Operating Instructions
Original Operating Instructions

StreamLink® CC 15

Automated, High-Throughput System for Clarification & Purification of mAb-Expressing Cultures

1000124755

SARTORIUS

Contents

1 About this Document

1.1 Scope

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

Device	Type
StreamLink® CC 15, comprising of:	061-8B01
2 filter stations	44-SLC15-F[****]
1 liquid handler	44-SLC15-L[****]

1.2 Accompanying Documents

- ▶ In addition to these instructions, observe the following documents:
  - StreamLink® CC 15 Software Operating Instructions
  - Instructions of the consumables, accessories, e.g., Sartobind® Rapid A Nano, Sartoclear® Disc, bottles for liquids etc.

1.3 Target Groups

The instructions are designed for the following target groups. The target groups must possess the knowledge listed below.

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

1.4 Symbols Used

1.4.1 Warnings in Operation Descriptions

⚠ WARNING
Denotes a danger with risk that death or severe injury may result if it is **not** avoided.

⚠ CAUTION
Denotes a hazard that may result in moderate or minor injury if it is **not** avoided.

NOTICE
Denotes a danger with the risk that property damage may result if it is **not** avoided.

1.4.2 Other Symbols

▶	Required action: Describes actions which must be carried out. The actions in the sequence must be carried out in succession.
▷	Result: Describes the result of the actions carried out.

2 Safety Instructions

StreamLink® CC 15 is a high-throughput system capable of automating clarification and | or purification processes for mAb-expressing cell culture samples derived from Ambr® 15 or any other suspension cell culture. The processed culture samples are delivered for subsequent offline analysis.

2.1 Intended Use

The device is designed for automated clarification and | or purification of low volume mAb-expressing cell culture samples. It is designed for research use only.

The device is suitable for the high-throughput processing of 10 ± 5 mL input volumes. The device can work outside of this range with degraded performance, e. g. lower recovery and | or longer execution times.

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

For the control of the clarification and | or purification processes, only the supplied control unit and the StreamLink® CC 15 software may be used.

The device is designed for processes involving Group 1 or 2 biological agents. Do **not** use the device for processes involving Group 3 or 4 biological agents (pursuant to Directive 2000/54/EC).

The clarification filters are designed for single-use and must be disposed of after use.

The device is intended exclusively for use in accordance with these instructions. Any further use beyond this is considered **improper**.

If the device is used **improperly**: The device's protective systems may be impaired. This can lead to unforeseeable personal injury or property damage.

The device is **not** a GMP product and | or **not** intended for use in the manufacturing of pharmaceutical products.

Operating Conditions for the Device

Do **not** use the device in potentially explosive environments. The device may only be used indoors in a standard laboratory environment.

Only use | connect approved filters, liquid lines and liquids to | on the device (for further information contact Sartorius).

2.1.1 Foreseeable Misuse

It is only safe to use the device when operated in accordance with its intended use. The following applications, for example, are **not** permitted:

- using the device as an *in vitro* diagnostic | medical device
- using the device outside the operating parameters, operating conditions, ranges and typical values

2.1.2 Modification to the Device

If the device is modified in any way: The safety of the device may be impaired or the device compliance may lose its validity.

The device may only be used with the equipment and under the operating conditions described in the Technical Data section of these instructions.

If you have questions about modifications to the device, contact Sartorius.

2.1.3 Device Repairs and Maintenance

Device repairs and maintenance may only be carried out by persons with appropriate specialized knowledge. If the device is **not** repaired or serviced by a specialist: The safety of the device may be impaired or the calibrations may lose their validity.

We recommend that any repair work, even that **not** covered by the warranty, is carried out by Sartorius Service or after consulting Sartorius Service.

Only carry out the maintenance work described in these instructions. For maintenance work that has to be carried out by Sartorius Service, contact Sartorius Service.

2.2 Personnel Qualification

If people who do **not** have sufficient knowledge on the safe handling of the device carry out work on the device: Those individuals may injure themselves or other persons nearby.

- ▶ Ensure that all individuals working on the device possess the necessary knowledge and qualifications (see chapter “1.3 Target Groups”, page 6).
- ▶ If a particular qualification is required for the actions described: Have these activities carried out by the required target group.
- ▶ If **no** particular qualification is required for the actions described: Have these activities carried out by the “user” target group.

2.3 Significance of these Instructions

Failure to follow these instructions might have serious consequences, e. g. danger to individuals.

- ▶ Read the instructions carefully and in full. The required actions in the instructions build on each other.
- ▶ Ensure that the information contained in these instructions is available to all individuals working on the device.
- ▶ Retain the instructions.
- ▶ If these instructions are lost, request a replacement.

2.4 Device Functionality

A damaged device or worn-out parts can cause malfunctions or lead to hard-to-detect hazards.

- ▶ Only operate the device when it is safe and in proper working order.
- ▶ Comply with the maintenance intervals.
- ▶ Have any damage repaired immediately by Sartorius Service.

2.5 Safety Equipment

The covers of the device protect persons who work with the device against the hazards and harms associated with it, e. g. electrical current. If the device's safety equipment is disassembled or modified: People may be seriously injured.

- ▶ Do **not** disassemble, modify, or disable the covers of the device.

2.6 Safety Information on the Device

Symbols, e. g. warnings and safety stickers, are safety information for handling the device. Missing or illegible safety information may lead to serious injuries (see chapter "3.12 Symbols on the Device", page 26).

- ▶ Do **not** conceal, remove, or modify the symbols.
- ▶ Replace the symbols if they become illegible.

2.7 Electrical Equipment

2.7.1 Damage to the Electrical Equipment of the Device

Damage to the electrical equipment of the device, e. g. damaged insulation, can be life-threatening. Contact with parts at high voltage represents a danger to life.

- ▶ If the electrical equipment of the device is defective, immediately switch off and disconnect the mains power supply.
- ▶ Keep live parts away from moisture. Moisture can cause short circuits.
- ▶ Contact Sartorius Service.

2.7.2 Power Block and Power Supply Cable

Serious injury can result, e. g. from electric shocks, if an unsuitable | inadequately rated power supply cable or unsuitable power supply unit is used.

- ▶ The device must be connected to earth at all times.
- ▶ Only use the original power block and original power supply cable.
- ▶ If the power block or power supply cable needs to be replaced: Please contact Sartorius Service. Do **not** repair or modify the power supply unit or power supply cable.

2.8 Conduct in an Emergency

If there is immediate danger of personal injury or equipment damage, e. g. due to malfunctions or dangerous situations, take the device out of operation immediately.

- ▶ Switch off the device at the main switch.
- ▶ Disconnect the mains plug on the power supply connection cable from the power supply at the installation site.
- ▶ Have any malfunctions repaired immediately by Sartorius Service.

2.9 Accessories, Consumables and Spare Parts

The use of unsuitable accessories, consumables and spare parts can affect the functionality and safety of the device and have the following consequences:

- — Risk of injury to persons
- — Damage to the device
- — Device malfunctions
- — Failure of the device

- ▶ Only use approved accessories, consumables, and spare parts supplied by Sartorius.
- ▶ Only use accessories, consumables, and spare parts that are in good working order.

2.10 Personal Protective Equipment

Personal protective equipment protects against risks arising from the device. If the personal protective equipment is missing or unsuitable: People might get injured.

Protective equipment designation	Explanation | examples
Safety glasses	Protect eyes against chemical spray, e. g. NaOH.
Safety gloves	Protect against chemicals and injuries.
Protective work clothing	Lab coat: Protects against chemicals and injuries.

- ▶ Wear appropriate personal protective equipment.
- ▶ Tie your hair back.
- ▶ If the operating area, or the process in which the device is used, requires additional safety precautions: Wear the additional personal protective equipment.

2.11 Pump Pressure

The peristaltic pump can create high pressure: Liquid lines can burst and can cause injury, e. g. burns to the skin and permanent eye injury.

- Do **not** clamp or block the liquid lines.
- Do **not** change the purification filters during operation.
- During the process, only perform work on the device that is requested of the user on the screen of the control unit.
- Do **not** remove the purification filter when still under pressure or if it still contains cleaning solution.
- Check the connections of the liquid lines before use.
- Check that the liquids have been loaded correctly.
- Wear personal protective equipment.

2.12 Leakage of Cleaning Solution during Automatic Cleaning

When the device is cleaned automatically, all components supplying fluid are cleaned. In this process, cleaning solution is pumped through the liquid path of the filter station at low pressure.

2.12.1 Damaged or Unsuitable Liquid Lines

If liquid lines are damaged, incorrectly connected, or unsuitable: The cleaning solution may leak out uncontrollably and injure personnel, e. g. causing burns to the skin and permanent eye injury.

- Only use liquid lines approved and recommended by Sartorius.
- Install all parts of the liquid lines in the order described.
- Do **not** modify the liquid lines.
- Check the liquid lines for any visible damage, blockages, or detached connections before automatic cleaning begins.
  - If required: Replace damaged or blocked liquid lines. Connect any detached liquid lines to the device (see chapter “15.1 Accessories”, page 66).
- Wear personal protective equipment.

2.12.2 Blocked Liquid Lines

If parts of the liquid lines become blocked: Overpressure may occur in the liquid lines, causing the cleaning fluid to be pumped through the liquid lines at high pressure.

The overpressure may cause damage to parts of the liquid lines, cleaning solution may leak out uncontrollably and this may injure personnel, e. g. causing burns to the skin, permanent eye injury.

- Only use liquid lines approved and recommended by Sartorius.
- Install all parts of the liquid lines in the order described.
- Do **not** seal or clamp off the waste fluid outlet of the waste liquid line. The cleaning solution must be able to run off unobstructed.
- If the waste bottle is full: Empty the waste bottle. Follow the prompts on the screen of the control unit.

- If a blocked liquid line is displayed as a fault on the screen of the control unit: Follow the commands on the screen of the control unit and replace the liquid lines affected.
- The rinsing | cleaning is an automatic process. Do **not** leave the device in an unclean state.
- Wear personal protective equipment.

2.12.3 Incorrectly Connected Liquid Lines or Bottles for Liquids

If the liquid lines are incorrectly connected to the device or the bottles for liquids: The (automatic cleaning) process **cannot** be correctly performed. This can cause the cleaning solution and other liquids to escape uncontrollably and cause injuries, e. g. causing burns to the skin and permanent eye injury.

- Observe the correct assignment of the bottles for liquids and the liquid lines:
  - The cleaning solution bottle must be connected to the [NaOH] connection.
  - The waste bottle must be connected to the “Waste” outlet.
  - The waste liquid line and other liquid lines must **not** be allowed to come loose, kinked or blocked during operation.
  - The buffers supply and waste bottles are correctly connected to the system liquid line.
  - The liquid line ends at the bottom of the bottle.
- Wear personal protective equipment.
- Fittings must be free of damage, correctly fitted and leak free.
- If liquid lines are damaged, kinked of blocked: Replace them with the liquid lines approved and recommended by Sartorius.
- Before starting a process: Ensure that the amount of buffer in the bottles is sufficient.
- The waste filter container must be emptied after each run.

2.12.4 Incorrect Performance of Automatic Cleaning

If the automatic cleaning is **not** performed correctly, e. g. with inadmissible cleaning solution: The cleaning solution can escape uncontrollably and cause injuries, e. g. causing burns to the skin and permanent eye injury.

- Do **not** connect [NaOH] to any other inlet connection as this may cause the pressure to exceed the admissible pressure during automated cleaning.
- Only use approved cleaning solutions.
- Wear personal protective equipment.

2.12.5 Leaking Cleaning Solution

If the cleaning solution has leaked: The cleaning solution can cause injuries, e. g. causing burns to the skin and permanent eye injury.

- If the cleaning solution came in contact with skin or eyes: Immediately rinse the affected parts of the skin or eyes with water and follow emergency safety procedures to minimise injury.

- ▶ Observe the safety and occupational health and safety information for the cleaning solution being used, e. g. handling, storage and conduct in emergency situations.
- ▶ Clean the device.

2.13 Leaking Liquids in the Device

The peristaltic pump conveys liquids through the liquid lines and around the filter stations, and the liquid handler robot moves liquids around the device.

If the liquid lines or bottles are damaged: The liquids can escape uncontrollably. Persons can slip or be injured, e. g. causing burns to the skin and permanent eye injury.

- ▶ Wear personal protective equipment.
- ▶ If liquids came in contact with skin or eyes: Immediately rinse the affected parts of the skin or eyes and follow emergency safety procedures to minimize injury.
- ▶ Observe the safety and occupational health and safety information for the process fluids and system fluids being used, e. g. handling, storage and conduct in emergency situations.
- ▶ Clean the device.

2.14 Residual Cleaning Solution

If there is residual cleaning solution in the device or liquid line, e. g. after a power failure or after a control unit crash: The cleaning solution can cause injuries, e. g. causing burns to the skin and permanent eye injury.

- ▶ Wear personal protective equipment.
- ▶ The cleaning solution must be removed from the device and the liquid line as required.

2.15 Unsuitable Liquids

Using unsuitable liquids may carry the danger of chemical burns and damage to the device.

- ▶ Use only liquids suitable for the device.
- ▶ Observe the safety and occupational health and safety information for the liquids being used, e. g. handling, storage and conduct in emergency situations.
- ▶ Do your own risk assessment according to the local guidelines and WHO guidelines regarding biohazards and safety levels when using other liquids than recommended.

2.16 Working on the Device

During the process, only perform work on the device that is requested of the user on the screen of the control unit. If unrequested work is carried out on the device during the process: The process can be disturbed. This may have an unforeseeable impact and may cause injuries, e. g. skin injuries caused by leaking process solutions.

- During the process, only perform work on the device that is requested of the user on the screen of the control unit.
- If liquids have leaked: Follow the safety and occupational health and safety information for the process solutions or system fluids used, and clean the device.

2.17 Magnetic Forces

Some device covers, the peristaltic pump covers, the waste filter containers, the connection between the filter station and the liquid handler base are secured to the housing of the device using magnets. Magnets can interfere with pacemakers or other medical implants. People with pacemakers or other medical implants can be affected.

- Those with pacemakers or other medical implants must maintain a safety distance of at least 0.1 m from the device.
- Identify the danger of magnetic forces at the installation site.

2.18 Rotating or Moving Parts

2.18.1 Peristaltic Pump

When the liquid lines are inserted into or removed from the peristaltic pump: The peristaltic pump must be switched off. Fingers could be injured if the rotating pump heads are touched.

- Disconnect the device from the power supply before performing any work on the peristaltic pump.
- During the purification and clarification process, do **not** touch the pump heads.
- Wear personal protective equipment.
- Tie your hair back.

2.18.2 Clarification Filter Clamp, Index Wheel and Filter Holder

When new clarification filters are inserted into or removed from the filter stations during operation: Fingers could be injured if touched during operation.

- Do **not** insert fingers or foreign objects into the clarification filter clamp or index wheel during operation.
- Do **not** touch or block the clarification filter clamps and purification filter holder during operation.
- Wear personal protective equipment.
- Tie your hair back.

