Product Information

Single Use Cells

inline control

www.optek.com

For over 30 years, optek has focused on measuring process liquids through their interaction with light in facilities all over the world. Although global, optek remains a family owned company with a team of more than 100 qualified, customer-driven professionals.

Our confidence is born from experience. With the expertise of more than 30,000 installations worldwide, our value to the customer resides in providing a superior product that pays back.

As a global partner to various industries, optek offers the most advanced technologies including superior signal amplification, inline calibration support, PROFIBUS® PA, FOUNDATION™ Fieldbus and multilingual user interfaces for easy onsite operations.

Our support ensures long term satisfaction with programs such as “SpeedParts” and “SwapRepair” to provide our customers sustainable operations and minimized downtime at the lowest cost of ownership.

Conformity to international (ISO 9001), industry-specific (FM/ATEX approval) or company standards is easily achieved with optek. Wherever process composition is controlled, the name optek has become synonymous with world-class products and support.

Optimize your process with optek inline control.

Content

See our various product and application brochures for further details

Single Use Cells | 03

- No cross contamination
- No cleaning or validation
- Minimal hold-up volume
- OPL adaptation figure for maximum accuracy
- Up to 5 parallel measurements
- USP Class VI and FDA approval

Why Single-Use Downstream?

The single-use approach offers several significant advantages over conventional stainless steel systems. There is no need for cleaning or cleaning validation, eliminating cross contamination risks. This leads to shorter down times between batches, improving productivity. In applications where hazardous materials such as cytotoxic drugs or other potent biological materials are being processed, the Single Use Cells offer additional protection for operators who are isolated from these hazards.

Environmental Impact

The environmental impact is also improved by eliminating the need for harmful chemicals used to sanitize conventional systems. Generally, single-use components are professionally disposed of, usually incinerated, which is much more energy efficient than cleaning the stainless steel systems.

Single Use Cells

optek's Single Use Cell (S.U.C.) system consists of the disposable cell, a stainless steel cell holder with conductivity sensor, proven optical sensors and a converter capable of operating optical, pH and conductivity sensors.
This system is designed to optimize separation, purification and concentration processes in single-use chromatography and ultra-filtration systems. Multiple configurations are available depending on your application.

S.U.C. Design

optek Single Use Cells are manufactured in a clean room facility and are gamma irradiation ready. Special UV transparent quartz optical windows are pressed directly into the S.U.C. body, without the use of gaskets or sealants. During this process the specific cell calibration data is measured and calculated before it is recorded on the S.U.C. Label. The intuitive design of the SUC Holder makes it possible to only install the S.U.C. one way, leaving no room for user error. All Single Use Cells conform to **USP Class VI** and have **FDA approval**.

S.U.C. Labels

Each label is specific to the individual S.U.C. with a sensor constant for conductivity measurements and an OPL adaptation figure for optical models (SUC 04/SUC 05/SUC07). The table below shows an example of a SUC 07 label:

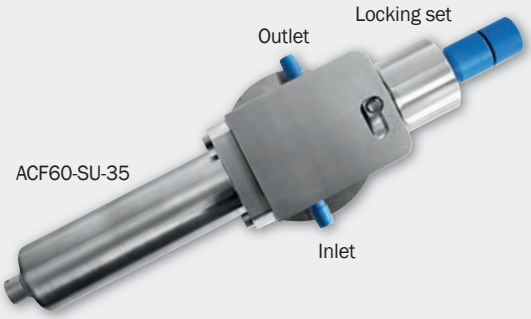
Details	Exemplary data
Serial number S.U.C.	P0-22990-0005
Name	SUC07-T-0.375-002.5
optek part number	1106-0025-0102-00
Linesize	ID 3/8"
OPL	2.5700 mm
Conductivity: sensor constant	1.0035
UV OPL adaptation	0.9728
Manufacturing date	2018-11-20
optek-Danulat GmbH, 45356 Essen, Germany	

S.U.C. Installation

The S.U.C. is easily installed into the process with the SUC Holder assembly. Each SUC Holder is equipped with the conductivity sensor ACF60-SU-35 (except the SUC Holder OPT with the SUC 04, which is only for optical measurements). The S.U.C. specific data from the label which includes the sensor constant and the OPL adaptation data is then entered into the ''Calibration SUC'' menu in the C8000 universal converter, which guarantees precise, repeatable measurements.

