



MesaLabs

PCD Selection Guide

Process Challenge Devices (PCD's) are Ethylene Oxide (EO) sterilization process challenge devices as defined in ISO 11135-1:2007. They are a unique, patented packaging of Biological Indicators (BIs) or Self Contained Biological Indicators (SCBIs). PCD technology provides the ultimate in convenience, sterilization efficiency, reliability and cost savings for industrial sterilization users.

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 Biological Indicator (BI) or Self Contained BI (SCBI). The D_{eo} values listed are nominal values and are for reference and comparison only. These values were derived by laboratory testing using a Biological Indicator Evaluator Resistometer (BIER) vessel.

Reorder No.	BI Manufacturer	D_{eo} min
PCD 2.1	Namsa BI Disc, DN-06	28
PCD 2.12	Namsa BI Strip, STN 06	28
PCD 2.13	Mesa EZTest EZG/6 SCBI	58
PCD 2.2	Steris BI Strip, NA005	28
PCD 2.5	Mesa BI Strip 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 2.8	Namsa MiniStrip BI, STN 062	28
PCD 2.9	3M Attest™ 1294-S RRBI	58
PCD 4.1	Namsa BI Disc, DN-06	21
PCD 4.13	Mesa EZ Test EZG/6 SCBI	50
PCD 4.2	Steris BI Strip, NA005	21
PCD 4.5	Mesa BI Strip 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
PCD 6.1	Namsa BI Disc, DN-06	12
PCD 6.13	Mesa EZ Test EZG/6 SCBI	35
PCD 6.2	Steris BI strip, NA005	12
PCD 6.5	Mesa BI Strip 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
PCD 7.1	Namsa BI Disc, DN-06	9
PCD 7.13	MESA EZ Test EZG/6 SCBI	26
PCD 7.2	Steris BI Strip, NA005	9
PCD 7.5	Mesa BI Strip in Glassine, SGMG/6	14
PCD 7.7	Steris Bi Strip in Glassine, NA005	14
PCD 7.6	3M Attest™ 1264-S SCBI	26
PCD 7.9	3M Attest™ 1294-S RRBI	26
PCD 5.1	Namsa BI Disc, DN-06	4
PCD 5.2	Steris BI Strip, NA005	4
PCD 5.13	Mesa EZ Test EZG/6 SCBI	13
PCD 5.5	Mesa BI Strip in Glassine, SGMG/6	6
PCD 5.62	3M Attest™ 1264-S SCBI	13
PCD 5.92	3M Attest™ 1294-S RRBI	13
PCD 8.13	Mesa EZTest EZH/6 SCBI	(H2O2)

Wide Product Range

- PCD EO Resistances (D_{eo}) of 4 to 58 minutes are readily available.
- Reduced SCBI incubation and release times help minimize total process turnaround times.

Reduced Costs

- Elimination of in-house produced internal test packs greatly reduces material, labor and overhead costs.
- External mounting of PCDs on each load minimizes recovery costs.
- Release times using SCBI technology reduces product inventory in the pipeline.

Quality and Safety

- All PCD components are manufactured in ISO 13485:2003 certified facilities. Mesa Labs has critical supplier agreements with numerous large & small medical devices companies world-wide.
- Each PCD is supplied with a certificate of quality conformance. All critical components are fully traceable.
- PCD identification is unique and load specific for sterilization and microbial qualification in case of BI failure.
- Employee EO exposure is minimized during BI recovery.
- PCDs are shelf stable per manufacturer's certification and confirming studies.

PCDs are available in a wide range of EO resistance values to meet any combination of product and EO process requirements. Mesa Labs can also develop and assist with qualification of custom PCDs to satisfy unique customer needs for any gas sterilization process.