ÄKTA readyflux™ TFF system 500

SMALL-SCALE, SINGLE-USE TANGENTIAL FLOW FILTRATION SYSTEM

The ÄKTA readyflux™ TFF system 500 is a single-use tangential flow filtration (TFF) system designed for process development (PD) and small-scale GMP manufacturing. Optimized for low-volume purification workflows, it delivers high-performance separation and concentration for advanced therapies including mRNA, viral vectors, monoclonal antibodies (mAb), and antibody drug conjugates (ADC). The system can be used in both upstream and downstream workflows.

Scale filtration from PD to GMP manufacturing on one platform

- Integrated ÄKTA readyflux platform enables scalability from process development to large-scale GMP manufacturing, accelerating development time and simplifying process transfer.
- Interactive process picture UNICORN™ software with pre-defined phases and an intuitive, user-friendly interface streamlines method creation, reducing setup time and minimizing the need for programming expertise.
- Innovative system design with low minimum working and hold-up volumes ensures high concentration factors and high product recovery, specifically for low-volume applications.
- The ⅛ inch single-use flow kit featuring an integrated 1 L recirculation tank with active mixing enables rapid changeovers, reducing cleanroom downtime, and is available in basic and plus configurations to meet diverse process requirements.
- Compatible with both filter cassettes and hollow fiber cartridges, offering flexibility for a wide range of filtration applications.

System overview

As a member of the ÄKTA readyflux family, the ÄKTA readyflux TFF system 500 unlocks new capabilities for small-scale manufacturing (Figure 1). Designed for TFF (also called cross flow filtration), it integrates seamlessly with the automated UNICORN control software — featuring intuitive, phase-based method creation using the phase library that eliminates the need for programming expertise or extensive operator training. This reduces onboarding time and minimizes the risk of human error. The system features real-time, in-line monitoring and control of critical process parameters (CPP), ensuring robust process oversight. Connectivity via an external laptop supports streamlined operations, while the software's built-in support for



Fig 1. The ÄKTA readyflux TFF system 500.

electronic batch records enables U.S. Code of Federal Regulations (CFR) Title 21 Food and Drugs, Part 11: Electronic Records; Electronic Signatures (21 CFR Part 11) compliance, ensuring data integrity and audit readiness.

The ÄKTA readyflux TFF system 500's advanced engineering minimizes both minimum working and hold-up volumes, enabling high concentration factors and higher product recovery, specifically optimized for low-volume bioprocessing workflows where material conservation is critical.

The ⅛ inch single-use flow kit features a 1 L recirculation tank with active magnetic mixing. It can be quickly installed in less than 15 minutes, significantly reducing the changeover time between batches and cleanroom downtime, thereby improving operational efficiency while minimizing the risk of cross-contamination. A built-in load cell provides precise weight measurement, ensuring accurate process control. Pre-calibrated, integrated sensors for pressure, conductivity, temperature, flow, UV, and pH enable precise monitoring and control of CPPs, and combined with controlled mixing, ensure robust performance and batch-to-batch consistency.

The ÄKTA readyflux TFF system 500 features a compact, benchtop design optimized for cleanroom integration, minimizing spatial footprint without compromising functionality. It is compatible with both flat sheet cassettes and hollow fiber cartridges, supporting flexible deployment across diverse filtration modalities. The system accommodates holders for both membrane options. The cassette holder is supported directly on the system, without the need for an external holder, and is available as a separate item. A mounting plate is included with the system. The mounting plate makes it possible to fit the cassette holder (CSUH040) to the system (Figure 2). The system is also supplied with an integrated hollow fiber holder, designed to accommodate up to two hollow fiber units.



Fig 2. The ÄKTA readyflux TFF system 500 features a cassette holder supported directly on the system. The cassette holder is a standard holder (CSUH040).

Flow kit

The ⅛ inch single-use flow kit is engineered for low minimum working and hold-up volumes, enabling high concentration factors and maximizing product recovery for low-volume applications. It includes a 1 L recirculation tank with active magnetic mixing, a single-use pump head, and flow kit tubing. Integrated sensors provide real-time monitoring of recirculation tank volume/weight, pressure, conductivity, temperature, permeate flow, UV, and pH. The system supports a flow rate range of 5 to 500 mL/min, offering precise control for low-volume microfiltration and ultrafiltration processes.