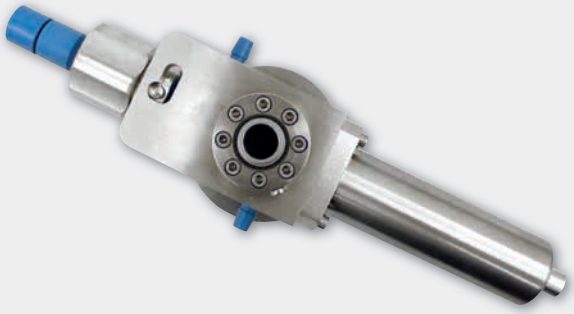
The SUC Holder-Pre /-Post is positioned on the skid at an angle (optek recommends between 15° - 75°) to allow the S.U.C. to drain completely and in the case of SUC 03/07 where a pH probe is fitted, to allow an angulated position for the pH electrode. optek Single Use Cells are delivered to the customer double-wrapped in plastic to ensure no contamination is possible and to conform to all industry standards. They are usually connected to the tubing before the whole assembly is sterilized using gamma irradiation.

04 S.U.C Designs



optek SUC 03 in SUC Holder Pre R
(right mounting version)

optek SUC 04 in
SUC Holder OPT



optek SUC 07 in SUC Holder Post L
(left mounting version)

Primarily designed for pre- and post-column chromatography monitoring, integral parts of the S.U.C. system include the holder and locking set mechanism. This innovative design guarantees proper installation.
To enable easy and fast installation into the process instrumentation the SUC Holder is already equipped with the conductivity sensor ACF60-SU-35.

SUC Holder Pre-Column

The SUC Holder Pre is available in L (left mounting) and R (right mounting) versions and is designed for the SUC 01 and SUC 03.

SUC Holder OPT

The SUC Holder OPT is specifically designed for the purely optical measuring SUC 04. Two versions are available, depending on which sensor is to be used.

SUC Holder Post-Column

The SUC Holder Post is available in L (left mounting) and R (right mounting) versions and is designed for the SUC 05 and SUC 07. Additionally, there are two options of window ring combinations depending on the sensor to be connected.

SUC Holder OPT Geometry

The SUC Holder OPT has a different design with guide rails which position the SUC 04 correctly in the holder. Everything is secured once the cell is in place by the locking mechanism.

Conductivity Sensor ACF60-SU-35

Compatible with all S.U.C. designs. (except the optical measurement only SUC 04) the ACF60-SU-35 conductivity sensor was primarily designed for the control of pre- and post-column chromatography.

Patented Design

The patented arrangement of the four current electrodes around the two potential electrodes results in a greatly reduced sensitivity to sensor fouling and polarization. Connected to an optek C8000 converter, a measuring range from 0 µS/cm up to 150 mS/cm is possible for both Pre and Post Holder sensors. The integrated temperature sensor in the ACF60-SU-35 provides accurate temperature compensation.

Hold-up Volumes

The S.U.C. reduces hold-up volumes compared to conventional stainless steel systems e.g., a post-column SUC 07 with a 1 mm optical path length (OPL) has a hold-up volume of 22 mL, a conventional system would require 2 sensor bodies with a total hold-up volume of over 56 mL.

Available Models:

	SUC 01	SUC 03	SUC 04	SUC 05	SUC 07
Conductivity	✓	✓	–	✓	✓
pH	–	✓	–	–	✓
Optical	–	–	✓	✓	✓
Example					

S.U.C Designs | 05

ACF60-SU-35

S.U.C.

