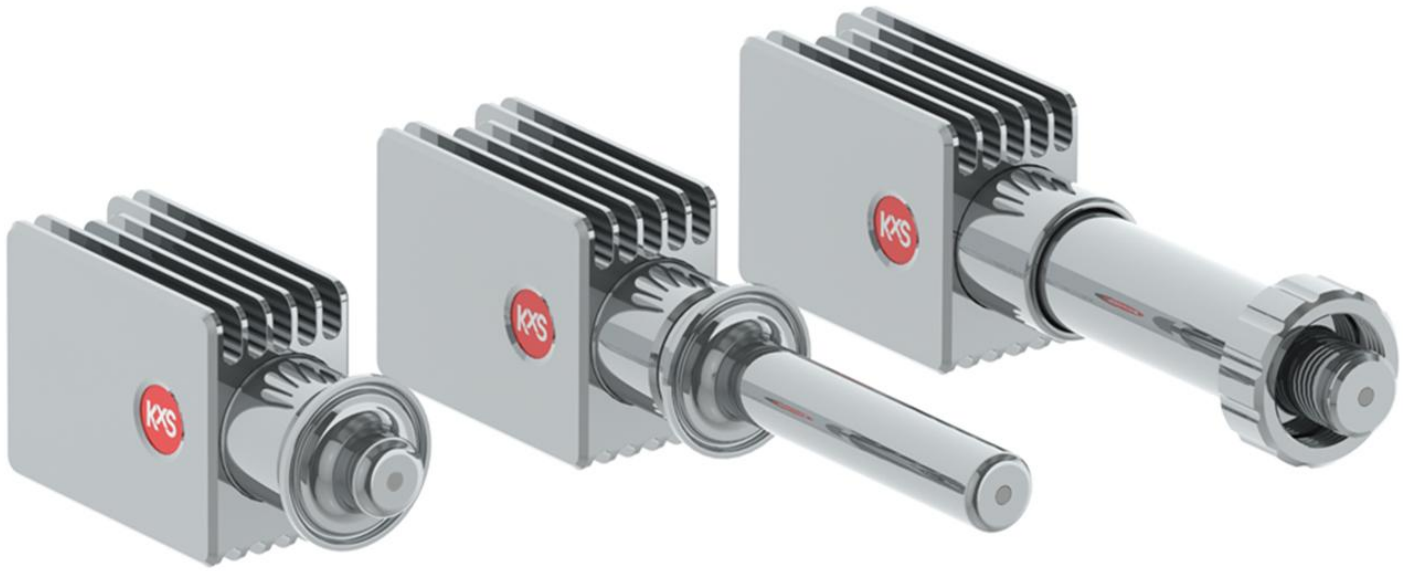
Inline PAT tool for real-time process insights



KxS Ingold refractometer DCM-20 for bioprocessing and pharmaceuticals

Technology that is built on over 40 years of industry-leading experience

KxS Technologies specializes in digital inline refractometry and advanced concentration measurement for demanding industrial processing, including bioprocessing, pharmaceuticals, semiconductors, food, sugar, chemicals, and pulp and paper.

In line with FDA's process analytical technology (PAT) framework, the KxS DCM-20 Ingold refractometer provides real-time, inline measurement of concentration % by weight, g/l and refractive index to improve process control. Integrated into biopharmaceutical workflows — including cell and gene therapy (CGT) — it offers deeper insights into process conditions and product quality attributes.

DCM-20 refractometers meet the highest hygienic standards, enabling safe installation in bioreactors, fermenters, purification skids and production pipelines.

Compact models connect via sanitary or VARINLINE® fittings and can be paired with Single-piece SFC flow cells for optimal flow and easy installation in small diameter pipelines. Probe models mount directly into standard 1" Ingold ports on bioreactors and fermenters or install via sanitary clamps in larger pipelines, vessels, tanks and crystallizers.

The DCM-20 offers dual 4–20 mA outputs and Modbus TCP for modern automation integration. Measurement, diagnostics and configuration are accessed through the built-in web interface on computer, tablet or mobile device, and no transmitter is required.

For facilities requiring local monitoring and operator interface, the Modular Connection Unit (MCU) provides a stainless-steel transmitter with display and access functions.

Proven performance in bioprocessing and pharmaceutical manufacturing

- **Real-time PAT-supported decision-making** — compressing development time and enhancing process understanding and optimization
- Monitoring and control of **real-time protein concentration** during downstream purification (e.g., Ultra filtration UF, Diafiltration DF, tangential flow filtration TFF)
- Identification of **cellular activity differences** under varying bioreactor operating conditions, improving understanding of optimal culture environments
- Defining **liquid product quality and consistency** in active pharmaceutical ingredients (API)
- Downstream purification of **virus-like particles (VLPs) in vaccine manufacturing**; sucrose density gradients can be monitored to distinguish virus-rich fractions
- Ensuring **carbon source concentration** (e.g., dissolved sugars) in fermentation processes
- And many more applications

How refractometer is used to improve protein purification control strategies

Real-time inline measurement can significantly improve monitoring and control throughout a multistep protein purification process. By tracking concentration continuously rather than relying on intermittent grab samples, operators gain clearer visibility into key purification stages — including ultrafiltration/diafiltration (UF/DF), hold and mixing tanks, and chromatography steps.

