

# KF Comm 2 Software

## User Guide

For use with

- KrosFlo® KR2i Tangential Flow Filtration (TFF) System
- KrosFlo® KMPi Tangential Flow Filtration (TFF) System



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**Customer Support**

[customerserviceUS@repligen.com](mailto:customerserviceUS@repligen.com)

508-845-6400

**Repligen Corporation**

111 Locke Drive

Marlborough, Massachusetts 01752

[www.repligen.com](http://www.repligen.com)

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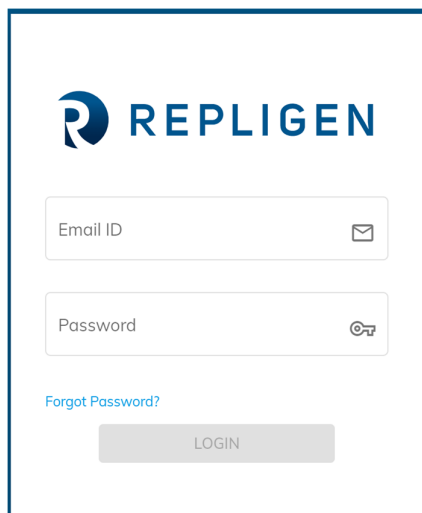
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## 1. Set-up of KF Comm 2 and 2C Software

### 1.1 Downloading KF Comm 2 and 2C Software

Once you have purchased the Repligen KrosFlo® TFF System, our admin team will create a user account for you using your registered email address. You will receive an email with a link to download KF Comm 2 and/or KF Comm 2C. Your email will also contain a temporary password which will allow you to access the KF Comm 2 download module. Upon logging in for the first time you will be prompted to create a new password.

Figure 1. Login Screen for Software Download Module



The login page also has a '**Forgot password**' feature. In case you forget your password, you may click here and enter your registered email address. A new temporary password will be sent to your registered email ID and you may use that to login and create a new password.

Once you successfully log in, you will land on your account details page. There are 4 sections on this page:

1. Organization details:
  - Customer ID (**default/non editable - assigned by Repligen**)
  - Customer name (**default/non editable - assigned by Repligen**)
  - Address (**editable**)
2. Primary contact information:
  - Name (**editable**)
  - Email (**default/non editable - assigned by Repligen**)
  - Phone (**editable**)
  - Title (**editable**)
3. Secondary contact information:
  - Name (**editable**)
  - Email (**editable**)
  - Phone (**editable**)
  - Title (**editable**)
4. License details (**default/non editable - assigned by Repligen**):

- Assigned license keys for KF Comm 2C. This section will show license keys only for KF Comm 2C. KF Comm 2 does not require license keys to activate.

**Figure 2. View Account Details**

The screenshot displays the 'View Account Details' interface. On the left, a navigation menu includes 'Account Details' (highlighted), 'KFComm 2', and 'KFComm 2C'. The main content area is titled 'View Account Details' and features an 'EDIT' button in the top right. A progress indicator at the top of the form shows four steps: 1. Organization details, 2. Primary contact, 3. Secondary contact, and 4. License details. The 'Organization details' section contains three input fields: 'Customer ID' (with value 'CId-0001'), 'Customer name' (with value 'Lattice Innovations'), and 'Address'. A blue arrow button is positioned at the bottom right of the form.

To edit/update any of the account details, please click the 'edit' button (Figure 2) on the top right corner of the page. Upon updating the information, please click the 'save' button (Figure 3).

**Figure 3. Save Button**

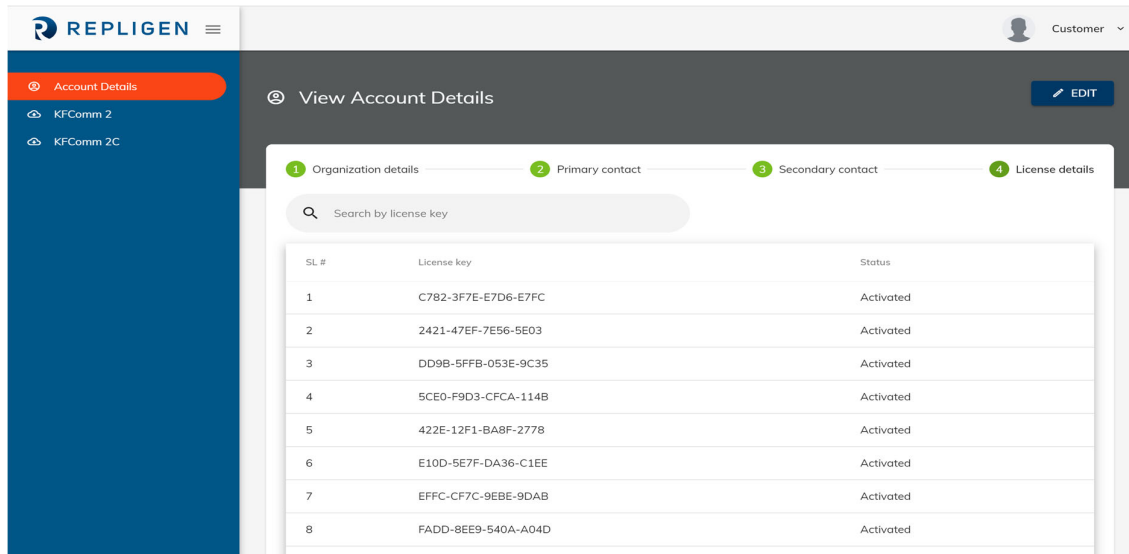


Users who have purchased KF Comm 2C will see options for both KF Comm 2 and KF Comm 2C on the left navigation menu as shown in Figure 2. KF Comm 2 is the default version of the software and KF Comm 2C is our 21CFR11 compliant version of the software. KF Comm 2C requires a one-time activation key for every license purchased. Only users who have purchased KF Comm 2C from Repligen directly will receive activation keys which can be seen in their Account details page. Once a key has been used to activate a license, the status of the license will switch from 'Not Activated' to 'Activated' as can be seen in Figure 4. By default, all license keys assigned to a user will be in 'Not Activated' state. Once a user downloads KF Comm 2C they will be prompted to use their activation key to verify their license. Upon successful verification, the status of the license key will change to 'Activated' on this page.

**Note:** A single user account can have multiple license keys. All licenses purchased will be reflected on the same account linked to the registered email address of the customer.

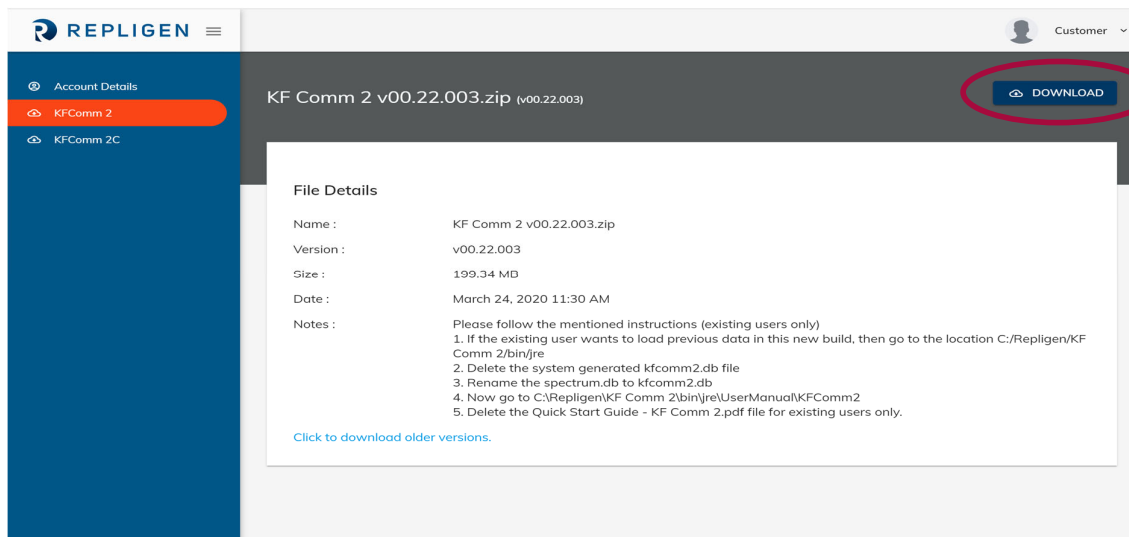


Figure 4. License Details



To download KF Comm 2 or KF Comm 2C, please click on the respective software version in the left navigation menu. Once you click here you will be redirected to a page which has all the details for the latest version of the software available for download (Figure 5). This includes details including the name, version, size of file, date of upload and release notes from the manufacturer. Click the download button on the top right corner to download this version of the software.

Figure 5. Download Software



If you require older versions of the software, you may click the link on the bottom of the page as seen in Figure 5. This will take you to a repository of archived software versions that are available for you to download (Figure 6). You may select the version you would like to download and click the download icon on the top right corner of the page to start your download.

**Figure 6. Archived Software Versions**

The screenshot shows a web interface for 'KF Comm 2C List'. On the left is a blue sidebar with navigation links: 'Account Details', 'KFComm 2', and 'KFComm 2C'. The main content area has a search icon and a cloud icon. Below this is a table with the following data:

File name	Version name	Type	Size
KF Comm 2C v00.13.000.zip	v00.13.000	KF Comm 2C	170.21 MB
KF Comm 2C v00.12.001.zip	v00.12.001	KF Comm 2C	170.12 MB

To the right of the table is a 'Selected file details' panel for the selected file 'KF Comm 2C V00.13.000.Zip'. It lists the following details:

- File Name:** KF Comm 2C V00.13.000.Zip
- Version name:** v00.13.000
- Type:** KF Comm 2C
- Size:** 170.21 MB
- Date:** September 12, 2019 6:20 PM
- Notes:** 1. License Key activation 2. Alarms and stops 3. Trial details and alarms and stop tab 4. Trial ID change 5. UI Changes 6. Issue fixes

**Figure 7. Software License Agreement**

The screenshot shows the 'REPLIGEN' logo in the top left and a 'Customer' dropdown in the top right. The main heading is 'Software License Agreement'. Below the heading is a text block: 'To download the software please accept and proceed. The terms and conditions of usage are mentioned in the document below. Please read terms and conditions before accepting.' There is a link for 'Download License Agreement'. Below that is a checkbox labeled 'I accept the software license agreement'. A note states: 'The default username and password is SuperAdmin and Password@123'. At the bottom are two buttons: 'BACK' (orange) and 'ACCEPT' (blue).

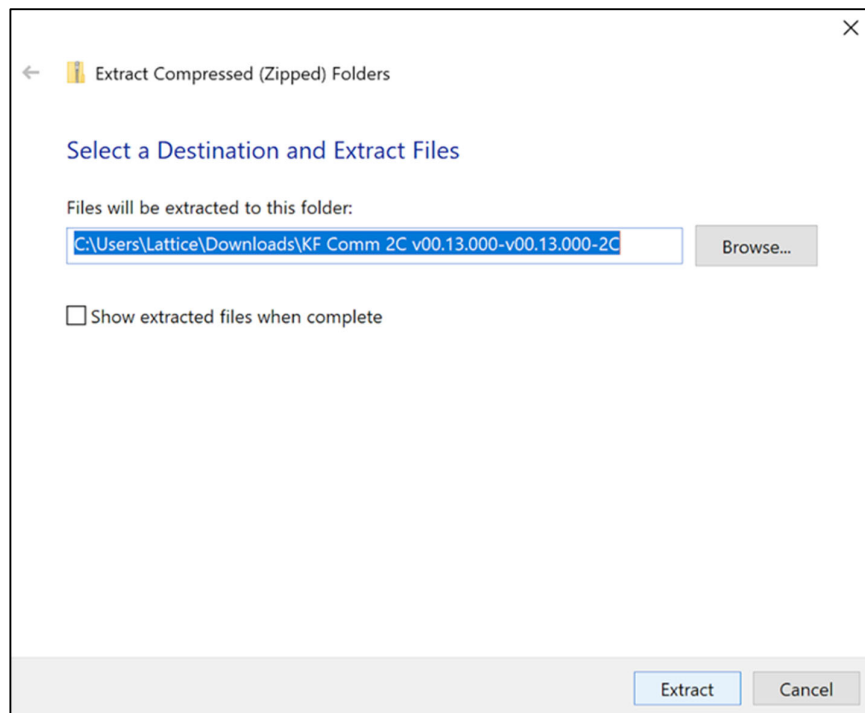
**Figure 8. Download Progress**

The screenshot shows a download progress bar with a file icon on the left. The text reads: 'KF Comm 2C v00.1....zip' followed by an upward arrow icon. Below the filename, it shows '3.6/170 MB, 2 mins left'.

## 1.2 Installing KF Comm 2 Software

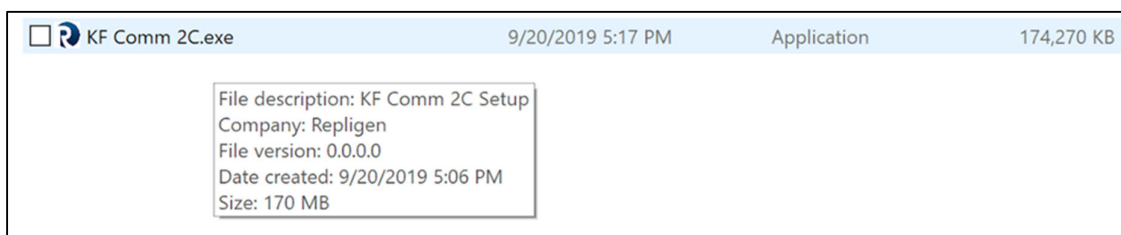
The file you downloaded is a zip file. This needs to be extracted before starting the installation process. Open the folder where you have downloaded the file and extract file from the zipped folder (Figure 9). You can also browse select the file storage location/folder.

Figure 9. Extract Files

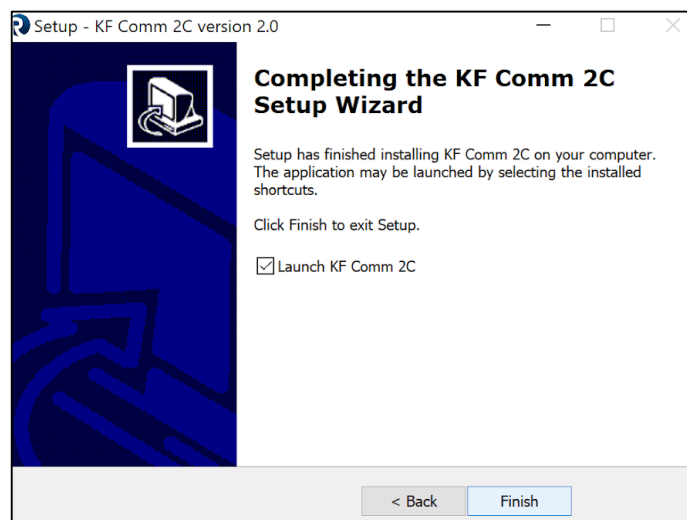


Once you have extracted the files, click the executable file (KF Comm 2.exe or KF Comm 2C.exe) depending on which version you have downloaded.

Figure 10. Click to Begin Installation



Follow the instructions once the installer starts. Once the installation is complete, select the 'Launch KF Comm 2C' and click 'Finish' to start the software (Figure 11).

**Figure 11. Finish Installation and Launch KF Comm 2C Software**

If you have installed KF Comm 2, you are now ready to use the software.

If you have installed KF Comm 2C, you must now launch the software and activate your license key in order to use the software.

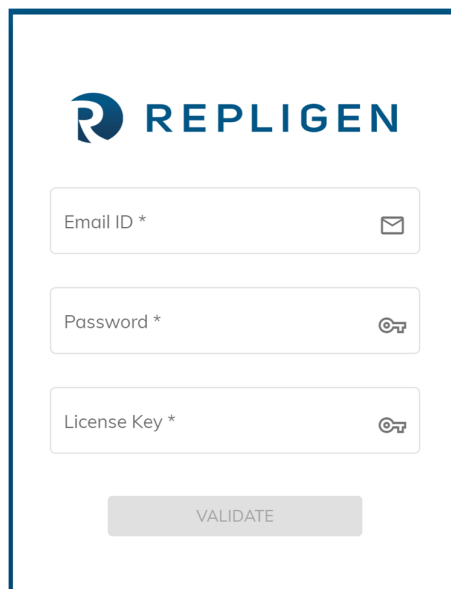
### 1.3 Activating KF Comm 2C Software

Once you have completed the installation you must launch KF Comm 2C and complete your activation in order to use the software.

**Note:** You must be connected to the internet to complete this step in order to authenticate the license key provided to you on your customer profile page (Figure 4). If you are not connected to the internet during this step, your software will not be authenticated, and you will not be able to use it. This is the only step in using KF Comm 2C that requires you to connect to the internet.

Upon launching KF Comm 2C, you will be prompted to enter your Email ID, Password and License Key (Figure 12). Please enter the email ID and password you have used for your online customer portal along with any one of the license keys provided to you by Repligen (available on license details page - Figure 4). One license key can only be used for one system. Make sure you use a license key that is in '**Not Activated**' state on your customer portal. Once it has been verified, it will change to '**Activated**' state. Upon validation of the license key, you are now ready to use KF Comm 2C.

Figure 12. License Key Activation



The screenshot shows a web form for license key activation. At the top is the Repligen logo. Below it are three input fields: 'Email ID \*' with an envelope icon, 'Password \*' with a key icon, and 'License Key \*' with a key icon. At the bottom of the form is a 'VALIDATE' button.

**Note:** In case you receive a validation error message, please make sure your license key is correct. If your license key is correct, please check that you are connected to the internet. In case the system is still not validating the license key, please contact our customer support team to assist you.

## 2. KF Comm 2/2C Software User Roles

### 2.1 Roles and Features

The KF Comm 2 and 2C have multiple roles and features associated with it. There are 4 available roles in KFComm2 and 5 roles (one additional) in KF Comm 2C. The additional role in KF Comm 2C is that of an 'Auditor'.

1. Super Admin (both):
  - There is only 1 Super Admin for the entire system
  - Upon first time login, Super Admin shall edit own user profile
  - Primary role is user creation and user management
  - Can view all access logs
  - Cannot access any other roles from Super Admin account
2. Admin (both):
  - There can be multiple admins in the system
  - Admins can create other Admins
  - Primary role is user creation and management
  - Can view all access logs
3. Auditor (KF Comm 2C only):
  - View only access to access logs
  - View only access to user list
  - View only access to trial logs
4. Manager (both):
  - Create and manage recipes for auto modes
  - Start and edit trials (Auto Mode, Manual Mode, Set-up breakdown Modes)

- View historical logs
  - Edit system trial settings (units, significant figures)
  - Run tubing/pump calibrations
  - Run pressure calibrations
5. Technician (both):
- View recipe list for auto modes
  - Start and edit trials (*auto mode, manual mode, set-up breakdown modes*)
  - View historical logs
  - View system trial settings (units, significant figures)
  - Run tubing/pump calibrations
  - Run Pressure calibrations

A detailed table mapping the roles to features can be found in Section 2.1.

It is possible for a single user account to have up to 2 roles. For example, an Admin could assign themselves the role of a Manager to carry out features that only a **‘Manager’** role has access to. Table 1 below shows the possible combinations allowed in the system. There are two limitations to this rule:

1. Super Admin cannot be assigned secondary role.
2. Auditor cannot be assigned secondary role.

**Table 1. Primary and Secondary Roles**

Administrator roles	Technical roles
Super Admin	<ul style="list-style-type: none"> <li>• None</li> </ul>
Admin	<ul style="list-style-type: none"> <li>• Manager</li> <li>• Technician</li> <li>• Neither</li> </ul>
Auditor	<ul style="list-style-type: none"> <li>• None</li> </ul>
None	<ul style="list-style-type: none"> <li>• Manager</li> <li>• Technician</li> </ul>

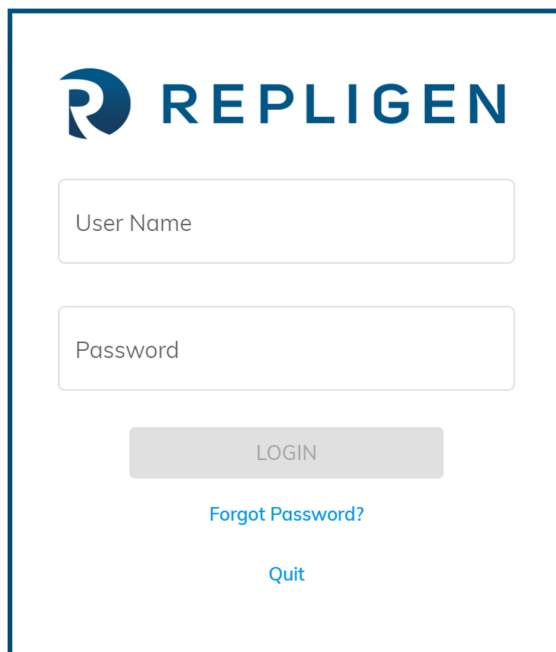
**2.2 Login (All Roles)**

Upon completing the installation and activating the software (KF Comm 2C) the landing page of the software will be a login screen. The first user to login to the system needs to be the Super Admin. In the case of KF Comm 2C, the login credentials will be as follows:

**Username** - Username as updated by the customer on the customer portal

**Password** – Password is same as the customer portal password

In the case of KF Comm 2, there are default credentials for the Super Admin on first login. Once the super admin logs in for the first time, they can update their credentials. Default credentials are mentioned on the customer portal from where the software was downloaded. In case you face any trouble, please contact Repligen customer support.

