

qEV TANGENTIAL FLOW FILTRATION (TFF)

USER MANUAL



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1 DEFINITIONS AND WRITING CONVENTIONS

This manual contains warnings and precautionary statements to help prevent personal injury and/or damage to the TFF when properly followed. Safety and special notices, including the symbols described in [Table 1](#), are presented in boxes throughout the guide.

Table 1: Safety and Hazard Symbols

	This symbol indicates general advice on how to improve procedures or recommends measures to take in specific situations.
	WARNING: Indicates a hazardous situation that could result in death or serious injury if not avoided. Do not proceed until all specified conditions are fully understood and met.
	CAUTION: Indicates a hazardous situation that could result in minor or moderate injury if not avoided. Ensure all specified conditions are fully understood and met before proceeding.

Acronyms and definitions used in this manual are defined in [Table 2](#).

Table 2: Terminology Used in this Manual

TERM	DEFINITION
Molecular weight cut-off (MWCO)	Molecular weight at which >90% of molecules are retained
Permeate	The fluid that passes through the filter membrane
Retentate	The retained fluid (concentrate)
qEV	Izon's size exclusion chromatography columns
TMP	Transmembrane pressure
PRV	Pressure-regulating valve
ΔP	DeltaP: The difference in pressure between the feed and the retentate

2 SAFETY AND HAZARDS

2.1 Safe Use Requirements and Specifications



Users must thoroughly review the complete User Manual before assembling, setting up, or operating the TFF, and keep it readily accessible during operation. Operate the system strictly as outlined in the documentation to avoid potential hazards that could result in personal injury or equipment damage. Adhere to the safe use requirements specified in [Table 3](#) below. Using the equipment in an unspecified manner may compromise the protection it provides.

Table 3: Safe Use Requirements and Specifications

SAFE USE REQUIREMENT		SPECIFICATION
Operating Temperature	Indoor Use	4-40 °C
Operating Humidity		0-90 %
Rated Power		120 W
Voltage and Frequency		110~220 V 50-60 Hz
Scale Maximum Load Weight		20 kg
Maximum System Operating Pressure		Tubing-dependent. The supplied (SGG00000AE29) tubing set contains two tubing sizes. For 6.4 mm tubing, maximum pressure is ≤ 18 psi; for 3.2 mm tubing, maximum pressure is ≤ 29 psi.
Flow Rate		Tubing-dependent (0.14 - 2.22 L/min for Standard version, or 0.14 - 4.5 L/min for the GMP-ready TFF system)
Maximum Pump Speed		600 rpm
Tubing Lifetime		2 hours / 10 cycles, whichever comes first
Tubing Compatibility		1.6 mm wall thickness

Do not attempt to run the TFF outside of the conditions listed in [Table 3](#).

Liquid will be in contact with the following materials on the TFF. Please ensure that your application is compatible with these materials:

Table 4: Composition of materials in contact with the liquid

COMPONENT	MATERIALS
Tubing	Silicone
Pressure sensor	Stainless steel 316L and 304, fluoroelastomer (FKM)
Pressure flow cell	Polyether ether ketone (PEEK)
Pressure sensor seal	Ethylene Propylene Diene Monomer (EPDM)

2.2 Hazards

The TFF is a laboratory product. If biohazardous samples are present, adhere to current Good Laboratory Practices (cGLP) and comply with any local guidelines specific to your laboratory and location.

 WARNING	Repair of the instrument must only be carried out by an Izon-approved technician.
 WARNING	Be careful of electrocution. Izon instruments are only to be operated with Izon supplied leads and power supplies. Failure to use the correct power supply may result in invalid operation. The TFF must be installed into Earth Grounded Protected Outlets ONLY. To minimise the influence of external noise from the environment, position equipment away from electrical switching gear and interfering equipment
 WARNING	The system operates at high pressure. Please set an appropriate high-pressure alarm threshold based on the pressure resistance performance of the tubing, filter and system.
 WARNING	Before each use, carefully check all tubing for kinks or blockages, as this may cause tubing breakage. Tubing damage may result in fluid being sprayed from pump. Use appropriate measures to protect operator and instrument.
 CAUTION	Before running the instrument, make sure it is clean and clear of any obstructions. Check that the surrounding environment complies with operating and regulatory requirements.
 CAUTION	The use of the protective glasses and other appropriate Personal Protective Equipment (PPE) is always recommended when operating and maintaining this product.
 CAUTION	Hazardous chemical or biological agents. Please ensure your safety by wearing appropriate protective clothing, glasses, and gloves that are resistant to the substances used. Take care to avoid spillage. Follow local and national regulations for safe operation and maintenance of this product.

	Tubing and moving parts may fail if maintenance is not performed as detailed in Section 7.2: Maintenance
	The pressure value of the overpressure warning and protection shutdown shall be set according to the requirements, and the system should not be operated above this pressure.
	The system C drive contains necessary components for running the program. Please do not delete files on the hard disk without authorisation, as this may cause failure to start. Please note that the qEV TFF File folder contains historical process data and editing it may result in data loss.
	Administrators should check regularly whether the system and the transitory disk are infected with viruses, and back up the data.

2.3 Emergency Shutdown

If an emergency situation arises while the TFF is in operation you can perform an emergency shutdown to rapidly switch off the fluid flow.

1. Press the EMERGENCY STOP button ([Figure 1](#)). This will immediately stop the pump motor. Other components remain powered on and no data is lost.



Figure 1. EMERGENCY STOP button.

2. If required, switch off the mains power supply using the system power switch, disconnect the power cord or switch off the power supply. Please note this may result in loss of data and run status.
3. To restart after an emergency shutdown or power failure, reset the EMERGENCY STOP button by turning it clockwise.
4. If the system is still switched on, click the 'Continue' button on the TFF console.
5. If the system was switched off, restore power and switch on the console.



