

KYTOPEN

The Future in Cell Therapy Discovery & Manufacturing



Flowfect Discover™

Instructions for Use

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1. Important User Information

The information in this Instructions for Use pertain to Flowfect Discover™. Instructions for Use should be easily accessible to users of the Flowfect Discover™.

Flowfect® is a registered trademark of the Kytopen Corporation.



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1.1 Support

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2. Introduction

Flowfect® technology offers a scalable, non-viral solution to deliver genetic payloads to cells in order to augment their functionality. The technology also enables continuous flow genetic manipulation of cells in a platform that can be easily automated and can be used to process both small and large sample volumes.

Kytopen's Flowfect® technology is a proprietary electromechanical technology used for transfection through a combination of the Flowfect Discover™ equipment, Flowfect Buffer™, and Flowfect Tips™ consumable.

3. Intended Use Statement

Flowfect Discover™ is for Research Use Only (RUO).

Flowfect Discover™ is intended for low volume, high throughput transfection tasks in a research laboratory. The system harnesses electro-chemo-mechanical phenomena to permeate the membranes of cells in a small sample (50-100 µL) and allow translocation of extracellular materials into the cell. Cell engineering using plasmid DNA, ribonucleic proteins (RNPs), and messenger RNA are examples of relevant activities intended to be performed with this system. Additionally, the system can perform liquid handling tasks that may improve user experience or the quality of the cell engineering effort before and after transfection. The device requires the use of Flowfect Tips™ and Flowfect Buffer™ for proper operation.

Due to the nature of the configuration of Flowfect Discover™ and the samples, the device shall not be used outside of a BSL-2 space.

Flowfect Discover™ is not intended for diagnosis, treatment, or prevention of disease.

For more information on our transformative technology please visit our website at www.kytopen.com.

4. Regulatory Information

Flowfect Discover™ is designed to conform with the following Standards and Regulations:

- Electrical Safety compliance as required for Field Evaluation performed against the following:
 - UL 61010-1:2010 3rd ed. 07/19/2019 - Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirements
 - National Electrical Code 2020 (US)
- Electromagnetic Compatibility and Interference
 - EMC Directive 2014/30/EU
 - 47 CFR Part 15 Subpart B
 - ICES-003

5. Supporting Information

5.1 Reference Material

Reference	Location
Tecan Cavro® Magni Flex Operating Manual	<ul style="list-style-type: none"> Desktop of Flowfect Discover™ touchscreen (folder Instructions for Use) Kytopen's website: https://www.kytopen.com/flowfect-connect

5.2 Glossary of terms

Flowfect Discover™	All reusable and consumable hardware and software for the discovery and optimization scale platform.
Flowfect Discover™ control unit	Subsystem containing the waveform generation and controls electronics. Also referred to in this document as control unit.
Electric Discharge Manifold (EDM)	Subsystem housed by the Liquid Handler used to establish an electrical connection between Flowfect Tips™ and control unit.
Flow cell	Proprietary Kytopen technology consisting of electrodes and a region for transfection.
Flowfect Buffer™	Proprietary Kytopen transfection solution.
Flowfect Tips™	Kytopen's proprietary single-use tips designed for use with the Flowfect Discover™.
Graphical User Interface (GUI)	Component enabling the user to access designated system programs and execute workflows.
Profile	Run-time file used by the software to define parameters used by Flowfect Discover™.
Software	Controls operation of the Flowfect Discover™; manages routines, configuration files, and log files.
Plate configuration	A file defining a runnable experiment with the Flowfect Discover™. Consists of plate mapping and experimental information.
Liquid handler	Subsystem containing the liquid handling hardware.

6. Technical Specifications

6.1 Flowfect Discover™ Control Unit Specifications

Weight	50lb/23kg
Dimensions	14 in (W), 25 in (D), 24 in (H) 35.5 cm (W), 63.5 cm (D) 61 cm (H)

6.2 Flowfect Discover™ Electric Discharge Manifold (EDM) Specifications

Weight	4.4lb/2kg
Dimensions	3.75 in (W), 10 in (D), 5.71 in (H) 9.5 cm (W), 25.4 cm (D) 14.5 cm (H)

6.3 Flowfect Discover™ Liquid Handler Specifications

Weight	273lb/124kg
Dimensions	36 in (W), 31 in (D), 50 in (H) 78 cm (W), 91 cm (D) 126 cm (H)

For liquid handler specifications consult the Tecan Operating Manual (Ref. Section 5.1).

6.4 Software Specifications

Flowfect Discover™ is compatible with Flowfect Discover™ software version 1.2 or later. Kytopen recommends using the Google Chrome browser.

It is strongly recommended to use the latest software version. Contact Kytopen Support (Section 1.1) for more information.

6.5 Equipment Ratings

Power Supply

Parameter	Value
Line voltage (single phase)	120VAC
Frequency	60Hz
Liquid Handler Fuse	F16AH500V
Control Unit Fuses	Slow blow 1.5A, 250V, 5X20mm Slow blow 2A, 250V, 5X20mm

Operating Conditions

Flowfect Discover™ has been tested for use under the following environmental conditions:

- For indoor use only.
- Operating Altitude: 0 – 2000m
- Operating Temperature: 20 – 25 °C
- Operating Humidity: 40 – 60% relative humidity (non-condensing)
- Mains supply voltage fluctuation up to $\pm 10\%$ of the nominal voltage
- Overvoltage category: II
- Pollution Degree: 2

Input and Output Connections

- USB-C (1)
- USB-A (2)
- CAT6 Ethernet (1)

7. Flowfect Discover™ Overview

7.1 Components

Flowfect Discover™ includes reusable and single use components. Diagrams of Flowfect Discover™ with individual components are shown in Figure 1, Figure 2, and Figure 3 below.

Reusable Components:

- Control unit
- Liquid handler
- Touch screen
- Power cord (x2; one each for control unit and liquid handler)
- Electric Discharge Manifold (EDM)
- EDM high power cable
- EDM low power cable
- EDM grounding cable (do **not** disconnect this cable)
- Ethernet cable to connect liquid handler and control unit

Single Use Components and SKUs required. Contact Kytopen for ordering.

- Flowfect Buffer™ (KYT-3005, KYT-3006, KYT-3007)
- Flowfect Tips™ (KYT-3002)

NOTE: Flowfect Tips™ are designed for single use; repeated use is not supported.

NOTE: Flowfect Discover™ configuration is specific to Flowfect Tips™. Use of any other type of tips is not supported.

NOTE: Flowfect Discover™ performance is designed for use of Flowfect Buffer™. Use of any other type of media is not supported.

Materials not provided (these items must be supplied by the user):

- 96-well input plates for cells and payload
 - **NOTE:** Flowfect Discover™ is calibrated for Bio-Rad Hard-Shell® 96-Well PCR Plates (catalog #HSP9601). Contact Kytopen for alternatives.
- 96-well deep well plate for output
 - **NOTE:** Flowfect Discover™ is calibrated for NEST Scientific 2.2mL 96-Well Deep Well Plate (catalog #503062). Contact Kytopen for alternatives.
- USB-C drive (for uploading Flowfect® Profiles and downloading log files)
- USB-C keyboard and mouse (optional for use with Flowfect Discover™ software)

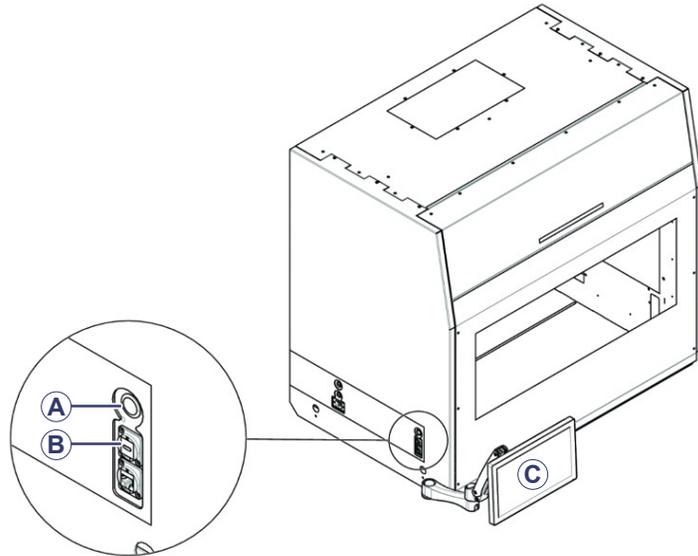


Figure 1: Flowfect Discover™ liquid handler (from left)

- A** Liquid handler power button
- B** USB-C port on liquid handler
- C** Liquid handler touch screen

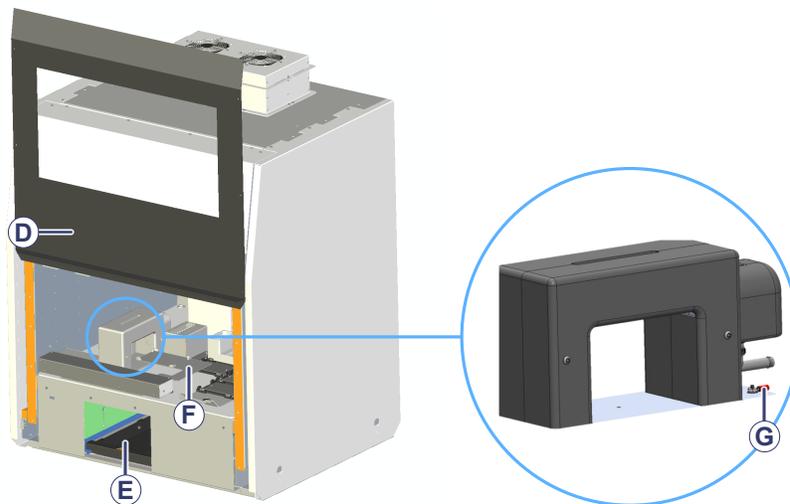


Figure 2: Flowfect Discover™ liquid handler (on the left) and Electric Discharge Manifold (EDM) (on the right)

- D** Front safety panel
- E** Waste drawer
- F** Plate shuttle
- G** EDM grounding cable

