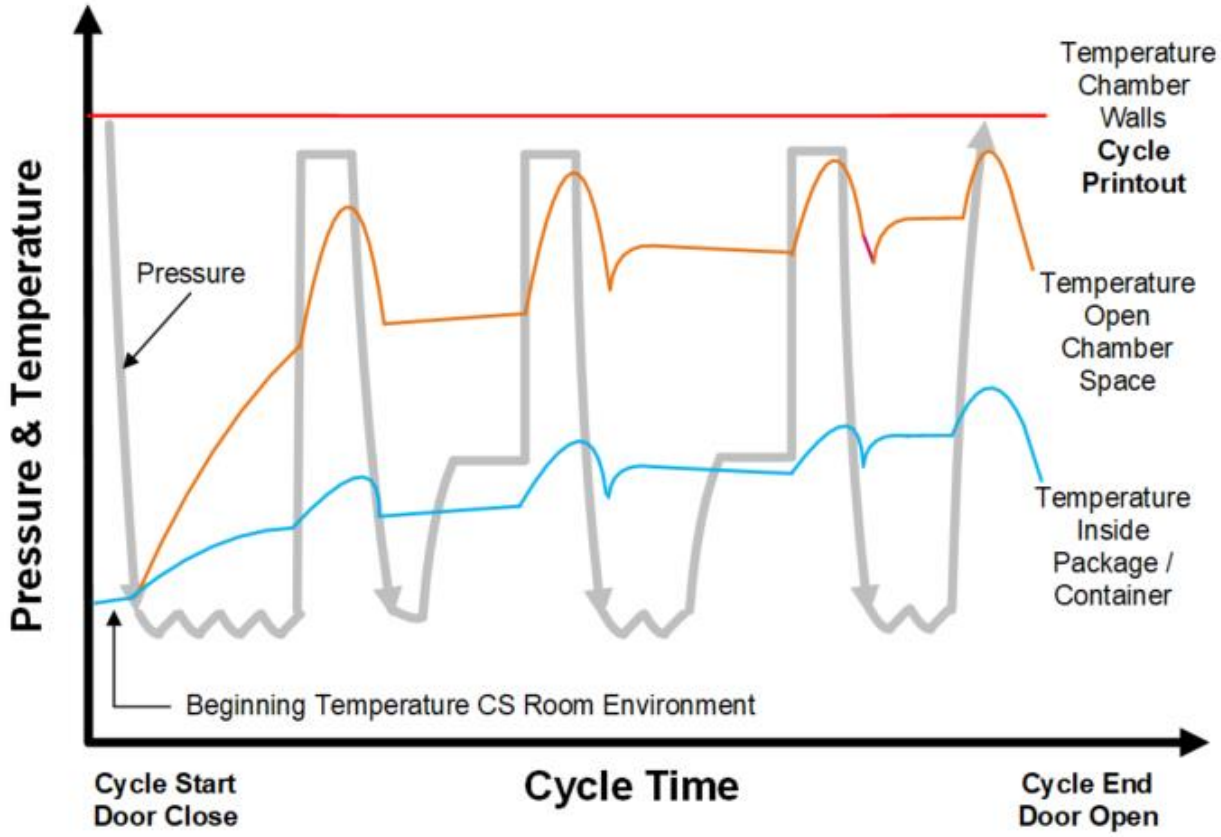
*Under normal routine processing conditions for current steam sterilizers on the market

Actual temperature inside the loaded chamber can vary based on many factors. The line graph and color ratios depicted are for illustrative purposes only.

VH2O2 Temperature Process Variable and Location

Temperature varies at different locations in a loaded chamber.*

Temperature inside a pack is cooler than temperature reported on the cycle printout.*



*Under normal routine processing conditions for current VH2O2 sterilizers on the market
**Reference 3M Document *EM-05-711998*

Actual temperature inside the loaded chamber can vary based on many factors. The line graph and color ratios depicted are for illustrative purposes only.

Polling Question Number 6

Under normal routine VH2O2 processing conditions in healthcare, which is closer to truth?

a) VH2O2 available inside a pack is less than reported cycle printout.

b) VH2O2 available inside a pack is close to reported cycle printout.

c) I am not sure.

Polling Question Number 6

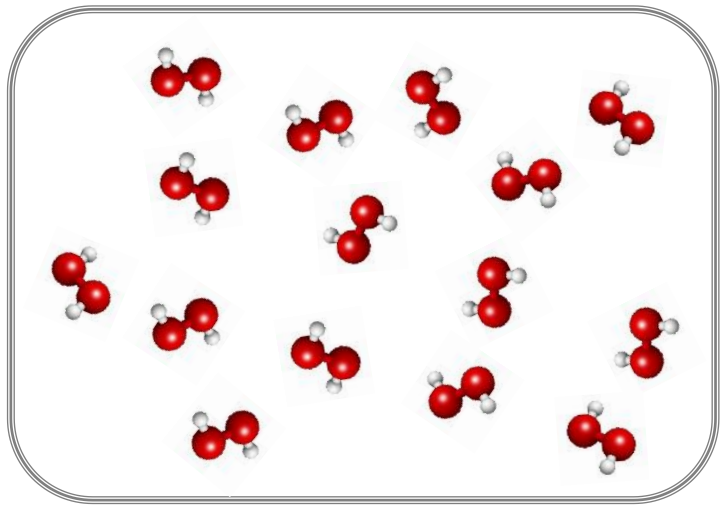
Under normal routine VH2O2 processing conditions in healthcare, which is closer to truth?

a) VH2O2 available inside a pack is less than reported cycle printout. 

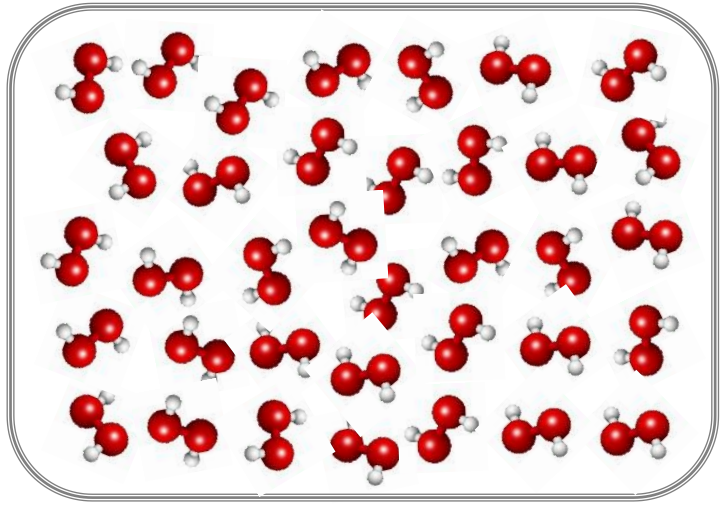
b) VH2O2 available inside a pack is close to reported cycle printout.

c) I am not sure.

Example...Sterilant Concentration Levels



Lower Concentration mg/L



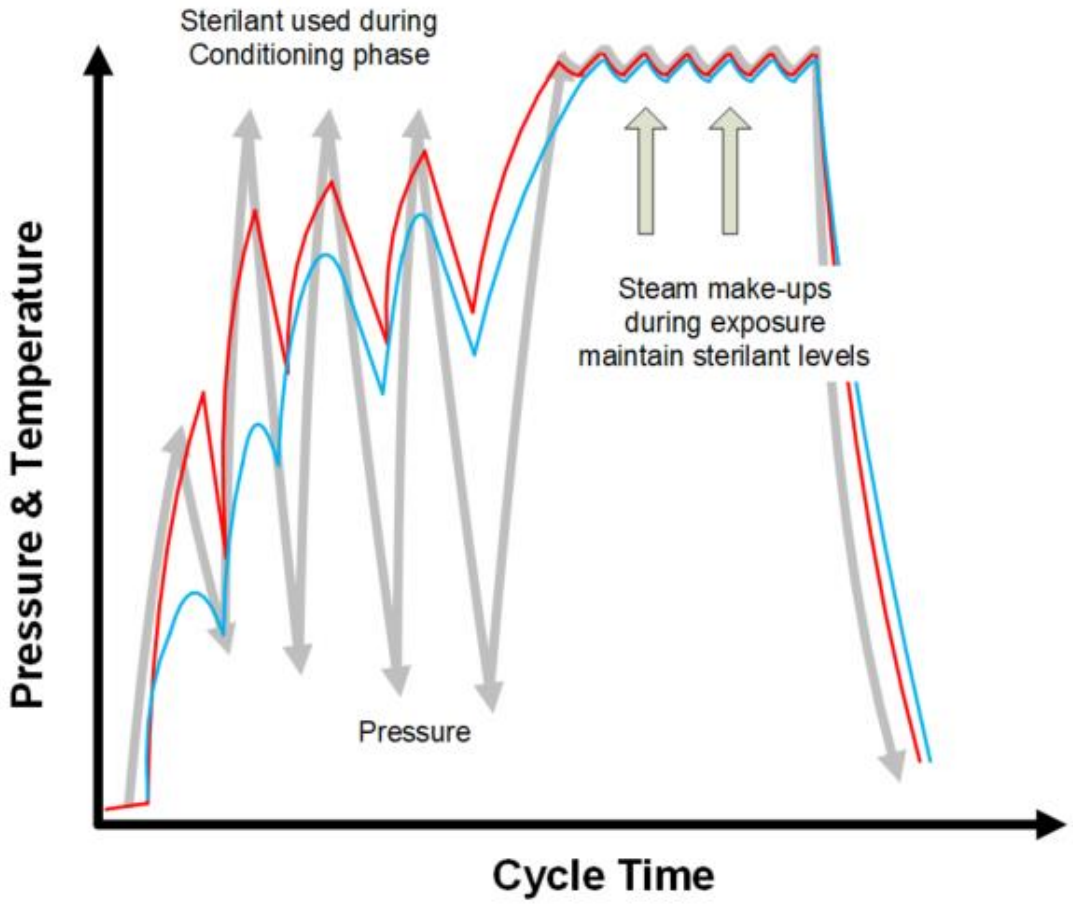
Higher Concentration mg/L

One of (or part of) these sterilant molecules must touch every surface of a device to achieve sterilization.

