Operating Instructions
Original Operating Instructions

Virus Counter® Plus

For Rapid Virus Quantification

1000089769

SARTORIUS

Contents

1 About these Instructions

1.1 Scope

These instructions are part of the instrument; they must be read in full and stored. These instructions apply to the following versions of the instrument:

Instrument | Product	Type | Version
Virus Counter® Plus	VIR-92394
Virus Counter® Plus Software	3.4.21304.1 and higher

1.2 Related Documents

- In addition to these instructions, please refer to the following documents:
  - Product inserts | reagents
  - Virus Counter® Plus Golden Rules
  - Virus Counter® Plus Best Practices Guide

1.3 Target Groups

These instructions are addressed to the following target groups. The target groups must possess the knowledge specified below.

Target group	Knowledge and Qualifications
Operator	The operator is familiar with the instrument and the associated work processes. The operator understands the hazards which may arise when working with the instrument, and knows how to prevent them.*
Operating engineer | laboratory manager	The operating engineer | laboratory manager makes decisions about the use and configuration of the instrument.*
Administrator	The administrator is responsible for integrating the instrument into the production process. The administrator ensures the reliable functioning of the system and instrument software.*

* If a person in the target group operates the software interface of the instrument, they are also the “user”.

1.4 Symbols Used

1.4.1 Warnings in Operation Descriptions

⚠ DANGER
Denotes an immediate hazard that will result in death or serious injury if it is **not** avoided.

⚠ WARNING
Denotes a hazard that may result in death or severe injury 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 hazard that may result in property damage if it is **not** avoided.

1.4.2 Other Symbols Used

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

Figures in these Instructions

The figures on the operating display of the instrument may differ from those in these instructions.

2 Safety Information

2.1 Intended Use

The Virus Counter® Plus instrument is intended to be used together with the Virus Counter® Plus software for the quantification of virus samples in near real time. It is intended for counting viruses and other nanoparticles in pharmaceutical and biotechnological production and laboratory operations.

The Virus Counter® Plus instrument and associated software and consumables are intended for general laboratory research applications. Do **not** use for diagnostic or therapeutic procedures or patient-connected applications; accordingly these have **not** been submitted for FDA approval. Any other application above or beyond this or any modifications to the unit without the written permission of the manufacturer is **not** considered proper use.

The software is installed on the PC supplied. The PC must be connected to the Virus Counter® Plus instrument. All process sequences must be controlled on the screen.

Each PC is specific to the instrument provided and must **not** be replaced or used for purposes other than running Virus Counter® Plus software. Do **not** install any other programs on the PC.

Do **not** use the instrument for processes involving risk group 3 or 4 biological agents (pursuant to Directive 2000/54/EC).

The instrument is intended exclusively for use in accordance with these instructions. Any further use beyond this is considered improper. If the instrument is used improperly: The instrument's protective systems may become impaired.

The instrument must only be operated with the sample bay door securely closed. The instrument will operate with the sample bay door opened in reduced speed "safety mode" but use with the door open is considered improper use (see chapter „3.9 Protective Equipment", page 22).

Caution: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Operating Conditions for the Instrument

Do **not** use the instrument in potentially explosive environments. Only use the instrument indoors.

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

The installation site must be free of potential overhead leak sources (i.e., plumbing, or fluid storage reservoirs) and must **not** be located under common work or storage areas.

Please contact Sartorius Service with any questions regarding appropriate workspace for the instrument. The instrument should only be configured and installed by authorized Sartorius Service.

2.1.1 Modifications to the Instrument

If the instrument is modified, for example by attaching extra components: The safety of the instrument may be impaired or the instrument compliance may lose its validity.

If you have any queries regarding modifications to the instrument, contact Sartorius Service.

2.1.2 Instrument Repairs and Maintenance

Any repair and service work shall be carried out by Sartorius Service or trained personnel. Maintenance procedures can be found in chapter „10 Cleaning and Maintenance“, page 50.

2.1.3 Foreseeable Misuse

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

- Operating the instrument with the sample bay door open.
- Operating the instrument with items in the sample bay which may impede the operation of the sample probe.
- Operating the instrument without the sample plate and consumables vial rack correctly inserted.
- Operating the instrument without adequate consideration being taken in safe placement of cabling, constituting a potential trip hazard.
- Operating the instrument without filling Plus® fluid prior to use.
- **Not** emptying the waste reservoir prior to use.
- Using blocking agents to manipulate the door sensor.
- Operating the instrument with the left or right safety panels open.

