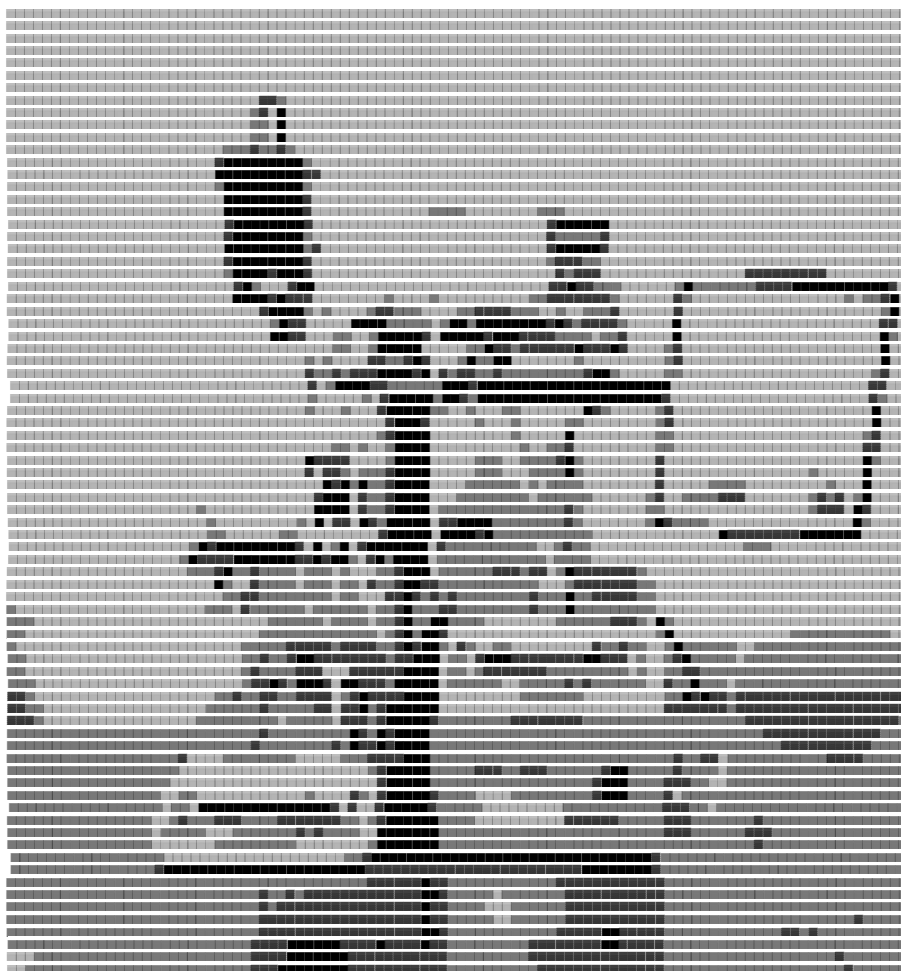


CrosserTFF™

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CrosserTFF™

Crosser Tangential Flow Filtration (TFF) System

The CrosserTFF is a modular system offering process automation for a wide range of ATMP and therapeutic antibody GMP manufacturing processes. The CrosserTFF mini is especially suitable for personalized manufacturing, capable of precision working volumes (2mL), small footprint (45 cm²), and modular customization options. CrosserTFF is fully scalable from 2mL to 500L UF/DF processes across 4 peristaltic pump modules. GMP qualification services and 24CFR11 compliant software add-ons are available upon request.



Figure 1 The CrosserTFF system configured for 2 mL ~ 3 L scale

System Highlights

- Personalized manufacturing ready
- High dynamic range: 2mL to 500L UF/DF
- Small factory footprint: 45 cm²
- Pressure control: ±0.05 psi, latency: 2 min
- GMP ready, clinically proven
- 100% single-use flow path

System Overview

All software, hardware, and automatic backpressure control valves were developed in-house and offer industry-leading control precision and latency. The 100% disposable flow path is compatible with hollow fiber, cassette filters, and single-use pressure sensors from multiple suppliers.

System Components

The main system components are shown in **(Figure 1)**. The core system consists of up to two peristaltic pumps each paired with a digital scale. Three ports are available for monitoring the feed, retentate, and permeate pressures using single-use pressure sensors. The digital scales can be configured with the following modules:

UF/DF Scale	Max. weight	Accuracy
2 mL ~ 3 L	3kg	±0.01g
50 mL ~ 5 L	5kg	±0.01g
300 mL ~ 30 L	30kg	±0.1g
600 mL ~ 60 L	60kg	±1g
2 L ~ 200 L	200kg	±5g
5 L ~ 500 L	500kg	±50g

The peristaltic pumps can be configured with the following modules and tubing sizes:

