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VH2O2

Technical information sheet

3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD

Product description

The 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD (referred to hereinafter as the 1295PCD and/or challenge pack) is designed as a standard method of rapid and reliable routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes. Each challenge pack contains a 3M™ Attest™ Rapid Readout Biological Indicator 1295 (pink cap, referred to hereinafter as the 1295 BI) and a 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348 (referred to hereinafter as the 1348 CI) (Figure 1). The 1295PCD is a single-use device.

Figure 1. 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD components

3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD

3M™ Attest™ Rapid Readout Biological Indicator 1295

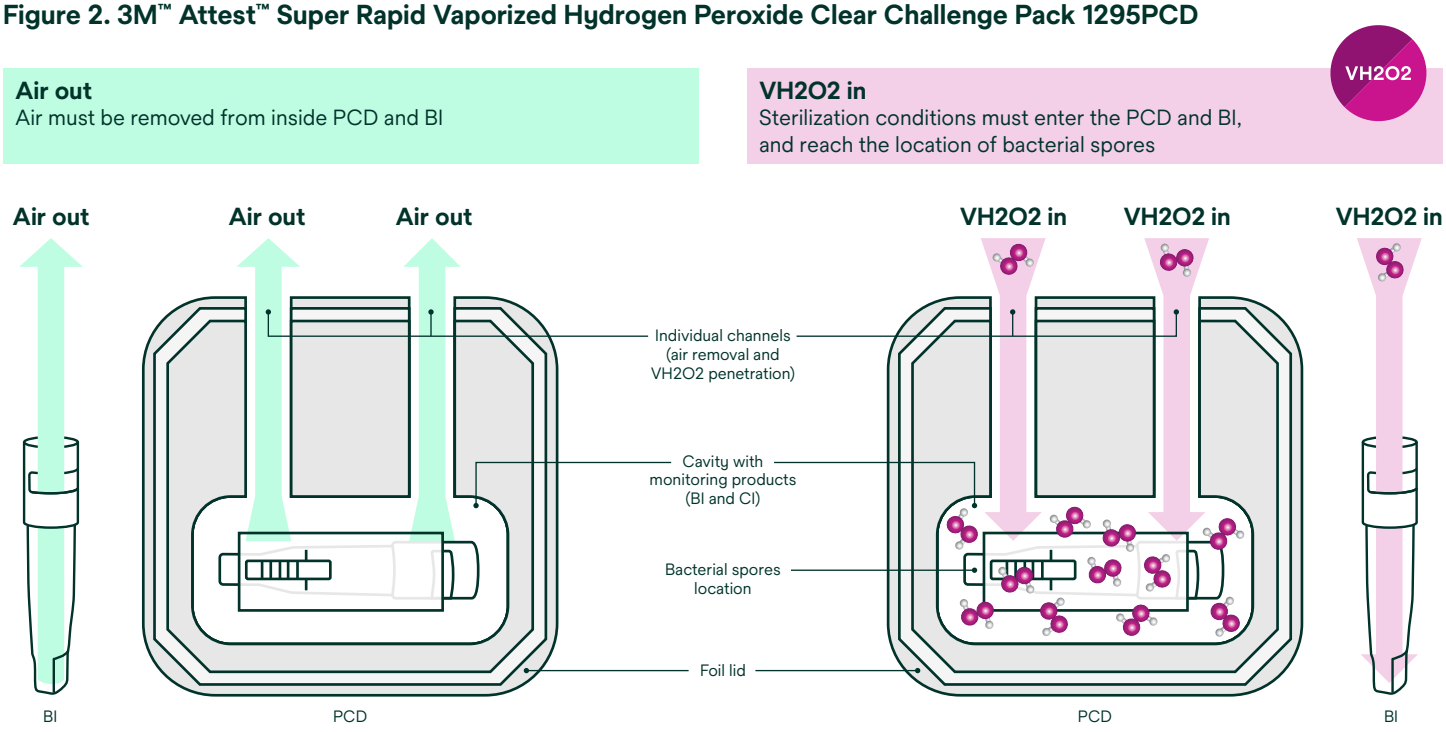
3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348

Technical design

The physical design of the 1295PCD provides a 1295 BI and 1348 CI (Type 4 CI) in a self-contained configuration (PCD) that allows a consistent and defined challenge which provides a higher level of quality assurance monitoring of vaporized hydrogen peroxide sterilization cycles as compared to standalone BIs or BIs placed in sterilization peel pouches. The 1295PCD design also eliminates the need to purchase and use pouches and assemble the BI and CI in a pouch.