Sanitary Design:

- **Assembly of the S.U.C.** (including the sensing element) **automatically connects to the conductivity sensor ACF60-SU-35**
- **Individual conductivity sensor constant for maximum accuracy and repeatability**

SUC 01

Originally designed for pre-column chromatography measurements the SUC 01 measures conductivity including a temperature compensation.

The label on the SUC 01 provides the data specific to that cell including the conductivity sensor constant. This sensor constant data is entered into the calibration menu in the C8000 universal converter. Whenever the SUC 01 is replaced with a new one, the new conductivity sensor constant data is simply entered into the calibration menu of the C8000 converter.

SUC 03

The SUC 03 measures conductivity with a temperature compensation measurement with the addition of a pH adapter for pH measurements.

The SUC 03 with the pH adapter is compatible with a broad variety of standard pH electrodes (Ø 12 mm x 120 mm).

SUC 04

The optek SUC 04 is the only purely optical version of the Single Use Cell, which was designed for the optimization of downstream separation processes. The SUC 04 together with the SUC Holder OPT allows for a wide range of optek UV or turbidity sensors to be connected, depending on the process needs. Each SUC 04 is marked with a serial number and OPL adaptation data during manufacture in a clean room facility to ensure absolute measurement accuracy.

There are two separate versions of the SUC Holder OPT, depending on which sensor is needed for the process. Mounting on the skid is usually made so that the SUC 04 is at 90° providing a vertical flow upwards through the SUC 04 and allowing for the SUC 04 to drain completely.

SUC 05

Designed to monitor separation, purification and concentration processes in disposable systems, the optek SUC 05 provides conductivity measuremts with a temperature compensation, together with optical mesurements.

The label on the SUC 05 provides the data specific to that cell including the conductivity sensor constant and the OPL adaptation data. This sensor constant and OPL adaptation data is entered into the calibration menu in the C8000 universal converter, ensuring the highest measurement accuracy.

SUC 07

Developed for the same applications as the SUC 05 the SUC 07 provides the same measurements as the SUC 05, conductivity with a temperature compensation and optical measurements, with the addition of pH measurements all in one Single Use Cell, which makes the SUC 07 quite unique.

All optek SUC 04, SUC 05 and SUC 07 versions are available with a standard 1 mm, 2.5 mm and 10 mm OPL (optical path length), together with a wide range of line sizes from ¼ in. up to 1 in..

optek SUC 07 Conductivity, Optical, pH and Temperature Measurements

06 S.U.C. Technical Data

Technical Data	S.U.C. Holder Including ACF60-SU-35	SUC Hoder OPT
Material (non wetted)	SS 316 L	
Measuring range	0 µS/cm to 150 mS/cm Accuracy: ± 2 % of measuring value ± 0.4 µS/cm (dependent on ambient and process temperature being equal)	N/A
Temperature compensation of conductivity sensor	Accuracy ≤ 0.8 % of measuring value at temperature conditions (T ambient - T process) ≤ ± 20 °C (± 68 °F)	N/A
Protection	IP65	N/A
Cleanability	Cleaning with standard cleaning agents (alcoholic surface disinfectants, quaternary ammonium compounds) is permitted.	
	Caution! Ensure that windows are clean and dry and the contact unit for the electrodes is dry before starting measurement.	Caution! Ensure that windows are clean and dry before starting measurement.
Technical Data	**SUC 01 / SUC 03 / SUC 05 / SUC 07**	**SUC 04**
Material (wetted)	Conductivity electrode pins: stainless steel 1.4435 (SS 316L), dF < 1%, BN2	N/A
	Windows (SUC 04, SUC 05, SUC 07): Quartz, UV transparent Gasket: EPDM (FDA, USP class VI) Sensor body: Polyphenylsulfone (PPSU) The plastic and elastomeric wetted parts of the sensor have passed the bio-reactivity tests according to USP <87> and <88> class VI and comply with FDA Regulations 21 CFR 177.2600. All wetted parts are of non-animal origin and any materials of animal origin or containing animal substances are not used during manufacture. All wetted parts are of bovine-free origin and any materials of bovine origin or containing TSE have not been used during manufacture.	
Material (non wetted)	Adhesive: Epoxy LOCTITE M-31CL	
Surface (wetted parts)	Ra < 0.8 µm	
Process connection	Hose barb	
Line size	1/4 in., 3/8 in., 1/2 in., 5/8 in., 3/4 in., 1 in.	
OPL (SUC 05, SUC 07)	1 mm, 2.5 mm, 10 mm, others on request	
Shelf life	36 months after manufactoring date	
Temperature and Pressure Ratings		
Process pressure	0 - 6 bar (0 - 87 psi) May be reduced in combination with pH probe. Refer to corresponding instruction manual for specifications of pH probe	0 - 6 bar (0 - 87 psi)
Process temperature	2 - 50 °C (35.6 - 122 °F) May be reduced in combination with pH probe. Refer to corresponding instruction manual for specifications of pH probe	2 - 50 °C (35.6 - 122 °F)
Ambient conditions	Temperature during operation: 2 - 30 °C (35.6 - 86 °F) Relative humidity 80 % for temperature up to 31 °C (87 °F)	

