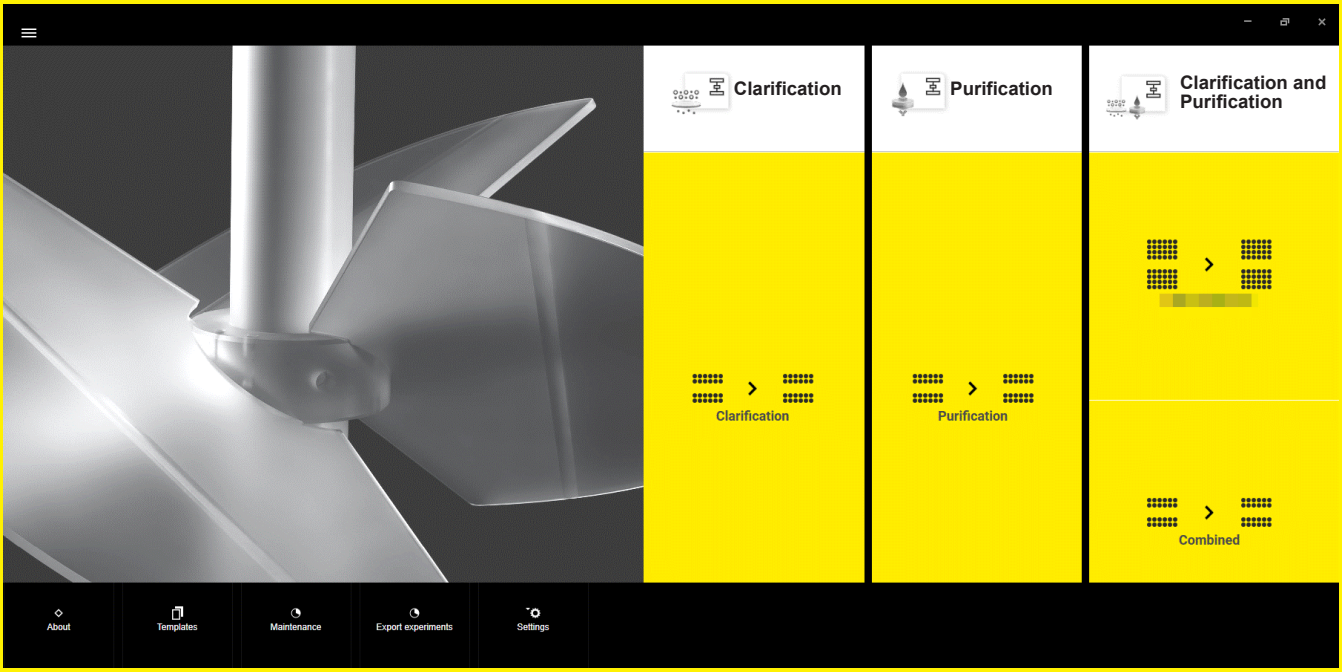
Operating Instructions

Original Operating Instructions

StreamLink CC 15 Software

Software for Controlling the StreamLink CC 15 Automated, High-Throughput System



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Contents

1 About these Instructions

1.1 Scope

These instructions are part of the software. These instructions apply to the software in the following versions:

Software	Version
StreamLink CC 15 software	16.4.0 and higher

1.2 Related Documents

▶ In addition to these instructions, observe the following documentation:
  – Instructions for the StreamLink CC 15 hardware

1.3 Target Groups

Target group	Knowledge and qualifications
User	The user is familiar with the operation of the software and the associated work processes. The user understands the hazards which may arise when working with the software and knows how to prevent them. The user has been trained in the operation of the product.
Operating engineer | laboratory manager	The operating engineer | laboratory manager makes decisions about the use and configuration of the product. The operating engineer | laboratory manager has been trained in the operation of the product.
Administrator	The administrator is responsible for integrating the product into a network or a production process. The administrator ensures the reliable functioning of the product. The administrator has been trained in the operation of the product.

1.4 Symbols Used

▶	Required action: Describes activities that must be carried out. The activities in the sequence must be carried out in succession.
▷	Result: Describes the result of the activities carried out.
[ ]	Refers to operating and display elements. Indicates status, warning, and error messages.

2 Safety Information

2.1 Intended Use

The software must be installed on the supplied control unit. The control unit must be connected to the StreamLink CC 15 device. All process sequences must be controlled on the screen of the control unit.

The process sequences can be adjusted automatically and individually. In order to do this, the process sequences must be defined in templates.

2.2 Performance Specification

The device is provided with pre-set templates for clarification only, purification only and combined processes. The user can define their own templates.

2.3 Automatic Processes

If automatic processes are executed as part of a template: Automatic actions are performed on the hardware, e. g. rinsing the liquid lines with cleaning solution.

If these automatic sequences are interrupted or changed: The processes may be disrupted. This may have unforeseen consequences, e. g. leakage of fluids. Personnel can be injured, e.g. skin irritation, if fluids escape.

- ▶ Do **not** interrupt automatic sequences that are being carried out as part of the template.
- ▶ Do **not** perform any software updates while processes are being carried out on the hardware.

3 Introduction

3.1 User Interface

After starting the software, the main screen is displayed. All other screens can be opened from this main screen.