Do not restore power and restart the system until the emergency situation has been fully resolved.

2.4 Unpacking

Table 5: Instrument Specifications

COMPONENT		SPECIFICATION
Console	Dimensions	407 x 375 x 373 mm
	Weight	18.3 kg
Scale	Dimensions	308 x 79 x 300 mm
	Weight	6.3 kg



Exercise caution and use proper manual handling techniques when lifting or moving the instrument as it is heavy and may cause injury if incorrectly handled.

2.5 Transport

Before moving or shipping the TFF, decontamination procedures must be performed. Always move or ship the TFF with the supplied packaging materials, which will protect the instrument from damage. Use appropriate heavy object lifting techniques so as to avoid injury. If appropriate packing materials cannot be obtained then contact your local Izon Science office.

2.6 Disposal



The TFF contains electrical materials; it should be disposed of as unsorted waste and must be collected separately, according to the European Union Directive: Waste Electrical and Electronic Equipment. The user is fully responsible for ensuring that the obsolete Equipment and/or Consumables are recycled or disposed of in accordance with this and/or any other relevant laws and regulations in the countries where the instrument is being recycled or disposed of. Contact your local Izon Science representative for more information.

3 INTRODUCTION TO THE TFF

3.1 Overview

Tangential flow filtration is a process that concentrates and purifies samples or exchanges buffer. By flowing samples across the filter membrane rather than through it, the rate of membrane clogging is reduced, allowing continuous filtering over a long period of time.

3.2 Intended Use

The qEV TFF is a tangential flow filtration system designed for concentration, clarification, and diafiltration of biological samples and research formulations of pharmaceutical solutions.

The system is compatible with both membrane cassettes and hollow fibre filters.

This instrument is for use by operators who are experienced in operating bioprocessing equipment and handling biological materials.

For system verification, it is recommended that cGLPs are followed to ensure reliable and reproducible results.

4 ASSEMBLY AND SETUP INSTRUCTIONS

4.1 System Components

1. EMERGENCY STOP

4. 10" Touch Screen

5. Pressure Regulating Valve (PRV)

6. Feed Peristaltic Pump

2. Buzzer - ALARM

3. Indicator Light

7. Retentate Pressure Sensor

8. Feed Pressure Sensor

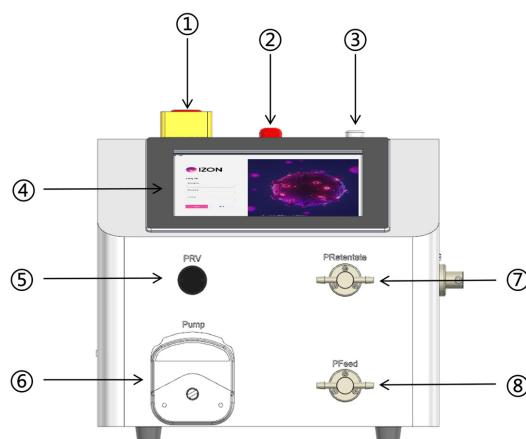


Figure 2. Front layout.

9. USB Connection Port

10. Mass 2 Connection Port

11. Mass 1 Connection Port

12. Power Input

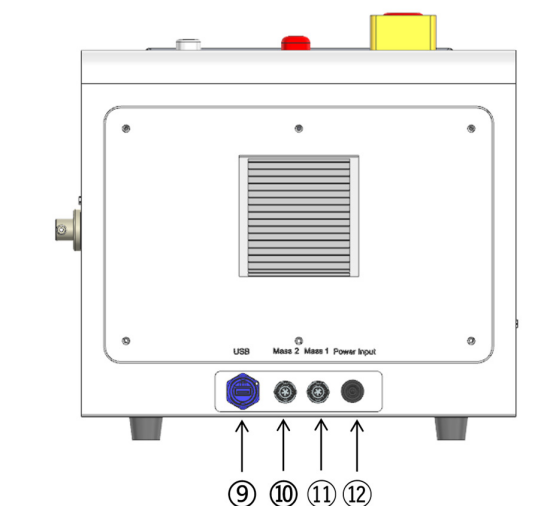


Figure 3. Back layout.



Figure 4. Scale.

The components and quantities provided are given in [Table 6](#).

Table 6: Contents of TFF shipment

1	TFF console	2	Scales (x2)
3	Tubing set SGG00000AE29 (x1)	4	DC/AC adapter
5	Power cord	6	Stylus pen

The following components are required for operation and/or maintenance of the TFF but are not provided:

- Replacement tubing set, available from the Izon store
- Filter ([Table 7](#))
- Containers for input and collected liquids (bottles or bags)
- Calibration weight (4-15 kg)
- Laboratory stand (optional)

Table 7: Filter Specifications

PROPERTY	SPECIFICATION
MWCO	3-750 kDa, commonly 100 kDa and 300 kDa
Volume	1 L, 10 L, 20 L
Flow rate	Consult the filter manufacturer's specifications for compatibility with your TFF pump's maximum flow rate. For EV processing, keep the shear rate below 2000s^{-1} to avoid shear-induced damage.
Compatibility	Suitable for use with the downstream SEC process and cleaning fluids
Surface area	26-2500 cm^2

Filters must meet these specifications for use with the TFF.

4.2 Assembling and Installing the TFF

1. Unpack the TFF and box contents.



We recommend that you keep the box and packaging materials in case the TFF needs to be returned for servicing.



If you choose not to keep the materials, please recycle them wherever cardboard recycling services are provided.

