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# Unlock clarity in PCD standards & best practices

## 1 What exactly is a PCD?

A process challenge device (PCD) is an "item providing a defined resistance to a cleaning, disinfection or sterilization process and used to assess performance of the process." (ISO 11139)

**Why it's important:** The term PCD can refer to many different products and solutions, so it's important you know what type(s) of PCDs your facility uses and understand whether you're adhering to current industry best practices, not just basic standards.

## 2 What are PCD performance requirements, according to industry standards?

International standards for both steam sterilization (ISO 17665 [6]) and vaporized hydrogen peroxide (VH2O2) sterilization (ISO 22441 [7]) state that PCDs need to be validated for use. Importantly, however, international standards do not provide PCD design nor applicable performance requirements for healthcare facilities.

**Why it's important:** Not all PCDs are created equal. Accountability is on SPD teams to ensure they are selecting effective PCDs to match the needs of their equipment, their facility policies and procedures and the operational goals of their SPD.

If your facility is using PCDs, make sure you understand the cycle parameters of both the PCDs themselves, as well as the sterilizer equipment for which they are validated. Confirm the criteria matches what your facility requires.

## 3 What are the recommended uses of PCDs, according to industry standards?

According to international standards (ISO 11138-7 [9]), PCDs are designed so that the placement of the biological indicator within the PCD constitutes a location that is deemed to represent a suitably stringent challenge to the process. In other words, facilities may benefit from using PCDs that contain BIs within them, versus using standalone BIs.

**Why it's important:** It can be difficult to consistently ensure a standard challenge to the process when monitoring with standalone BIs. Using a PCD can streamline processes and help eliminate the variability in assembly from using a standalone BIs.

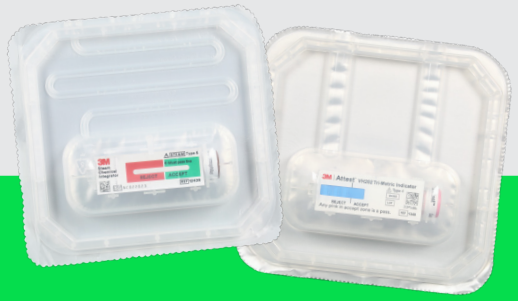
## 4 How often should PCDs be used, according to industry standards?

### Vaporized hydrogen peroxide (VH2O2) sterilization

In the United States, standards (AAMI ST58 [10]) recommend BIs within PCDs (or an FDA-cleared BI-containing quality monitoring device) be used for vaporized hydrogen peroxide (VH2O2) sterilization monitoring for each cycle type every day the sterilizer is in use, but preferably in every load, and for every load containing implants that have been cleared for low temperature sterilization. In other words, facilities should preferably be monitoring every non-implant load, as well as every applicable implant load, with a BI.

**Why it's important:** Using PCDs containing a BI (and in our case, a Type 4 Tri-Metric chemical indicator as well) for low-temperature, VH2O2 sterilization is an effective way to maintain quality and compliance.

In fact, we strongly recommend you monitor every load with a PCD, including both implant and non-implant loads.



## Why Solventum PCDs make a difference

- Our latest PCDs feature a contemporary lumen challenge design
- All of our latest PCDs contain a Type 5 chemical integrator (steam) or Type 4 Tri-Metric chemical indicator (VH2O2) in addition to a super-rapid biological indicator
- Our PCDs are validated for compatibility with most sterilizer cycles, brands and models
- Only Solventum indicators are backed by BSI Kitemark™ certification

bsi Sterilization Indicators KITEMARK™

### Dive deeper

See why so many manufacturers, SPD leaders and quality teams are re-evaluating how they select, validate and rely on PCDs.

**Scan to view our whitepaper and get more clarity on PCDs, standards and best practices.**

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