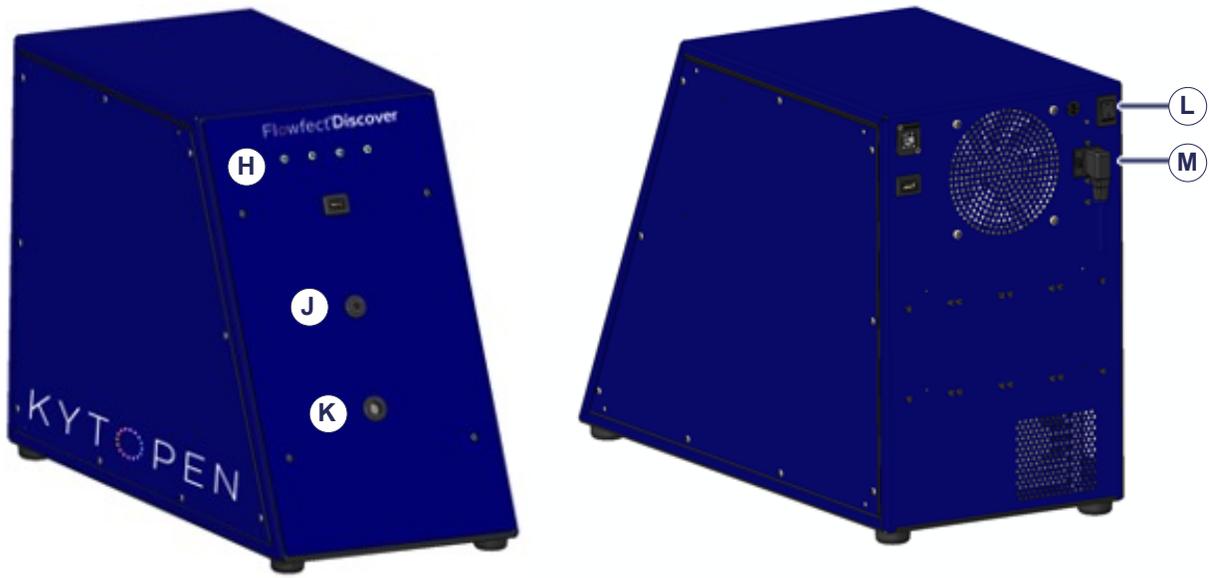


Figure 3: Flowfect Discover™ control unit, front and back

- | | | | |
|----------|----------------------|----------|---------------------------|
| H | LED Status lights | L | Control unit power switch |
| J | EDM low power cable | M | Control unit power cable |
| K | High power EDM cable | | |

7.2 Status Light Indicators

There are four LED status lights on the front of the Flowfect Discover™ control unit. Their meanings are described in the table below. When a light is referred to by numerical position, this refers to the position from left.

LED sequence	Status	Description
	Power on	The first LED light is illuminated when the Flowfect Discover™ control unit is powered on.
	Ready	The second LED is illuminated when the internal server is running and tracking instrument state.
	High Voltage On	The third LED light is illuminated when electricity is being applied during a Flowfect Discover™ run.
	Error	The fourth LED is illuminated when an error is detected. The status light remains illuminated until the error is resolved.

8. General Operating Instructions

8.1 Restrictions

Flowfect Discover™ is intended for Research Use Only (RUO).

Always follow laboratory protocols for appropriate personal protective equipment (PPE) in the environment in which Flowfect Discover™ is being used.

8.2 Safety and Environmental Considerations – Please read carefully

Symbol	Meaning
	<p>Follow the instructions for use.</p> <p>To ensure safe, reliable operation, always operate the Flowfect Discover™ according to the instructions in this manual.</p> <p>The Flowfect Discover™ is not intended to operate continuously but rather intermittently under the control of its software, as described in these user instructions.</p> <p>The equipment must be operated only by a trained operator skilled in the intended use.</p>
	<p>Flowfect Discover™ is not for use in a potentially explosive environment.</p> <p>Always use the power cords and cables provided with the Flowfect Discover™. Use of an inadequate, under-rated power cord may cause an unsafe condition</p>
	<p>Warning – Mechanical hazard</p> <p>The liquid handler has mechanical components to the device and care should be taken when interacting with it.</p> <p>Take care while configuring the deck of the liquid handler, including installing Flowfect Tips™ and handling other reagents or consumables.</p>
	<p>Do NOT reuse the consumable materials – Single Use Only</p> <p>Flowfect Buffer™ and Flowfect Tips™ are designed for a single use; repeated use is not supported.</p> <p>Repeated use of the Flowfect Tips™ may cause super-heating of residual fluid, resulting in a breach of fluid seal integrity, permanent damage to the equipment, increased risk of exposure to biohazard to the operator, or increased risk of electric shock to the operator.</p>
	<p>Caution, risk of electric shock</p> <p>The EDM electrodes pose an electric shock risk. An electric shock could cause death or personal injury. Do NOT manipulate the electrodes. Any manipulation of the electrodes must be performed by Kytopen personnel.</p>

Symbol	Meaning
	<p>Biohazard Waste</p> <p>After using the Flowfect Buffer™ and the Flowfect Tips™, dispose in a biohazard container and follow your laboratory's safety instructions for proper waste disposal practices.</p>
	<p>Do not use if consumable package is damaged.</p> <p>Do not use Flowfect Tips™ or Flowfect Buffer™ if the packaging is opened or damaged due to an increased risk of contamination to consumables.</p>
	<p>Temperature limit</p> <p>Flowfect Buffer™ shall be stored at 2 – 8°C and used at room temperature (20°C).</p>

8.3 Installation

- 8.3.1 Flowfect Discover™ installation, including installation qualification and operational qualification, is performed by Kytopen.
- 8.3.2 Always use Flowfect Discover™ on a flat surface large enough for both the liquid handler and control unit to be placed (minimally, 50x31 in or 113.5x91 cm.)
- 8.3.2.1 A minimum of 1.5" (3.8cm) clearance behind the instrument is necessary to allow for the carboy tubing to drain properly from the rear right hand corner of the instrument.
- 8.3.3 **Never move the liquid handler** (Figure 1). Contact Kytopen support (see Section 1.1) if this is required at any point after installation.
- 8.3.4 When it is necessary to move the *control unit*, lift the instrument by *two persons*, holding the instrument at the bottom corners of the unit at the locations indicated in Figure 4 below.

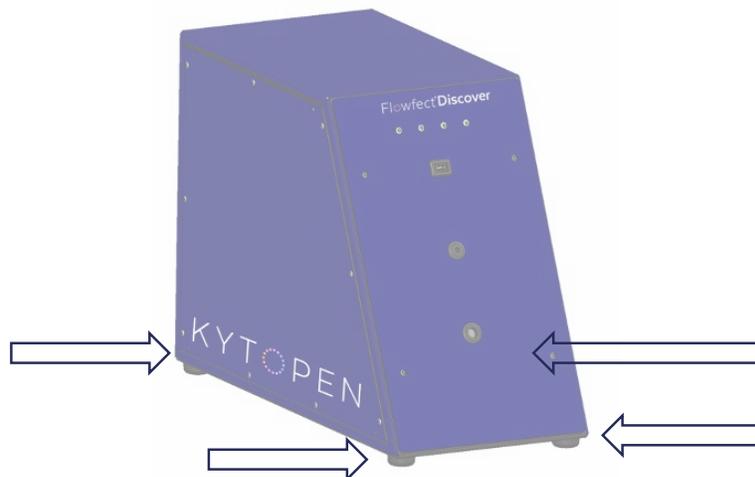


Figure 4: Hold the control unit at the bottom corners when moving it

8.4 Powering On and Off

- 8.4.1 To turn on the system, press the power button on the left side of the liquid handler (see Figure 1, component A). The liquid handler will begin the initialization process.
- 8.4.2 For routine shut down of the liquid handler, use the Windows start menu on the touch screen.
- 8.4.3 For a forced shut down of the liquid handler, press the power button for five (5) seconds to shut down the instrument and touch screen.
- 8.4.4 The control unit power switch (Figure 3, component L) always remains in the on position. The control unit will power on with the liquid handler (step 8.4.1).
- 8.4.5 The system is ready for use when the first two LEDs on the control unit **and** the lights inside the liquid handler are illuminated.

8.5 Waste Disposal

Dispose all used Flowfect Tips™ into a biohazard container. Refer to the laboratory's safety instructions regarding disposal practices.

Dispose used Flowfect Buffer™ in compliance with local regulation for liquid biohazardous wastes.

Dispose all carboy waste in compliance with local regulation for liquid waste.

8.6 Maintenance and Cleaning

8.6.1 General Maintenance

Never open the Flowfect Discover™ control unit. **Do not** change or modify the external or internal parts. The control unit will be serviced and maintained by Kytopen. All repairs and service are the responsibility of Kytopen Corp. Contact Kytopen support (see Section 1.1) if any repair and service is needed.

8.6.2 Carboy Maintenance

Two 10L carboys are provided with the instrument. The first carboy is for input liquid and has 8 lines that feed into the instrument for the 8 pipettor channels. The input carboy should be filled deionized water and must be filled with at least 4" of liquid prior to each run. Kytopen recommends filling the input when it drops between one-third and one-half full.

The second carboy is for waste and has a single, one inch diameter output tube to drain waste from the liquid handler. The waste carboy should be emptied when the carboy is halfway full.

At least 1.5" clearance behind the instrument is necessary to allow for the tubing to drain properly from the rear right hand corner of the instrument.

The output container contains waste from the input lines of the liquid handler and should be discarded in compliance with local regulations for liquid waste.

8.6.3 Cleaning Guidelines

If needed, Kytopen recommends cleaning the external surfaces of Flowfect Discover™ (including electric discharge manifold (EDM), control unit, and liquid handler) with a non-abrasive cloth using the following cleaning agents:

- 70% alcohol (ethanol or isopropanol)
- 10% bleach
- LpH (Phenolic Disinfectant)
- Vesphene
- Sporicidin

The control unit and liquid handler should be cleaned between each run to ensure good working condition and limit cross contamination.

Refer to Section 5 Maintenance of the Tecan Operating Manual (referenced in this document in Section 5.1) for recommended cleaning and maintenance of the Liquid Handler.

9. Workflow

Interacting with the Flowfect Discover™ software GUI is done via the touchscreen connected to the liquid handler (Figure 1, component C). If desired, an external keyboard and mouse can be connected to interact with the GUI for desktop mode. Contact Kytopen Support for assistance with connecting a keyboard and mouse if not done at installation.