Each flow kit is gamma irradiated (25 to 40 kGy), double bagged, and available with tri clamp (TC) connectors or with AseptiQuik™ S connectors for aseptic connection. The flow kit is delivered fully assembled as a single unit, with the permeate and transfer sections coiled and clearly labeled for ease of installation. It can be installed in less than 15 minutes by following the procedure provided in the operating instructions.

The flow kit is available in two configurations — basic and plus, enabling flexibility for different process requirements. Both configurations include four pressure sensors located on the feed, retentate, and permeate lines, and upstream of the feed tank. In the basic flow kit configuration, the conductivity/temperature sensor is located on the retentate line, and the flow meter is located on the permeate line. In the plus configuration, additional sensors for pH/temperature, UV, and conductivity/temperature are also located on the permeate line, supporting procedures such as installation qualification/operational qualification (IQ/OQ) and advanced process setup (Figure 3). The flow kit has a limited operational time of 48 hours after initial wetting within a 14-day period.

Transfer line

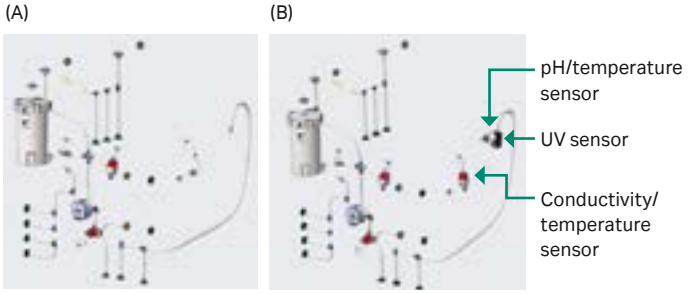


Fig 3. In the basic flow kit (A), the conductivity/temperature sensor is located on the retentate line and the flow meter is located on the permeate line, while the plus flow kit (B) includes additional sensors for UV, conductivity/ temperature, and pH on the permeate line.

The transfer line has three inlets that can be used for diafiltration buffer, product feed, and equilibration buffer. A peristaltic pump transfers the buffers or product into the recirculation line. The pump can also be used for automated fed-batch operations. An air sensor allows complete loading of the sample and prevents air from entering into the system. An air filter is included in the transfer line to filter air during sample recovery by air blow down. A secondary air filter is connected to an external air integrity tester, enabling inline filter integrity testing.

Recirculation line

The recirculation line has four inlets for liquids: for filter flushing, filter cleaning, equilibration buffer, and filter storage. The ÄKTA readyflux TFF system 500 utilizes a low-shear diaphragm recirculation pump with a single-use pump head integrated into the flow path. Pressure sensors are positioned in both the feed line and in the retentate line, along with sensors for conductivity and temperature. Product recovery is facilitated through a low-point drain, enabling efficient and complete drainage of the system. Transmembrane pressure (TMP) is regulated via a retentate pressure control valve (PCV), allowing precise control of filtration conditions. It is recommended to prime the pump at full speed to ensure complete removal of air traces in the pump head. The by-pass line in the recirculation loop is provided specifically for pump priming, protecting the filter from potential damage during startup.

Permeate line

The permeate line includes sensors for pressure, conductivity, temperature, flow, UV, and pH, enabling precise monitoring and control throughout the filtration process. The permeate PCV can be used for permeate flux control during microfiltration operations.

Reservoirs

A 1 L recirculation tank is integrated within the single-use flow kit and features active mixing via a magnetic stirrer bar to ensure homogeneous mixing. The recirculation tank is mounted on a load cell assembly, enabling accurate weight measurement.

External connections

The system includes ports for external customer I/O and integration with peripheral equipment such as external weighing scales. Up to four external tanks can be connected, enabling configurations such as permeate collection on an external scale for enhanced process monitoring and control. For low permeate flow rates, an external scale can be used to ensure accurate measurement.



Fig 4. The ÄKTA readyflux TFF system 500 with laptop connectivity.

