Terragene®

Bionova® PCD98
Biological Indicator | Process Challenge Device for VH2O2 Sterilization

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R00 | May 2026

1. Introduction

Effective sterilization monitoring in healthcare facilities is a critical component of infection prevention programs. For vaporized hydrogen peroxide (VH2O2) sterilization processes, the use of biological indicators (BIs) is essential to demonstrate process efficacy. However, current monitoring practices in many Sterile Processing Departments (SPDs) rely on standalone BIs placed inside sterilization pouches, a methodology that lacks standardization, introduces operator variability, and provides a lower level of process challenge than best practice guidelines recommend.

Terragene, introduces Bionova® PCD98, the first Terragene Process Challenge Device (PCD) designed specifically for VH2O2 sterilization monitoring. PCD98 integrates a Self-Contained Biological Indicator (SCBI) with a standardized process challenge architecture, delivering a defined, reproducible, and more rigorous challenge to the sterilization cycle, without the need for a sterilization pouch or manual assembly. Results are available in 5 minutes using the Bionova® Hyper auto-reader (BHY), with full digital traceability through the Bionova® Q platform.

2. Product Description

Bionova® PCD98 is a single-use, self-contained biological indicator (SCBI) and process challenge device (PCD) designed for vaporized hydrogen peroxide sterilization monitoring. Each PCD98 unit consists of:

- A polypropylene tube containing a spore-inoculated carrier (*Geobacillus stearothermophilus* ATCC® 7953)
- A glass ampoule containing liquid culture medium
- A colored plastic cap with a permeable barrier that allows VH2O2 penetration
- A process indicator printed on the label that changes from violet to green upon exposure to hydrogen peroxide

Key Product Specifications

Organism	*Geobacillus stearothermophilus* ATCC® 7953
Readout time (rapid)	5 minutes at 60 ± 2 °C (fluorescence detection)
Visual confirmation	5 days (color change) / 7 days (optional extended confirmation)
Reader / Incubator	Bionova® Hyper (BHY) auto-reader
Shelf life	2 years from date of manufacture
Storage conditions	10–30 °C, 30–80% RH, away from light and sterilizing agents
Digital integration	Bionova® Q platform (DataMatrix code on label)

3. PCD vs. Standalone Biological Indicator: Understanding the Difference

A critical distinction must be made between a standalone biological indicator and a process challenge device (PCD). While both use biological spores to assess sterilization efficacy, their challenge level, standardization, and clinical relevance differ significantly.

3.1 What Is a Process Challenge Device (PCD)?

Per ANSI/AAMI ST58:2024, a Process Challenge Device (PCD) is defined as a test pack containing a BI (or a BI and a CI) that is used to assess the effective performance of a sterilization process by providing a challenge to the process equal to or greater than the challenge posed by the most difficult item routinely processed.

This is a fundamentally different requirement from what a standalone BI in a sterilization pouch can provide. A PCD simulates the worst-case sterilization scenario, the most difficult device to sterilize, by creating physical barriers to sterilant penetration, air removal, and spore exposure. If the process is effective under these demanding conditions, it provides strong evidence that all items in the load were also adequately sterilized.

3.2 Comparison: Conventional Monitoring vs. PCD98

Parameter	Bionova® BT98 (BI in pouch)	Bionova® PCD98
Challenge level	Determined by pouch permeability	Defined by PCD architecture
Standardization	Variable: depends on pouch brand, assembly technique, operator	Fixed and reproducible by design
Assembly required	Yes, manual assembly of BI + pouch	No, ready to use
Result time	5 minutes (fluorescence)	5 minutes (fluorescence)
Process indicator	Integrated in BT98 label	Integrated in PCD98 label

4. The Challenge Concept: Why PCD98 Provides a Greater Assurance

The core principle behind a PCD is that it must simulate conditions equal to or more challenging than the most difficult device routinely sterilized. This concept, well-established in steam sterilization (Steam test packs - AAMI ST79), has historically been absent in VH2O2 monitoring.