**Figure 13. KF Comm 2 and 2C Software Login Screen**

If a user has forgotten their password, they can click on the **'Forgot Password'** button on the login page. Upon clicking this, the user is prompted to enter their username and send a request to the administrators to reset their password. This process has been explained in the User management section below.

In KF Comm 2C, if a super admin forgets their password, they will be prompted to enter the licence key used to activate the system in order to reset their password.

In KF Comm 2, if a super admin forgets their password, they need to use the default password assigned to them when they first downloaded and installed the system. The default username and password can be found on the online module from where you downloaded the software. If you have any trouble with this, please contact customer support.

### 3. Administrator Roles User Guide

#### 3.1 User Management (Super Admin/Admin)

##### 3.1.1 User List

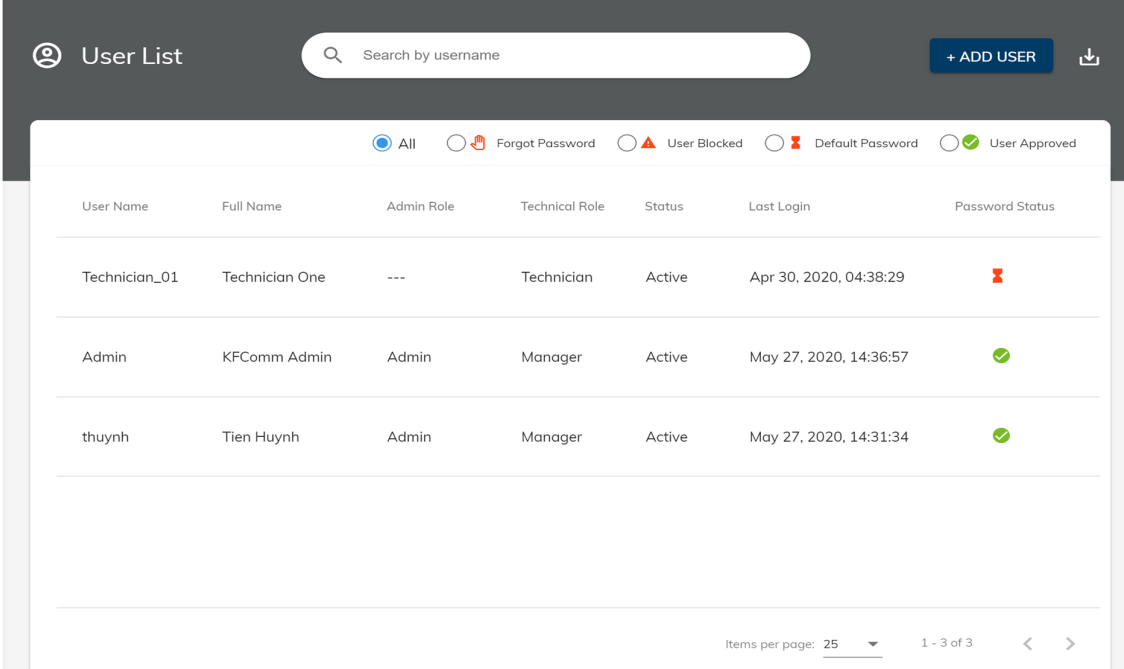
Upon logging in as a Super Admin or Admin, you are directed to the user management page as seen in Figure 14 below. This page shows you a list of all users that have been added to the platform including their username, full name, roles, status, last login and password status. You may use the search bar on the top of the page to search for users by username. The user list also allows you to filter pending actions regarding password status. Since this is a completely offline system once it has been activated, any user credential requests need to be verified and acted upon by administrators. Hence, if a user forgets their password, the admin needs to update their password and notify them offline with a temporary login before they can regain access to the system. The password status column allows the admins to view any pending actions they may have for users on their system. There are 4 possible states in the password status column:

1. **Forgot password:** User is requesting password change by clicking forgot password on their login screen. In such a case, administrators need to click on the user details and generate a new password for the user. They proceed to notify the user offline about their new

password. When the user logs in with the temporary password, they are prompted to create their own fresh password in order to maintain data security as per 21CFR11 guidelines.

2. **User blocked:** On the login screen a user has 3 attempts before they are blocked from the system. If a user enters the wrong password 3 times, the account is blocked and manually needs to be unblocked by the administrators before they can regain access to the system. When a user is blocked, their user status is changed from **'Active'** to **'Inactive'**. In order to unblock the user, the administrator must click on the user in the user list and change their status to **'Active'**.
3. **Default password:** When an administrator assigns a temporary password to a user in the case that they have been blocked, forgotten password or added as a new user to the system, the password status is set to **'Default password'**. This is a system generated temporary password that needs to be handed over to the user offline.
4. **User approved:** When a user logs in using the temporary password provided to them by the administrator, they are prompted to create a new password. Upon creating a new password, the password status changes to **'User approved'** and their status is **'Active'**.

Figure 14. User List



User Name	Full Name	Admin Role	Technical Role	Status	Last Login	Password Status
Technician_01	Technician One	---	Technician	Active	Apr 30, 2020, 04:38:29	✘
Admin	KFComm Admin	Admin	Manager	Active	May 27, 2020, 14:36:57	✔
thuynh	Tien Huynh	Admin	Manager	Active	May 27, 2020, 14:31:34	✔

### 3.1.2 Add New User

The administrator also has the option to add new users by clicking the **'Add user'** button on the top right-hand corner of the page. When they click on the add user button, they are directed to a new page to enter user details (Figure 15).



Figure 15. Add User

The screenshot shows the 'Add User' form in the REPLIGEN interface. The form is titled 'Add User' and has a 'SAVE' button in the top right corner. The form fields are as follows:

- Prefix: Mr. (dropdown)
- First Name: Test
- Middle Name: (empty)
- Last Name: User
- User Name: TestUser\_01
- Phone No: (empty)
- Email ID: TestUser\_01@gmail.com
- Default Password: kob\$RQ88 (with a 'Generate' button)
- Administrator Roles: Admin (selected), Auditor, Neither
- Technical Roles: Manager (selected), Technician, Neither
- Status: Active (dropdown)

The add user page allows the administrators to add user details including:

1. Full name with prefix.
2. User name (**mandatory and non-editable**).
3. Phone number.
4. Email ID (**mandatory**).
5. Default password:
  - a. Admin can choose to create password themselves or click the generate button for a system generated default password. This password will need to be shared with the user for the first time that they try to login to the system.
6. Administrator roles.
7. Technical roles.
8. Status (Active or Inactive):
  - a. An administrator can choose to make a user account inactive in the case that the user is not currently using the system or needs to be blocked from using the system.

**Note:** KF Comm 2 and 2C allows administrators to add and edit user details, however a user may not be deleted. If a user account needs to be blocked for any reason the administrator needs to change their status to Inactive to prevent them from logging into the system.

After completing the user details, the administrator must click the save button on the top right corner of the page to complete this process.

### 3.1.3 Edit User

In order to edit user details, an administrator can click on the user from their user list and they will be directed to a page with the user details. Once here the administrator can click on the 'Edit' button on the top right corner of the page to edit user details (Figure 16). The administrator can also manually update password of the user by clicking the 'Update password' button on the page.

Figure 16. Edit User

The screenshot shows the 'Update User Details' interface. On the left is a navigation menu with 'User Management' selected. The main area contains a form with the following fields and options:

- Name:** Mr. (dropdown), First Name \* (Technician), Middle Name, Last Name \* (One)
- User Name:** Technician\_01
- Phone No:** (empty)
- Email ID \*:** technician\_01@gmail.com
- Password:** (masked with dots)
- Administrator Roles:** Admin, Auditor,  Neither
- Technical Roles:** Manager,  Technician, Neither
- Status \*:** Active (dropdown)

Buttons for 'Update Password', 'SAVE', and a close 'X' are visible at the top right of the form.

### 3.1.4 Password Reset

When an administrator resets a user password or assigns a new temporary password to a user, they need to inform the user of the new password offline. Once the user logs in using these temporary credentials they are prompted to create a new secure password which is not accessible to the administrator (Figure 17). Till such time as the new password has not been created, the administrator can view the default password on the user details page. However, once a new password has been created, the administrator can no longer view the user’s password to maintain system security.

Figure 17. Create New Password

The 'Create New Password' dialog box contains the following elements:

- Logo:** REPLIGEN
- Text:** Please Create New Password
- Input Fields:** Password \*, Retype Password \*
- Buttons/Links:** Confirm, [Go back to login](#)

### 3.1.5 My Profile

Once a user has logged in, they can click on the **'My Profile'** button on the top right corner of the page to edit personal details (Figure 18). Users can use this page to change the following fields:

1. Name.
2. Phone number.
3. Email address.
4. Password.

This page can also be used to view (not edit) Username, role and status as set by the system administrators.

**Figure 18. My Profile**

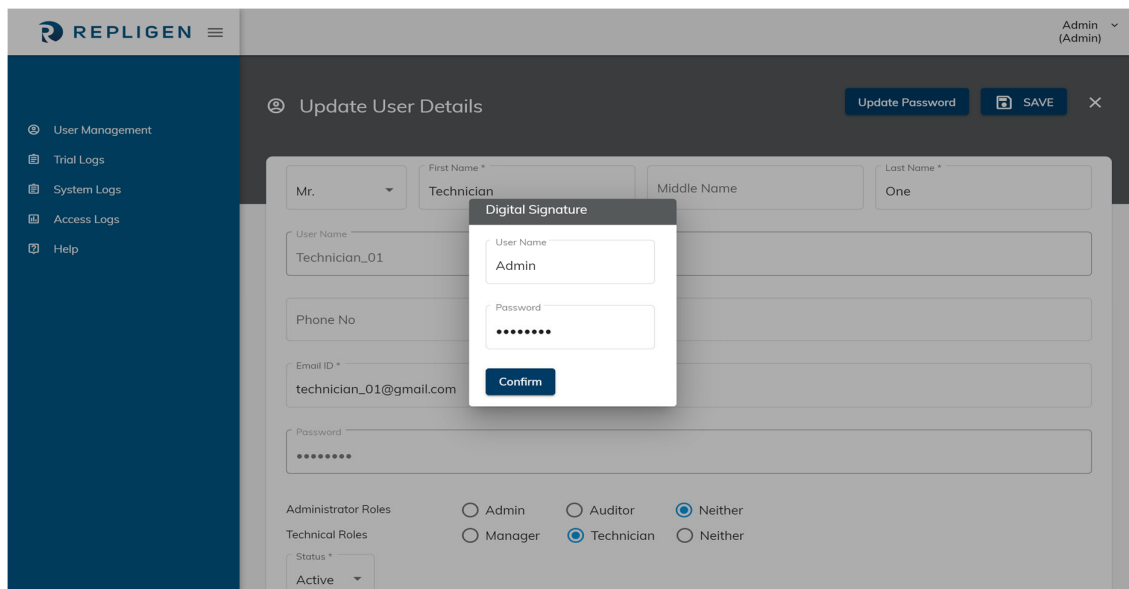
The screenshot displays the 'My Profile' interface. On the left is a dark blue sidebar with a menu containing 'User Management', 'Trial Logs', 'System Logs', 'Access Logs', and 'Help'. The main content area has a header 'My Profile' and a dropdown menu in the top right corner with options: 'Admin (Admin)', 'My Profile', 'Logout', and 'Close KF COMM'. The profile form includes:
 

- Name fields: 'Dr.' (dropdown), 'First Name' (KFCOMM), 'Middle Name', and 'Last Name' (Admin).
- 'Username' field containing 'Admin'.
- 'Phone No' field.
- 'Email ID' field containing 'admin@repligen.in'.
- 'Administrator Roles' section with radio buttons for 'Admin' (selected), 'Auditor', and 'Neither'.
- 'Technical Roles' section with radio buttons for 'Manager' (selected), 'Technician', and 'Neither'.
- 'Status' dropdown menu set to 'Active'.

### 3.1.6 Digital Signature

In KF Comm 2C, any user details modification action will prompt a digital signature request on clicking the **'Save'** button. Upon verification of digital signature this action will get recorded on the access logs page for audit purposes. The digital signature prompt will ask for your username and password. Only authorized personnel will be able to perform this action. If your role does not permit you access to perform the specific function the digital signature will not be accepted, and the change will not be logged (Figure 19). This feature is only available on KF Comm 2C.

Figure 19. Digital Signature



### 3.1.7 Switch Roles

If a user is assigned multiple roles, they are prompted to select which role they would like to enter the system at the time of login. In order to switch roles, the user must log out of the system and log back in while selecting the alternate role.

Figure 20: Switch roles



### 3.1.8 User Management (Auditor) – KF Comm 2C Software

Upon logging in, the auditor is redirected to the User management page. The auditor has view only access to all users and user details. Auditor can also download the user list to a .xls format. However, the downloaded file is no longer considered a controlled copy.

### 3.1.9 Access Logs (Super Admin, Admin, Auditor)

Super Admin and Auditors can view all access logs from across the system in this section. Any event that requires users to login, logout, save or edit data gets recorded in the access logs list. Each log is timestamped and contains the following information:

1. Username.
2. Full name.
3. Role Details.
4. Action (login, exit browser, stop run etc.).
5. Event Date/timestamp.
6. Performed on.

Access logs are available to both KF Comm 2 and 2C users and are available in a view only format. Auditors and the Super Admin can also download access logs by clicking the download button on the top right corner of the page (**Figure 21. Access Logs**). Auditor role is only available in KF Comm 2C.

**Figure 21. Access Logs**

User Name	Full Name	Role	Action	Event Date/Time	Performed On
thuynh	Tien Huynh	Admin	Login	May 27, 2020, 14:27:54	thuynh
thuynh	Tien Huynh	Manager	Logout	May 27, 2020, 14:27:43	thuynh
thuynh	Tien Huynh	Manager	Login	May 27, 2020, 14:09:31	thuynh
Admin	KFComm Admin	Manager	Login	May 8, 2020, 21:52:32	Admin
Admin	KFComm Admin	Manager	Login	May 7, 2020, 16:43:34	Admin

## 4. Set-up, Operation and System Functionality

### 4.1 Basic Set-up

1. Mount the KrosFlo® TFF System on a flat, horizontal surface with no more than two pump heads attached (see 4.5.1 for pump head set-up details).
2. Connect both octopus cables to the back of the KrosFlo® TFF System.
3. Connect up to three pressure transducers to the pressure transducer octopus cable ports as suitable for application.
4. Connect one (if using KR2i of KrosFlo® FS15) or up to two (if using KMPi of KrosFlo® FS500) Automatic Backpressure Valves (ABV) to the auxiliary component octopus cables “**Valve 1**” (“**Valve**” for KrosFlo® KR2i) and/or “**Valve 2**” (see section 4.5.1 for ABV set-up details).
5. Connect power cable to the KrosFlo® TFF System.
6. Follow guidelines and diagrams below to determine which auxiliary components are required to operate specific pump modes for Manual, Auto Mode and Set-up breakdown Modes (see section 5.5 for pump mode set-up details).
  - a. If using Auxiliary Pump, configure Auxiliary pump before starting application (see section 11.2 for auxiliary pump set-up details).

- b. After connecting auxiliary components, power on the KrosFlo® TFF System first before powering on auxiliary components.
7. Connect ProConnex™ TFF Flow Paths to KrosFlo® TFF System.
8. Open KF Comm 2/2C and log in as Manager or Technician to create recipes for Auto Mode/Set-up breakdown Mode or begin Manual Mode.

**Note:** In case the device USB gets disconnected from the system or if the COM port detects a temporary disconnection, the system will go into recirculation mode and try to autoconnect. If it is not able to autoconnect within 3 minutes, the system will continue in recirculation mode and the user will need to unplug and replug the USB port and click the Autoconnect button in their trial. Upon doing this, the system will resume the run to its last configured state and continue normal operation.

## 4.2 System Settings

Managers can edit basic system settings pertaining to information such as units and significant figures being used in the system. The system settings menu can also be used to change the default parameter of the UV/Aux channels on the KONDUiT add-on module.

Users can also check and update the compatible firmware version for their KR2i/KMPi system from the system settings menu.

**Figure 22. System Settings: Part 1**

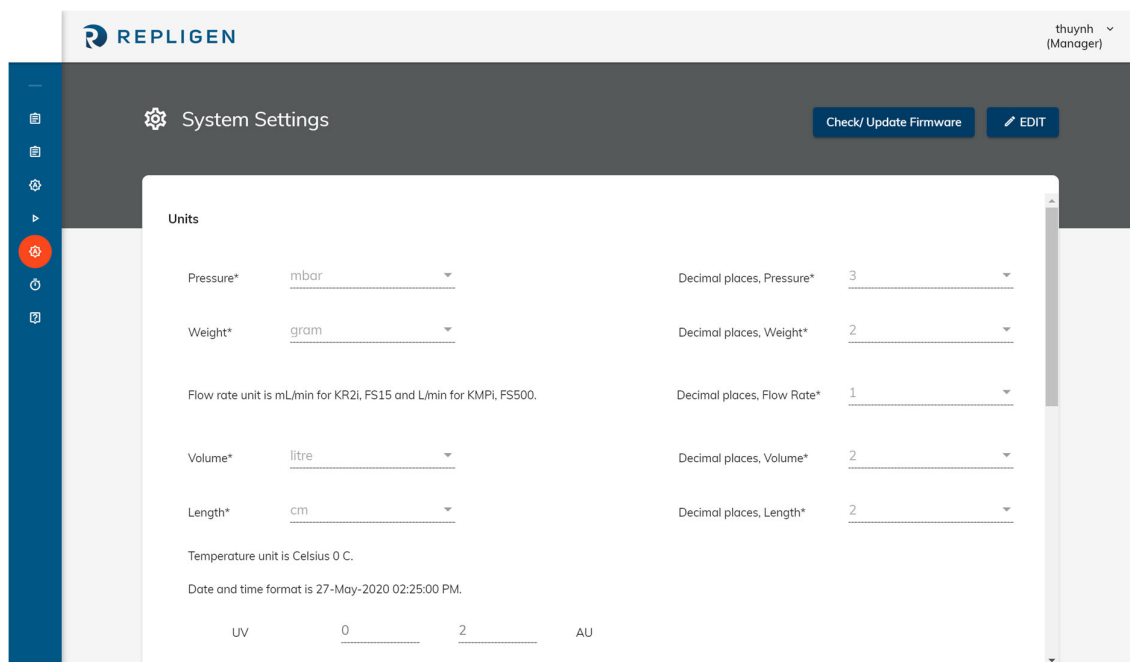
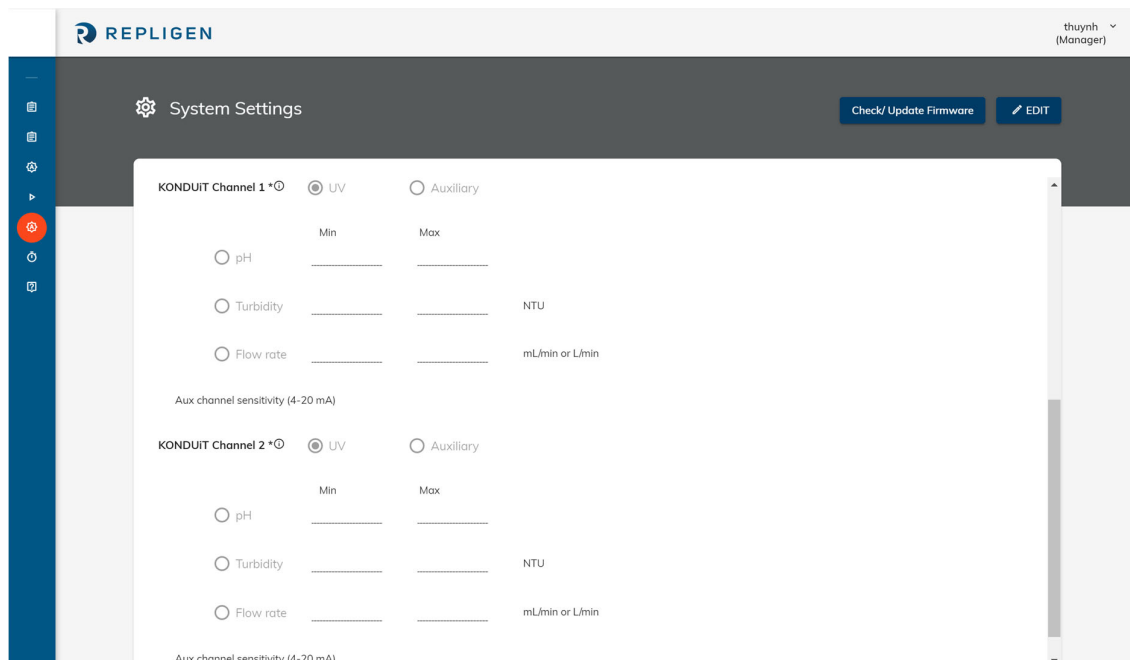


Figure 23. System Settings: Part 2



1. Pressure:
  - a. Units:
    - psi (default)
    - mbar
    - bar
  - b. Decimal places (0-3).
2. Weight:
  - a. Units:
    - gram
    - kg
  - b. Decimal places (0-2).
3. Flow rate:
  - a. Unit (default and non-editable):
    - mL/min (KR2i and KrosFlo® FS15)
    - L/min (KMPi and KrosFlo® FS500)
  - b. Decimal places (0-2).
4. Volume:
  - a. Unit:
    - ml
    - Liter
  - b. Decimal places (0-2).
5. Length:
  - a. Unit:
    - cm
    - mm
    - inch
  - b. Decimal places (0-2).