Data given are subject to changes without prior notice.

Assembly of a SUC 07

8 Measurements
5 Sensors
2 S.U.C.'s
1 Converter

C8000 Universal Converter

The optek C8000 universal converter combines electrochemical and photometric sensors into one integral system.

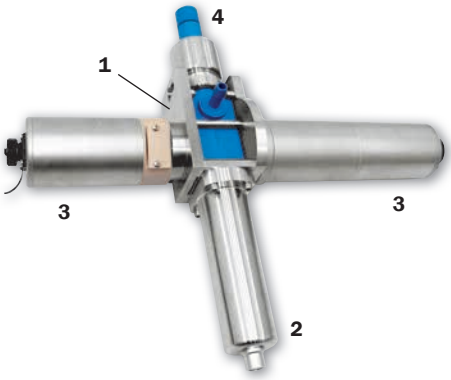
Built specifically for the biotech industry, the C8000 monitors the most important parameters in downstream processes such as UV, pH, conductivity and temperature. optek's C8000 universal converter and Single Use Cells are the ideal choice for single-use downstream processing.

C8000 Software Features

- 8 parameter sets (incl. range, display etc.)
- 16 linearization tables (max. 11 points)
- 8 offset and slope sets
- Auto zero (local or remotely activated)
- Password protection (3 levels and none)
- Memory (non-volatile) retains all configurations and logged data.

Chromatography Pre- and Post-column

With the optek C8000 universal converter, it is possible to monitor both pre- and post-column chromatography measurements with one single converter. A total of 8 measurements can be displayed from 5 sensors connected to 2 optek Single Use Cells (S.U.C.).



1) Fully assembled SUC Holder Post L with SUC 07
2) ACF60-SU-35 conductivity sensor
3) AF46-VB dual channel UV sensor with calibration adapter
4) pH adapter

C8000 Benefits

A variety of configurations and features are included to meet the most demanding needs of any process. The open architecture of the C8000 allows the user to define mA outputs and create user defined units.

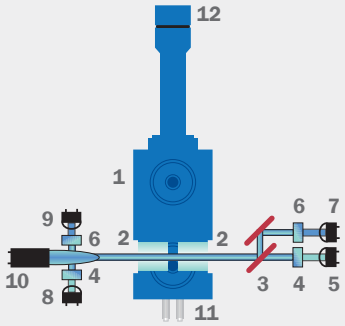
The C8000 and S.U.C. are compatible with most Ø 12 mm x 120 mm VarioPin™ glass pH electrodes with integrated PT100 or PT1000, allowing users to choose the probe that works best for their process.