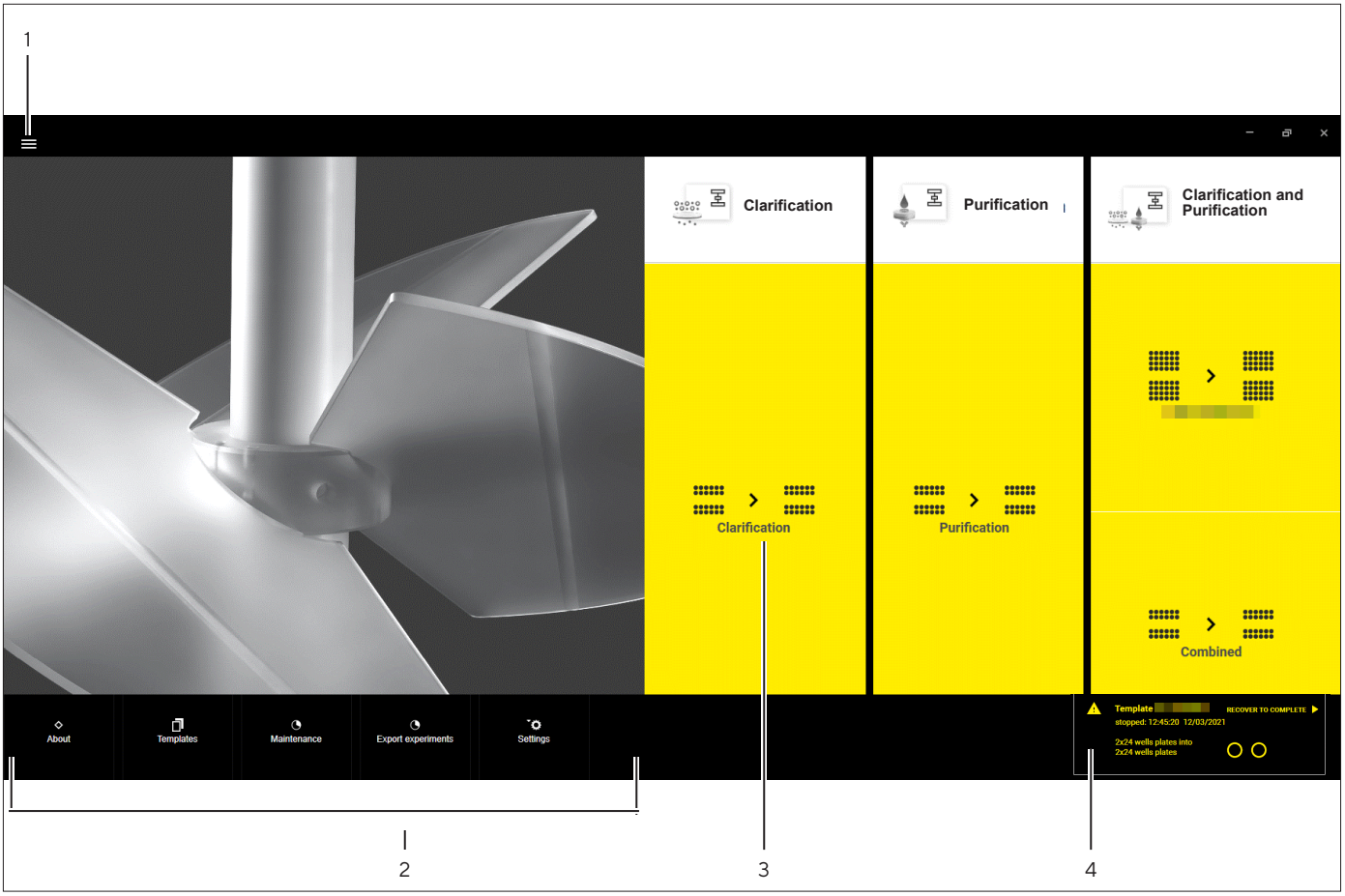


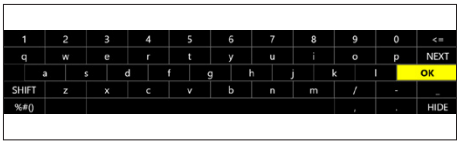
Fig. 1: Main Screen

Pos.	Name	Description
1	[Home] Button	Opens and closes the main screen.
2	Quick links	Opens different submenus, e. g. settings.
3	Last used tiles	Displays latest used templates that enable to access directly to the run menu for starting a run.
4	Last Run Recovery	Is present if the last run was stopped before it was fully completed. Indicates details on the run and option to reload in that run.

3.2 Navigation

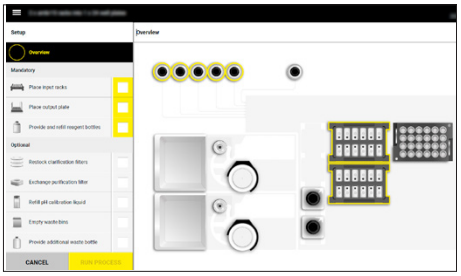
The software can be fully operated by touch. If desired, a mouse and | or keyboard (**not** supplied with the device) can be connected to the control unit.

Procedure



- ▶ Click on an input field.
- ▷ The keyboard slides up automatically.
- ▶ Confirm your entry with [OK].

- ▶ For navigating in the sub menus you can use the button bars at the top of the page or the arrows at the bottom of the page.