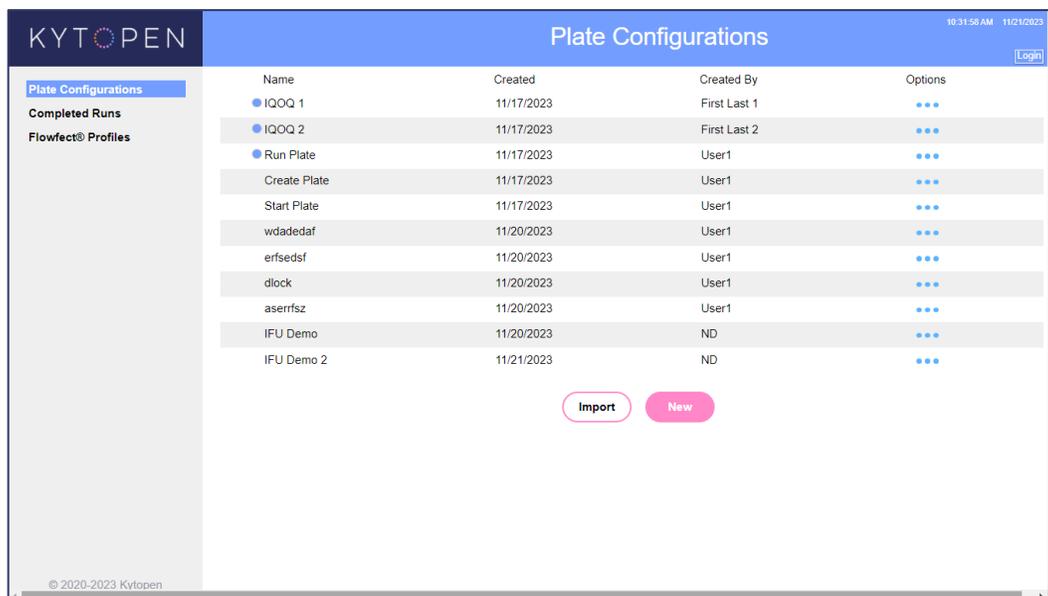
NOTE: Occasionally the instruction differs between touchscreen and mouse interactions. When different, desktop mode instructions are listed after the corresponding touchscreen mode instruction.

9.1 Creating a Plate Configuration

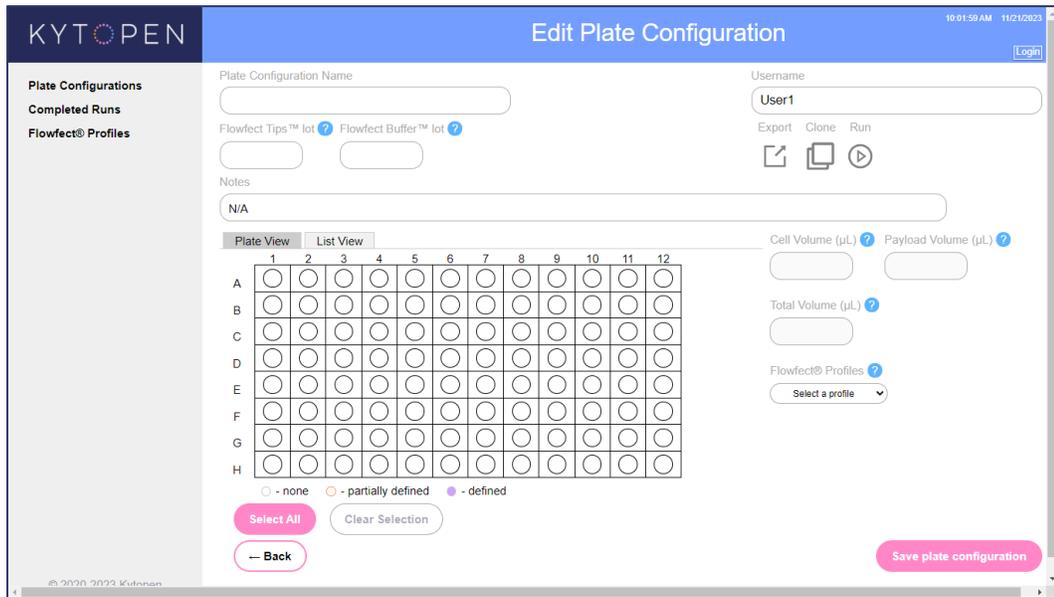
This section will describe how to configure a plate for Flowfect Discover™. If the plate is already configured, proceed to Section 9.4 to run the plate. If a plate configuration is available to import, proceed to Section 0.

9.1.1 Upon startup, the Flowfect Discover™ software will be displayed on the touch screen. If the software has not auto launched, open a web browser, and enter 10.0.0.1 in the address bar to launch the Flowfect Discover™ software.

9.1.2 To create a new plate for the experiment, select **Plate Configurations** from the left sidebar. Then tap or click the **New** button to create a new plate.



9.1.3 Enter the Plate Configuration Name and Username. Optional entries include Flowfect Tips™ lot, and Flowfect Buffer™ lot, and Notes for the plate configuration.



9.1.4 For each well, enter the cell and payload volumes (µL), then select the Flowfect® profile to be applied.

9.1.4.1 **Plate View** allows assigning each well by interacting with the plate shown on the touchscreen and provides a visual overview of each well status (defined, partially defined, none). Toggle to **List View** to assign well information as a list of all wells.

9.1.4.2 The minimum total volume of each sample (cells and payload) is 50 µL. The maximum total volume of each sample (cells and payload) is 100 µL.

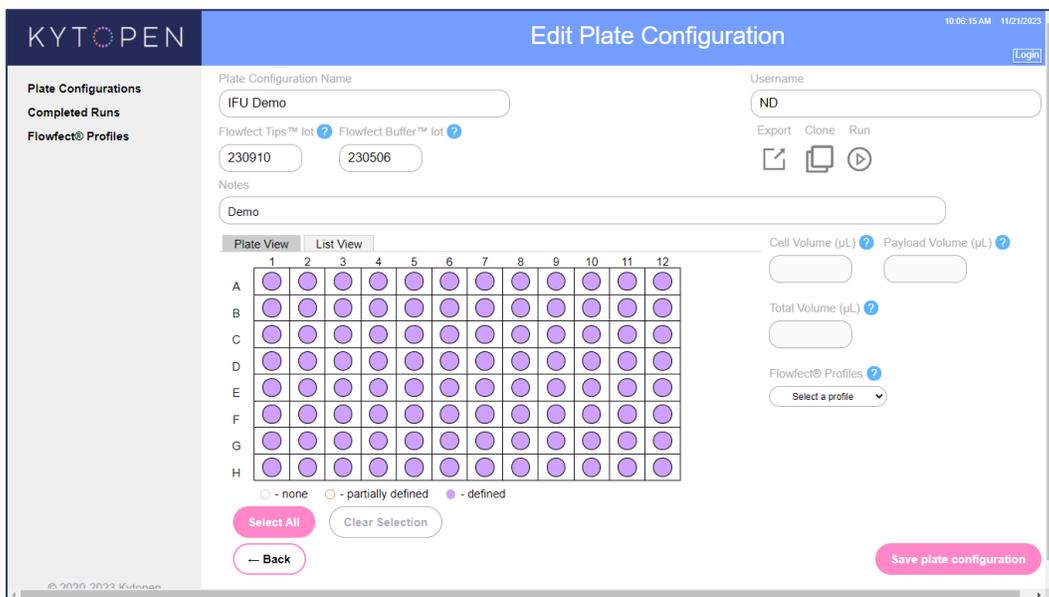
NOTE: The various consumables used in this workflow will retain a small amount of fluid that can amount to 5-10% of the input volume. Kytopen recommends adjusting volumes as needed to manage this difference in input and output volumes.

9.1.5 To apply common values across multiple wells, select the relevant wells and input common information such as Flowfect® profile or volume.

9.1.5.1 In touchscreen mode, to select multiple wells and apply the same value for volume or Flowfect® Profile, tap and drag the desired wells on the touch screen. Entire columns or rows can also be selected by tapping the corresponding number (1-12) or letter (A-H), respectively.

9.1.5.2 In desktop mode, to select multiple wells and apply the same value for volume or Flowfect® Profile, press the **Control** and **Shift** keys on the keyboard while selecting the relevant wells with the mouse.

9.1.6 When all samples are entered and the plate configuration is completed, tap or click **Save plate configuration**.

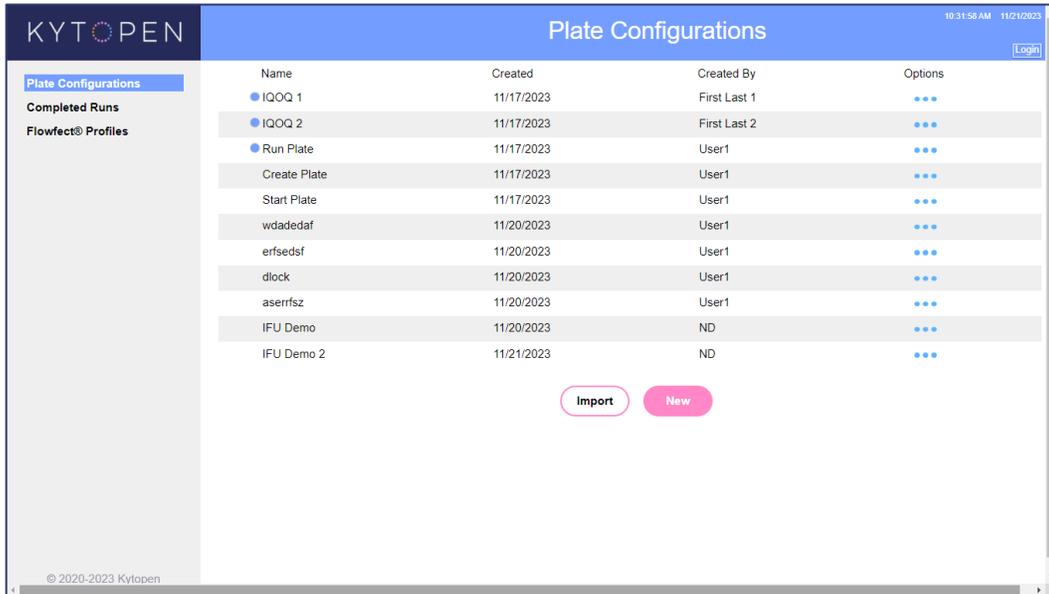


To run a plate configuration, proceed to Section 9.4.