C8000 Sensor Combinations with S.U.C. *	
1 Optical Sensor	
AF16 VIS-NIR Absorption	1
AF26 Dual Channel Color	1
AF45 UV-Absorption	1
AF46 Dual Channel UV	1
4 Electrochemical Sensors	
pH-probe	2
Conductivity optek ACF (6-pol)	2

* Depending on S.U.C. model used

For more information on C8000 including technical data, accessories, data transfer capabilities and housings, see our C4000/C8000 product information brochure or visit: www.optek.com

08 S.U.C. Applications: Chromatography



Model AF46 Dual Channel Absorption (UV)

1 SUC 07
2 Windows
3 Beam splitter
4 Filter A
5 Measurement detector A
6 Filter B
7 Measurement detector B
8 Reference detector A
9 Reference detector B
10 Lamp module
11 ACF60-SU-35 electrode pins
12 pH Adapter

No window gaskets used

The Importance of Chromatography Monitoring

Monitoring the ''mobile phase'' or eluent is extremely important, as the conductivity and pH of the mobile phase can be used to influence the retention time of the analyte as it passes through the chromatography column (or stationary phase). A UV absorption sensor is then used to detect the concentration of various protein fractions in the eluate as they emerge from the column.

Pre-Column Chromatography Monitoring

For process optimization of Pre-column conductivity and pH measurements there are two S.U.C. options:
The SUC 01 (conductivity and temperature measurement) or the SUC 03 (conductivity and temperature measurement plus pH).

The integrated ACF60-SU-35 conductivity sensor provides measurements in the range of 0 µS/cm to 150 mS/cm with temperature compensation.

Post-Column Chromatography Monitoring

Depending on the process needs there are two S.U.C. options for the post column measurements.
The SUC 05 (UV measurement and conductivity with temperature measurement) or the SUC 07 (UV measurement and conductivity plus pH).

UV Measurements

When monitoring the elution process in a chromatography process an optek AF45 single channel UV absorption or AF46 dual channel UV absorption sensor is used to measure the concentration of protein

Dual Wavelengths

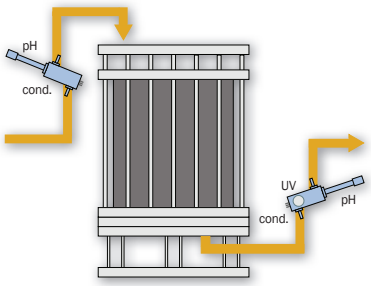
A 280 nm UV module is used to detect very low protein concentrations with the highest sensitivity to best detect start and end point for the pooling of fractions. A secondary wavelength is used simultaneously to monitor the elution at the higher concentration ranges.

Having the same performance characteristics as standard stainless steel systems, but with a reduced hold-up volume, the S.U.C. is easy to install and is fully compatible with the optek range of UV, NIR and color absorption sensors. A NIST-traceable standards calibration set is optionally available, to increase the confidence in your measurements (for details see page 11).

Application (example)

Pre-and Post-column Chromatography Monitoring

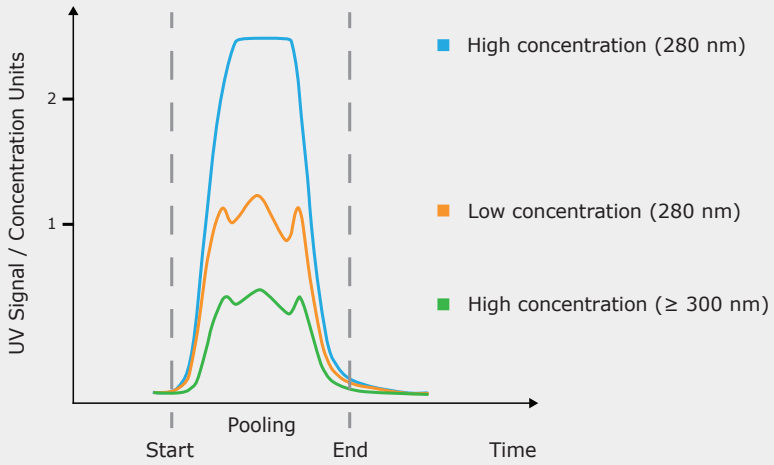
During purification, accurate, reliable and repeatable measurements are necessary to ensure accurate pooling to maximize yields and protein/DNA fraction purity.