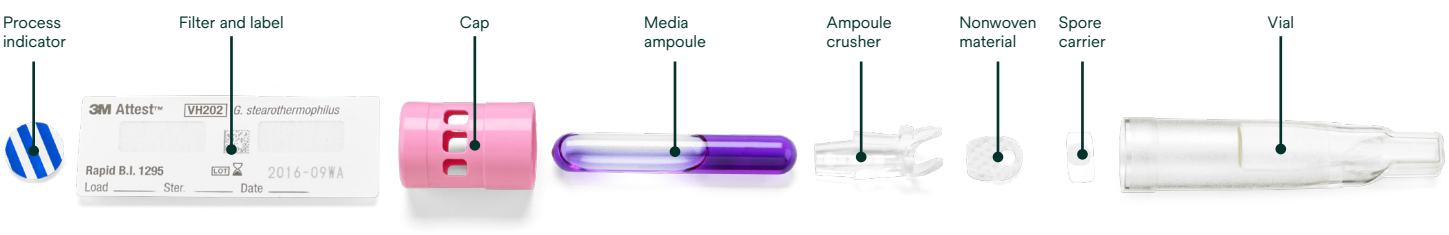
The design mimics the challenge of air removal and vaporized hydrogen peroxide penetration posed by individual devices, individual packages, and device loads. It consists of a clear plastic shell, with two individual channels. The two individual channels connect to a cavity containing the monitoring products and all are covered by a foil lid (Figure 2).

Figure 2. 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD



The 1295 BI (see Figure 3) is a self-contained biological indicator specifically designed for rapid and reliable routine monitoring of vaporized hydrogen peroxide sterilization processes when used in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater (hereinafter referred to as the 490 Auto-reader having software version 4.0.0 or greater) or a 3M™ Attest™ Mini Auto-reader 490M (hereinafter referred to as the 490M Auto-reader) or a 3M™ Attest™ Auto-reader 490H (hereinafter referred to as the 490H Auto-reader). See Figure 4 and Figure 5 for images of the 490M and 490. The 1295 BI is a single-use device.

Figure 3. Component diagram of 3M™ Attest™ Rapid Readout Biological Indicator 1295



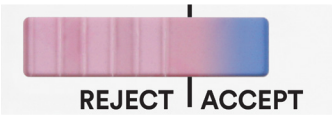
The rapid readout result has been correlated with a 7-day visual pH color change result following the FDA's Reduced Incubation Time protocol. The time to result is determined by the software version programmed on the Auto-reader. 1295 BIs incubated in a 490 or 490H Auto-reader having software version 4.0.0 or greater or 490M Auto-reader have a 24-minute reduced incubation time result that correlates to the 7 day (168 hours) visual readout result ≥97% of the time. Please reference the instructions for use for additional information on the use of the 1295 BI.

Figure 4. Image of the 3M™ Attest™ Mini Auto-reader 490M

Figure 5. Image of the 3M™ Attest™ Auto-reader 490

The 1348 CI is a chemical indicator consisting of a non-cellulose based coated indicator strip sensitive to vaporized hydrogen peroxide, contained in a film laminate. The 1348 CI verifies that the stated values for the three critical parameters of exposure time, temperature, and concentration of vaporized hydrogen peroxide have been achieved. Upon exposure to vaporized hydrogen peroxide, the color of the coated indicator strip progressively changes from blue to pink along the strip. The progression of the blue to pink color change along the strip is visible through a window marked "REJECT" and "ACCEPT" zones. The extent of the progression depends on exposure time, temperature, and concentration of vaporized hydrogen peroxide (see example interpretation of 1348 CI in Figure 6). The 1348 CI is a single-use device. The 1348 CI is a Type 4 indicator as categorized by ISO 11140-1:2014.

Figure 6. Interpretation chart for 3M™ Attest™ Vaporized Hydrogen Peroxide Tri-Metric Chemical Indicator 1348

Unprocessed	Acceptable processed PASS	Unacceptable processed FAIL
		
		
	If a color change to pink has entered the ACCEPT zone, it is considered a pass.	If a color change to pink has not entered the ACCEPT zone, it is considered a fail. Please reference the instructions for use for additional information.

