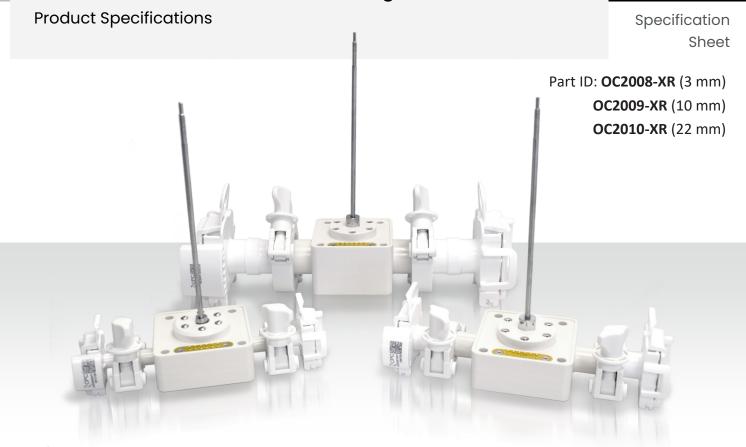
CTech™ FlowVPX® Irradiated GxP Single-Use Flow Cells



Overview

The CTech™ FlowVPX® Irradiated Flow Cells are designed to provide an in-line measurement solution compatible with the FlowVPX variable pathlength system. The FlowVPX System uses unique, patented variable pathlength technology (VPT) to unlock the power of Slope Spectroscopy® measurement methods for highly regulated drug manufacturing processes. The Single-Use Flow Cell is designed to be more cost-effective, eliminating the need for tedious cleaning and maintenance and reducing the risk of cross-contamination.

The FlowVPX Irradiated Single-Use Flow Cell is a low bioburden flow cell constructed with a polyphenylsulfone (PPSU) body and standard tri-clamp connections with AseptiQuik® connectors to allow for easy, contamination-free connections. It mates directly with the FlowVPX Head and Detector Module. The flow cell was designed with a precision ethylene propylene diene monomer (EPDM) diaphragm seal, which forms a barrier around the integral Flow Fibrette® Optical Component and ensures a contained process-measurement area. Additionally, it is equipped with FlowVPX SmartCell™ Technology, which directly communicates with the FlowVPX Head and provides insightful process data and traceability. The Flow Cell is x-ray irradiated with a minimum dose of 25 kGy inside the flow path.

For more information about the Single-Use Flow Cell or variable pathlength technology, please contact a Repligen analytical sales specialist.



eatures Benefits	
Polyphenylsulfone (PPSU)	High-performance polymer material allows for reliable and wear-resistant use in manufacturing environments.
AseptiQuik Connectors	3 mm: AseptiQuik S (Item # AQS33004HT) 10 mm: AseptiQuik G (Item # AQG33012HT) 22 mm: AseptiQuik L (Item # AQL33024HT)
Irradiation	X-ray, minimum 25 kGy inside flow path
low Cell Specifications	
Flow Path Inner Diameter	3 mm: 3.0 mm (0.12 in) 10 mm: 9.5 mm (0.37 in) 22 mm: 22.1 mm (0.87 in)
Dimensions (width x height x depth)	3 mm: 187 x 210 x 74 mm (7.4 x 8.3 x 2.9 in) 10 mm: 204 x 204 x 73 mm (8.0 x 8.0 x 2.9 in) 22 mm: 255 x 229 x 81 mm (10.0 x 9.0 x 3.2 in)
Weight	3 mm: 340 g (0.75 lbs) 10 mm: 360 g (0.79 lbs) 22 mm: 646 g (1.42 lbs)
Maximum Pathlength	3 mm: 3.0 mm (0.12 in) 10 mm: 5.0 mm (0.20 in) 22 mm: 5.0 mm (0.20 in)
Maximum Hold-Up Volume	3 mm: 2.9 ml 10 mm: 24.6 ml 22 mm: 109.4 ml
Maximum Pressure	4.1 bar (60 psi)
Process Contact Materials	 316L stainless steel EPDM seals Platinum-cured silicone, USP Class VI, animal-derived component free (ADCF) Medical-grade epoxy PPSU UV-grade fused silica windows Polycarbonate, USP Class VI, ADCF
Non-Process Contact Materials	 PPSU 316/316L stainless steel Viton sealant Glass-filled nylon Medical-grade epoxy Gold-plated electrical contacts Torlon PAI Hydrophobic polyethersulfone with PTFE strip membrane, USP Class VI
Operating Conditions	
Maximum Cycle Count	150,000 cycles (One cycle is a complete Quick Slope measurement or Fixed Slope measurement sequence.)
Operating Temperature	3 mm: 4°C-40°C (39°F-104°F) 10 mm: 1°C-40°C (34°F-104°F) 22 mm: 1°C-40°C (34°F-104°F)

Further Details	
Flow Cell Chemical Compatibility	Customer is responsible for validating the use of their product-specific chemicals and effects on the Flow Cell.
AseptiQuik Connector Chemical Compatibility	See manufacturer's site (<u>cpcworldwide.com</u>)
Shelf Life	18 months from manufactured date when kept in proper storage conditions.
Storage Conditions	5–25°C (41–77°F), <70% relative humidity and free of condensation. Store with seals intact and protected from UV light and ozone.
Hardware Compatibility	FlowVPX instrument
Instrument Support	Single-use Flow Cells should not be used for structural support of the FlowVPX instrument. The FlowVPX instrument should be mounted using the FlowVPX Standard Mount accessory or other suitable mounting to support the weight of the FlowVPX Head.
Software Requirement:	CTech™ ViPER® ANLYTX Software v1.2.x or newer

Customer Support Options	
Support and training	Repligen is committed to customer success from predelivery through installation and training.
More information	Final application suitability of all materials and ratings are the sole responsibility of the user. Specified pressure and temperature ratings may be subject to limitations. Contact a Repligen's Analytics Representative for more information.
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