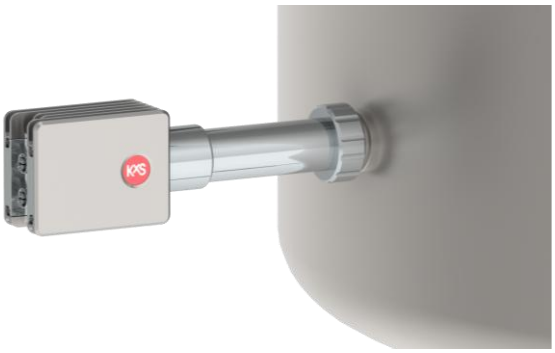
Continuous refractive index measurement enables better detection of concentration trends, identification of process deviations, and more consistent endpoint determination, supporting stronger control strategies and improved batch-to-batch reproducibility and precision.

In addition to monitoring the main purification sequence, the inline refractometer can also detect phenomena such as *protein concentration stratification* during high-concentration UF operations, ensuring the process remains well-mixed and representative.

It can likewise verify homogeneity in collection tank mixing steps and track concentration during chromatography steps, providing a versatile PAT tool that enhances process understanding and control.

Installation examples

1” Ingold connection for bioreactors and fermenters



1.5” or 2.5” sanitary clamp connection for tanks, bioreactors, fermenters and large pipelines

0.5” Pharma Single-Piece flow cell and sanitary mini clamp for small pipelines

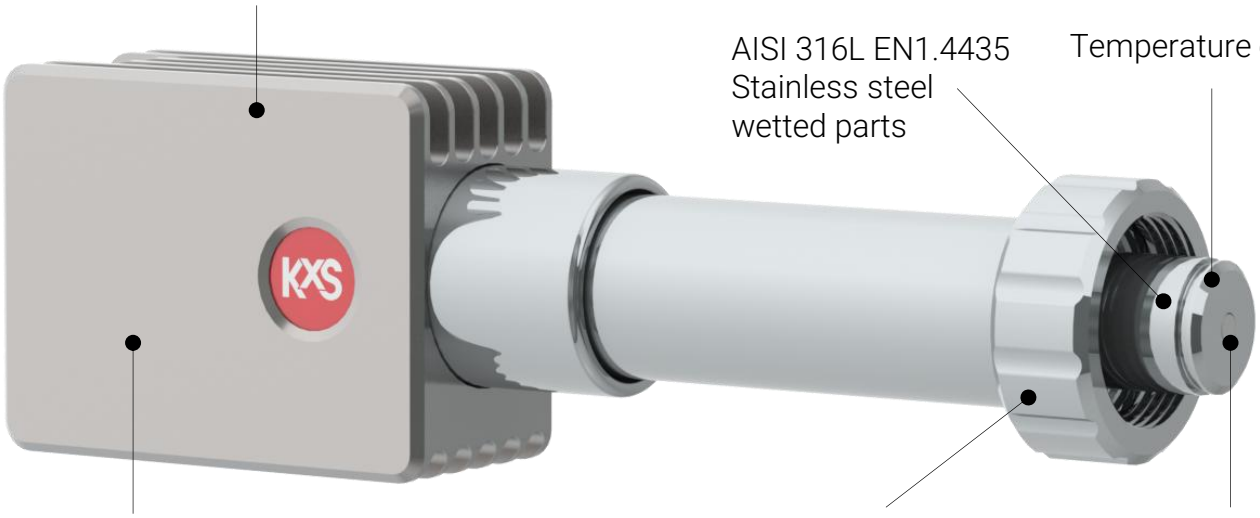
Single-piece SFC flow cell for straight pipe connection is innovation that offers significantly better flow velocity on prism compared to traditional elbow-mounted systems.

- Best laminar flow = keeps prism (measurement window) clean
- Minimizes dead spaces and risk of contamination
- Pressure rating up to 55 bar (800 psi)
- Scalable to process line sizes from 1” to 6”

The straight pipe connection simplifies the mounting point selection for horizontal and vertical pipes.