2.18.3 Liquid Handler Robot

If body parts come into contact with the liquid handler robot while in operation: Body parts could get caught. This can lead to injuries.

- Do **not** insert fingers or foreign objects into the liquid handler robot and keep clear of the liquid handler when in operation (orange light on the robot head is lit when active).
- The liquid handler robot head should be free to move during operation.
- Wear personal protective equipment.
- Tie your hair back.
- Do **not** operate the device with a damaged | bent pipette tip (see chapter “9.5 Recovering from a Bent Pipette Tip”, page 55).

2.18.4 Filter Station

When liquid is moved from vessels on the liquid handler bed to the filter station and vice-versa while the user has left obstructions on the bed or nearby the device: The liquid handler can crash | the pipette tip can get bent which can lead to injuries.

- The liquid handler bed and filter station should be free of obstacles during operation.
- Make sure that the appropriate lids for the loaded labware holder and microplate holders are in place.
- Make sure that the labware items containing the samples are suitable for the labware holder used.

2.19 Ergonomics When Working on the Device

To reduce stresses for all persons working on the device, observe the following requirements:

- Set up the control unit so that all persons can work comfortably.
- Limit the weight of bottles for process solutions that are installed on the device. To do so, use bottles with a low volume, for example, or do **not** fill large bottles to the top.
- Set up the waste container in an easily accessible position.

3 Device Description

3.1 Device Overview

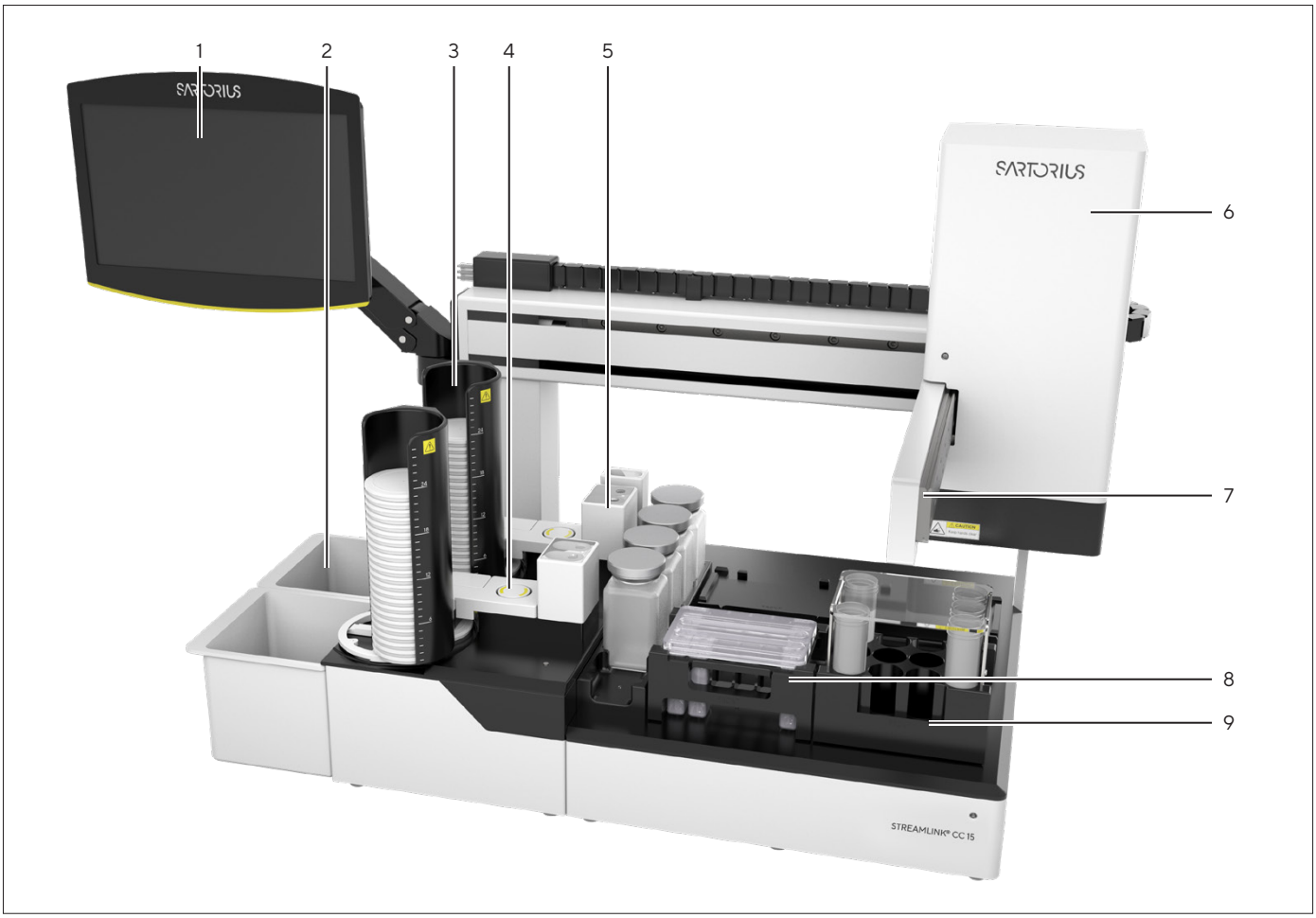


Fig. 1: StreamLink® CC 15 (front view)

Pos.	Name	Description
1	Control unit	Controls the processes. Contains the StreamLink® CC 15 software.
2	Waste filter container	Collects the used filters.
3	Clarification filter stack holder	Holds the clarification filters.
4	Filter station peristaltic pump	The main pump used for clarification and purification processes.
5	Input | output cups	For samples. They have a cover to minimize dust ingress.
6	Liquid handler head	Encloses the pipette and lid picker.
7	Liquid handler robot	Moves the liquid handler head to transfer samples.
8	Input Samples	To be clarified and | or purified.
9	Output Samples	Samples that have been clarified and | or purified.

3.2 Filter Stations

Each filter station has 1 clarification filter stack holder.

Fig. 2: Filter station

Pos.	Name	Description
1	Clarification filter clamp	Holds the clarification filter during clarification.
2	Clarification filter index wheel	Moves clarification filter from the clarification filter stack holder to the clarification filter clamp and then to the waste filter container.
3	Purification filter luer lock thumbwheel	Holds the purification filter in place.
4	Purification filter	
5	Purification filter holder	Slides up and down to clamp or release the purification filter.

3.3 Liquid Handler

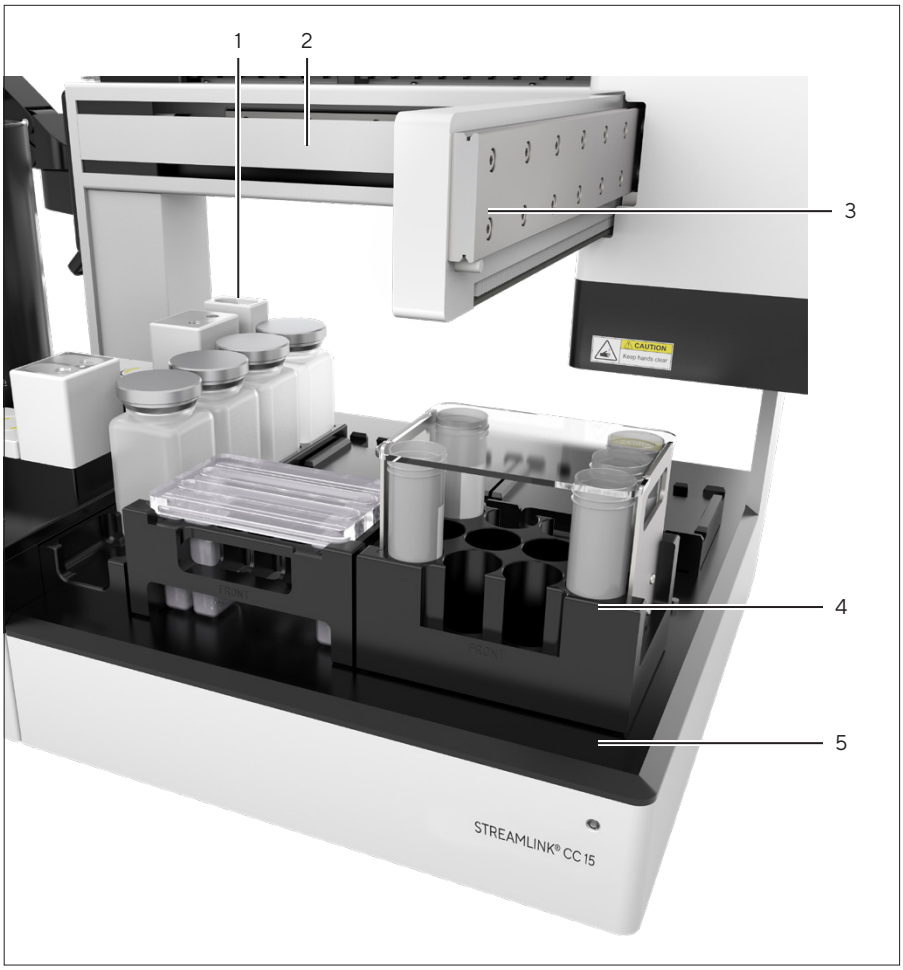


Fig. 3: Liquid Handler

Pos.	Name	Description
1	Pipette wash station	
2	X-axis	The liquid handler head can move left and right using this axis.
3	Y-axis	The liquid handler head can move forward and backward using this axis.
4	Labware holder	
5	Liquid handler bed	Has different positions to load different types of labware holders.

3.4 Filters

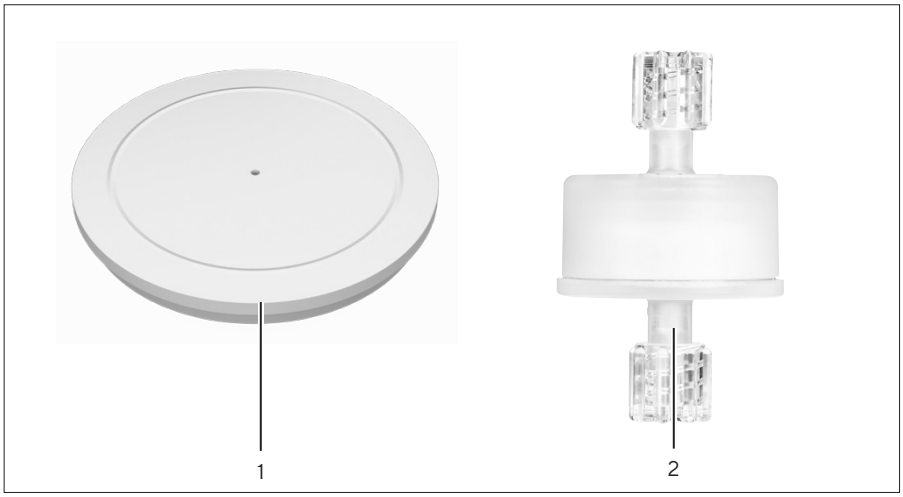


Fig. 4: Filters used in the device

Pos.	Name	Description
1	Clarification filter	Multi-layer depth filter for clarification of the input sample.
2	Purification filter	Compatible purification device for isolation of the molecule of interest.

3.5 Liquid Handler Connections

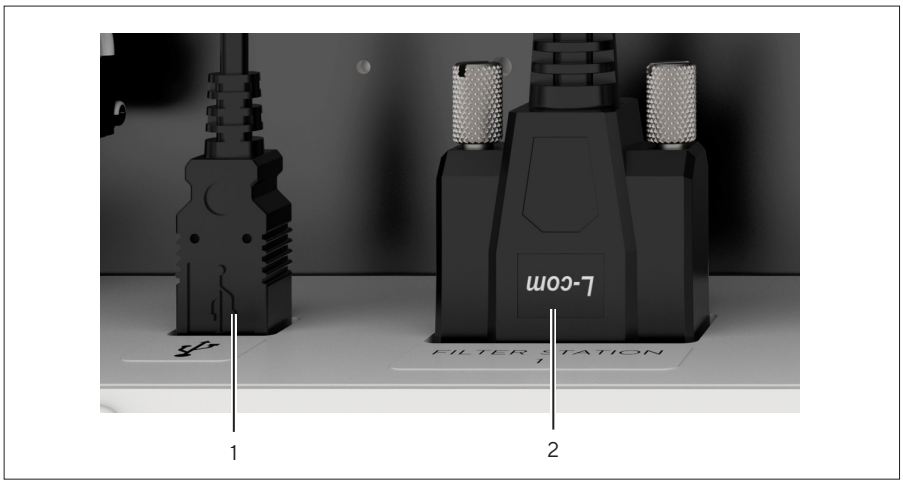


Fig. 5: Liquid Handler Connections

Pos.	Name	Description
1	Communication	Receives the communication cable. Used to connect the device to the control unit. Is designed as a USB connector.
2	[FILTER STATION 1] | Power & Comms	Used to supply power and communications to the respective filter station. Is designed as a D-Sub connector.

3.6 Filter Station Connections

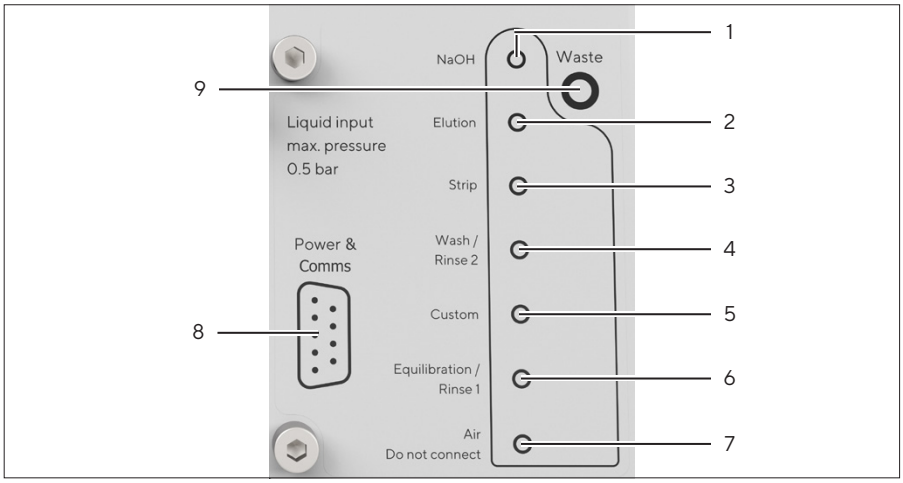


Fig. 6: Liquid connections on a filter station

Pos.	Name	Description
1	[NaOH]	Cleaning solution for clean-in-place (CIP) of the system and purification device
2	[Elution]	Low pH buffer for disassociating target antibody from Protein A in the purification device
3	[Strip]	Low pH buffer for stripping residuals from the purification device
4	[Wash/Rinse 2]	Higher conductivity buffer for removing non-specifically bound protein and DNA from the membrane prior to elution
5	[Custom]	Spare liquid line
6	[Equilibration/Rinse 1]	Standard buffer for rinsing of the system and equilibration of the purification device
7	[Air] [Do not connect]	
8	[Power & Comms]	Used to supply power to the unit. Receives the communication cable. Used to connect the filter stations to the control unit. Is designed as a D-Sub connector.
9	[Waste]	For transfer of waste liquids to the waste bottle

3.7 Liquid Handler Liquid Connections

The bottles for the liquid handler liquid connections are located to the left of the device.