2. Place the TFF and scales on a flat, level bench top, with the Mass 1 (Feed) scale on the left of the instrument and the Mass 2 (Permeate) scale on the right of the instrument.
3. Plug the Mass 1 Scale connection cable into the Mass 1 port and tighten the threaded ring to prevent loosening.
4. Plug the Mass 2 Scale connection cable into the Mass 2 port and tighten the threaded ring to prevent loosening.
5. Connect power cable to the console.
6. The scales must be calibrated prior to first use. See [Section 7.1 on page 29](#) for details.

The TFF system is now ready to use.

The first time you start the TFF you will need to create one or more user accounts and set permissions.

-  We recommend changing both the Login and Signature Passwords of the Administrator account on first log in to keep the system secure.

- [illegible]

-  When adding or modifying users, do not use special characters, such as: / \ : * ? " < > | Enter key in the Username.

Permission Groups define the functionality available to a user. The system has 5 Permission Groups: Administrator, Engineer, Power User, Operator and Guest. The Permissions available and which Group(s) they are assigned to are detailed in Table 8 below. Administrators can change which permissions are assigned to each Group

Table 8: Permissions

PERMISSION	DESCRIPTION	PERMISSION GROUP(S)
User Setup	Whether the user can access Admin Tools → User Setup. Only the Administrator Group has this permission.	Administrator
Settings	Whether the user can access Admin Tools → Settings.	Administrator, Engineer
Component Calibration	Whether the user can access Instrument Setup → Component Calibration.	Administrator, Engineer
Method Edit	Whether the user can create and edit methods and method queues in the Method menu.	Administrator, Engineer, Operator, Guest
History Data	Whether the user can access Data → History Data.	Administrator, Engineer, Power User, Operator, Guest
Start Run Manually	Users without this permission can only run the system using an existing saved method, but not manually.	Administrator, Engineer, Power User
Manual Intervention In Method	Users with this permission can manually change the control during system running, such as adjusting PRV open % and changing flow rate.	Administrator, Engineer, Power User
Run Control	Whether the user can access the four operation control buttons.	Administrator, Engineer
Signature	Users with this permission can sign off on data.	Administrator, Engineer
Audit Trail	Whether the user can access Admin Tools → Audit Trail	Administrator, Engineer, Power User, Operator, Guest
Exit	Whether the user can exit the qEV TFF software.	-

6. Once a new user has been created, use the dropdown menu next to the current user's name in the top panel of the user interface to log out.
7. Ask the newly created user to log in and follow the prompts to set a password. The default password for new users is left blank for the initial login.



Remember to get users to change both their Login and Signature passwords.

8. Repeat this process for each new user you wish to add.

Administrators can modify permission groups for existing users by selecting the user account to be modified and clicking 'Edit...'. Administrators can remove user accounts by clicking 'Delete...'. Changes will take effect the next time the user logs in.

When deleting users or changing assigned groups, ensure that there is always at least one Administrator user in the Users list. If all Administrator users are deleted, you will no longer be able to perform user management.

5.2 Navigating the Software Interface

The main interface consists of 3 parts, ① Function Control Area, ② Process Control Area, and ③ Display Area, as shown in Figure 6 below.

