

CUSTOM SENSORS & TECHNOLOGY

A DIVISION OF CUSTOM SAMPLE SYSTEMS

BIOPROCESSING PRODUCTS & APPLICATIONS OVERVIEW

WHO WE ARE & WHAT WE DO FOR BIOPROCESSING

For over 40 years, Custom Sensors & Technology has been a leading provider of process analytical technology (PAT) for several industries including biopharmaceutical and biomanufacturing. In recent years, PAT has gained considerable momentum in these industries because of the potential for continuous real-time quality assurance resulting in improved operational control, compliance, and product yield. CST continues to demonstrate its adaptability by developing new products that meet and exceed users' requirements in the rapidly expanding biopharmaceutical and biomanufacturing sectors. By utilizing CST's robust process photometric transmitters, inline probes, and flow cells, users have continuously improved the quality and control of their process.

PX2 / PX2+

The PX2 and PX2+ Photometric Transmitters were designed for use in continuous processing monitoring applications including chromatography, tangential flow filtration (TFF)/crossflow filtration, depth filtration, centrifugation, fill and finish operations, and fermentation processes. Available in single and dual wavelength configurations, the PX2/PX2+ can be equipped with light sources from 200-2400 nm to measure absorbance or fluorescence. In most biomanufacturing applications, the PX2/PX2+ utilizes long-life LEDs at 260, 280, 300, 310, and/or 880 nm. Users communicate with the transmitter via one or two 4-20 mA outputs (scaled from 0-3 AU), RS-485 (Modbus), and USB-B to CST software. An LED backlight indicator alerts users to changes in the PX2's operating status. The PX2/PX2+ is typically installed with a process interface accessory, such as a probe or flow cell, with two fiber optic cables that send and receive light to and from the sensor.



Measurement Range: 0-3 AU

Accuracy: $\pm 1\%$ of full scale or better from 0-2 AU, $\pm 2\%$ from 2-3 AU

Repeatability: $\pm 0.5\%$ of full scale or better

Wavelength Range: 200-2400 nm

LED Wavelengths: 260, 280, 300, 310, and 880 nm (other wavelengths available upon request)

Other Light Sources: Xenon Flash Lamp, Tungsten Halogen Lamp

Analog Output: 4-20 mA, isolated

Digital Output: RS-485 (Modbus)

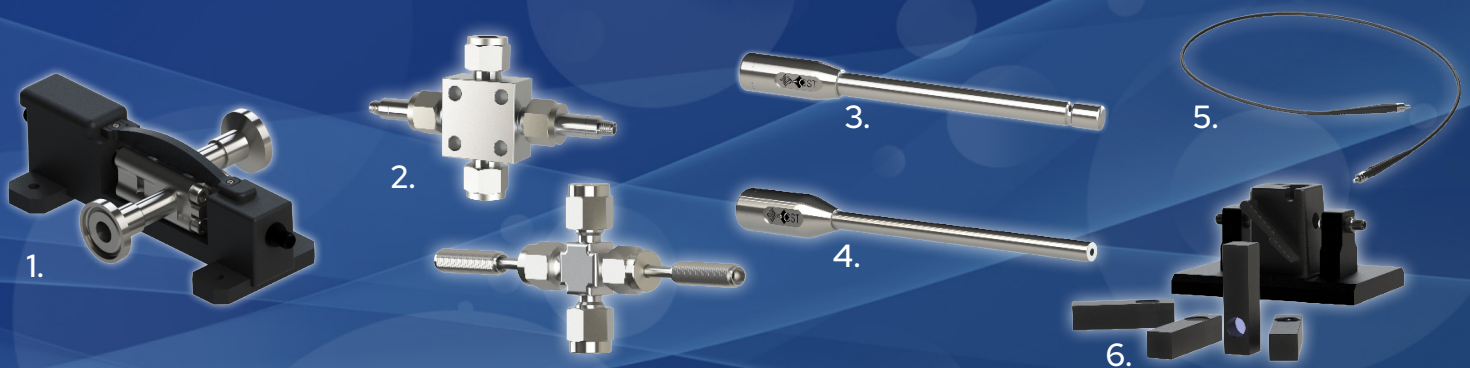
Power Requirements: 24 VDC nominal (12-48 VDC)

Response Time: 1 second or less
PX2+ includes 3.2" touchscreen display

PHOTOMETRIC PROCESS MONITORING ACCESSORIES

CST offers a full product line of photometric process monitoring accessories to be used with the PX2/PX2+ including the EZ-CAL Flow Cell, Variable Path Length Cross Flow Cells, Sanitary Cross Flow Cells, Transmission Probes, Fluorescence Probes, Fiber Optic Cables, Cuvette Holders, and ND Standards.