In VH2O2 sterilization, the critical variables that determine cycle efficacy are: exposure time, temperature, and VH2O2 concentration. Any physical barrier, whether a lumen, tight packaging, or enclosed cavity, reduces the access of sterilant to the organism being tested. A standalone BI in a pouch is exposed to sterilant through a relatively permeable surface, whereas complex instruments (rigid endoscopes with long narrow lumens, cables, cameras) present far greater challenges to sterilant penetration.

4.1 How PCD98 Creates Its Challenge

PCD98 creates its defined and reproducible challenge through its self-contained architecture:
- The organism (*G. stearothermophilus* ATCC® 7953) is enclosed within a polypropylene tube sealed with a permeable barrier cap.
- The cap acts as a controlled diffusion barrier: VH2O2 must penetrate through this barrier to reach the spore carrier at the bottom of the tube (Figure 1).
- The geometry and material properties of the tube create a defined restriction to sterilant penetration, mimicking the challenge posed by instruments sterilized in daily practice.
- This architecture is fixed by design and manufacturing specifications, not dependent on operator technique or pouch brand.

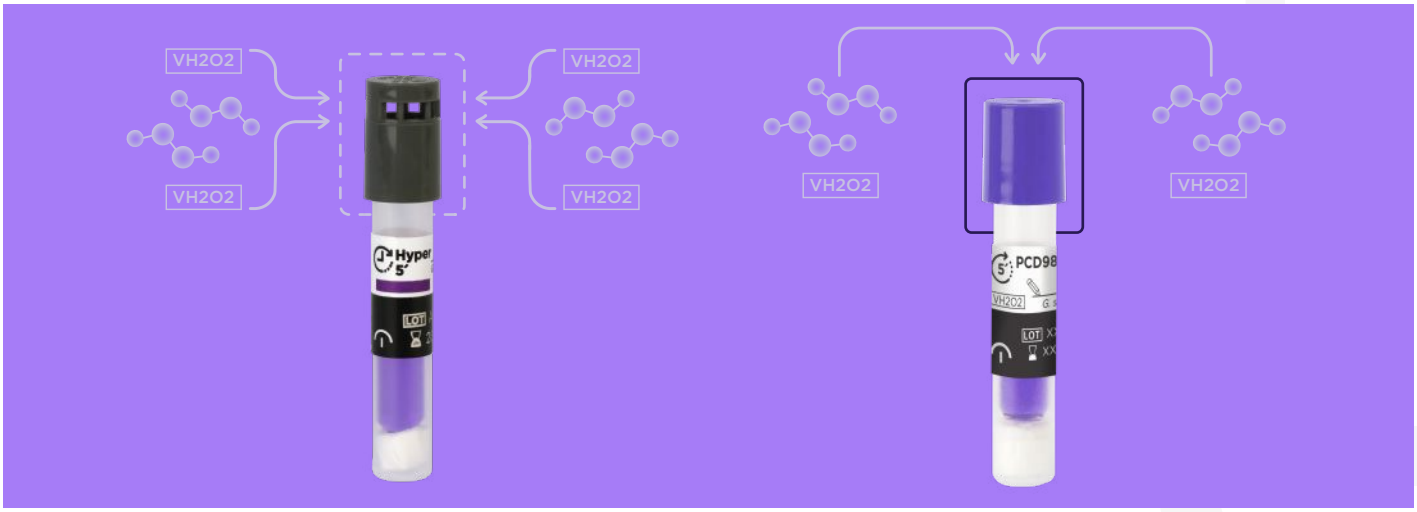

Figure 1. Comparison between PCD98 and BT98 cap design

The cap design of PCD98 is central to its function as a process challenge device. Because vaporized hydrogen peroxide exhibits relatively limited diffusion capacity compared to other sterilizing agents, a single pinhole-sized aperture is sufficient to create a meaningful and clinically relevant challenge. This restricted entry point imposes a controlled barrier that operates in both directions: during the vacuum phase of the sterilization cycle, air must evacuate the interior of the device through the same narrow pathway before sterilant can effectively reach the spore carrier; and during the exposure phase, VH2O2 must diffuse inward through that same constriction to contact the organism. Both processes, air removal and sterilant penetration, are simultaneously challenged by the pinhole geometry, making the overall sterilization demand on the device substantially greater than what a more open configuration would impose.