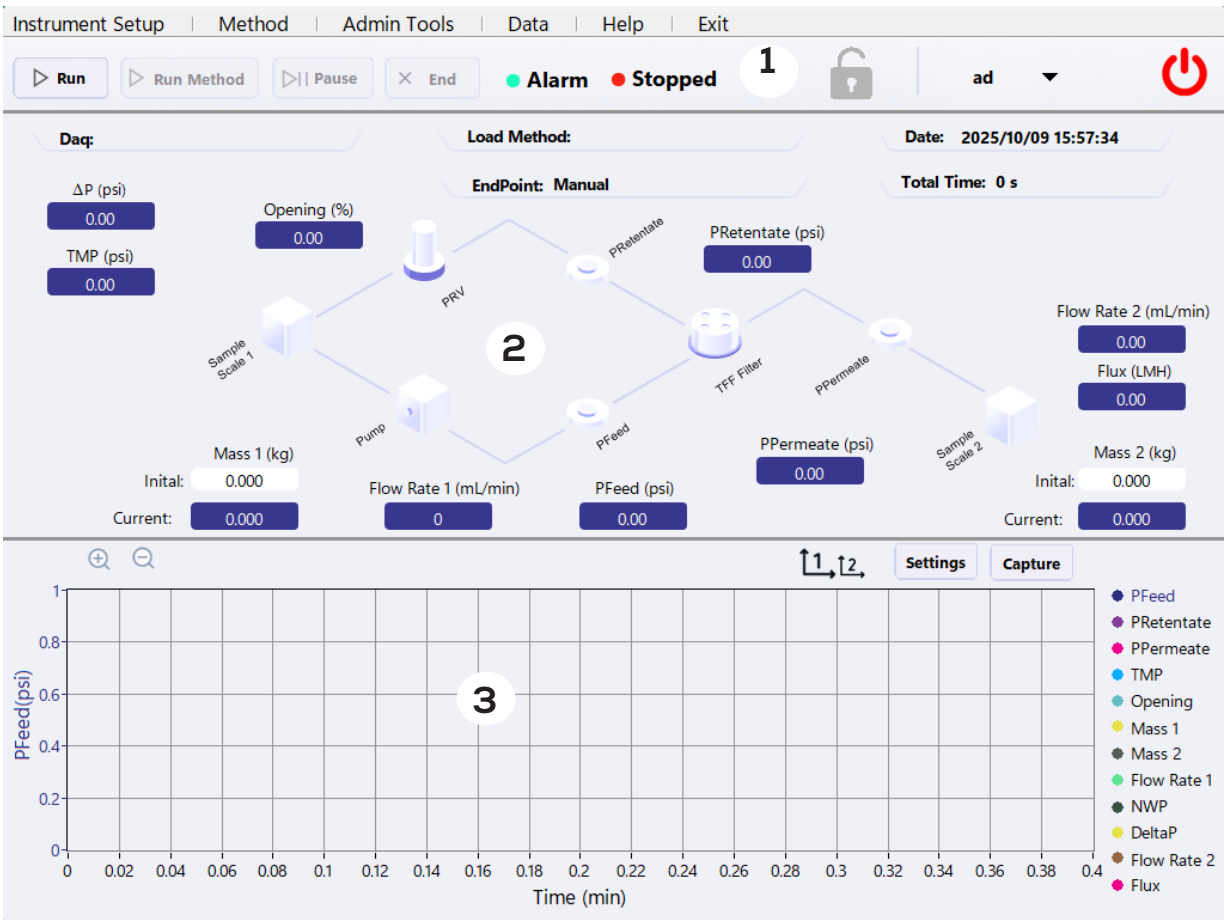


Figure 6. Three main areas of the software interface. 1) Function Control, 2) Process Control, 3) Graph Display

The Function Control Area

The features of the Function Control Area are described below.

Table 9: Menu Bar

MENU	SUBMENU	DESCRIPTION
Instrument Setup	Component Calibration	Calibrate the feed scale, permeate scale and pump.
	Connections	Check connection status of components and set COM ports.
	Alarm Setup	Set alarm pressure limits, enable low feed pressure alarm and feed mass alarm.
	Manual Run Settings	Set the pump and PRV for a manual run.
Method	Create New Method	Create pre-set methods based on templates, including Integrity Test, Cleaning, Concentration, Diafiltration, Flushing and Normalised Water Permeability.
	Load Custom Method	Load a pre-set method.
	Edit Current Method	Edit the currently loaded method.
	Create Method Queue	Create a list of pre-set methods to run consecutively.
	Load Method Queue	Load a pre-set list of methods to run consecutively.
	Edit Method Queue	Edit the currently loaded method queue.
Admin Tools	User Setup	Create, edit and remove users and manage user permissions.
	Audit Trail	View, filter and export the audit trail.
	Settings	Change system settings including switching the units used for pressure between psi and bar.
	System Alarm History	View events that have triggered alarms.
	System Log Message	View events logged by the system.
	Software Version	Display the version of the current software.
Data	History Data	View and create reports for recorded datasets.
	Data Manager	Export, import and update files.
Help	-	Link to Izon Support page.
Exit	-	Exit the software without shutting down the console.

The four run control buttons are used to control the operating state of the system.

- ▶ **Run:** Starts a manual run
- ▶ **Run Method:** Starts a pre-programmed run
- ▶ **Pause/Continue:** Temporarily stops the system. If clicked the pump will stop, all curves will pause, and the method being run will be suspended. Click 'Continue' to resume running.

- **End:** Stops the run and saves the data.

The two indicator lights display the system status.

- Alarm indicates whether there are signals exceeding or falling below the specified limits. If red, please check the alarm information by clicking Admin Tools → System Alarm History.
- The second light indicates the instrument status: green for running, yellow for paused, and red for stopped.

The lock icon indicates whether the software has been locked by the User or timed out. The software locks automatically after 30 minutes of inactivity. However, the system will continue to run while locked.

The dropdown menu next to the user icon allows account administration.

- **Lock:** Prevents unauthorised access during a shift change or temporary absence. Password is required to unlock the system.
- **Log Out:** Allows users to change over without exiting the software or pausing a run.
- **Change Display Picture:** Provides the option to upload a user profile image for display next to the dropdown menu.
- **Change Login Password:** Changes the password used to log in/unlock the system.
- **Change Signature Password:** Changes the password used to sign off data.

The power icon allows shut down of both the software and console. Note that to switch off the instrument you must use the power button located on the side of the main unit.

The Process Control Area

The process control area is used for direct control of the system's hardware and for monitoring real-time data from pressure sensors and scales. Components that are running are outlined in pink. During a run, arrows on the flow paths indicate the direction of flow and dark blue boxes indicate the pressure, flow or mass at a given sensor.

System components can be controlled by clicking on their respective icon to open a popup menu. Details of parameters that can be set in this way are described in [Table 10](#).

Table 10: Editable Process Control Fields

ICON	OPENS	FUNCTION(S)
Sample Scale 1	Control Scale Popup	Tare, Clear Tare or Zero the Feed Scale
PRV	Set PRV Mode Popup	Allows choice between Fixed or TMP modes and setting of associated % or psi value
Pump	Set Pump Mode Popup	Allows choice between Flow or ΔP modes and setting of corresponding mL/min or psi value
Sample Scale 2	Control Scale Popup	Tare, Clear Tare or Zero the Permeate Scale

The Graph Area

The graph area plots run information in real time. Choose between displaying one or two graphs using the toggle in the top right (Figure 7).



Figure 7. Graph toggle with two-plot display selected.

The Settings button provides options for changing the scale of the X-axis, what is plotted on the Y-axis and formatting such as line colour and width. If multiple parameters are selected for display on a given graph, you can switch between them by clicking the name of the one you wish to view in the key on the right side.

The Capture button allows the current graph to be snapshotted and saved as a .bmp file.

5.3 Creating Run Methods

Methods provide automated control of the TFF system. They can be preprogrammed in the Method → Create New Method menu using one of the following workflow templates:

- **Concentration:** increases the concentration of the sample by removing excess volume.
- **Diafiltration:** exchanges the buffer in the sample through cycles of concentration and re-dilution with the new buffer.
- **Flushing:** rinses the system.
- **Cleaning:** recirculates fluid to clean the system.
- **Normalised Water Permeability:** checks the permeability of the membrane. This can be used for QC of new cartridges and checking a cartridge before re-use. Reduced permeability means that a filter is clogged. Please refer to the manufacturer's filter instructions for details.
- **Integrity Test:** checks the filter membrane is not damaged and there are no leaks in the setup. Please refer to the manufacturer's filter instructions for details.

