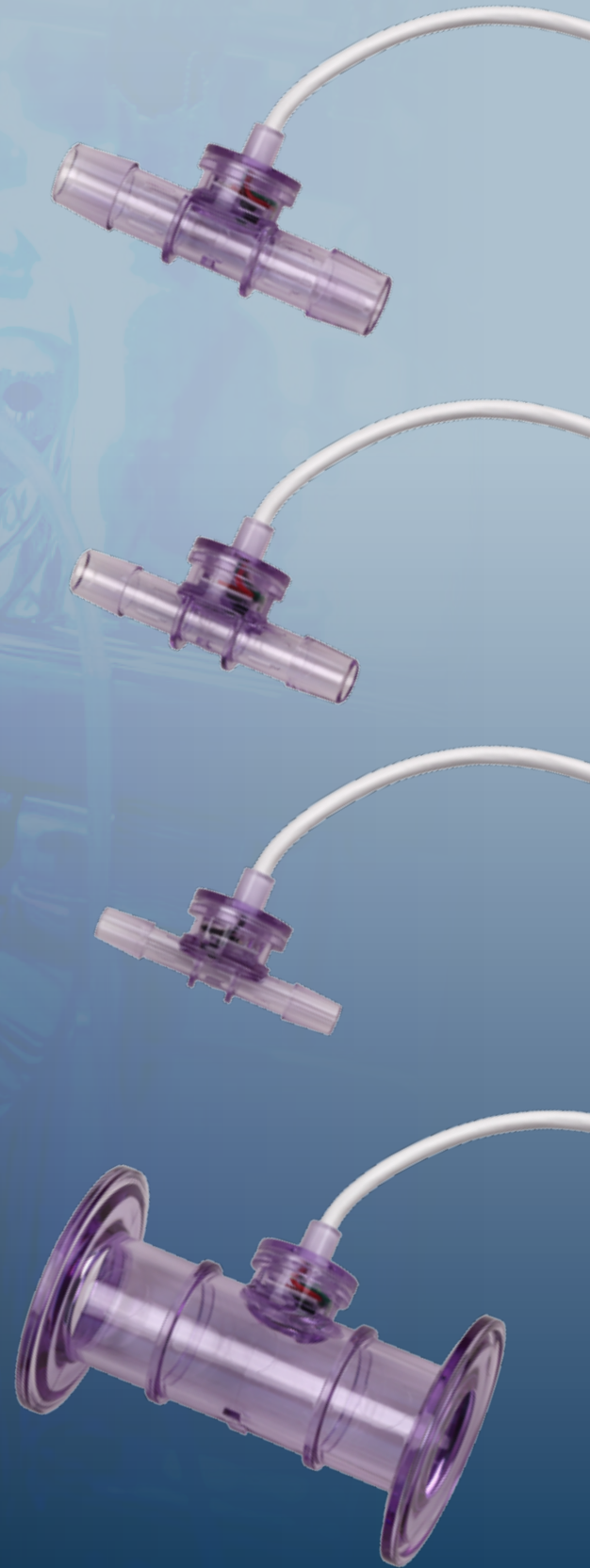


BioPharm HP-PRT® Sensors



**Accurate High-Pressure Process
Monitoring from the
Pressure Monitoring Experts**

Two Decades of Proven Accurate Process Pressure Monitoring...

Now available direct from the *original manufacturer*

Utah Medical Products, Inc. (UTMD) is the original developer of single use blood pressure transducers used globally in the critical care units of hospitals. Its sensor chips, designed for accurate static and dynamic fluid pressure monitoring, have been manufactured and distributed since 1985. UTMD's BioPharm HP-PRT® (High Pressure, Piezo-Resistive Transducer) is a next-generation development from this pioneering medical application. What is not well known, until now, is that UTMD has been providing highly accurate pressure sensing for biopharm manufacturing lines for up to two decades.

These sensors are now available direct to the biopharmaceutical market from UTMD.

BIOPHARM HP-PRT® SENSORS

UTMD's BioPharm HP-PRT single-use pressure sensors measure the static and dynamic pressure of gases and liquids accurately and cost effectively and are available in pressure ranges up to 75 PSI. Applications for BioPharm HP-PRT sensors include

- multi-stage depth filtration,
- TFF/crossflow filtration,
- chromatography processes,
- glass and disposable bioreactor pressure monitoring,
- filling operations,

and many more. BioPharm HP-PRT sensors have the convenience and benefits of a single-use system while providing the accuracy and durability of the traditional measurement techniques. These single-use sensors have been proven to be a dependable alternative to the stainless-steel pressure transducers and gauges used in biopharmaceutical processes.

BioPharm HP-PRT sensors are manufactured under tight tolerances with controlled documentation. To assure calibration, sensors are 100% tested prior to shipment and arrive ready to use. Shipments

include a certificate of compliance. Individual NIST-traceable calibration certificates are available upon request. The sensors are manufactured in UTMD's ISO 13485 certified facilities in ISO Class 7 cleanrooms.

BioPharm HP-PRT sensors are available in a variety of in-line, flow-through housings for applications requiring tubing barbs, luer connectors or sanitary flanges. The flow-through design reduces dead space and obstructions in the flow path that can cause a pressure drop and/or flow resistance. The disposable sensor connects to most data acquisition systems with a reusable interface cable.