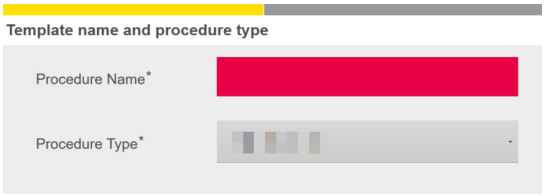
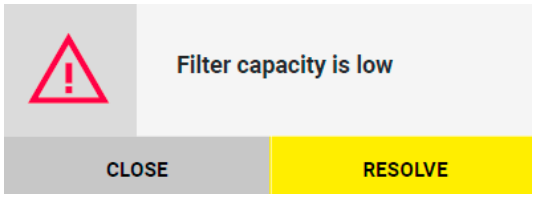
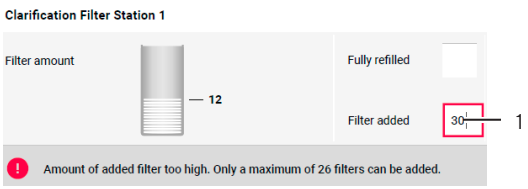
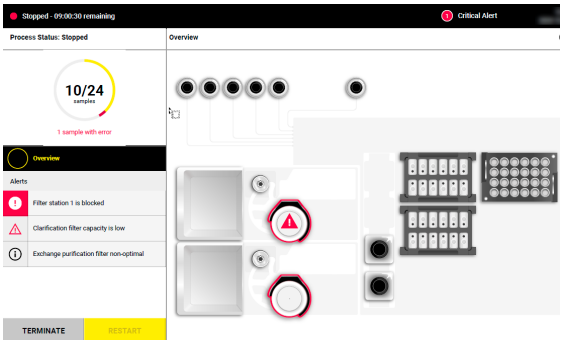
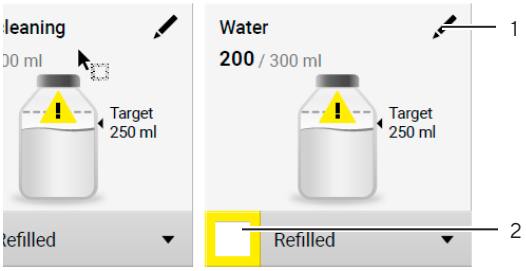


- ▶ Items in the list can be selected to update the mimic | present detailed information | allow updates or the items on the mimic can be clicked to navigate to the same location.
- ▶ Clicking the [Overview] button will bring the mimic back to the high level view.

3.3 Integrated Help | Alerts

The integrated help is displayed at relevant times in the software. They indicate that something needs to be changed in the current settings or that the user needs to confirm a window.

The alerts are shown in the upper right corner of the header. Some alerts can be critical resulting in a process stop.

Help	Procedure
	▷ If the entry in an input field is invalid: The input field is highlighted in red, e. g. in the template creation: ▶ Change the entry in the input field.
	▷ If a system interaction is needed: A help message will be displayed. ▶ Click on [RESOLVE] to see the required actions.
	▷ If the entry in an input field is invalid: The input field is framed in red and a help text is being displayed. ▶ Change the entry in the input field according to the suggested help text (1).
	▷ If an error on the hardware appears: The item of concern is highlighted red and a warning triangle is shown. Help text is also displayed. ▶ Click on the respective item(s). ▶ Follow the required actions. ▶ Click on [RETRY].
	▷ If bottles need to be provided | refilled: A yellow warning triangle will be displayed. ▶ If necessary: Click on the black pencil (1) if more detailed changes are required, e. g. bottle size changes. ▶ Refill the respective bottle. ▶ The drop down can be changed between “Refilled“ and “Filled to target“. ▶ Tick the [Refilled] (2) checkbox to confirm that the bottles are full.

4 Operation

4.1 Creating a Template

In order to run a batch, either pre-set templates can be used or a template can be created in which the different phase parameters are defined for each process.

The software guides through the template creation. It leads through different entry fields which need to be filled out.

Procedure

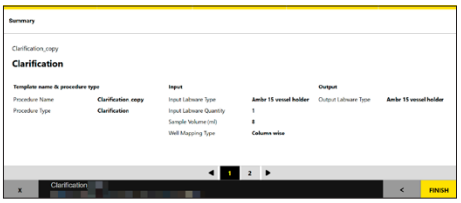
▶ Navigate to the [Templates] screen and use the [+] button to add a new template, or clone an existing template and edit to change.

▶ Name the template and select the procedure type.

▶ Fill out the entry fields according to the desired process making sure the template matches the labware | volumes to be loaded.

▶ If desired: Tick the [Enable 2nd filter] box.
▷ The total number of clarification filters to load might then be higher than the number of samples to process in order to deal with a potential retry.

▶ You can always go back and forth using the arrows in the right corner of the screens.
▷ Validation is performed on parameters to ensure a consistent template run. Errors are shown in red highlight and when the edit box is selected the warning will be presented above the on screen keyboard.
▷ The yellow bar (1) indicates the progress.



▷ A summary of the defined process is shown.

▶ Click on the [FINISH] button in the template menu to save the template and the user. There is no option save an incomplete template.
▷ A run can be now created by using the template.

4.2 Editing an Existing Template

It is possible to edit an already existing template. Note that the predefined templates **cannot** be edited, only clones or new ones.

Procedure

- ▶ In the last used section on the home screen or in the [Templates] screen, double click to edit the selected template.
- ▶ Click on the [Edit] button at the top of the [Templates] screen.

- ▶ Change the entry fields according to the desired process making sure the template matches the labware | volumes to be loaded.

4.3 Running a Batch

In order to start a process on the hardware a batch needs to be created.

The software will guide through the required actions.

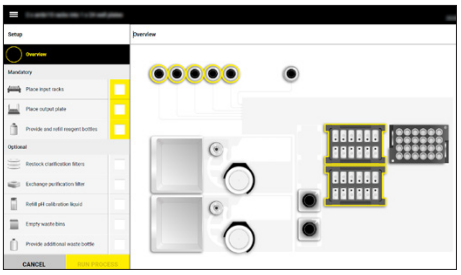
Procedure

- ▶ Choose a template in the [Templates] screen.
- ▶ Click on the [PLAY] button.

- ▶ The last batch can recovered.

Experienced users can now check the check boxes on the main list.

New users can select an item and use the detailed guidance information displayed for each item.



RUN PROCESS

- ▶ Execute the tasks which are being displayed on the screen, e. g. refill the reagent bottles, empty the waste filter container.
- ▶ Execute the tasks in the preferred order.
- ▷ The mandatory tasks are marked yellow as well as the items on the overview. They will loose the yellow marking once completed.
- ▶ After a completion: Click on the checkboxes to mark that a task has been fulfilled.
- ▶ Click on the [RUN PROCESS] button to start a process.