This dual restriction closely mirrors the challenge presented by cannulated or lumen-bearing instruments, one of the most demanding device categories in any VH2O2 sterilization load. In a narrow-lumen instrument, trapped air must first be displaced before sterilant can penetrate to the distal end; the longer, narrower, and more tortuous the lumen, the more demanding this process becomes. The pinhole aperture of PCD98 replicates this same physical dynamic in a standardized, reproducible format: a defined internal cavity from which air evacuation is restricted, and into which sterilant access is equally constrained. A passing result under these conditions provides meaningful evidence that the sterilization process was capable of overcoming the type of geometric challenge posed by the most difficult instruments routinely processed, which is precisely the purpose a process challenge device is designed to serve.

Challenge Principle: From Basic to High Confidence

The diagram below illustrates the challenge gradient across different monitoring approaches and device types in VH2O2 sterilization:

Monitoring Method	Challenge Level	Device Equivalent
Standalone BI (no pouch)	Basic	Simple, non-lumen items
BI in sterilization pouch	Moderate	Standard pouched items
Bionova® PCD98	**High – Standardized**	**Standard instruments, cables, cameras, scopes**

4.2 Why Challenge Standardization Matters

A fundamental limitation of the conventional approach (BI + pouch) is that the challenge level is not fixed. It depends on:

- The pouch manufacturer and material composition (plastic film thickness, vapor transmission rate, coating type)
- The pouch lot-to-lot variation (adhesive, laminate layers, process indicators)
- How the operator assembles the pouch (orientation, sealing) and the position within the sterilizer chamber (which may differ between operators and shifts)

In contrast, PCD98 is manufactured to fixed dimensional specifications from well-characterized materials (polypropylene tube, permeable cap), with no pouch, and no operator-dependent assembly step. Each unit provides the same defined challenge, cycle after cycle, at any facility.

5. Key Advantages of Bionova® PCD98

Ready to Use, No Pouch Required

PCD98 is used directly in the sterilizer without assembling a pouch. This eliminates a manual step prone to error and reduces preparation time in the SPD.

Greater, Standardized Challenge

PCD98 provides a higher and more consistent challenge than a standalone BI in a pouch. The challenge is defined by the device architecture, not by operator assembly or pouch brand.

5-Minute Results

Fluorescence-based detection with the Bionova® Hyper autoreader enables results in just 5 minutes, allowing faster load release decisions compared to conventional BI systems.

Integrated Process Indicator
A process indicator label (violet to green upon VH2O2 exposure) is integrated directly into PCD98. No separate chemical indicator is needed to verify sterilant contact.

Digital Traceability (Bionova® Q)
Each PCD98 carries a DataMatrix code enabling full digital integration with the Bionova® Q platform, automatic registration, audit-ready records, and reduced transcription errors.

Reproducible Placement
PCD98 is placed directly in the most challenging location in the chamber (as identified by the sterilizer manufacturer or by prior validation), without the need to construct a test pack or insert it in a tray.

Reduced Operational Variability
By eliminating manual assembly steps and pouch selection, PCD98 minimizes the sources of operator-dependent variability that can compromise monitoring reliability.

6. Instructions for Use. A Summary

The following summarizes the key steps for using Bionova® PCD98. Always refer to the complete Instructions for Use (IFU) document for full details, warnings, and precautions.