Steam Sterilant Process Variable and Location

Process designed for steam to be uniform throughout the loaded chamber.*

Process designed for steam inside a pack to be comparable to reported on cycle printout.*



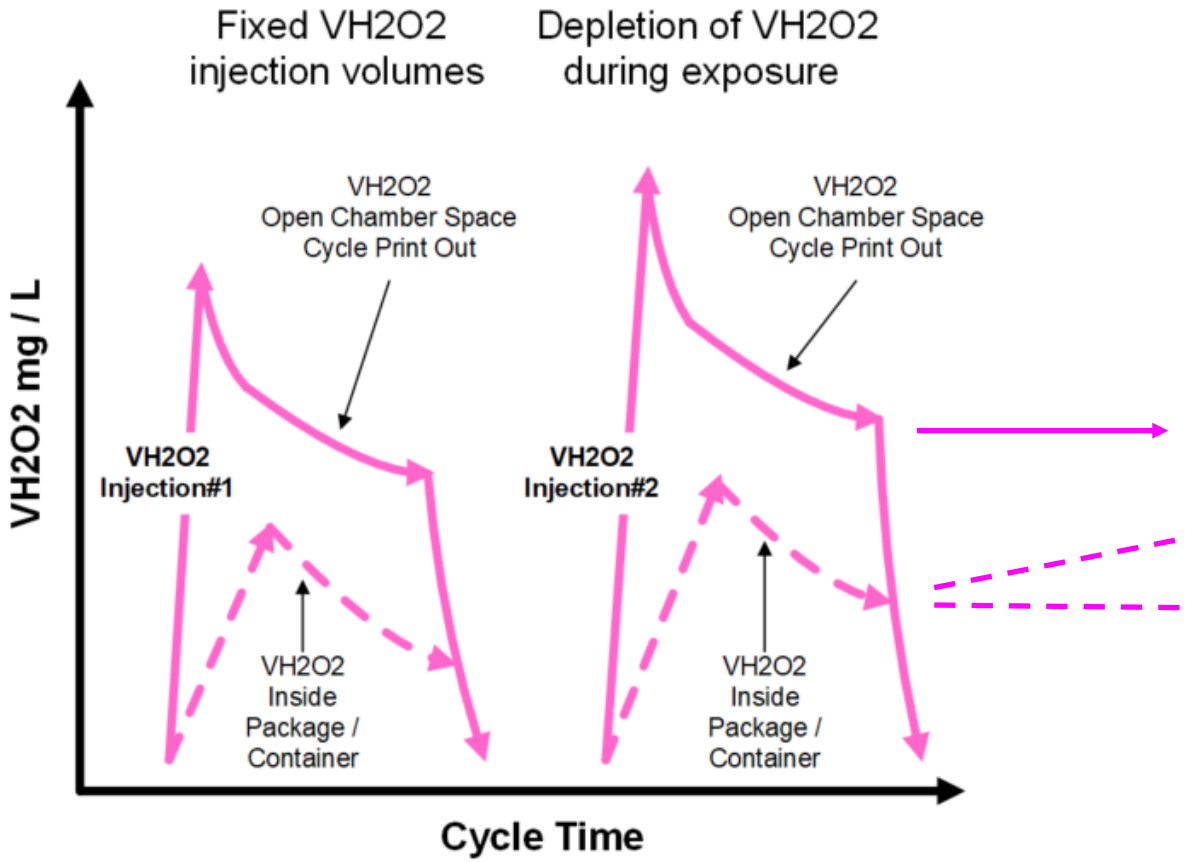
Actual steam inside the loaded chamber can vary based on many factors. The line graph and color ratios depicted are for illustrative purposes only.

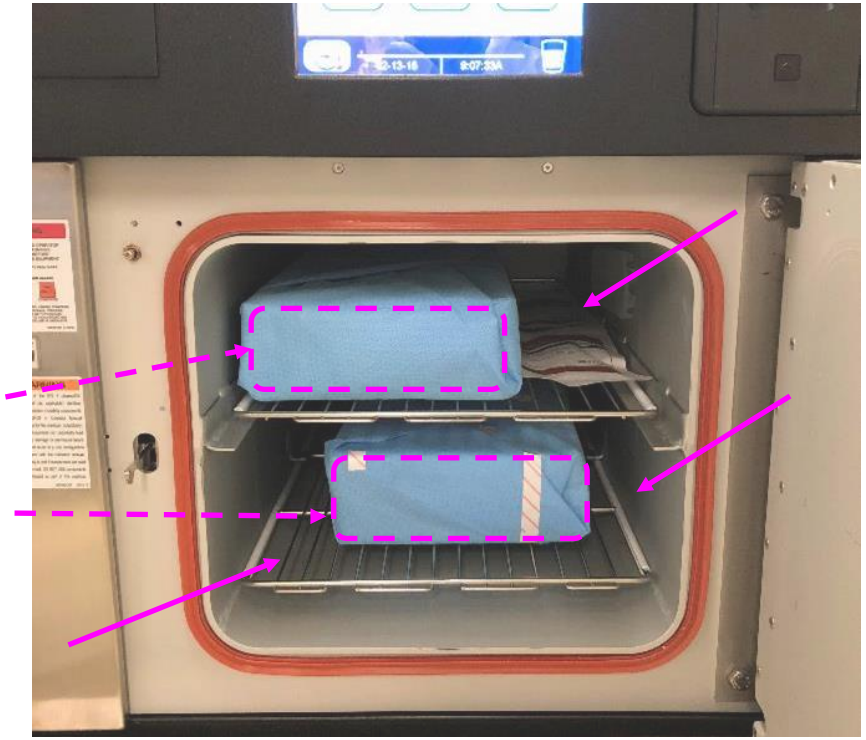
*Under normal routine processing conditions for current steam sterilizers on the market

VH2O2 Sterilant Process Variable and Location

VH2O2 concentrations can vary at different locations in a loaded chamber.*

VH2O2 available for sterilization inside a pack is lower than the VH2O2 measured outside a pack as recorded on the cycle printout.*