2.2 Qualifications of Personnel

Persons who do **not** possess adequate knowledge about how to use the instrument may injure themselves and other persons

If a particular qualification is required for an activity: The target group will be specified. If **no** qualification is specified: The activity may be carried out by the “operator” target group.

2.3 Instrument Functionality

Non-functioning instrument parts, e.g., as a result of damage or wear, can cause malfunctions. There is a risk of injury to persons.

- If instrument parts are **not** functional: Do **not** use the instrument.
- Comply with the maintenance intervals (for intervals and maintenance tasks, see chapter „10.5 Maintenance Schedule“, page 51).
- Have any damage repaired immediately by Sartorius Service.

2.4 Protective Equipment

The protective equipment on the instrument protects persons who work with the instrument against the hazards associated with it, e.g., electrical current. If the instrument's protective equipment is dismantled or modified: People may be seriously injured.

- Do **not** dismantle, modify, or disable the protective equipment (see chapter „3.9 Protective Equipment", page 22).

2.5 Safety Information on the Instrument

Symbols, e.g., warnings and safety labels, are safety information for handling the instrument. Missing or illegible safety information may result in this information **not** being observed. There is a risk of injury to persons.

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

2.6 Electrical Equipment

2.6.1 Damage to the Instrument's Electrical Equipment

Damage to the instrument's electrical equipment, e.g., damaged insulation, can be life-threatening. Contact with parts under voltage represents a danger to life.

- If the electrical equipment of the instrument is defective, turn off the power supply and contact Sartorius Service.

2.6.2 Power Supply Cable

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

- Only use the original power supply cable.
- If the power supply cable needs to be replaced: Please contact Sartorius Service.
- Do **not** repair or modify the power supply cable.

2.7 Conduct in an Emergency

If an emergency occurs, e.g., due to malfunctions of the instrument or dangerous situations: People might get injured. The instrument must be immediately taken out of operation:

- ▶ Disconnect the power supply cable from the mains power supply socket at the installation site.
- ▶ Secure the instrument to prevent it from restarting.
- ▶ Call Sartorius Service to repair any malfunctions.

2.8 Accessories, Consumables, and Spare Parts

The use of unsuitable accessories, consumables, and spare parts can affect the functionality and operating reliability of the instrument and have the following consequences:

- Risk of injury to persons
- Damage to the instrument
- Instrument malfunctions
- Failure of the instrument

- ▶ Only use accessories, consumables, and spare parts that have been approved by Sartorius for this instrument (see chapter „16 Consumables“, page 76).

2.9 Personal Protective Equipment

Personal protective equipment protects against risks arising from the instrument. If the personal protective equipment is missing or is unsuitable for the work processes on the instrument: Persons may be injured.

The following personal protective equipment must be worn:

- Protective work clothing
- Safety gloves
- Safety glasses
- Safety boots

2.10 Unexpected Start-up of the Instrument

Depending on the settings of the PC and the instrument, components of the instrument may start moving unexpectedly after a power outage and cause injury to personnel in close proximity.

- ▶ Observe the information on the behavior of the instrument after a power outage (see chapter „8.1 Operating Modes“, page 41).

2.11 Moving Parts

If people come into contact with moving parts, e.g. sample | consumables tray or sample probe, body parts such as hands and fingers may get caught.

- Do not open the sample bay door during operation.
- Wear personal protective equipment (see chapter „2.9 Personal Protective Equipment“, page 11).

2.12 Biological Agents

Biological agents (risk group 1 and risk group 2) can cause disease in humans and could pose a hazard to employees.

- The instrument should be operated within a biological safety cabinet when working with biological agents of risk group 2.
- Waste bottles must be filled with 100 mL bleach to ensure that a final 10% bleach concentration is achieved with waste fluids to decontaminate the waste bottles.
- Wear appropriate personal protective equipment.
- Ensure that reservoirs for sample and syringe waste are correctly connected and sealed to the waste tube.
- Use appropriate measures suitable for biological agents respective to their biosafety level.

2.13 Aerosols

Aerosols generated within the instrument are minimized due to the positive displacement syringe-driven system, however, the generation of aerosols can**not** be ruled out. This can cause contamination or infection from biological agents or chemicals.