1 Converter		2 S.U.C.'s	5 Sensors	8 Measurements
C8480	Pre-column	Line size: 0.50 in. **SUC 03** PN: 1106-0000-0103-01 Volume: 20 mL	**ACF60-SU-35** (patented 6 electrode, 4 pole design)	**Conductivity:** 0 µS/cm to 150 mS/cm
			PF12 (various pH electrodes)	**Temperature:** 2 - 50 °C (35.6 - 122 °F) * **pH:** 0 - 14 pH
	Post-column	Line size: 0.50 in. **SUC 07** PN: 1106-0025-0103-00 OPL: (optical path length) 2.5 mm Volume: 23 mL	**ACF60-SU-35** (patented 6 electrode, 4 pole design)	**Conductivity:** 0 µS/cm to 150 mS/cm **Temperature:** 2 - 50 °C (35.6 - 122 °F) *
			PF12 (various pH electrodes)	**pH:** 0 - 14 pH
			AF46 Dual channel UV Absorption	**UV Absorption:** at 280 nm ** at 300 nm **

* Depending on type of pH probe used
** Wavelengths available for specific process needs

High Protein Concentrations | 09



Ultra-High Protein Concentration Monitoring

Determining protein or DNA concentrations of cell extracts is an essential step in bioprocessing. The next generation of monoclonal antibody (mAb) based therapeutics and advances in upstream and downstream technologies all require online monitoring. This has created a need to measure ultra-high protein concentrations in the range of 40 – 500 mg/mL or even higher.

These ultra-high protein concentrations can no longer be monitored by the standard wavelength modules usually used for chromatography, measuring at 280 nm or 300 nm, even with the smallest OPL (optical path length).

When monitoring a standard single-use chromatography elution process, usually a 280 nm UV module is used to detect very low protein concentrations with the highest accuracy to best determine start and end point for the pooling of fractions. This module however, cannot be used to detect ultra-high protein concentrations since the end of the linear range will be reached at around 25 mg/mL.

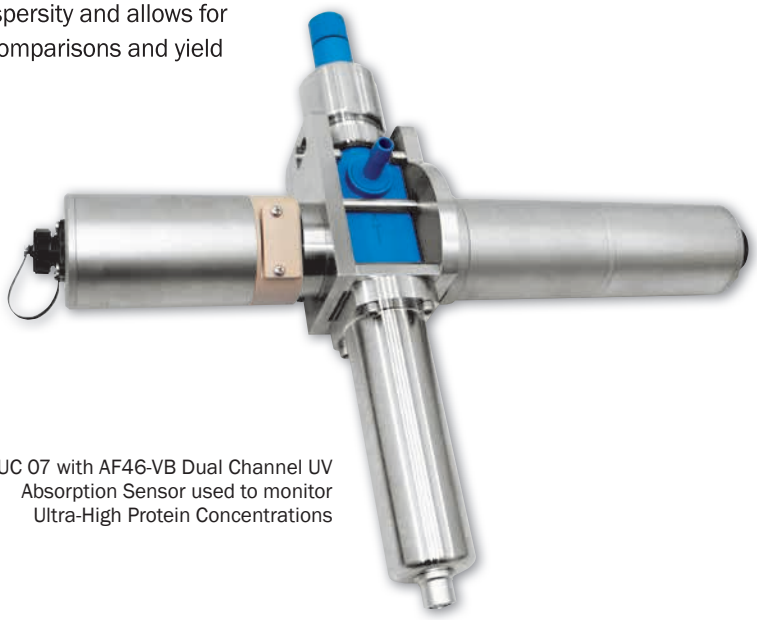
Combining Sensitivity and Dynamic Range Dual Channel UV

To monitor these ultra-high protein concentrations and the whole elution peak a special high concentration wavelength module is used that allows the measuring of protein concentrations higher than 500 mg/mL (depending on the type of protein).