Each template allows customisation of parameters such as the target concentration factor or weight of permeate, as well as flow and pressure.

Table 11: Parameters controlling run methods.

ITEM	MODE (APPLICABLE RUN TYPES)	DESCRIPTION
Pump	Pressure (Integrity Test)	The pump speed will automatically adjust to maintain 90 - 110% of the target pressure.
	Flow (Concentration, Diafiltration, Flushing, Cleaning, Normalised Water Permeability)	The pump speed will automatically adjust to reach the target flow rate. Please refer to both the filter and tubing specifications for the recommended target flow rate.
	ΔP (Concentration, Diafiltration, Flushing, Cleaning, Normalised Water Permeability)	The pump speed will automatically adjust to maintain 90 - 110% of the target DeltaP.
End point	Duration (Integrity Test, Flushing, Cleaning, Normalised Water Permeability)	The method will run for the target duration, then stop.
	Concentration Factor (Concentration)	The method will concentrate the input solution by this factor. For example if starting with 1 L and a concentration factor of 10 the system will run until there is 1/10 = 0.1 L of concentrate.
	Mass of Permeate (Concentration, Flushing)	The method will run until the permeate mass reaches the target weight. Note this should not exceed the weight specification of the scale (Table 3).
	Diafiltration Volume (Diafiltration)	The volume to be run in order for the buffer to be considered fully exchanged.
PRV	Fixed (Concentration, Diafiltration, Flushing, Cleaning, Normalised Water Permeability)	The open % of the PRV will be fixed at the specified value. At higher closed % more back pressure will be applied, causing more liquid to pass through the membrane rather than recirculating.
	TMP (Concentration, Diafiltration, Flushing, Cleaning, Normalised Water Permeability)	The open % of the PRV will automatically adjust to maintain 90 - 110% the target TMP.

5.4 Creating Method Queues

Queues allow multiple methods to be run consecutively. They can be preprogrammed in the Method → Create Method Queue menu. The instrument will run the queue in order, starting from the most recently added method (i.e. the first method you add to the queue will run last).

5.5 History and Logs

Alarm History

When alarms occur, the system will automatically pop up an alarm screen to display the alarm information. When readings return to acceptable levels, alarms will be marked in green in the alarm screen.

Clicking Admin → System Alarm History opens a list of alarm events and details including the time and type of alarm.

System Log

System logs record details of operating events, including user, event type, event, time of occurrence, and accumulated feed volume for traceability. When historical data is loaded, corresponding logs can also be retrieved. Users cannot modify or delete a log. Logs are stored encrypted.

Audit Trail

Clicking Access → Audit Trail, will open the Audit Trail popup.

Audit trails are used to view system activities, such as logins and settings changes. Once the TFF is started, actions are captured into a database in a sequential manner using absolute time stamps. Thus, if system time is changed, data is modified, or even a file is deleted, it can be traced back through the Audit Trail function.

Users can set the number of records per page. Click 'Query' to go to the last page. Click 'Export to CSV' to export records as a CSV file to a user-specified folder.

6 OPERATING INSTRUCTIONS

6.1 Installing Tubing

Tubing set SGG00000AE29 is supplied with the system. Please note that permeate tubing may be labelled as filtrate tubing on the packaging.

Please refer to [Figure 8](#) for the tubing layout and letters indicating which length of tubing should be used for each step described below.

1. Cut tubing to your desired lengths.
2. Open the pump housing by moving the silver lever all the way to the left.
3. Load feed tubing (A) through the pump ([Figure 2](#)), ensuring that the hose barb connector in the middle of tubing (A) is to the left of the system, well clear of the pump, and not between the pump and the feed pressure sensor.
4. Close the pump housing by pushing the lever all the way to the right.
5. Connect feed tubing (A) and (B) to either side of the feed pressure sensor ([Figure 2](#)) and fix in place with zipties or clamps.
6. Connect retentate tubing (C) and (D) to either side of the retentate pressure sensor ([Figure 2](#)) and fix in place with zipties or clamps.
7. Load tubing (D) into the PRV ([Figure 2](#)).
8. Connect permeate tubing (E) and (F) to either side of the permeate pressure sensor on the right hand side of the instrument and fix in place with zipties or clamps.
9. Connect the feed tubing (B), retentate tubing (C) and permeate tubing (E) to the TFF filter.

Once the tubing set is connected, one end of each of the feed tubing (G), retentate tubing (D) and permeate tubing (F) should be left free and will be placed in the appropriate feed or collection container. Tubing clamps are pre-installed on each line and can be used to shut off flow.



Ensure clamps/zipties are tightened and tubing is firmly attached to sensors and connectors.