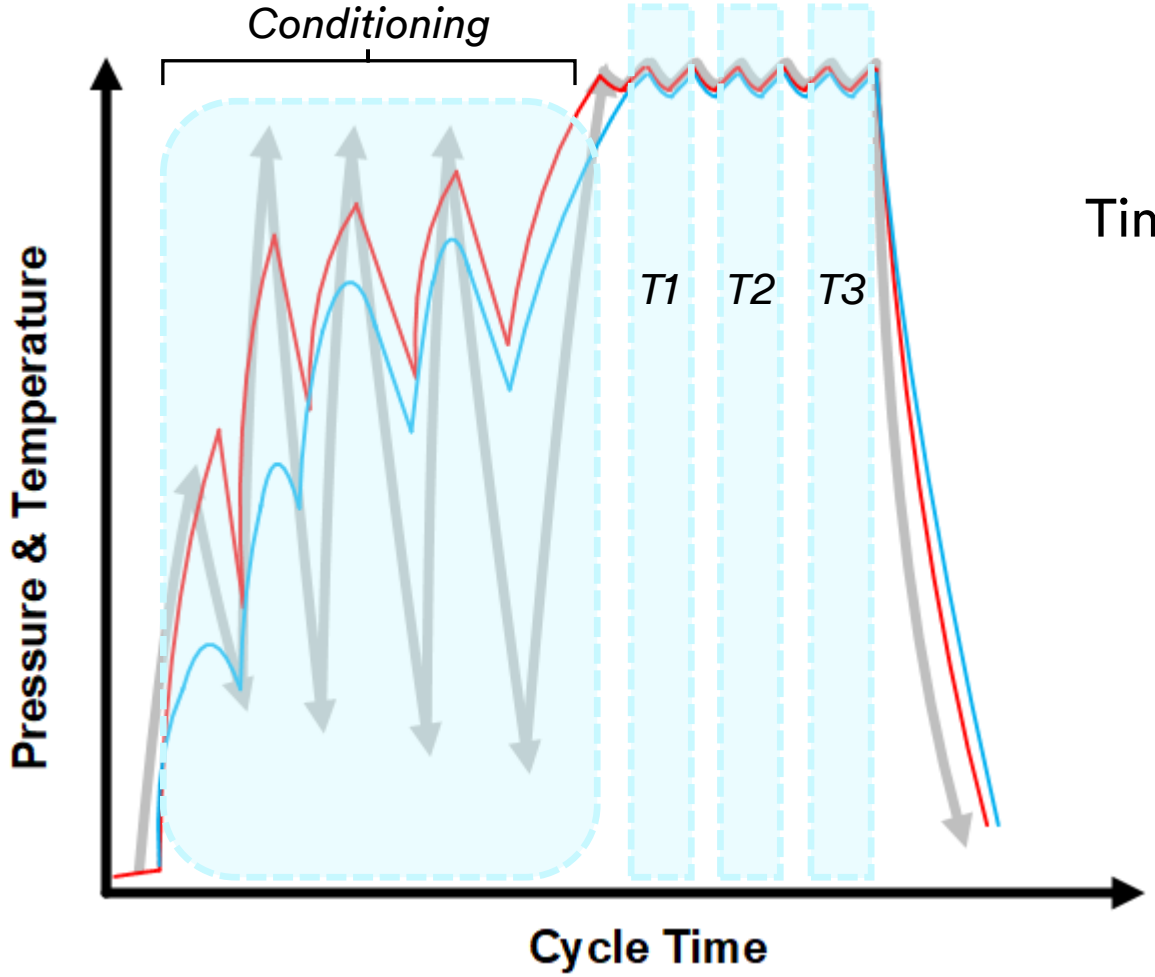
*Under normal routine processing conditions for current VH2O2 sterilizers on the market
**Reference 3M Document *EM-05-692858*

Actual VH2O2 concentration inside the loaded chamber can vary based on many factors. The line graph and color ratios depicted are for illustrative purposes only.

Steam Time Process Variable

Time relates to time at exposure conditions to (temperature and sterilant).

Exposure conditions are relatively constant plus additional time is added with sterilant in used in conditioning.



Time: Exposure Conditions

T1 ≈ T2 ≈ T3 + Conditioning

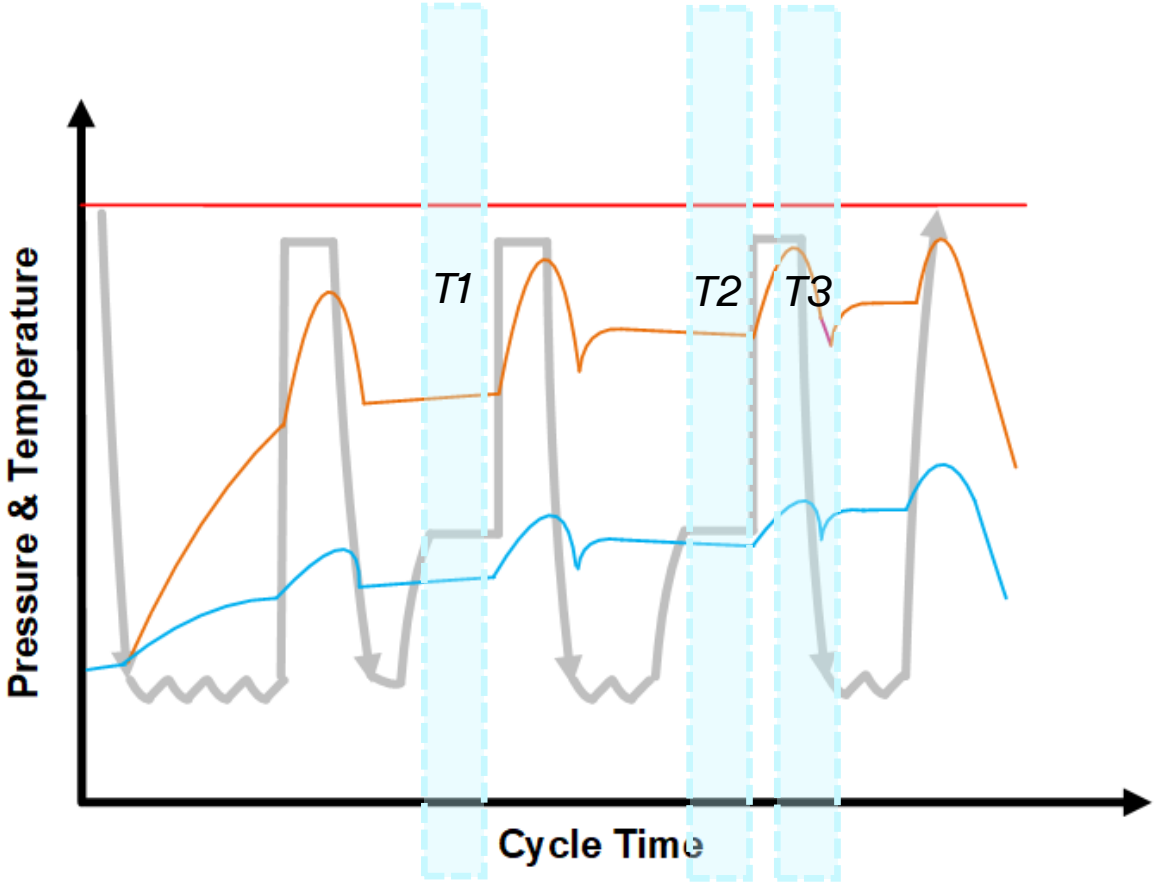
VH2O2 Time Process Variable

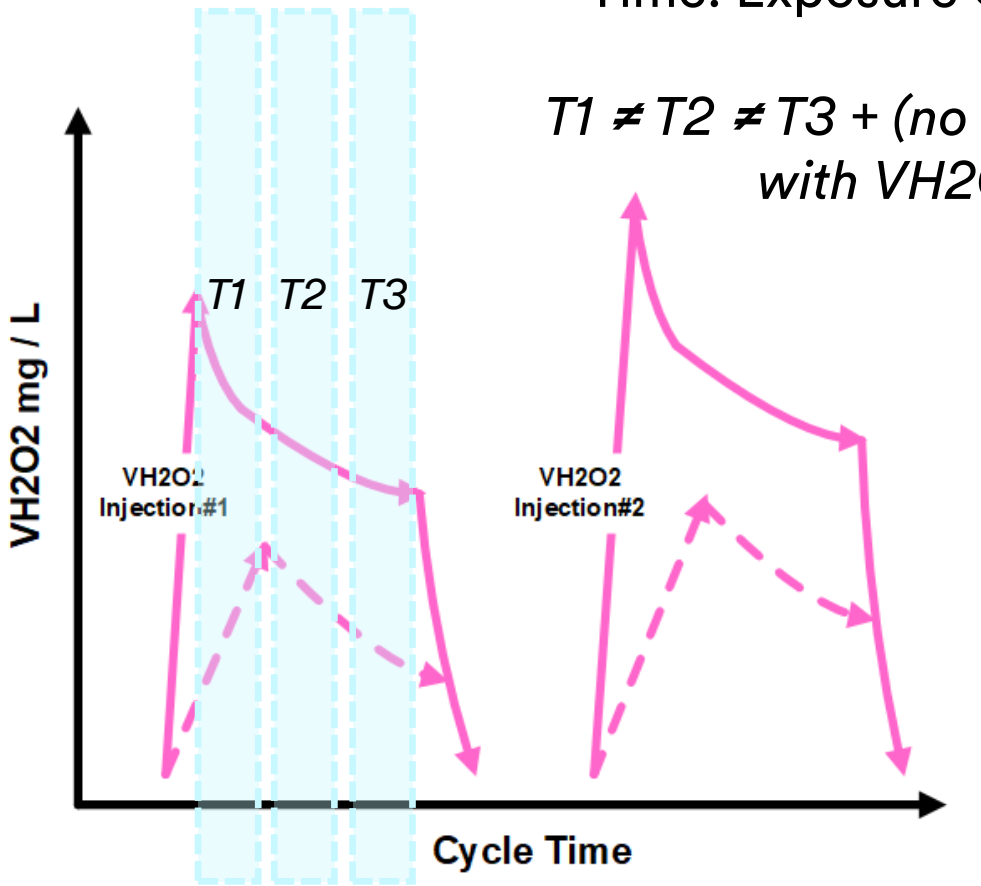
Time relates to time at exposure conditions (temperature and sterilant).

Exposure conditions are not constant for VH2O2 sterilization.