6. Temperature unit is °C.
7. UV
  - a. Default Range – 0.000 to 2.000 AU
  - b. Unit
    - i. AU
  - c. Decimal place (0-3)
8. AUX Konduit Channel 1 (Yes/No – Default is 'No') – If yes is selected, user can choose Aux parameter from the following and define their min and max range. Aux channel sensitivity is from 4-20 mA so user must be sure to select min/max value range of Aux parameter with this reference sensitivity. Parameter selected under channel 1 will be reflected in endpoints during recipe creation. Channel 1 is used for **Endpoint/setpoint** monitoring. Following parameters can be selected:
  - a. pH.
  - b. Turbidity (NTU).
  - c. Flow rate (ml/min or L/min).
9. AUX Konduit Channel 2 (Yes/No – Default is 'No') – If yes is selected, user can choose Aux parameter from the following and define their min and max range. Aux channel sensitivity is from 4-20 mA so user must be sure to select min/max value range of Aux parameter with this reference sensitivity. Channel 2 is used for observation. Following parameters can be selected:
  - a. pH.
  - b. Turbidity (NTU).
  - c. Flow rate (ml/min or L/min).

### 4.3 Pump controls

The pump control interface can be used to interact with all features of the system. This screen will appear when the KF Comm 2 Software is opened as Manager or Technician role. Main pump can only be controlled via the console on KF Comm 2. User may choose to use automated filtration modes or manual modes to control device.

### 4.4 Technical terms

The KrosFlo® TFF System alternates through different functions based on user defined set points suitable for the user's application – These combinations of functions are pump modes. All pump modes are composed of different sequences of concentration and diafiltration functions.

Basic concepts of tangential flow filtration:

1. **Concentration:** Reduce volume of process solution.
2. **Diafiltration:** Wash permeable molecules from the process solution.

**Note:** Auxiliary components are associated with the following most commonly used automated functions and actions:

3. **Feed scale:** Weighs feed reservoir to monitor concentration and diafiltration functions.
4. **Permeate scale:** Weighs Permeate reservoir to monitor concentration and diafiltration functions.
5. **Diafiltration pump:** Replenishes Feed reservoir volume during diafiltration function; usually Auxiliary pump 1 is used in most modes.
6. **Permeate pump:** Controls permeation rate for MF applications: usually Auxiliary pump 2 is used in most modes.



7. **ABV 1:** Controls TMP, retentate, pressure.
8. **ABV 2:** Controls TMP, permeate pressure.
9. **Konduit:** If concentration or diafiltration set point in hardware set-up is set to conductivity or UV/Aux set points, then Konduit signals when pump mode ends.

#### 4.5 Modes

KF Comm 2 offers 3 different mode selections. Auto mode, Manual Mode and Set-up breakdown Mode. Users can use the recipe builder feature to customize auto modes and set-up breakdown modes based on the configuration and experiments they are running. Manual mode gives users direct access to all auxiliaries connected.

**Table 2. Auxiliary Components Required for Pump Modes**

Pump mode	Feed scale	Permeate scale	Auxiliary pump 1	Auxiliary pump 2	ABV	Konduit
Manual						
C	Optional_1	X		Optional_2		Optional_3
D	X	X	X	Optional_2		Optional_3
C/D	X	X	X	Optional_2		Optional_3
C/D/C	X	X	X	Optional_2		Optional_3
C/D/D/C	X	X	X	X		Optional_3
C/D/C/D	X	X	X	X		Optional_3
CFC	X	X	X	Optional_2		Optional_3
CF/D/C	X	X	X	Optional_2		Optional_3
Flushing	Optional_1	X		Optional_2		Optional_3
NWP	Optional_1	X		Optional_2	X	Optional_4
Cleaning	Optional_1	X		Optional_2		
Vacuum	X	X				Optional_3
Flux excursion CV	X	X	X		X	Optional_4
Flux excursion C	Optional_1	X	X	Optional_2	X	Optional_4

#### Legend:

1. **X:** Mandatory auxiliary component.
2. **Optional\_1:** The Feed scale is only required in applications using C Mode if user does not want to input starting Feed scale values.
3. **Optional\_2:** Auxiliary pump 2 is optional for applications that utilize it as a Permeate pump, such as MF applications.
4. **Optional\_3:** Konduit is only required if end point selected is UV/Aux or conductivity. It can be used as an optional device in applications to monitor UV/Aux or conductivity and alarms, stop points can be set as optional terminators.
5. **Optional\_4:** Konduit is only mandatory if user wants to use Temperature channel 1 to measure temp values for NWP. User may manually input temperature for NWP calculations if they choose not to use a Konduit.

**Note:** All diagram examples in the sections below can be used for both KrosFlo® KMPi TFF Systems, and KrosFlo® KR2i TFF Systems.

**Note:** Concentration Factor (CF) is calculated for C and CFC steps only. For any D steps the calculation for CF is suspended of concentration factor and Diafiltration Volume (DV) calculations are initiated.

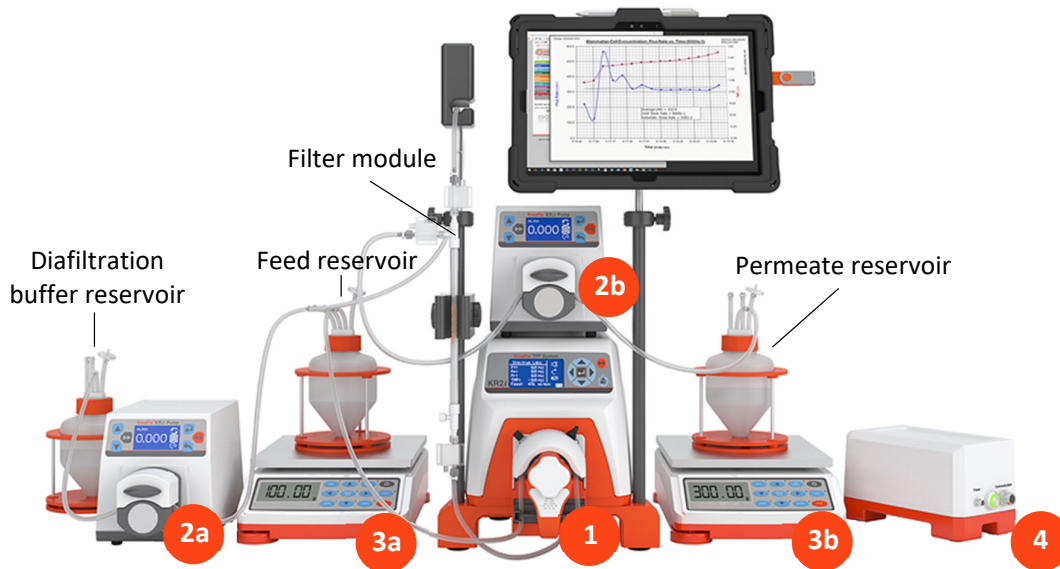
**Note:** For both the initial and final Concentration Factor the calculation is from the initial weight (either from scale or user input).

#### 4.5.1 Manual Mode

**Note:** Valves are intentionally left out of the diagrams below for visual clarity.

- Users can start/stop main pump, Auxiliary pumps (1 or 2), tare scales, pressure sensors, change tubing sizes, start/stop manual valve control
- This mode allows the customer to check and make sure the main pump and all auxiliary components are operational and connected

**Figure 24. Manual Mode set-up**

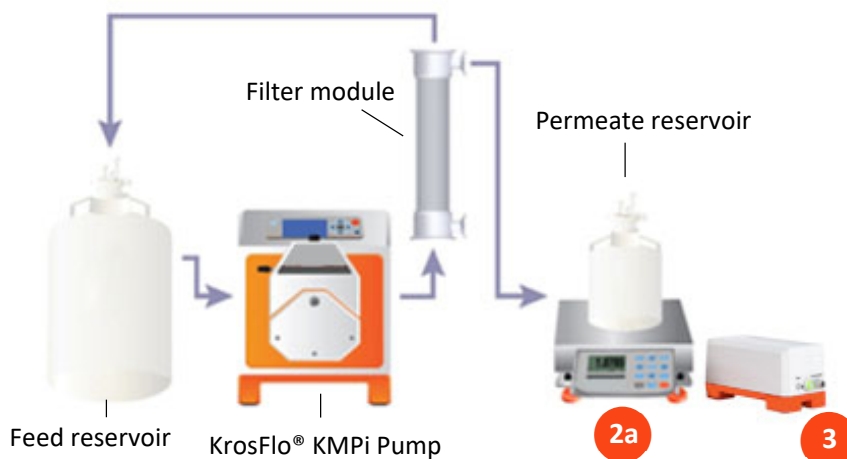


1. Any combination of auxiliary components is possible in Manual Mode – the only required component is the KrosFlo® TFF System Pump itself. The image above is a full set-up with all auxiliary components.
2. Auxiliary pumps (connect up to two):
  - a. Connect Auxiliary pumps to the auxiliary component cable’s “**Auxiliary pump 1/Diafiltration**” port.
  - b. Connect auxiliary pumps to the auxiliary component cable’s “**Auxiliary pump 2/Permeate**” port.
  - c. Connect Auxiliary pump power cable(s).
3. Auxiliary scales (connect up to two):
  - a. Connect the auxiliary component cable’s “**Feed scale**” port.
  - b. Connect the auxiliary component cable’s “**Permeate scale**” port.
4. Konduit:

- a. Connect Konduit Ch1 and/or Ch2 ports for “UV/Aux” and/or “Conductivity/Temp” ports.

#### 4.5.2 C Mode set-up

Figure 25. C Mode set-up



1. Auxiliary pumps (optional):
  - a. (Optional) To control permeate rate, connect auxiliary pump to the auxiliary component cable’s “Auxiliary pump 2/Permeate” port.
  - b. (Optional) Connect power cable to Auxiliary pump 2.
2. Auxiliary scales:
  - a. Connect scale to the auxiliary component cable’s “Permeate scale”.
3. Konduit:
  - a. Connect Konduit Ch1 and/or Ch2 ports for “UV/Aux” and/or “Conductivity/Temp” ports.

##### 4.5.2.1 KF Comm set-up

1. End points (any one mandatory).
  - CF (requires Feed scale or initial feed weight)
  - Weight of permeate (requires Permeate scale)
  - UV (requires Konduit)
2. Recirculation flow rate (main pump).
3. Operating pressure (optional – requires ABV on retentate or permeate line to control operating pressure).

##### 4.5.2.2 Sequence of operation

1. Start run:
  - a. Pause and stop options available.
2. Data collection begins.
3. Main pump ramps up to recirculation flow rate.
4. Permeate pump (if any) starts at user input flow rate.
5. ABV operating pressure control (if any) starts.
6. Once target end point is reached (CF, weight of permeate or UV):

- a. ABV1 opens if on TMP or retentate control.
- b. ABV2 closes if on permeate control.
- c. Permeate pump (if any) stops.
- d. Main pump stops.
- e. Data collection stops.
- f. Data is saved in trial logs.

#### 4.5.2.3 Concentration Mode example

Concentration Mode may be used to flush the module to prepare it for use. For example, some modules must be flushed with 2 ml of water for every  $\text{cm}^2$  of its surface area. The module in the example below has a surface area of  $\sim 0.80 \text{ m}^2$  which means the module must be flushed with  $\sim 16 \text{ ml}$  of water.

To automate flushing the module on the KrosFlo® TFF System while using only a Permeate scale, the user can simply start with 32 kg of water in the Feed reservoir, input the value into the KrosFlo® TFF System as 32 L of Feed Hold up and set feed status to empty. Then the user must set the concentration factor setpoint to 2X. Once 16 kg of water has been moved from the Feed scale to the Permeate scale, C Mode will end.

**Table 3. Concentration Mode example**

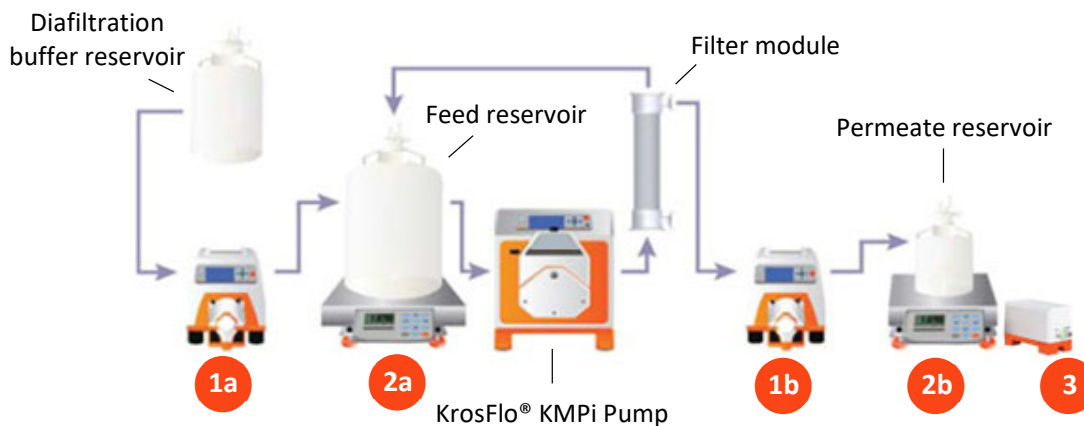
	*Feed scale weight (kg)	Permeate scale weight (kg)
Initial	32	0
After 2x concentration	16	16

\*Feed scale is optional in this example to demonstrate how to use feed hold up option.

#### 4.5.3 D, C/D and C/D/C Mode set-up

**Note:** Permeate pump is optional and shown in the diagram as an example for applications that require permeate control.

**Figure 26. D, C/D, C/D/C Mode set-up**



1. Auxiliary pumps:
  - a. Connect Auxiliary pump to the auxiliary component cable's "**Auxiliary pump 1/Diafiltration**" port.
  - b. Connect second Auxiliary pump to the auxiliary component cable's "**Auxiliary pump 2/Permeate**" port.
  - c. Connect Auxiliary pump power cable(s).
2. Auxiliary scales:
  - a. Connect first scale to the auxiliary component cable's "**Feed scale**" port.
  - b. Connect second scale to the auxiliary component cable's "**Permeate scale**" port.
3. Konduit:
  - a. Connect Konduit Ch1 and/or Ch2 ports for "**UV/Aux**" and/or "**Conductivity/Temp**" ports.

#### 4.5.3.1 D Mode

##### 4.5.3.2 KF Comm set-up

1. End points (any one mandatory).
  - DV (requires Feed scale and Diafiltration pump)
  - Weight of permeate (requires Permeate scale)
  - UV (requires Konduit)
  - Conductivity (requires Konduit)
2. Recirculation flow rate (main pump)
3. Operating pressure (optional – requires ABV1 on retentate or ABV2 permeate line to control operating pressure).

##### 4.5.3.3 Sequence of operation

1. Start run:
  - a. Pause and stop options available.
2. Data collection begins.
3. Main pump ramps up to recirculation flow rate.
4. Permeate pump (if any) starts at user input flow rate.
5. Diafiltration pump starts to maintain feed weight for DV calculation.
6. ABV operating pressure control (if any) starts.
7. Once target end point is reached (DV, weight of permeate, UV or conductivity):
  - a. ABV 1 opens if on TMP or retentate control.
  - b. ABV 2 closes if on permeate control.
  - c. Permeate pump (if any) stops.
  - d. Diafiltration pump stops.
  - e. Main pump stops.
  - f. Data collection stops.
  - g. Data is saved in trial logs.

#### 4.5.3.4 C/D Mode

##### 4.5.3.5 KF Comm set-up

1. Set-up for C step:
  - a. End points (any one mandatory).

- CF (requires feed scale or initial feed weight)
  - Weight of permeate (requires Permeate scale)
  - UV (requires Konduit)
2. Set-up for D step:
    - a. End points (any one mandatory).
      - DV (requires feed scale and Diafiltration pump)
      - Weight of permeate (requires Permeate scale)
      - UV (requires Konduit)
      - Conductivity (requires Konduit)
  3. Recirculation flow rate (main pump).
  4. Operating pressure (optional – requires ABV on retentate or permeate line to control operating pressure).

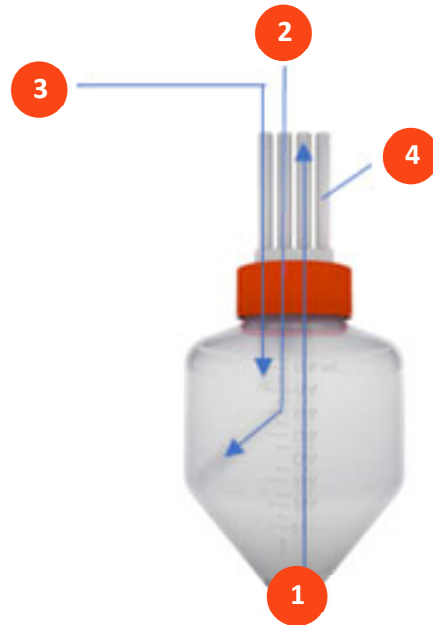
#### 4.5.3.6 Sequence of operation

1. Start run:
  - a. Pause and stop options available.
2. Data collection begins.
3. Main pump ramps up to recirculation flow rate.
4. Permeate pump (if any) starts at user input flow rate.
5. ABV operating pressure control (if any) starts.
6. Once C step target end point is reached (CF, weight of permeate, UV):
  - a. Change to D Mode.
  - b. Maintains all current parameters for pumps and pressure.
7. Diafiltration pump starts to maintain feed weight for DV calculation.
8. Once target end point for D step is reached (DV, weight of permeate, UV or conductivity):
  - a. ABV 1 opens if on TMP or retentate control.
  - b. ABV 2 closes if on permeate control.
  - c. Permeate pump (if any) stops.
  - d. Diafiltration pump stops.
  - e. Main pump stops.
  - f. Data collection stops.
  - g. Data is saved in trial logs.

#### 4.5.3.7 C/D Mode example

C/D Mode may be used for a fed-batch concentration, followed by a diafiltration.

**Note:** *This constant feed concentration followed by a diafiltration can be done with the CDDC Mode when 2 auxiliary pumps are available (see section 5.5.1.4 C/D/C/D and C/D/D/C Mode set-up). Also, the CD Mode can be done without the vacuum addition if the full sample fits in the process vessel on the scale.*

**Figure 27. Feed reservoir port orientation for CD Mode**

On the Feed reservoir with four ports, set up the ports as described below to create a vacuum that will draw excess feed into the Feed reservoir from the extra Feed reservoir:

1. **Feed line to filter:** Connect tubing from this line through pump head to filter's feed port.
2. **Retentate line from filter:** Connect tubing from filter retentate port to this line.
3. **Buffer:** Connect through Aux pump 1 to Diafiltration buffer reservoir.
4. **Vent:** Connect to extra Feed reservoir.

On both the extra Feed reservoir and Diafiltration buffer reservoir, install a vent. Ensure that Diafiltration pump head is closed on the tubing between the Diafiltration buffer and the Feed reservoir.

The result of the set-up is that the vacuum will pull the entirety of the extra Feed reservoirs contents as volume is depleted from the process reservoir during the C function of the C/D Mode. Once the contents of the extra Feed reservoirs are depleted, the vacuum will pull air. After the concentration set point is reached, the KrosFlo® TFF System will then switch to D Mode until the diafiltration set point is reached.