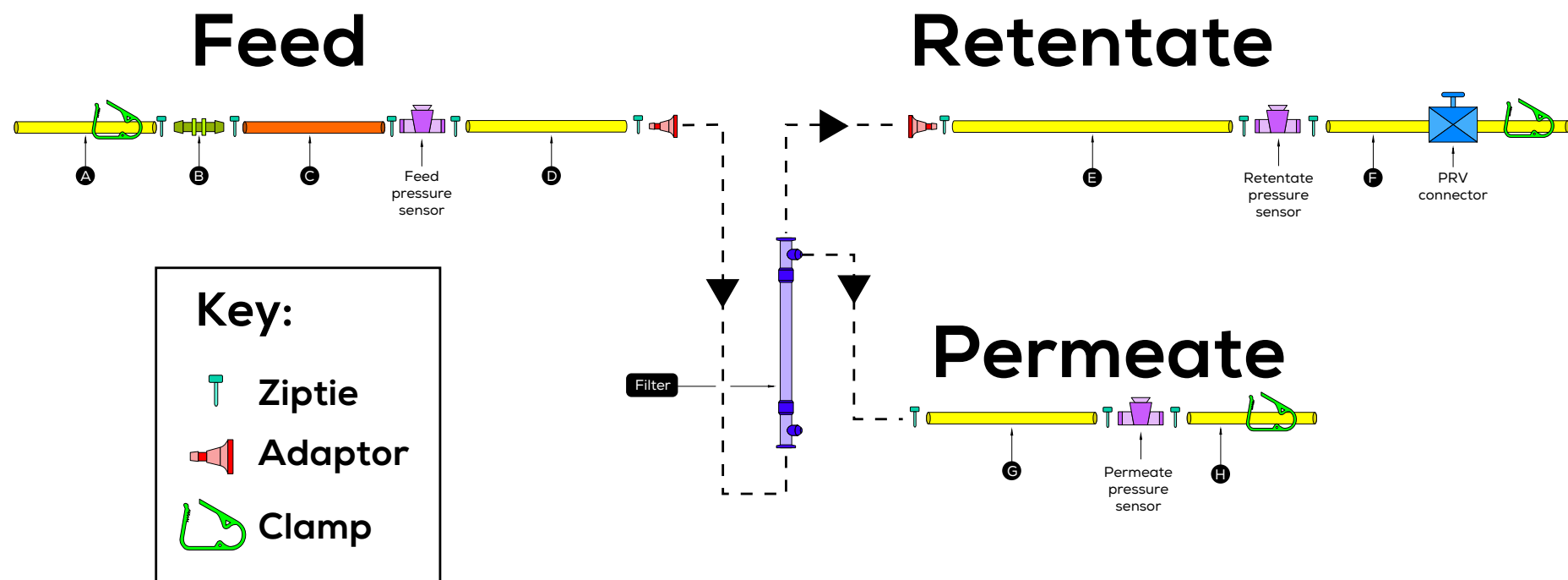


Figure 8. Tubing Set SGG00000AE29

6.2 System Start Up

1. Ensure you carry out the daily maintenance as described in [Section 7.2: Maintenance](#) before each use of the system.
2. Switch on the instrument by pressing the power switch to the "I" position.
3. Wait for the initialisation screen to load, then log in to the system.

6.3 Alarm Settings

Always ensure alarms are set correctly before running the TFF system.

1. Click Instrument Setup → Alarm Setup to open the Alarm Setup menu.
2. Specify upper limits for the feed, retentate, permeate and TMP pressures.



Ensure you set the upper pressure limits suitable for the tubing (set #SGG00000AE29). For 6.4 mm tubing, ensure the maximum pressure is ≤18 psi. For 3.2 mm tubing, ensure the maximum pressure is ≤29 psi.

3. Optionally set limits for the feed mass and lower feed pressure. These can be used to detect a leak in the system.
4. Ensure that all required alarms have their corresponding checkbox ticked.
5. Click 'OK' to save the changes.

An Alarm information box will be displayed on the screen if the monitored values exceed or fall below specified limits and the system will automatically pause. The alarm will be recorded in the Alarm History, which can be found under Admin Tools → System Alarm History.

6.4 Component Calibration

1. Go to Instrument Setup → Component Calibration to open the calibration screen ([Figure 9](#)).
2. Select 'Pump' from the 'Select Component' dropdown menu.
3. Select the tubing size you are using from the 'Tube Size' dropdown menu.
4. Follow the on-screen instructions to determine the maximum flow rate, using the selected tubing size for testing, even if the instructions do not update to reflect the selection in the dropdown menu.
5. Make a note of the value that is calculated in the Full Speed box.



Ensure you do not exceed this value when setting run parameters.

Figure 9. Pump calibration guide.

6.5 Run Setup

Table 12: Tubing configuration for each run type.

RUN TYPE	FEED END	RETENTATE END	PERMEATE END
Wetting	Water	Same as feed	Waste
Integrity	Air then clamped	Air then clamped	Air/clamped
Permeability	Water	Same as feed	Waste
Flushing	Water on mass 1 scale	Waste	Waste on mass 2 scale
Cleaning	Cleaning agent on mass 1 scale	Cleaning agent then flushed to waste	Clamped then to waste on mass 2 scale
Concentration	Sample on mass 1 scale	Same as feed	Waste on mass 2 scale
Diafiltration	Sample on mass 1 scale, top up with new buffer as needed	Same as feed	Waste on mass 2 scale

1. Tare the scales with appropriate empty containers in place. You can access the scale controls by clicking on the scale icon in the process control section of the interface (Figure 10).

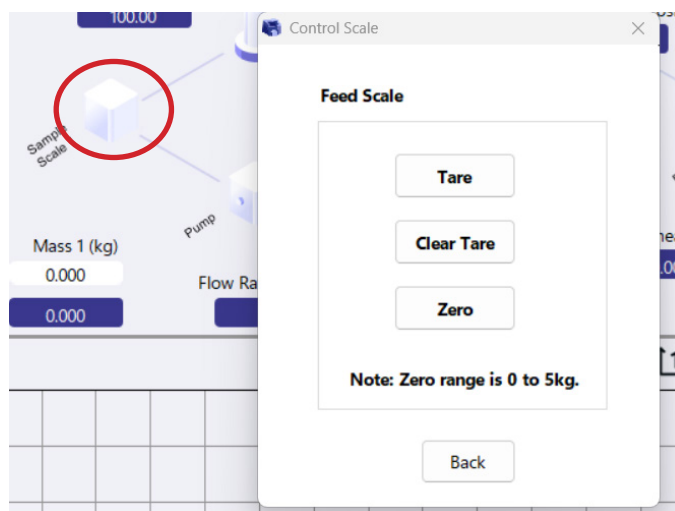


Figure 10. Scale icon and popup menu.