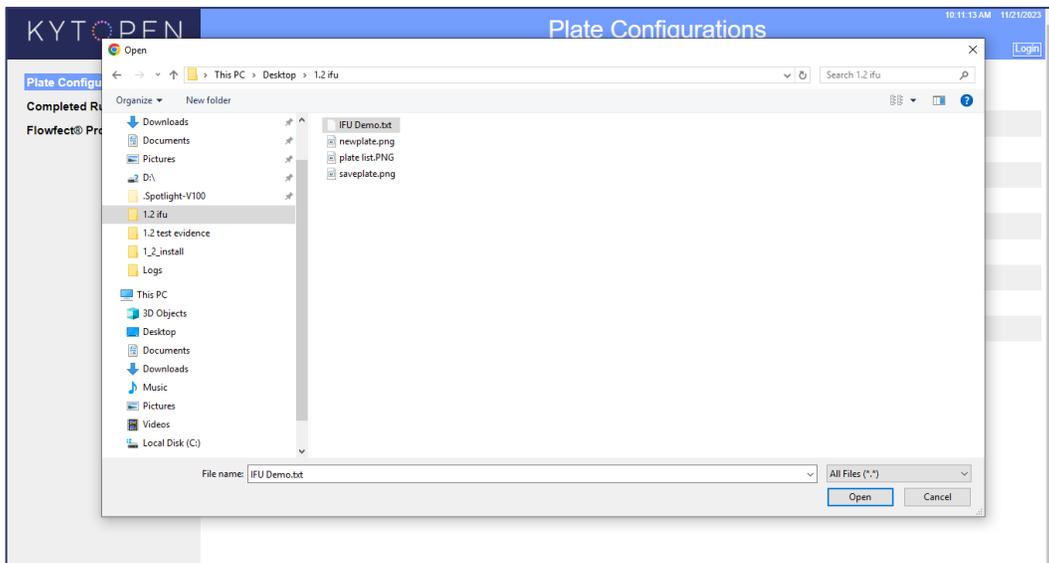
9.2 Importing and Editing Plate Configurations

A plate (in the format of a .txt file) may be available for import if the plate has been exported from another Flowfect Discover™ device. Additionally, a plate can be defined via a Microsoft Excel template provided by Kytopen.

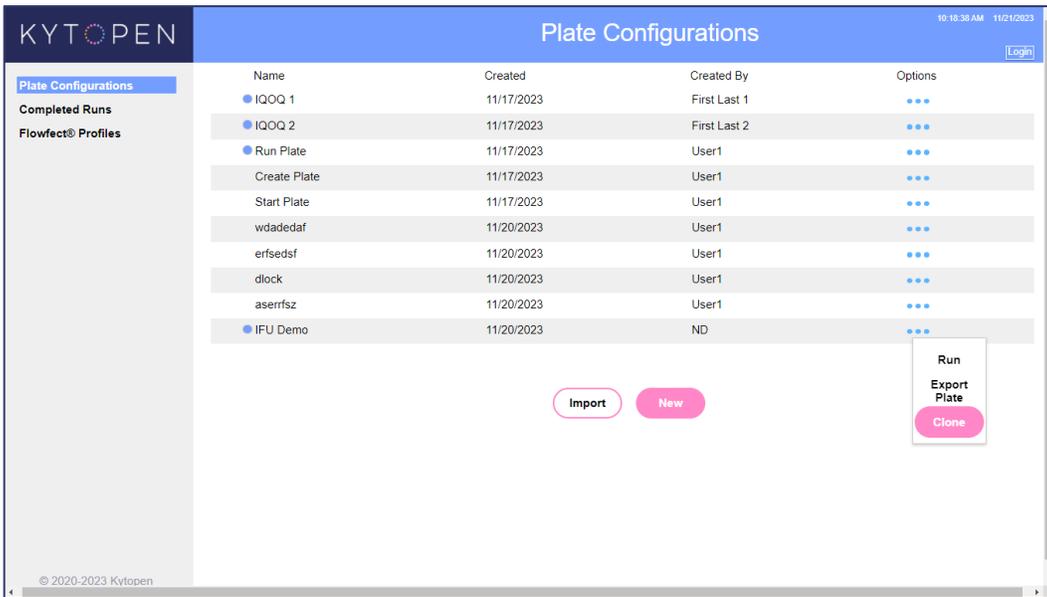
9.2.1 To import a pre-defined plate, tap or click the **Import** button. A file browser pop up will appear. Navigate to the corresponding folder or storage location and select the plate configuration to import.



9.2.2 Existing plates can be edited if they have not yet been run; these plates are marked with a blue dot. Tap or click a plate marked with a blue dot to edit it; the plate configuration will open on the subsequent screen



9.2.3 Plate configurations that have already been run cannot be edited. Instead, open the 3-dot menu and tap or click **Clone**. After cloning the plate, additional edits can be made.

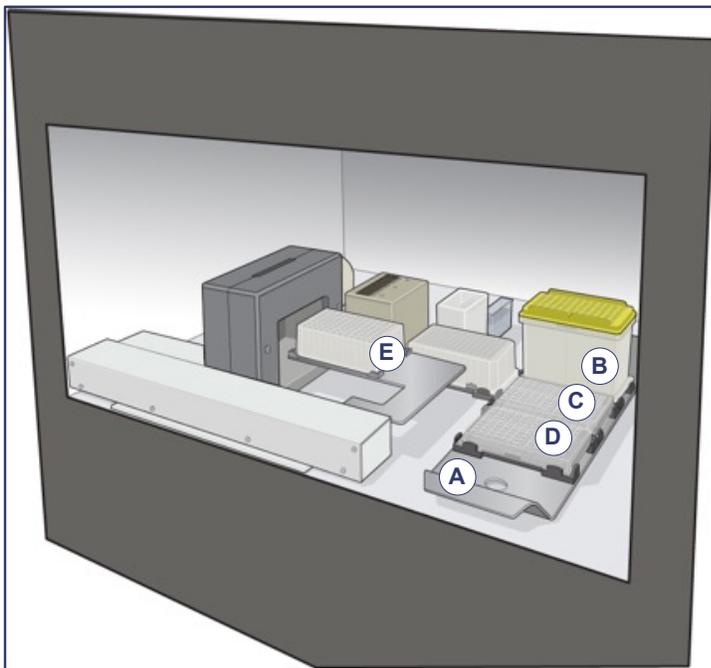


9.3 Flowfect Discover™ Liquid Handler Work Deck Set Up

The work deck set up of the Flowfect Discover™ liquid handler is shown in Figure 5. Ensure all consumables and materials are easily accessible before starting the set up process.

For additional information about the liquid handler work deck and its components, review section 5.2.7 of the Tecan Cavro® Magni Flex Operating Manual (reference provided in Section 5.1).

To minimize potential for cross-contamination of samples, Kytopen advises users to populate the work deck from back to front (B, C, D) as shown in Figure 5 and described in the following steps.



- A** Four-position carrier
- B** Disposable Tips holder
- C** 96-well plate with payload
- D** 96-well plate with cells
- E** Deep well output plate

Figure 5: Flowfect Discover™ work deck

- 9.3.1 Open the front safety panel.
- 9.3.2 Snap the tray of the Flowfect Tips™ onto the Disposable Tips holder which sits as shown in Figure 5, position **B** on the four-position carrier.

NOTE: Disposable tips and all 96-well plates must be oriented with the A1 location positioned toward the upper left-hand corner of the work deck.

- 9.3.3 Ensure the tip tray is oriented properly as shown in Figure 6, with the alignment indicator of the tray in the upper left corner when placed in the Disposable Tips holder.

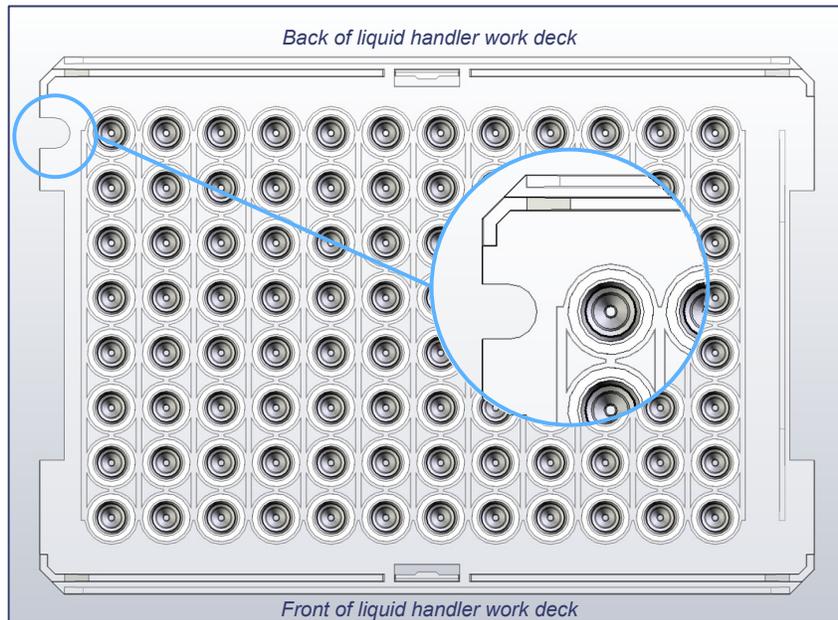
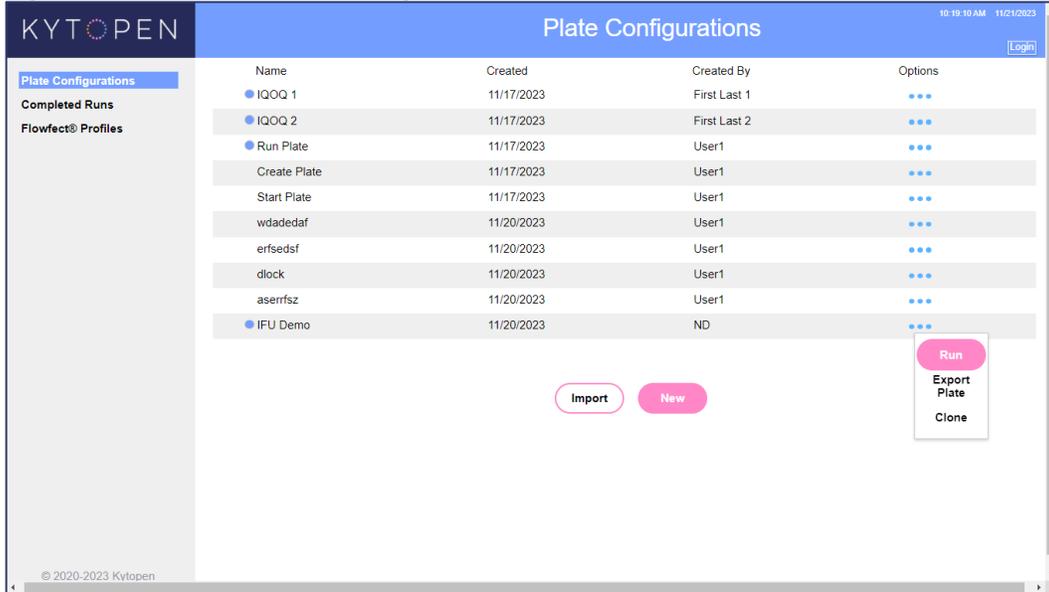