Indications for use

United States

Use the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or a 3M™ Attest™ Mini Auto-reader 490M or a 3M™ Attest™ Auto-reader 490H as a standard method of routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes in the follow systems:

System	Cycles
STERRAD 100S® Sterilization System	Default cycle
STERRAD NX® Sterilization System	Standard and Advanced cycles
STERRAD 100NX® Sterilization System	Standard, Flex, Express, and Duo cycles
STERRAD NX® with ALLClear® Technology Sterilization System	Standard and Advanced cycles
STERRAD 100NX® with ALLClear® Technology Sterilization System	Standard, Flex, Express,and Duo cycles
V-PRO® 1 Low Temperature Sterilization System	Lumen cycle
V-PRO® 1 Plus Low Temperature Sterilization System	Lumen and Non Lumen cycles
V-PRO® maX Low Temperature Sterilization System	Lumen, Non Lumen, and Flexible cycles
V-PRO® 60 Low Temperature Sterilization System	Lumen, Non Lumen, and Flexible cycles
V-PRO® maX 2 Low Temperature Sterilization System	Lumen, Non Lumen, Flexible, and Fast Non Lumen cycles
V-PRO® s2 Low Temperature Sterilization System	Lumen, Non Lumen, Flexible, and Fast cycles
SteroScope® Sterilization System	Default cycle

Outside the United States

In countries outside of the U.S. where this product is exempt from pharmaceutical and medical device laws, regulations, and regulatory oversight you may elect to use the device in the following:

Use the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD in conjunction with the 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater or a 3M™ Attest™ Mini Auto-reader 490M or a 3M™ Attest™ Auto-reader 490H as a standard method of routine monitoring and performance qualification (operational and performance) and for process validation of vaporized hydrogen peroxide sterilization processes.

Performance characteristics

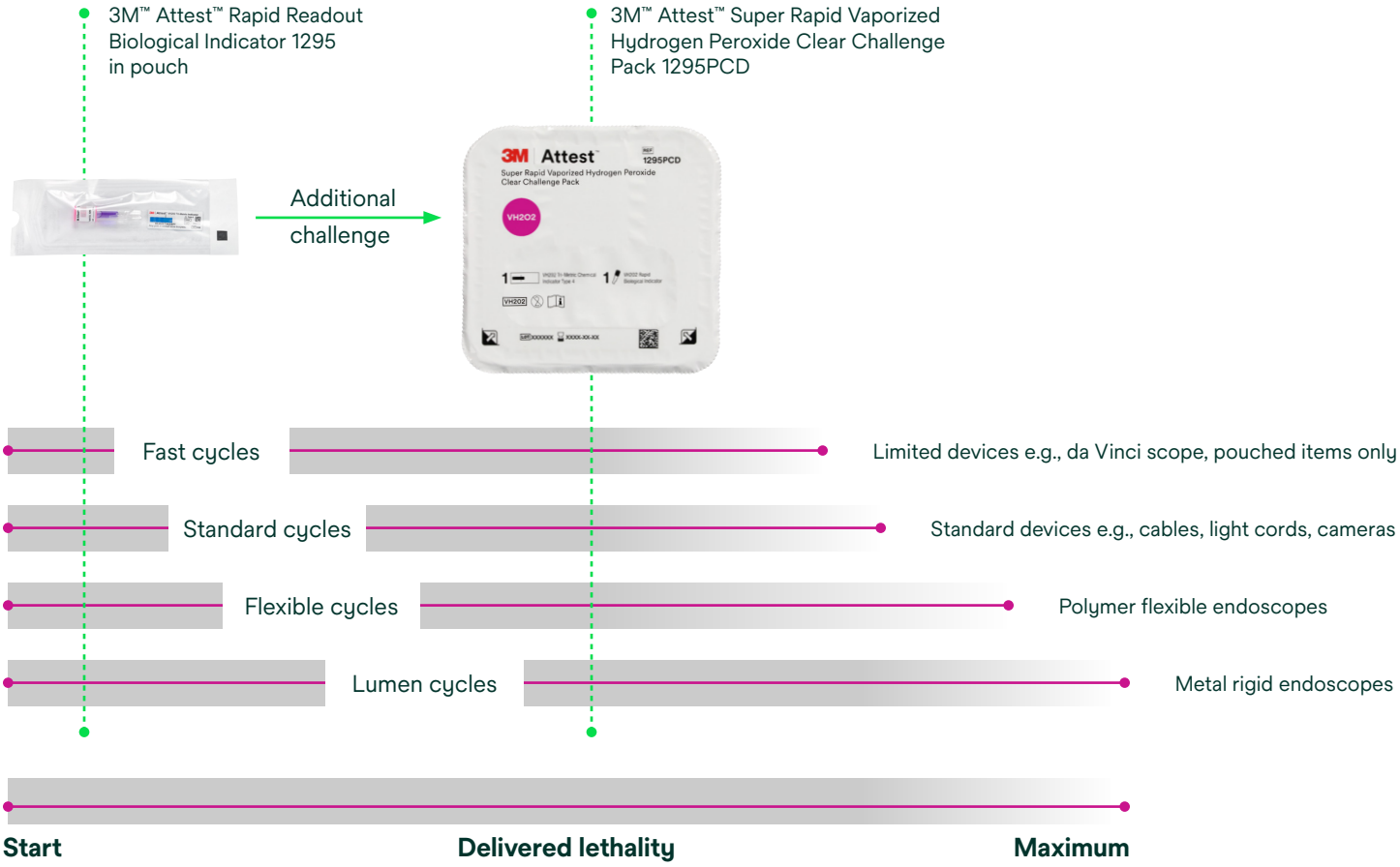
As documented in the Indications for Use, the 1295PCD has been currently validated and demonstrated compatible in 31 vaporized hydrogen peroxide sterilization cycle types, 12 models of vaporized hydrogen peroxide sterilizers, and across three different manufacturers of sterilizers.