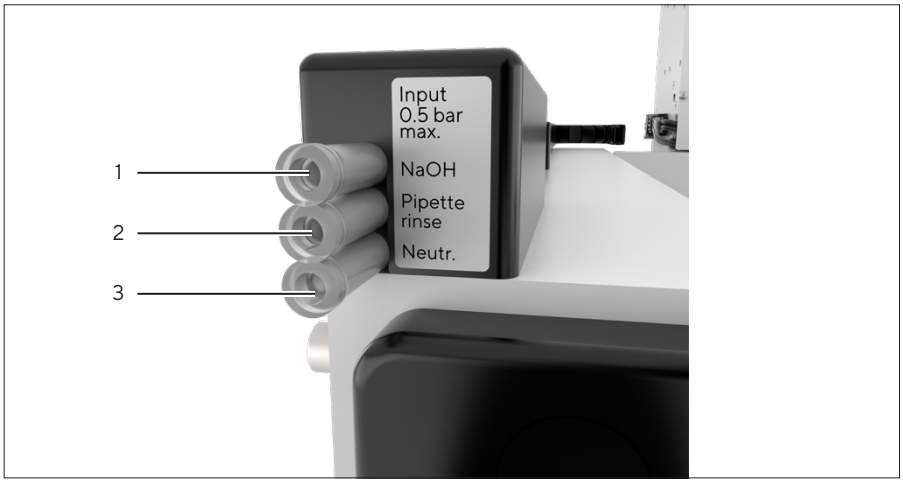


Fig. 7: Liquid Handler Liquid Connections

Pos.	Name	Description
1	[NaOH]	Cleaning solution for the CIP of the system and purification device.
2	[Pipette rinse]	Liquid for rinsing of the pipette.
3	[Neutr.]	Buffer for neutralizing the output sample after purification.

3.8 Bottle Positions

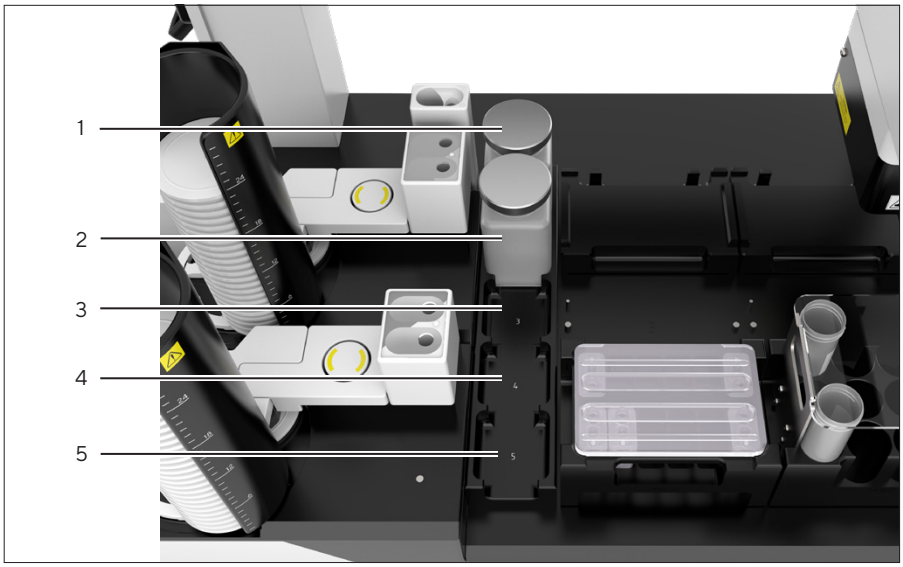


Fig. 8: Bottle positions for buffers on the liquid handler bed

Pos.	Name	Description
1	[1]	System storage solution
2	[2]	pH electrode storage solution
3	[3]	pH 4 calibration buffer
4	[4]	pH 7 calibration buffer
5	[5]	Spare

3.9 Liquid Lines

Each liquid line end is provided with a label to identify the connections.

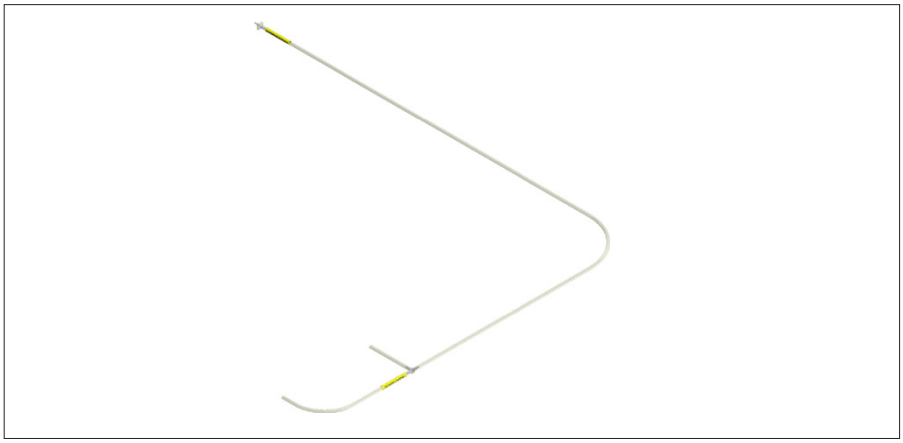


Fig. 9: Liquid Line (example)

3.10 Process Description

3.10.1 Diagram of the Filter Station Flow Path Showing all Sensors | Valves

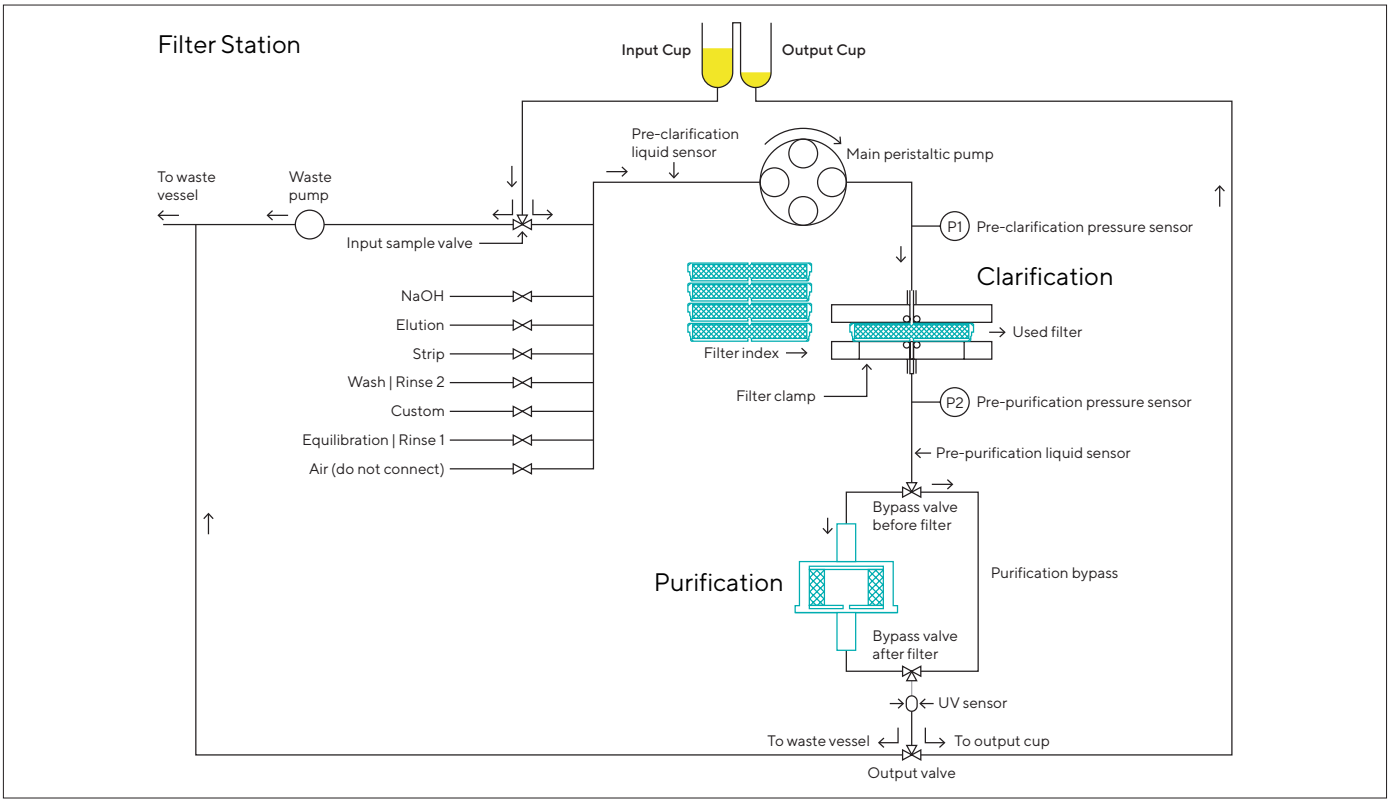


Fig. 10: Clarification | Purification Process on the Filter Stations

3.10.2 Diagram of the Liquid Handler Flow Path Showing all Sensors | Valves

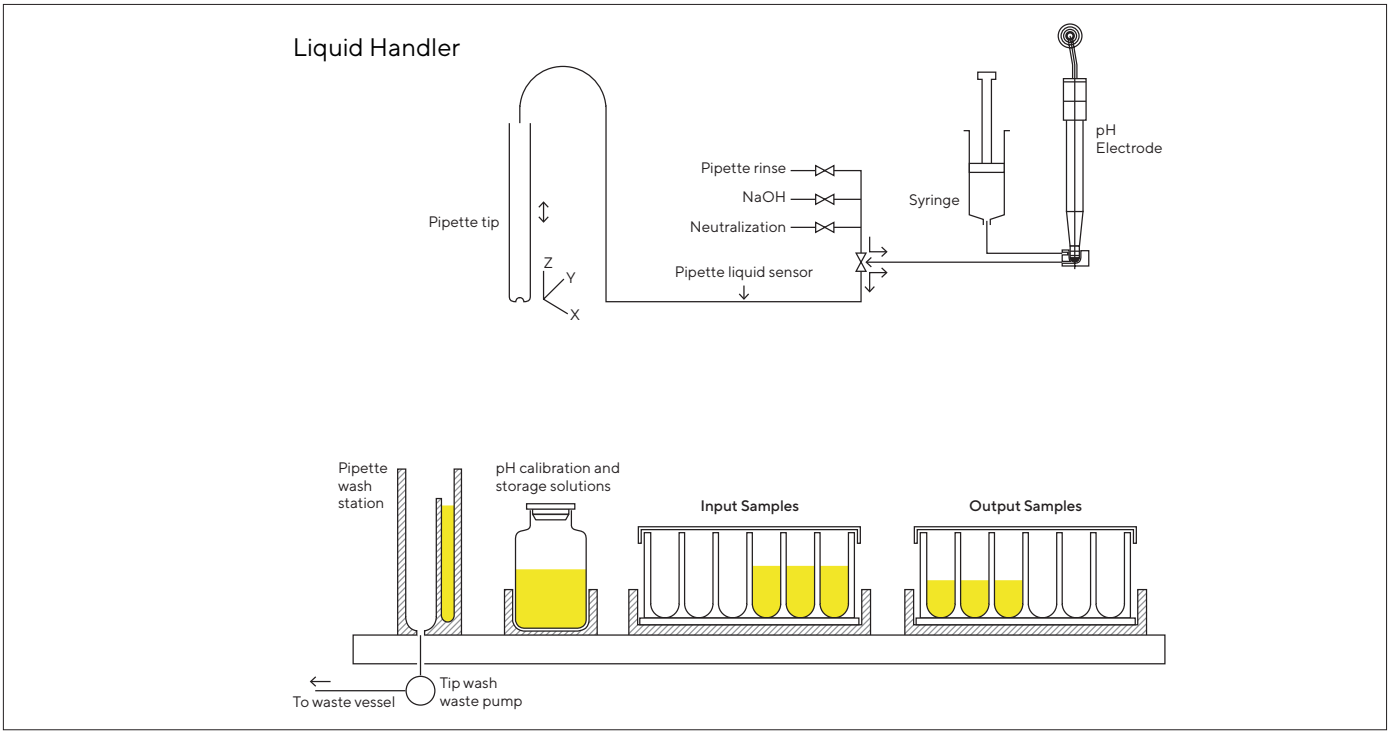


Fig. 11: Process on the Liquid Handler

3.11 Status Lights

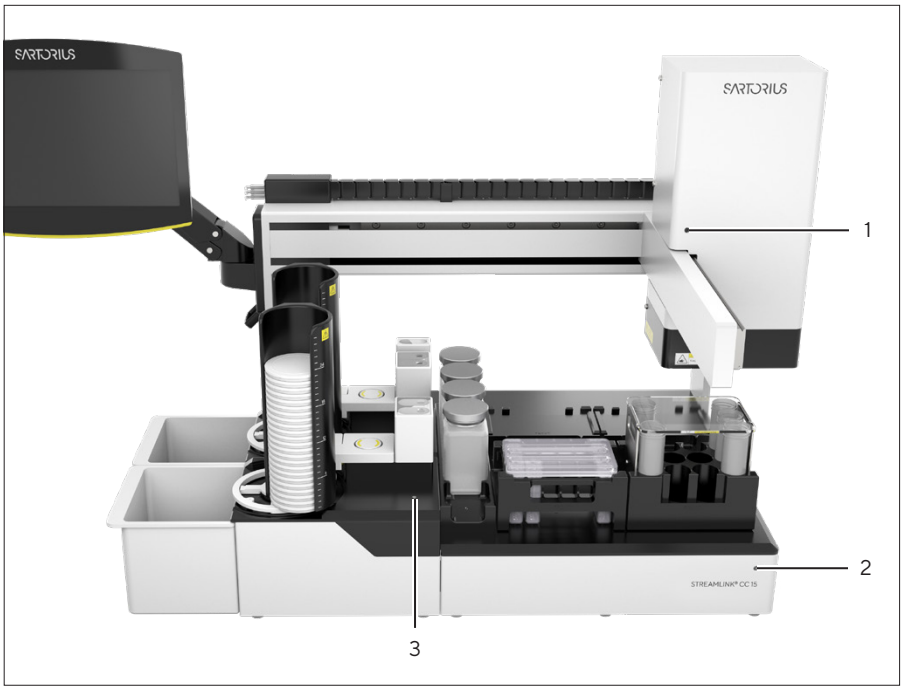


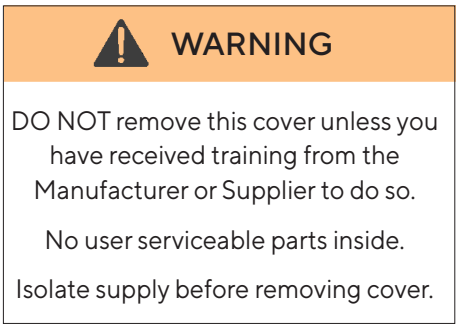
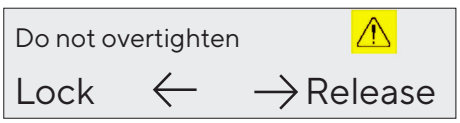
Fig. 12: Status lights on the device

Pos.	Name	Description
1	Robot active light	Indicates the status of the liquid handler robot. The orange light is on when the robot motors are energized.
2	Liquid handler power light	Light is illuminated when the liquid handler is powered.
3	Filter station power lights	Lights are illuminated when the filter stations are powered.