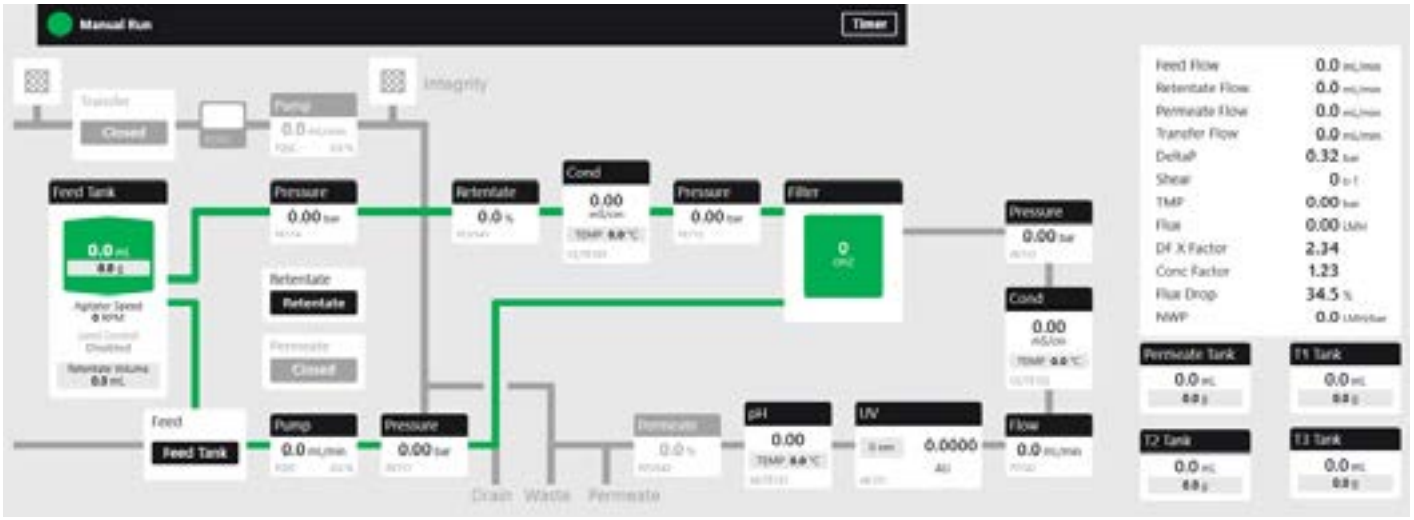


Fig 5. The process picture of the UNICORN software enables real-time monitoring and comprehensive control of CPPs.

Designed for a low minimum recirculation volume

Low hold-up volume

The system hold-up volume refers to the volume of liquid in the filtration system, excluding the filter and any additional tubing. To obtain the total system hold-up volume, the filter and any additional tubing hold-up volumes need to be added to the hold-up volume of the flow kit. For optimal process efficiency and product recovery, the system and filter should be selected for the lowest hold-up volume while still meeting other performance requirements of the process. The ÄKTA readyflux TFF system 500 has a hold-up volume of 13 mL, of which approximately 3 mL or less is typically non-recoverable.

Low minimum working volume

The system's minimum working volume represents the minimum volume of fluid in the recirculation line required to operate the system at the desired crossflow rate without drawing air into the recirculation line. The minimum working volume is determined by the design of the system (recirculation tank, feed and retentate tubing, and additional jumpers if used to connect filters), the filter hold-up volume, and the crossflow rate. When designing a filtration process, it is critical to ensure that the target recirculation volume is not less than the system's minimum working volume.

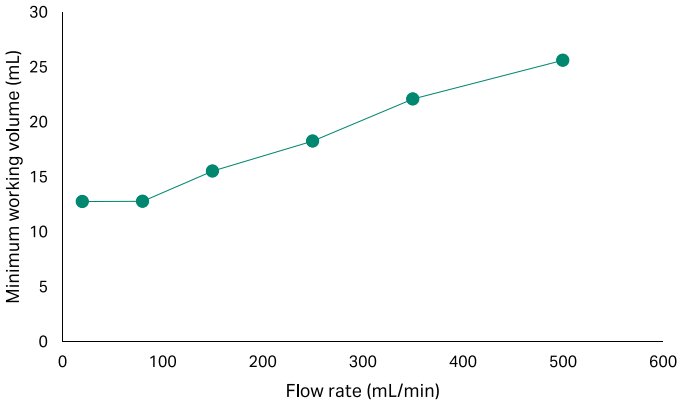


Fig 6. Minimum working volume (recirculation line excluding filter) at different feed flow rates with the ÄKTA readyflux TFF system 500 flow kit using purified water.