Time: Exposure Conditions

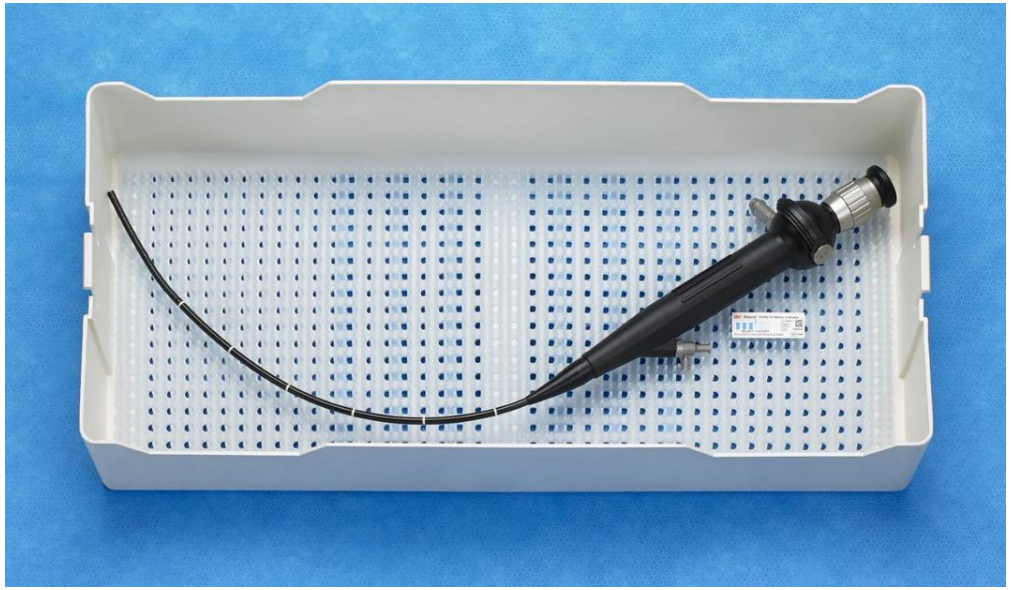
T1 ≠ T2 ≠ T3 + (no conditioning with VH2O2)





Process Variables and Packages

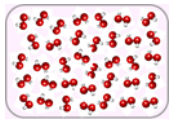
VH2O2 critical process variables can vary inside different package types, with different materials and devices, in the same load, in the same cycle.*



By process design package type has less impact for Steam process variables.

*Under normal routine processing conditions for current VH2O2 sterilizers on the market
**Reference 3M Document *EM-05-692858*

Steam and VH2O2 Processes & Variables Summary

	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

International Standards: Steam and VH2O2

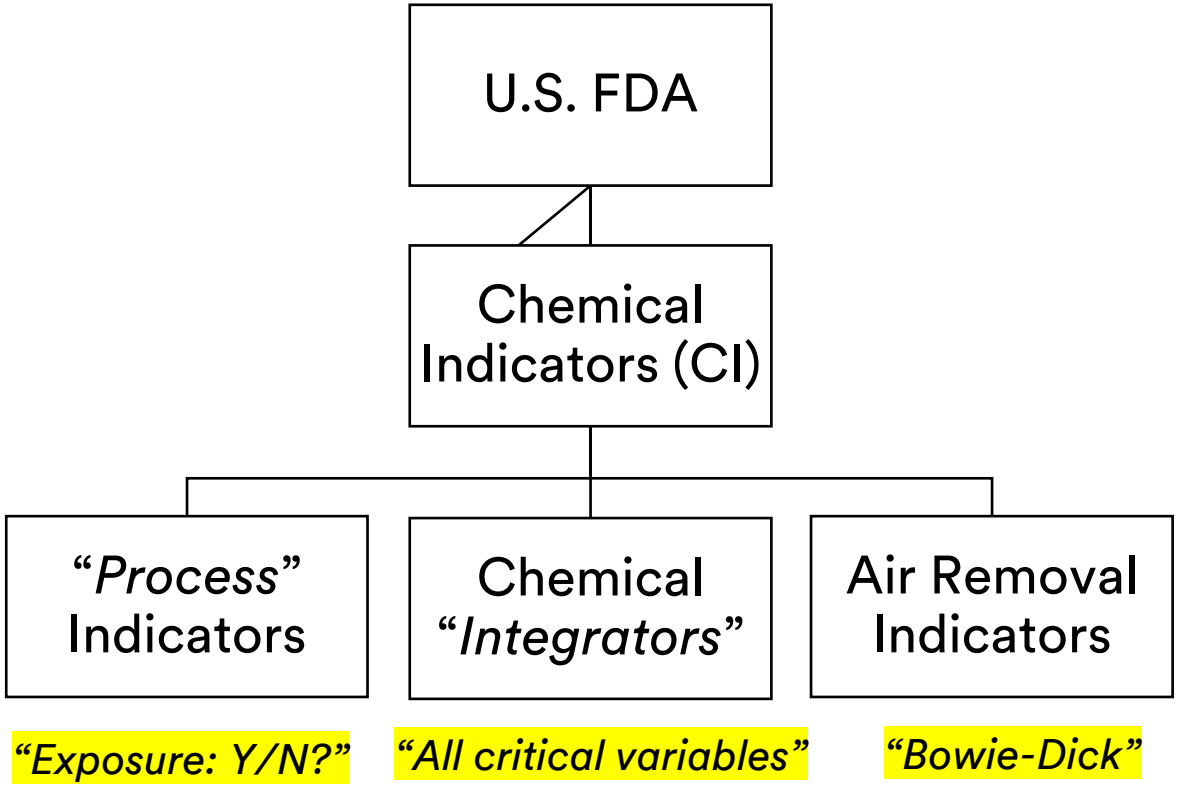
Content	Steam	VH2O2
Sterilizer Equipment	BS EN 285:2015 *Sterilization. Steam sterilizers. Large sterilizers*	DRAFT prEN 17180 *Vaporized hydrogen peroxide sterilizers - Requirements and testing*
Sterilization Process	ISO 17665-1:2006 *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*	ISO 22441 Committee Draft *Vaporized hydrogen peroxide- development, validation routine control of process*
Performance of BIs	ISO 11138-3:2017 *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes*	DRAFT ISO/WD-1 11138-6 *Part 6: Biological indicators for hydrogen peroxide sterilization processes (no current performance criteria to date)*

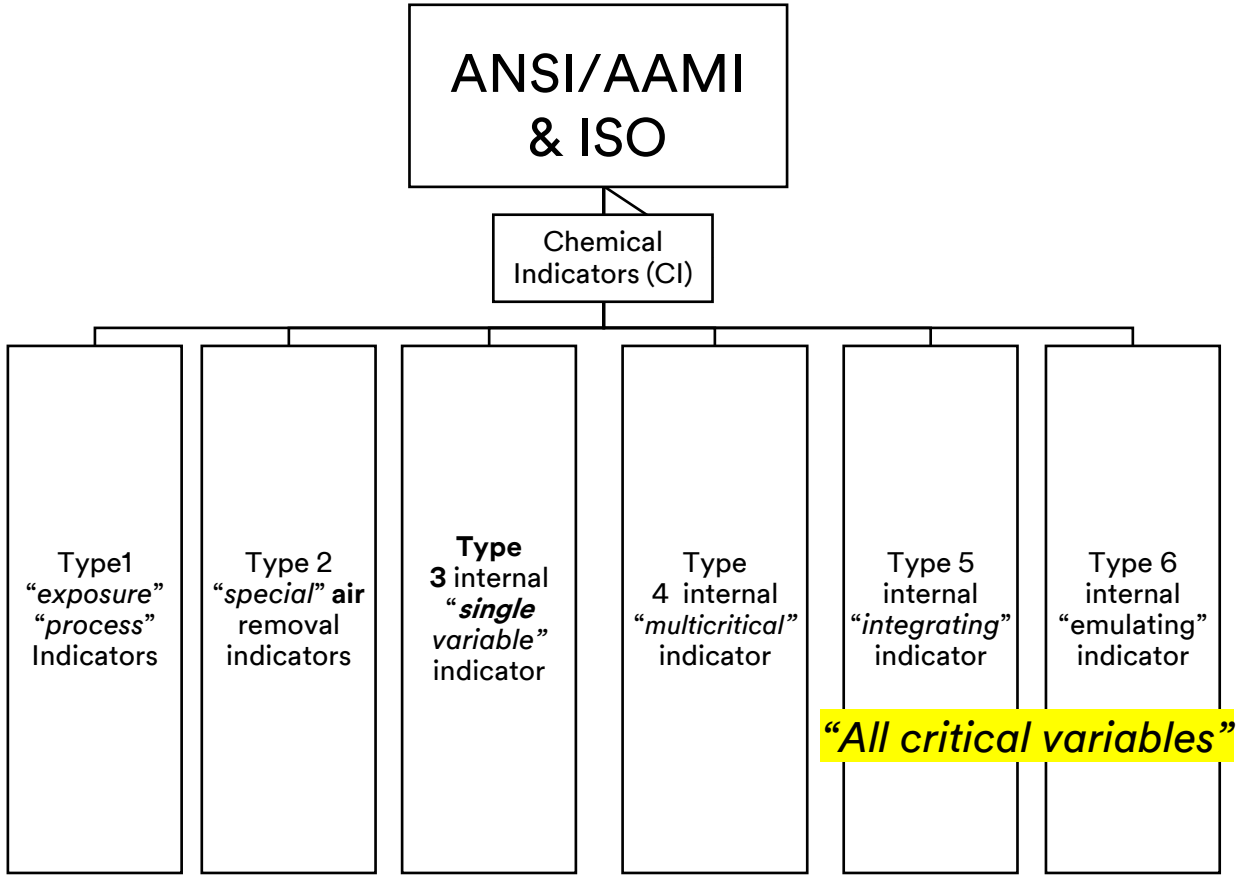
Although VH2O2 sterilization has been used in healthcare ~30 years, standards are only in development