The KrosFlo® TFF System will be able to properly calculate the concentration factor because it will know that a fed-batch concentration is taking place when the Permeate scale increases while the Feed scale weight stays constant.

**Table 4. Concentration/Diafiltration Mode example**

	Feed scale weight (kg)	Permeate scale weight (kg)
Initial	20	0
After 10x concentration	2	18
After 7x diavolume wash	2	32

#### 4.5.4 C/D/C Mode

##### 4.5.4.1 KF Comm set-up

1. Set-up for first C step:
  - a. End points (any one mandatory).
    - CF (requires Feed scale or initial feed weight)
    - Weight of permeate (requires Permeate scale)
    - UV (requires Konduit)
2. Set-up for D step:
  - a. End points (any one mandatory).
    - DV (requires Feed scale and Diafiltration pump)
    - Weight of permeate (requires Permeate scale)
    - UV (requires Konduit)
    - Conductivity (requires Konduit)
3. Set-up for second C step:
  - a. End points (any one mandatory).
    - CF (requires Feed scale or initial feed weight)
    - Weight of permeate (requires Permeate scale)
    - UV (requires Konduit)
4. Recirculation flow rate (main pump).
5. Operating pressure (optional – requires ABV on retentate or permeate line to control operating pressure).

##### 4.5.4.2 Sequence of operation

1. Start run:
  - a. Pause and stop options available.
2. Data collection begins.
3. Main pump ramps up to recirculation flow rate.
4. Permeate pump (if any) starts at user input flow rate.
5. ABV operating pressure control (if any) starts.
6. Once first C step target end point is reached (CF, weight of permeate, UV):
  - a. Change to D Mode.
  - b. Maintains all current parameters for pumps and pressure.
7. Diafiltration pump starts to maintain feed weight for DV calculation.
8. Once target end point for D step is reached (DV, weight of permeate, UV or conductivity):
  - a. Change to C Mode.
  - b. Maintains all current parameters for pumps and pressure.
9. Diafiltration pump stops.
10. Once target end point for second C step is reached (CF, weight of permeate or UV):
  - a. ABV 1 opens if on TMP or retentate control.
  - b. ABV 2 closes if on permeate control.
  - c. Permeate pump (if any) stops.
  - d. Main pump stops.
  - e. Data collection stops.
  - f. Data is saved in trial logs.



#### 4.5.4.3 C/D/C Mode example

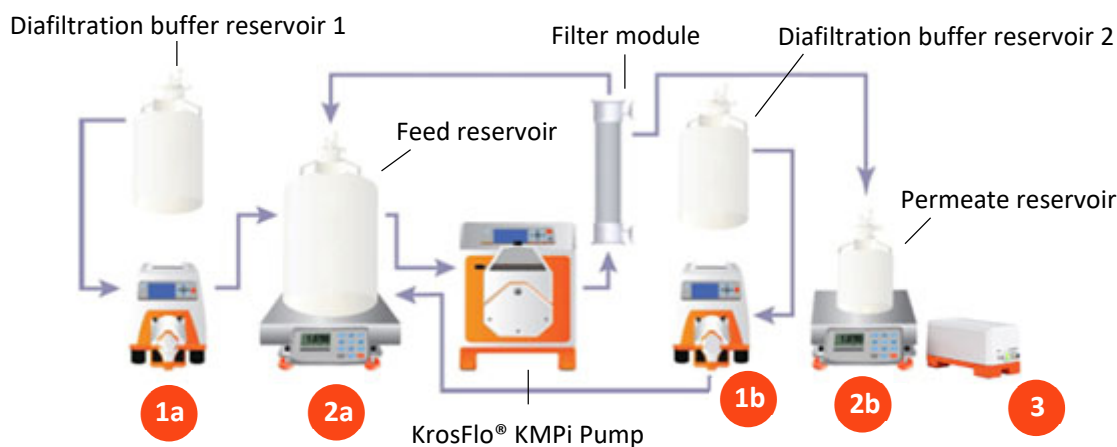
C/D/C Mode may be used to further concentrate the process solution after diafiltration.

**Table 4. CDC Mode example**

	Feed scale weight (kg)	Permeate scale weight (kg)
Initial	20	0
After 10x concentration	2	18
After 7x diavolume wash	2	32
After 20x concentration	1	33

#### 4.5.5 C/D/C/D and C/D/D/C Mode set-up

**Figure 28. C/D/D/C and C/D/C/D Mode set-up**



1. Auxiliary pumps:
  - a. Connect first Auxiliary pump to the auxiliary component cable's "Auxiliary pump 1/Diafiltration" port.
  - b. Connect second Auxiliary pump to the auxiliary component cable's "Auxiliary pump 2/Permeate" port.
  - c. Connect Auxiliary pump power cables.

**Note:** Auxiliary pump 1/Diafiltration will function as Diafiltration pump 1, and the Auxiliary pump 2/Permeate will function as Diafiltration pump 2.

2. Auxiliary scales:
  - a. Connect first scale to the auxiliary component cable's "Feed scale" port.
  - b. Connect second scale to the auxiliary component cable's "Permeate scale" port.
3. Konduit:
  - a. Connect Konduit Ch1 and/or Ch2 ports for "UV/Aux" and/or "Conductivity/Temp" ports.

#### 4.5.5.1 C/D/D/C Mode

#### 4.5.5.2 KF Comm set-up

1. Set-up for first C step:
  - a. End points (any one mandatory).
    - CF (requires Feed scale or initial feed weight)
    - Weight of permeate (requires Permeate scale)
    - UV (requires Konduit)
2. Set-up for first D step:
  - a. End points (any one mandatory).
    - DV (requires Feed scale and Diafiltration pump)
    - Weight of permeate (requires Permeate scale)
    - UV (requires Konduit)
    - Conductivity (requires Konduit)
3. Set-up for second D step:
  - a. End points (any one mandatory).
    - DV (requires Feed scale and Diafiltration pump)
    - Weight of permeate (requires Permeate scale)
    - UV (requires Konduit)
    - Conductivity (requires Konduit)
4. Set-up for second C step:
  - a. End points (any one mandatory).
    - CF (requires Feed scale or initial feed weight)
    - Weight of permeate (requires Permeate scale)
    - UV (requires Konduit)
5. Recirculation flow rate (main pump).
6. Operating pressure (optional – requires ABV on retentate or permeate line to control operating pressure).

#### 4.5.5.3 Sequence of operation

1. Start run:
  - a. Pause and stop options available.
2. Data collection begins.
3. Main pump ramps up to recirculation flow rate.
4. ABV operating pressure control (if any) starts.
5. Once first C step target end point is reached (CF, weight of permeate, UV):
  - a. Change to D Mode.
  - b. Maintains all current parameters for pumps and pressure.
6. Diafiltration pump 1 starts to maintain feed weight for DV calculation for first D step.
7. Once target end point for first D step is reached (DV, weight of permeate, UV or conductivity):
  - a. Change to second D Mode.
  - b. Maintains all current parameters for pumps and pressure.
  - c. Stops Diafiltration pump 1.
8. Diafiltration pump 2 starts to maintain feed weight for DV calculation for second D step.
9. Once target end point for second D step is reached (DV, weight of permeate, UV or conductivity):

- a. Change to C Mode.
  - b. Maintains all current parameters for pumps and pressure.
  - c. Stops Diafiltration pump 2.
10. Once target end point for second C step is reached (CF, weight of permeate or UV):
- a. ABV1 opens if on TMP or retentate control.
  - b. ABV2 closes if on permeate control.
  - c. Main pump stops.
  - d. Data collection stops.
  - e. Data is saved in trial logs.

#### 4.5.5.4 C/D/D/C Mode Example

C/D/D/C Mode may be used to wash the solution with two different buffers.

**Note:** In CDDC Mode, Aux pump 2 functions as Diafiltration pump 2. For this functionality test, prepare two Buffer reservoirs that both lead into the Feed reservoir, and have one line go through Aux pump 1n and the other line go through Aux pump 2.

**Table 5. C/D/D/C Mode example**

	Feed scale weight (kg)	Permeate scale weight (kg)
Initial	20	0
After 10x concentration	2	18
After 7x diavolume 1 wash	2	32
After 8x diavolume 2 wash	2	48
After 20x concentration	1	49

#### 4.5.5.5 C/D/C/D Mode

##### 4.5.5.6 KF Comm set-up

1. Set-up for first C step:
  - a. End points (any one mandatory).
    - CF (requires Feed scale or initial feed weight)
    - Weight of permeate (requires Permeate scale)
    - UV (requires Konduit)
2. Set-up for first D step:
  - a. End points (any one mandatory).
    - DV (requires Feed scale and Diafiltration pump)
    - Weight of Permeate (requires Permeate scale)
    - UV (requires Konduit)
    - Conductivity (requires Konduit)
3. Set-up for second C step:
  - a. End points (any one mandatory).
    - CF (requires Feed scale or initial feed weight)
    - Weight of permeate (requires Permeate scale)
    - UV (requires Konduit)
4. Set-up for second D step:
  - a. End points (any one mandatory):

- DV (requires Feed scale and Diafiltration pump)
  - Weight of permeate (requires Permeate scale)
  - UV (requires Konduit)
  - Conductivity (requires Konduit)
5. Recirculation flow rate (main pump).
  6. Operating pressure (optional – requires ABV on retentate or permeate line to control operating pressure).

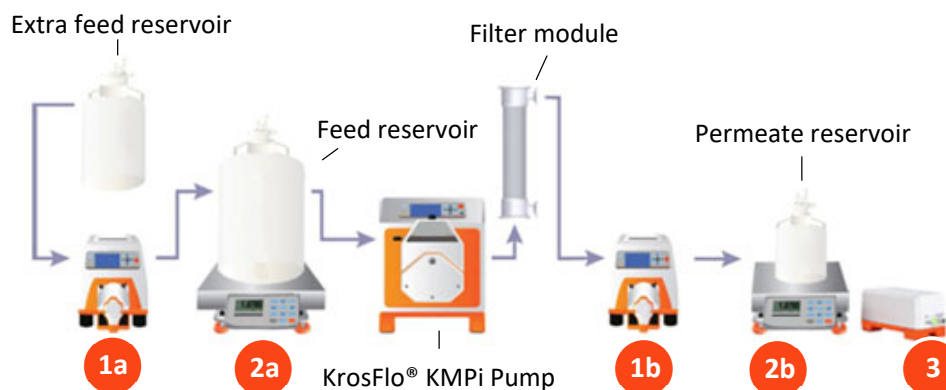
#### 4.5.5.7 Sequence of operation

1. Start run:
  - a. Pause and stop options available.
2. Data collection begins.
3. Main pump ramps up to recirculation flow rate.
4. ABV operating pressure control (if any) starts.
5. Once first C step target end point is reached (CF, weight of permeate, UV):
  - a. Change to D Mode.
  - b. Maintains all current parameters for pumps and pressure.
6. Diafiltration pump 1 starts to maintain feed weight for DV calculation for first D step.
7. Once target end point for first D step is reached (DV, weight of permeate, UV or Conductivity):
  - a. Change to second C Mode.
  - b. Maintains all current parameters for pumps and pressure.
  - c. Stops Diafiltration pump 1.
8. Once second C step target end point is reached (CF, weight of permeate, UV):
  - a. Change to second D Mode.
  - b. Maintains all current parameters for pumps and pressure.
9. Diafiltration pump 2 starts to maintain feed weight for DV calculation for second D step.
10. Once target end point for second D step is reached (DV, weight of permeate, UV or conductivity):
  - a. ABV1 opens if on TMP or retentate control.
  - b. ABV2 closes if on permeate control.
  - c. Main pump stops.
  - d. Data collection stops.
  - e. Data is saved in trial logs.

#### 4.5.6 CFC Mode set-up

**Note:** Permeate pump is optional and shown in the diagram as an example for applications that require permeate control.

**Figure 29. CFC Mode set-up**



1. Auxiliary pumps:
  - a. Connect Auxiliary pump to the auxiliary component cable's "**Auxiliary pump 1/Diafiltration**" port.
  - b. Connect second Auxiliary pump to the auxiliary component cable's "**Auxiliary pump 2/Permeate**" port.
    - Connect Auxiliary pump power cables
    - The **Auxiliary pump 1/Diafiltration pump** will function as constant feed pump
2. Auxiliary scales:
  - a. Connect first scale to the auxiliary component cable's "**Feed scale**" port.
  - b. Connect second scale to the auxiliary component cable's "**Permeate scale**" port.
3. Konduit:
  - a. Connect Konduit Ch1 and/or Ch2 ports for "**UV/Aux**" and/or "**Conductivity/Temp**" ports.

##### 4.5.6.1 KF Comm set-up

1. End points (any one mandatory):
  - CF (requires Feed scale and constant feed pump)
  - Weight of permeate (requires Permeate scale)
  - UV (requires Konduit)
2. Recirculation flow rate (main pump).
3. Operating pressure (optional – requires ABV on retentate or permeate line to control operating pressure).

##### 4.5.6.2 Sequence of operation

1. Start run:
  - a. Pause and stop options available.
2. Data collection begins.
3. Main pump ramps up to recirculation flow rate.
4. Permeate pump (if any) starts at user input flow rate.

5. Constant feed pump starts to maintain constant feed weight.
6. ABV operating pressure control (if any) starts.
7. Once target end point is reached (CF, weight of permeate, UV).
  - a. ABV1 opens if on TMP or retentate control.
  - b. ABV2 closes if on permeate control.
  - c. Permeate pump (if any) stops.
  - d. Constant feed pump stops.
  - e. Main pump stops.
  - f. Data collection stops.
  - g. Data is saved in trial logs.

#### 4.5.6.3 CFC Mode example

CFC Mode may be used to concentrate a sample that does not fit into the Process reservoir.

**Note:** In CFC mode, Aux pump 1 adds additional sample into the Process reservoir. User can select the end point condition to either deplete the extra Feed reservoir completely or stop the Aux pump 1 at a concentration factor set point.

**Note:** If the depletion of the extra Feed reservoir is selected, CF might exceed setpoint.

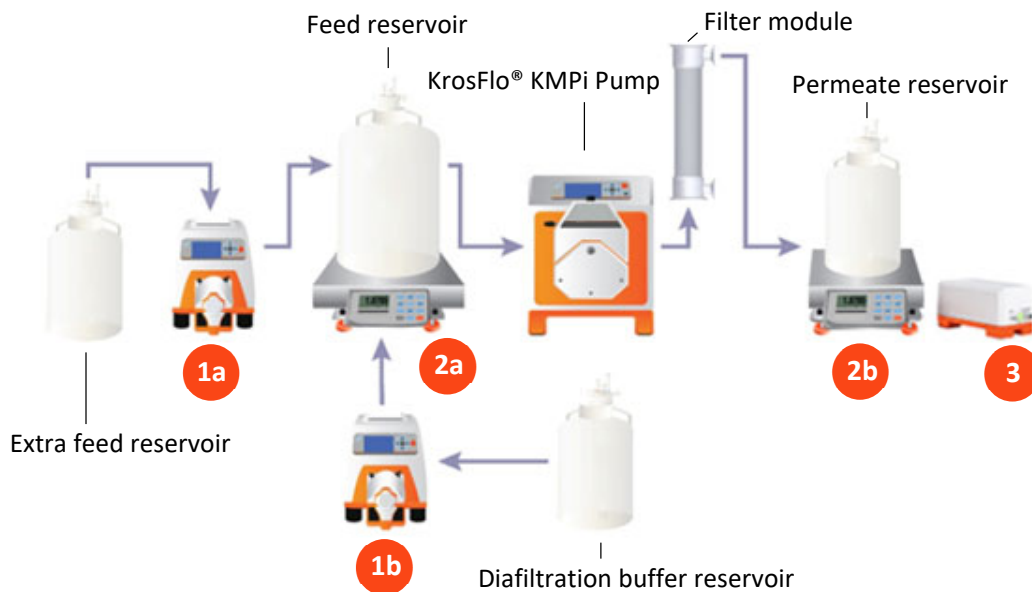
**Note:** Aux pump 1 will stop running once the Feed scale detects no additional sample added.

**Table 6. CFC Mode example**

	Extra Feed scale weight (kg)	Feed scale weight (kg)	Permeate scale weight (kg)
Initial	20	20	0
After 10x concentration	0	4	36

#### 4.5.7 CFC/D/C Mode set-up

Figure 30. CFC/D/C Mode set-up



Auxiliary pumps:

- a. Connect Auxiliary pump to the auxiliary component cable's "**Auxiliary Pump 1/Diafiltration**".
- b. Connect second Auxiliary pump to the auxiliary component cable's "**Auxiliary pump 2/Permeate**" port.
  - o Connect Auxiliary pump power cables
  - o The **Auxiliary Pump 1/Diafiltration pump** will function as constant feed pump and **Auxiliary Pump 2/Permeate pump** will function as the Diafiltration pump
2. Auxiliary scales:
  - a. Connect first scale to the auxiliary component cable's "**Feed scale**" port.
  - b. Connect second scale to the auxiliary component cable's "**Permeate scale**" port.
3. Konduit:
  - a. Connect Konduit Ch1 and/or Ch2 ports for "**UV/Aux**" and/or "**Conductivity/Temp**" ports.

##### 4.5.7.1 KF Comm set-up

1. Set-up for first CFC step:
  - a. End points (any one mandatory).
    - CF (requires Feed scale or initial feed weight).
    - Weight of permeate (requires Permeate scale)
    - UV (requires Konduit)
2. Set-up for D step:
  - a. End points (any one mandatory).
    - DV (requires Feed scale and Diafiltration pump)
    - Weight of permeate (requires Permeate scale)
    - UV (requires Konduit)
    - Conductivity (requires Konduit)

3. Set-up for second C (not constant feed) step:
  - a. End points (any one mandatory).
    - CF (requires Feed scale or initial feed weight)
    - Weight of Permeate (requires permeate scale)
    - UV (requires Konduit)
4. Recirculation flow rate (main pump).
5. Operating pressure (optional – requires ABV on retentate or permeate line to control operating pressure).

#### 4.5.7.2 Sequence of operation

1. Start run:
  - a. Pause and stop options available.
2. Data collection begins.
3. Main pump ramps up to recirculation flow rate.
4. Permeate pump (if any) starts at user input flow rate.
5. Constant feed pump starts to maintain constant feed weight.
6. ABV operating pressure control (if any) starts.
7. Once first CFC step target end point is reached (CF, weight of permeate, UV):
  - a. Change to D Mode.
  - b. Maintains all current parameters for pumps and pressure.
  - c. Stop constant feed pump.
8. Diafiltration pump starts to maintain feed weight for DV calculation.
9. Once target end point for D step is reached (DV, weight of permeate, UV or conductivity):
  - a. Change to second C (not constant feed) Mode.
  - b. Maintains all current parameters for pumps and pressure.
  - c. Diafiltration pump stops.
10. Once target end point for second C step is reached (CF, weight of permeate or UV).
  - a. ABV1 opens if on TMP or retentate control.
  - b. ABV2 closes if on permeate control.
  - c. Main pump stops.
  - d. Data collection stops.
  - e. Data is saved in trial log.

#### 4.5.7.3 CFC/D/C Mode example

CFC/D/C Mode may be used to further concentrate the process solution after diafiltration.

**Note:** User can select the end point condition to either deplete the extra Feed reservoir completely or stop the Aux pump 1 at a concentration factor set point.

**Note:** If the depletion of the extra Feed reservoir is selected, CF might exceed setpoint.

**Note:** Aux pump 1 will stop running once the feed scale detects no additional sample added.



**Table 7. CFC/D/C Mode example**

	Extra Feed scale weight (kg)	Feed scale weight (kg)	Permeate scale weight (kg)
Initial	10	20	0
After 10x concentration	0	3	27
After 7x diavolume wash	0	3	48
After 20x concentration	0	1.5	49.5

#### 4.5.8 Vacuum Mode

The purpose of Vacuum Mode is to enable the user to use Constant Feed Mode and/or Diafiltration Mode without the need of auxiliary pumps. The solution is drawn into the Feed reservoir by the vacuum created in the reservoir as the solution permeates out of the filter.

**Note:** Permeate stop first function will be disabled and has no effect in this mode.

Mandatory instruments:

- Main pump
- Permeate scale
- Feed scale

Optional instruments:

- ABV (recirculation pressure control)
- Konduit (for data monitoring)

##### 4.5.8.1 KF Comm set-up

- No end points for this mode
- Main pump recirculation flow rate
- Operating pressure

##### 4.5.8.2 Sequence of operation

1. Start run:
  - a. Pause and stop options available.
2. Options for “**Concentration**” and “**Diafiltration**” available for user depending how they would like to use this mode.
3. Main pump ramps up to flow rate.
4. Data collection begins:
  - a. If Concentration Mode is selected, concentration factor is calculated and displayed.
  - b. If diafiltration is selected, diafiltration volume is calculated and displayed.