Interactive process picture UNICORN software

The interactive process picture UNICORN control software with pre-defined phases streamlines method creation and is based on an integrated controller. Its intuitive, user-friendly interface uses the familiar Windows environment.

The run sequence is determined by the end-user for control of a specific process. A graphical interface helps you create the process sequence. Conventional line programming can be performed by advanced users. The UNICORN software contains the tools needed to perform almost any type of TFF process at different scales, from setting up and running a method to evaluating the data.

The software includes four modules:

- ***Method Editor:*** provides an easy interface to create or modify methods.
- ***System Control:*** allows performing and monitoring the run in real time.
- ***Evaluation:*** supports data analysis and report generation.
- ***Administration:*** used to set up user access, view logs, and manage the built-in SQL Server™ database tools.

External user audits have shown that the UNICORN development process offers good adherence to the framework, principles, and practices described in GAMP™ 5 and that the functionality of the product is acceptable for use in a cGMP regulated environment in a manner that complies with 21 CFR Part 11. The UNICORN software uses a standard for open platform communication (OPC UA), allowing for real-time and historical data access as well as third-party software control. Ethernet/IP protocol is used to communicate with a Rockwell PLC.

Method creation

The Method Editor features built-in application support and contains all instructions needed to control a run. The interface provides easy viewing and editing of the run parameters.

The UNICORN software includes a library of predefined phases for creating or editing your own methods (Figure 7). Each phase reflects a step in the process, such as filter equilibration, product transfer, concentration, or diafiltration. A method is created or edited by dragging and dropping phases from the Phase Library to the Method Outline and entering process parameters in the Phase Properties pane. These predefined phases can be used as-is or as templates for developing customized methods tailored to specific process needs. A wide range of control options and monitors are available to ensure that the process is run according to set specifications and that the batch is completed on time.

Parameters for filter cassettes and hollow fiber filter cartridges from Cytiva are predefined in the software. By selecting the cartridge in the Phase Properties pane, filter parameters (e.g., filter area, lumen diameter, and total membrane surface area) are automatically programmed into the method. For non-Cytiva filters, users can manually enter the required parameters directly within the Phase Properties pane—no text editing is needed.

For added flexibility, advanced users can edit programming instructions directly in the Text Instructions pane.



Fig 7. Automated methods can quickly and easily be created by dragging and dropping phases in the Method Editor of the UNICORN software.

System control

The ***System Control*** module is used to start, monitor, edit, and control a run in real time. Features of the ***System Control*** module include:

- Full control during manual or programmed runs. Parameters can be changed at any time and are included in the run log.
- Real-time flow scheme showing the current flow path, valve positions, and monitor values for TFF flow paths (Figure 5).
- Allowing control of up to three instruments, with an individual layout for each system.
- ***Method Queue*** function to enable unattended operation of multiple methods in queues.

The ÄKTA readyflux TFF system 500 features the following control parameters:

- Automated feedback control of the filtration process (e.g., TMP, delta pressure, permeate flux, recirculation tank level maintenance).
- Filtration-specific end point monitoring during different run modes (e.g., concentration factor, permeate flux, retentate volume, conductivity).
- Automated maintenance alerts based on component-defined run hour limits.

Evaluation

With UNICORN 7.13 SP1 software or later, the Evaluation module provides a simplified user interface optimized for the most commonly used workflows, such as quick evaluation and comparison of results (Figure 7).

The ***Evaluation*** module features:

- Simplified interface, including single-click operations with instant feedback for operations.
- Preview results for quick data evaluation.
- Comparison of results in overlay and tile view.
- Sorting results according to running parameters to see trends in data.