4.4 Interrupting | Resuming to a Running Batch

A running batch can be paused during operation if necessary.

Procedure

- ▶ Click on the [PAUSE] button to stop a process.
- ▷ Actions will continue until the current in progress samples are fully processed. No next samples will be started.
- ▶ Whilst on pause: Items in the [Overview] can be updated, e.g. loading clarification filters | refilling bottles.
- ▶ Once on pause, either close or resume to the batch.

4.5 Exporting Templates

Procedure

- ▶ Select a template in the [Templates] screen.
- ▶ Click on the [Export] button at the top of the screen.

- ▶ Select the export folder, template etc.
- ▶ Click the [OK] button.
- ▷ The file will be created in documents\Templates.

4.6 Reports

When a run is completed: You will be prompted to navigate to the [Report] screen. This page can also be navigated to via the left hand side navigation buttons.

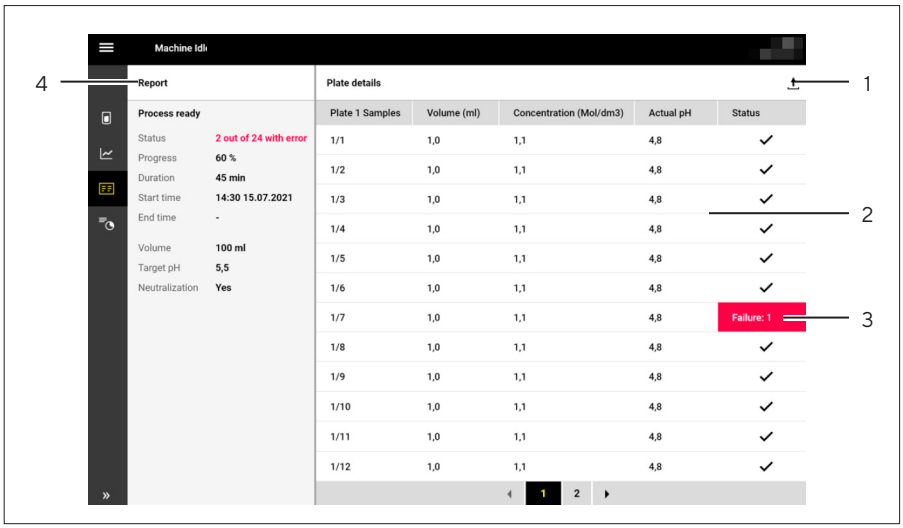


Fig. 2: [Report] screen

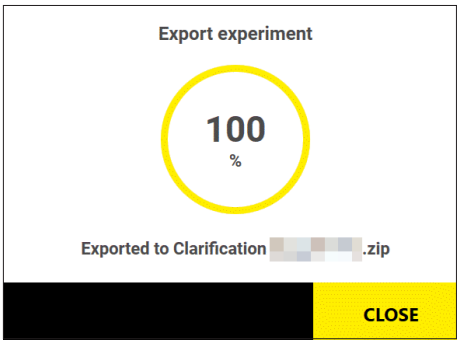
Pos.	Name	Description
1	Export	Produces a file containing the data shown on this page.
2	Error message	Faults are indicated per sample.
3	Sample details	Shows a table with the samples listing out the key variable data for each samples processing.
4	Report	Shows information about the run, e.g. status | time started | samples remaining.

4.7 Exporting Experiments

The [Export experiments] screen is available from the main screen and will list all the experiments which have been saved on a local device.

Procedure

- ▶ In the main screen, click on the [Export experiments] button.
- ▶ Select an experiment and click the [Export] button on the top to zip up the data.



- ▷ The file is stored automatically in the local Documents\StreamLink CC 15\Exports folder. It can be copied off to another machine to be used, e.g. an external data viewer program.

4.8 Settings

4.8.1 System Settings

Procedure

▶ Click on the [Settings] menu in the quick links and select [System].
▷ These settings, among others, can be adjusted:

Parameter	Setting Values	Description
GENERAL SETTINGS		
Show units conversion tool tip	Activated | deactivated	Can be activated | deactivated to display the conversion to another unit.
SYSTEM SETTINGS		
Number of filter stations*	1 | 2	Displays the currently used number of filter stations.
FILTER STATION CONNECTION SETTINGS		
Is Emulated	Activated | deactivated	Defines whether the software is to be connected to an emulation program or to the physical filter stations: — When emulation mode is activated: The software starts and connects to the emulation program. — When emulation mode is deactivated: The software connects to the filter stations at the start of a batch.
LIQUID HANDLER BASE CONNECTION SETTINGS		
Is Emulated	Activated | deactivated	Defines whether the software is to be connected to an emulation program or to the physical liquid handler base: — When emulation mode is activated: The software starts and connects to the emulation program. — When emulation mode is deactivated: The software connects to the liquid handler base at the start of a batch.
LIQUID HANDLER HEAD CONNECTION SETTINGS		
Is Emulated	Activated | deactivated	Defines whether the software is to be connected to an emulation program or to the physical liquid handler head: — When emulation mode is activated: The software starts and connects to the emulation program. — When emulation mode is deactivated: The software connects to the liquid handler head at the start of a batch.

Parameter	Setting Values	Description
PERIODIC FILE EXPORT SETTINGS		
Periodic export enabled	Activated | deactivated	Defines whether process data should be exported as a csv file on a regular basis. The target folder or the export template can be selected.
Periodicity	30 s – 5 m	Defines the export cycles.
TEMPLATE PHASE VERSION		Displays the selected version of the phases.
PASSWORD SETTINGS		
Maintenance password*		Used for managing the maintenance password. The maintenance password is required to carry out certain functions, e.g. to change the number of filter stations.
Firmware password*		Used for managing the firmware password. The firmware password is required to approve certain functions of the firmware.
* Password required		

▶ Follow the instructions on the screen and apply the desired settings.
▷ The settings are saved and immediately implemented.