Examine U.S. FDA guidelines, ISO 11140-1:2014, AORN, and ANSI/AAMI Regarding Chemical Indicators

Chemical Indicators: U.S. FDA and ANSI/AAMI and ISO

Steam





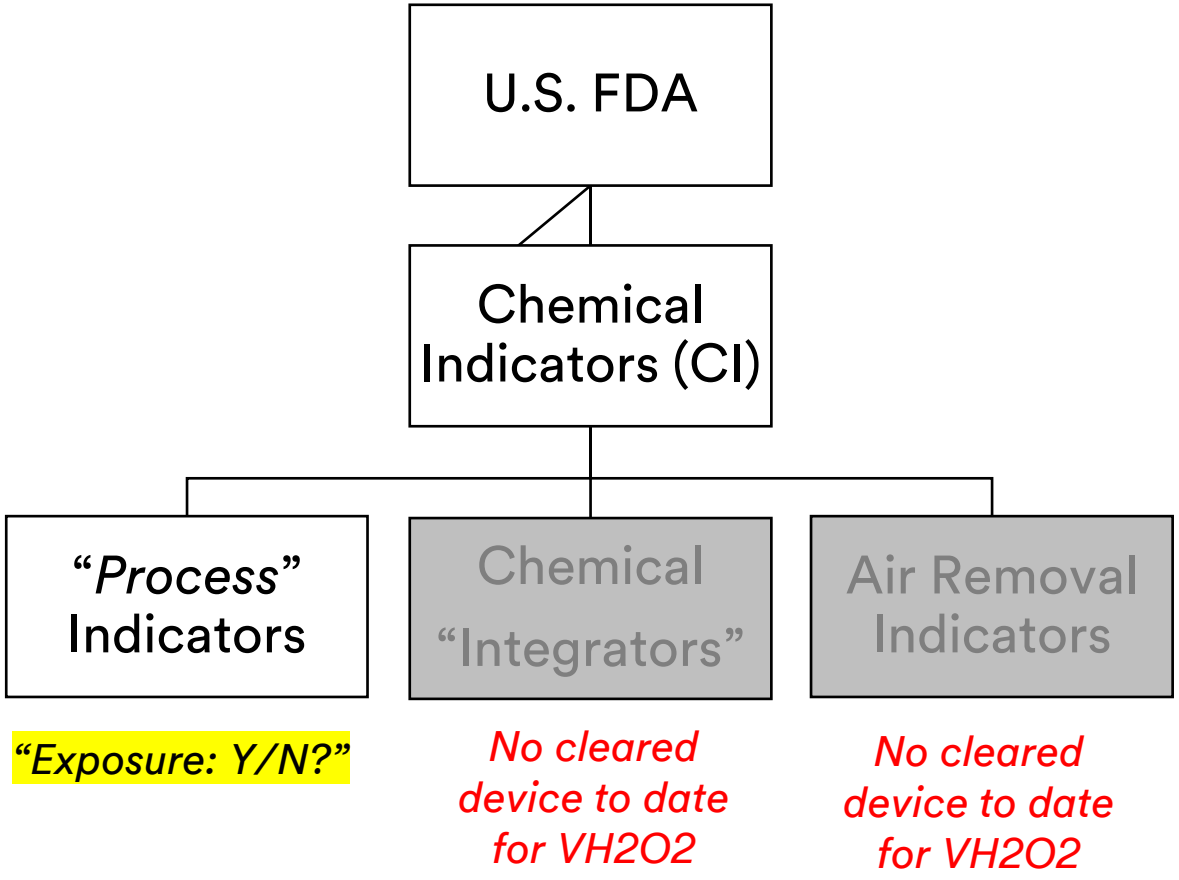
U.S. FDA does NOT substantiate ISO claims.

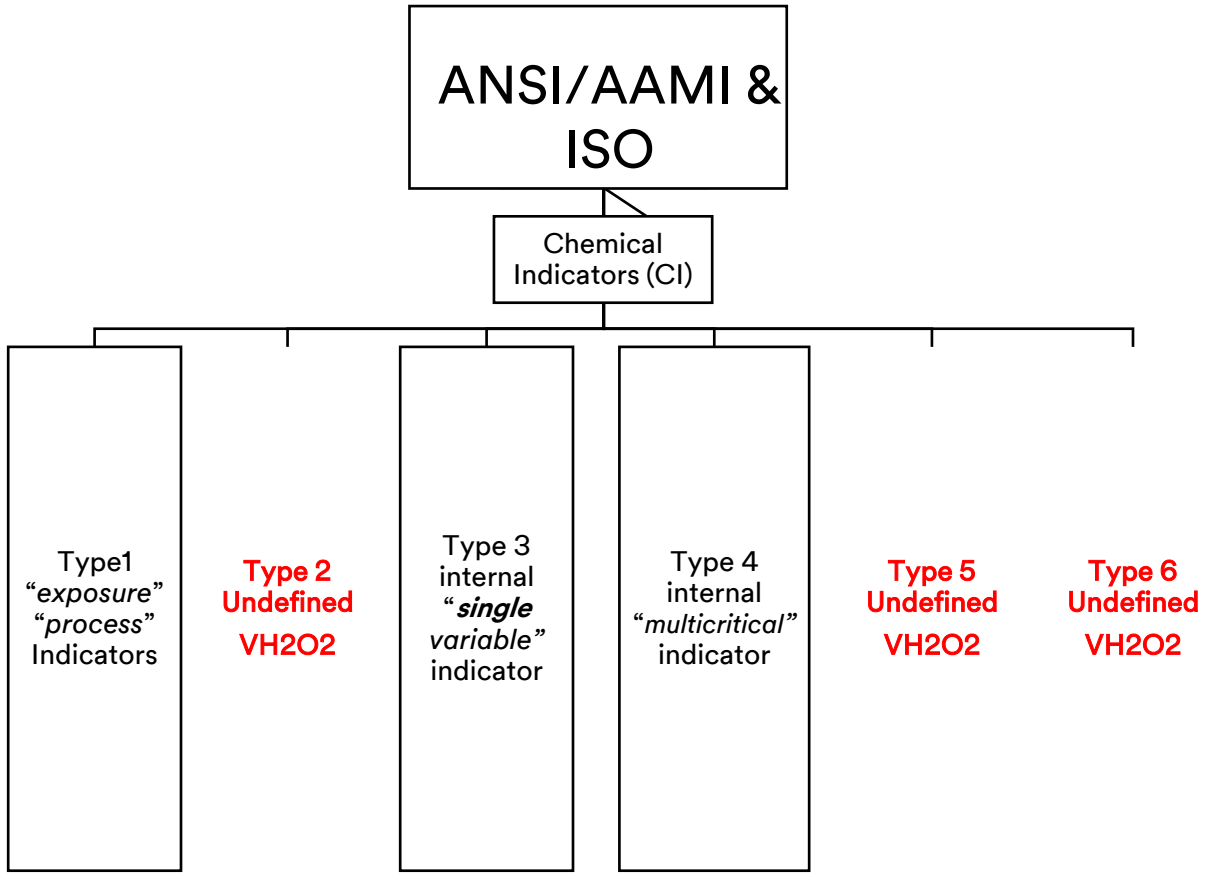
ISO claims are 'self-certified' or certified through an accredited agency (e.g., BSI).