Standards and guidelines lack applicable performance requirements for PCDs used in monitoring VH2O2 sterilization in healthcare. The 1295PCD is first of its kind in healthcare. The evolution of the design of the 1295PCD began with assessing the performance of 30 vaporized hydrogen peroxide sterilization cycle types to understand the vaporized hydrogen peroxide conditions to obtain sterilization. After understanding the many vaporized hydrogen peroxide sterilization conditions used in clinical settings, iterations of the 1295PCD design evolved through several concepts (e.g., one channel vs two channels) and versions during bench testing and clinical evaluation activities to establish the challenge of the 1295PCD. After the design was frozen and successful design verification, clinical field testing was performed to characterize the performance and demonstrate compatibility of the 1295PCD in 31 vaporized hydrogen peroxide sterilization cycle types, 12 models of vaporized hydrogen peroxide sterilizers, and across three different manufacturers of sterilizers. Finally, the 1295PCD design was validated to demonstrate the consistent and defined challenge of the 1295PCD.

The 1295PCD provides the same consistent and defined challenge to each cycle type that is monitored, but different vaporized hydrogen peroxide sterilization cycles deliver different sterilization conditions based on the cycle type. This fact applies to vaporized hydrogen peroxide sterilization cycles globally. This concept is illustrated in Figure 7. Please note the diagram contains examples as estimates for illustrative purposes only.

In **Figure 7** the gray lines represent the nominal delivered lethality of a vaporized hydrogen peroxide sterilization cycle. Vaporized hydrogen peroxide cycle types are designed to sterilize different device types (e.g., metal lumened rigid endoscopes for a Lumen cycle or polymer lumened flexible endoscopes for a Flexible cycle). Therefore, vaporized hydrogen peroxide cycle types deliver different sterilization conditions to the devices in the load. In the example in Figure 7, Lumen Cycles are designed to deliver more lethality to the load, pack, and devices as compared to Fast Cycles, Standard Cycles and Flexible Cycles. The Flexible cycles are designed to deliver more lethality to the load, pack, and devices as compared to Fast Cycles, Standard Cycles but not Lumen cycles. Furthermore, the gradient in the gray lines represents (as an example illustration) the possible variation in the delivered lethality of the cycle. This variation in delivered lethality results from a combination of factors, including but not limited to cycle-to-cycle performance, variation introduced by the sterilizer operator and the sterile processing environment. Vaporized hydrogen peroxide sterilization cycles are technique sensitive where the operator of the sterilizer, the one loading the sterilizer chamber and selecting the cycle type, has a significant impact on the outcome of the sterilization cycle. Operator variables that have a significant impact on the success of the vaporized hydrogen peroxide sterilization cycle include but not limited to the load weight, packaging type and material composition, device type and material composition, the moisture content of the load items, and the overall temperature of the load at the beginning of the cycle.