4.8.2 Licences

In this menu, “Core“ and “Online Control“ modules are presented with the current status, e.g. expired | licensed.

Procedure

▶ Click on the [Settings] menu in the quick links and select [Licenses].
▶ To request keys, click on the [GET KEY] button.
  ▶ If there is connection to the internet and an installed e-mail client: Select [CREATE E-MAIL].
  ▷ A pop-up opens with all relevant information appears.
  ▶ Alternatively, click on [COPY] in order to have the relevant information copied.
  ▶ Send the information to the respective e-mail address.
▶ Once the keys are received: Click the [ENTER KEY] button, paste or type in the key and confirm with the [ACTIVATE] button.

4.8.3 E-mail Settings (Release 8 only)

Procedure

▶ Click on the [Settings] menu in the quick links.
▶ Click on the [EMAIL] tab.
▷ These settings, among others, can be adjusted:

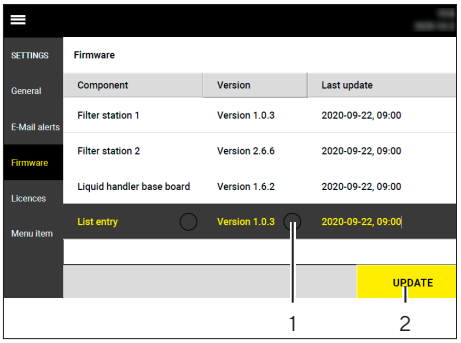
Parameter	Setting values	Explanation
SEND MAIL (SMTP)	Activated | deactivated	Defines if the software can send status e-mails.
Support SSL	Activated | deactivated	Defines if SSL should be used.
RECEIVE MAIL (IMAP)	Activated | deactivated	Defines if the software can receive status e-mails.

Parameter	Setting values	Explanation
User Details		
Active	Activated | deactivated	Defines if a user profile is activated or deactivated for receiving status e-mails.
Email address	HTML | HTML for mobile phones | Text only | Short form	Defines the format of the status e-mails, e.g., HTML, text only.
Day time | Night time | Weekends	Activated | deactivated	Defines when status e-mails should be sent, e.g., during the day, at the weekend.
Send channel alarms | Send hardware fault...| Send user prompt alerts | Send status emails	Activated | deactivated	Defines which information should be sent in the status e-mails, e.g., alarms.

▶ Follow the instructions on the screen and apply the desired settings.
▷ The settings are saved and immediately implemented.

5 Updating the Firmware

Procedure



▶ Click on the [SETTINGS] menu and select [Firmware].
▷ The screen shows the components, version numbers and the date of the last update.
▶ Select the required update (1).
▶ Click on the [UPDATE] (2) button.

▷ The updates are being installed.

6 Maintenance Operations

The [Maintenance] screen is available from the main screen. Maintenance operations have to be executed outside of an active run.

There are categories available on the left side navigation section. Each section will contain a list of operations in the main table section from which can be chosen. A brief description and “last executed” are shown.

6.1 General Maintenance Operations

Procedure

- ▶ Select the desired maintenance operation, e.g.:
  - Priming the liquid lines
  - Calibrating the pH probe
  - Draining the liquid lines
  - CIP
  - ...
- ▶ Click the [START] button to activate the desired maintenance operation.
- ▷ A mimic is shown.
- ▶ Execute the tasks which are being displayed on the screen.
- ▷ The automated operation will start once the appropriate step is acknowledged.
- ▶ The estimated time remaining and results at the end will be displayed.

6.2 Teaching the Pipette Tip Position

At the initial setup or after a new tip has been installed: The position of the tip needs to be taught by a supervisor or service user.

The teach panel is a standalone application linked to the StreamLink CC 15 software. Teaching is done with one type of labware. This will allow accessing of all different labware types from the main application.

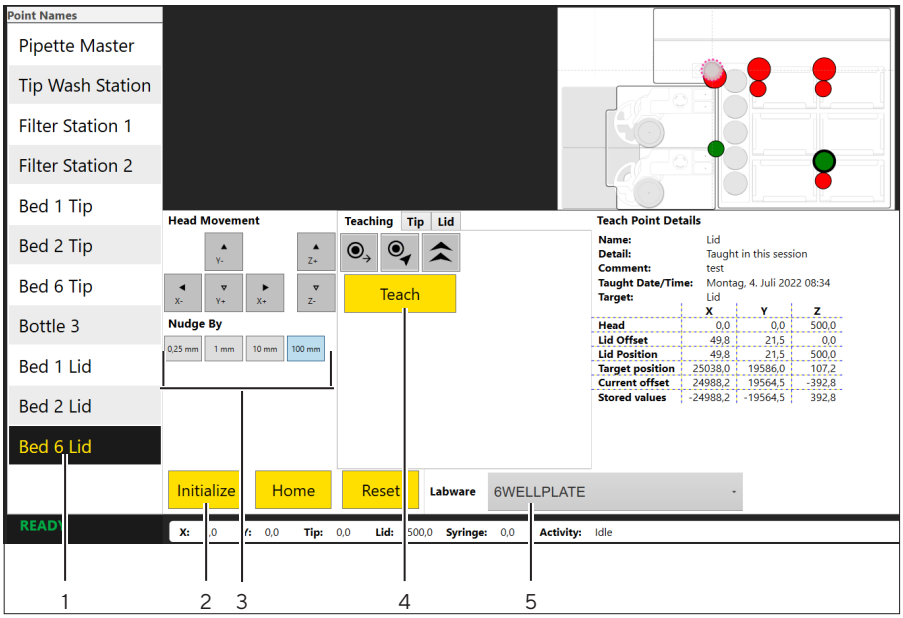
Requirements

For lid | labware teaching: The labware to be loaded has been selected.