2. Add the required sample/buffer to the appropriate containers.
3. Attach the tubing ends to the appropriate sample/waste containers.

6.6 Starting a Run



Ensure that all necessary pressure alarms are activated prior to initiating a run.

There are two options for running the TFF system—manually or via a preset method.

Proceeding with a Manual Run

1. Set the pump and PRV mode in the Manual Run Settings menu. Descriptions of these modes can be found in [Table 11](#).



Ensure you set a suitable speed for the tubing size prior to initiating a manual run.

2. Click the 'Run' button in the function control area.
3. Enter the surface area of the filter being used.
4. Click the 'Save Data' checkbox. Note if you do not choose to save the data it will be temporarily stored in the Temp folder.
5. Select the filepath for the data to be saved in by clicking Browse and selecting the required folder or enter a batch name, which will create a new folder.
6. Enter a name for the data file in the 'Daq Name' field. This will be the file name within the batch folder.
7. We recommend ticking the 'Add absolute time identifier?' checkbox. This ensures the file name is unique by adding absolute time as a suffix to the file name.
8. Click 'Start Run'.

Running a Preset Method

1. Click on Method → Load Custom Method and select the name of the method you wish to run from the list.
2. Click the 'Run Method' button in the function control area to open the run confirmation screen.
3. Enter the surface area of filter being used.
4. Click the 'Save Data' checkbox. Note if you do not choose to save the data it will be temporarily stored in the Temp folder.
5. Select the filepath for the data to be saved in by clicking Browse and selecting the required folder or enter a batch name, which will create a new folder.
6. Enter a name for the data file in the 'Daq Name' field. This will be the file name within the batch folder.
7. We recommend ticking the 'Add absolute time identifier?' checkbox. This ensures the file name is unique by adding absolute time as a suffix to the file name.
8. Click 'Start Run'.
9. Depending on the method type, there may be on-screen instructions to follow during the run.

6.7 Recommended Workflow

Required workflow is dependent on your application and QC requirements. An example of a typical workflow is illustrated in [Figure 11](#).

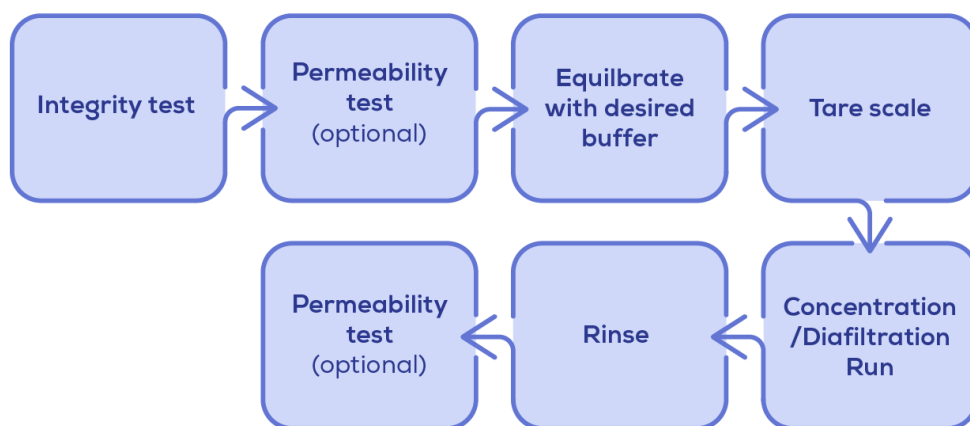


Figure 11. End-to-end workflow.

6.8 Monitoring a Run

The process control area will show the flow path and component states during a run.

The real-time plots in the graph area show the data measured by each sensor during the run. Click the parameter name on the right hand side of the plots to switch between metrics. The Y-axis units will change automatically for the selected data.

A run can be paused and restarted using the buttons in the function control area.

6.9 Ending a Run

- 1. Click 'Stop' in the function control area at any time to end a manual run or cancel a preset method. Preset methods will stop automatically when the specified end point is reached unless they are cancelled sooner.
- 2. After each run stops, wait for the system to automatically adjust the PRV back to fully open. This can be confirmed by a quick visual check of the PRV .



Do not change any settings or exit the software while the system is resetting, as it may cause incorrect opening/closing of the PRV.

6.10 Generating a Run Report

All data are saved on the system disk and can be reviewed in the TFF software once the run completes. Run data can also be used to generate a PDF report for export (Figure 12).