Figure 6: Flowfect Tips™ tray orientation

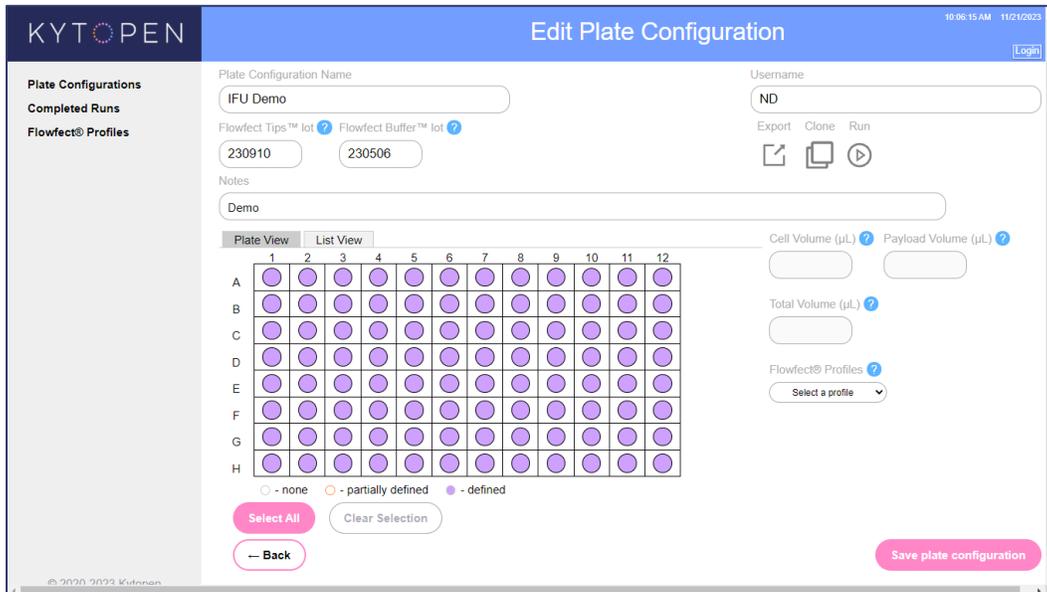
- 9.3.4 Place the 96-well plate containing payload as shown in Figure 5, position **C** of the 4-position carrier.
- 9.3.5 Place the 96-well plate containing cells as shown in Figure 5, position **D** of the 4-position carrier.
- 9.3.6 Place the output deep well plate on the plate shuttle (Figure 5, position **E**).
- 9.3.7 Remove all lids from consumables placed on the work deck, working from back to front to avoid contamination.
- 9.3.8 Close the front safety panel.

9.4 Running a Plate Configuration

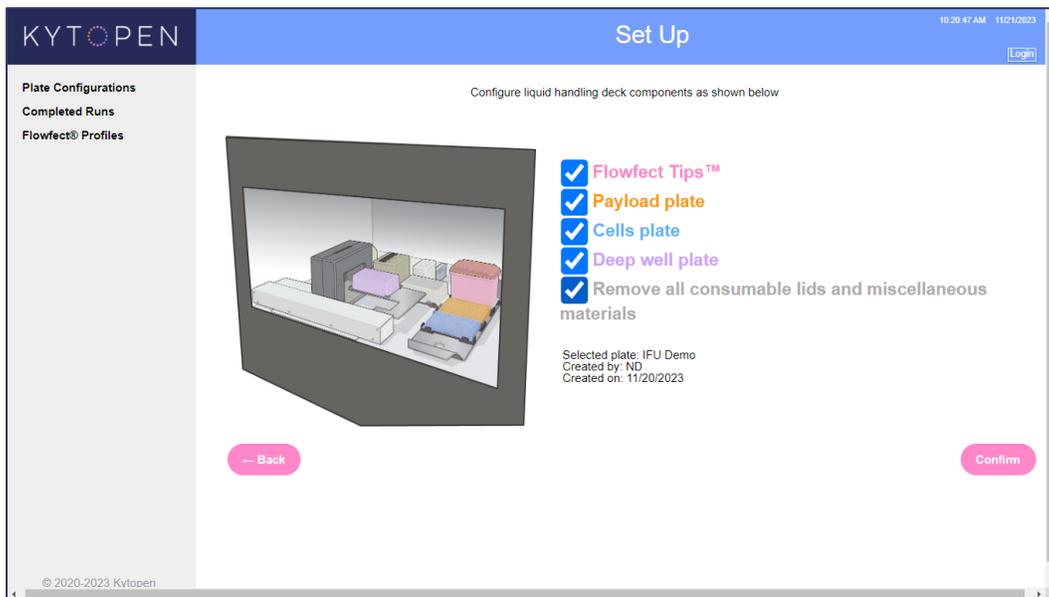
- 9.4.1 Prior to running a plate configuration, always check the levels of fluid in the carboys to ensure proper operation. For carboy maintenance, see Section 8.6.2.
- 9.4.2 Identify the plate configuration to be run by the Flowfect Discover™. Plate configurations that have not yet been run are marked by a blue dot.
- 9.4.3 Open the 3-dot menu and tap or click **Run**.



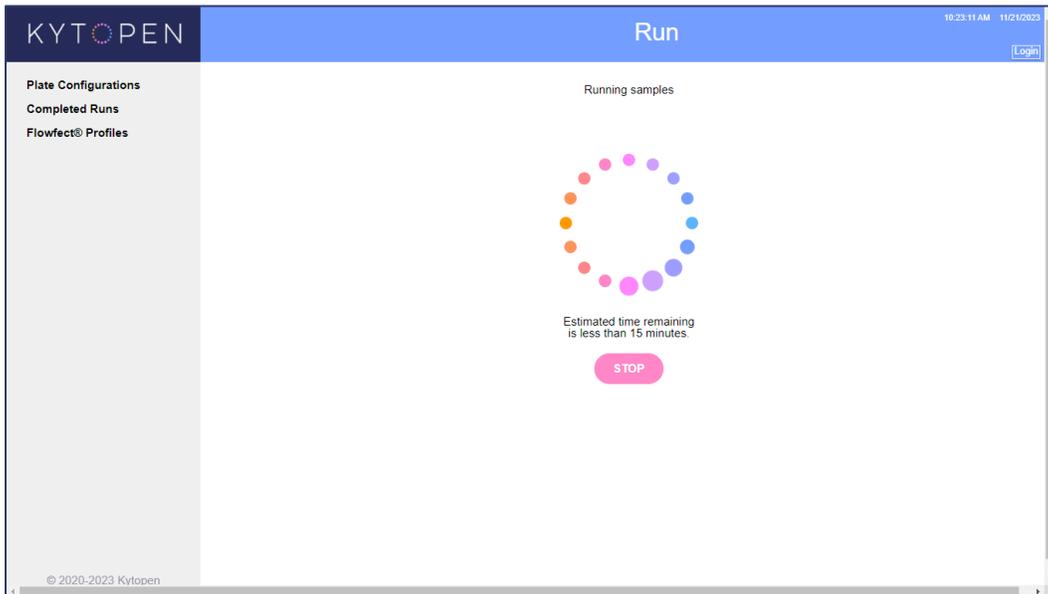
- 9.4.3.1 Alternatively, a run can be started by pressing the play button on the Plate Configuration page. This button is gray and disabled until a Plate Configuration is saved.



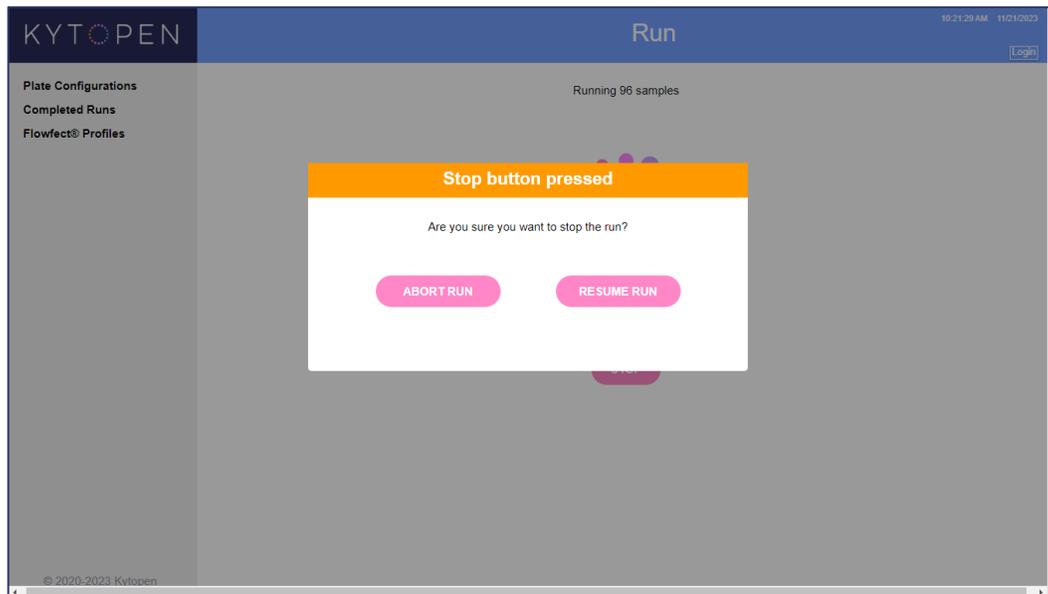
9.4.4 On the Set Up page, select the checkboxes to confirm the plates and deck are configured as described on screen and in Section 9.3. Tap or click **Confirm** to proceed.



9.4.5 A loading screen will appear while the run is in progress.



9.4.6 If for any reason the Run should be stopped while processing, tap or click the **Stop** button. The door will unlock and a confirmation pop up will appear. Tap or click **Abort Run** to stop the run or **Resume Run** to resume the run.



- 9.4.7 Once the run has completed, review the on-screen results. The liquid handler will begin the reinitialization process in the background.
- 9.4.8 To conduct another run, begin at Section 9.1, Creating a Plate Configuration.

9.5 Post Transfection

- 9.5.1 Once the liquid handler is done reinitializing, open the front safety panel to remove the deep well output plate with processed material.

NOTE: Kytopen recommends covering the output plate prior to removal from the work deck.

- 9.5.2 Remove all other well plates and safely discard.
- 9.5.3 Remove unused tips from the work deck.
- 9.5.4 Discard used Flowfect Tips™ after single use by pulling the waste drawer out.
- 9.5.5 Close the front safety panel.

10. Data and Profile Management

10.1 Download Kytopen Log Files

There are two types of logs available to download. The Basic Log provides basic information for runs. This includes plate name, notes for the run, and the result of each well. This log is provided as a .csv file and is unencrypted and intended for end-user evaluation. The Basic Log can be accessed and downloaded by an Operator.