Figure 7. Delivered cycle lethality and defined challenge of the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD



The diagram contains examples as an estimate for illustrative purposely only. Always follow device manufacturer's instructions for use for processing.

Design verification activities, clinical field testing, and design validation to establish the consistent and defined challenge of the 1295PCD required extensive performance testing. Table 1 outlines the extensive performance data generated as part of the required testing for the U.S. FDA clearance and to demonstrate the overall appropriateness and compatibility of the 1295PCD to monitor and qualify vaporized hydrogen peroxide sterilization processes.

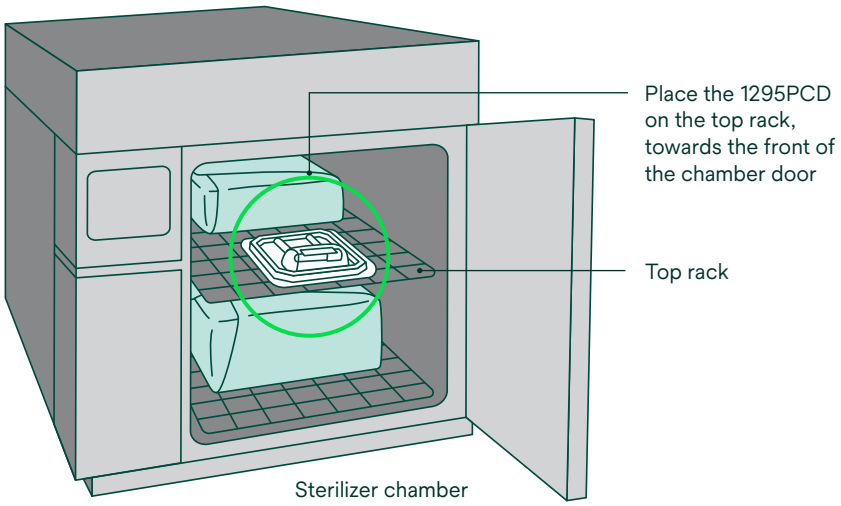
Table 1. 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD performance testing for appropriateness and compatibility

Performance test	Reference standard/ document	Purpose of the performance testing	Sample size	Acceptance criteria	Results
Seal strength and peel force of the 1295PCD foil lid[3]	ASTM F88/ F88M-15: Standard Test Method[4]	Demonstrate the acceptable mechanical seal strength and the peel force of the 1295PCD heat sealed foil lid.	Multiple foil lots and multiple polypropylene lots with statistically significant test sample sizes.	≥8.5lbF and ≤20lbF lbF = pounds force	PASS
	ASTM F2824-10: Standard Test Method[5]	Demonstrate the acceptable mechanical seal strength and the peel force of the 1295PCD heat sealed foil lid.	Multiple foil lots and multiple polypropylene lots with statistically significant test sample sizes.	≥8.5lbF and ≤20lbF lbF = pounds force	PASS
Functionality — Characterization of the Consistent and Defined Challenge of the 1295 PCD[6]	U.S. FDA Guidance[7] and ANSI/AAMI/ISO 11138-1:2017[8]	Demonstrate the 1295 BI and 1348 Tri-Metric CI inside the 1295PCD have a greater challenge to the sterilization process vs. the standalone 1295 BI and 1348 Tri-Metric CI.	Multiple lots of 1295PCDs with multiple 1295 BI lots and multiple 1348 Tri-Metric CI lots. Statistically significant test sample sizes.	Fractional vaporized hydrogen peroxide exposure cycles demonstrate 1295 BI and 1348 Tri-Metric CI inside the 1295PCD have a greater challenge to the sterilization process vs. the standalone 1295 BI and 1348 Tri-Metric CI.	PASS
Functionality — Characterization of the Consistent and Defined Challenge of the 1295 PCD[6]	U.S. FDA Guidance[7] and ANSI/AAMI/ISO 11138-1:2017[8]	Demonstrate the acceptable Survival of the 1295PCD in a minimum exposure time performance cycle.	Multiple 1295 BI lots. Multiple 1348 Tri-Metric CI lots. Statistically significant sample sizes. Ongoing testing for each new 1295PCD lot.	All 1295 BIs Survive/Positive All 1348 Tri-Metric CIs Reject/Fail	PASS
		Demonstrate the acceptable Kill of the 1295PCD in a maximum exposure time performance cycle.	Multiple 1295 BI lots. Multiple 1348 Tri-Metric CI lots. Statistically significant test sample sizes. Ongoing testing for each new 1295PCD lot.	All 1295 BIs Inactivated/Negative All 1348 Tri-Metric CIs Accept/Pass	PASS
Functionality — Characterization of the Consistent and Defined Challenge of the 1295 PCD[9]	U.S. FDA Guidance[7]	Demonstrate the appropriateness and compatibility of the 1295PCD in all indicated vaporized hydrogen peroxide sterilizers and cycles in a full cycle during clinical field testing.	Multiple 1295 BI lots. Multiple 1348 Tri-Metric CI lots. Statistically significant test sample sizes.	All 1295 BIs Inactivated/Negative All 1348 Tri-Metric CIs Accept/Pass	PASS
		Demonstrate the appropriateness and compatibility of the 1295PCD in all indicated vaporized hydrogen peroxide sterilizers and cycles in a fractional exposure cycle during clinical field testing.	Multiple 1295 BI lots. Multiple 1348 Tri-Metric CI lots. Statistically significant test sample sizes.	All 1295 BIs exhibit appropriate fractional response. All 1348 Tri-Metric CIs exhibit appropriate fractional response.	PASS