1. Label the PCD98 with the sterilizer number, cycle number, and date of processing.
2. Place PCD98 in the most challenging location of the sterilizer chamber, as identified by prior testing or the sterilizer manufacturer's instructions. Do NOT place inside a pouch or package.
3. Secure PCD98 to prevent displacement during the cycle. If using tape (Terragene® Cintape® CT40 only), do not cover the cap orifice or the process indicator on the label.
4. Run the sterilization cycle as usual.
5. After cycle completion, remove PCD98 wearing gloves and safety glasses. Verify the process indicator has changed from violet to green (sterilant contact confirmed). A non-colorchanged indicator should prompt investigation.
6. Activate PCD98 by crushing the glass ampoule using the individual ampoule crusher provided or the crusher on the Bionova® Hyper auto-reader. Shake vigorously downward to fully wet the spore carrier.
7. Incubate the processed PCD98 and a positive control (unprocessed unit from the same lot) in the Bionova® Hyper auto-reader at 60 ± 2 °C for a maximum of 5 minutes.
8. Read the result: fluorescence detected = sterilization FAIL (positive). No fluorescence = sterilization PASS (negative). The positive control must show a positive result for the test to be valid.
9. Record results and discard used units per local waste disposal regulations.

7. Regulatory and Standards Alignment

7.1 Standards PCD98 Complies With

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

7.2 Standards Whose Compliance PCD98 Facilitates

ANSI/AAMI ST58:2024 Chemical sterilization and high-level disinfection in health care facilities — recommends BIs used within PCDs for routine VH2O2 monitoring

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 a sterilization process for medical devices

NOTE: PCD98 has been developed and validated following Terragene's rigorous internal validation framework, built upon the general principles established by the applicable international standards. Relative resistance characterization was conducted to confirm that PCD98 provides a consistently greater challenge to the VH2O2 sterilization process than a standalone biological indicator, supporting its intended use as a process challenge device. It is worth noting that, at present, no internationally harmonized technical protocol exists specifically for the functional evaluation of VH2O2 PCDs, a gap that reflects the novelty of this product category rather than any limitation of the device itself. In this context, Terragene's validation approach represents current best practice for this class of devices.

8. Integration with the Bionova® Hyper Ecosystem

PCD98 is not a disconnected product, it is the centerpiece of the Bionova® Hyper integrated solution for VH2O2 sterilization monitoring. Together, the components of this ecosystem deliver speed, accuracy, and digital traceability in every sterilization cycle.

Component	Product	Role
BI / PCD	Bionova® PCD98 (also BT98 standalone BI)	Standardized sterilization challenge and biological detection
Auto-reader	Bionova® Hyper (BHY)	Incubation at 60 ± 2 °C and 5-minute fluorescence readout
Digital platform	Bionova® Q	Automatic data capture, audit-ready records, full traceability per cycle

The DataMatrix code on each PCD98 label enables the Bionova® Q platform to automatically associate the BI result with the sterilizer, cycle, date, operator, and load data, creating a fully auditable digital record without manual transcription. This reduces human error, simplifies regulatory audits, and supports continuous quality improvement in the SPD.

9. Conclusion

Bionova® PCD98 represents a significant advance in VH2O2 sterilization monitoring, addressing three critical limitations of conventional BI-in-pouch approaches:

• Lack of standardization: PCD98 provides a fixed, reproducible challenge defined by device architecture, not operator technique.

• Insufficient challenge level: PCD98 provides a greater challenge than a standalone BI in a pouch, elevating confidence in sterilization assurance.

• Slow and fragmented workflows: PCD98 is ready to use, requires no assembly, delivers results in 5 minutes, and integrates digitally with Bionova® Q.

PCD98 is Terragene's first VH2O2 process challenge device and a key addition to the Bionova® Hyper ecosystem. It enables Sterile Processing Departments worldwide to align with ANSI/AAMI ST58:2024 best practice recommendations, reduce monitoring errors, and achieve full digital traceability, cycle by cycle, every day.