3.12 Symbols on the Device

Symbol	Meaning
	Fingers may be trapped and injured when working on the device. For any maintenance work on the syringe or liquid handler head, the device must be disconnected from the power supply. The symbols are visible only when the covers have been removed.
	The fluid-bearing parts of the device may contain biological substances which may be harmful to health. The label is included in the scope of delivery for the device. It can be affixed to the device if required.
	The fluid-bearing parts of the device may contain chemical substances which may be harmful to health. The symbol is affixed to the NaOH bottle.
	Remove the clarification filter stack holder before lifting or moving the filter stations.

3.13 Warning Information on the Device

	This label is applied to the left hand side of the liquid handler robot. Risk of injury from electrical current when removing the liquid handler robot. The cover may only be removed when the power supply is switched off.
	This label is applied to the back of the liquid handler upright, on base of the liquid handler, and on the base of the filter stations. Risk of injury when removing any of these covers. These covers may only be opened by personnel who have been trained by Sartorius or by Sartorius' suppliers. There are **no** user serviceable parts in the device.
	Fingers could be injured if touched during operation. Do **not** touch, insert fingers or foreign objects into the liquid handler working area when in motion.
	Risk of release of fluid. Purification filter must be depressurized before filter is released. Rotate the purification filter luer lock thumbwheel to lock or release the purification filter. To avoid damage to the purification filter housing: Do **not** overtighten the thumbwheel.
	The label is attached on the wire to the UV LED inside the filter station.

Liquid input max. pressure 0.5 bar Input 0.5 bar max.	This label is applied to the left hand side of the liquid handler liquid connections and on the filter station connections. Do **not** exceed the admissible pressure of 0.5 bar on the liquid lines attached.
WARNING When Portable Appliance Testing This product is equipped with a Functional Ground Only Earth Bond Test must be performed at no more than 200mA	This label is applied to the rear of the liquid handler. Testing at current greater than 200 mA can result in damage to power supply unit and loss of functional earth.

3.14 Information on the Device

Label	Description
StreamLink® CC 15 - Liquid Handler Fuse No. | Description | Rating | Part No. F1 | SYSTEM SUPPLY | T4A | X-1591 ⎓ DC 24 Volts 4 Amps 	Contains electrical information about the liquid handler: – Fuse Type, Rating, Part Numbers – Direct current: 4 A | 24 V – USB connection
FILTER STATION 1	Positioned on the liquid handler to identify where the filter stations are to be connected: FILTER STATION 1 | FILTER STATION 2.

3.15 Labels on the Bottles | Liquid Lines

Label	Description
Waste. Do not clamp	The outlet of the waste liquid line must **not** be sealed or clamped off. The symbol is affixed to the waste liquid line attached to the bottle lid.
NaOH Pipette Rinse Neutralization Elution Strip Wash / Rinse 2 Equilibration / Rinse 1 Custom	Each liquid line end is provided with a label to identify the connections. The naming of the liquid lines match the naming of the bottles and | or labels on the device. The bottle labels have a blank space to write in details.
Waste Waste bottle to have open vent	The waste bottle must have an open vent. This label is affixed to the waste bottle.

4 Installation

4.1 Scope of Delivery

Article	Art. No.
StreamLink® CC 15, comprising of the following items: — StreamLink® CC 15 liquid handler — StreamLink® CC 15 filter station x2 — StreamLink® CC 15 controller	061-8B01
— Feed | Waste bottle set	061-2B20
— Feed | Waste bottle lid set	061-2B21
— Feed connection tubing set	061-2B22
— Liquid handler bottle set	061-2B23
— Liquid handler bottle lids	061-2B24
— Operating instructions	
— Spare covers	
— Biohazard label	
— Tools for system assembly	

4.2 Selecting an Installation Site

Procedure

▶ Make sure that the following conditions are met at the installation site:

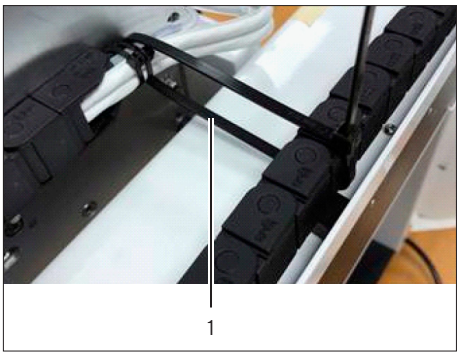
Condition	Features
Ambient conditions	— Suitability tested (for ambient conditions, chapter “14.4 Ambient Conditions”, page 62). — Adequate lighting
Setup surface	— Stable, even surface with little vibration — Level surface | optional: levelling platform (see chapter “15.1 Accessories”, page 66) — Sufficiently dimensioned for the device and the peripheral devices (for the space requirements of the device and accessories see chapter “14.3 Set up Dimensions”, page 62). — Sufficient load-bearing capacity for the device and the peripheral devices even when full (for device weight, see chapter “14.1 Dimensions and Weight”, page 61).
Access to parts relevant to operation	Convenient and safe

4.3 Unpacking

Personnel: 2 users

Procedure

- ▶ Open the top of the crate and remove the smaller boxes.
- ▶ ⚠ **CAUTION** Impairment of pacemakers or other medical implants due to magnetic forces between the filter station and the liquid handler base assembly. Maintain a safety distance of at least 0.1 m from the device.
- ▶ **NOTICE** Risk of filter station dropping onto user's feet and damage to the device from improper handling! Do **not** lift the device by the clarification filter stack holder. Only lift the device by its base.
- ▶ Lift off the exterior cardboard sleeve to give access to the lower half of the crate.
- ▶ ⚠ **CAUTION** Heavy weight of the device! Lift the liquid handler on to the bench with 2 persons.
- ▶ Unpack the other boxes.
- ▷ Power cables and labware holders will be supplied in separate packaging to crate.
- ▶ Remove the cable tie (1) holding the liquid handler head in position.



- ▶ Check that the feet are **not** damaged during installation and movement of the device.
- ▶ Original packaging may be retained for future storage or transport of the device, or recycled in accordance with local regulations.

4.4 Acclimatization

When a cold device is brought into a warm environment: The temperature difference can lead to condensation from humidity in the device (moisture formation). Moisture in the device can lead to malfunctions.

Procedure

- ▶ Allow the device to acclimatize for approx. 2 hours at the installation site. The device must be disconnected from the power supply during that time.

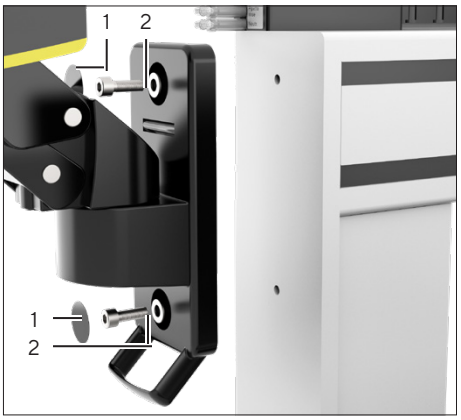
4.5 Mounting the Control Unit

The device can be placed on a bench with the control unit mounted on a monitor arm or the device can be placed in a hood with the control unit mounted separately outside the hood.

The control unit consists of a NUC, monitor, monitor arm and the respective cables.

Bench Mounting

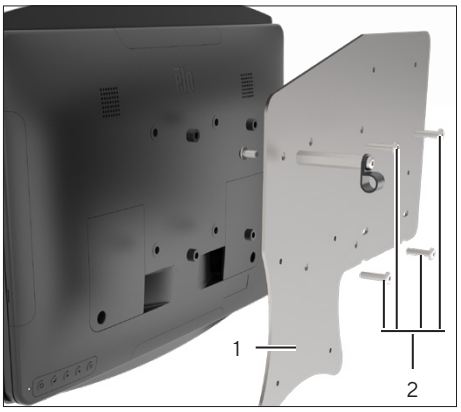
Procedure

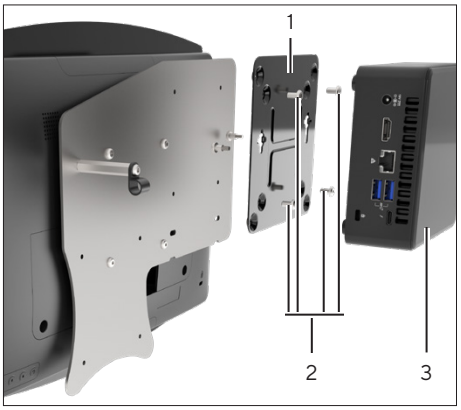


- ▶ Mount the arm of the control unit on side of liquid handler using 2 spacers and hex bolts (2).
- ▶ Apply the black covers (1) over the bolt heads.

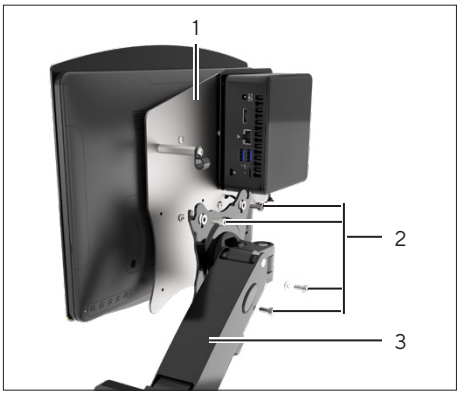
- ▶ Plug in the power and the HDMI cable to the monitor.

- ▶ Mount the support plate, monitor and the NUC on the monitor arm. To do so:
  - ▶ Attach the monitor to the support plate (1) using 4 screws (2) and spacers.

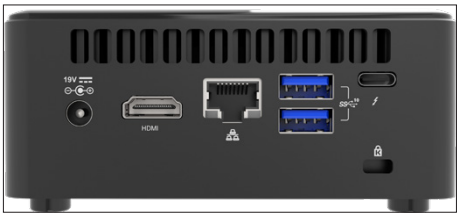




- ▶ Attach the NUC mounting plate (supplied with NUC) (1) to the support plate using 4 screws (2).
- ▶ Mount the NUC (3) on the NUC mounting plate (1).



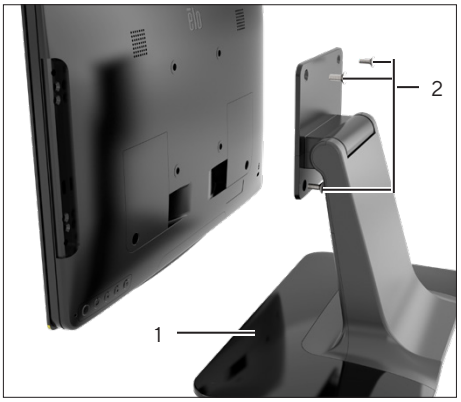
▶ Attach the support plate (1) to monitor arm (3) using 4 screws and spacers (2).



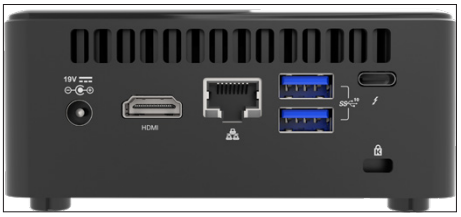
▶ Connect the HDMI cable to NUC.
▶ Connect the USB cable for touch screen to monitor and NUC.
▶ Connect the NUC power cable to NUC.
▶ Arrange all cables neatly using cable ties.

Hood Mounting

Procedure



▶ Mount the monitor on stand (1) adjacent to the hood using 4 screws and spacers (2).
▷ The NUC unit is **not** mounted, but rests on the bench.



▶ Connect the HDMI cable to monitor and NUC.
▶ Connect the USB cable for touch screen to monitor and NUC.
▶ Connect the monitor power cable to monitor.
▶ Connect the NUC power cable to NUC.
▶ Arrange all cables neatly using cable ties.

4.6 Positioning the Liquid Handler

Procedure

▶ Position the liquid handler with sufficient space on the left for the control unit and bottles and clear space on the right side for drag chain and plate lids (see chapter “14.3 Set up Dimensions”, page 62 for required space).

5 Getting Started

5.1 Connecting the Power Supply

Procedure

- ⚠ **WARNING** Severe injuries caused by using defective power supply cables! Check the power supply cable for damage, e. g., cracks in the insulation.
  - If required: Contact Sartorius Service.
- Check whether the country-specific power plug matches the power supply at the installation site.
  - If required: Replace the country-specific power plug adapter.
  - If required: Conduct Portable Appliance Testing in accordance with local regulations (site engineer).
  - If required: Contact Sartorius Service.
- **NOTICE** Damage to the device due to excessive input voltage! Check whether the voltage specifications on the manufacturer's ID label match those of the power supply at the installation site.
  - If the input voltage is too high: Do **not** connect the device to the power supply.
  - Contact Sartorius Service.
- Connect the device to the power supply (see chapter "14.2 Power Supply", page 61).

5.2 Connecting the Liquid Handler to the Control Unit

The device must be connected to the control unit using the communication cable.

Requirements

- The NUC and all associated components are set up and connected to the power supply or the NUC.
- The control unit is positioned near to the device, on the left.

Procedure

- Connect the USB cable provided to the "communication" connection.
- Connect the other end of the cable to the NUC.

5.3 Connecting the Waste Bottle

The waste bottle supplied must be connected to the waste liquid connection on both filter stations and the liquid handler waste liquid line.

Procedure

- ▶ Place the waste bottle in an easily accessible position near the device. The waste bottle must be easily accessible for emptying.
- ▶ Screw on the bottle lid.
- ▶ **NOTE** Risk of pressurisation! The waste bottle must remain vented.
- ▶ ⚠ **WARNING** Risk of injuries caused by leakage of cleaning solution during automatic cleaning! Connect the “waste” liquid line from each filter station (1) and the liquid handler to the waste bottle. All possible precautions should be taken to avoid the waste liquid line coming loose during operation.
- ▶ ⚠ **WARNING** Risk of injury from leaking cleaning solution during automatic cleaning! Do **not** seal or clamp off the tubing of the waste liquid line. The cleaning solution must be able to run off unobstructed.
- ▶ Check that there is no kinking or blockage in the liquid lines once connected.