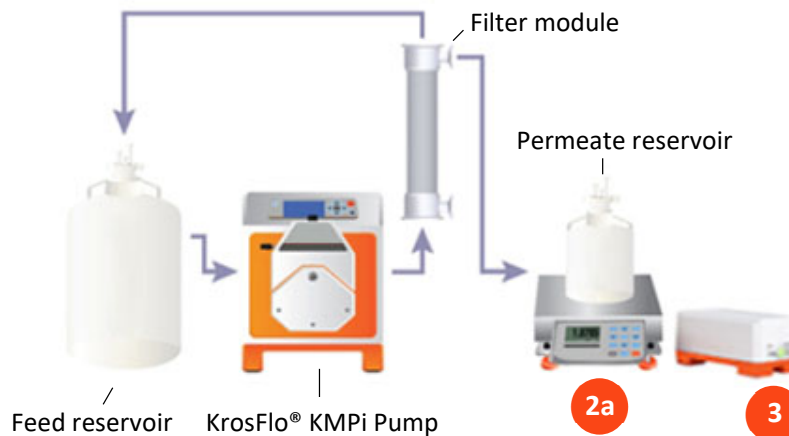
**Note:** In this mode, there are no aux pumps.

5. ABV operating pressure control (if any) starts.
6. Since there are no end points to Vacuum Mode, user must click stop to terminate this experiment.
7. At “**stop**” request:
  - a. ABV1 opens (if on TMP or retentate control).
  - b. ABV2 closes (if on permeate control).
8. Main pump stops.

9. Data collection stops.
10. Data is saved in trial logs.

#### 4.5.9 Flushing Mode

Figure 31. Flushing Mode set-up



1. Auxiliary pumps:
  - a. (Optional) To control permeate rate, connect Auxiliary pump to the auxiliary component cable's "**Auxiliary pump 2/Permeate**" port.
  - b. (Optional) Connect Auxiliary pump 2's power cable.
2. Auxiliary scales:
  - a. Connect scale to the auxiliary component cable's "**Permeate scale**".
3. Konduit:
  - a. Connect Konduit Ch1 and/or Ch2 ports for "**UV/Aux**" and/or "**Conductivity/Temp**" ports.

##### 4.5.9.1 KF Comm set-up

1. End points selection.
  - Duration (min)
  - Permeate weight (if selected, Permeate scale is mandatory)
2. Recirculation flow rate (main pump).
3. Operating pressure (ABV).

##### 4.5.9.2 Sequence of operation

1. Start:
  - a. Pause and stop options available.
2. Main pump ramps up to target flow rate.
3. ABV operating pressure control (if any) starts.
4. At endpoint (duration or permeate weight).
  - a. ABV1 opens if on TMP or retentate control.
  - b. ABV2 closes if on permeate control.
  - c. Main pump stops.
  - d. Data collection stops.

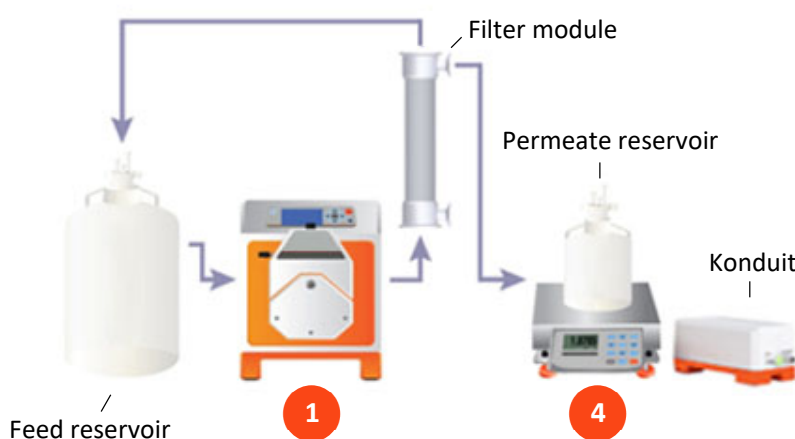
- e. Data is saved in trial logs.

#### 4.5.10 NWP Mode

**Purpose:** Normalized Water Permeability (NWP) is a method used to determine filter cleanliness after cleaning. NWP is also used to determine the water flux of a new module. Clean water is passed through the filter membrane under set pressure and temperature conditions. The flux rate of clean water (LMH) divided by the trans-membrane pressure (TMP) equals NWP, which is compared against standards to evaluate cleanliness.

**Note:** *Permeate stop first and recirculation pressure control are not available for this mode. User may choose to use a Konduit for temperature measurement. However, if you do not wish to use a Konduit you may input the starting temperature of water at the beginning of the run for the purposes of system calculations.*

Figure 32. NWP Mode set-up



Mandatory equipment:

1. Main pump.
2. Automatic back pressure valve (for TMP control only) (not pictured).
3. Pressure transducers (all 3 for TMP calculation) (not pictured).
4. Permeate scale (for flux rate calculation).

##### 4.5.10.1 KF Comm set-up

1. Set points selection.
  - Number of pressures set points (1-5)
  - Duration per setpoint (min)
  - TMP set point(s)
2. Temperature of water (°C) is automated if using Konduit. If user is not using a Konduit they must enter water temperature.
3. Recirculation flow rate (main pump).

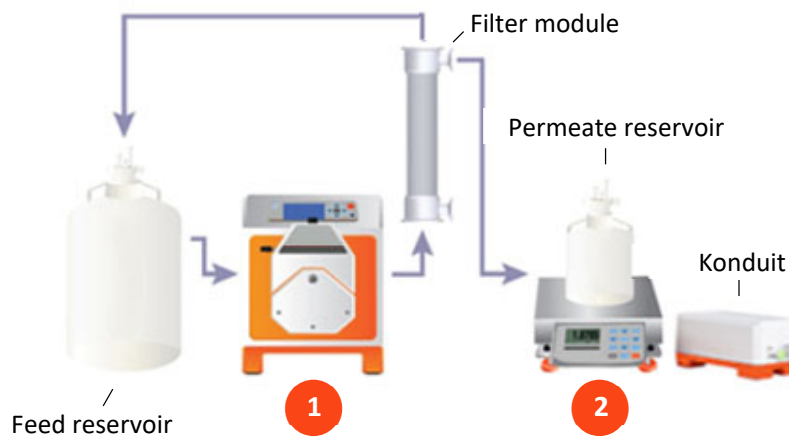
##### 4.5.10.2 Sequence of operation

1. Start:
  - a. Pause and stop options available.
2. Main pump starts at recirculation flow rate.

3. ABV starts to attain first operating pressure setpoint.
4. Once setpoint is achieved, system tries to maintain operating pressure ( $\pm 5\%$  for set duration):
  - a. Collect data:
    - Filtrate flux
    - Transmembrane pressure
  - b. Once set TMP at set duration is achieved, ABV moves to attain next operating pressure.
  - c. Steps repeated until all set points are achieved.
5. Main pump stops.
6. ABV opens.
7. Data collection stops.
8. Data is saved in trial logs.

#### 4.5.11 Cleaning Mode

Figure 33. Cleaning Mode set-up



**Note:** User may use a Permeate pump to clamp off the permeate line, however the use of a Permeate pump is not necessary

Mandatory equipment:

1. Main pump.
2. Permeate scale (for endpoint control).

**Note:** Permeate stop first, Recirculation pressure control and Konduit are unavailable for Cleaning Mode.

##### 4.5.11.1 KF Comm set-up

1. End points selection.
  - Duration (min)
  - Permeate weight (if selected, Permeate scale is mandatory)
2. Recirculation flow rate (main pump).
3. Operating pressure (ABV).
4. Permeate pump connected (Y/N).
  - If yes, you must enter permeate flow rate

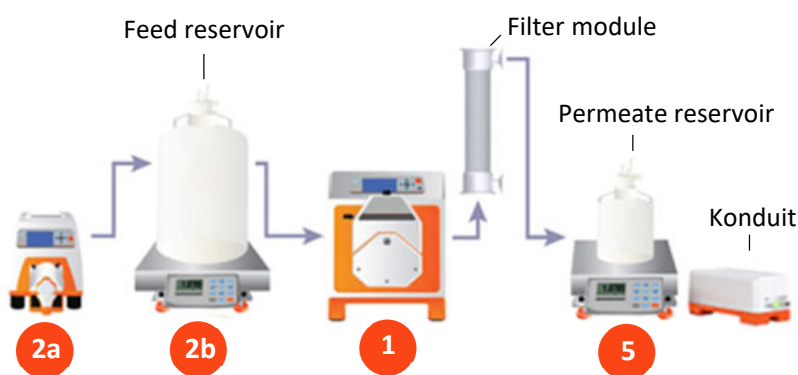
#### 4.5.11.2 Sequence of operation

1. Start:
  - a. Pause and stop options available.
2. Step 1: Permeate line closed:
  - a. **User Action:** Clamp off permeate line (manually) if Permeate pump not connected.
  - b. Permeate pump stops (if connected).
  - c. Main pump starts and ramps up to target flow rate.
  - d. Operating pressure control starts (If permeate line is closed, should not have added backpressure. May cause large pressure increases).
  - e. Main pump stops at target duration.
  - f. **User Action:** Replace cleaning solution with fresh cleaning solution.
3. Step 2: Permeate line open:
  - a. Press “**Resume permeate cleaning**”.
  - b. **User Action:** Open permeate line (manually) if permeate pump not connected.
  - c. Main pump starts and ramps up to target flow rate.
  - d. Permeate pump starts at user input flow rate.
  - e. Operating pressure control starts (if selected).
  - f. **User Action:** Press “**Stop**” to terminate Cleaning Mode.
4. On pressing stop:
  - a. ABV1 opens if on TMP or retentate control.
  - b. Main pump stops.
  - c. Permeate pump stops.
  - d. Data collection stops.
  - e. Data is saved in trial logs.

#### 4.5.12 Flux Excursion Mode

**Purpose:** Measure flux rate.

**Figure 34. Flux Excursion Mode**



Mandatory equipment:

1. Main pump.
2. For constant volume on Feed Scale Mode:
  - a. Constant Feed pump (Auxiliary pump 1).
  - b. Feed scale.
3. Automatic Back Pressure Valve (for TMP control only) (not pictured).

4. Pressure transducers (all 3 for TMP calculation) (not pictured).
5. Feed/Permeate scale (for flux rate calculation).

**Note:** Permeate stop first and recirculation pressure control are not available during this mode.

#### KF Comm Set-up

1. Set points selection:
  - Number of pressures set points (1-3)
  - TMP set point(s)
  - Number of recirculation flow rate set points (1-3)
  - Recirculation flow rate setpoint(s)
  - Duration per TMP setpoint (min) (within +/- 1 psi)
2. Temperature of water (°C) is automated if using Konduit. If user is not using a Konduit they must enter water temperature.
3. Select either Flux excursion Constant Volume Mode (Aux pump 1 will act as constant feed pump) or Flux excursion Concentration Mode (Aux pump 1 not required).

#### 4.5.12.1 Sequence of operation

1. Start:
  - a. Pause and stop options available.
2. Main pump starts at first recirculation flow rate set point.
3. ABV 1 starts to attain first operating pressure setpoint.
4. Once setpoint is achieved, system tries to maintain operating pressure ( $\pm 5\%$  for set duration):
  - a. Collect data:
    - Filtrate flux
    - Transmembrane pressure
  - b. Once set TMP at set duration is achieved, ABV 1 moves to attain next operating pressure.
  - c. Steps repeated until all TMP set points are achieved.
5. Steps repeated until all recirculation flow rate set points are achieved.
6. Main pump stops.
7. ABV 1 opens.
8. Data collection stops.
9. Data is saved in trial logs.

## 5. System set-up using KF Comm 2/2C Software (Managers and Technicians)

### 5.1 Recipe creation

Only Managers can create recipes. Once recipes are created, Super Admin, Auditor and Technicians have view access to recipe lists, however only Managers can update recipes. To create a recipe, Managers must select the Recipe List button from the left navigation menu and proceed to click the Add button on the top right-hand corner of the page.

Figure 35. Recipe List - Create Recipe

Recipe Name	Mode Name	Created By	Created On	# of Trial
C Mode Retentate Flow Control	C	Admin	May 5, 2020, 08:24:39	2
CDDC Cassette	C/D/D/C	Admin	Apr 29, 2020, 09:09:12	1
NWp	NWP	Admin	Apr 29, 2020, 09:03:48	0
cfc	CFC	Admin	Apr 29, 2020, 04:38:23	3

Items per page: 25 1 - 13 of 13

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### 5.1.1 Step 1: Recipe Details

User needs to input the following details:

1. Recipe name.
2. Mode.
  - a. Automated filtration modes:
    - C Mode
    - D Mode
    - CD Mode
    - CDC Mode
    - CDDC Mode
    - CDCD Mode
    - CFC Mode
    - CFCDC Mode
  - b. Set-up breakdown Modes:
    - Flushing Mode
    - Cleaning Mode
    - NWP Mode
    - Vacuum Mode
    - Flux excursion Mode:
      - Constant volume
      - Concentration
3. End point values for selected run steps.
4. Notes – Any notes the user may want to add can be input here.
5. Run as safe (Yes/No) - If the user selects 'Yes' (default) then the system does not allow user to edit any settings during a run.

Figure 36: Recipe Creation Step 1.1

Figure 37. Recipe Creation Step 1.2

### 5.1.2 Step 2: Main Pump Set-up

User needs to input the following details:

1. Pump name.
  - KR2i (ml/min)
  - KMPi (L/min)
  - KrosFlo® FS15 (ml/min)
  - KrosFlo® FS500 (L/min)
  
2. Number of heads (1 or 2).

**Note:** For KrosFlo® FS15 and FS500 only 1 head can be selected.



3. Pump direction (clockwise or counter-clockwise).

**Note:** All Set-up breakdown Modes can only run clockwise.

**Note:** For KrosFlo® FS15 and FS500 you cannot choose pump direction.

4. Flow control:
  - Feed
  - Retentate – For retentate flow control, ABV is mandatory on retentate line
5. Tubing size (auto populates based on pump type selected).

**Note:** For KrosFlo® FS15 and FS500 no tubing size is selected.

**Note:** If the KR2i pump is selected, user has the option of selecting HP tubing. HP tubing is only compatible with HP pump, so user needs to make sure they are using both HP pump and HP tubing for KR2i in this case.

6. Flow rate.

**Note:** System will auto validate if the input flow rate is valid based on tubing specifications.

7. Ramp up time (1-15 seconds; default – 3 seconds).

**Figure 38. Recipe Creation Step 2**

### 5.1.3 Step 3: Filter and Permeate Tubing

User needs to input the following details:

1. Filter type.
  - a. Hollow fiber.
    - Catalogue:
      1. Part number (drop down).
    - Generic:
      - Fiber count (auto generated for catalogue part)
      - Fiber ID (auto generated for catalogue part)

- ECS (auto generated for catalogue part)
    - Surface area (auto generated for catalogue part)
  - b. Cassette.
    - Catalogue:
      1. Part number (drop down).
      2. No of cassettes.
    - Generic:
      - Number of channels (auto generated for catalogue part)
      - Width (auto generated for catalogue part)
      - ECS (auto generated for catalogue part)
      - Surface area (auto generated for catalogue part)
- 2. Permeate hold up volume calculation (yes or no).
  - a. Input directly:
    - Permeate tubing hold up volume
  - b. Calculate:
    - Tubing size on permeate line
    - Tubing length.
    - Permeate tubing hold up (auto generated)
- 3. Total permeate hold up volume (auto calculated).

Figure 39. Recipe Creation Step 3.1

Figure 40. Recipe Creation Step 3.2

#### 5.1.4 Step 4: Aux Pumps

User needs to input the following details:

1. Number of aux pumps (0-2).

**Note:** System auto generates options based on mode. For example, if CDDC Mode selected, minimum 2 Aux pumps are required. If CD Mode selected, user can select minimum 1 Aux pump as Diafiltration pump or choose an additional Aux pump as optional Permeate pump.

2. Aux pump 1:
  - a. Type - (KrosFlo® KR1r, KR1 or IP pump).

**Note:** System auto generates compatible aux pump options. For example, if main pump is KR2i, user cannot select IP pump as Aux pump.

- b. Pump function - (Diafiltration, Constant feed or Permeate).

**Note:** System auto generates possible pump functions for selection. For example, if mode selected is CFC, possible options for Aux pump will be only Constant feed (mandatory) and Permeate (optional).

- c. Tubing size - (drop down list of compatible tubing).

**Note:** System auto generates possible list of compatible tubing with Aux pump selected.

- d. Flow rate (user input).

**Note:** System validates entered flow rate based on selected tubing properties.

**Note:** If Permeate pump is selected, system auto generates tubing as permeate tubing selected during step 3 of set-up.

**Note:** User cannot enter flow rate for Diafiltration or Constant feed Modes. Flow rate is dynamically calculated during run for these modes.

- e. Aux pump 2 (same as Aux pump 1).

**Figure 41. Recipe Creation Step 4**

### 5.1.5 Step 5: ABV Set-up

User needs to input the following details:

1. ABV 1:
  - a. ABV type - (KR2i or KMPi).

**Note:** KMPi ABV can be used with all pumps. KR2i ABV can only be used with KR2i and KrosFlo® FS15.

## b. Operating pressure control:

- TMP
- Retentate
- Permeate

**Note:** User cannot select Permeate control if using a permeate Aux pump.

**Note:** User cannot select Permeate control if using only one ABV on Retentate Flow Control Mode.

**Note:** For TMP/Retentate based control, please ensure ABV is on retentate line. For Permeate based control, please ensure ABV is on permeate line.

## c. Mode:

- Auto – If user would like operating pressure control during run, they must select Auto ABV control

**Note:** Only TMP and Retentate pressure control can use Auto ABV mode.

- Manual – If user selects, manual, they do not have operating pressure control available to them. They can manually control % pinching of ABV during run from the run flow diagram.

**Note:** Permeate pressure control can only be used with manual selection.

## d. Valve start position:

- Open (0%)
- Half (50%)
- Closed (100%)
- Custom (user input value)

## e. Operating pressure.

**Note:** Please make sure you check maximum tolerated pressure of your filters before entering this value.

## 2. ABV 2:

- a. Same as above.

**Note:** User may only select ABV 2 if they are using KMPi or KrosFlo® FS500.

## 3. Recirculation pressure control (slow for valve) – Yes/No.

**Note:** Recirc = Slow for valve = main pump slowdown --> When ABV is unable to control pressure, the main pump will slow down gradually until pressure is in control.

4. Recirculation pressure control - % per unit time.
5. Retentate tubing size (drop down selection auto populated based on compatible tubes with main pump and ABV selected).

