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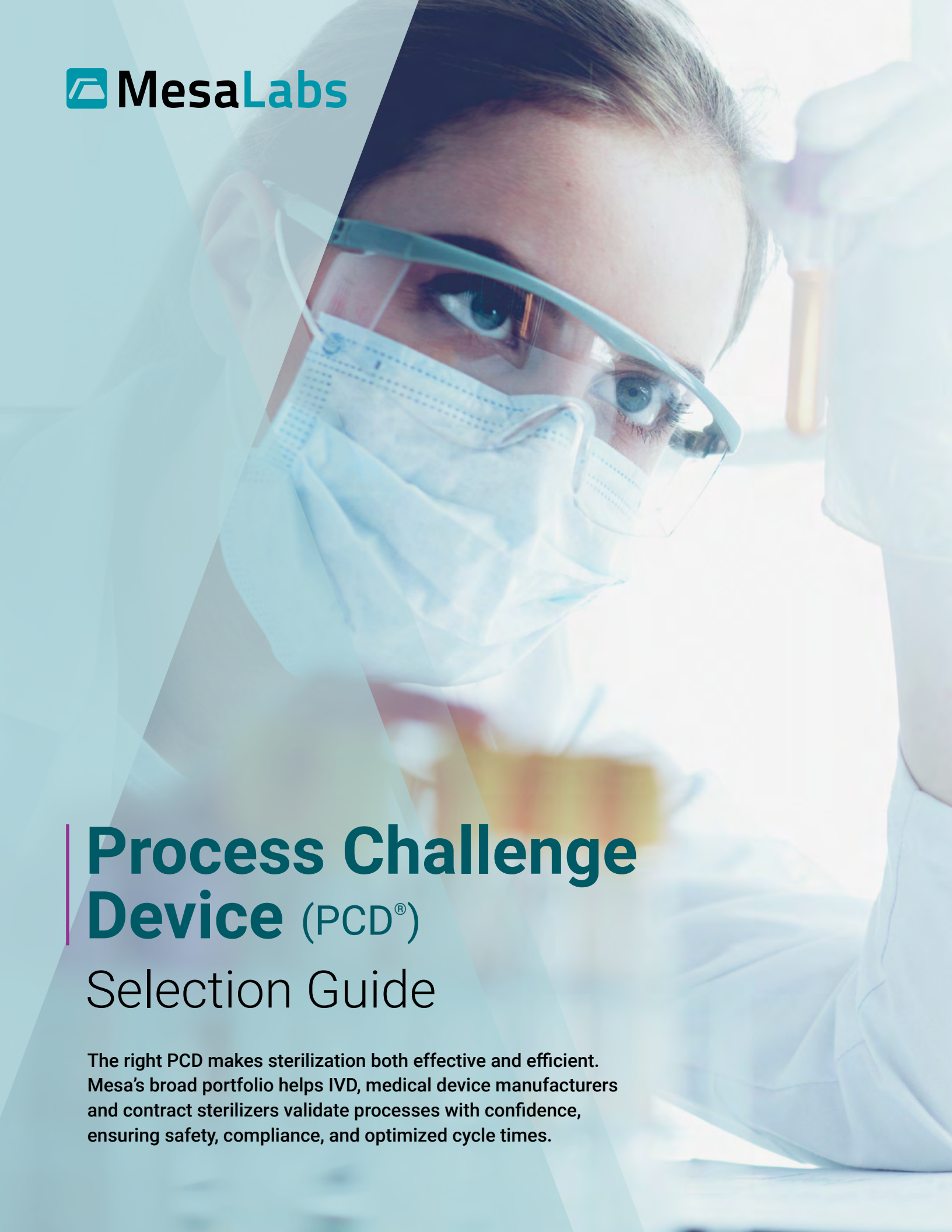


Process Challenge Device (PCD®)

Selection Guide

The right PCD makes sterilization both effective and efficient. Mesa's broad portfolio helps IVD, medical device manufacturers and contract sterilizers validate processes with confidence, ensuring safety, compliance, and optimized cycle times.

PCDs: The Backbone of Reliable Ethylene Oxide Sterilization

Sterilization validation is essential in pharmaceutical, medical device, and in vitro diagnostics (IVDs) industries, where products must meet strict regulatory standards to protect patient safety.

A Process Challenge Device (PCD) is a standardized test tool that provides a defined resistance to sterilization, presenting a greater challenge than a typical load, by enclosing a biological or chemical indicator with a difficult-to-penetrate barrier. In ethylene oxide (EO) sterilization, PCDs containing biological indicators (BIs), which are standardized populations of highly resistant bacterial spores, are the most reliable tools for verifying sterility and achieving the required Sterility Assurance Level (SAL).