All Flow Cells and Probes can be constructed from 316SS, Hastelloy C-276, Titanium, Monel, or other materials upon request. Sealing material options include Viton (FKM), Kalrez (FFKM), or EPDM that meet USP Class VI requirements.



FLOW CELLS

1. EZ-CAL Flow Cell

- The 3/8" EZ-CAL extractive flow cell gives users an integrated means of calibration.
- Solid standards or cuvettes can be inserted into the optical path of the flow cell to make calibration and validation procedures simple.
- Available with sanitary flanges, compression, or VCO/VCR fittings.
- Optical Path Length: 1-100 mm

2. Variable Path Length Cross Flow Cells & Sanitary Cross Flow Cells

- These can be provided with several different connection/flange options for 1/8", 3/8", 1/2", or 3/4" tubing.
- Optical Path Length: 0.1-10 mm

PROBES

3. Transmission Probes

- Standard probe insertion length of 220 mm (custom lengths available).
- Optical Path Lengths: 1-20 mm

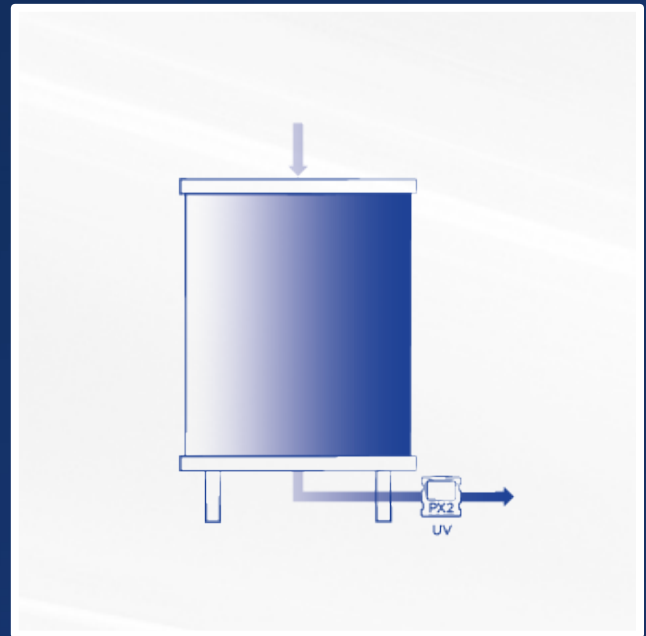
4. Front Surface Fluorescence Probes

5. FIBER OPTIC CABLES

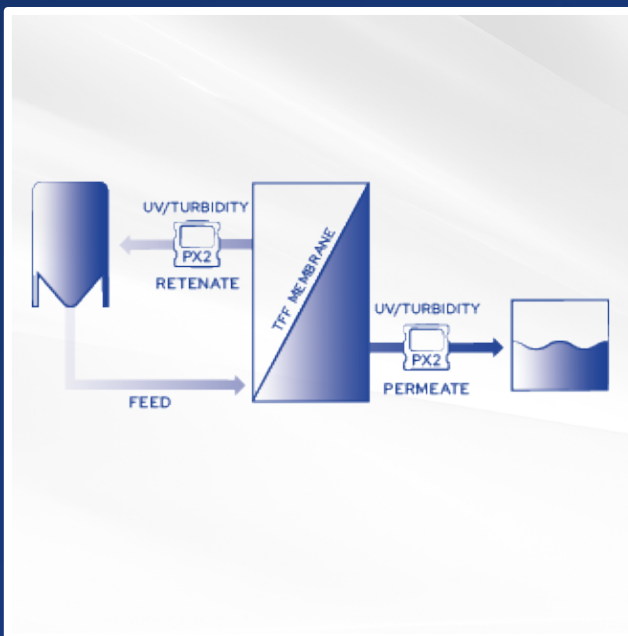
6. CUVETTE HOLDERS & NEUTRAL DENSITY STANDARDS

CHROMATOGRAPHY (A280, 260/280 nm, 280/300 nm)