Figure 42. Recipe Creation Step 5.1

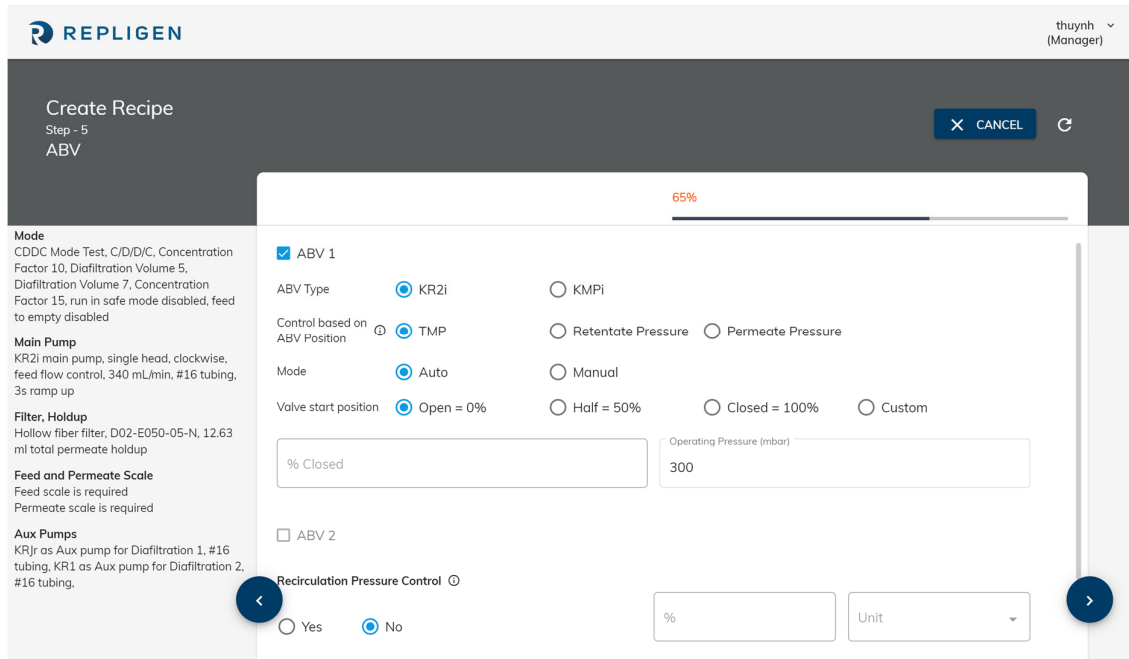
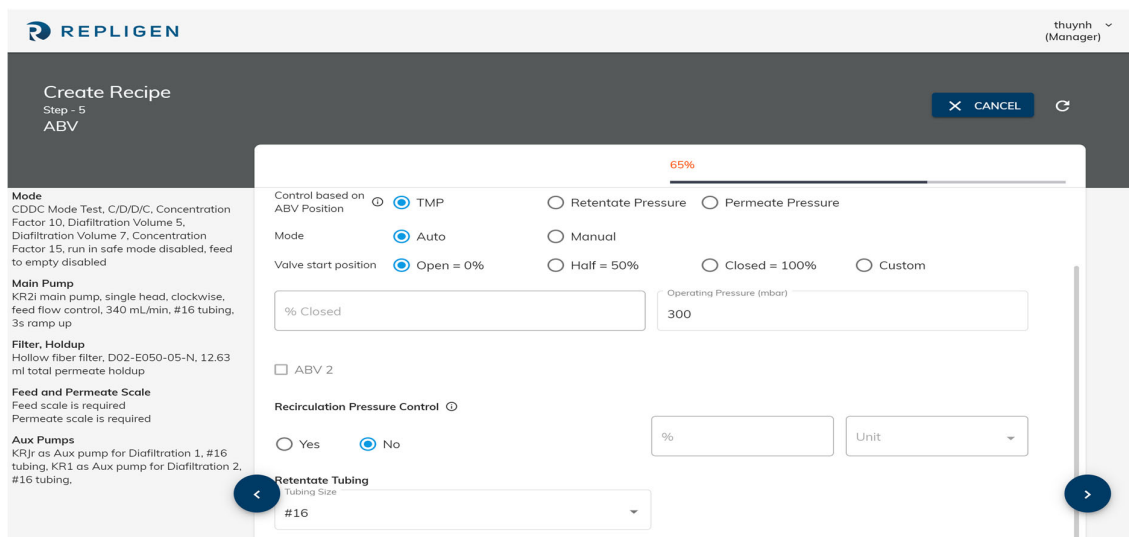


Figure 43. Recipe Creation Step 5.2



5.1.6 Step 6: Konduit

User needs to input the following details:

1. UV/Aux Channel 1 (Yes/No).

**Note:** Inactive if end point is not UV/Aux.

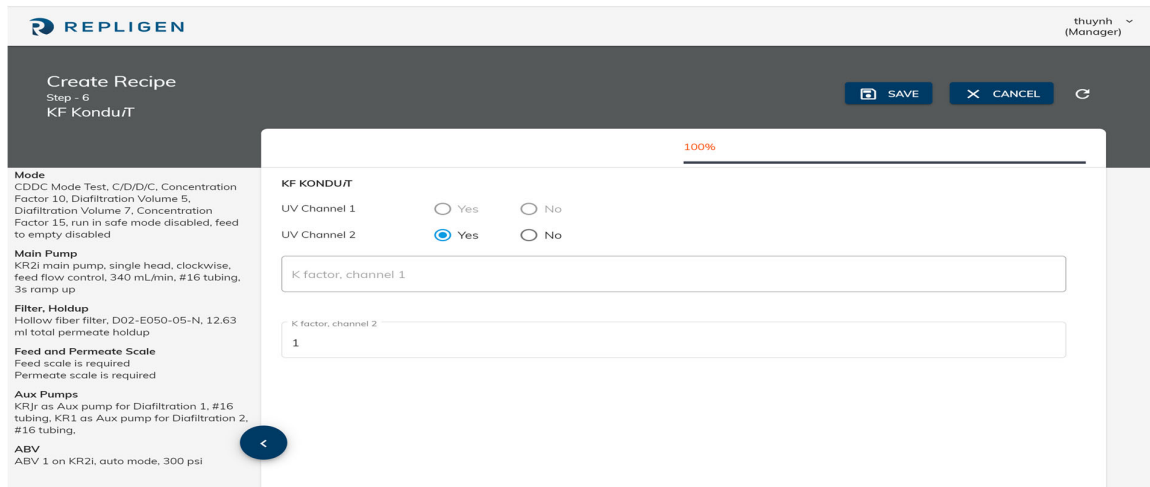
**Note:** Go to system settings page to activate AUX sensor.

2. UV/Aux Channel 2 (Yes/No).
3. K Factor Channel 1 (printed on conductivity cable).

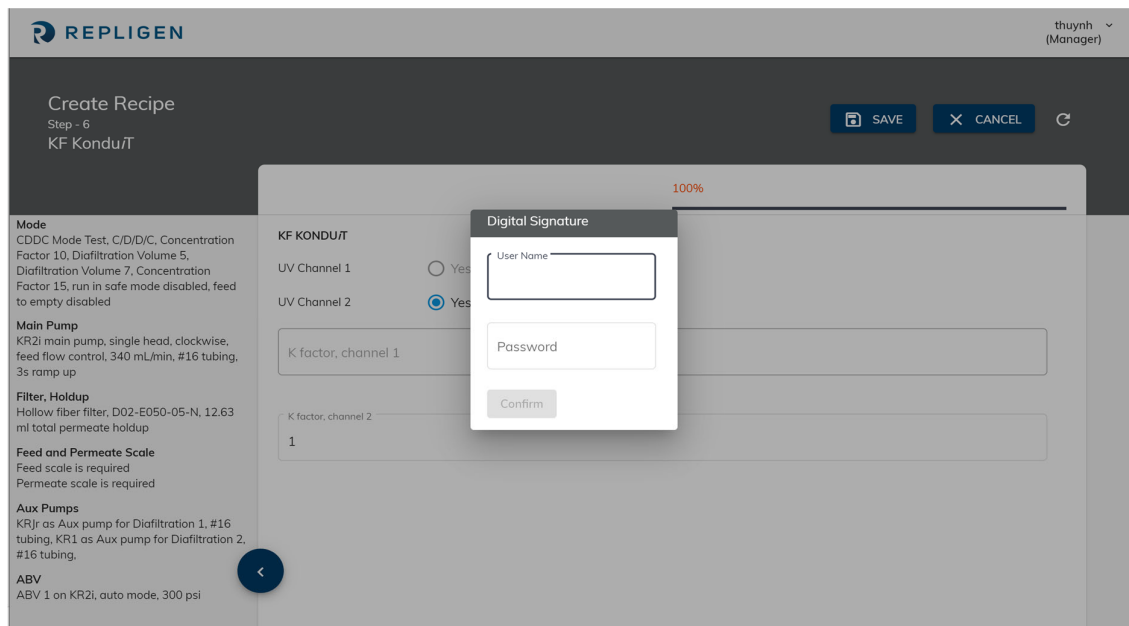
**Note:** Inactive if end point is not conductivity.

4. K Factor Channel 2 (printed on conductivity cable).
5. Save to complete recipe creation. Digital signature will be required for user authentication (manager) for KF Comm 2C.

**Figure 44. Recipe Creation Step 6**



**Figure 45. Recipe Creation Digital Signature Verification**



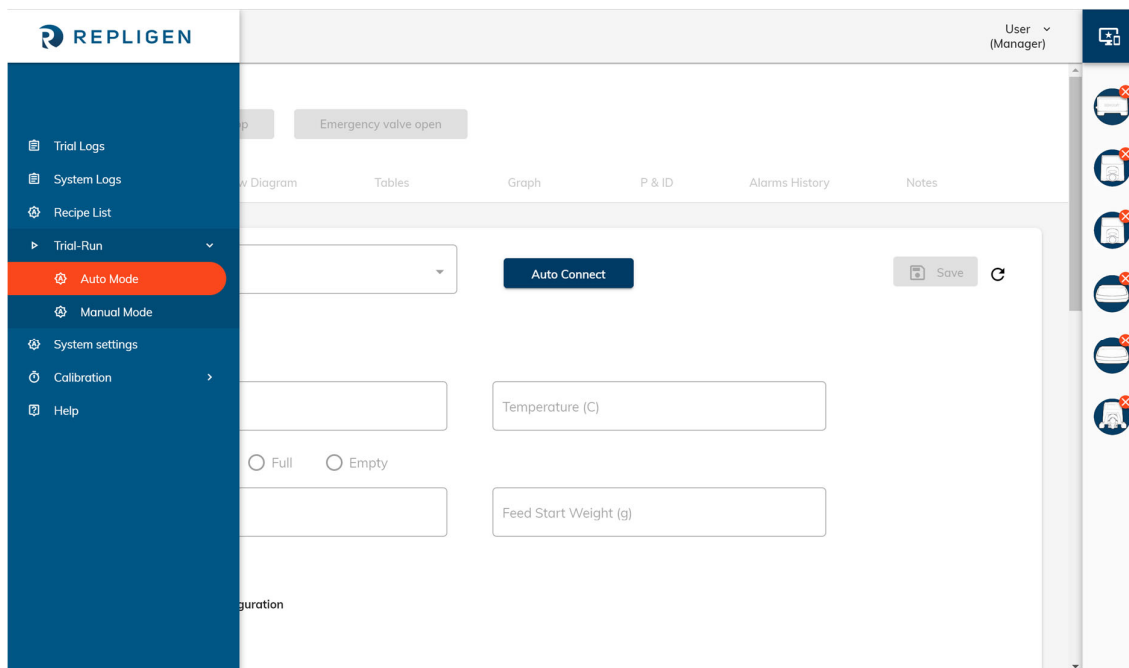
## 5.2 Recipe List

All recipes created by Managers can be viewed in the recipe list tab.

## 5.3 Trial Creation

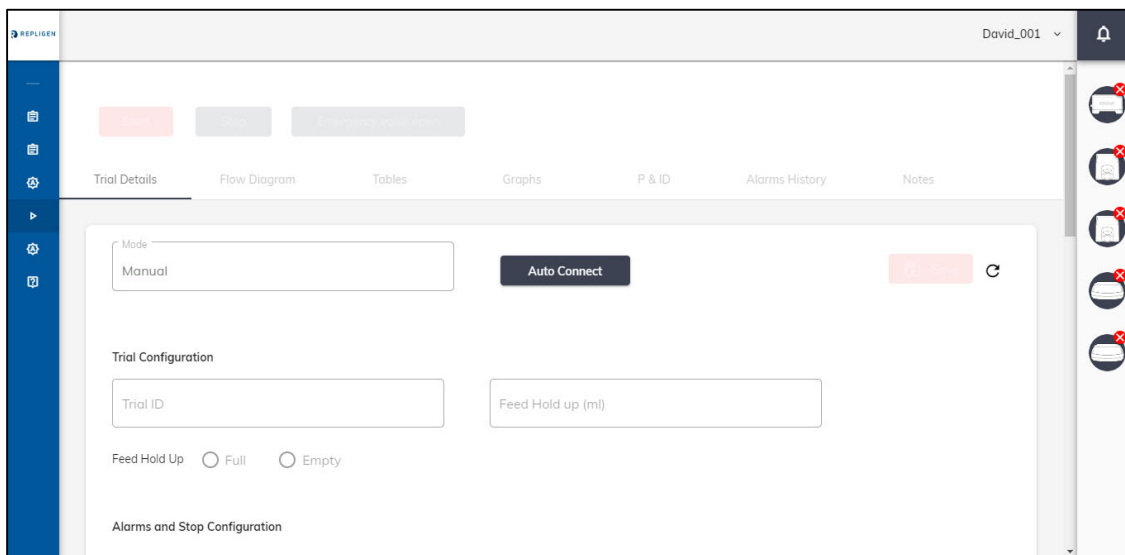
Upon logging in, Managers and Technicians are directed to the trial configuration page. Users first need to select whether they are going to set-up using Auto Mode or Manual Mode. This can be done using the left navigation menu and selecting Auto Mode or Manual Mode under the trial run section.

Figure 46. Trial Creation (Auto or Manual Mode)



### 5.3.1 Manual Mode pre-run configuration

Figure 47. Manual Mode - pre-run configuration



In order to configure Manual Mode, the user must enter the following before starting a run:

1. Trial ID.
2. Feed hold up volume.

**Note:** Empty feed hold up implies there is no sample in the tubing. If there is any fluid in the tubing, please select feed hold up as full and enter feed hold up weight.

3. Feed hold up status (empty/full).



#### 4. Alarms and Stop configuration (Section 5.3.2.1).

Once this is complete, click the save button at the top of the page to proceed to start trial.

Once the trial has started users can perform any of the below options as master run control features:

1. Pause.
2. Stop.
3. Emergency valve open/resume.

In KF Comm 2C pause and stop features require a digital signature verification from a manager or technician. Emergency valve open does not require a digital signature.

### 5.3.2 Auto Mode Pre-run Configuration

Once a user has opened the auto mode pre run configuration page, they must click the 'Auto-Connect' button to connect to the pump before they can configure and start the trial. Once a connection has been established with the COM port, the connected device icons on the right-hand side of the page will have a check mark next to them. A list of icons can be found in Section 8. Once the system has successfully auto connected, user need to select a 'Recipe name' from the drop-down menu to load the recipe details.

**Figure 48. Auto Mode Trial Config. Step 1**

Once a user has selected the recipe name, the system loads a pre-run configuration page where the user needs to input trial information such as:

1. Trial ID.
2. Feed hold up (Empty/Full).

**Note:** Empty feed hold up implies there is no sample in the tubing. If there is any fluid in the tubing, please select feed hold up as full and enter feed hold up weight.

3. Feed hold up weight.

4. Feed start weight (if no feed scale is detected).
5. Alarms/Stop configuration.

### 5.3.2.1 Alarms and Stop Configuration

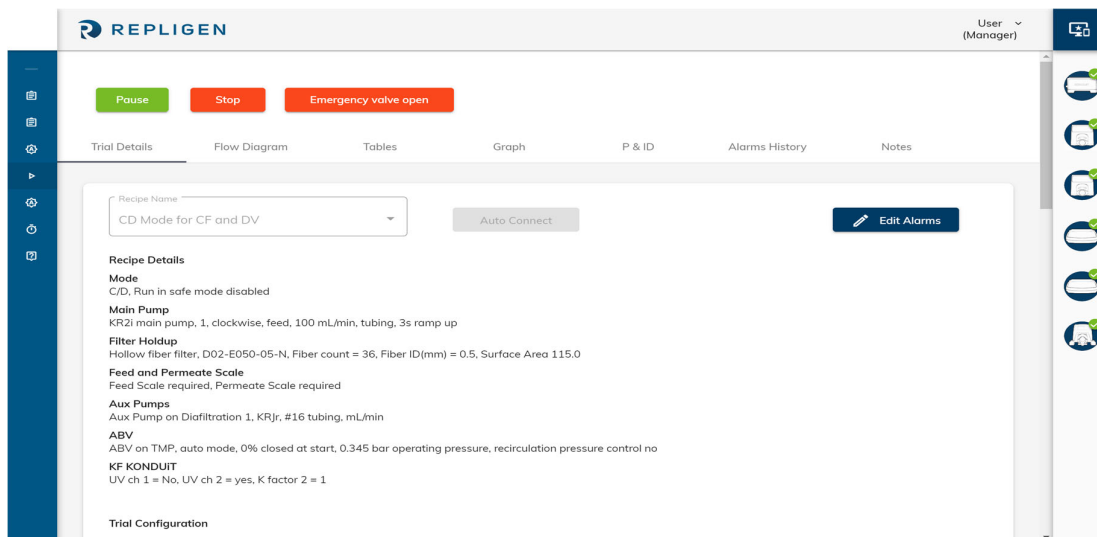
Alarms and stops are non-mandatory fields in KF Comm 2 and 2C. Repligen recommends enabling alarms for 21CFR11 compliance. A user may choose to input terminal values for alarms and stops. Selecting an alarm cause the KrosFlo® TFF System to generate an audible alarm with the alarm text on the screen. A stop value is an extreme case that causes the entire system to stop running. By default, all these fields are blank, and the user needs to input values with an understanding of the different components being used in their system. The table of alarms is below (Table 8).

**Table 8. Alarms and Stops**

Parameter	Alarms and stops
Feed weight Permeate weight Feed pressure Permeate pressure	<ul style="list-style-type: none"> <li>• Low alarm</li> <li>• High alarm</li> <li>• Low stop</li> <li>• High stop</li> </ul>
Aux/UV	<ul style="list-style-type: none"> <li>• High Ch 1 alarm</li> <li>• High Ch 2 alarm</li> <li>• High Ch 1 stop</li> <li>• High Ch 2 stop</li> </ul>

Once this is complete, click the save button at the top of the page to proceed to start trial (Figure 48. Start trial).

**Figure 49. Start Trial**



Once the trial has started users can perform any of the below options as master run control features:

1. Pause.
2. Stop.
3. Emergency valve open/resume.

In KF Comm 2C pause and stop features require a digital signature verification from a manager or technician. Emergency valve open does not require a digital signature.

At any point during the trial, a user can pause the trial and click the edit button to edit/change endpoints or alarms.

*Note: Only endpoints that have not yet been achieved can be modified.*

At any point during the trial, a user can close the software using the 'Close KF Comm' button from the dropdown menu on the top right corner of the page. If KF Comm is closed during a trial or a user logs out during a trial without ending the trial, the trial will continue, and data will keep getting logged on the backend. When a user logs back on, they will be able to see all datapoints that were logged while the software was closed/user was logged out.

## 5.4 Trial Control

Once the trial has started, the user can select from 7 different pages to view trial information.

1. **Trial details page:** Defined in section above.
2. **Flow diagram:** Default view page for trial. Only page to interface with device system parameters.
3. **Tables:** Allows user to view live and historical data in tables.
4. **Graphs:** Allows user to view live and historical data in graphs.
5. **P and ID:** Allows user to view live data in P and ID .
6. **Alarms history:** Keeps log of all alarms recorded from start of run.
7. **Notes:** Allows users to mark events and take notes during a run.

### 5.4.1 Flow Diagram

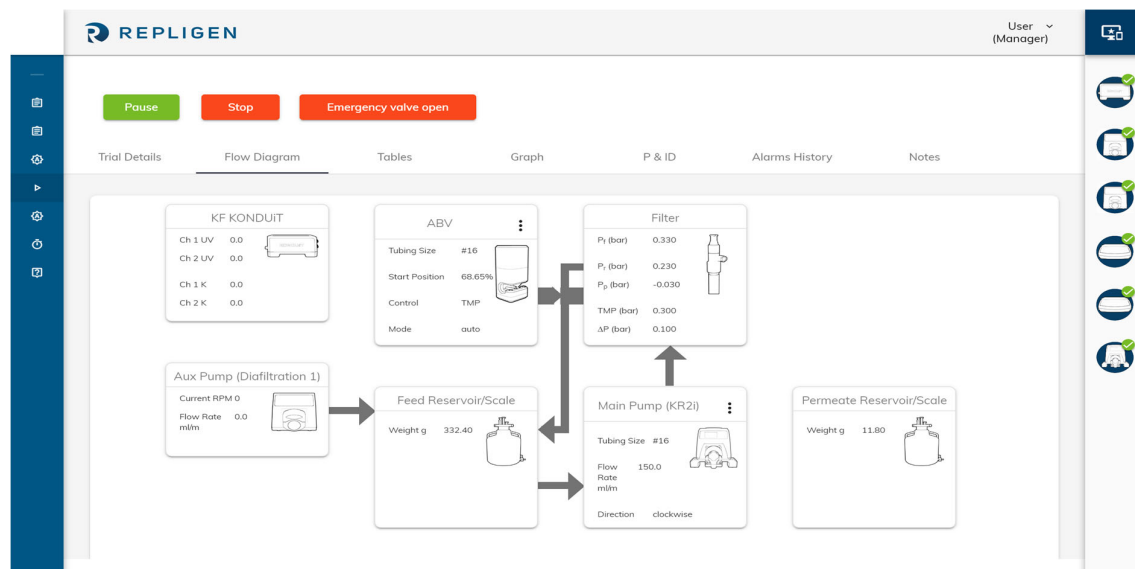
The flow diagram is the primary control page for interacting with the device. Once the run has started the user has a display of the experimental set-up in a card form. Each device is displayed in a card. By clicking on these cards, a user can view more detailed information about that specific device or auxiliary component. In auto mode, certain parameters can also be edited by clicking on the card once the system is paused. A list of available functions that can be edited during a run in both Auto and Manual modes is given below.