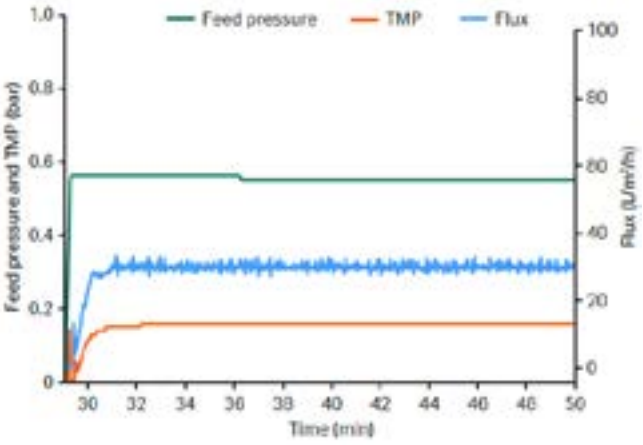
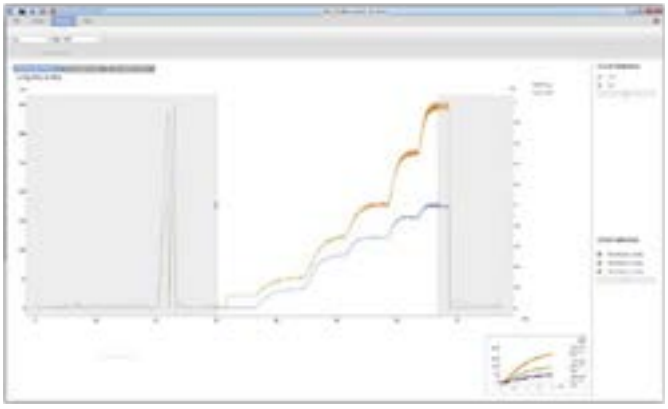


Fig 8. Example of user-selected curves. Run data are captured in real time and easily evaluated using the Evaluation module post a run.

The ÄKTA readyflux TFF system 500 supports several TFF evaluation algorithms for analysis of generated results:

- **Process optimization** is used to analyze process characterization experiments in which a series of set points are tested. The plot is used to visualize flux versus TMP (Figure 8).
- **Diafiltration time optimization** allows identifying the concentration factor for which the least time is required to complete the diafiltration.
- **Capacity plot** can be used to evaluate the capacity of the filter.
- **Normalized water permeability (NWP):** The membrane permeability can be tested using the NWP function. This test is performed to ensure that the filter cleaning process is still effective and to determine the lifetime of a filter. The test enables the user to not only automatically calculate the NWP from a result file, but also to plot results from multiple cycles on a single plot.
- **Any vs any:** Any vs any is used to graphically display data from any two curves generated during concentration, buffer exchange, or cell culture clarification. The analysis provides the possibility to plot any process parameter captured as a curve from a filtration system.

(A)



(B)

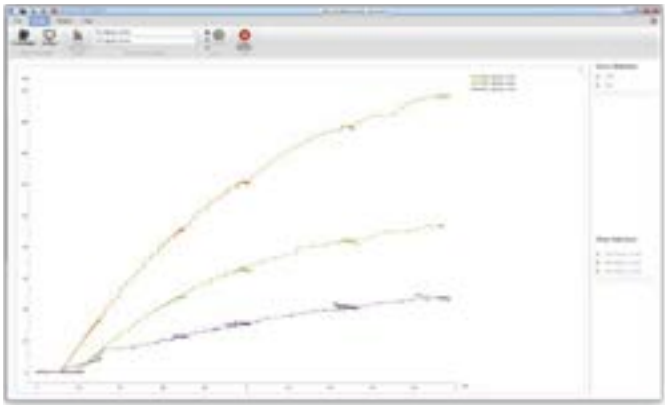


Fig 9. Flux vs TMP curve. (A) Run data plotted in the UNICORN software result file. (B) Graph for flux vs TMP generated in the Evaluation module.

Regulatory

Robust and hygienic design

All wetted polymer materials and/or pressure holding parts have been tested and classified according to USP <88> Class VI; Biological Reactivity Tests *in vivo* and are animal-derived component-free or in compliance with EMA 410/01, Rev.3. Used materials are traceable back to their production batches.

The flow path is produced and packed under controlled conditions in a clean room environment (class ISO 7) using validated procedures. The ÄKTA readyflux TFF system 500 flow kits are delivered in double plastic bags to protect against contamination. The flow kit is gamma irradiated (25 to 40 kGy).