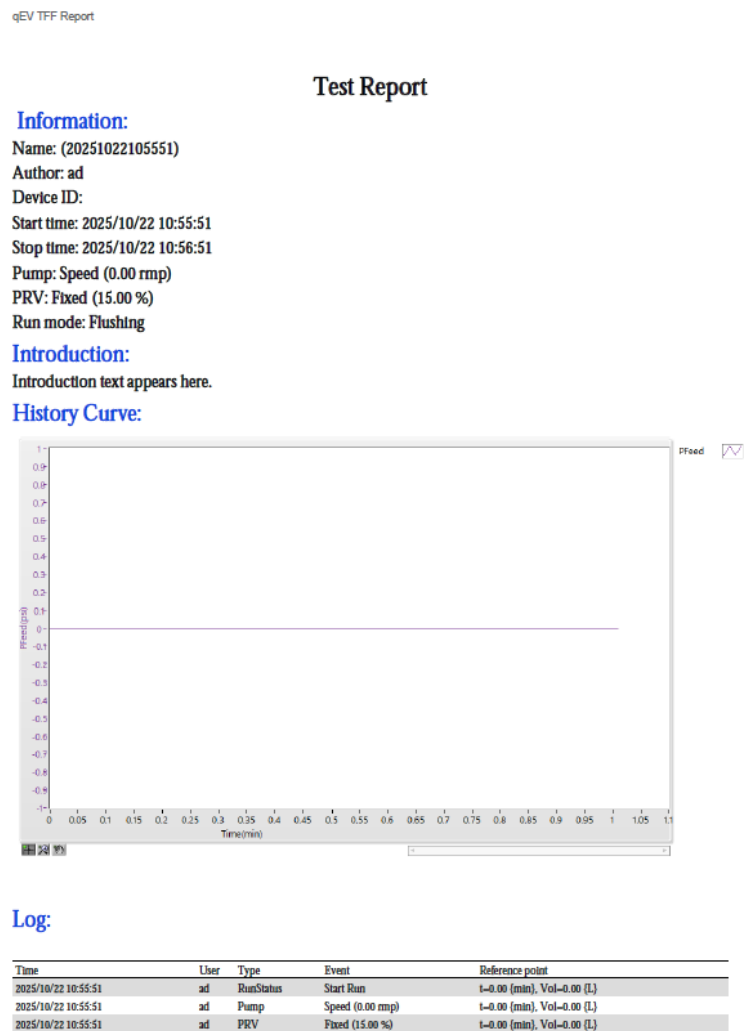


Figure 12. Example PDF Report

- 1. Click Data → History Data to open the historical data screen.

2. Click 'Select Daq File' to select the data file to be viewed or exported. The following tabs are available:
 - **Basic Message:** Lists basic information about the run.
 - **Curve View:** Shows the full dataset for all metrics with the same graphs and plotting functionality as the graph area in the main interface (See ["5.2 Navigating the Software Interface" on page 15](#)).
 - **Log view:** Lists system log entries corresponding to the loaded run data.
 - **PDF Report:** Allows customisation of content and PDF report generation.
3. Switch to the PDF Report tab and enter a title for the report in the 'Report Title' field.
4. On the left hand side, check the boxes to add an introduction and/or conclusion section to the report and use the free text fields to add the wording for these sections.
5. On the right hand side select which system information will be included in the report.
6. Click 'Generate PDF Report' and enter a file name for the report.
7. To view the newly generated report click 'Preview PDF Report' and select the file name from the list.

6.11 Shutting Down

1. If the tubing and/or filter will be re-used we recommend flushing with 0.5 M sodium hydroxide as a disinfectant. Check the filter specifications for compatibility prior to disinfection and check that all tubing connections are still firmly attached prior to running sodium hydroxide through the system.



Ensure that appropriate PPE, including eye protection, is worn when handling sodium hydroxide.

2. After each use of the instrument, rinse with a large volume of deionised water, especially in the presence of high salt buffers.
3. Click the power icon to shut down the computer.
4. Confirm you want to quit the system.
5. Turn off the instrument using the power switch on the left side of the unit.

7 MAINTENANCE AND TROUBLESHOOTING

7.1 Calibration

Scale Calibration

The scales should be calibrated before first use of the instrument, any time the unit is moved or reassembled, and at an appropriate interval for routine maintenance. We recommend monthly recalibration.

You will need a calibration weight of between 4kg and 15kg to calibrate the scales.

1. Click Instrument Setup → Component Calibration to open the Calibration screen.
2. Select the scale to be calibrated in the top right corner.
3. Calibrate the scales following the instructions on the screen.
4. Repeat for the other scale.

7.2 Maintenance

Daily Maintenance

1. Clean and wipe the exterior surface of the instrument.
2. Check pump tubing, PRV seals, and sensor connections for leaks or wear.
3. The flexible tubing provided with the TFF system requires regular replacement. Before operating the system, inspect the tubing to ensure the following:
 - Tubing sections are installed at the correct locations.
 - All fittings are properly installed and locked.
 - Tubing sections and connections are free of visual damage, such as cracks, leaks, crease lines or other wearing.
 - Tubing is not kinked or flattened.
4. Replace the pump tubing after it has completed 10 operational cycles, or has been running for 40 hours, whichever comes first. Inspect the pump tubing regularly to monitor for signs of wear.

Quarterly Maintenance

1. Inspect the system for leaks in valves, connections and pump.
2. Check the condition of gaskets.
3. Replace the seals of the PRV.

Semi-Annual Maintenance

1. Dismantle and clean all fittings.
2. Verify that all safety elements are not damaged and are working properly.
3. Inspect the pump.

Annual Maintenance

To support the optimal function of your TFF system we recommend booking in an annual maintenance service with your Izon representative. Maintenance checks include:

1. Visual inspection for corrosion, perishing or any other degradation in components.
2. Verify tightening of the main connections of the console.

Replacement Parts

To enquire about spare parts, consumables, repairs and maintainance, please contact Izon Support.

Troubleshooting

Table 13: Troubleshooting guide

OBSERVATION	SOLUTION
Touch screen does not work.	Restart the system.
Reading deviation between the pressure sensor and a calibrated pressure meter is over 0.25%.	Recalibrate the pressure sensor.
Deviation between the reading of the scale and the calibrated weight is over 0.5%.	Recalibrate the scale.
Bubbles or air lock in the tubing.	Change the level of the tubing to work the bubble out to an open end.

8 CONTACT US

If you have any questions or issues, please raise a support ticket at support.izon.com and an Izon representative will be in touch.

9 MANUFACTURER'S DETAILS

The qEV TFF system is manufactured by Theseus Biotech Co, Ltd.

(有数云集生物科技 (上海) 有限公司).

Address:

2F, Building 21, No. 388 Shengrong Road, Zhangjiang, Pudong New Area, Shanghai, China