Placement in the sterilizer

The 1295PCD provides a consistent and defined challenge for every cycle that is monitored. Since different vaporized hydrogen peroxide cycle types deliver different sterilization conditions, the 1295PCD has been designed, verified, and validated for placement in a standardized location in vaporized hydrogen peroxide sterilizer chambers (see Figure 8). The 1295PCD is placed on the top rack or shelf in the sterilizer chamber, towards the front of the chamber door for each cycle type monitored. Standardized placement provides two benefits: (1) balances (level sets) the defined challenge across different sterilization conditions. The additional challenge provided by the placement in the worst-case chamber location is already designed into the challenge of the 1295PCD (2) simplifies and standardizes the use of the 1295PCD.

Figure 8. Standardized placement of the 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD in the loaded sterilizer chamber



Use in performance qualification and process validation (in addition to routine monitoring)

The 1295PCD is designed as a standard method of rapid and reliable routine monitoring and performance qualification of vaporized hydrogen peroxide sterilization processes. The 1295PCD has been U.S. FDA cleared for performance qualification of vaporized hydrogen peroxide sterilization processes listed in the Indications for Use. The definition of performance qualification of sterilization processes varies globally. Outside the U.S. the 1295PCD can be used in performance qualification (operational and performance) and for process validation of vaporized hydrogen peroxide sterilization processes.

ANSI/AAMI ST58:2024[10] *Chemical Sterilization and High-Level Disinfection In Health Care Facilities* provides guidance for the vaporized hydrogen peroxide sterilizer qualification test procedure with BIs (section 8.6.5.5.1). Per AAMI ST58 all gaseous chemical sterilizers should be tested using BI PCDs upon installation, relocation, sterilizer malfunctions, major repairs, and sterilization process failures that were not resolved successfully. *Sterilizer testing after installation, relocation, and major repairs should be conducted by the Sterilizer Service Technician providing guidance in collaboration with the healthcare facility. The testing should be performed between the time the sterilizer is installed, relocated, or repaired and the time it is released for use or returned to service in the health care facility. Personnel should follow the sterilizer manufacturer's written IFU, which should include recommendations for use of an FDA-cleared BI and PCD, the location and method of placement of the BI PCD in the chamber, number of cycles to run and which cycle(s) should be tested. Testing should be performed in an empty chamber except for the BI PCD.*

Solventum can provide instructions on how to use the 1295PCD for the qualification of vaporized hydrogen peroxide sterilizers in U.S. healthcare facilities.

For use of the 1295PCD for performance qualification (operational and performance) and for process validation outside the U.S. follow your local or regional guidelines and standards. In some regions there are third party testing companies (contract testing companies) that can assistance in performance qualification (operational and performance) and process validation. Contact Solventum if there are questions on proposed protocols or procedures for this testing outside the U.S.

