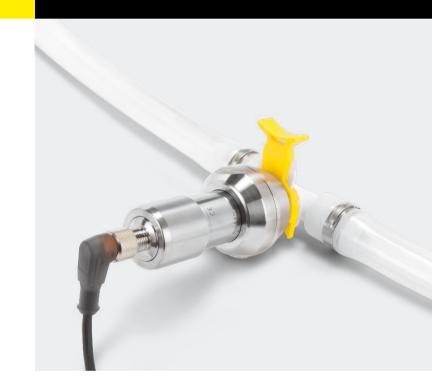
SARTURIUS

BioPAT® Pressure

Flexible In-line Pressure
Measurement from
Process Development to
Commercial Production



Benefits

- Non-invasive pressure measurement
- Available for tube diameters ranging from ¼" to 1" ID
- Compatible with a wide range of fluid properties
- Automatic temperature compensation
- New fixing mechanism integrated in the single-use pressure pipe

Product Information

The in-line pressure sensors of the BioPAT® Pressure family provide the right fit for all scales of your bioprocess. The new design allows a high degree of flexibility suitable for more applications in biomanufacturing and includes several improvements, resulting in better longevity, handling and accuracy.

The integration of the pressure sensor is fast and easy. The pressure pipes can be integrated into any single-use tube assembly without changing the inner diameter. The transmitter is then simply connected to the pipe through an integrated fixing mechanism and the measurement can start immediately.

The sensors of the BioPAT® single-use Pressure family are highly chemically resistant and compatible with a broad spectrum of liquids with respect to viscosity, opaqueness, corrosiveness and temperature.

Benefits of Using BioPAT® Pressure

The integration of the new BioPAT® single-use Pressure sensor comes with several advantages.

- Portfolio extension. The BioPAT® Pressure pipes are available for tubing from ¼" up to 1" ID, with hose barb connection. Additionally, ¾" and 1" ID pipes are available with sanitary Tri-Clamp connection.
- One transmitter for all sizes. The multi-use pressure transmitter can be used with all pressure pipes sizes without the need for recalibration. All electronic components are installed in the transmitter, preventing unnecessary disposal of electronic waste with the single-use pipes.
- Integrated fixing mechanism in the single-use pressure pipes makes installation easier and guarantees a reliable connection to the pressure transmitter.
- Longer life span. The new metal membrane on the BioPAT® Pressure Transmitter does not deteriorate. To protect the integrity of this surface, a removable and reusable protection cap is assembled on the transmitter.
- Higher accuracy. A comprehensive adjustment procedure, with assembled single-use pressure pipes, during manufacturing of the BioPAT® Pressure Transmitter assures better measurement accuracy.
- High chemical resistance compatible with ADC applications.
- 100% Integrity control in production ensures optimal robustness and performance within your application.

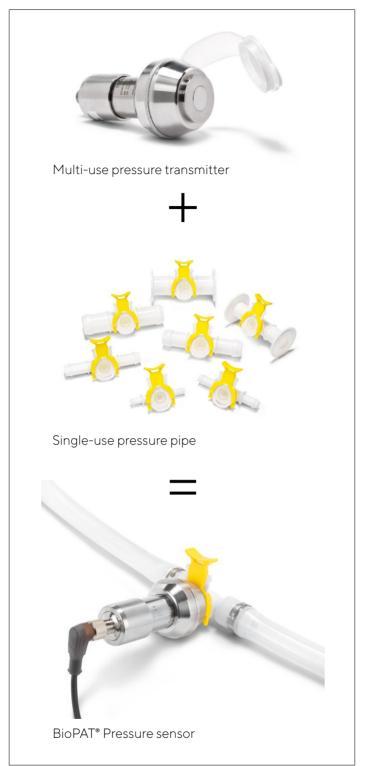


Figure 1: The BioPAT® Pressure Sensor Is the Combination of a Single-Use Pressure Pipe and a Multi-Use Transmitter

Measurement Principle

The BioPAT® Pressure sensor uses the piezoresistive effect to accurately and quickly determine the pressure. Figure 2 depicts the measurement principle of the sensor. Once the pressure pipe is assemble onto the transmitter, the silicone membrane on the single-use pressure pipe contacts with the metal membrane on the transmitter. While measuring,

pressure variations result in a force applied to membranes that is detected by a piezoresistive pressure sensor inside the transmitter. In addition, an integrated thermometer automatically corrects the influence of temperature in the outlet signal.