5.4 Connecting the Bottles for Supply Liquids

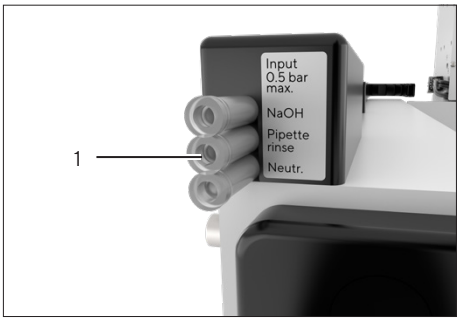
Position the bottles for liquids next to the device on the laboratory table, ensuring that the bottles are on the left side of the device.

The bottles for liquids should be connected to the liquid lines of the device.

The NaOH bottle is shared between the liquid lines from the filter station and the liquid handler.

Procedure

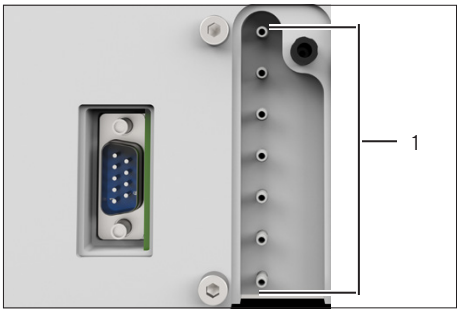
- ▶ ⚠ **WARNING** Risk of injuries caused by leakage of cleaning solution during automatic cleaning! Only use approved cleaning solutions and liquids (see chapter “14.7 Approved Liquids“, page 63).
- ▶ ⚠ **CAUTION** Leaking liquids due to siphoning! If a liquid line is disconnected, the free end must be retained in an elevated position higher than the bottle lid (or clamped) to prevent siphoning.
- ▶ Check to make sure that the bottles for liquids are positioned on the left side, near the device.
  - ▶ If required: Reposition the bottles for liquids.
- ▶ To improve ergonomics for people working on the device: Place the bottles in an easily accessible position.
- ▶ Screw on each bottle lid.
- ▶ Connect the liquid connections (1) from the liquid handler to the corresponding bottles for liquids.
  - ▶ Fit the liquid lines through the bottle caps.
  - ▶ Make sure the end of the liquid lines are touching the bottom of the bottles.
  - ▶ Gently tighten the liquid line clamp ring on the bottle cap until the liquid line is secure.



▶ Check whether the tubings of the liquid handler liquid lines have been assigned to the correct bottles for liquids:

Connection	Liquid
[NaOH]	Cleaning solution for clean-in-place (CIP)
[Pipette rinse]	Liquid for rinsing of the pipette
[Neutr.]	Neutralisation: Buffer for neutralising the output sample

▶ If the liquid handler liquid lines are **not** assigned correctly: Disconnect and reconnect the liquid lines of the bottles for liquids.
▶ Check that there is no kinking or blockage in the liquid lines once connected.
▶ Connect the liquid connections (1) from the filter stations to the corresponding bottles for liquids.
▷ The filter station liquid inputs are connected in series when 2 filter stations are used.



▶ **NOTICE** The device can be damaged due to incorrect connection of liquids! Only approved liquids should be connected to the device (see chapter “14.7 Approved Liquids“, page 63).
▶ ⚠ **WARNING** Risk of injuries caused by leakage of cleaning solution during automatic cleaning! The bottle for the cleaning solution must be connected to the [NaOH] connection. Check whether the tubing of the filter station liquid lines have been assigned to the correct bottles for liquids:

Connection	Liquid
[NaOH]	NaOH
[Elution]	Elution Buffer
[Strip]	Stripping buffer
[Wash | Rinse 2]	Wash buffer
[Equilibration | Rinse 1]	Equilibration buffer | PBS

▶ ⚠ **CAUTION** Leaking liquids due to siphoning! If a liquid line is disconnected, the free end must be retained in an elevated position higher than the bottle lid (or clamped) to prevent siphoning.
▶ If the filter station liquid lines are **not** assigned correctly: Disconnect and reconnect the liquid lines of the bottles for liquids.

5.5 Connecting the Filter Stations

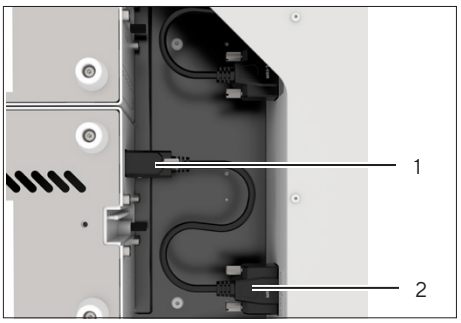
The right side of each filter station and the left side of the liquid handler are magnetic.

Requirements

- All liquid lines have been connected.
- All connections have been made.

Procedure

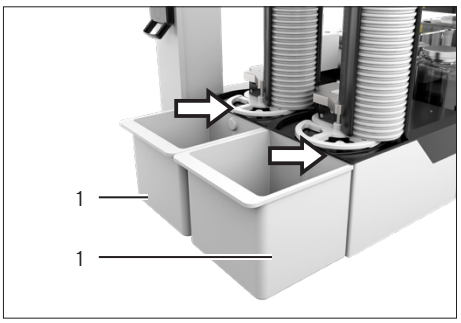
- ⚠ **CAUTION** Impairment of pacemakers or other medical implants due to magnetic forces between the filter station and the liquid handler base assembly. Maintain a safety distance of at least 0.1 m from the device.
- **NOTICE** Risk of filter station dropping onto user's feet and damage to the device from improper handling! Do **not** lift the device by the clarification filter stack holder. Only lift the device by its base.
- Check that there is **no** dust on the magnets each time the filter station is connected | disconnected.
- Connect the D-sub connector cable to the liquid handler (2) [FILTER STATION 1] | [FILTER STATION 2] connections and the [Power & Comms] connection on each filter station (1).



- Click the location magnet of each filter station to the corresponding location magnet of the liquid handler and slide the filter station towards the liquid handler.
- If the location magnet does not fully engage with the hole: Try slightly elevating either the liquid handler or the filter station to help alignment.
- Mount the clarification filter stack holders on each filter station by sliding them down onto the 2 location dowels.
- **Do not** lift the filter station by the filter stack.

5.6 Connecting the Waste Filter Containers

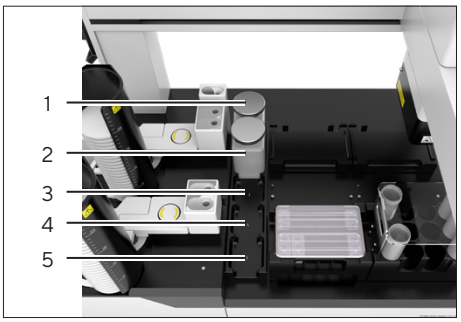
The 2 waste filter containers are to be placed on the left side of the filter station.



Procedure

▶ Attach the 2 waste filter containers (1) to the filter stations.

5.7 Placing the Calibration and Storage Solution



Procedure

▶ Place the bottles (1) for calibration and storage buffers on the dedicated positions on the liquid handler bed (for approved liquids see chapter 14.7, page 63):

Name	Description
[1]	Purification | device storage solution
[2]	pH electrode storage solution
[3]	pH 4 calibration buffer
[4]	pH 7 calibration buffer
[5]	Spare

▶ Remove the screw lid and put on the plain bottle lid.
▶ Make sure that the lids are free of debris, residue or stickers.

6 Process Preparation

6.1 Checking Liquids and Liquid Lines

Requirements

- The control unit is ready for operation.
- The device has been connected to the power supply.

Procedure

- ▶ Check that the waste liquid line and liquid lines are **not** loose, kinked or blocked.
- ▶ Check that the buffer supply lines and waste bottles are correctly connected to the system liquid line.
- ▶ Check that each liquid line ends at the bottom of the bottle.
- ▶ Check that the amount of buffer in the bottles is sufficient for the process.

6.2 Rehydrating pH Electrodes

New pH electrodes which are supplied dry and pH electrodes which have been stored dry for more than a week must be rehydrated. If pH electrodes have been stored dry for less than a week: Rehydration is **not** required.

Procedure

- ▶ See chapter “8.3.1 Replacing the pH Electrode“, page 51 for details on how to install | remove the pH electrode.
- ▶ Rehydrate the pH electrode by dipping the bulb of the electrode in pH electrode storage solution prior to installation (see chapter “14.7 Approved Liquids“, page 63). Immerse only the glass tip of the pH electrode in the liquid. The rehydration of the pH electrode takes 4 hours minimum | optimum 12 hours.
- ▶ As alternative to manual rehydration of the pH electrode: Follow the procedure on the software maintenance panel for pH electrode rehydration (see instructions of the StreamLink® CC 15 software).
- ▶ To preserve the performance and lifetime of the pH electrode once rehydrated if it is not installed in the device: See chapter “12.2 Storing pH Electrodes“, page 58 for recommend method of storing wet pH electrodes.

6.3 Teaching the Pipette Tip Position

After installation or transport of the device, a teach procedure must be followed for the pipette tip.

Procedure

- ▶ Follow the instructions on the StreamLink® CC 15 software accessed from the maintenance screen.
- ▶ If the pipette is bent, see chapter “9.5 Recovering from a Bent Pipette Tip“, page 55.

7 Operation

7.1 Starting a Process

The desired purfication and | or clarification processes must be selected and started on the screen of the control unit. The control unit automatically performs a calibration, cleaning and pressure test before starting the process.

Requirements

- The control unit is ready for operation.
- The device is prepared for the process (see Chapter "6 Process Preparation," page 46).

⚠ WARNING

Injuries due to escaping cleaning solution during automatic cleaning!

▶ Wear personal protective equipment.

Procedure

▶ ⚠ **WARNING** Risk of injuries caused by leakage of cleaning solution during automatic cleaning! Do **not** connect [NaOH] to any other inlet connection as this may cause the pressure to exceed the admissible pressure during automated cleaning (settings for automatic cleaning, see instructions of the StreamLink® CC 15 software).

▶ Select and start a purification and | or clarification process (recipe) on the screen of the control unit (see the instructions of the StreamLink® CC 15 software).

▷ The device automatically performs a function check, calibration and cleaning of the device.

▶ When the pressure test fails: Check the O-rings for leakage.
  ▶ If required: Contact Sartorius Service.

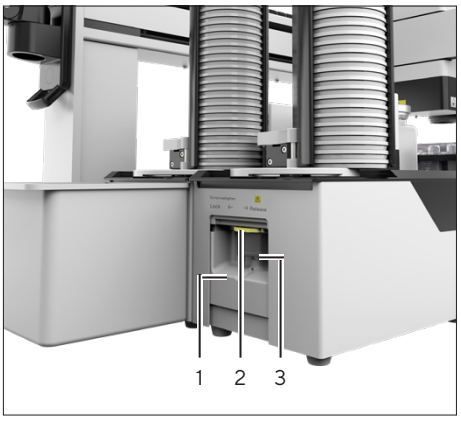
▶ After selecting a process: The StreamLink® CC 15 software will guide through all physical activities required before the process starts.

7.2 Installing Purification Filters

Requirements

– The user is prompted to install the 2 purification filters on the screen of the control unit.
– There are **no** old filters installed.

Procedure



▶ **NOTICE** Device can malfunction due to the use of incompatible filters! Ensure that the filters are compatible with the device (for compatibility, see chapter “14.5 Filters“, page 62).
▶ Remove the caps from each purification filter.
▶ Push the purification filter holder (1) down to its lowest position.
▶ Install the bottom luer connection (3) of the purification filter.
▶ Gently turn the filter body in the direction indicated on the filter station to lock. Do **not** overtighten.
▶ Push the filter up so that the upper luer connector engages with the thumb-wheel (2).
▶ While maintaining light upward force on the purification filter, turn the thumbwheel (2) in the direction indicated on the filter station to tighten it until resistance is felt.
▶ **NOTICE** Damage to the purification filter when the pressure is too high! Do **not** overtighten!

▶ Perform the “Prime new purification device“ procedure via the maintenance panel on the StreamLink® CC 15 software.

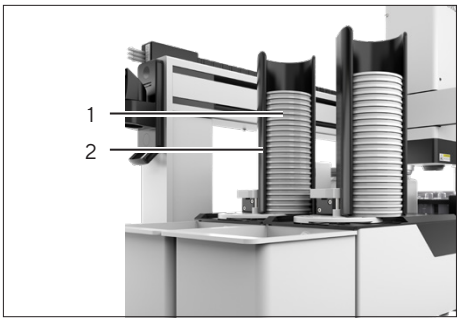
7.3 Loading Clarification Filters

Each filter station can hold a maximum of 30 clarification filters.

Requirements

The user is prompted to load the clarification filters on the screen of the control unit.

Procedure



▶ **NOTICE** Device can malfunction due to the use of incompatible filters! Ensure that the filters are compatible with the device (for compatibility, see chapter “14.5 Filters“, page 62).
▶ Load sufficient clarification filters (1) into the 2 clarification filter stack holders (2).
▶ It is recommended to load an excess number of clarification filters in case more than expected are needed for the process.
▶ Ensure clarification filters are loaded the correct way up. The top side is marked on the filters.

7.4 Loading Samples

The areas for the samples are marked.

Requirements

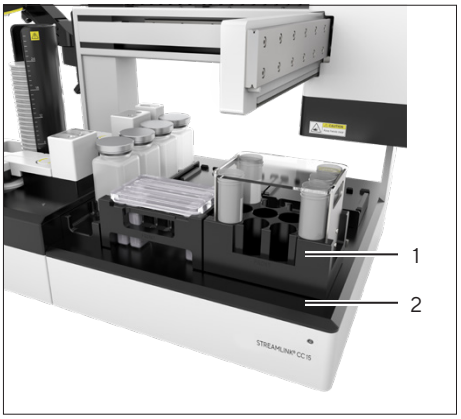
The user is prompted to load samples on the screen of the control unit.

Procedure

- ▶ **NOTICE** Device can malfunction due to the use of unsuitable labware or unsuitable labware holders! Ensure that the labware and labware holders are suitable (for suitability, see chapter “15.1 Accessories“, page 66 and chapter “14.6 Centrifuge Tubes“, page 63).
- ▶ Place the samples into the respective labware holder.
- ▶ Check whether the labware items containing the samples are suitable for the labware holders used:

Labware item	Labware holder
Ambr® 15 vessel rack	Ambr® 15 rack holder with lid
6-well deep well (2x rows of 3) with lid	Microplate holder
12-well deep well with lid	Microplate holder
24-well deep well with lid	Microplate holder
Centrifuge tubes (15 mL): 4 rows of 6	24x 15 mL tube holder with lid
Centrifuge tubes (50 mL): 3 rows of 4	12x 50 mL tube holder with lid

- ▶ Remove the Ambr® 15 vessels caps.
- ▶ Remove the centrifuge tube caps.