The PX2 UV absorbance sensor for protein A capture provides accurate, reliable data measurements post-column. It features a contact closure that allows users to zero on the solvent background. The PX2 can be equipped as a single channel 280 nm sensor or as a dual channel 280/300 nm sensor. The 280 nm measurement is used for sensitive low concentration measurements to determine the beginning and end points for pooling, while the 300 nm measurement is used for high concentration measurements when the signal at 280 nm is beyond the measurable range (3 AU). This allows users to measure concentrations up to 200 mg/mL or higher. The PX2 can also be configured to measure 260/280 nm simultaneously to give users an indication of purity level and nucleic acid contamination. The 880 nm PX2 can be used for monitoring turbidity and resin efficiency. Process chromatography in downstream purification typically involves two or more chromatographic unit operations to clear host-cell protein (HCP), nucleic (for protein products), and viral impurities with sufficient product recovery. The PX2 allows users to track equilibration, load, wash, elution, and post-elution cleaning processes. When coupled with our flow cells or probes, the PX2 greatly increases process efficiency while ensuring product purity and eliminating the need for offline testing.



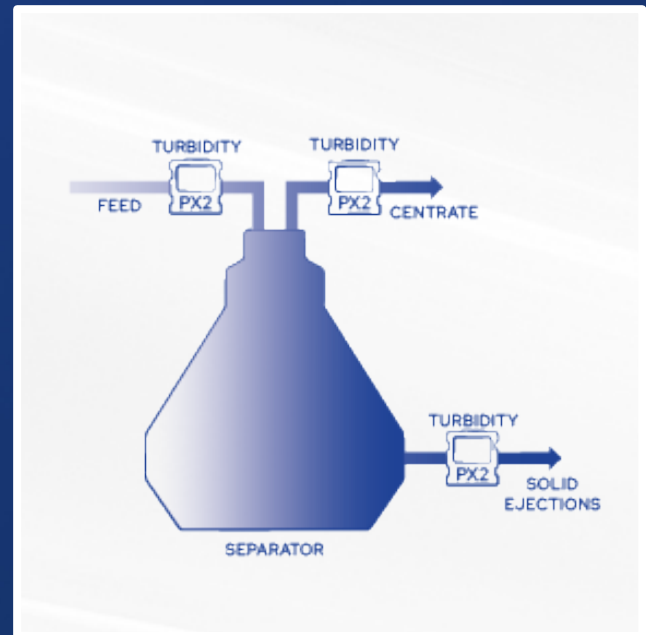
TFF/Crossflow Filtration/Ultrafiltration/Diafiltration (UV & Turbidity)



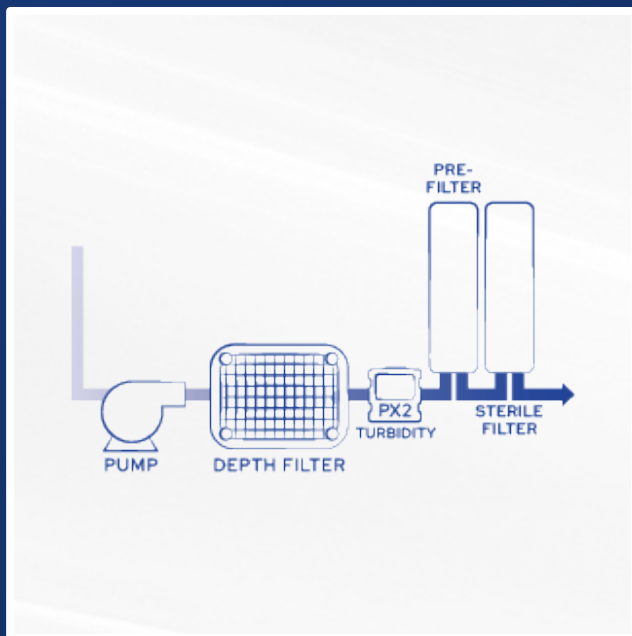
Tangential Flow Filtration, also known as Crossflow Filtration or UF/DF (Ultrafiltration/Diafiltration), is a rapid and efficient method for separation and purification of biomolecules. It is different from other filtration systems in that the fluid path is passed parallel to the filter, rather than being pushed through a membrane. This method is preferred for its continuous filtration and reproducible performance. The PX2 detects the product protein or mRNA in the retentate and permeate. A 280 nm PX2 is installed on the permeate stream to monitor low protein concentrations and for signs of filter breakthrough. A dual wavelength PX2 is installed on the retentate loop to monitor high protein concentrations. This eliminates the need for manual sampling of the highly concentrated retentate.