The Diagnostic Log contains system information and is intended for system evaluation and troubleshooting. This file is encrypted, and accessible by Kytopen Operators only.

10.1.1 To view the Basic Log for an individual run, select **Completed Runs** from the left sidebar.

10.1.2 Tap or click the desired run to view the results page.

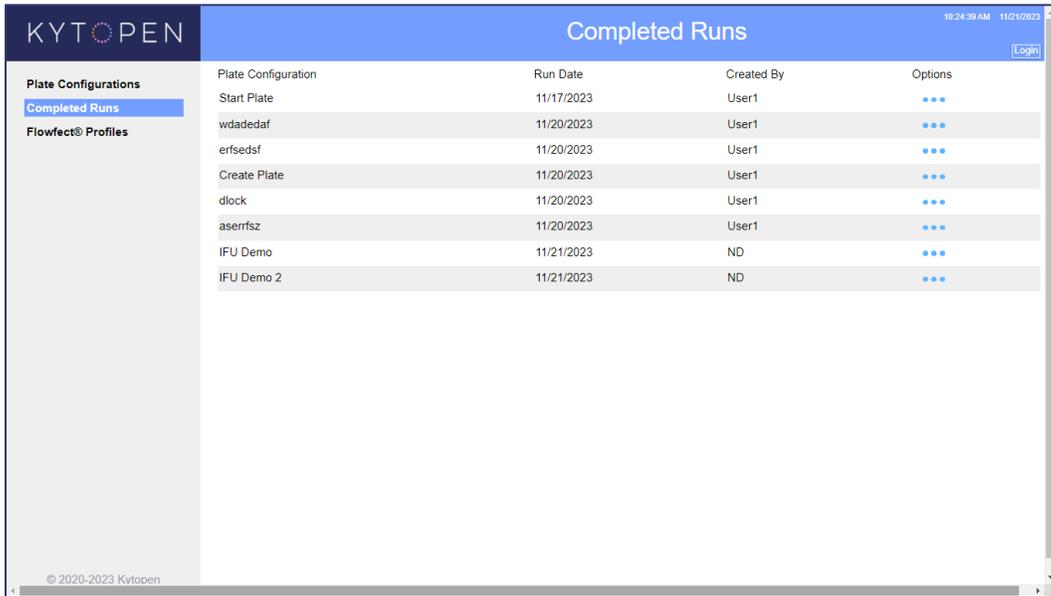
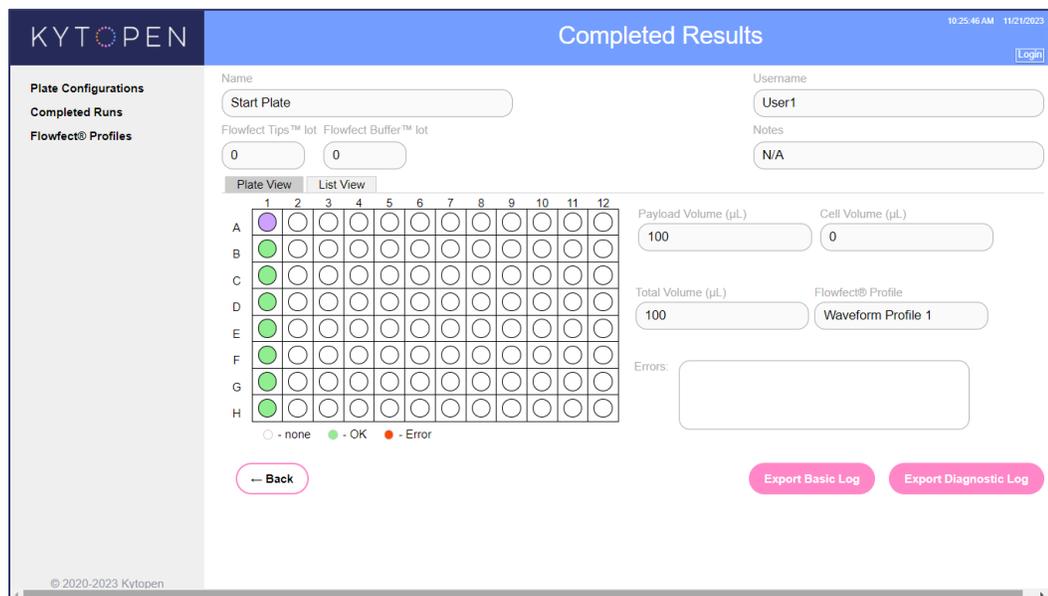


Plate Configuration	Run Date	Created By	Options
Start Plate	11/17/2023	User1	...
wdadedaf	11/20/2023	User1	...
erfsedsf	11/20/2023	User1	...
Create Plate	11/20/2023	User1	...
dlock	11/20/2023	User1	...
aserrfsz	11/20/2023	User1	...
IFU Demo	11/21/2023	ND	...
IFU Demo 2	11/21/2023	ND	...

10.1.3 An overview of the plate results including any errors is displayed. Tap or click each well to view the volumes and Flowfect® profile used.

10.1.4 Tap or click **Export Basic Log** to initiate download of the Basic Log in .csv format.

10.1.5 Tap or click **Export Diagnostic Log** to initiate download of a .zip file which includes two encrypted log files, readable by Kytopen Operators.



10.1.6 All log types are saved to the **Downloads** folder of Flowfect Discover™, accessible via the touchscreen interface.

10.1.7 To move log files off the Flowfect Discover™, insert a USB drive into the port located on the left-hand side of the Flowfect Discover™ liquid handler.

10.1.8 Tap and hold the filename(s) until the context menu appears, then select **Copy** and select the destination folder in the Windows File Explorer.

TIP: In desktop mode, right-click the filename(s) to bring up the context menu.

In the event of an issue Kytopen recommends sending the Diagnostic Log to Kytopen Support for troubleshooting help.

10.2 Download Tecan Cavro® Magni Flex Log Files

In some instances, the log files from the Tecan Cavro Magni Flex liquid handler may be needed. If Kytopen support or field service personnel are not on-site, follow the steps below to retrieve these log files.

10.2.1 Open a new Windows Explorer window using the **Start** menu on the touch screen.

10.2.2 Navigate to the following folder location:

```
C:\Desktop\Build\net48\DataStore\Tecan.ExampleXls\MAP.Services.Logging.Service\LogFile
```

10.2.2.1 Alternatively, a shortcut called **LogFile** may be placed on the desktop. Double tap the folder icon to open the folder.

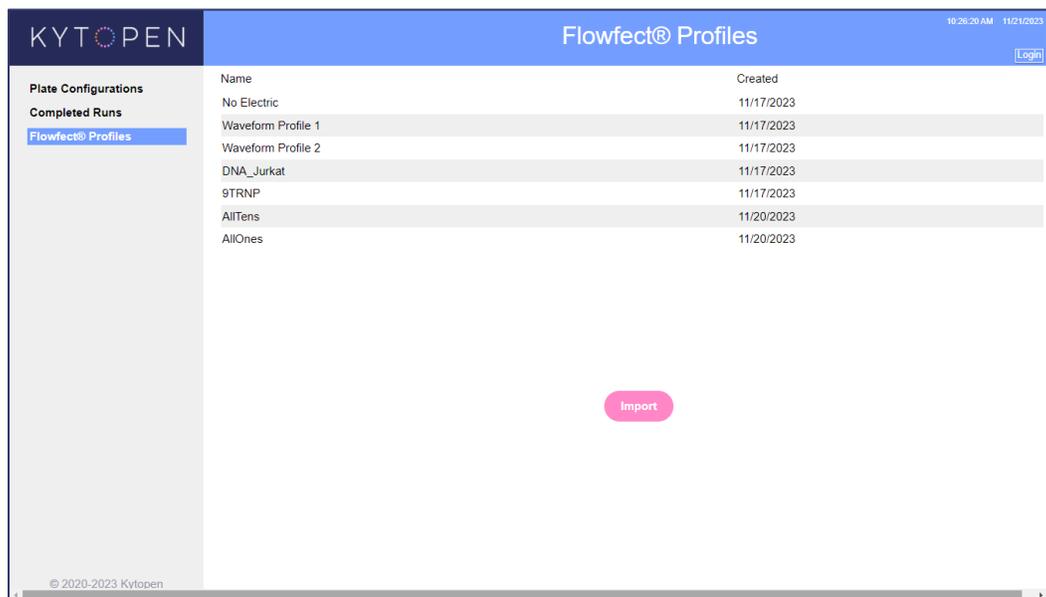
10.2.3 Log files are named with the date logs occurred on. Copy the log files from the relevant days to a USB drive, inserted to the left side panel of the liquid handler.

10.3 Uploading a New Flowfect® Profile

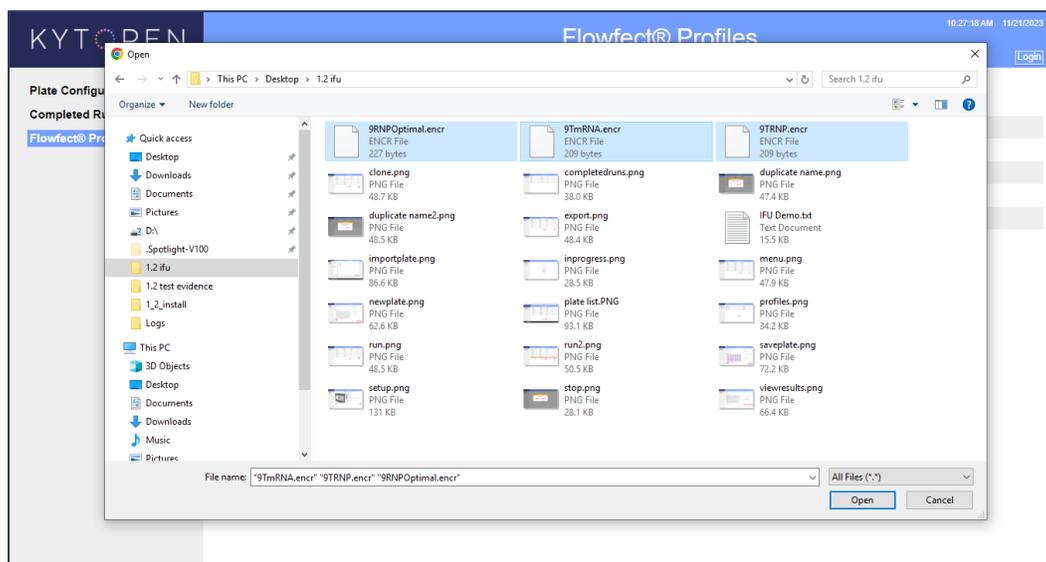
To upload a new Flowfect® Profile to the Flowfect Discover™ instrument, follow the steps below.