Key design features of Ingold model

KxS DCM-20 Ingold refractometer is protected by Utility Model FI 13493 Y1, ensuring a unique, purpose-designed solution available exclusively from KxS Technologies

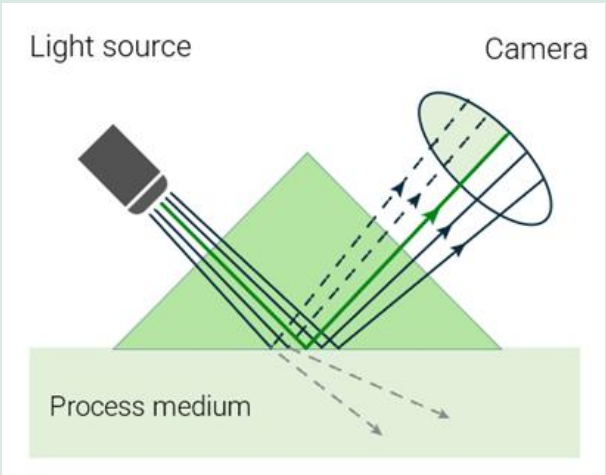


Optical refractive index measurement principle

KxS process refractometers DCM (digital concentration monitoring) employ the physical phenomenon of Refractive Index to define liquid concentration.

Optical concentration measurement is based on Snell’s law and the critical angle of total reflection to provide precise readings.

Light is emitted from an LED and directed towards the interface between an optical window and the liquid being measured. As the concentration of the liquid changes, specific angles of the light are totally reflected and partially reflected back, producing light and shadow interface that is captured by a digital camera sensing element.



This interface is detected by the light-activated camera pixels and converted into refractive index (RI).

The RI values can be directly used or further translated into any concentration units, such as percentage by weight. This method ensures that measurement signals are provided instantaneously, allowing for real-time process control.

KxS inline refractometer DCM-20 specifications

Refractive Index range:	Full range, nD=1.3200...1.5300 (equal by definition to 0...100%wt)
Output units:	Brix; Conc% by weight; g/l; refractive index RI
Measurement precision:	± 0.025 Brix/% by weight
Measurement accuracy:	± 0.0004 refractive index RI
Speed of response:	1 sec. undamped
Optics:	No mechanical adjustments and digital measurement with 4000-pixel CMOS camera 589 nm wavelength (sodium D-line), light emitting diode (LED) Built-in Pt-1000 temperature sensor (linearization according to IEC 751) Proprietary 6th generation image recognition algorithm for precise optical image detection
Temperature compensation:	Automatic, instrument individual zero-point calibration
Calibration:	NIST traceable calibration, verification with standard RI liquids
Wetted parts:	AISI316L EN 1.4435 Stainless steel, Sapphire prism (optical window), PTFE prism gasket USP <88> Class VI, FDA 21 CFR 177.1550 (perfluorocarbon resins) EPDM O-ring ADI free, USP <88> Class VI - 121°C, FDA 21CFR177.2600 a-d, e, f Sensor housing AISI316 EN 1.4404 Stainless Steel
Surface roughness	Ra 0.38 µm (15 µ inch), electropolished (no animal derived ingredients ADI)
Hygienic design:	For the 1.5" sanitary connection 3-A Sanitary Standard 46-04 symbol authorization and EHEDG (European Hygienic Equipment Design Group) Type EL Class I certified
Process connection:	Ingold 25mm (1") (insertion length customizable); Single-piece SFC flow cell for 1"…6" process lines (straight pipe connection), optional flow cell housing connections with sanitary or DIN/ANSI flanges; 1.5" and 2.5" sanitary connection, VARINLINE®. DCM-20 Ingold refractometer fastening arrangement and refractometer design is protected by Utility Model FI 13493 Y1, granting KxS Technologies the exclusive right to commercially exploit the invention
Process pressure:	Ingold model: -1 to 16 bar (-14.5 to -232 psi) according to standard Ingold weld-in sockets Other models: -1...55 bar (-14.5...800 psi) depending on process connection
Process temperature:	Compact sensor: -15°C (5°F)...100°C (212°F) continuous process temperature Probe sensor: -15°C (5°F)...130°C (266°F) continuous process temperature Withstand 130 °C Clean-in-Place CIP and Steam-in-Place SIP sequences
Ambient temperature:	-15°C (-40°F)...65°C (149°F)
Sensor protection class:	IP67, Nema 4X
Installation:	Indoor, unclassified area
Sensor weight:	Compact: 1.3 kg (2.9 lbs), Probe: 1.7 kg (3.75 lbs)
Outputs and connections:	
Digital M12 connector:	24VDC power supply, Modbus TCP for user interface and PLC connection, standard sensor cable length 10 m(33 ft), max 70 m(230 ft)
Analog M12 connector:	24VDC power supply, 2 pcs independent 4-20 mA user configurable outputs, standard cable length 10 m(33 ft), max, 200 m(660 ft). Max. load 1000 Ohm
Sensor Power consumption:	max. 2.6W
Options:	Modular Connection Unit MCU with enclosure, display/user interface Independent 7" Web HMI, full color touch screen interface Cleanroom sensor cover –CG Direct integration with Rockwell's Ethernet IP or Siemens Profinet PLC communications ATEX/IECEx approval for Ex ec mc IIC t4 Gb/Gc

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