#### Manual Mode:

1. Main pump:
  - Direction
  - RPM
  - Tubing size
  - Flow rate (requires tubing size)
2. Aux pump(s):
  - Pump type (KRJr/KR1/IP)
  - RPM
  - Tubing size
  - Flow rate (requires tubing size)
3. ABVs:
  - ABV Type (KR2i/KMPi)
  - Mode (Auto/Manual)
  - Control (TMP/Retentate)

- Operating pressure
  - Tubing size
  - Position
4. Scales:
    - Tare
- Auto Modes:
1. Main pump:
    - Direction
    - Flow rate
  2. Aux pump(s):
    - Flow rate
  3. ABV:
    - Position (Manual)
    - Operating pressure (Auto)
  4. Feed scale
    - Tare

Figure 50: Card Layout



To edit a card during a run, click pause and proceed to click on the card. Once you click on the card, it will flip over and allow you to update information. For example, if you wanted to change the flow rate of the main pump in Figure 50, you would click on the card and it would flip over (as seen in Figure 51). Once you have made the change, click save and resume the run.

Figure 51. Edit Card

Main Pump ×

Main Pump Direction

CW     CCW

flow rate

---

SAVE

### 5.4.2 Tables

At any time during a run, users can navigate to the Tables page to view live and historical data of the current run. The default view on the tables page can be seen in

Figure 52. However, a user can select more fields to view by clicking the add remove column button. The system gives users multiple options of fields they would like to view in their table list by selecting this option (Figure 53).

Figure 52. Table List (Default)

**REPLIGEN**
User (Manager)

Pause
Stop
Emergency valve open

Add/Remove Column

Timestamp	Pump rpm (rpm)	P feed (bar)	P retentate (bar)	P permeate (bar)	TMP (bar)	M feed (g)	M permeate (g)
Apr 7, 2020, 21:31:31	125.0	0.070	0.000	-0.030	0.060	341.20	3.10
Apr 7, 2020, 21:31:21	125.0	0.070	0.000	-0.030	0.060	341.50	2.80
Apr 7, 2020, 21:31:11	125.0	0.070	0.000	-0.030	0.060	341.80	2.50
Apr 7, 2020, 21:31:00	125.0	0.070	0.000	-0.030	0.060	342.10	2.30
Apr 7, 2020, 21:30:50	125.0	0.070	-0.000	-0.030	0.060	342.40	1.90
Apr 7, 2020, 21:30:39	125.0	0.060	-0.010	-0.030	0.050	342.60	1.70
Apr 7, 2020, 21:30:29	125.0	0.060	-0.010	-0.030	0.050	342.90	1.50
Apr 7, 2020, 21:30:18	125.0	0.060	-0.010	-0.030	0.050	343.10	1.20
Apr 7, 2020, 21:30:08	125.0	0.060	-0.010	-0.030	0.050	343.40	1.00
Apr 7, 2020, 21:29:57	125.0	0.060	-0.010	-0.030	0.060	343.60	0.70
Apr 7, 2020, 21:29:47	125.0	0.070	-0.000	-0.030	0.060	343.90	0.50

**Figure 53. Table List (Add/Remove Columns)**

---

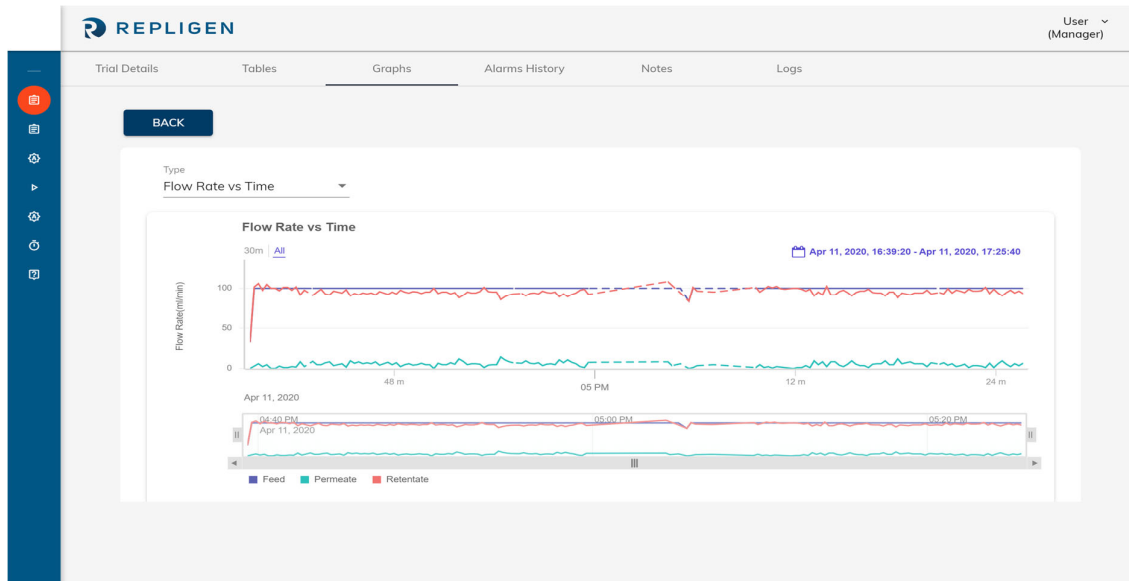
- Temp 1
- Temp 2
- Conductivity 1
- Conductivity 2
- VT
- Aux Pump 1
- Aux Pump 2
- ABV 1
- ABV 2
- Diaf Vol 2
- Total permeate weight
- Shear Rate
- Status
- DP
- Q Permeate
- Q Retentate
- Flux
- UV Ch 1
- UV Ch 2

### 5.4.3 Graphs

Users can select the graphs option to see visual representations of their experiment. Both live and historical graph views are available on the system. Users can select from the following graph options:

1. Pressure and concentration factor vs time.
2. Flow rate vs time.
3. Pressures (feed, retentate, permeate, TMP,  $\Delta P$ ) vs time.
4. Flux vs time.
5. Flux vs TMP (for Flux C, Flux CV and NWP Mode).
6. DV & Conductivity vs time.
7. Pressures (feed, retentate, permeate, TMP,  $\Delta P$ ) and Concentration Factor vs VT (available in Trial Logs - Historical data only).
8. Flux vs Concentration factor.
9. Konduit Ch 1 and Temperature vs time.
10. Konduit Ch 2 and Temperature vs time.

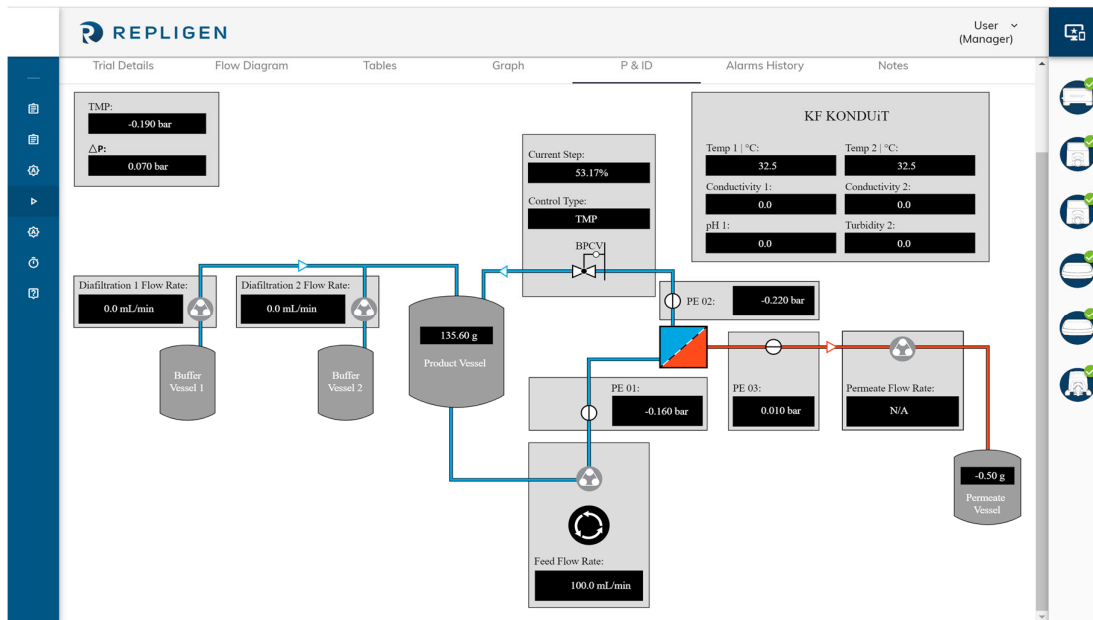
Figure 54. Graphs



#### 5.4.4 P and ID

Users can choose to view experimental parameters in real time using P and ID can use this tab to monitor their trial.

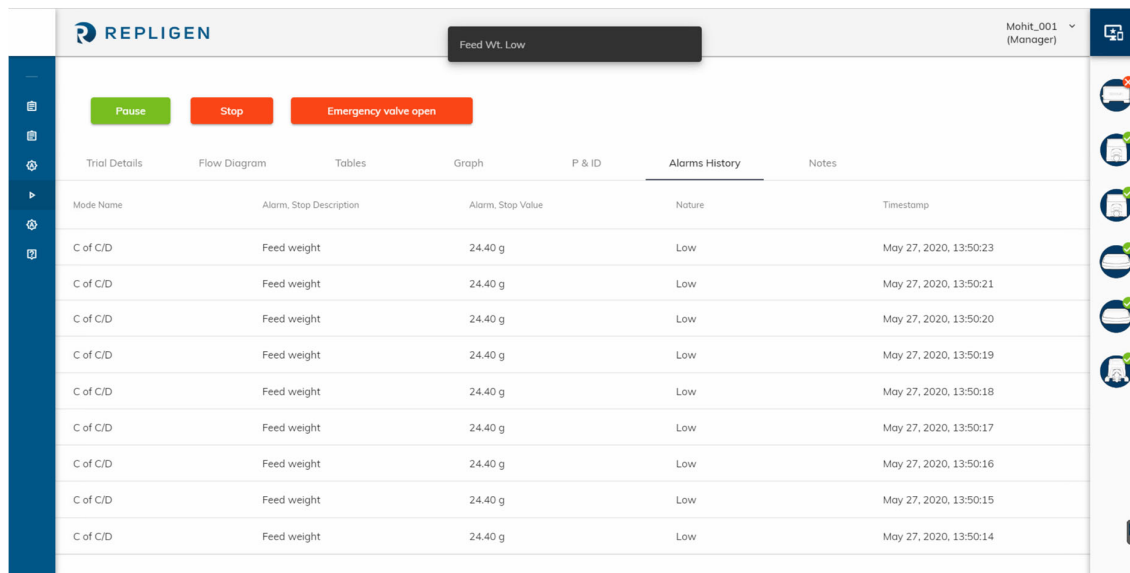
Figure 55. P and ID



### 5.4.5 Alarm History

Each time an alarm is detected during a run, a notification pops up at the top of the screen highlighting the type of alarm. The main pump will also make an audible alarm sound when alarms are detected. To view a detailed log of alarm history during the run, users can select the alarm history tab. Each alarm has a timestamp and the step of the run in which the alarm was detected.

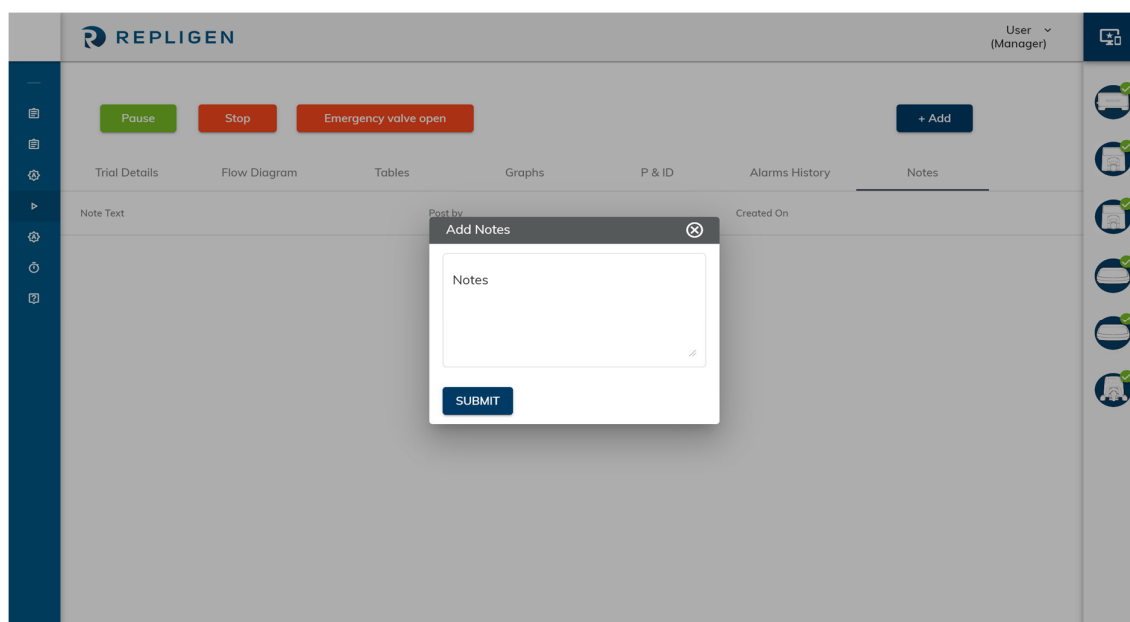
Figure 56. Alarm History



### 5.4.6 Notes

Managers and Technicians can navigate to this section to take notes during the run. Each note is time stamped and will be available for users to view in the trial logs.

Figure 57. Notes





### 5.4.7 Screen timeout

At any time during a run if the system detects inactivity for a period of 15 minutes (KF Comm 2C) and 60 minutes (KF Comm 2), this is considered as a screen time out event. In KF Comm 2C, this event requires authorized users (Manager/Technician) to enter their digital signature to access any trial controls. However, during this time, the device and trial keeps running unaffected in the background.

### 5.4.8 End of a Run/Trial logs

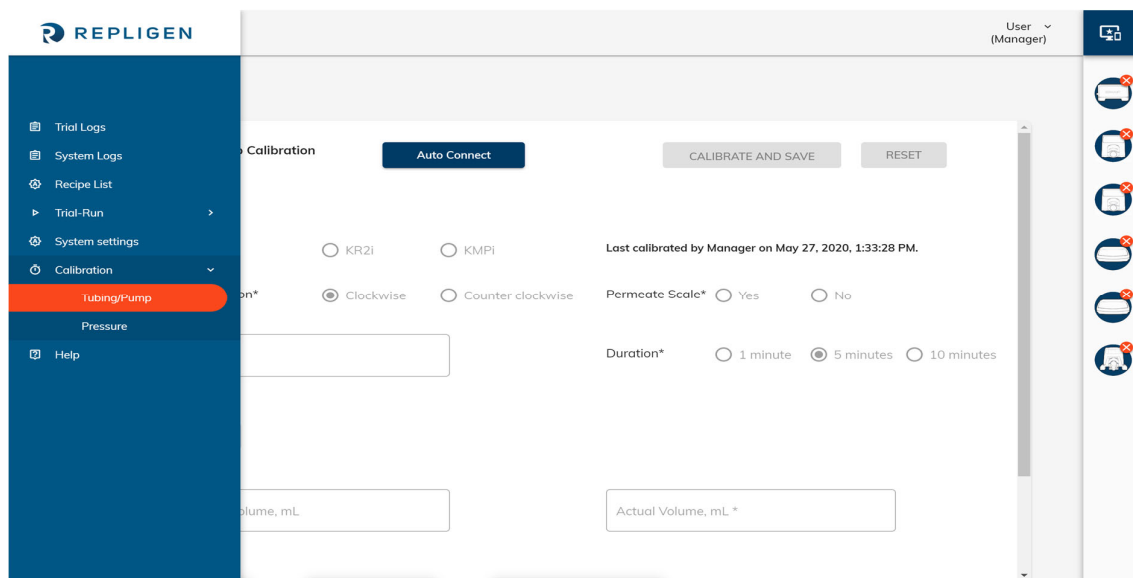
At the end of a run (either end points are reached, or user clicks “**Stop**”) the trial information is stored in the trial logs page. All historical data recorded during each trial is available in the trial logs. You can view trial logs by clicking on the button in the left navigation menu (**Figure 46**. Trial Creation (Auto or Manual Mode)). Trial logs can be downloaded in both excel and pdf formats. For excel download, user can select the interval of data to be downloaded, and in pdf download the default value of interval is set at 1 minute per data point.

*Note: If the PC goes into sleep mode, the system will move into recirculation mode where all the auxiliary devices will stop, and the main pump will continue running at its current flowrate. Once the system is out of sleep mode, the trial will resume as normal. It is recommended, that the system administrator removes sleep mode option from the PC settings to avoid this event from occurring.*

## 6. Calibration

The calibration menu can be accessed from the side navigation. Calibration cannot be performed while a trial is in progress.

**Figure 58. Calibration: Menu**



### 6.1 Tubing/Pump Calibration

#### 6.1.1 Connect Device

The main pump must be connected before starting calibration. Click on “**Auto Connect**” to proceed. Last calibration details – user name and date/time – are displayed at this time.

Figure 59. Calibration: Auto Connect

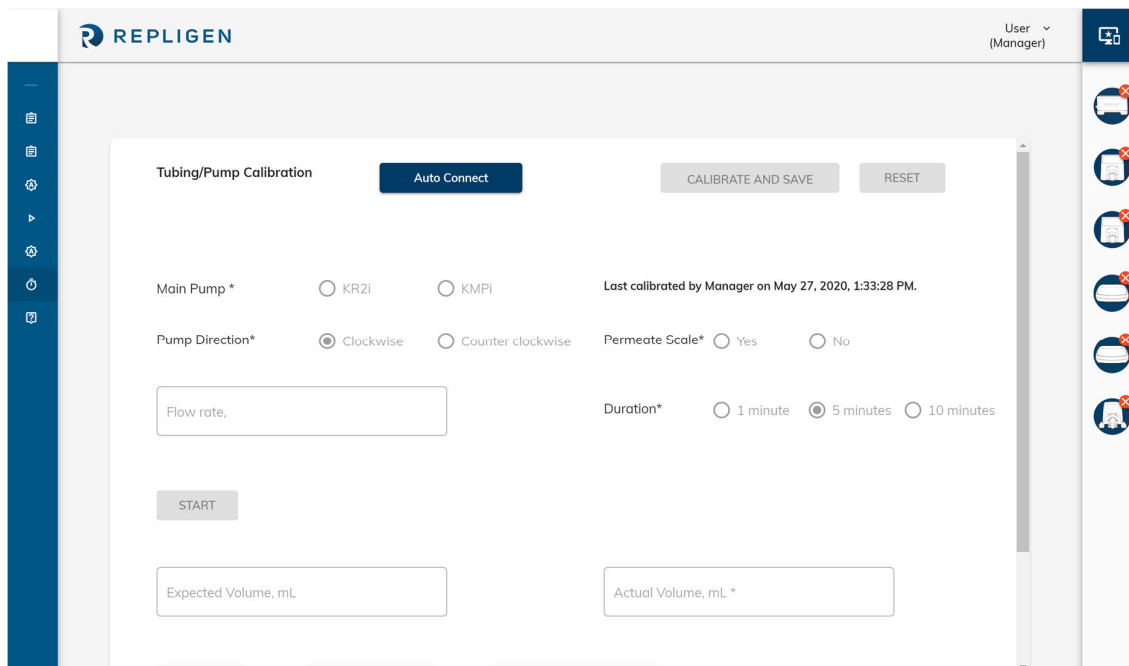
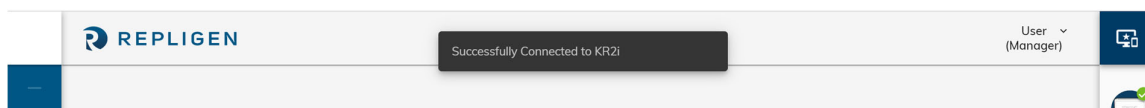


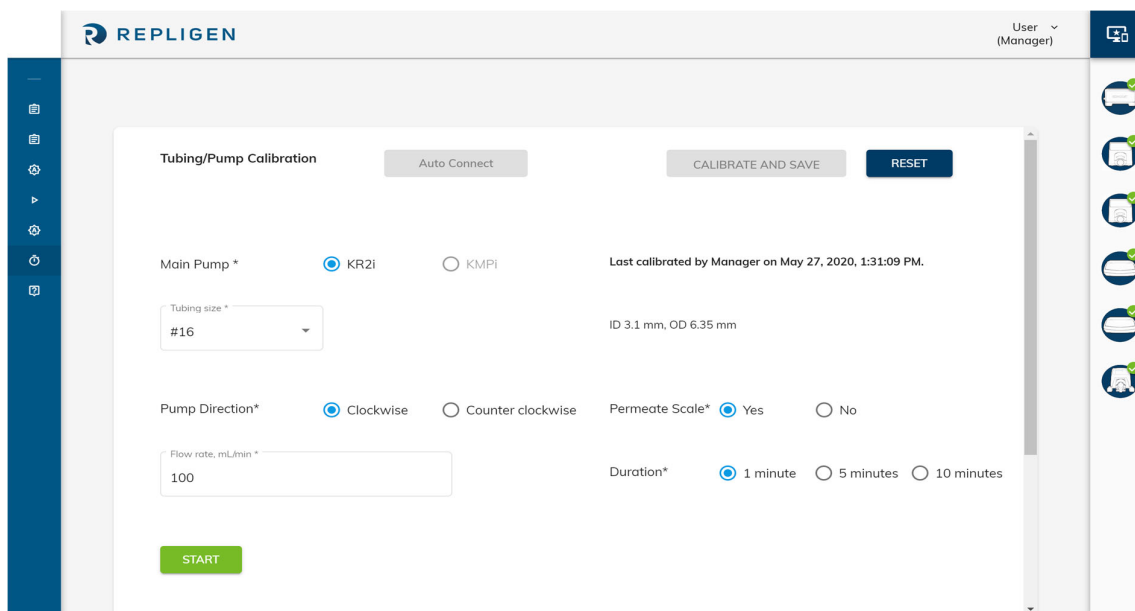
Figure 60. Auto Connect Confirmation Message



### 6.1.2 Configure Calibration

Once the main pump is detected, tubing size, pump direction, availability of Permeate scale, flow rate and duration must be entered. The expected volume is automatically calculated.