- ▶ Put the labware holders (1) on the marked areas on the liquid handler bed (2) making sure “FRONT” label is to the front.
- ▶ Place the lids correctly on the loaded labware holders and plates.
- ▶ Verify there is **no** debris, **no** labels and **no** residue on the lids.

- ▶ Remove any obstacles from the liquid handler bed and make sure that the liquid handler robot is free to move.
- ▶ Ensure there is sufficient clear space on the right hand side of the liquid handler (see chapter “14.3 Set up Dimensions“, page 62).
- ▶ Confirm on the screen of the control unit how many labware holders are used and in which bed positions they are placed.

7.5 Running a Process

For details of selecting a process template, editing parameters and running a process please refer to the software manual.

The user will be guided by instructions displayed on the screen.

The user must follow these instructions to run a process, take any actions as required during a run, and unload at the end of a run.

⚠ CAUTION

Risk of injury due to moving parts!

If body parts come into contact with the device while in operation: Body parts could get caught. This can lead to injuries.

- ▶ Do **not** insert fingers or foreign objects into the device | parts of the device and keep clear of the liquid handler when in operation (orange light of the robot active light is lit).
- ▶ The liquid handler bed and filter stations should be free of obstacles during operation. Only the plates and lids should be in place.

NOTICE

Failure due to incorrectly selected process template or parameters!

Take care to select the correct template and to correctly set parameters for the process to be run. Selecting the wrong template and | or incorrect process parameters can result in multiple failures, e. g., filtrations being incomplete, blockages, liquid handling errors, the loss of samples etc.

- ▶ Check that the required processing matches the template on the StreamLink® CC 15 software.
- ▶ Check that the liquids loaded in the device match the selected template in the StreamLink® CC 15 software.
- ▶ Check that the labware holders are positioned correctly.
- ▶ In the case of successive runs, ensure the automatic CIP of the filter stations and the liquid handler has completed.

Requirements

- — All liquids and liquid lines have been checked (see chapter 6.1, page 38).
- — The automatic function check, calibration and CIP has been completed.

Procedure

- ▶ Fill in the corresponding information on tracked consumables, input volumes, bed numbering etc. on the screen of the control unit as required.
- ▶ Make sure that enough filters are loaded in the filter stations as required on the screen of the control unit.
- ▷ The total number of clarification filters to load might be higher than the number of samples to process in order to deal with a potential retry or the activation of the second filter switch option in the template.
- ▶ Follow the prompts on the screen of the control unit, e. g. prompts to insert filters or carry out steps to correct malfunctions.

7.6 Ending a Process

Procedure

▷ As part of the end of a process, the device automatically executes a full CIP of the filter stations and the liquid handler. It is advised to wait for the end of this process before interacting with the device to collect the output samples and remove the input labware.

▶ **NOTICE** Failure to complete the automatic CIP can result in multiple failures, blockages, loss of samples, degraded purification device performance, degraded pH probe performance and system contamination! When pausing the routine to collect samples: Restart the CIP in the StreamLink® CC 15 software.

▶ When having emptied the waste bottle before the CIP has finished: Make sure it has been correctly reconnected before restarting the CIP (see chapter "7.9 Emptying the Waste Bottle", page 44).

▶ Ensure the CIP is carried out successfully before restarting any new run on the device.

7.7 Emptying the Waste Filter Containers

The waste filter containers have to be emptied after each process.

⚠ WARNING

Risk of injury from leaking cleaning solution during automatic cleaning!

▶ Do **not** seal or clamp off the waste outlet of the waste liquid line. The cleaning solution must be able to run off unobstructed.

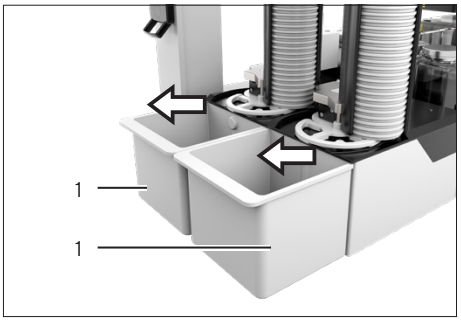
▶ If the waste filter containers are full: Remove, empty and replace the waste filter containers.

▶ Do **not** run the device without the waste filter containers in position.

▶ Wear personal protective equipment.

Procedure

▶ **⚠ CAUTION** Impairment of pacemakers or other medical implants due to magnetic forces between the filter station and the liquid handler base assembly. Maintain a safety distance of at least 0.1 m between the waste filter container and the pacemaker | medical implant.



▶ If the waste containers are filled or the screen of the control unit displays the prompt to empty the waste containers: Detach the 2 waste filter containers (1) from the filter station.

▶ Empty each waste filter container and discard the used filters appropriately.

▶ Take care not to spill any residual cell culture that may leak from the used filters.

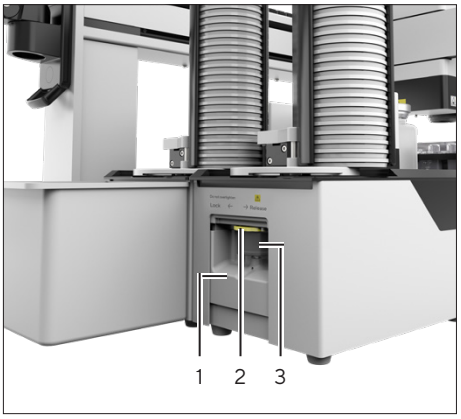
▶ Clean the waste filter containers (see chapter "8.2.3 Cleaning the Waste Filter Containers", page 49).

7.8 Removing Purification Filters

Requirements

- All processes on the device have ended.
- The user is prompted to remove the purification filters on the screen of the control unit.
- The waste filter containers have been removed.

Procedure



▶ ⚠ **WARNING** Risk of injury from pressurized filters! Do **not** remove the purification filter when still under pressure, in operation or if it still contains cleaning solution.

▶ Turn the purification filter luer lock thumbwheel (2) in the direction shown on the filter station label to release the filter upper luer lock connection.

▶ Once the upper luer is released: Gently push down on the filter holder (1) to lower the filter.

▶ Turn the body of the filter (3) in the direction shown on the filter station to release the lower luer lock connection.

▶ **NOTICE** Damage to the device! Do **not** run the filter station without a purification filter installed. Running the filter station without a filter may result in the leakage of cleaning solutions.

7.9 Emptying the Waste Bottle

⚠ WARNING

Risk of injury from leaking cleaning solution during automatic cleaning!

▶ Do **not** run the device without a waste bottle connected.

▶ Do **not** seal or clamp off the "waste fluid outlet" of the waste liquid line. The cleaning solution must be able to run off unobstructed.

▶ If the waste bottle is full: Replace or empty the waste bottle.

▶ Wear personal protective equipment.

Procedure

▶ If the waste bottle is full or the screen of the control unit displays the prompt to empty the waste bottle:

  ▶ Remove lid including the waste liquid line from the waste bottle leaving the waste liquid line attached to the bottle lid.

  ▶ Empty or replace the waste bottle.

  ▶ Replace the lid with its attached waste liquid lines on the waste liquid bottle (chapter "5.3 Connecting the Waste Bottle", page 34).

7.10 Preparing the Device for Downtime

Procedure

- If no further processes are planned to be run on the device:
  - Decommission the device (chapter “10 Decommissioning“, page 56).
  - Store the device (chapter “12 Storage and Shipping“, page 58).

8 Cleaning and Maintenance

8.1 Automatic Cleaning of the Device

8.1.1 In Between Sample CIP | End of Run CIP

The automatic cleaning process is part of a clarification | purification process, e. g. at the end of the process | between samples. The steps for the automatic cleaning are stored in the templates on the StreamLink® CC 15 software.

It is possible to pause the process cleaning to recover samples or to remove labware holders (see chapter “7.6 Ending a Process“, page 43).

Procedure

- ▶ ⚠ **CAUTION** Risk of injuries caused by leakage of cleaning solution during automatic cleaning!
  - ▶ Check all liquid lines for visible damage and leaky connections.
  - ▶ Wear personal protective equipment.
- ▶ ⚠ **WARNING** Risk of injuries caused by leakage of cleaning solution during automatic cleaning! Do **not** connect [NaOH] to any other inlet connection as this may cause the pressure to exceed the admissible pressure during automated cleaning (settings for automatic cleaning, see instructions of the StreamLink® CC 15 software).
- ▷ The cleaning process starts automatically, e. g. at the end of a process | between samples.
- ▶ Follow the instructions on the screen of the control unit.

8.1.2 System CIP

The system CIP can be selected in the templates on the StreamLink® CC 15 software at any time via the maintenance screen.

The user is guided through the system CIP process. The necessary steps are displayed on the screen of the control unit (information on the phases, see operating instructions for the StreamLink® CC 15 software).

Contact Times with Cleaning Solution

The pH electrode comes into contact with the cleaning solution (NaOH).

The longer the pH electrode is in contact with the cleaning solution, the shorter the lifetime of the pH electrode. In addition, long contact times with the cleaning solution lead to a longer stabilisation phase of the pH electrode after automatic cleaning.

It is recommended that the contact time with the cleaning solution be kept as short as possible. The minimum time for automatic cleaning is sufficient to clean the liquid-carrying components. For system CIP allow more time for pH stabilization following a CIP with NaOH.

Requirements

All processes on the device have ended.

Procedure

- ▶ ⚠ **CAUTION** Risk of injuries caused by leakage of cleaning solution during automatic cleaning!
  - ▶ Check all liquid lines for visible damage and leaky connections.
  - ▶ Wear personal protective equipment.
- ▶ ⚠ **WARNING** Risk of injuries caused by leakage of cleaning solution during automatic cleaning! Do **not** connect [NaOH] to any other inlet connection as this may cause the pressure to exceed the admissible pressure during automated cleaning (settings for automatic cleaning, see instructions of the StreamLink® CC 15 software).
- ▶ Start the deep cleaning on the screen of the control unit (see the instructions of the StreamLink® CC 15 software).
- ▶ Follow the instructions on the screen of the control unit.

8.2 Manual Cleaning of the Device

Requirements

- All processes on the device have ended.
- The device is turned off.

NOTICE

Corrosion or damage to the device due to unsuitable cleaning agents!

- ▶ Do **not** use corrosive, chloride-containing and aggressive cleaning agents, e. g. hydrogen peroxide H_2O_2.
- ▶ Do **not** use cleaning agents that contain abrasive ingredients, e. g. scouring agents, steel wool.
- ▶ Do **not** use spraying | autoclaving procedures.
- ▶ Only use suitable cleaning agents and follow the product information for the cleaning agent used (see chapter “14.11 Cleaning Agents and Cleaning Procedures“, page 64).

⚠ CAUTION

If the filter station is turned upside down, there is the risk of the clarification filter stack holder falling onto the user's feet, as the stack is not secured onto the bed, but is resting on 2 dowels.

- ▶ Remove the clarification filter stack holder before turning the filter station over.
- ▶ Do **not** lift the filter station by the clarification filter stack holder.
- ▶ Do **not** remove covers.

8.2.1 Cleaning around and below the Filter Stations

Procedure

- ⚠ **CAUTION** Impairment of pacemakers or other medical implants due to magnetic forces from the filter station, the liquid handler base assembly and the waste filter containers. Maintain a safety distance of at least 0.1 m between the device and the pacemaker | medical implant.
- Lift off the clarification filter stack holder from each filter station.
- Remove the filter stations from the liquid handler by pulling the filter stations to the left to overcome the magnetic coupling force.
- Move the filter stations approximately 100 mm to the left. Avoid stress on the D-Sub connector cable and the liquid line connections.
- Remove the liquid lines from the bottles.
- Disconnect the liquid lines from the barbed connectors at the inlet to the filter stations.
- Use absorbent material to soak up any liquid that leaks from the liquid lines.
- Disconnect the D-sub connector cable provided to the “communication” connection from each filter station.
- If applicable: Clean the D-sub connectors if they came into contact with spilt fluids. They must **not** be left wet.
- Check that there is **no** dust on the magnets. If necessary: Clean the magnets (see chapter “Cleaning the Magnets“, page 48).
- If corrosion has ocurred: Contact Sartorius Service.

8.2.2 Cleaning the Filter Stations

Cleaning Surfaces of the Filter Stations

Procedure

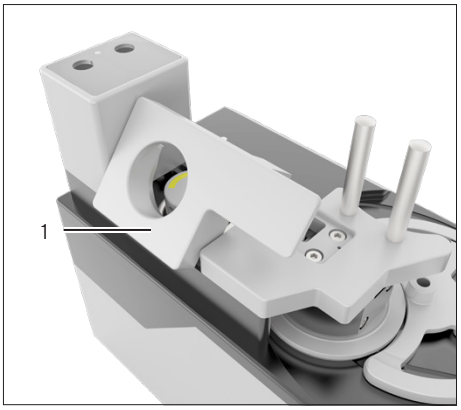
- Clean the filter stations using a soft lint free cloth and mild detergent.
- Wipe the surface in and around the filter clamp. The filter index wheel can be moved by hand.
- Take care **not** to dislodge the O-rings.
- Inspect and if necessary gently clean the input and output cups.
- Wipe the other external surfaces of the filter station.

Cleaning the Magnets

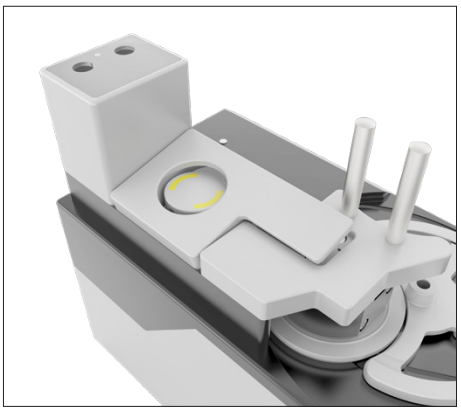
If there has been a spill or leakage of liquid on or in the peristaltic pump: The pump cover can be removed to allow the area beneath to be cleaned. The cover is held in place by magnets.

Procedure

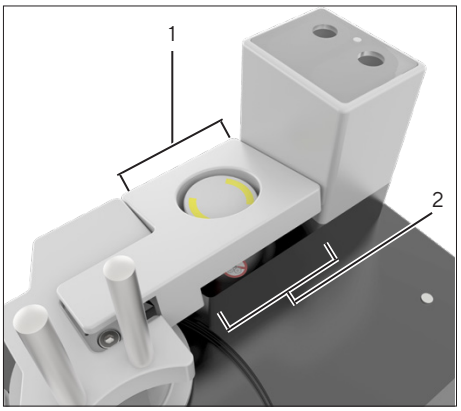
- ▶ ⚠ **CAUTION** Impairment of pacemakers or other medical implants due to magnetic forces from the magnets in the pump cover. Maintain a safety distance of at least 0.1 m between the device and the pacemaker | medical implant.
- ▶ Lift the cover vertically upwards to remove the covers.
- ▶ Clean the magnets using a soft lint free cloth and mild detergent.
- ▶ If particles of magnetic material are stuck to the magnets: Either remove them with gloved thumb and fingers or use plastic tweezers.