- Use appropriate measures suitable for biological agents respective to their biosafety level.
- During operation and after finishing measurements keep the sample bay door closed for at least 10 minutes after sample processing to allow aerosols to settle.
- The instrument should be operated within a biological safety cabinet (biological agents risk group 2).
- Wear appropriate personal protective equipment.

2.14 Analysis Laser

Under normal use conditions, the instrument is considered a Class 1 laser instrument. A class 3B laser is built in the instrument and is blocked from user interaction. The laser radiation can cause serious eye damage, including blindness, or skin damage.

- Do **not** open safety panels. The safety panels are a secondary safety barrier for the laser.
- Do **not** remove any laser safety covers.
- Repair only by Sartorius Service.
- Note the warning label on the instrument.

2.15 Consumables

There is a risk of serious injuries due to chemical substances.

- Only reagents approved by Sartorius may be used in the operation, cleaning, and maintenance of this instrument.
- The reagents must be placed in the consumables vial rack in the correct order to avoid incorrect mixing of the reagents (see chapter 7.8, page 36).
- Wear appropriate personal protective equipment.

2.16 Heavy Weight of the Instrument

The instrument has a high intrinsic weight. When lifting and transporting the instrument, there is a danger of injury, e.g., as a result of the instrument falling.

- Get help from additional persons when lifting and transporting the instrument.
- Use suitable conveyance instruments, e.g., trolleys, for long transport routes.

3 Instrument Description

3.1 Instrument Overview

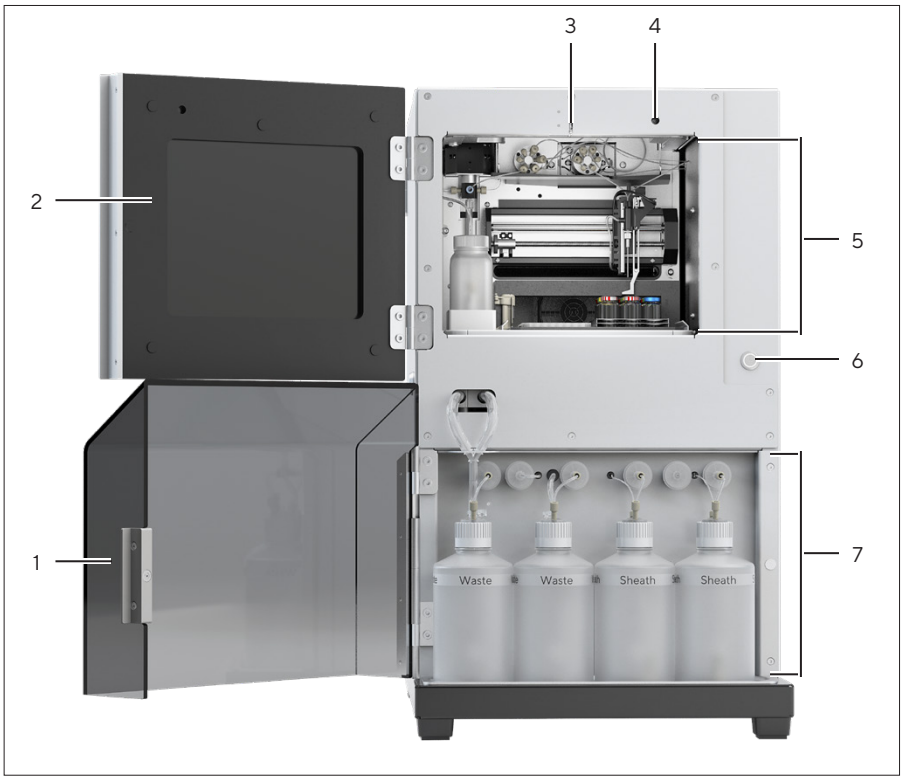


Fig. 1: Virus Counter® Plus – front view

Pos.	Name	Description
1	Fluid bay door	
2	Sample bay door	
3	Door safety sensor sample bay	The sensor checks whether the sample bay door is open or closed.
4	Status LED sample bay	The LED shows the status of the instrument (see chapter „11.1 Troubleshooting Overview“, page 59).
5	Sample bay	Main operating part of the instrument for loading samples and reagents.
6	Power on | off button	When powered up, the surround is solid white. The LED shows the status of the instrument (see chapter „11.1 Troubleshooting Overview“, page 59).
7	Fluid bay	Pressurized and unpressurized reservoirs for waste and operating fluids.