10.3.1 Insert a USB drive with the new profile to the port located on the left-hand side of the Flowfect Discover™ liquid handler.

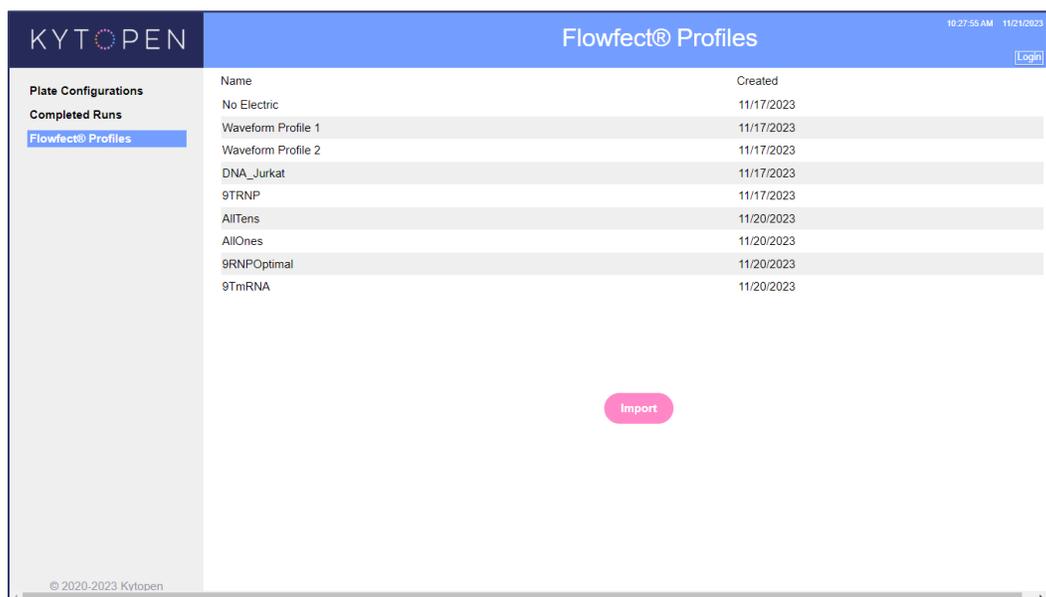
10.3.2 In the Flowfect Discover™ software, select Flowfect® Profiles from the sidebar.



10.3.3 Tap or click the **Import** button. A file browser pop up will appear. Navigate to the corresponding folder and select the Flowfect® profile(s) to import.



10.3.4 The new Flowfect® profile(s) will now appear in the list and be available for plate configurations.



10.3.5 To use the new profile in a run, select **Plate Configurations** on the sidebar and open the plate in which the profile will be used, or create a new plate.

10.4 Performing a backup of Flowfect Discover™

10.4.1 Insert a USB drive the port located on the left-hand side of the Flowfect Discover™ liquid handler.

10.4.2 Locate the **Build** folder on the desktop of the liquid handler computer.

10.4.3 Back up the Build folder by copying it to the USB drive.

10.4.4 Rename the folder copied to the USB drive **Backup_Build**.

10.5 Performing a software update on Flowfect Discover™

Certain software updates will be available to do independently. When Kytopen personnel are required to perform the software update, a Preventative Maintenance visit will be scheduled.

10.5.1 Prior to updating, perform a backup as described in Section 10.4

10.5.2 Rename the existing Build folder on the desktop.

10.5.3 Insert a USB drive to the port located on the left side panel of the liquid handler.

10.5.4 Double click the Kytopen Discover Installer.msi file to start the installation process.

10.5.5 After the installer completes running, wait one minute then restart the instrument via the Start menu.

11. Troubleshooting

Certain troubleshooting actions can be completed by following the instructions below. If further help is needed, please reach out to the Kytopen support team as outlined in Section 1.1.

In the event of an issue Kytopen recommends sending the encrypted data file to Kytopen Support for troubleshooting help (Section 1.1).

11.1 Error Messages

The control unit signals an error as described in Section 7.2. Specific error messages are displayed on the touch screen. These messages and related resolution actions are summarized below.

In all cases, if the problem persists, contact Kytopen Support

Error	Recoverable	Explanation and Resolution
System froze during a run	No	When the system freezes during a run, this is likely due communication between the components failing. Due to this communication failure, recovery is not possible via the GUI. Check all wires and cables to ensure nothing is unplugged or loose. Perform a system restart according to Section 0. Flowfect Discover™ will remove any Flowfect Tips™ remaining attached to the liquid handler arm during the startup process.
Run Stopped because no fluid flow was detected	Yes	No volume in cell and payload plates is detected. Check the work deck and continue or try again.
Run ended because signal to Flowcell was not as expected.	Yes	Wrong buffer fluid used, or a fluid leak caused an internal short circuit. Replace all consumables and restart the run.
Run ended because Stop button on screen was pressed.	N/A	User manually stopped the run; depending on the reason for manual stop, resume or exit the run.

Error	Recoverable	Explanation and Resolution
X- or Y-axis Motor Collision or Stall	No	An X- or Y-axis motor collision can be result of miscalibration. Contact Kytopen Support immediately.
Z-axis Motor Collision or Stall	No	On the GUI, select “Abort Run” in the error message window. The system will reinitialize and prepare for the next run, including removing any Flowfect Tips™ still attached. Prior to beginning a new run, ensure work deck items are properly placed as described in Section 0, including all lids removed. Ensure no other consumables or components are placed on the work deck.
Tip pickup issue	Yes	Ensure Flowfect Tips™ are placed on work deck in the correct orientation (see step 9.3.3).
Automatic tip removal issue	Yes	If the Flowfect Tips™ are not ejected automatically, manually remove the Flowfect Tips™ in a counterclockwise motion: <div data-bbox="1295 814 1435 1314" data-label="Image"> </div>
3 or more tips failed analysis	Yes	Can occur when the system detects no voltage was applied to 3 or more samples in a single column. If this is intentional (i.e. a no-electric Flowfect® profile was used), tap or click Resume Run on the pop-up modal. Otherwise, check the system setup before continuing.
Failed to connect to control unit	Yes	Check all wires and cables to ensure nothing is unplugged or loose. Wait 1-2 minutes before trying again.
No connection to control unit	No	Ensure all machine hardware is powered on and system is plugged in.

Error	Recoverable	Explanation and Resolution
bad_signal	N/A	Appears on Completed Results page in list view; No voltage was applied to the individual well. Check the log file for more details.
no_contact	N/A	Appears on Completed Results page in list view; No current occurs when there is poor contact with the Flowfect Tip™.
over_current	N/A	Appears on Completed Results page in list view; An individual well received higher than expected current. Check the log file for more details.
Door lock error	Yes	The liquid handler was not able to automatically lock the door. Open and close the door, then tap or click Resume run.

11.2 Known Issues and Workarounds

The following known issues list is current as of software version 1.2. If the problem persists after trying the workaround, contact Kytopen support team as outlined in Section 1.1.

Kytopen Bug ID	Summary	Workaround
SETB-1481	Fatal error when running a plate with columns containing <8 wells.	<ol style="list-style-type: none"> 1. Design plate to use all wells in a column. 2. Alternatively, add dummy values to the empty well(s). During the run, an error will appear warning of 3 or more errors in a column resulting from the empty wells. Tap continue run to proceed instead.
SETB-935	When the detailed log file is too big, it has trouble downloading	Contact Kytopen to schedule a visit so a Field Service Engineer can manually retrieve the log file(s)

12. Document Change History

Version	Detailed Description of Change
0	Initial Release
1	<p>Section 5.2: added definition of Graphical User Interface (GUI); removed statement “includes Graphical Interface (GUI)” from the definition of software.</p> <p>Section 6.3: combined the instruction regarding software version and the note instructing to contact Kytopen support into a single paragraph.</p> <p>Section 7.1: Figure 2, added Front Safety Panel label (D); updated the labeling and legend for other components in Figure 2 and Figure 3 accordingly.</p> <p>Section 8:</p> <ul style="list-style-type: none"> • Step 8.4.1 changed instruction to refer to entire system; added instruction about initialization starting. • Reformatted the notes regarding shutting down of liquid handler to be instructions 8.4.2 and 8.4.3. • Step 8.4.4 updated instruction to reflect current implementation. • Step 8.4.5 added instruction to describe when the system is ready for use. <p>Section 9.1:</p> <ul style="list-style-type: none"> • Step 9.1.3, edited to include Username as a required field. • Step 9.1.4 changed Note about maximum volume to instruction step 9.1.4.1 and added the minimum total volume of each sample (50 µL). Added a Note about residual volume retained in consumables (5-10% of input volume). • Step 9.1.5, Added a new step to instruct the user on selecting multiple wells from previous information in Step 9.1.4 Notes. Changed Tips to instruction steps 9.1.5.1 and 9.1.5.2 with Touchscreen and Desktop instructions respectively. Updated the Desktop instruction to reflect current implementation. <p>Section 9.2:</p> <ul style="list-style-type: none"> • Step 9.2.1 Added “or storage location” to the instruction. <p>Section 9.3:</p> <ul style="list-style-type: none"> • Section 9.3, updated work deck order to swap payload and cells plate location, with payload now being placed in location C and cells in location D in Figure 5, Steps 9.3.3 and 9.3.4. Changed Flowfect® Tips to Disposable Tips holder” in Figure 5 legend for (B). • Step 9.3.2 Added reference to Disposable Tips holder to location of Flowfect® Tips to match the updated legend (B) in Figure 5. • Step 9.3.3 added step to clarify the correct orientation of the tray with Flowfect® Tips when placed in the Disposable Tips holder, including Figure 6. Renumbered subsequent steps. • Step 9.3.6 added “working from back to front to avoid contamination” to the instruction. <p>Section 9.4:</p> <ul style="list-style-type: none"> • Step 9.4.3 updated the GUI screenshot to correctly represent the placement of items in the work deck (tips, payload, cells, in that order).