Both these measurements can be realized in one SUC 05 or SUC 07 with a dual channel AF46 UV absorption sensor. The primary wavelength measures concentration of protein for pooling purposes while the secondary wavelength is used to simultaneously capture ultra-high concentrations. Monitoring the whole elution peak reveals potential deviations from the desired monodispersity and allows for batch to batch comparisons and yield calculations.

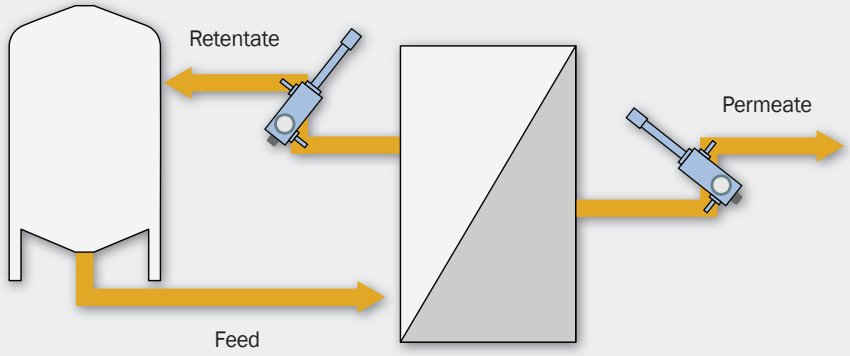
Additional sensor options include a module for the detection of impurities such as protein aggregates that might impact the quality of the manufactured biophamaceutical.

For more information on AF46 including technical data, see our C4000/ C8000 product information brochure or visit: ***www.optek.com***



optek SUC 07 with AF46-VB Dual Channel UV Absorption Sensor used to monitor Ultra-High Protein Concentrations

10 | S.U.C. Applications: Tangential-Flow Filtration (TFF) Ultra-/Diafiltration (UF/DF)



The Importance of TFF or UF/DF monitoring

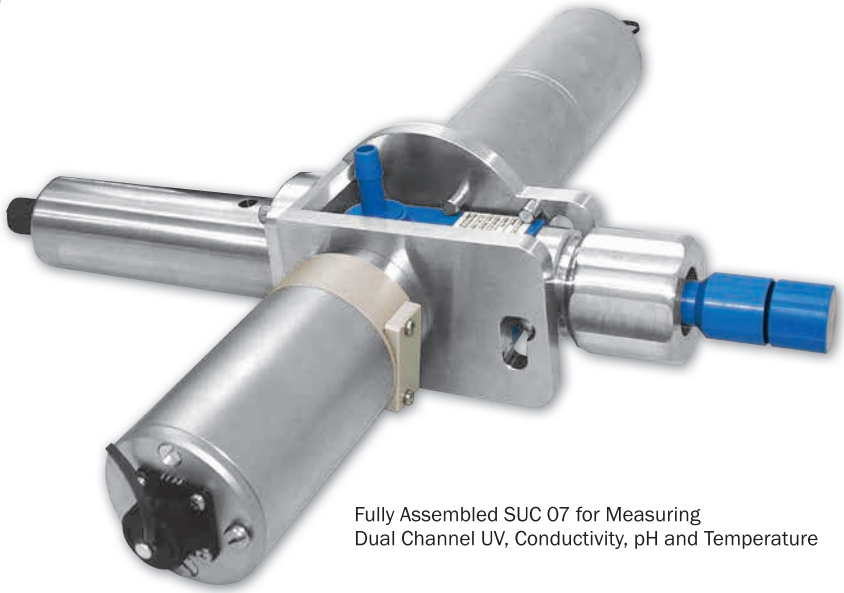
Tangential-Flow Filtration (TFF) or Ultrafiltration (UF), Diafiltration (DF) is used between chromatography steps to concentrate proteins or change the buffer conditions to prepare it for subsequent chromatography steps. Usually, a UV absorption sensor is installed on the permeate stream to detect the lowest protein concentrations for filter integrity control. Another UV sensor installed on the retentate loop is used to monitor and control the high protein concentrations in the retentate stream, which is an advantage as it provides constant feedback of the retentate loop and eliminates manual sampling of these highly concentrated process streams.