- ▶ To replace the pump cover, place the short side of the white pump cover (1) in position, being careful **not** to push the tube down.



- ▶ Rotate the pump cover until it rests over the pump rotor.



- ▶ Squeeze between the white pump cover on short side (1) and black pump base (2).
- ▷ The magnets in the pump cover will automatically locate the pump cover.

8.2.3 Cleaning the Waste Filter Containers

Requirements

- — All processes on the device have ended.
- — The waste filter containers have been removed (see chapter 7.7, page 43).

Procedure

- ⚠ **CAUTION** Impairment of pacemakers or other medical implants due to magnetic forces between the filter station and the liquid handler base assembly. Maintain a safety distance of at least 0.1 m between the waste filter container and the pacemaker | medical implant.
- Spray a surface cleaner (see chapter "14.11 Cleaning Agents and Cleaning Procedures", page 64) and wipe down the waste filter containers.
- Take care **not** to spill any residual cell culture that may leak from the used filters.
- When completely removed from the device: Wash the waste filter containers in sink with a max. temperature of 50 °C.

8.2.4 Cleaning the Liquid Handler Surface

Requirements

The filter stations have been removed.

Procedure

- Remove the labware holders and clean them by immersion in water with a mild detergent.
- Wipe the external surfaces of the liquid handler using a soft lint free cloth and surface cleaner. If necessary: Mild detergents can be used.
- If necessary: Move the liquid handler head by hand to facilitate cleaning.
- Manually pull the stainless steel tip down.
- Inspect and if necessary clean the tip using a soft lint free cloth and surface cleaner (see chapter "14.11 Cleaning Agents and Cleaning Procedures", page 64).
- Do **not** move the liquid handler head while the tip is lowered.
- Push the tip back up once inspection and | or cleaning is finished.

8.3 Maintenance Schedule

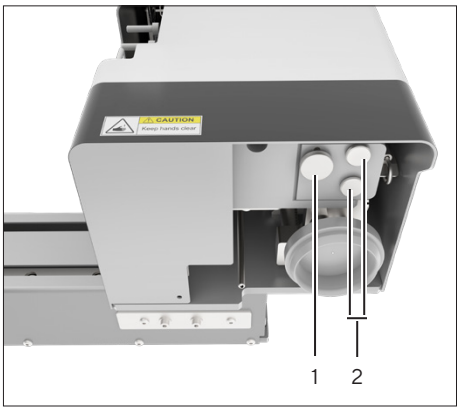
Interval	Part	Action	Chapter, page	Target group
Each time the filter station is disconnected | connected	Magnets	Inspect and clean the magnets.	8.2.2, 48	User
Annually (recommended)	pH electrode	Replace the pH electrode.	8.3.1, 51	User
	Liquid handler syringe	Have the liquid handler syringe replaced. Contact Sartorius Service for this.		
Annually	Device	Have a general function test performed on the device. Contact Sartorius Service for this.		
	O-rings in the filter holder	Have the O-rings in the filter holder replaced. Contact Sartorius Service for this.		
As required	Liquid lines	Have all liquid lines from the device replaced. Contact Sartorius Service for this.		

8.3.1 Replacing the pH Electrode

Requirements

The pH electrode is supplied wet (with a cap) or has been rehydrated if supplied dry (without a cap) (see chapter “6.2 Rehydrating pH Electrodes“, page 38).

Procedure



- ▶ Move the liquid handler head to the front.
- ▶ Undo the larger thumb screw (1) under the liquid handler head.
- ▶ Remove the pH electrode with its lower housing.
- ▶ **NOTE** Damage to the connector! Avoid splashing the connector with any liquid when replacing the pH electrode.
- ▶ Undo the BNC connector on cable.
- ▶ Undo the smaller thumb screws (2) and retain lower housing.
- ▶ Dispose of the old pH electrode.

- ▶ The replacement pH electrode (see chapter “15.1 Accessories“, page 66) may be supplied wet (with a cap) or dry (no cap). If a cap is fitted: Remove the cap and dispose of the liquid. The cap may be disposed of, or retained for future storage of the pH electrode.
- ▶ Attach the replacement pH electrode to lower housing using the thumb screws (2).
- ▶ Check that the 2 O-rings are still attached to the lower housing.
- ▶ Reattach the BNC connector to the new pH electrode.
- ▶ Raise the pH electrode assembly into the liquid handler head while feeding the cable up.
- ▶ When the pH electrode assembly is positioned correctly: Tighten the larger thumb screw.
- ▶ In order to hydrate and calibrate the pH electrode: Follow the instructions on the StreamLink® CC 15 software.
- ▶ Check for leaks from the pH electrode assembly.

9 Malfunctions

9.1 General malfunctions in the clarification or purification process

Malfunction	Cause	Correction	Chapter, page	Target group
The clarification and | or purification process **cannot** be correctly performed.	The components on the device are faulty, e. g. blocked liquid lines.	Follow the instructions on the screen of the control unit. The type of malfunction and the actions necessary to correct the malfunctions will be displayed on-screen.		User
	The settings of the control unit are unsuitable.	Follow the instructions on the screen of the control unit. The type of malfunction and the actions necessary to correct the malfunctions will be displayed on-screen.		User
	Not enough clarification filters | supply liquids have been loaded or the device has used too many.	Follow the instructions on the screen of the control unit to refill clarification filters or supply liquids (see instructions of the StreamLink® CC 15 software).	7.3, 40	User
The liquids are contaminated, the system is blocked and the sample is lost.	The internal flow path is blocked or partially blocked due to use of unsuitable liquids or other foreign matter in the system.	— Stop the process on the screen of the control unit (stopping a process, see instructions of the StreamLink® CC 15 software). — Run a system CIP to break down any biological matter. — If the problem persists: Contact Sartorius Service.		User
The waste filter container has overflowed and the system is unable to eject used filters.	The waste filter container has **not** been emptied.	Follow the instructions on the screen of the control unit to pause and empty the waste filter container (see instructions of the StreamLink® CC 15 software).	7.7, 43	User
The pumps have stopped and an over-pressure fault is displayed.	The liquid waste lines are clamped, kinked or blocked or there is an internal blockage resulting in an overpressure state.	— Inspect the waste liquid lines. — Inspect the filter station input | output cups for blockages. — If it is safe to do so: Run a CIP (see instructions of the StreamLink® CC 15 software). — If the problem persists: Contact Sartorius Service.		User
The process does **not** start. | The process stops prematurely.	The D-sub connector | USB cable is **not** correctly screwed in place.	— Correctly connect the liquid handler via USB cable to the control unit. — Correctly connect the 2 filter stations to the liquid handler via D-sub connectors.	5.2, 33	User

Malfunction	Cause	Correction	Chapter, page	Target group
The liquid handler robot crashes | The pipette tip gets bent.	— There is an obstruction on the liquid handler bed or to the side of the liquid hander. — The filter stations are not located correctly.	— Stop the process on the screen of the control unit (stopping a process, see instructions of the StreamLink® CC 15 software) and remove any obstacles. — Check the location of the filter stations and use the teach screen to check the master taught position. Straighten the tip to align with the master taught position or have a new tip refitted by Sartorius Service and reteach (see instructions of the StreamLink® CC 15 software).		User
The liquid handler crashes into the labware holders or picks the wrong samples.	The wrong | unsupported labware holders have been used or the labware holders have been placed in the wrong position on the liquid handler bed.	Stop the process on the screen of the control unit (stopping a process, see instructions of the StreamLink® CC 15 software) and place the labware holders in the correct positions (marked areas on the liquid handler bed).	7.4, 41	User
	The incorrect labware holder has been selected in the template.	Stop the process on the screen of the control unit (stopping a process, see instructions of the StreamLink® CC 15 software) and select the matching template.		
The liquid handler fails to pick up lids.	The labware holder has been fitted with a label which prevents the liquid handler from picking up the lids or the lids have cracks.	Stop the process on the screen of the control unit (stopping a process, see instructions of the StreamLink® CC 15 software) and change the labware holders | use labware holders without a label on top.		User
	The teach height is incorrect.	Check the teach height. If the problem persists: Contact Sartorius Service.		User
	The vacuum system has failed.	Contact Sartorius Service.		

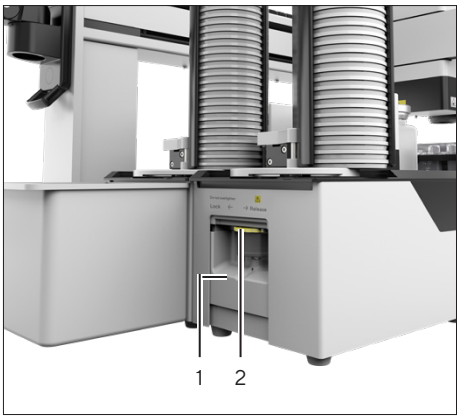
9.2 Malfunctions due to Leaking Liquids

Malfunction	Cause	Correction	Chapter, page	Target group
Liquids are escaping from the device.	The liquid lines are damaged, blocked, or connected incorrectly.	Stop the process on the screen of the control unit (stopping a process, see instructions of the StreamLink® CC 15 software).		User
		Check the liquid lines and the correct connections to the device | bottles.	6.1, 38	User
Liquids are escaping from the filter stations.	The O-ring around the clarification filter is damaged, missing or worn out.	Have the O-rings replaced by Sartorius Service.		
Overflow from the pipette wash station or the filter station input | output cups.	There is a blockage in the input | output cups or pipette wash station outlet due to a waste pump failure.	— Stop the process on the screen of the control unit (stopping a process, see instructions of the StreamLink® CC 15 software). — Wipe out the liquid from the device. — Check that the connectors between the filter station and the base are dry. — Check for blockage in the input | output cups or the pipette wash station. — If the failure comes from a filter station: Disable it and continue the run (see instructions of the StreamLink® CC 15 Software). — If the failure comes from the pipette wash station: Manually remove the samples in the bed and filter station input | output cups. — Contact Sartorius Service.		User
Liquids are leaking from the waste bottle.	The waste bottle has **not** been emtied.	Empty the waste bottle.	7.9, 44	User

9.3 Malfunctions due to Liquid Bottles

Malfunction	Cause	Correction	Chapter, page	Target group
None | not enough liquid is being pumped.	Bottles are **not** connected correctly.	Stop the process on the screen of the control unit (stopping a process, see instructions of the StreamLink® CC 15 software) and connect | refill the respective bottles.	5.4, 34	User
	There is **not** enough liquid in the bottle.			

9.4 Removing a Purification Filter when Damaged, Blocked or Free Spinning



Procedure

- ▶ ⚠ **CAUTION** Risk of injury from escaping liquids! When the clamp comes free: There may be a release of liquid. Ensure you have absorbent paper towel placed around the device to soak it up. Wear safety gloves.
- ▶ Remove the waste filter container (see chapter “7.7 Emptying the Waste Filter Containers”, page 43).
- ▶ Hold the purification filter to prevent it from turning.
- ▶ Turn the purification filter luer lock thumbwheel (2) in the release direction.
- ▶ As the purification filter luer lock thumbwheel (2) is being turned, push down the filter and the lower part of the clamp (1) at the same time.
- ▶ When the upper part of the filter is free: Hold down the lower part of the clamp (1) while simultaneously lifting and turning the filter in the release direction.
- ▶ Remove the purification filter when it is free.

9.5 Recovering from a Bent Pipette Tip

Procedure

- ▶ Use the teach screen to check the master taught position (see instructions of the StreamLink® CC 15 software).
- ▶ Straighten the tip to align with the master taught position and reteach.
- ▶ If the pipette tip requires a replacement: Contact Sartorius Service.

10 Decommissioning

Requirements

- All clarification | purification processes on the device have ended.
- There are **no** filters in the device.

Procedure

- ▶ Empty the device (for draining the liquid lines see instructions on the maintenance panel of the StreamLink® CC 15 software).
- ▶ Turn the device off.
- ▶ Disconnect the power supply connection cable at the installation site.
- ▶ Remove the pH electrode and store it accordingly (see chapter "12.2 Storing pH Electrodes", page 58).
- ▶ Remove the bottles for calibration and storage solution.
- ▶ Disconnect the device from all liquid bottles:
  - waste bottle
  - bottles for supply liquids
- ▶ Remove and empty the waste bottle (see chapter "7.9 Emptying the Waste Bottle", page 44).
- ▶ Remove and empty the waste filter containers (see chapter "7.7 Emptying the Waste Filter Containers", page 43).
- ▶ Clean the device (see chapter "8 Cleaning and Maintenance", page 46).

11 Transport

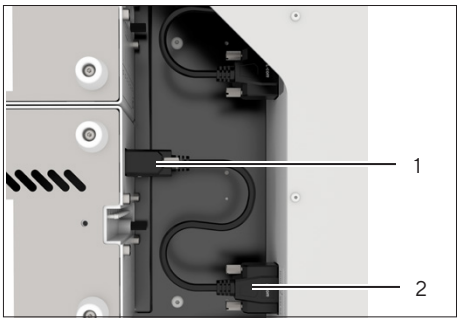
11.1 Disassembling the Device

Requirements

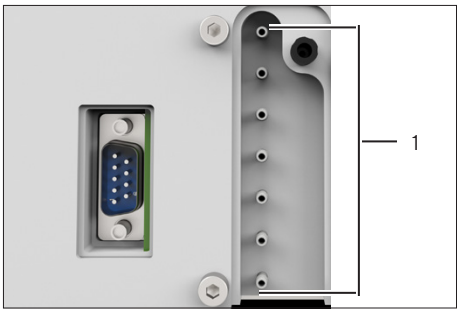
The device has been decommissioned (see chapter 10, page 56).

Procedure

- ▶ Disassemble the device as follows:
  - ▶ Lift off the clarification filter stack holder from each filter station.
  - ▶ ⚠ **CAUTION** Impairment of pacemakers or other medical implants due to magnetic forces from the filter station, the liquid handler base assembly and the waste filter containers. Maintain a safety distance of at least 0.1 m from the device.
  - ▶ Remove the filter stations from the liquid handler by pulling the filter stations to the left to overcome the magnetic coupling force.



- ▶ Disconnect the D-sub connector cable from the liquid handler (2) [FILTER STATION 1] | [FILTER STATION 2] connections and the [Power & Comms] connection on each filter station.
  - ▶ Disconnect all liquid lines from the device.
  - ▶ Use absorbent material to soak up any liquid that leaks from the liquid lines.



- ▶ Disconnect the liquid connections (1) from the filter stations.

- ▶ Disconnect the USB cable provided to the “communication” connection and the cable to the NUC from the liquid handler.
- ▶ Disconnect all the cables from the monitor and NUC.

- ▶ Optional: De-mount the monitor and NUC by following the instructions in chapter “4 Installation“, page 29 in reverse.