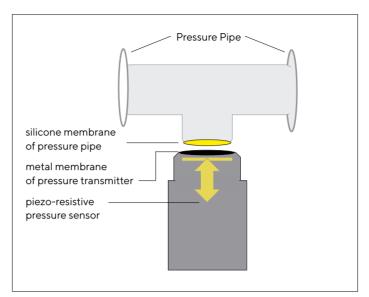


Figure 2: The BioPAT® Pressure Sensors Use the Piezoresistive Effect To Determine the Pressure

Sensor Transfer Sets

The BioPAT® Pressure sensors can be purchased as configured sensor transfer-sets for functional filtration units. The sensors are part of a comprehensive single-use and advanced analytics portfolio that provides robust and reliable measurements of critical process parameters and enables highly automated single-use bioprocessing within your design space.

Data Read-Out

The BioPAT® Pressure sensor has a analog outlet signal (4-20 mA) that can be read-out using different options:

- Sartorius Bioprocessing Systems. The sensors are fully integrated in the hardware and software of the Sartorius single-use upstream and downstream bioprocessing platforms, for example FlexAct*.
- Benchtop indicator. The display of this stand-alone solution allows a direct read-out of the pressure value. The analog signal can also be further transmitted to a control unit of choice. The connections and pin assignment of the transmitter are explained in detail under 'Technical Specifications'.
- Integration into other control units. The BioPAT® Pressure
 Transmitter is supplied with a 5 m open-ends cable, which
 transports the signal and simultaneously powers the
 transmitter through the current loop. The pin assignment

of the transmitter is explained in detail under 'Technical Specifications'.

Please note that Sartorius does not provide a stand-alone software for the pressure sensor. Software integration is only given with the Sartorius bioprocessing systems.

Qualification and Quality Assurance

All products from the BioPAT® Pressure family comply with the quality and safety requirements of typical biopharmaceutical processes. Full batch traceability and quality control assure that the single-use pressure pipes follow the directives and guidelines of the relevant regulatory agencies.

A comprehensive analysis procedure includes, among others:

- Extractable studies
- EMA/410/01 compliance
- RoHs/REACH compliance
- Non-cytotoxic (according to ISO-10993-1, -5, -12 and USP <88>Class VI)

Influence of Process Conditions

Temperature

The pressure sensors measure reliably over a wide range of temperature (4-40 °C) thanks to a pre-programmed automatic temperature compensation in the transmitter

Liquid Suspensions

The measurement accuracy of the BioPAT® Pressure sensors remains unaffected by changes of the flowing liquids. The stated accuracy has been confirmed for:

- Protein suspensions (BSA 200 g/L)
- Particles (diatomaceous earth 50 g/L)
- Cell suspensions (baker's yeast 80 g/L dry weight)

Measurement Range and Accuracy

The BioPAT* Pressure transmitter can measure from 0 to 5 bar(g). Due to the needed contact pressure (0.1 to 1 bar) between single-use pressure pipe and transmitter, the effective measurement range of the combined measurement system is 0-4 bar(g).

Measurement Range	System Accuracy*
0-2 bar(g)	80 mbar
2-4 bar(g)	4% c.v.

c.v. = current valu

2

^{*}The system accuracy is calculated as 1-Sigma accuracy (mean deviation to reference measurement + 1 standard deviation) and is valid for the usage of any transmitter with any single-use pressure pipe component.

Technical Specifications

Single-Use Pipes

Material	In contact with product:	PBT (polybuthylene terephthalate) Tempered liquid silicone rubber
	Other:	PP (polypropylene) ABS (acrylonitrile butadiene styrene)
Operating temperature range	4-40 °C	
Chemical resistance ¹	1M NaOH at 40 °C for 2 h 20% solutions at 25 °C for 1 h of: DMAc (N,N-dimethylacetamide), DMSO (Dimethyl sulfoxide), DMF (N,N-dimethylformamide), PG (Propylene glycol), ACN (acetonitrile), NMP (N-methyl-pyrrolidone)	
Shelf-life	Prior to gamma irradiatio	on: 3 years. After gamma irradiation: 3 years.