Procedure

▶ Start the StreamLink CC 15 Teach Panel.

▶ Check the labware selected (5).
▶ Click the [Initalize] (2) button.
▶ Select the [Pipette Master] teach point first from the visualized map or from the list (1):



▶ Use the respective buttons (3) to change the position.
▶ Click the [Teach] (4) button.
▶ Repeat this for any other teach point in any order.
▷ The teach points turn green after being taught and the teach point details are described in the table to the right.
▷ There are options to check teach points by going back to the locations or attempt to pick lids | wells.

7 Troubleshooting

7.1 Disruptions in Process Sequence

Fault	Cause	Correction	Chapter, page
A template **cannot** be started.	The template contains errors or the settings are incorrect.	The software guides through required troubleshooting actions.	
A template **cannot** be started.	The software is unable to connect to the hardware.	Check whether the emulation mode is activated.	
		If required: Deactivate the emulation mode.	4.8.1, 13
	The control unit is **not** connected to the hardware.	Check the connection from the control unit and hardware (how to connect see instructions for the StreamLink CC 15 hardware).	
	The licenses for the product are **not** acitvated.	Activate the licenses.	4.8.2, 14

7.2 Checking Exception Errors

If an exception error occurs, e. g. a template **cannot** be loaded or settings are incorrect: A display containing information on the exception error opens.

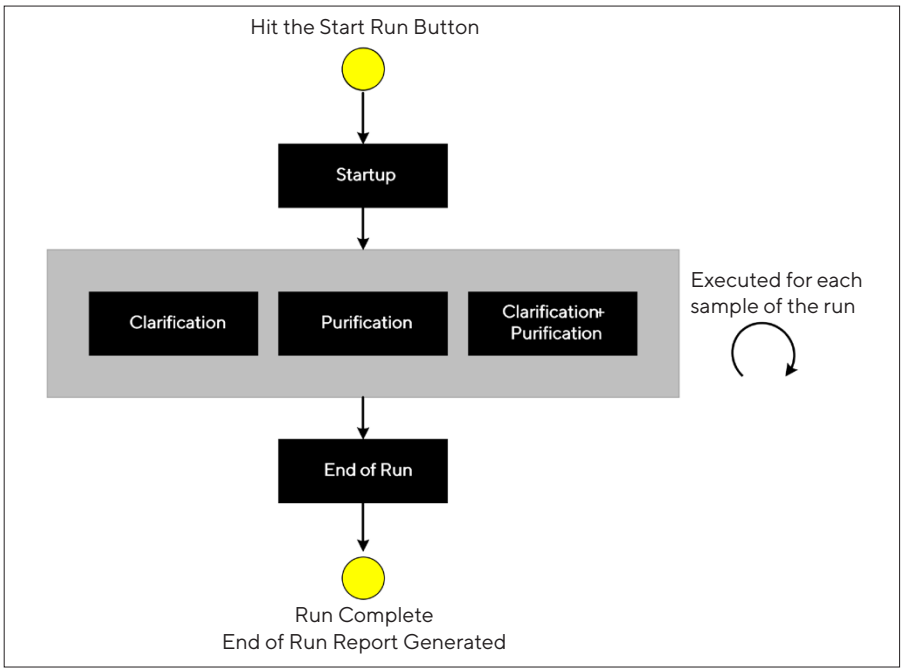
Procedure

- ▶ Check the description of the exception error in the [EXCEPTION ERROR] display.
- ▶ Close the display. To do this, click on the [FINISH] button.
- ▶ Repeat the procedure.
- ▶ If the exception error occurs again: Click on the [DETAILS] button.
- ▷ The details are shown.
- ▶ Click on the [Copy] button.
- ▷ The error description is copied to the clipboard.
- ▶ Copy the error description into a text processing program or email program, and send to the e-mail address Royston-Support@Sartorius.com.