ISO 11140-1:2014 & *Guidance for Industry and FDA Staff Premarket Notification [510(k)] Submissions for Chemical Indicators; December 2003*

Chemical Indicators: U.S. FDA and ANSI/AAMI and ISO

VH2O2



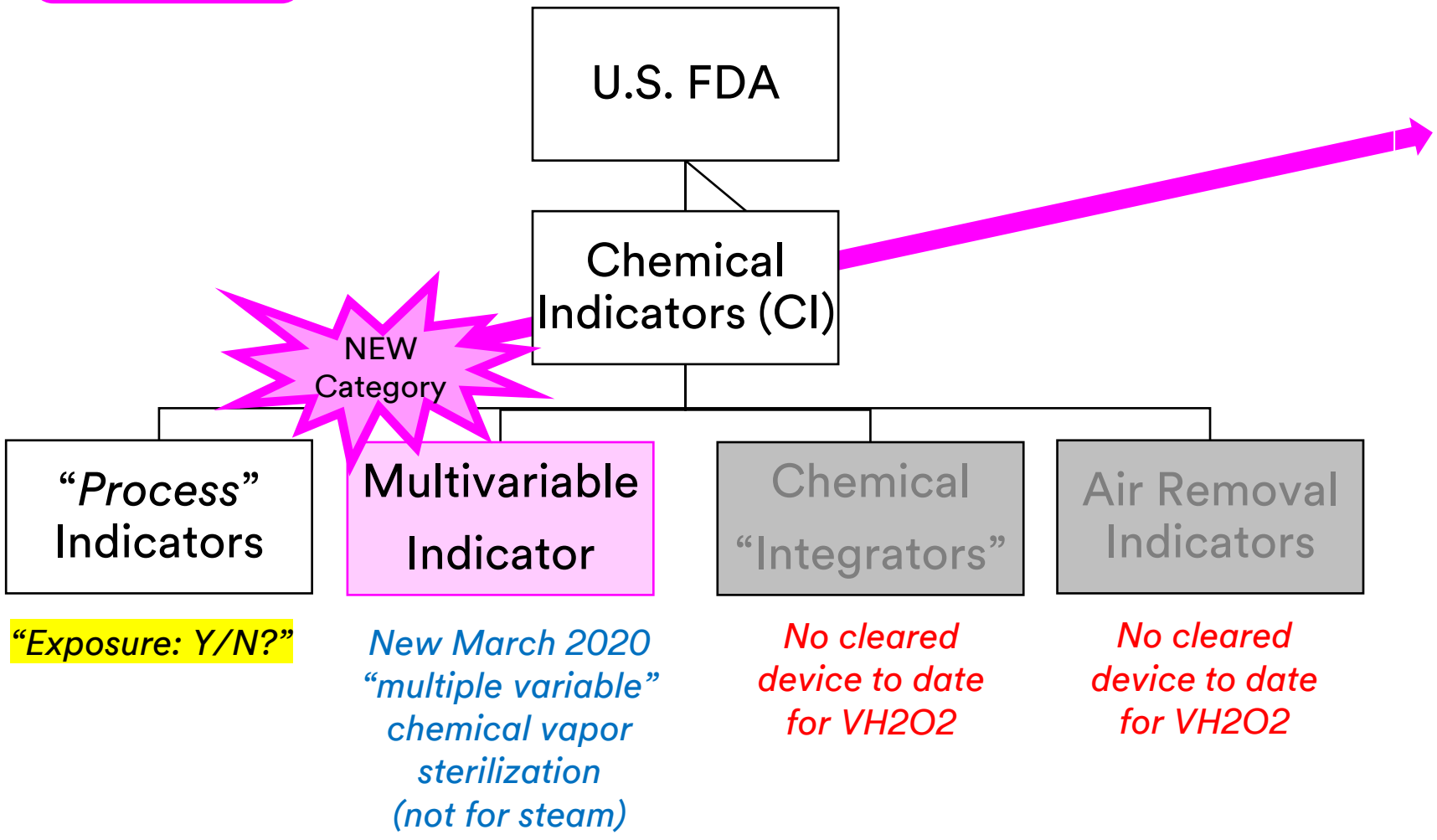


VH2O2 has fewer ISO CI Types

ISO 11140-1:2014 & *Guidance for Industry and FDA Staff Premarket Notification [510(k)] Submissions for Chemical Indicators; December 2003*

Chemical Indicators: U.S. FDA and ANSI/AAMI and ISO

VH2O2



First and only VH2O2 chemical indicator to <u>independently</u> monitor three (3) critical variables VH2O2 sterilization:

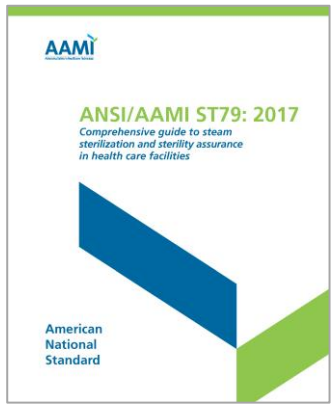
- Exposure time
- Temperature
- VH2O2 concentration

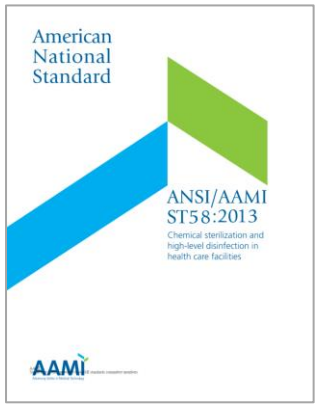
ANSI/AAMI and AORN: What is the Role of Chemical Indicators ?

ANSI/AAMI ST79:2017 Section 13.5.2.1

ANSI/AAMI ST58:2013 Section 9.5.3.1

AORN Guideline for Sterilization Recommendation 10.4





- ❑ *Assist in the detection of potential sterilization failures:*
  - ✓ *incorrect packaging, incorrect loading of the sterilizer, or sterilizer malfunctions.*

- ❑ *Immediately verify that one or more of the conditions necessary for sterilization has been achieved within each package.*

- ❑ *Although CIs do not verify sterility,*
  - ✓ *they help detect procedural errors and equipment malfunctions.*

Chemical Indicators: ANSI/AAMI Comparison

Internal Chemical Indicators

ANSI/AAMI ST79:2017 **Steam** (13.5.2.2.2, 13.5.2.1)	Comparison	ANSI/AAMI ST58:2013 **VH2O2** (2.14, 9.5.3.2, 9.5.4.3)
These indicators can be any type (Type 3, 4, 5, or 6)	≠	*Only Type 1 is applicable Type 1 not required*
Preferably a Type 5 or Type 6 indicator	≠	*Only Type 1 is applicable Type 1 not required*
A Type 5 CI within a BI PCD for implants should be used	≠	*CI not mentioned*
Should be FDA cleared	=	*Should be FDA cleared*

Chemical Indicators: ANSI/AAMI Comparison

Internal Chemical Indicators

The goal of steam and VH2O2 sterilization is the same: sterile devices for patients.

VH2O2 sterilization currently has lower quality assurance monitoring expectations in ANSI/AAMI standards for internal pack monitoring, yet the tools are available.

As an industry, we must raise the level of quality assurance monitoring for VH2O2 sterilization to what we expect for steam sterilization.

Chemical Indicators: AORN Comparison

Internal Chemical Indicators

AORN Recommendations Steam 2020 (10.4.1 – 10.4.3)	Comparison	AORN Recommendations VH2O2 2020 (10.4.1 – 10.4.3)
Type 5 CI or Type 6 CI inside/internal	≠	~~*Type 5 CI or Type 6 CI inside/internal*~~ *Does not exist for VH2O2*
Type 3 CI or Type 4 CI may be used inside/internal (conditional)	=	*Type 3 CI or Type 4 CI may be used inside/internal (conditional)*
PCD monitoring (containing a BI and a Type 5 CI) for each load containing an implantable device	≠	*CI not mentioned for implants and VH2O2*
Should be FDA cleared	=	*Should be FDA cleared*

Chemical Indicators: AORN Comparison

Internal Chemical Indicators

Reminder: Goal of steam and VH2O2 sterilization is the same: sterile devices for patients.

AORN expects the same level of internal pack quality assurance monitoring for both steam and VH2O2 sterilization.

AORN recommendations currently do not align with the current ISO defined CI Types available for VH2O2 sterilization.

As an industry, we must raise the level of quality assurance monitoring for VH2O2 sterilization to what we expect for steam sterilization.

Chemical Indicators: AORN Recommendations

Guidelines for packaging systems (reference for the user – direct quote)

Sections 10.4

Use external and internal chemical indicators (CIs) specific for the sterilization method with each package.

Chemical indicators are used to immediately verify that one or more of the conditions necessary for sterilization have been achieved within each package. The purpose of the external CI is to differentiate between processed and unprocessed items. Chemical indicators do not establish whether the item is sterile, but they do demonstrate that the contents were exposed to sterilant. Although CIs do not verify sterility, they help detect procedural errors and equipment malfunctions.

Chemical Indicators: AORN Recommendations

Guidelines for packaging systems (reference for the user – direct quote)

10.4.1

Place a type 1 CI (ie, process indicator) on the outside of every package unless the internal indicator is visible through the packaging material.

10.4.2

Place a type 5 CI (ie, integrating indicator) or type 6 (ie, emulating indicator) inside every package.

10.4.3

A type 3 CI or type 4 CI may be used within a package to meet requirements for internal monitoring.

10.4.4

If the interpretation of the external or internal process indicators suggests inadequate or questionable processing, do not use the items.

What Does a Failed Internal Chemical Indicator Represent?

ANSI/AAMI ST58: 9.5.3.3 Nonresponsive or inconclusive chemical indicators

(reference for the user – direct quote)

If the interpretation of the CI suggests inadequate processing, the contents of the package should not be used.

The interpreter should inform the appropriate supervisor, who should return the complete unused package, including load identification and the CI, for appropriate follow-up.

The department head or designee in the sterilizing department should then decide whether to recall that sterilized load.

This decision should be based on the results of physical monitoring, the results of CIs elsewhere in the load, and, if applicable, the results of biological monitoring.