Figure 61. Configure Tubing/ Pump Calibration

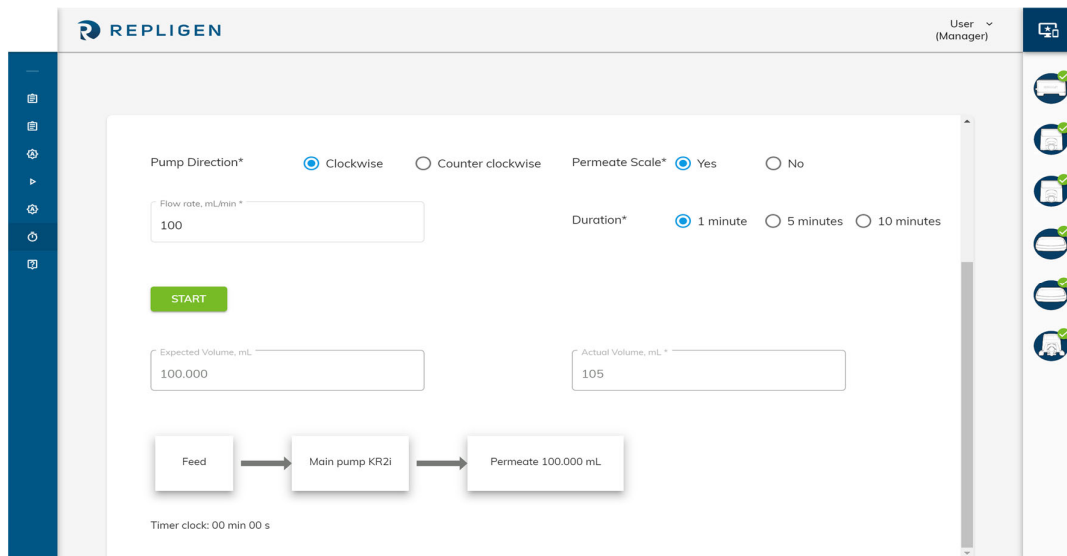


### 6.1.3 Perform Calibration

Once calibration starts, a countdown timer is displayed at the bottom of the screen. Once the set time has elapsed, the timer resets to zero, and the actual volume as measured by the permeate scale is displayed.

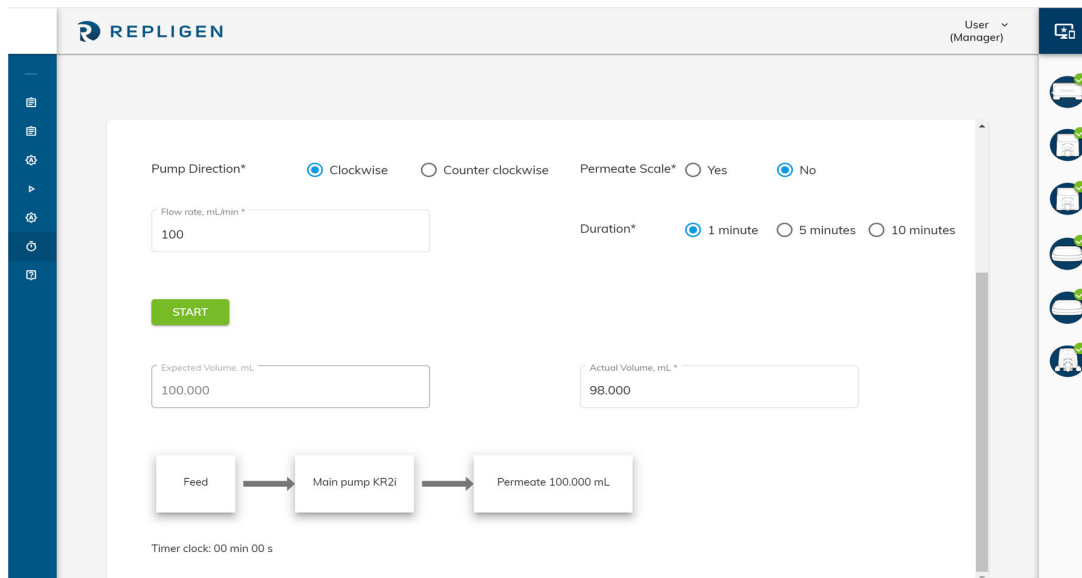
**The reading on the Permeate scale will be higher than the data displayed on this screen.** This is because ~1 ml of permeate flows through the system before calibration measurements begin.

**Figure 62. Calibration With Permeate Scale**



If the Permeate scale is not available, then the user will have the option to manually enter the actual permeate volume.

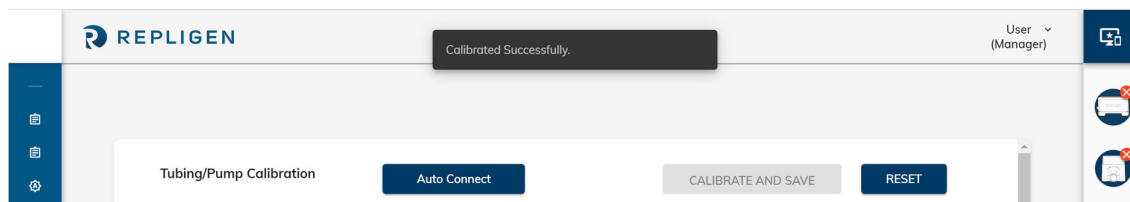
**Figure 63. Calibration Without Permeate Scale**



### 6.1.4 Calibration Complete

Once calibration has been saved, the system displays a confirmation message. The user can click on “Reset” to re-calibrate the system.

Figure 64. Confirmation and Reset

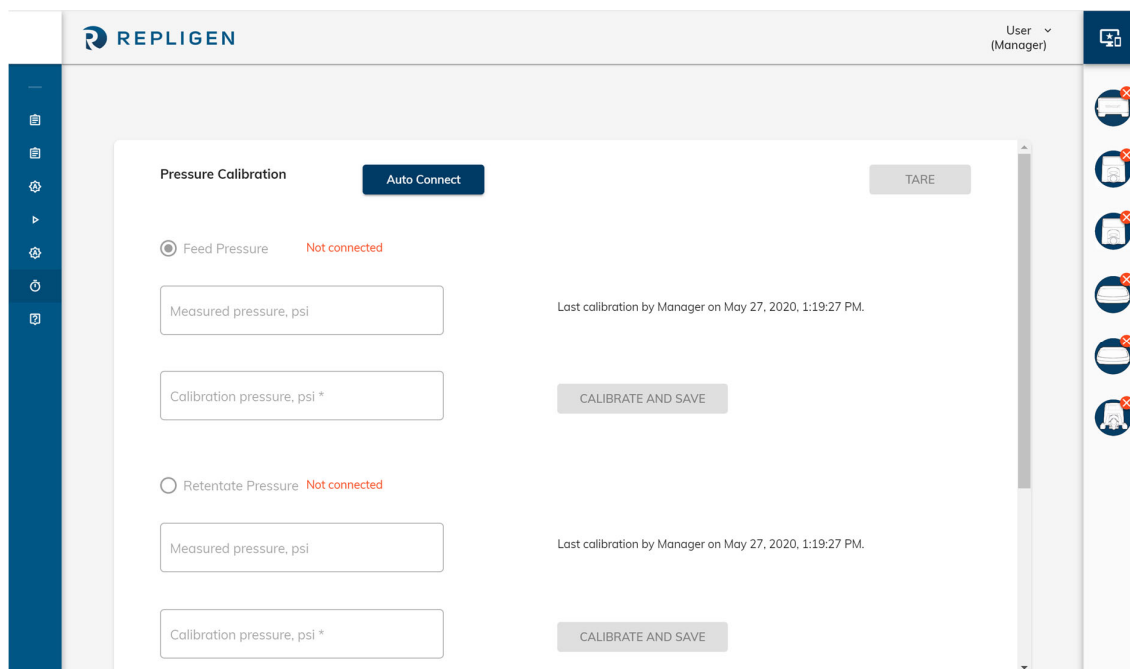


## 6.2 Pressure Calibration

### 6.2.1 Connect Device

Pressure sensors – feed, retentate and permeate – must be connected before starting their calibration. Click on “Auto Connect” to proceed. Last calibration details – user name and date/time – are displayed at this time.

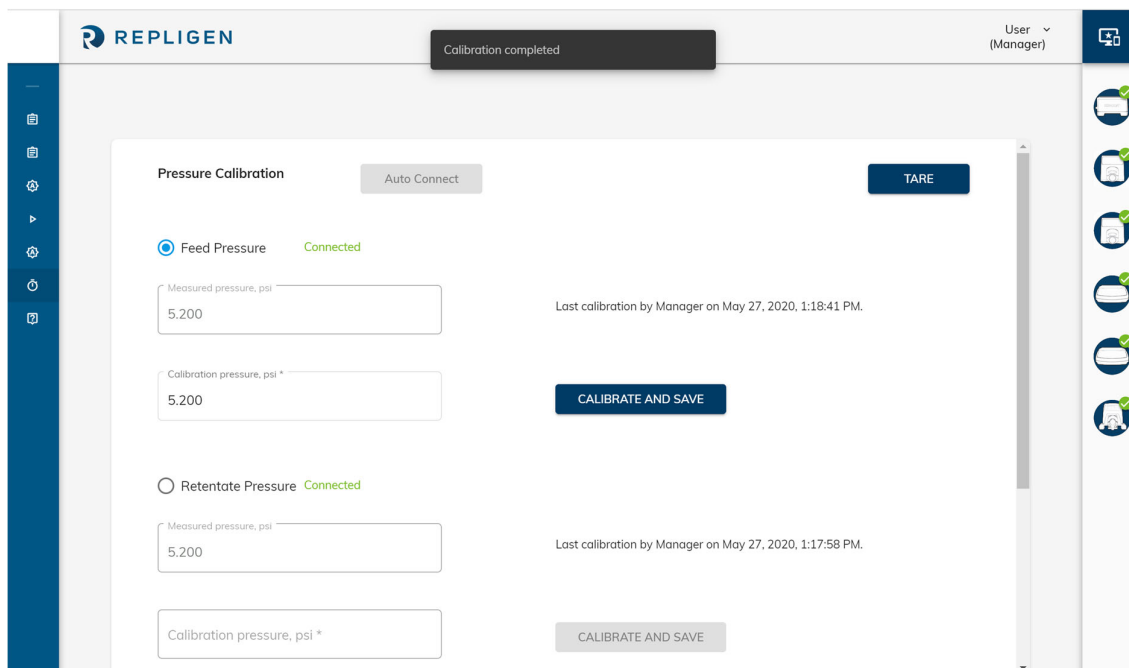
Figure 65. Auto Connect Devices



### 6.2.2 Calibrate

The user types in the actual value of the pressure and clicks on “Calibrate and Save”. This has to be repeated for all connected pressure sensors.

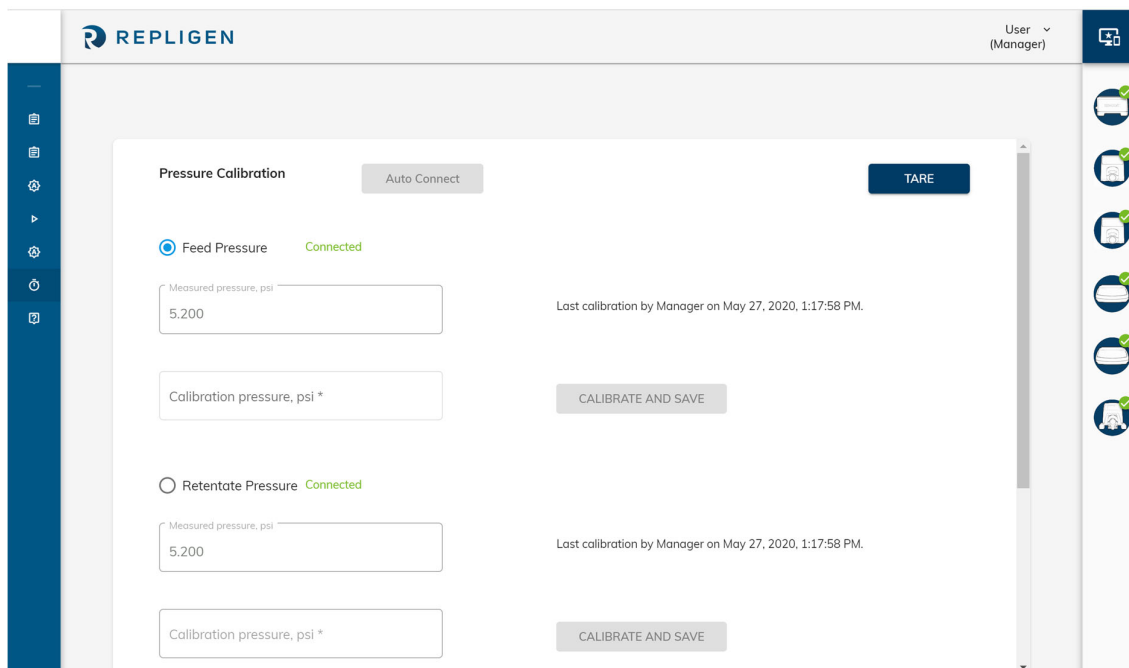
Figure 66. Calibrate and Save



### 6.2.3 Tare

The user can tare pressure sensors from the same screen. Once tared, all measured pressure values – feed, retentate and permeate – will reset to zero.

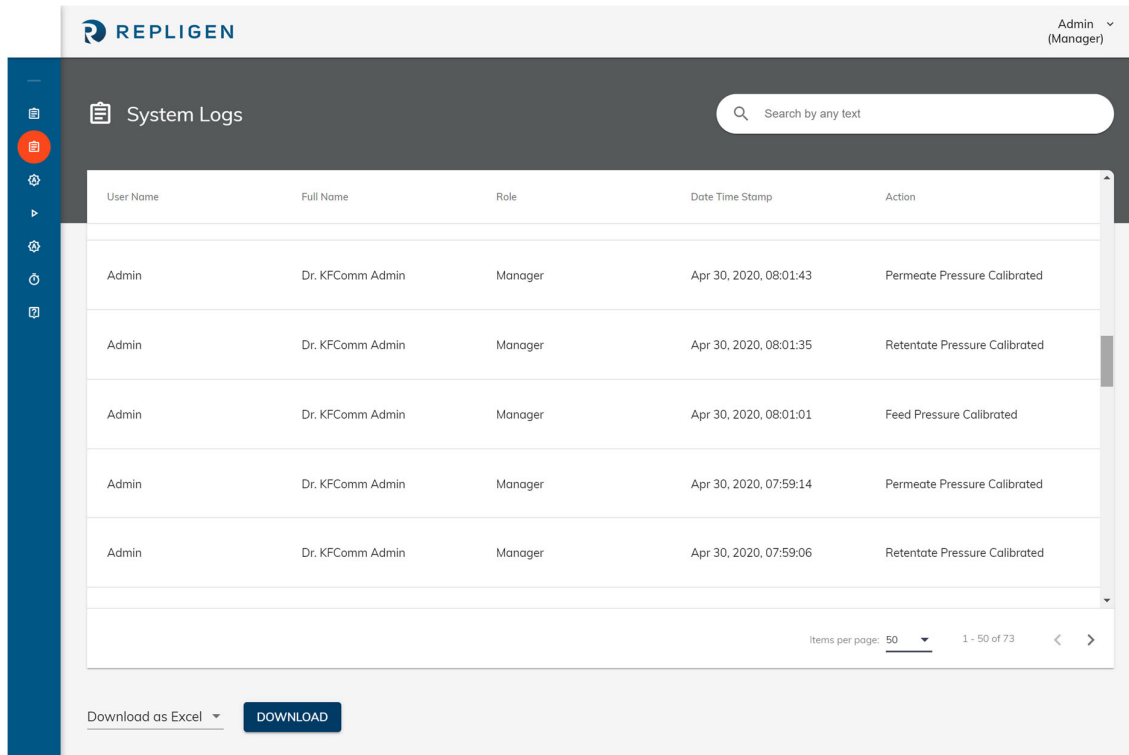
Figure 67. Tare Pressure



### 6.3 View Calibration Records

All calibration records are saved to system logs. Use the search field to retrieve a relevant set of results.

Figure 68. View Calibration Records



## 7. Mapping of user roles to features

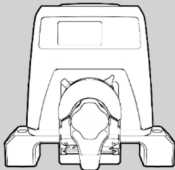

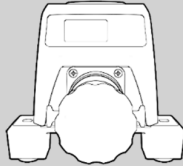
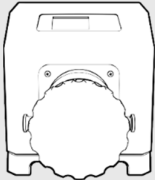
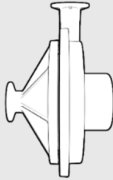




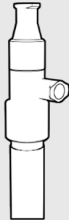
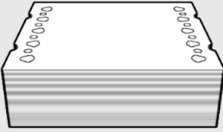
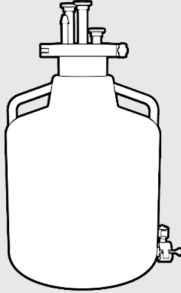
Table 9. Mapping of user roles to features

Actions	All	Super Admin	Admin	Auditor	Manager	Technician
Login	Yes	N/A	N/A	N/A	N/A	N/A
User management	N/A	Yes	Yes	View	No	No
My profile/Change password	Yes	N/A	N/A	N/A	N/A	N/A
Software updates	N/A	Yes	No	View	No	No
System settings	N/A	No	No	View	Yes	View
Crate recipe	N/A	No	No	No	Yes	No
Edit recipe	N/A	No	No	No	Yes	No
Calibration	N/A	No	No	No	Yes	Yes
Trial run -> Trial details	N/A	No	No	No	Yes	Yes
Trial run -> Flow diagram	N/A	No	No	No	Yes	Yes
Trial run -> P and ID	N/A	No	No	No	Yes	Yes
Trial run -> Table	N/A	No	No	No	Yes	Yes
Trial run -> Alarms	N/A	No	No	No	Yes	Yes
Trial run -> Graphs	N/A	No	No	No	Yes	Yes
Trial run -> Notes	N/A	No	No	No	Yes	Yes
Recipe list	N/A	No	No	View	Yes	View
Recipe list -> Recipe details	N/A	No	No	View	Yes	View
Trial list	N/A	View	View	View	View	View
Trial list -> Trial details	N/A	View	View	View	View	View
Trial list -> Trial table	N/A	No	No	View	View	View
Trial list -> Graphs	N/A	No	No	View	View	View
Trial list -> Alarms	N/A	No	No	View	View	View
Trial list -> Notes	N/A	No	No	View	Yes	Yes
Trial list -> Logs	N/A	View	No	View	View	View
Access logs (user management)	N/A	View	No	View	No	No

Actions	All	Super Admin	Admin	Auditor	Manager	Technician
Global settings	N/A	Yes	No	View	No	No

## 8. KF Comm 2 Software system icons

Table 10. KF Comm 2 Software: System icons

		
KrosFlo® KR2i Pump	KrosFlo® KMPi Pump	KrosFlo® FS15
		
KrosFlo® FS500	Magnetic levitating pump	KrosFlo® KR Jr Auxiliary Pump
		
Automatic Backpressure Valve (ABV)	Weight scales	Konduit Add-on Module
		
Spectrum® Hollow Fiber Filters	TangenX™ Flat Sheet Cassettes	Reservoir

## 9. Index

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Download software.....	9	System icons .....	69
License details.....	7, 9	System settings.....	13, 21, 53