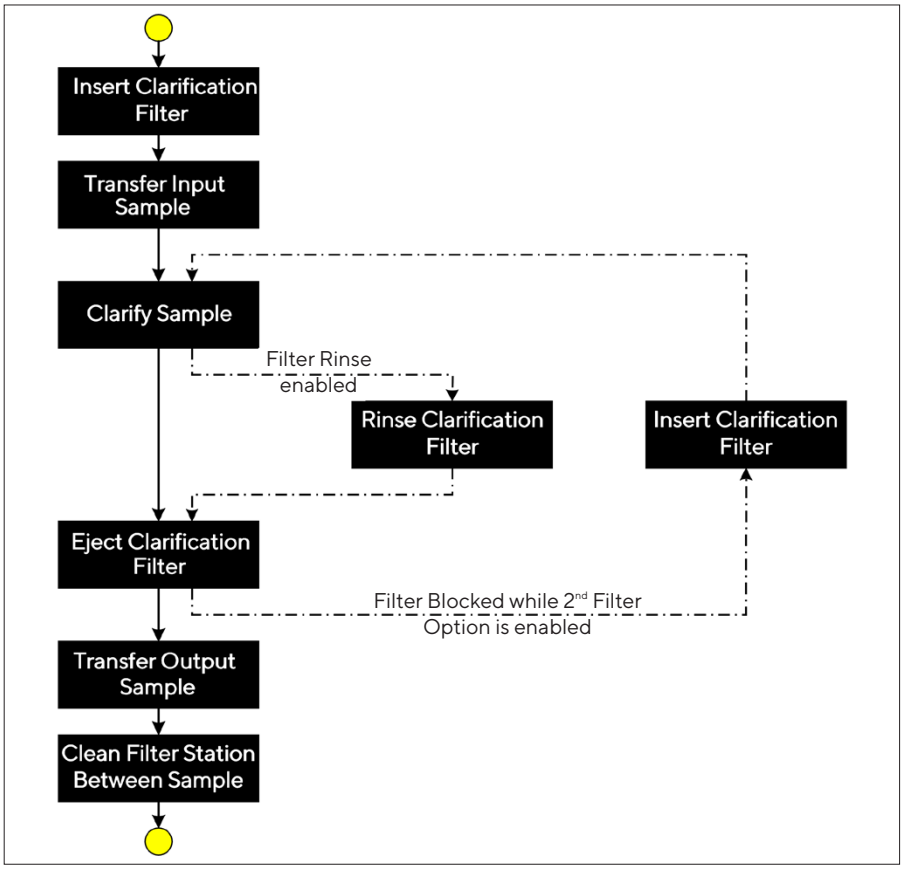
8 Appendix

8.1 Process Flowcharts

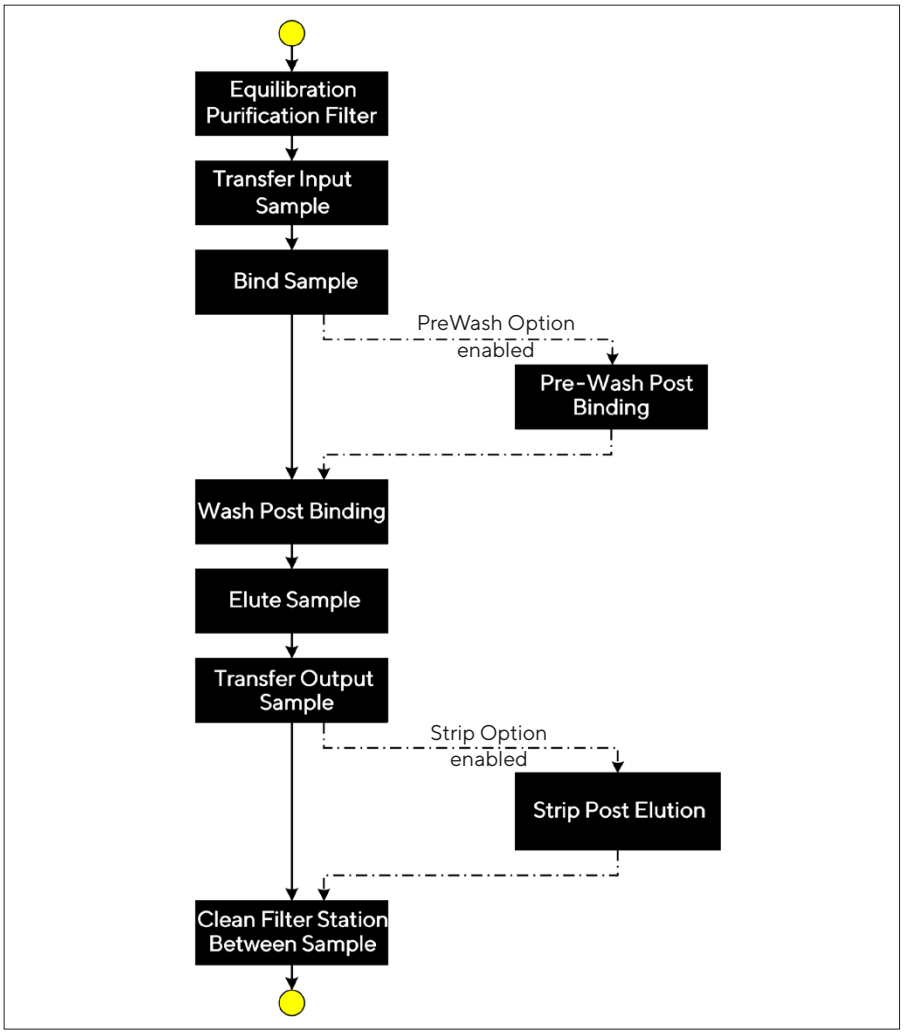
8.1.1 Complete Run Process Flowchart



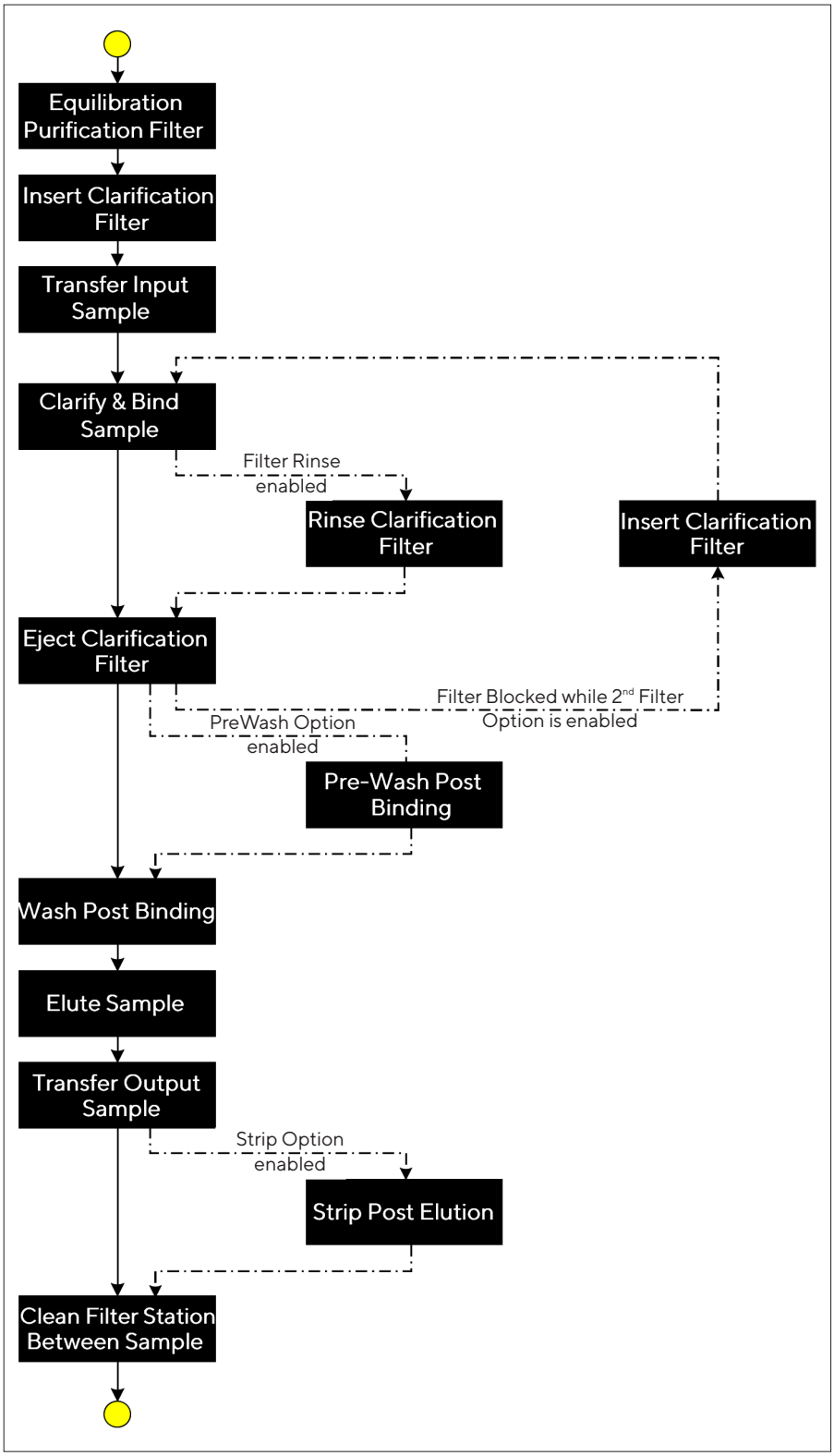
8.1.2 Clarification Run Process Flowchart



8.1.3 Purification Run Process Flowchart



8.1.4 Combined Run Process Flowchart



8.2 Description of the User Phases

User Phase Name	Description	Applicable Template
Bind Sample	After loading the sample in the filter station, pump it through the purification filter to capture the product.	Purification
Clarify and Bind Sample	Pump the sample through the clarification filter to remove large particulate. The filtered sample is directly loaded into the purification device to capture the product.	Clarification + Purification
Clarify Sample	Pump the sample through the clarification filter to remove large particulate.	Clarification
Clean Filter Station between Sample	Circulate several cycles of buffer and NaOH through the system flowpath, purification device and cups to clean the filter station and avoid carryover between samples.	Clarification Purification Clarification + Purification
Eject Clarification Filter	Eject a used clarification filter after a sample has been filtered. It then pushes the clarified sample remaing in the flowpath in the purification device and flush cells from the upstream flowpath to prepare for pumping buffer during purification.	Clarification Clarification + Purification
Elute Sample	Pump elution buffer through the purification filter to recover the captured protein. It comes in 2 versions depending if the peak cutting option is selected or not. — No peak cutting selected: The system collects all of the elution as output sample to be collected. — Peak cutting: The collection of the eluted output sample is based on UV absorbance threshold defined by the user to islate a peak of protein concentration.	Purification Clarification + Purification
Equilibrate Purification Filter	At the start of a sample process involving purification, flow through equilibration buffer to ensure the purification filter has a stable neutral pH. It also calibrates the UV sensor with the elution buffer absorbance.	Purification Clarification + Purification