If biological monitoring was performed but the results are not yet available, the remaining packages from the same load should be quarantined and should not be used until the BI results are obtained.

What Does a Failed Internal Chemical Indicator Represent?

ANSI/AAMI ST58: 9.5.3.3 Nonresponsive or inconclusive chemical indicators

(reference for the user – direct quote)

Rationale:

If a CI is nonresponsive or inconclusive, it is possible that the entire load is nonsterile (i.e., the sterilization process failed).

It is also possible that errors in loading or packaging have resulted in sterilization failures in some, but not all, packages in the load.

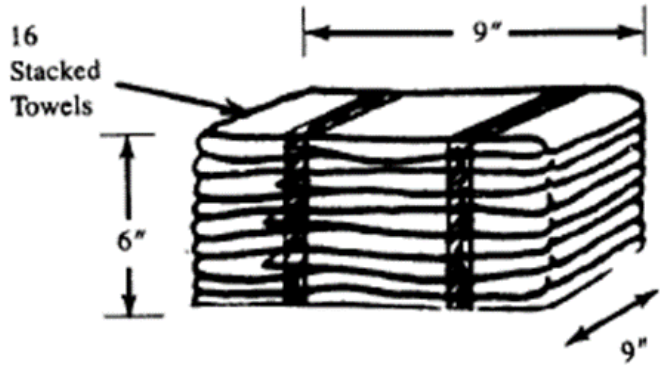
Therefore, a single nonresponsive or inconclusive CI should not be considered definitive evidence that the entire load is nonsterile.

The supervisor should exercise professional judgment in determining whether to recall the entire load, taking into account all factors having a bearing on the efficacy of the cycle and all performance indicators.

Steam and VH2O2 Process Challenge Devices

Process Challenge Device

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.



AAMI ST79:2017 *Section 13.5.3.1 and AAMI ST58:2013 Section 9.5.4.1*

Process Challenge Devices (PCDs)

Steam ✓

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

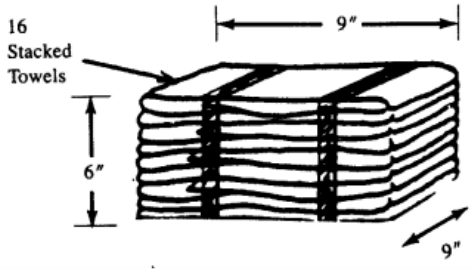


Figure 8—Preparation of the 16 towel PCD (BI challenge test pack)

EO ✓

ANSI/AAMI ST41:2008
Example…EO routine BI test pack

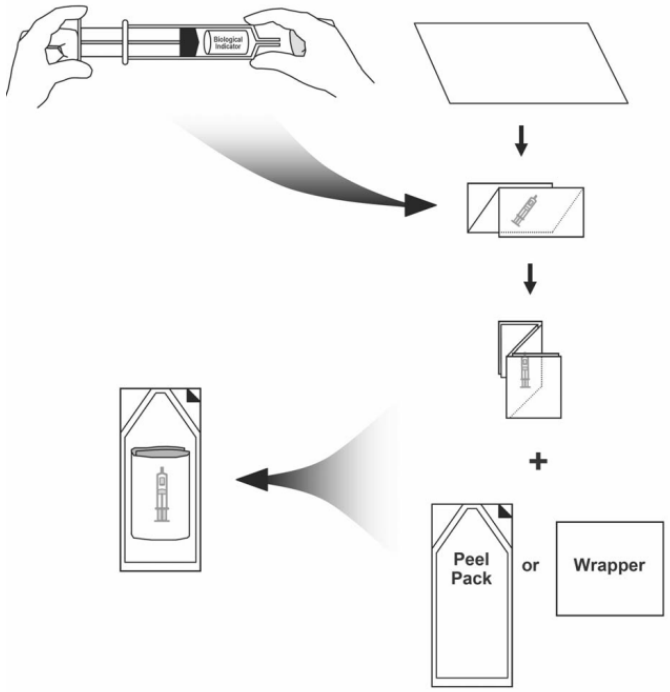


Figure 3—Preparation of the PCD (routine BI test pack) (drawing not to scale)

VH2O2 ?

ANSI/AAMI ST58:2013
No example

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

Process Challenge Devices (PCDs)

Steam

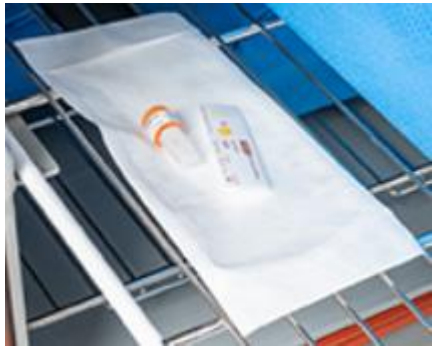
Common commercially available BI PCD example

EO

Common commercially available BI PCD example

VH2O2

Commonly used BI quality monitoring methods



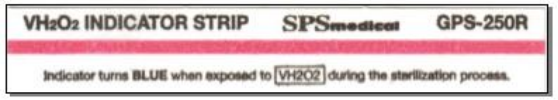
U.S. FDA clearance required for process challenge device or test pack.

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.

Common BI quality monitoring tools used in VH2O2.

BIs in pouch or bare BI.

Internal Pack CIs and BIs in VH2O2 Sterilization



Pack Control

- CIs play a different role.
- CIs are located inside packages in load.
- Performance Specifications are defined by ISO per Type (ISO 11140-1:2014).
- ANSI/AAMI ST58:2013 9.5.3.1…*assist in the detection of potential sterilization failures incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer.*

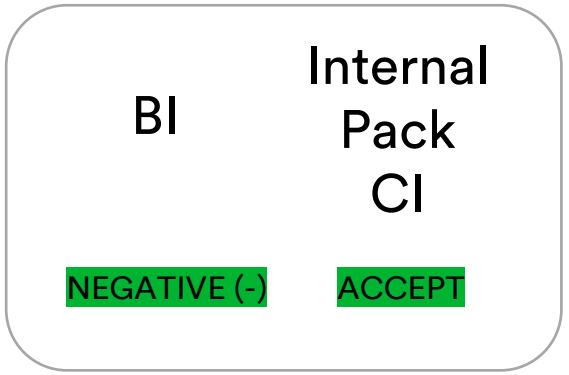
Load Control

- BIs play a different role.
- BIs located in (pouch/bare) in chamber space.
- Performance Specifications not currently defined by ISO Standards.
- ANSI/AAMI ST58:2013 9.5.4.1…*are intended to demonstrate whether the conditions were adequate to achieve sterilization.*

U.S. FDA cleared VH2O2 internal CIs for use in the U.S. Manufacturer labelled as Type 4 for VH2O2 sterilization

Review Possible Outcomes 1:

On the same VH2O2 sterilized load, SPD department observes a negative BI.
OR observes an ACCEPT internal pack CI.



a) This is an expected outcome.

b) Everything was properly prepared and delivered.

c) All items in the load are sterile.

d) These are two important outcomes for assurance of sterility.

e) Both A and D.

Review Possible Outcomes 1:

On the same VH2O2 sterilized load, SPD department observes a negative BI.
OR observes an ACCEPT internal pack CI.

BI	Internal Pack CI
NEGATIVE (-)	ACCEPT

a) This is an expected outcome.

~~b) Everything was properly prepared and delivered.~~

~~c) All items in the load are sterile.~~

d) These are two important outcomes for assurance of sterility.

e) Both A and D. 

Review of Possible Outcomes 1

BI	Internal Pack CI
NEGATIVE (-)	ACCEPT

On the same VH2O2 sterilized load, SPD department observes a negative BI. The OR observes an ACCEPT internal pack CI.

- This is an expected outcome and are two important outcomes for assurance of sterility.
- Monitoring tools assist in detecting when something went wrong (not that everything was properly prepared and delivered).
- Assurance of sterility is comprised of all activities that provide confidence that product is sterile (not just these two results).
- There is no practical way to confirm all items in the load are sterile.

Review Possible Outcomes 2:

On the same VH2O2 sterilized load, SPD department observes a positive BI and a **REJECT** internal pack CI.

BI	Internal Pack CI
POSITIVE (+)	REJECT

a) This is a possible outcome.

b) Load should be rejected, reprocessed, supervisor notified.

c) Can only happen if sterilizer printout failed.

d) OK to release load if the sterilizer printout was a PASS.

e) Both A and B.

Review Possible Outcomes 2:

On the same VH2O2 sterilized load, SPD department observes a positive BI and a **REJECT** internal pack CI.

BI	Internal Pack CI
POSITIVE (+)	REJECT

a) This is a possible outcome.

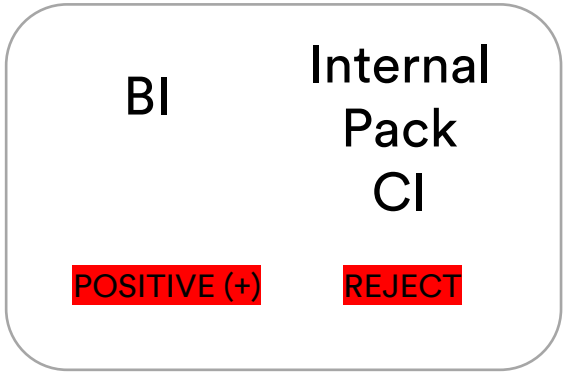
b) Load should be rejected, reprocessed, supervisor notified.