PCDs are used as either internal (IPCDs) or external (EPCDs):

+ IPCDs mimic the most difficult-to-sterilize location within a product or load and are placed inside loads to confirm sterilant penetration.
+ EPCDs are easier-to-retrieve devices placed outside the load for routine monitoring, designed with higher resistance than IPCDs to provide greater confidence in cycle performance.

Because PCDs are central to both validation and monitoring, their quality directly affects sterilization reliability. Homemade or non-standardized PCDs may appear cost-effective, but they introduce variability, degrade over time, and increase the risk of error - ultimately undermining sterility assurance.

Mesa Labs PCD®s address these risks with a patented, BI system designed specifically for EO sterilization. Manufactured under strict quality controls, they deliver reproducibility, standardized resistance (D-value), and validated performance, ensuring confidence in both validation and routine sterilization.

Understanding D-Values and PCD Selection

The D-value (Decimal Reduction Time) quantifies microbial resistance to a sterilization process. It represents the time required, under defined EO conditions (concentration, temperature, humidity, exposure) to reduce a microbial population by 90% (1 log). A higher D-value indicates greater resistance, requiring longer sterilization exposure.

Sterilization cycles are developed around product characteristics and natural bioburden. D-values are central to validation, providing a quantitative basis for confirming that selected parameters reliably inactivate the most resistant organisms and ensure sterility assurance.

In EO sterilization, target D-values are calculated from half-cycle exposure times and the required spore log reduction (SLR). In practice, approximate product D-value can be obtained by dividing the half-cycle exposure time by 8.

> **Learn More in Our PCD Configuration Guide:**
> info.mesalabs.com/sdc-ls-pcd-configuration-guide

This D-value provides a key benchmark for selecting PCDs for routine sterilization. When combined with spore population and device configuration, it helps ensure PCDs represent an appropriate challenge to the validated cycle. By comparing the nominal resistance of the PCD to the half-cycle D-value, manufacturers avoid under-processing, which risks sterility failure, and over-processing, which can damage products or extend cycles unnecessarily. This balance supports:

+ Optimized exposure times
+ Lower energy costs
+ Reliable sterility assurance

A practical approach is to evaluate three PCDs with different resistance levels to identify one that is slightly more resistant than the IPCD for the cycle:

+ One PCD with a D-value close to the validated reference D-value
+ One PCD with a slightly lower D-value
+ One PCD with a slightly higher D-value

Explore the Industry's Widest PCD Portfolio

Mesa' s PCD® line offers a broad range of standardized devices, with nominal D-values ranging from 3 to 58 minutes to match diverse cycle configurations.

In real-world use, biological indicator (BI) resistance often increases tenfold compared to naked indicators. For example, a BI with a 3-minute D-value may show 30+ minutes effective resistance when embedded in complex packaging. To address this multiplication, Mesa's portfolio spans the full 3-58 minute range.

By systematically combining pouch types with biological indicators, Mesa delivers predictable, validated D-values across the full range. This engineered approach removes trial-and-error from PCD selection and ensures resistance is appropriately matched without compromising validation.

NOMINAL D-VALUES ON MESA PCD PRODUCTS

Mesa PCDs have a nominal D-value based on testing in a resistometer under controlled conditions (600 mg/L EO, 54 °C, 60% relative humidity) with the PCDs as the only objects in the chamber. These values provide a standardized reference for resistance.

However, performance in full-scale EO sterilizers can vary due to load size, temperature shifts, humidity, EO charging times, vacuum removal times, and cycle parameters. Thus, nominal D-values serve as a consistent baseline, while actual resistance must always be confirmed within the user's validated sterilization cycle.

PCD TYPES

PCDs are segmented into types based on resistance. They are available in multiple BI formats like strips, discs, or self-contained biological indicators (SCBIs).

Why SCBI Technology Outperforms the Rest

Mesa SCBI PCDs® are specifically designed for EO sterilization and are compliant with ISO 11135:2014 for both validation and routine monitoring. SCBIs are closed systems integrating both the microbial spores and the growth medium in a single, self-contained unit. They have a variety of unique patented packaging of BIs containing *Bacillus atrophaeus* spores to match your process.