Associated and applicable standards

The 1295PCD complies with the definition of a PCD (also known as test pack) and may be used to facilitate compliance to the following standards.

- ANSI/AAMI ST58:2024, *Chemical Sterilization and High-Level Disinfection In Health Care Facilities*
- AORN, *Guidelines for Perioperative Practice*
- ISO 11138-1:2017, *Sterilization of health care products — Biological indicators — Part 1: General Requirements*
- ISO 11140-1:2014, *Sterilization of health care 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*
- CDC, *Guideline for Disinfection and Sterilization in Healthcare Facilities*, 2008 Update: May 2019
- *Guidance for Industry and FDA Staff Biological Indicator (BI) Premarket Notification [510(k)] Submissions* Document issued on: October 4, 2007
- ISO 22441:2020, *Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*
- ISO 11138-7:2019, *Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results*
- ISO 14937:2009, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation, and routine control of sterilization process for medical devices*
- ANSI/AAMI PCD TIR31:2003, *Process Challenge Devices/Test Packs For Use In Health Care Facilities*
- CAN/CSA Z314:23, *Canadian medical device reprocessing in all health care settings*
- AS 5369:2023, *Reprocessing of reusable medical devices and other devices in health and non-health related facilities*
- APSIC 2017, *Asia Pacific Society of Infection Control — The APSIC Guidelines for Disinfection and Sterilization of Instruments in Health Care Facilities*
- Japanese Society of Medical Instrumentation (JSMI), *Guideline for Sterility Assurance in Healthcare Setting* 2021
- WS310.3-2016, Health Industry Standard *The people's Republic of China Central sterile supply department (CSSD) — Part 3: Surveillance standard for cleaning, disinfection and sterilization*
- GB27955-2020 *Hygienic requirements for low-temperature hydrogen peroxide gas plasma sterilizer*
- Korean Association of Central Supply Department Nurse (KACSDN), *The 4th Korean Sterilization Monitoring Standard 2017*
- Korean Association of Operating Room Nurses (KAORN), *Sterilization Guideline for Operating Room 2020*
- Brasil. MS. ANVISA. RDC n° 15, 2012. *Establishes requirements for good practices in the processing of health products and provides for other measures*

The 1295PCD may be used to facilitate compliance with the standards listed above. Demonstration of the appropriateness of a PCD for any particular application may be required and may be performed through comparative resistance studies as documented in standards. Currently there are no standards that detail the methods to evaluate the performance of PCDs.

Recyclability

The clear plastic shell is made from polypropylene and is recyclable. However, recycling programs for this product may not exist in your area. The foil lid must be completely removed to recycle the polypropylene plastic shell.

Storage and shelf life

Store 1295PCD in the original foil pouch under normal room conditions: 59–86°F (15–30°C). To ensure the product functions as intended throughout the labeled shelf life, store 1295PCDs in the foil pouch until use. Use the remaining 1295PCDs within 8 weeks of opening the foil pouch to prevent long-term exposure to environmental conditions. **Do not** store 1295PCDs near sterilants or other chemicals.

The 1295PCD has a 2-year shelf-life from the date of manufacture. **Do not** use the 1295PCD past the expiration date printed on the label.

References

1. Instructions for Use 3M™ Attest™ Super Rapid Vaporized Hydrogen Peroxide Clear Challenge Pack 1295PCD Issue Date: 2023-03, rev. 2, 34-8729-7332-5.
2. ISO 11139:2018, *Sterilization of health care products — Vocabulary of terms used in sterilization and related equipment and process standards*.
3. 3M Report EM-05-980792.
4. ASTM F88 / F88M-15: Standard Test Method for Seal Strength of Flexible Barrier.
5. ASTM F2824 – 10: Standard Test Method for Mechanical Seal Strength Testing for Round Cups and Bowl Containers with Flexible Peelable Lids.
6. 3M Report EM-05-897492.
7. *Guidance for Industry and FDA Staff Biological Indicator (BI) Premarket Notification [510(k)] Submissions Document issued on: October 4, 2007.*
8. ISO 11138-1:2017, Sterilization of health care products — Biological indicators — Part 1: General Requirements.
9. 3M Report EM-05-890351
10. ANSI/AAMI ST58:2024 *Chemical Sterilization and High-Level Disinfection In Health Care Facilities*.

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