~~c) Can only happen if sterilizer printout failed.~~

~~d) OK to release load if the sterilizer printout was a PASS.~~

e) Both A and B.

Review Possible Outcomes 2:

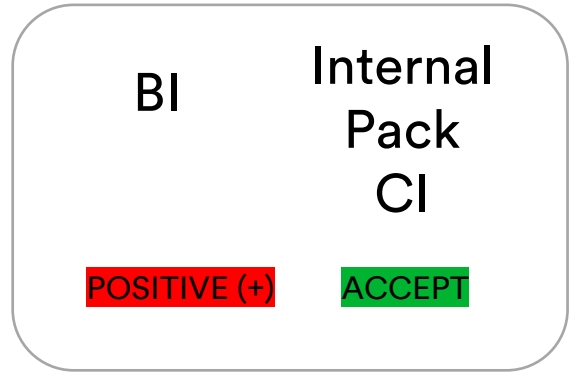


On the same VH2O2 sterilized load, SPD department observes a positive BI and a REJECT internal pack CI.

- This a possible outcome and the load should be rejected and reprocessed, and supervisor should be notified.
- It is very possible the sterilizer printout can PASS, but the BI and internal CI fail. In VH2O2 sterilization, all 3 tools are monitoring different locations of the process, and they play different roles in assurance of sterility.
- It is never OK release the load with a positive BI and a REJECT internal pack CI, irrelevant of the sterilizer printout result.

Review Possible Outcomes 3:

On the same VH2O2 sterilized load, SPD department observes a positive BI and ACCEPT internal pack CI.



a) Not a possible outcome; both should fail.

b) Load should be rejected, reprocessed, and supervisor notified.

c) Possible outcome; BI & CI different performance spec's.

d) Possible outcome; BI & CI different locations in process.

e) All three B, C, and D.

Review Possible Outcomes 3:

On the same VH2O2 sterilized load, SPD department observes a positive BI and ACCEPT internal pack CI.

BI	Internal Pack CI
POSITIVE (+)	ACCEPT

~~a) Not a possible outcome; both should fail.~~

b) Load should be rejected, reprocessed, and supervisor notified.

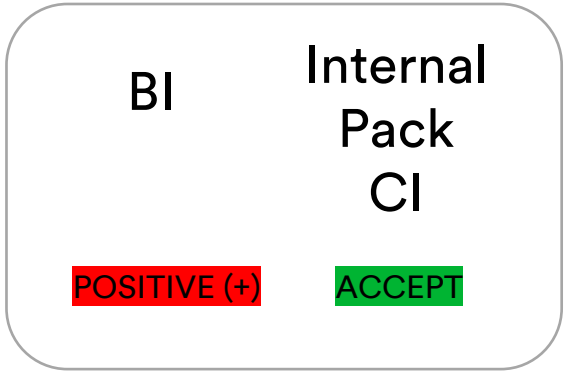
c) Possible outcome; BI & CI different performance spec's.

d) Possible outcome; BI & CI different locations in process.

e) All three B, C, and D.

Review Possible Outcomes 3:

On the same VH2O2 sterilized load, SPD department observes a positive BI and ACCEPT internal pack CI.



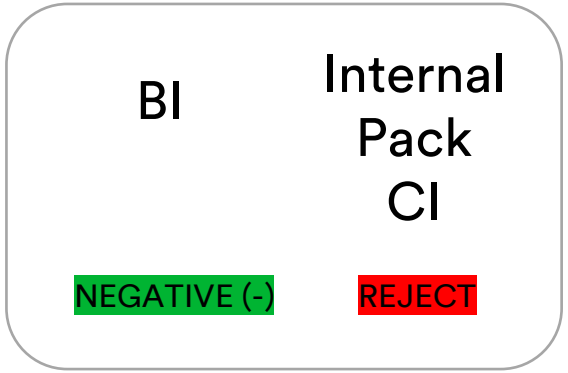
This is a very real outcome:

- Internal CIs and BIs play different roles in assurance of sterility.
- The BI and internal pack CI have different performance specifications.
- The BI and internal pack CI monitor different locations of the process.

- When the BI, monitoring the efficacy of the cycle fails, the load should be rejected and reprocessed, and supervisor should be notified.
- It is never OK to release the pack with the ACCEPT internal pack CI when the BI monitoring the efficacy of the same cycle failed.

Review Possible Outcomes 4:

On the same VH2O2 sterilized load, SPD department observes a negative BI.
OR observes a REJECT internal pack CI.



a) This outcome is not possible.

b) The pack with REJECT CI; reject pack and reprocess.

c) Possible outcome; BI & CI different performance spec's.

d) Possible outcome; BI & CI different locations in process.

e) All three B, C, and D.

Review Possible Outcomes 4:

On the same VH2O2 sterilized load, SPD department observes a negative BI.
OR observes a REJECT internal pack CI.

BI	Internal Pack CI
NEGATIVE (-)	REJECT

~~a) This outcome is not possible.~~

b) The pack with REJECT CI; reject pack and reprocess.

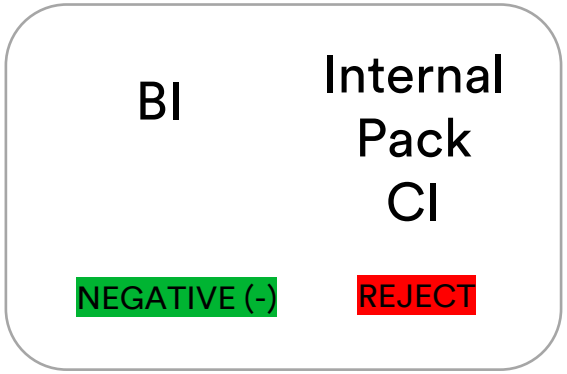
c) Possible outcome; BI & CI different performance spec's.

d) Possible outcome; BI & CI different locations in process.

e) All three b), c), and d). ✓

Review Possible Outcomes 4:

On the same VH2O2 sterilized load, SPD department observes a negative BI.
OR observes a REJECT internal pack CI.



This is a very real outcome:

- Internal CIs and BIs play different roles in assurance of sterility.
- The BI and internal pack CI have different performance specifications.
- The BI and internal pack CI monitor different locations of the process.

- A negative BI does not assure the sterility of the load.
- The BI monitors the efficacy of the cycle, the cycle's ability to inactivate a large population (> 1 million) of the most resistant microorganisms (bacterial spores).
- Assurance of sterility is comprised of all activities that provide confidence that product is sterile.
- REJECT CI reference ANSI/AAMI ST58: 9.5.3.3 Nonresponsive or inconclusive CIs.

Safe and Effective Use of VH2O2 in Healthcare

Top Priorities !

- Adhere to the sterilizer chamber loading weight limits.
  - Limits on weight and device types per models and cycles is complex!
  - Always refer to the sterilizer manufacturer's instructions for use.
- Adhere to loading weight limits for rigid containers.
- Assure packaging and devices are adequately dry.
- Double check the packaging is labelled for VH2O2 sterilization.
- Double check device is labeled for VH2O2 sterilization.
- Reduced or stop the use of extraneous materials in VH2O2.

Visit 3M.com and 3M Health Care Academy for recorded CE Webinars on VH2O2 sterilization and troubleshooting

Summary Learning Outcomes

- The goal of sterilization is to render product free from viable microorganisms. The goal is the same for steam and VH2O2 sterilization.
- Assurance of sterility is a qualitative concept comprising all activities that provide confidence that product is sterile.
- Steam and VH2O2 sterilization processes are designed differently. 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
- Currently AAMI and AORN monitoring recommendations are different between steam and VH2O2 sterilization.
  - **As an industry, we must raise the level of quality assurance monitoring for VH2O2 sterilization to what we expect for steam sterilization**
- Recently FDA cleared the very first multivariable CI for chemical sterilization (internal pack CI for VH2O2 sterilization; independently monitoring three critical variables).

Questions ?

References

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

ANSI/AAMI ST79:2017 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*

ANSI/AAMI ST58:2013 *Chemical sterilization and high-level disinfection in health care facilities*

Association of periOperative Registered Nurses (AORN) Perioperative Guidelines for Sterilization (2020)

ISO 11140-1:2014 *Sterilization of health care products — Chemical indicators — Part 1: General Requirements*

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Evaluation of a number of sterilization chemical indicators for monitoring vaporized hydrogen peroxide sterilization processes, Dr. Brian Kirk, Zentralsterilization, August 2020)

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Russel, Hugo, and Ayliffes. Sterilization. *Principles and Practice of Disinfection, Preservation and Sterilization*, 4th ed, 2004, Chapter 12, Blackwell Publishing, MA

Thank you !