Pump	Tube	ID (mm)	Flowrate (mL/min)
CRP330	#13	0.8	2.5 ~ 24.6 ($\pm 15\%$)
CRP330	#14	1.6	5.1 ~ 51.2 ($\pm 15\%$)
CRP330	#19	2.4	10.4 ~ 104.2 ($\pm 15\%$)
CRP330	#16	3.2	17.6 ~ 176.4 ($\pm 15\%$)
CRP330	#40	4	28.8 ~ 287.8 ($\pm 15\%$)
CRP330	#25	4.8	33.2 ~ 332.4 ($\pm 15\%$)
CRP1500	#19	2.4	21 ~ 210 ($\pm 15\%$)
CRP1500	#16	3.2	37 ~ 370 ($\pm 15\%$)
CRP1500	#40	4	50 ~ 500 ($\pm 15\%$)
CRP1500	#25	4.8	71 ~ 710 ($\pm 15\%$)
CRP1500	#17	6.4	120 ~ 1200 ($\pm 15\%$)
CRP1500	#18	7.9	155 ~ 1550 ($\pm 15\%$)
CRP2400	#19	2.4	32 ~ 320 ($\pm 15\%$)
CRP2400	#16	3.2	55 ~ 550 ($\pm 15\%$)
CRP2400	#25	4.8	110 ~ 1100 ($\pm 15\%$)
CRP2400	#17	6.4	190 ~ 1900 ($\pm 15\%$)
CRP2400	#18	7.9	240 ~ 2400 ($\pm 15\%$)
CRP6000	#15	4.8	200 ~ 2000 ($\pm 15\%$)
CRP6000	#24	6.4	300 ~ 3000 ($\pm 15\%$)
CRP6000	#35	7.9	500 ~ 5000 ($\pm 15\%$)
CRP6000	#36	9.6	600 ~ 6000 ($\pm 15\%$)
CRP13L	#26	6.4	0.4L ~ 4.3L ($\pm 15\%$)
CRP13L	#73	9.7	0.8L ~ 8.0L ($\pm 15\%$)
CRP13L	#82	12.7	1.3L ~ 13.0L ($\pm 15\%$)

Optional Components

Component	Specification
Single-use pressure sensor (RJ11, Utah)	0 ~ 25 psi
Pressure sensor flow cell extension adapter	ID 0.8 ~ 12.7 mm
24CFR11 compliance	Software Add-on
Installation and Operational Qualification (IQ/OQ)	Service + Documents

Software

The Crosser control software contains a user-friendly GUI dashboard (**Figure 2**) that can be used with minimal training. The software package is optionally available with 24 CFR Part 11 electronic records compliance for GMP readiness.

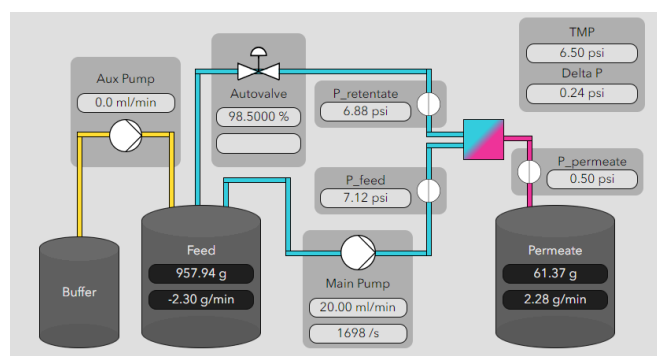


Figure 2. The P&ID interface of the control software

Software features

Feature	Description
P&ID interface	<ul style="list-style-type: none">Live piping & instrumentation diagram (P&ID) dashboard
Pressure control	<ul style="list-style-type: none">Automatic control of either transmembrane pressure (TMP) or retentate pressure
Shear rate	<ul style="list-style-type: none">Shear rate calculation for hollow fiber filters
Alarms and Stops	<ul style="list-style-type: none">Automatic detection of low or high levels of pressures and solution weights
Data backup	<ul style="list-style-type: none">Manual USB transferAutomatic FTP connection
Project folders	<ul style="list-style-type: none">Data and recipes organized and separated by project
User accounts	<ul style="list-style-type: none">Admin role: user and project managementPoweruser role: project managementUser role: operation onlyAuditor role: read only
Access security	<ul style="list-style-type: none">Password rule settingSession timeout lockUnauthorized login protection
Logging	<ul style="list-style-type: none">Audit trail logSystem log

System Specifications

Core system

Size	Various
Weight	30 kg
Software	Crosser control software
Networking	Ethernet (or WiFi)
Power consumption	<500W
Maximum flowrates	2.5 mL/min – 13 L/min
Minimum pump speed	0.1 rpm
Maximum scale weights	3 – 500 kg
Operating conditions	4 – 35 °C, 20 – 80% humidity
Noise	< 66dB

Ordering Information

Parts list

Crosser control software	20000
24 CFR part 11 software add-on	20001
Tablet computer	20002
Control box	20100
Pump aviation connector cable	20110
Pump, CRP330	20111
Pump, CRP1500	20112
Pump, CRP2400	20113
Pump, CRP6000	20114
Pump, CRP13L	20115
Digital scale cable	20120
Digital scale, 3kg	20121
Digital scale, 5kg	20122
Digital scale, 30kg	20123
Digital scale, 60kg	20124
Digital scale, 200kg	20125
Digital scale, 500kg	20126
Single-use pressure sensor	20130
Single-use pressure sensor adapter	20131
Disposable solution bag	20140
Disposable solution bottle with inserts	20141
Disposable flow-path tubing set	20142
Disposable tubing connector kit	20143
Automatic backpressure control valve	20150
Stand	20160
IQOQ service package	20170
Operational training package	20171

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