RIGOROUSLY CERTIFIED

To provide another level of robustness for single-use sensors, BioPharm HP-PRT sensor housings are constructed of highly durable and chemically inert Polycarbonate or Polysulfone. They have been evaluated to meet a broad spectrum of standards by one of the world's foremost testing laboratories. As a result, your processes will not be compromised. All fluid contact components have laboratory certifications that include:

- Extractables and Leachables
- Cytotoxicity
- LAL Testing
- Bioburden and Bacteriostasis Fungistasis
- Particulate
- USP Class VI

BioPharm HP-PRT pressure sensors are

- qualified for long-term storage (5-year shelf life),
- latex free,
- free from materials of animal origin or compliant with EMEA 410, and
- compatible with Gamma Irradiation and Ethylene Oxide sterilization processes.

Hose Barb Connection

Materials: Polysulfone or Polycarbonate

Sizes: 1/4", 3/8", 1/2"



Sanitary Flange Connection

Materials: Polysulfone or Polycarbonate

Sizes: 1/2", 1"



VALIDATION DATA

Manufacturing Locations	Midvale, Utah, USA	biopharm@utahmed.com
	Athlone, Co. Westmeath, Ireland	ireland@utahmed.com

Sensor Specifications

Operating Pressure Range:	-11.5 PSI to 75 PSI (above 30 PSI requires pre-qualified monitor)	
Zero Drift with Time:	<0.019 PSI / 8 hours after 10-minute warm-up	
Leakage Current:	<2 μ A	
Overpressure Protection:	-11.5 PSI to 75 PSI	
Operating Temperature:	2°C – 40°C	
Sensor Accuracy:	-10 to -7psi	\pm 5 % of reading
	-7 to 0psi	\pm 3 % of reading
	0 to 6psi	\pm 2 % of reading
	6 to 30psi	\pm 3 % of reading
	30 to 60psi	\pm 5 % of reading
Sensor output:	0.2584 μ V/V/PSI	
Excitation:	DC: 2-10 V; AC: 2-10 V _{rms} up to 5kHz	
Operating Life:	>2000 hours	
Output Impedance:	270 Ω – 400 Ω	
Input Impedance:	270 Ω – 400 Ω	
Shelf Life:	5 years from date of manufacture	

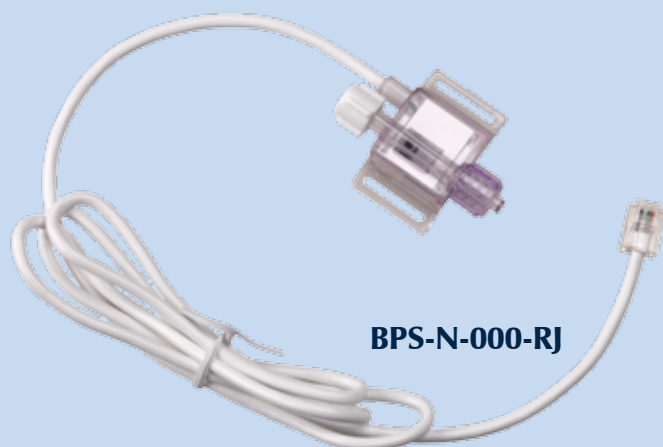
Study Reference

Test	Polysulfone	Polycarbonate	Comment
Extractables & Leachables	1697543	1697357	Evaluated per USP <665>. Summary Report Available.
Cytotoxicity	1739031	1739039	PASS - Score of 0 for both materials
LAL	1739036	1739034	PASS - Resulting EU per device well below the limits for medical devices in contact with cerebrospinal fluid or intraocular ophthalmic devices.
Bioburden/B&F Suitability	1716041		PASS - Bioburden levels were below the detectable limits for colony forming units on the test.
Particulate	1716042		Particulates routinely monitored
USP Class VI	1725584	1725585	USP Plastic Class VI-70°C, according to USP-NF <88>

Luer Connection

Materials: Polysulfone or Polycarbonate

Size: Standard Male/Female Luer Locks



BPS-N-000-RJ






Cables and Accessories

Contact UTMD for interface and extension cable options



Veri-Test Tester and Simulator

ORDERING INFORMATION

Connection and Size		Housing Material Polysulfone Polycarbonate		Vent Cap		Cable Connection Suffix			Calibration Documentation	
Barb	1/4"	BPS-N-025	BPC-N-025	No Suffix	No	No Suffix	Utah 12" cable		No Suffix	Tested, no Cert
	3/8"	BPS-N-038	BPC-N-038			-W	IP67 Waterproof 12" cable		-B	6 PSI Cert
	1/2"	BPS-N-050	BPC-N-050			-RJ	RJ11 42" cable		-30	30 PSI Cert
Flange	1/2"	BPS-N-5-5	BPC-N-5-5	-V	Yes	-XB	ODU Blue 22" cable		-60	60 PSI Cert
	1"	BPS-N-1-1	BPC-N-1-1			-XR	ODU Red 22" cable		-75	75 PSI Cert
Luer		BPS-[-]-000	BPC-[-]-000							

N - Non-Sterile
S - EO Sterilized

Most configurations are maintained in stock. Contact UTMD for availability of your particular configuration need.



UTAH MEDICAL PRODUCTS

United States

Utah Medical Products, Inc.
7043 South 300 West
Midvale, Utah 84047
Toll-free 800.533.4984
Tel +1 801.566.1200
Fax +1 801.566.2062
biopharm@utahmed.com

Europe

Utah Medical Products Ltd
Athlone Business & Technology Park
Athlone, Co. Westmeath N37 XK74
Ireland
+353 90 647 3932