Insert Clarification Filter	Insert a new clarification filter in the filter station and then, check correct clamping of the clarification filter after insertion via hold up pressure test.	Clarification Clarification + Purification
Neutralize Output Sample		Purification Clarification + Purification
Pre-Wash Post Binding	After loading the purification filter with sample, pump through the purification filter rinse buffer to wash any remaining waste and particulate other than the product itself (LDH, DNA, HCP...). This an optional post binding wash to enable using another type of buffers.	Purification Clarification + Purification
Recover From an Anomaly		Clarification Purification Clarification + Purification
Rinse Clarification Filter	After pumping the sample through the clarification filter, flush it with buffer to limit product loss because of hold-up volume. It is an optional phase.	Clarification Clarification + Purification

User Phase Name	Description	Applicable Template
Strip Post Elution	After collection of the eluted sample, pump through the purification filter some buffer with low pH to strip any remaining binded and remaining protein from the device. This is an optional phase.	Purification Clarification + Purification
Transfer Input Sample	Use the liquid handler to transfer a sample from the input bed location to the input cup of a filter station.	Clarification Purification Clarification + Purification
Transfer Output Sample	Use the liquid handler to transfer a sample from the output cup of a filter station to the dedicated output bed location.	Clarification Purification Clarification + Purification
Wash Post Binding	After loading the purification filter with sample, pump through the purification filter rinse buffer to wash any remaining waste and particulate other than the product itself (LDH, DNA, HCP...).	Purification Clarification + Purification

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The information and figures contained in these instructions correspond to the version date specified below.
Sartorius reserves the right to make changes to the technology, features, specifications and design of the equipment without notice.
Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote all genders.

Last updated:

10 | 2022

LM | Publication No.: SPC6078-e221001