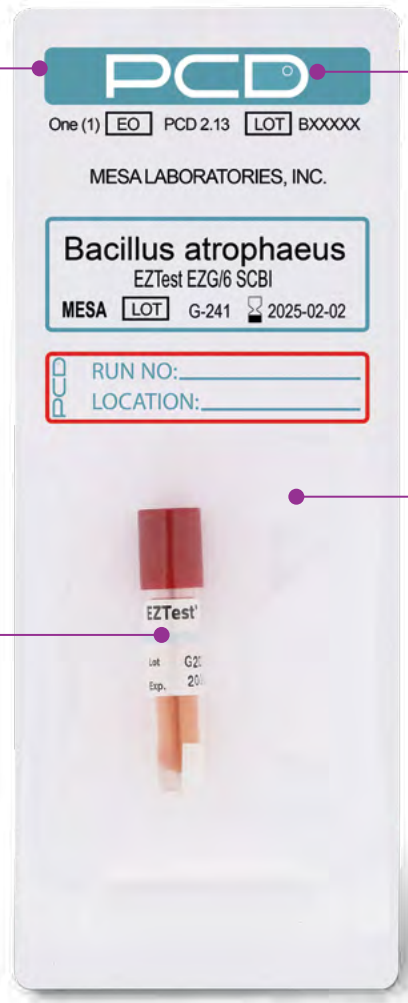
THE SCBI ADVANTAGE

+ No laboratory transfers required – results are contained within the unit
+ Reduced risk of contamination, handling errors, and variability
+ Faster turnaround
+ Greater consistency, control, and reproducibility in sterilization validation

> **The EZTest® SCBI is a specialized, easy-to-use PCD with a built-in color indicator that delivers clear visual results within 48 hours (EO). It incorporates a specially formulated soybean casein digest medium with a pH color indicator which turns a dramatic yellow when spores grow.**

Reduce Risk

+ Contains lot-specific information: PCD Type, PCD Lot Number, BI Lot Number, PCD/BI Expiration Date



Backer Card

+ White PVC card with a thumb notch at the bottom to hold the pouched BI in place
+ Contains a pressure-sensitive adhesive strip on the back to allow for adherence of the PCD to the exterior of the load

Pouch

+ Proprietary formulation of plastic films that allow EO gas to penetrate at different rates (nominal D-value range of 3 to 58 min)

Biological Indicator

+ Mesa, 3M, Steris
+ SCBIs which do not require clean bench for activation
+ Strips in glassine or naked
+ Discs

Our Selection Set: Your Shortcut to Confidence

To make the process of selection as simple as possible, Mesa offers a PCD Selection Set, to select the most appropriate EPCD for your EO sterilization process. Each set includes four PCD types calibrated with increasing resistance; from Type 7 (lowest challenge) to Type 2 (highest challenge).

BENEFITS

+ Aids in selection of the correct PCD for routine monitoring of EO sterilization cycles
+ Consists of four PCD types, each with a different resistance to EO
+ Uses Mesa's EZTest® Gas SCBI for fast and reliable results

Why Do More Manufacturers Choose **Mesa PCD®** ?

WIDE PRODUCT RANGE

+ EO PCDs available with nominal D-values from 3 to 58 minutes, covering a broad resistance spectrum.
+ Self-contained biological indicators (SCBIs) reduce incubation and release times, minimizing total process turnaround and eliminating the need for a clean bench.

REDUCED COSTS

+ Eliminates need for in-house produced PCDs, significantly lowering material, labor, and overhead costs.
+ External mounting of PCDs on each load minimizes recovery costs.
+ Faster release times with SCBI technology reduces product inventory in the pipeline.

QUALITY AND SAFETY

+ All PCDs are manufactured in an ISO 13485 certified facility. Critical components are received from approved suppliers, fully traceable, and undergo robust incoming testing.
+ PCDs have a measured resistance and help achieve compliance with ISO 11135.
+ Perforated, peel-off label allows load-specific identification for regulatory compliance.
+ Employee EO exposure is minimized during BI recovery.
+ PCDs are shelf stable per BI manufacturer's certification.

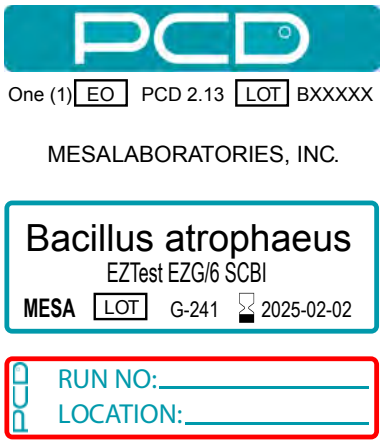
CONSISTENCY AND COMPLIANCE

+ Eliminates the variability and risk of homemade PCDs.
+ Standardized, easy-to-use commercially manufactured PCDs with a defined resistance provide monitoring confidence every cycle.