Centrifugation (Turbidity)

To clarify feed streams for downstream column chromatography, centrifugation is utilized to remove large cells and debris. The 880 nm PX2 reduces loss and improves product consistency and yield by monitoring turbidity at the feed outlet. This gives operators real-time indication of the centrifuge's performance and ensures the downstream consistency of the product. The 880 nm PX2 detects light that passes straight through a sample (forward light scattering).



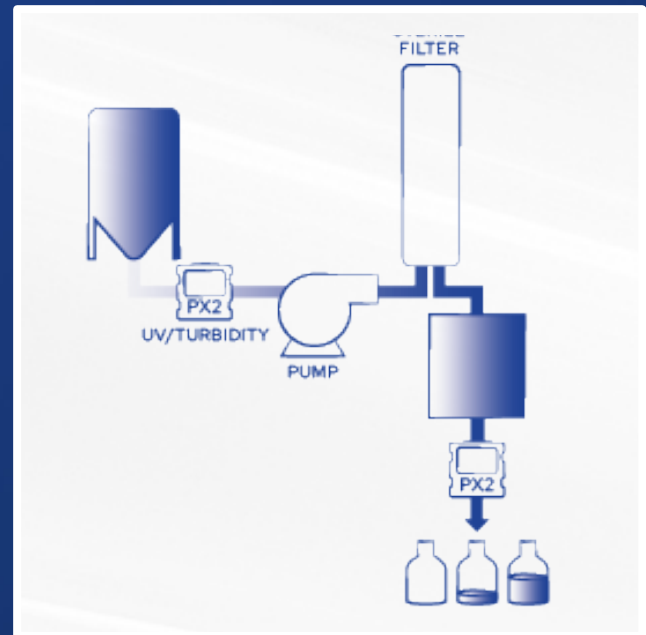
Depth Filtration (Turbidity)



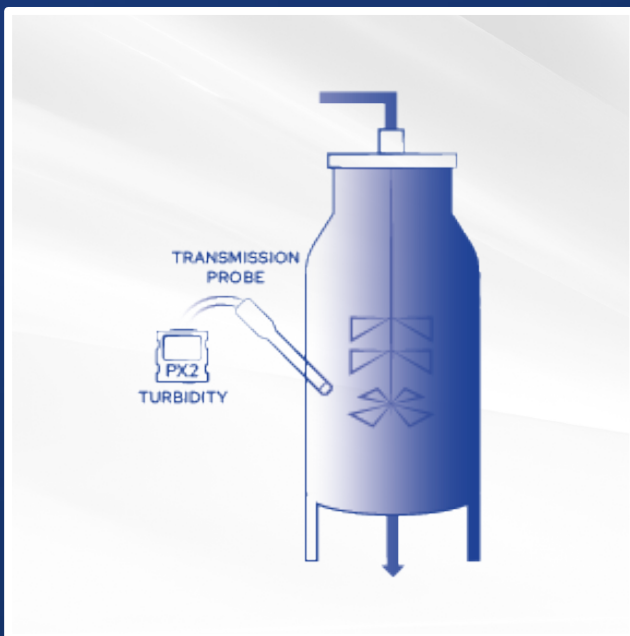
Depth filtration removes small particulates and aids in purification of a feed stream. The depth filter collects small particles by size exclusion and adsorption preventing disruption to downstream chromatography processes. Process efficiency and throughput can be improved by utilizing the 880 nm PX2 sensor. The 880 nm PX2 can detect when particles and cellular debris begin to break through the depth filter, giving operators real-time indication of the filter's performance and retention capacity.

FILL & FINISH (UV & TURBIDITY)

Special processes, procedures, and equipment are required to ensure product integrity during fill and finish operations. The PX2 can monitor UV absorbance, color, or turbidity of the final product, essentially eliminating the need for visual inspections. The PX2 greatly improves process efficiency and consistency of the final product.



FERMENTATION (TURBIDITY)



Installing the 880 nm PX2 with CST's robust process transmission probe directly into a fermenter or bioreactor gives operators real-time indication of cell growth. As product leaves the fermenter or bioreactor, turbidity is monitored to detect unclarified material. This increases efficiency by eliminating the need for offline testing. Available with various path lengths and insertion lengths, CST has the appropriate probe for any process.



CUSTOM SENSORS & TECHNOLOGY

A DIVISION OF CUSTOM SAMPLE SYSTEMS

www.customsensors.com

Sales@customsensors.com

531 Axminister Dr.
Fenton, MO 63026