Product documentation and services

Regulatory authorities expect manufacturers of pharmaceuticals to qualify equipment before use in production. Process safety is an integral part of the ÄKTA readyflux TFF system 500 concepts, including the single-use flow kit. The flow kit for the ÄKTA readyflux TFF system 500 is supported with an extensive documentation package.

- Product documentation: provides information about the materials used in wetted parts. Product documentation is delivered with the ÄKTA readyflux TFF system 500 Flow Kit. Extensive system documentation, such as drawings and schematics, is delivered with the ÄKTA readyflux TFF system 500.
- Validation guide: includes a description of the flow kit manufacturing process, qualification tests, and extractable information.
- Release documentation: the ÄKTA readyflux TFF system 500 is delivered with a functional test protocol. The flow kit is also delivered with a certificate of quality, including product release criteria.
- The system can be delivered with installation and operational qualification (IQ/OQ) documentation, and the qualification can be performed by certified Cytiva specialists.

Filters

The ÄKTA readyflux TFF system 500 is compatible with a broad range of commercially available hollow fiber filter cartridges and filter cassettes. Hollow fiber filter cartridges, such as the Xampler™, MidGee™, AXM, and AXH ultrafiltration and microfiltration cartridges can be used with the system using an adjustable filter holder.

In addition, the system supports a wide range of filter cassettes, including Minimate™ tangential flow filtration capsules, T-Series cassettes with Delta or Omega™ membrane, and the Cadence™ single-use TFF modules with Omega membrane. The recommended configuration includes the single-use TFF cassette holder (CSUH040), which, when used with the corresponding distribution plate (CSUP010), also enables the use of multi-use cassettes.

System specifications

General specifications

Dimensions (W × H × D)	715 × 759 × 836 mm
Weight	99 kg
Operating system software	Windows 10
Control system software	UNICORN 7.13 SP1 or later version
Control system	100 to 240 VAC ± 10%
AC voltage frequency	50/60Hz
Max. current consumption	1.4 to 1.0 A
Ingress protection	IP55
Compressed air interface	6.5 to 10 bar, ≥ 50 NL/min, oil- and particle-free
Weight scale connector	1 weight scale dedicated for permeate tank and 3 additional weight scales
Flow kit tubing diameter (i.d)	3.2 mm

Operating condition

Ambient relative humidity range	20% to 80%, non-condensing
Ambient temperature range	4°C to 30°C (39°F to 86°F)
Transport and storage temperature	4°C to 30°C (39°F to 86 °F)
Max operating pressure, feed, retentate, permeate	4 bar g (58 psi g)
Max operating pressure, transfer line	1.4 bar g (20 psi g)
Max operating pressure, feed tank	0.5 bar g (7.3 psi g)
Liquid temperature	4°C to 40°C
Fluid viscosity (recirculation)	4.66 cP

⅛ inch flow kit flow rate

Feed pump	5 to 500 mL/min
Transfer pump	1 to 250 mL/min (at 0.5 bar g / 7.25 psi g)

Sensor specifications	Range	Accuracy(1)
Air	Air/no air	N/A
Feed flow	5.0 to 500.0	± 3.0 mL/min or ± 12% of actual value(2)
Permeate flow (flow meter)	10.0 to 250.0(3)	± 3.0 mL/min or ± 10% of actual value(4)
Permeate flow (scale)	1.0 to 250.0(3)	± 2.0 mL/min(14)
Pressure (feed, retentate, and permeate)(5)	0.10 to 4.00(3)	± 0.10 bar g or ± 5% on actual value
Pressure (feed tank)(6)	0.10 to 0.50(3)	± 0.10 bar g
UV(7)(8)	0.0000 to 2.0000(9)	Linearity ± 2%
Conductivity (retentate and permeate)(10)	1.00 to 300.00(3)	1.00 to 200.00 mS/cm ± 5% on actual value 200.00 to 300.00 mS/cm ± 10% on actual value
pH(10)(11)	3.00 to 10.00(3)(10)(12)	± 0.30 pH
Temperature (retentate and permeate)(13)	5.0 to 40.0	± 1.0°C
Feed tank weight	1.0 to 1000.0	± 2.0 g or ±3% on actual value
Permeate tank weight (tank 1 weight)	0.0 to 6000.0	± 2.0 g(14)