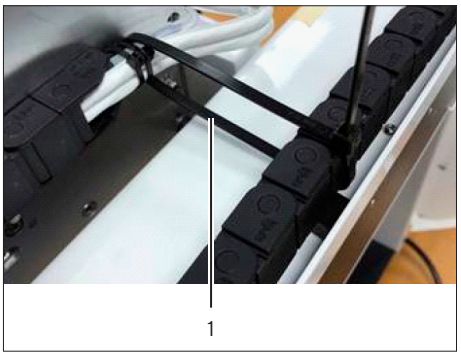
11.2 Transporting the Device

Personnel: 2 users

Requirements

The device has been disassembled (see chapter “11.1 Disassembling the Device“, page 56).

Procedure



- ▶ Ensure that the liquid handler head is secured to the X-axis using a tie-wrap (1).

- ▶ Transport the device.

12 Storage and Shipping

12.1 Storing the Device

Requirements

– The device has been decommissioned (see chapter "10 Decommissioning", page 56).
– The device has been disassembled (see chapter "11.1 Disassembling the Device", page 56).

Procedure

▶ If the liquid lines are removed from the device: Allow the liquid lines to dry completely.
▶ Store the device and liquid lines according to the ambient conditions (see chapter "14.4 Ambient Conditions", page 62).
▶ If the system is to be stored for a period of time or if the system is used in a dusty environment: Tape over the holes in the input | output cups between uses.

12.2 Storing pH Electrodes

Used pH electrodes when removed from the device (see chapter "8.3.1 Replacing the pH Electrode", page 51), must be stored as follows:

Storage Option	Storage Type
Recommended method	In storage solution for pH electrodes, e. g., 2.5M KCl buffer (as air tight as possible)
Alternative method	Dry storage

Procedure

▶ If the pH electrodes are to be stored in storage solution:
  ▶ Thoroughly rinse the pH electrodes with deionized water (DI). The connection cable and plug of the pH electrode must **not** be exposed to moisture.
  ▶ Dab the pH electrodes using paper towels.
  ▶ Place the pH electrodes in a container with storage solution. The connection cable and plug of the pH sensor must **not** be exposed to moisture.
  ▷ The cap supplied with the pH electrode (when supplied wet) is the most appropriate container to use if it is available.
  ▶ If using the cap: Pour pH electrode storage solution into the cap and place the cap over the bulb of the electrode. Keep the cap on until next use.
  ▶ If using a container: Pour pH electrode storage solution into a container so the liquid covers only the bulb of the electrode.

- ▶ If the electrode is being stored for a long time: Check the cap | container periodically to ensure the storage solution is still in the cap | container and keeping the bulb moist.

▶ If the pH electrodes are to be stored dry:
- ▶ Store the pH electrodes according to the ambient conditions (see chapter “14.4 Ambient Conditions“, page 62).
- ▷ The pH electrodes dry out. For re-use, the pH electrodes must be re-hydrated during the process preparation (see chapter “6.2 Rehydrating pH Electrodes“, page 38).

12.3 Returning Device and Parts

Defective devices or parts can be sent back to Sartorius. Returned devices must be clean, decontaminated, and packed properly.

Transport damage as well as measures for subsequent cleaning and disinfection of the device or parts by Sartorius shall be charged to sender.

Devices contaminated with hazardous materials, e. g., harmful biological or chemical substances, will **not** be accepted for repair or disposal. The devices must be decontaminated before shipping (for decontamination, see chapter “10 Decommissioning“, page 56).

Procedure

▶ Decommission the device.
▶ Ensure that the device has been disassembled (see chapter “11.1 Disassembling the Device“, page 56).
▶ Contact Sartorius Service for instructions on how to return devices or parts (please refer to www.sartorius.com).
▶ Pack the device and its parts properly for return.

13 Disposal

13.1 Decontaminating the Device

The device does **not** contain any hazardous materials that would necessitate special disposal actions.

The cultures and media (e. g., acids and bases) used during the process are potentially hazardous substances that might cause biological or chemical hazards.

If the device has come into contact with hazardous substances: Steps must be taken to ensure proper decontamination and declaration.

Requirements

The device has been cleaned.

Procedure

- ▶ Decontaminate the device. The user of the device is responsible for adhering to local government regulations on the proper decontamination and declaration for transport and disposal.

13.2 Disposing of Device and Parts

The device falls under the UK and EU's WEEE regulations.

The device and the device accessories must be disposed of properly by disposal facilities.

The consumables are designed and intended for single-use.

Requirements

The device has been decontaminated.

Procedure

- ▶ Dispose of the device. Follow the disposal instructions on our website (www.sartorius.com).
- ▶ Dispose of the packaging in accordance with local government regulations.
- ▶ Dispose of all components of the liquid lines, bottle sets, waste liquid lines and pH electrodes in accordance with local government regulations.

14 Technical Data

14.1 Dimensions and Weight

	Unit	Value
Packaging dimensions (length x width x height)	mm	1170 x 650 x 995
Weight, packed device	kg	80
Weight of heaviest item (liquid handler)	kg	27

14.2 Power Supply

	Unit	Value
Voltage	V_{AC}	230 | 120
Frequency	Hz	50 | 60
Current consumption	A	0.7 | 1.4
Mains connection via country-specific power supply connection cable		
AC power outlet at the installation site		
Required number of power sockets for a liquid handler		1
Required number of power sockets for control unit		2
Plugs to be connected to filtered power supplies or all 3 plugs to be connected to a single power strip.		
Type: Standard for country-specific EU, UK or US power plug		
Fuse in the mains plug for the liquid handler power supply connection cable (UK only)		
Quantity: 1		
Type: Miniature fuse, T, 10 A, HBC, 5 x 20 mm, ceramic		
Manufacturer: Littelfuse®, Littelfuse, Inc., Chicago, IL, USA		
Fuses in the mains plugs for the NUC and monitor power supply connection cables (UK only)		
Quantity: 2		
Type: Miniature fuse, T, 5 A, HBC, 5 x 20 mm, ceramic		
Manufacturer: Littelfuse®, Littelfuse, Inc., Chicago, IL, USA		

14.3 Set up Dimensions

	Unit	Value
Device with controller attached, excluding bottles		
Recommended (width x depth x height)	mm	1220 x 530 x 630
Recommended (width x depth x height), including levelling platform*	mm	1220 x 530 x 660
Device excluding controller and excluding bottles		
Recommended (width x depth x height)	mm	910 x 530 x 610
Recommended (width x depth x height), including levelling platform*	mm	910 x 530 x 640
Full system with bottles		
Recommended (width x depth x height)	mm	1350 x 530 x 630
Recommended (width x depth x height), including levelling platform*	mm	1350 x 530 x 660

* The use of the levelling platform allows the device to be set up on surfaces that are not flat and | or level.

14.4 Ambient Conditions

	Unit	Value
Conventional laboratory rooms, max. 2000 m above sea level		
Operating temperature	°C	+6 – +40
Relative humidity during operation, max.	%	60
Protection class according to EN 60529		IP2X

14.5 Filters

Approved filters
Sartoclear® Disc
Sartobind® Rapid A Nano

14.6 Centrifuge Tubes

Approved centrifuge tubes
For 50 mL centrifuge tube holders with lid: 50 mL centrifuge tubes from Corning, Falcon, VWR, TPP
For 15 mL centrifuge tube holders with lid: Conical 15 mL centrifuge tubes from Corning, Falcon, VWR, TPP

14.7 Approved Liquids

	Unit	Value
Liquids which do **not** contain cell clumps larger than Ø 0.25 mm and	or crystalline solids		
Ambient air		
Lab water, e. g. ultrapure water, reverse osmosis water (RO), or deionized water (DI)		
pH electrode storage solution: buffer containing 2.5M Potassium Chloride (KCl)		
Calibration buffer		
Low pH value | must meet with NIST traceable buffer guidelines	pH	4
Neutral pH value | must meet with NIST traceable buffer guidelines	pH	7
Elution: Low pH buffer (see instructions of Sartobind® Rapid A Nano for additional guidance)	pH	2.3 – 3.5
Strip: Low pH buffer	pH	~ 2
Wash | Rinse 2: Higher conductivity buffer	pH	6 – 8
Equilibration | Rinse 1: Standard buffer	pH	6 – 8
Cleaning solution		
Type: Sodium hydroxide (NaOH)		
Concentration, maximum	M	1
Purification device storage solution: e. g. PBS with 20 % ethanol (see instructions of Sartobind® Rapid A Nano for additional guidance)		

14.8 Acoustic Emission

	Unit	Value
Normal operation	dB(A)	67.2
Filters being ejected (short period of time)	dB(C)	93.8

14.9 Materials

Materials that come into contact with the process fluids and | or system fluids
Fused silica glass
Borosilicate glass
PE
TPE
PP
Nylon PA12
PVDF
Silicone
FEP
PVC
Stainless steel 304 | 316
EPDM
PEEK
PTFE

14.10 Filtration Volume

	Unit	Value
Filtration volume		
Minimum volume (nominal)	mL	5
Maximum volume (nominal)	mL	15

14.11 Cleaning Agents and Cleaning Procedures

Wiping the surfaces with aseptic cleaning agents which are suitable for the device materials, e. g. deionized water, followed by 70 % ethanol or 70 % isopropyl alcohol
No spraying procedures
No autoclaving
No hydrogen peroxide H_2O_2

14.12 IT Connection of the Device

IT connection	Required | optional	Reason for connection to the device	Required duration: Permanent | while work is being carried out
Network connection via Ethernet | WiFi	Optional	— View device status — Receive email notifications — Data transfer	While accessing the device

15 Accessories and Consumables

15.1 Accessories

This table contains an excerpt of the accessories that can be ordered.
For information on other products, please contact Sartorius.

Item	Quantity	Order number
Ambr® 15 vessel holder with lid	1	061-8B50
Microplate holder	1	061-8B51
50 mL centrifuge tube holder with lid	1	061-8B52
15 mL centrifuge tube holder with lid	1	061-8B53
Lid for Ambr® 15 vessel holder	1	061-8B60
Lid for centrifuge tube holder	1	061-8B61
Feed | Waste bottle set	1	061-2B20
Feed | Waste bottle lid set	1	061-2B21
Feed connection tubing set	1	061-2B22
Liquid handler bottle set	1	061-2B23
Liquid handler bottle lids	1	061-2B24
Syringe pump pH probe assembly	1	061-2B26
Levelling platform	1	061-8B30

15.2 Consumables

This table contains an excerpt of the consumables that can be ordered. For information on other products, please contact Sartorius.

Item	Quantity	Order number
Sartobind® Rapid A Nano	Box of 2	96R-PA19D-T11--V
Sartobind® Rapid A Nano	Box of 4	96R-PA19D-T11--A
Sartoclear® Disc	Box of 24	29DF020-DIA----2

16 Sartorius Service

Sartorius Service is available for queries regarding the device. Please visit the Sartorius website (www.sartorius.com) for information about the service addresses, services provided, or to contact a local representative.

When contacting Sartorius Service with questions about the system or in the event of malfunctions, be sure to have the device information, e. g., serial number, hardware, firmware, configuration, close at hand. Consult the information on the type label.

17 Conformity Documents

The attached documents declare the conformity of the device with the designated directives or standards.

Original

EG-/EU-Konformitätserklärung
EC / EU Declaration of Conformity

Hersteller / *Manufacturer*: **The Automation Partnership (Cambridge) Limited**
York Way, Royston, Hertfordshire, SG8 5WY, United Kingdom

erklärt in alleiniger Verantwortung, daß das Betriebsmittel

declares under sole responsibility that the equipment

Geräteart / *Device type*: Automatisiertes mikroskaliges Klär-und Reinigungssystem für die Prozeßentwicklung.
Automated microscale clarification and purification system for process development.

Baureihe / *Type series*: **StreamLink® CC 15 (Alle Varianten und Subsysteme)**
StreamLink® CC 15 (All Variants and sub-systems)

in der von uns in Verkehr gebrachten Ausführung allen einschlägigen Bestimmungen der folgenden Europäischen Richtlinien entspricht

in the form as delivered fulfils all the relevant provisions of the following European Directives

2014/30/EU	Elektromagnetische Verträglichkeit / *Electromagnetic compatibility*
2011/65/EU + 2015/863/EU	Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro-und Elektronikgeräten (RoHS) / *Restriction of the use of certain hazardous substances in electrical and electronic -equipment (RoHS)*
2006/42/EC	Maschinen / *Machines*

auf der Grundlage der geltenden Anforderungen der folgenden harmonisierten europäischen Normen, die bei der Konstruktion und Herstellung der Geräte verwendet wurden, einschließlich etwaiger zum Zeitpunkt der Erklärung geltender Änderungen:

based on the applicable requirements of the following harmonised European standards used in the design and manufacture of the equipment, including any amendments valid at the time this declaration was signed:

EN 61326-1:2013
EN IEC 63000:2018
EN ISO 12100:2010
EN ISO 14120:2015
EN ISO 13849-1:2015
EN ISO 13849-2:2012
EN 61010-1:2010+A1:2019
EN 61010-2-081:2020

Andere verwendete Normen / *Other standards used*:
EN 61508-1:2010
EN 61508-5:2010

Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen:

The person authorised to compile the technical file:

Sartorius Stedim Biotech GmbH,
August-Spindler-Straße 11,
D-37079 Göttingen, Germany

The Automation Partnership (Cambridge) Limited
Royston, 2023-03-01

Andrew Wylde
Manager of Hardware Development

Dominic Bushnell
Head of Operations Site

Doc: 2971444 TAP-9067-09-001 Issue 3 1 / 1 PMF: 061-8B01

Original

UKCA Declaration of Conformity

Manufacturer **The Automation Partnership (Cambridge) Limited**
York Way, Royston, Hertfordshire, SG8 5WY, United Kingdom

declares under sole responsibility that the machinery

Device type **Automated microscale clarification and purification system for process development.**

Model **StreamLink® CC 15 (All Variants and sub-systems)**

in the form as delivered fulfils all the relevant provisions of the following UK legislation:

Electromagnetic Compatibility Regulations 2016

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

Supply of Machinery (Safety) Regulations 2008

based on the applicable requirements of the following Designated Standards used in the design and manufacturing of the equipment, including any amendments valid at the time this declaration was signed:

EN 61326-1:2013
EN IEC 63000:2018
EN ISO 12100:2010
EN ISO 14120:2015
EN 61010-1:2010+A1:2019
EN 61010-2-081:2020

Other standards used
EN 61508-1:2010
EN 61508-5:2010

In addition to the above information, the manufacturer declares:

Person authorised to compile the technical file:

The Automation Partnership (Cambridge) Limited
York Way
Royston
Hertfordshire
SG8 5WY
UK

The Automation Partnership (Cambridge) Limited
Royston, 2023-03-02

Andrew Wylde
Manager of Hardware Development

Dominic Bushnell
Head of Operations Site

Doc: 2971445 **TAP-9067-09-002 Issue 2.00** 1 / 1 PMF: 061-8B01

Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen, Germany

Phone: +49 551 308 0
www.sartorius.com

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:

07 | 2023

LM | Publication No.: SPC6077-e230703