PCD Selection Set V.13

The Selection Set Contains 25 Each of PCD 2.13, PCD 4.13, PCD 6.13, PCD 7.13

All PCDs are identified by a N.X nomenclature. The "N" prefix delineates a particular polymeric film/pouch specification called a PCD 'Type'. This type is indicative of a particular EO resistance range. The ".X" suffix defines a particular BI or SCBI. The D-values listed are nominal values and are for reference and comparison only. These values were derived by laboratory testing an ISO 18472 compliant EO Resistometer.



Reorder No.	BI Manufacturer	D-value (min)
Type 2	**Most Resistance**	
PCD 2.1	Mesa UniQ® Disc, 1-10006mm	28
PCD 2.12	MesaStrip, SGM/6	28
PCD 2.13	Mesa EZTest®, EZG/6 SCBI	58
PCD 2.2	Steris BI Strip, NA005	28
PCD 2.5	MesaStrip in Glassine, SGMG/6	37
PCD 2.6	3M Attest™ 1264-S SCBI	58
PCD 2.7	Steris BI strip in glassine, NA005	37
PCD 2.9	3M Attest™ 1294-S RRBI	58
Type 3	**Least Resistance**	
PCD 3.13	Mesa EZTest®, EZG/6 SCBI	3
PCD 3.2	Steris BI Spore Strip, NA 005	3
PCD 3.5	MesaStrip in Glassine, SGMG/6	4
PCD 3.6	3M Attest™ 1264-S SCBI	5
PCD 3.9	3M Attest™ 1294-S RRBI	5
Type 4	**Medium Resistance**	
PCD 4.1	Mesa UniQ® Disc, 1-10006mm	21
PCD 4.13	Mesa EZTest®, EZG/6 SCBI	50
PCD 4.2	Steris BI Strip, NA005	21
PCD 4.5	MesaStrip in Glassine, SGMG/6	32
PCD 4.6	3M Attest™ 1264-S SCBI	50
PCD 4.7	Steris BI strip in glassine, NA005	32
PCD 4.9	3M Attest™ 1294-S RRBI	50

Reorder No.	BI Manufacturer	D-value (min)
Type 5	**Low Resistance**	
PCD 5.1	Mesa UniQ®, 1-10006mm	4
PCD 5.13	Mesa EZTest®, EZG/6 SCBI	13
PCD 5.2	Steris BI Strip, NA005	4
PCD 5.5	MesaStrip in Glassine, SGMG/6	5
PCD 5.62	3M Attest™ 1264-S SCBI	13
PCD 5.92	3M Attest™ 1294-S RRBI	13
Type 6	**Medium Resistance**	
PCD 6.1	Mesa UniQ® 1-10006mm	12
PCD 6.13	Mesa EZTest®, EZG/6 SCBI	35
PCD 6.2	Steris BI strip, NA005	12
PCD 6.5	MesaStrip in Glassine, SGMG/6	17
PCD 6.6	3M Attest™ 1264-S SCBI	35
PCD 6.7	Steris BI strip in glassine, NA005	17
PCD 6.9	3M Attest™ 1294-S RRBI	35
Type 7	**Medium Resistance**	
PCD 7.1	Mesa UniQ®, 1-10006mm	9
PCD 7.13	Mesa EZTest®, EZG/6 SCBI	26
PCD 7.2	Steris BI Strip, NA005	9
PCD 7.5	MesaStrip in Glassine, SGMG/6	14
PCD 7.6	3M Attest™ 1264-S SCBI	26
PCD 7.7	Steris BI Strip in Glassine, NA005	14
PCD 7.9	3M Attest™ 1294-S RRBI	26
Type 8 — H2O2 Cycles		
PCD 8.13	Mesa EZTest®, EZH/6 SCBI	(H_2O_2)

The **Right PCD is the Key** to True Sterility Assurance

Mesa's PCDs provide the best in convenience, sterilization efficiency, reliability and cost savings for industrial sterilization users.

Are you confident your current PCDs truly reflect your cycle's worst-case challenge?

Discover the PCD Solution That's Right for You

Our Promise. Your Partner.

With our extensive experience and expertise in biological indicators, Mesa Labs is your trusted partner in the industry. Our trained analysts are well-versed in regulatory guidelines, from sterilization cycle development to routine monitoring of your products. We specialize in various types of assays and are familiar with many brands of biological indicators.

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