Permeate Monitoring

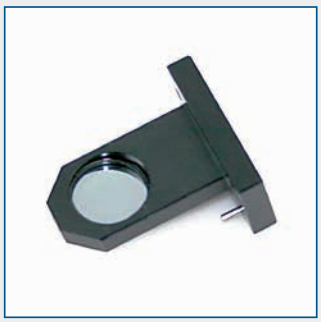
For permeate monitoring, there are two S.U.C. options including the SUC 05 (UV measurement and conductivity with temperature measurement) or the SUC 07 (UV measurement and conductivity with temperature measurement plus pH) using a standard 280 nm UV module with an Optical Path Length (OPL) of 10 mm for filter breakthrough detection. The integrated ACF60-SU-35 conductivity sensor provides measurements in the range of 0 µS/cm to 150 mS/cm with temperature compensation.

Retentate Monitoring

For retentate monitoring, the same cell types SUC 05 and SUC 07 are used, however, in combination with a singlewavelength or dual-wavelength UV sensor and an Optical Path Length (OPL) of 2.5 mm. The high protein concentrations are captured using optek's high-performance UV modules with the secondary UV wavelength allowing users to monitor protein concentrations above 500 mg/mL, which is equivalent to an Optical Density or absorbance of 600 to 700 OD (AU).



Fully Assembled SUC 07 for Measuring
Dual Channel UV, Conductivity, pH and Temperature



optek calibration accessories are specifically designed for nonintrusive calibration and verification of optek systems.

UV Sensors

Three series of solid filters are used to ensure confidence in measurements. The UV-L filter series is used to calibrate photometric accuracy and linearity. The UV-B filter series verifies integral blocking and the UV-S filter series tests for long-term stability of the sensor.

VIS/NIR Sensors

A special series of solid filters is available for each wavelength (range) to ensure best measurement performance. The calibration filters are used to calibrate photometric accuracy and linearity.

NIST-Traceable*

All optek UV/VIS filters ship with NIST-traceable certification. The optek calibration laboratory is equipped with a high quality reference spectrophotometer to assure quality and quick turnaround time for recertification of filters.

* NIST = National Institute of Standards and Technology

Concept

Advantages of optek calibration concept include:

- Only 1 filter (set) for multiple sensors ensures identical calibration and high comparability of results

- Only the filter needs to be sent back for recertification, while the sensor remains operating

- **Calibration Filters UV-L**
  Nominal absorption:
  0.45, 0.9, 1.8 and 2.4 CU*
- **Calibration Filter UV-B**
  Nominal absorption:
  > 3 CU*
- **Calibration Filters UV-S**
  Nominal absorption:
  Application specific
- **Calibration Filters VIS-L**
  Nominal absorption:
  0.45, 0.9 and 1.8 CU*
- **Calibration Filters NIR-L**
  Nominal absorption:
  0.45, 0.9 and 1.8 CU*

* CU = Concentration Units

- **Calibration Case**
  Holds up to 7 calibration filters
- **Calibration Cuvette**
  The unique calibration cuvette, FH03, enables product calibration without need to interfere with the process line.
  The cuvette allows users to create a correlation of absorption signals to the concentration of product or an equivalent substance, creating an easy link from lab to process.

Calibration Cuvette FH03

12 Contact

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inline control

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