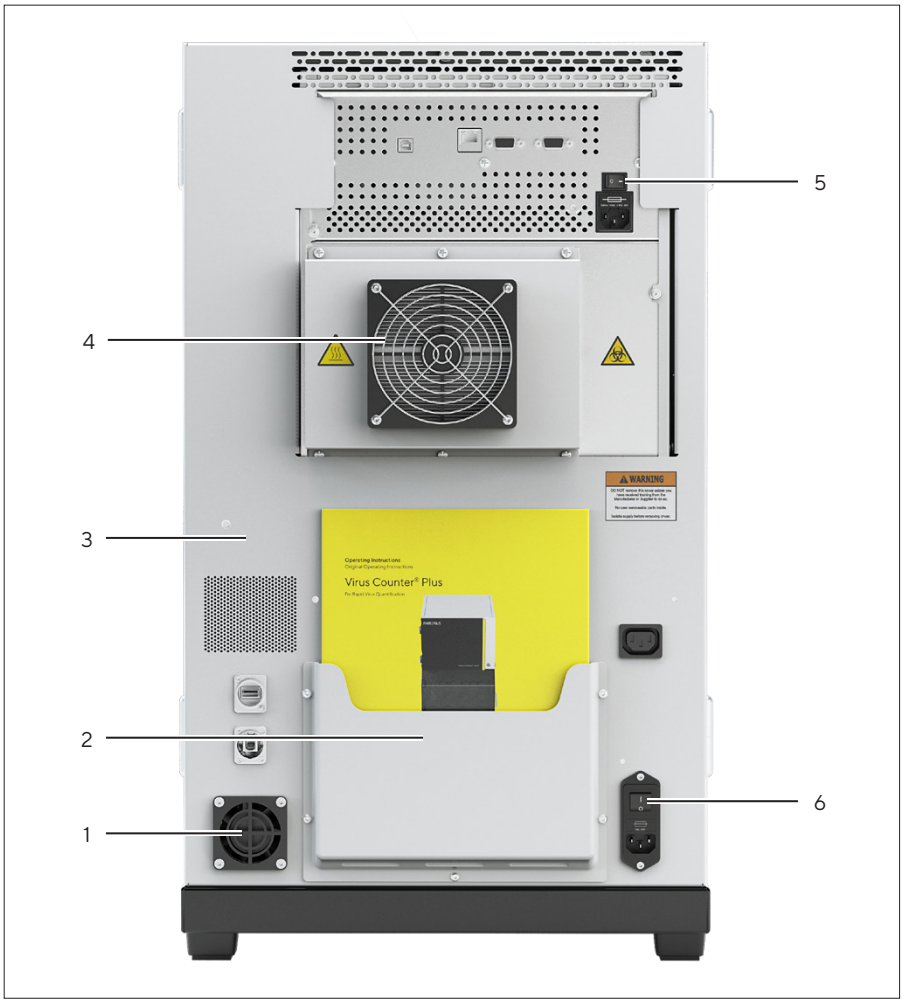


Fig. 2: Virus Counter® Plus – rear view

Pos.	Name	Description
1	Fan	Fan for cooling internal electronics
2	Manual holder	Recepticle for documents
3	Type plate	Manufacturer identification label
4	Cooling fan	Cooling fan for refrigeration unit
5	On | off switch sample bay	Switch for powering up and powering down the sample bay
6	On | off switch power supply	Switch for powering up and powering down the main power supply