Version	Detailed Description of Change
	<ul style="list-style-type: none"> Step 9.4.6 added a screenshot of the GUI and instruction to user the liquid handler will begin reinitialization. <p>Section 9.5</p> <ul style="list-style-type: none"> Step 9.5.1, added instruction to user wait for reinitialization process to end before opening the front safety panel <p>Section 10, Renamed to “Data and Profile Management” to better describe the contents.</p> <p>Section 10.1:</p> <ul style="list-style-type: none"> Changed all instances of “Summary Data” to “Basic Log” and “All Data” to “Diagnostic Log” throughout. Step 10.1.4 updated the GUI screenshot with corresponding log names. Added Step 10.1.5 to inform the user where log files are downloaded to. Added Step 10.1.7 to inform the user how to copy log files to a USB drive. <p>Section 11.1: changed the following entries:</p> <ul style="list-style-type: none"> Z-axis Motor Collision or Stall in “Recoverable” column from “Yes” to “No”. Added instructions to “Abort Run” and restart the system including the liquid handler. Added error and recovery instruction for Automatic tip removal issue. Changed “3+ out of 8 Samples Analyze as Errors” to “3 or more tips failed Analysis” to match the GUI Changed “Failure to initialize Peripheral” to “Failure to connect to control unit” to match the GUI Removed Dataflow issue row Changed “Loss of Connection (Socket)” to “No connection to control unit” to match the GUI. <p>Quick Use Guide: Edited instructions for configuring liquid handler work deck to provide details consistent with updates in section 9.3 as stated above.</p>
2	<ul style="list-style-type: none"> Changed all instances of Flowfect Discover™ to Flowfect Discover™ due to product name change and trademark filing status. Updated image and logo on cover page to use the new Flowfect Discover™ logo. Updated Figure 3 and Figure 4 images to use the new Flowfect Discover™ logos. Changed all instances of Flowfect® Tips to Flowfect Tips™ to reflect current trademark filing status. Changed all instances of Flowfect® Buffer to Flowfect Buffer™ to reflect current trademark filing status. Section 4, Regulatory Information, updated the testing standard from IEC 61010 to UL 61010 to reflect the testing performed; added additional relevant EMC standards and regulations included in the testing. Section 5.1, Reference Material, removed the broken hyperlink to Tecan Operating Manual and added new link to the location on Kytopen’s website. Section 6.3, Software Specifications, changed wording of Google Chrome suggestion from “It is recommended” to “Kytopen recommends using”.

Version	Detailed Description of Change
	<ul style="list-style-type: none"> • Section 7.1, Components, corrected cable connection between liquid handler and control unit to Ethernet • Section 8.3, Installation, added Step 8.3.2.1 with the minimum clearance required around the liquid handler. • Section 8.5, Waste Disposal, added information for carboy waste disposal. • Section 8.6, Maintenance and Cleaning, added subsections: <ul style="list-style-type: none"> ○ 8.6.1 General Maintenance with previous content from section 8.6 ○ 8.6.2 Carboy Maintenance, new section instructing the user on how to maintain carboy levels and waste disposal. ○ 8.6.3 Cleaning Guidelines with previous content from section 8.6 • Section 9.1, Added new step 9.1.4.1 which describes the difference between Plate View and List View for plate configurations. • Section 9.4, Added new step 9.4.1 to instruct the user to check the carboys prior to performing a run. • Section 10.1, Changed title to “Download Kytopen Log Files” • Added new Section 10.2, “Download Tecan Cavro® Magni Flex Log Files” with instructions to retrieve Tecan log files. Renumbered previous section 10.2 about Flowfect® Profiles to section 10.3. • Section 11.1, Error Messages table: <ul style="list-style-type: none"> ○ Added row for “System freezes during a run” ○ For “Z-axis Motor Collision or Stall” row, removed the option to resume run since this is not possible in the GUI. ○ For “Tip pickup issue” row, added “in the correct orientation” and reference to relevant workflow step. ○ For “3 or more tips failed analysis” row, added an explanation and recovery if this scenario was intentional.
3	<ul style="list-style-type: none"> • Updated product image on cover page. • Changed “<i>press</i>” instruction to “<i>tap and click</i>” throughout to make the instructions agnostic of touchscreen and mouse interactions. • Added Section 6.2, Electric Discharge Manifold (EDM) Specifications to include weight and dimensions of the EDM. Subsequent sections were renumbered. • Section 6.4, Software Specification, updated compatible software version to 1.2. • Section 7.1 Components, added SKUs for Kytopen single use components. Added “Contact Kytopen for ordering.” • Section 8.6.2 Carboy Maintenance, changed instruction from “...<i>keeping the input between...</i>” to “...<i>filling the input when it drops between...</i>” • Section 9, Workflow, updated the first part of the note to say, “<i>Occasionally the instruction differs between touchscreen and mouse interactions.</i>” • Section 9.1, Creating a Plate Configuration, updated the following steps: <ul style="list-style-type: none"> ○ 9.1.3, Split sentence into two to accommodate additional optional fields of Flowfect Tips™ and Flowfect Buffer™. Updated screenshot accompanying the instruction to match the updated GUI. ○ 9.1.4, replaced “<i>total volume of cells and payload</i>” with “<i>cell and payload volumes</i>” to match the updated GUI fields.

Version	Detailed Description of Change
	<ul style="list-style-type: none"> ○ 9.1.6, Removed step and accompanying Tip about randomization because the functionality was removed in software version 1.2. ○ 9.1.6 (previously 9.1.7), Updated screenshot accompanying the instruction to match the updated GUI. • Step 9.3.2, added a Note about location orientation for all work deck consumables. • Step 9.3.3, removed “<i>An audible clicking sound should indicate when the tray has snapped into place</i>” from the instruction because there is no audible feedback. • Section 9.2 Importing and Editing Plate Configurations, updated the following: <ul style="list-style-type: none"> ○ Summary, updated the format of the plate to import to .txt and replaced “<i>manually using a template</i>” with “<i>via a Microsoft Excel template...</i>” ○ 9.2.1 Updated screenshot accompanying the instruction to match the updated GUI. ○ 9.2.2 Replaced “<i>Select a plate...</i>” with “<i>Tap or click a plate...</i>” and “<i>... and press Open</i>” with “<i>the plate configuration will open on the subsequent screen</i>” to match new interactions with the updated GUI. Updated the screenshot accompanying the instruction. ○ 9.2.3, Replaced “<i>Clone the plate to edit by pressing the button</i>” with “<i>open the 3-dot menu and tap or click.</i>” Updated the screenshot accompanying the instruction to match the updated GUI. • Section 9.4, Running a Plate Configuration, updated the following steps: <ul style="list-style-type: none"> ○ 9.4.2, Replaced “<i>Select</i>” with “<i>Identify</i>” ○ 9.4.3, Replaced “<i>Press</i>” with “<i>Open the 3-dot menu and tap or click.</i>” Updated the screenshot accompanying the instruction to match the updated GUI. ○ Added new step 9.4.3.1 providing alternate method to start a run from the Plate Configuration page. ○ 9.4.4 and 9.4.5, Updated the screenshot accompanying the instruction to match the updated GUI. ○ 9.4.6, Added “<i>The door will unlock and...</i>” to the instruction. Changed instruction to say Abort Run and Resume Run to match the GUI; updated the screenshot accompanying the instruction to match the updated GUI. ○ 9.4.7, Removed the screenshot. • Section 10.1 Download Kytopen Log Files, updated the following steps: <ul style="list-style-type: none"> ○ 10.1.1, Removed the screenshot. ○ 10.1.2, Changed instruction from “<i>Select the desired run and press View Results to view...</i>” to “<i>Tap or click the desired run to view...</i>” updated the screenshot accompanying the instruction to match the updated GUI. ○ 10.1.3, made the following changes: <ul style="list-style-type: none"> ▪ Replaced “<i>A summary of each well in the plate will be displayed</i>” with “<i>An overview of the plate results including any errors is displayed.</i>”

Version	Detailed Description of Change
	<ul style="list-style-type: none"> <ul style="list-style-type: none"> ▪ Added "<i>Tap or click each well to view a summary and any errors that occurred</i>" to the instruction. ▪ Moved "<i>Tap or click Export Basic Log...</i>" to its own step 10.1.4, subsequent steps renumbered. ○ 10.1.5 (previously 10.1.4), updated the screenshot accompanying the instruction to match the updated GUI. • Steps 10.3.2, 10.3.3, and 10.3.4 updated the screenshot accompanying the instruction to match the updated GUI: • Added Section 10.4, Performing a backup of Flowfect Discover™ • Added Section 10.5, Performing a software update on Flowfect Discover™ • Section 11.1, Error messages: Added image for Automatic Tip Removal to clarify the proper direction of Flowfect Tips™ removal. • Added Section 11.2, Known Issues and Workarounds.

Flowfect Discover™ – Quick Use Guide

<p>Start-up</p>	<p>1 - Turn the Flowfect Discover™ liquid handler and control unit on with the respective power switches.</p> <p>2 - Wait for the first two status lights to be illuminated; the software is now ready to be used on the Touchscreen.</p>
<p>Enter Plate Information</p>	<p>3 - Configure plate with sample volumes, types, and Flowfect® profile to be applied.</p> <p>4 - Tap or click Save to apply the changes.</p> <p><i>Alternatively, import a pre-configured plate by tapping or clicking the Import button.</i></p>
<p>Configure Liquid Handling Deck</p>	<p>5 - Place the Flowfect Tips™ in the Disposable Tip holder on the liquid handler work deck; ensure that the tip tray alignment indicator is in the upper left corner.</p> <p>6 - Place the 96-well plates with payload and cells and the deep well output plate sequentially in the work deck.</p> <p>7 - Always load the work deck from back to front.</p> <p>8 - Remove all lids from consumables on the work deck, working from back to front.</p>
<p>Run and Disassembly</p>	<p>9 - In the Web GUI, select the desired Plate Configuration and tap or click Run.</p> <p>10 - Run Experiment.</p> <p>11 - After run is complete, samples will be in the output deep well plate.</p> <p>12 - Remove the output plate.</p> <p>13 - Review run results using the Completed Runs tab.</p>

Kytopen – Research Use Only

IFU - Flowfect Discover™ (DOC-404) Ver. 3

Approved By:

[\(CO-191\) Release of Flowfect Discover™ Software Version 1.2 Release Notes and updated Flofect Discover Instructions for Use](#)

Description

The release notes include summary of features, fixes, improvements, known issues and workarounds for Flowfect Discover™ Software Version 1.2, for customer use. The IFU was updated to reflect the new software features introduced with software version 1.2.

Justification

Release of Flowfect Discover™ Software Version 1.2.

Assigned To:	Initiated By:	Priority:	Impact:
Naomi Druy	Verona Outerbridge	Medium	Major

Version History:

Author	Effective Date	CO#	Ver.	Status
Naomi Druy	December 13, 2023 11:30 AM EST	CO-191	3	Published
Naomi Druy	July 25, 2023 3:43 PM EDT	CO-175	2	Superseded
Naomi Druy	April 19, 2023 9:32 AM EDT	CO-159	1	Superseded
Naomi Druy	March 31, 2023 10:08 AM EDT	CO-150	0	Superseded