(1) Loop accuracy within acceptance range. For dual accuracies: whichever value is greater.
(2) Calculated flow based on RPM on Feed pump P201.
(3) Measurement performed at room temperature, approximately 20°C.
(4) Accuracy valid after tube compensation.
(5) Used for detection of high system pressure. Pressure safety configured to operating pressure +10%.
(6) Used for detection of high system pressure in Feed tank. Pressure safety configured to 0.5 bar g.
(7) Instrument included in Flow Kit Plus version only.
(8) 2 AU with 2mm path length = 10 AU/cm, which equals other units as 10 CU/cm or 10 OD.
(9) Verified wavelength: 280 nm (UV1), 254 nm (UV2) and 215 nm (UV3).
(10) Temperature compensated from internal temperature sensor.
(11) Internal temperature sensor TE121 only used for compensation of the pH signal.
(12) Verified range: 4.00 – 10.00 pH.
(13) Integrated in conductivity meter.
(14) Valid for Mettler Toledo PBA639-A6, accuracy not guaranteed with other manufacturers or models.

Filter specification for ÄKTA readyflux TFF system 500

Hollow fiber filter cartridges	
Max. no. of cartridges	2
Cartridge size	16 to 290 cm^2
Filter cassettes	
No. of cassette holders	1
Total filter area (depending on application parameters)	10 to 1000 cm^2

Ordering information

Product	Description	Product code
ÄKTA readyflux TFF system 500	Single-use tangential flow filtration (TFF) system designed for process development and small-scale GMP manufacturing	Upon request through HQS
Flow Kit TC, ÄKTA readyflux TFF system 500	Flow path with tri clamp connectors, pump head and tubing, and sensors for pressure (F, R P), conductivity and temperature (R), and flow (P)	29807843
Flow Kit plus TC, ÄKTA readyflux TFF system 500	Flow path with tri clamp connectors, pump head and tubing, and sensors for pressure (F, R P), conductivity and temperature (R, P), flow, UV, and pH (P)	29745990
Flow Kit AQS, ÄKTA readyflux TFF system 500	Flow path with AseptiQuik connectors, pump head and tubing, and sensors for pressure (F, R P), conductivity and temperature (R), and flow (P)	29807845
Flow Kit plus AQS, ÄKTA readyflux TFF system 500	Flow path with AseptiQuik connectors, pump head and tubing, and sensors for pressure (F, R P), conductivity and temperature (R, P), flow, UV, and pH (P)	29807844
Single-use TFF cassette holder CSUH040	Filter cassette holder that can fit into the system holders. Mounting plate is delivered with the system.	CSUH040
Distribution plate with TC connectors	Single-use distribution plate needed to be able to run multi-use cassettes	CSUP010
Distribution plate with luer connectors	Single-use distribution plate needed to be able to run multi-use cassettes	CSUP002

Recommended product information

Supplier	Product	Description	Product code
Mettler Toledo	Stainless steel weighing platform (0 – 6000 g)	Permeate weighing scale for the ÄKTA readyflux TFF system 500	PBA639-A6
Murrelektronik	M12 connector	Adapter for connecting the permeate weighing scale	7000-17341-0000000

Additional tubing

Product	Description	Product code
TC jumper, 3.2 mm x 200 mm	High pressure tubing to connect permeate or retentate line to the flow kit or cartridge (6 pack)	29698474
TC jumper, 3.2 mm x 400 mm	High pressure tubing to connect permeate or retentate line to the flow kit or cartridge (6 pack)	29698475
AQ jumper, 3.2 mm x 200 mm	High pressure tubing to connect permeate or retentate line to the flow kit or cartridge (6 pack)	29698476
AQ jumper, 3.2 mm x 400 mm	High pressure tubing to connect permeate or retentate line to the flow kit or cartridge (6 pack)	29698477
AQ-TC jumper, 3.2 mm x 200 mm	High pressure tubing to connect permeate or retentate line to the flow kit or cartridge (6 pack)	29719942
AQ-TC jumper, 3.2 mm x 400 mm	High pressure tubing to connect permeate or retentate line to the flow kit or cartridge (6 pack)	29719943

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