3.2 Sample Bay

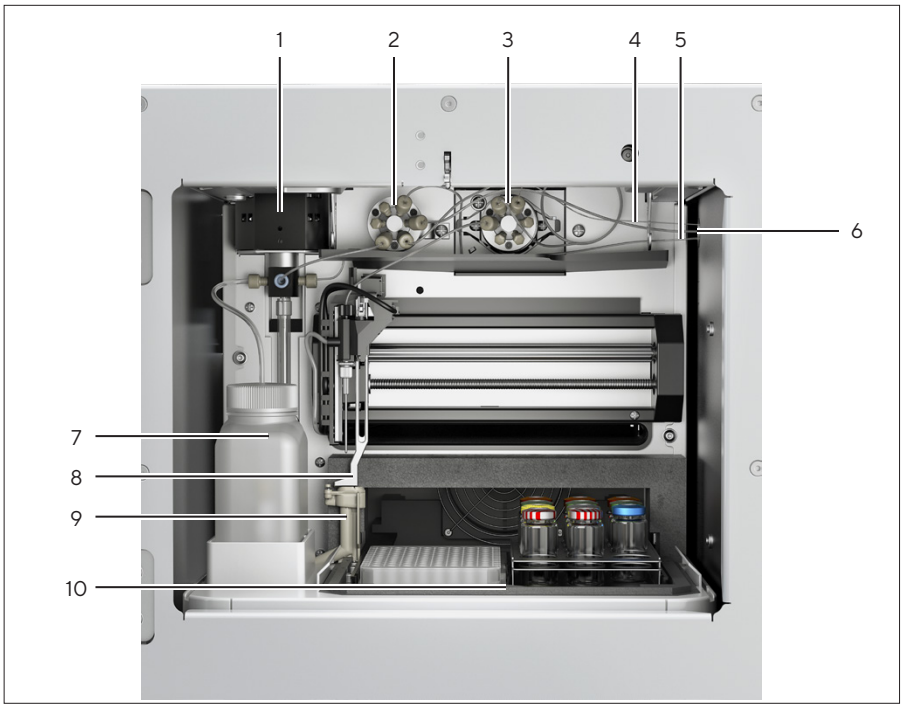


Fig. 3: Sample bay

Pos.	Name	Description
1	Syringe pump	Aspirates and dispenses sample and reagents for transportation into detector.
2	Microfluidic valve	Switches the method of fluid transportation by using either a syringe pump for direct transfer or air pressure for measurement purposes, both at a controlled flow rate.
3	Injection valve	Controls collection of reagent and sample.
4	Sample capillary	Transports sample fluid to detection point instrument.
5	Syringe tube	Transports the Plus® fluid to the syringe.
6	Pressure line	— For pressurized air — Pressurized air controls rate of fluid flowing through detector
7	250 mL ethanol bottle	Contains ethanol for routine system priming.
8	Vessel detection	Detects the presence of the wellplate and vials.
9	Waste and rinse station	Rinses the sample probe and dispenses to the waste bottle.
10	Sample | consumables tray	Moveable software-controlled compartment for sample.

3.3 Fluid Bay | 1 L Source Bottles

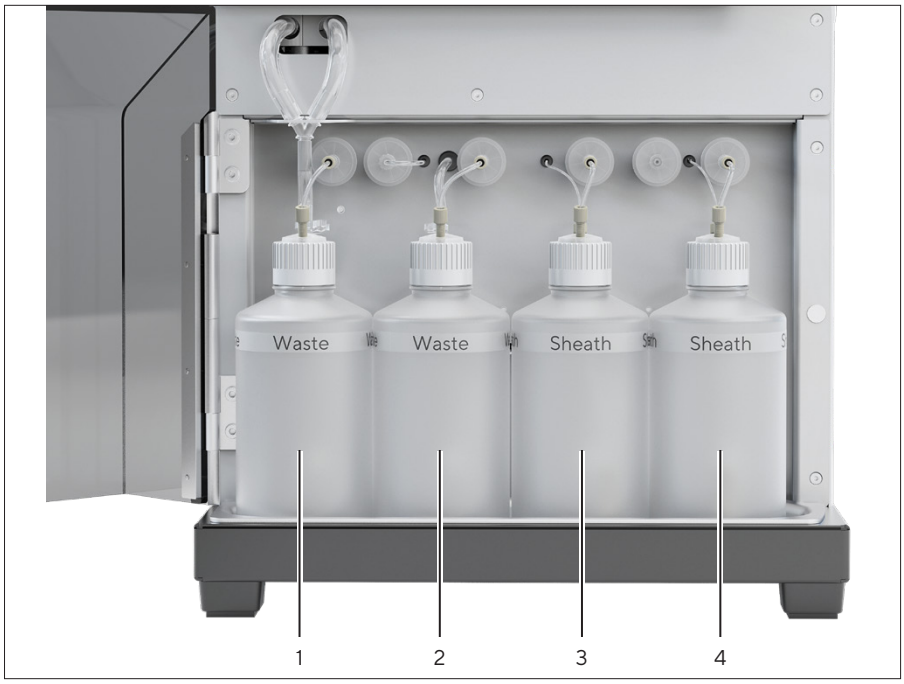


Fig. 4: Fluid bay

Pos.	Name	Description
1	Syringe waste (Waste 1)	Reservoir for the rinsing liquid from the sample probe.
2	Sample waste (Waste 2)	Reservoir for post analysis sample waste.
3	Plus® fluid (Sheath 1)	Drive fluid for syringe pump system.
4	Plus® fluid pressurized (Sheath 2)	Fluid used in instrument detector.
Not shown	1 L system wash bottles	Contain cleaning fluid. Used for routine maintenance of the system.
Not shown	1 L ethanol bottles	Used for priming and hydrating a dry instrument (new instrument and after long-term shutdown).