¹ tested in 1 year aged irradiated pipes

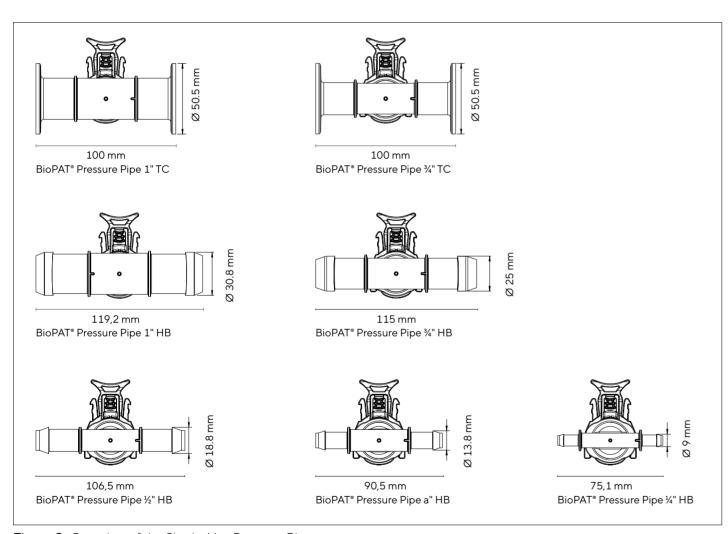


Figure 3: Overview of the Single-Use Pressure Pipes

Pressure Transmitter

48 × 100 mm 4-40 °C
4-40°C
IP67
4-20 mA analog M12x1 plug
24 V DC (± 10%) via power adaptor or external supply (e.g. open ends cable)
Every year (advisable) On-site adjustments and recalibration services are available on request. For more information, please contact our Technical Support Services.
Clean and disinfect using alcohol based surface cleaners
Open ends cable (5 m)

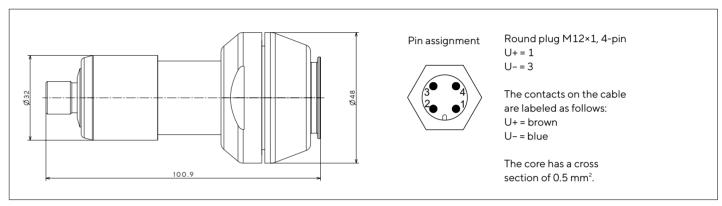


Figure 4: BioPAT® Pressure and Respective Electronic Connections

4

Benchtop Pressure Indicator

Housing dimension (H × W × L)	65 × 110 × 150 mm
Housing material	Aluminum
IP-Code	IP65
Supply voltage	24 V DC (± 10%) via power adaptor or external supply
Inlet Outlet Plugs	M12 x1, 4-pol M12 x 1, 5-pol
Supplied with	Power supply cable (1.75 m, M12 x1 plug, 24V DC, 220 mA) Connection cable to transmitter (1.1 m, 2x M12 x1 plug)

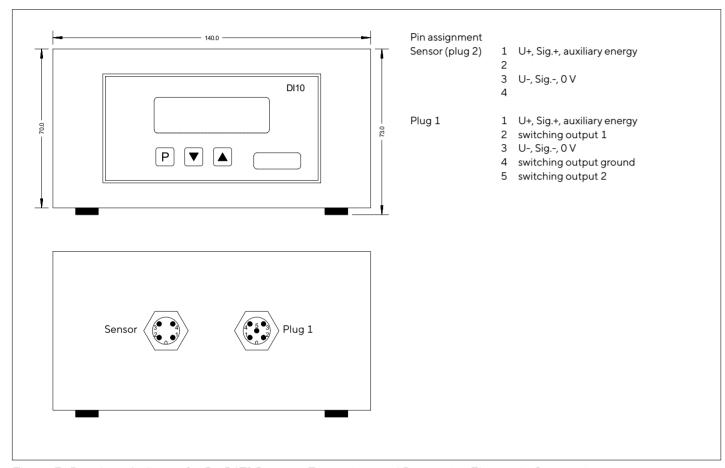


Figure 5: Benchtop Indicator for BioPAT® Pressure Transmitter and Respective Electronic Connections

Ordering Information

Single-Use Pipes

For your convenience, the BioPAT® Pressure single-use pipes are also available in fully configurable, pre-assembled, sterile and ready-to-use assemblies. For more information, please consult the "Single-Use Filtration and Sensor Solutions" Brochure, the Data Sheet "Filter & Sensor Transfer Sets" or contact our sales office.

Order Number	Size	Connection
BPD0010	½" (6.35 mm)	Hose barb
BPD0011	3/4" (9.53 mm)	Hose barb
BPD0012	½" (12.7 mm)	Hose barb
BPD0013	³¼" (19.05 mm)	Hose barb
BPD0014	³¼" (19.05 mm)	Tri-clamp
BPD0015	1" (25.4 mm)	Hose barb
BPD0016	1" (25.4 mm)	Tri-clamp

Note: The BioPAT® Pressure single-use pipes can only be order in multiples of 10 units

Pressure Transmitter

Order Number	Description
BPD0005	BioPAT® Pressure Transmitter, 0 – 4 bar(g)

Accessories

Order Number	Description
BPD0101	Digital indicator for BioPAT®
	Pressure Transmitter

Germany

Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen Phone +49 551 308 0

For further contacts, visit www.sartorius.com

USA

Sartorius Stedim North America Inc. 565 Johnson Avenue Bohemia, NY 11716 Toll-Free +1 800 368 7178