3.4 Filters

Fig. 5: Filters, fluid bay

Pos.	Name	Description
1	Waste exhaust air filter	Filters the exhaust air of the waste.
2	Sample air filter	Filters the air used to push the sample liquid into the detector.
3	Waste sample filter	Filters the air used to pressurize the sample waste bottle.
4	Syringe filter	Filter for atmospheric air vent for fluid used by syringe pump.
5	Air-pump filter	Air intake filter for air pump.
6	Plus® fluid filter	Filter for air pressure used to push sheath fluid into detector.

3.5 Connectors

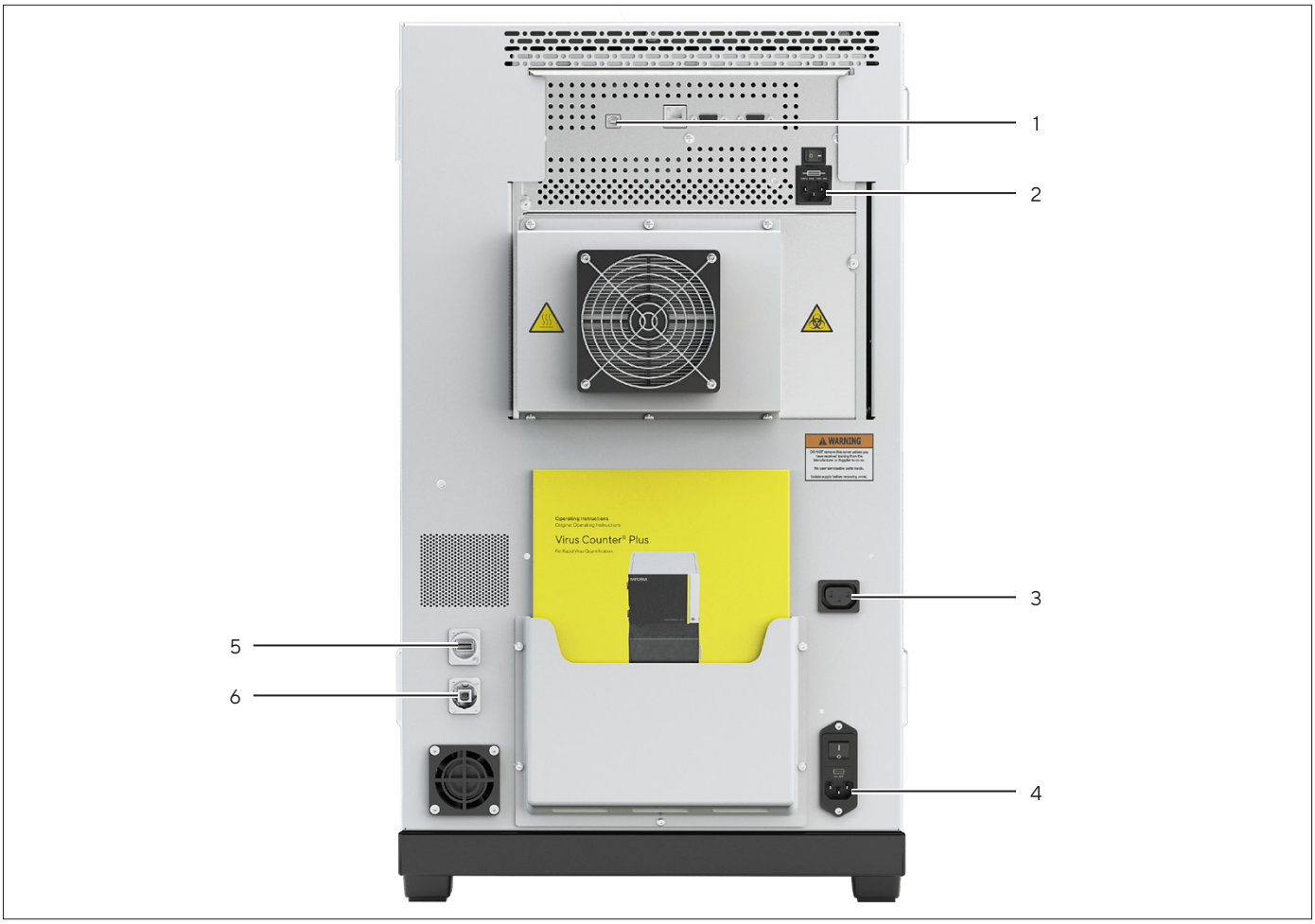


Fig. 6: Connectors on rear side

Pos.		Name	Description
1		USB-socket, sample bay	Standard USB-B connector to connect the autosampler.
2		Autosampler power connector	Input power supply for the autosampler.
3	Autosampler 200 VA (Max)	Autosampler main power connector	Output power supply for the autosampler.
4	**Mains Power** Fuse: 2x 5A(T), 250V, HBC, 20 x 5mm	Main power connector	Main power supply for the complete instrument.
5	Laptop	USB socket, PC	
6	Autosampler	USB socket , autosampler	

3.6 Consumables Vial Rack and Sample Tray with Sealing Material

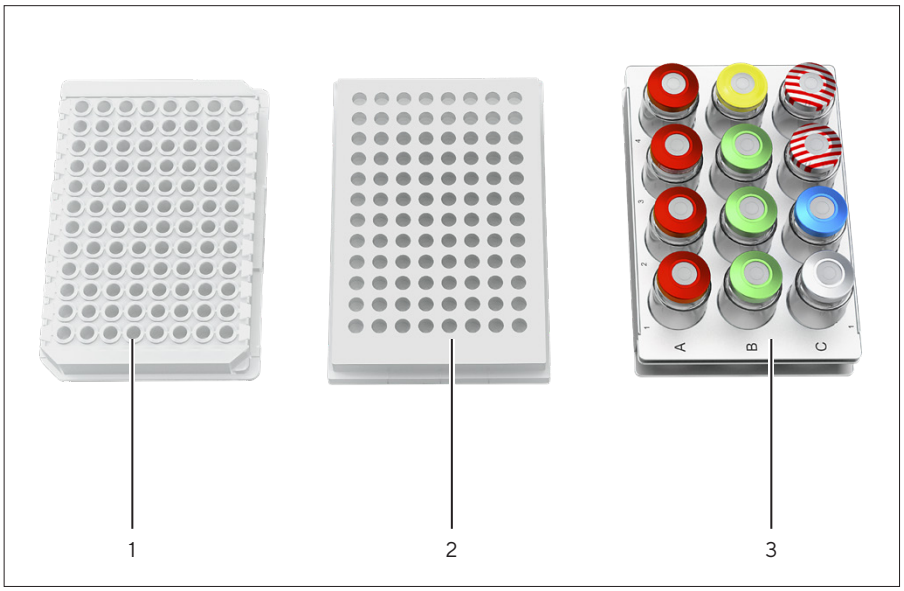


Fig. 7: Sample plate without | with sealing mat and consumables vial rack

Pos.	Name	Description
1	Sample plate	Contains samples, locks into sample | consumables tray.
2	Sealing mat	Seals the samples to prevent fluid escape during operation.
3	Consumables vial rack	— Contains vials of consumables. — Locks into sample | consumables tray.

3.7 Chiller Cover

Fig. 8: Chiller Cover

Pos.	Name	Description
1	Chiller cover	For use in conjunction with chiller. Protects the samples from temperature changes. It is required to maintain samples at temperature setting when chiller is used.

3.8 Service Panel

Fig. 9: Service panels, side view

Pos.	Name	Description
1	Service panel, right side	Only allowed to be opened by Sartorius Service.
2	Service panel, left side	

3.9 Protective Equipment

The instrument is equipped with a door safety sensor on the sample bay door. If the door is not securely closed, the instrument will only operate at a greatly reduced speed (safety mode) to avoid any potential risk of injury due to moving parts. The door should be closed securely for normal operation.

3.9.1 Disconnecting Instrument

The „on | off“ switches for sample bay and the power supply on the rear panel of the instrument are not considered as a safe isolator from the main power supply. The instrument is only entirely disconnected if the power plug on the power supply cable is removed from the power supply socket at the installation site.

3.10 Symbols on the Instrument

3.10.1 Warning and Information Labels

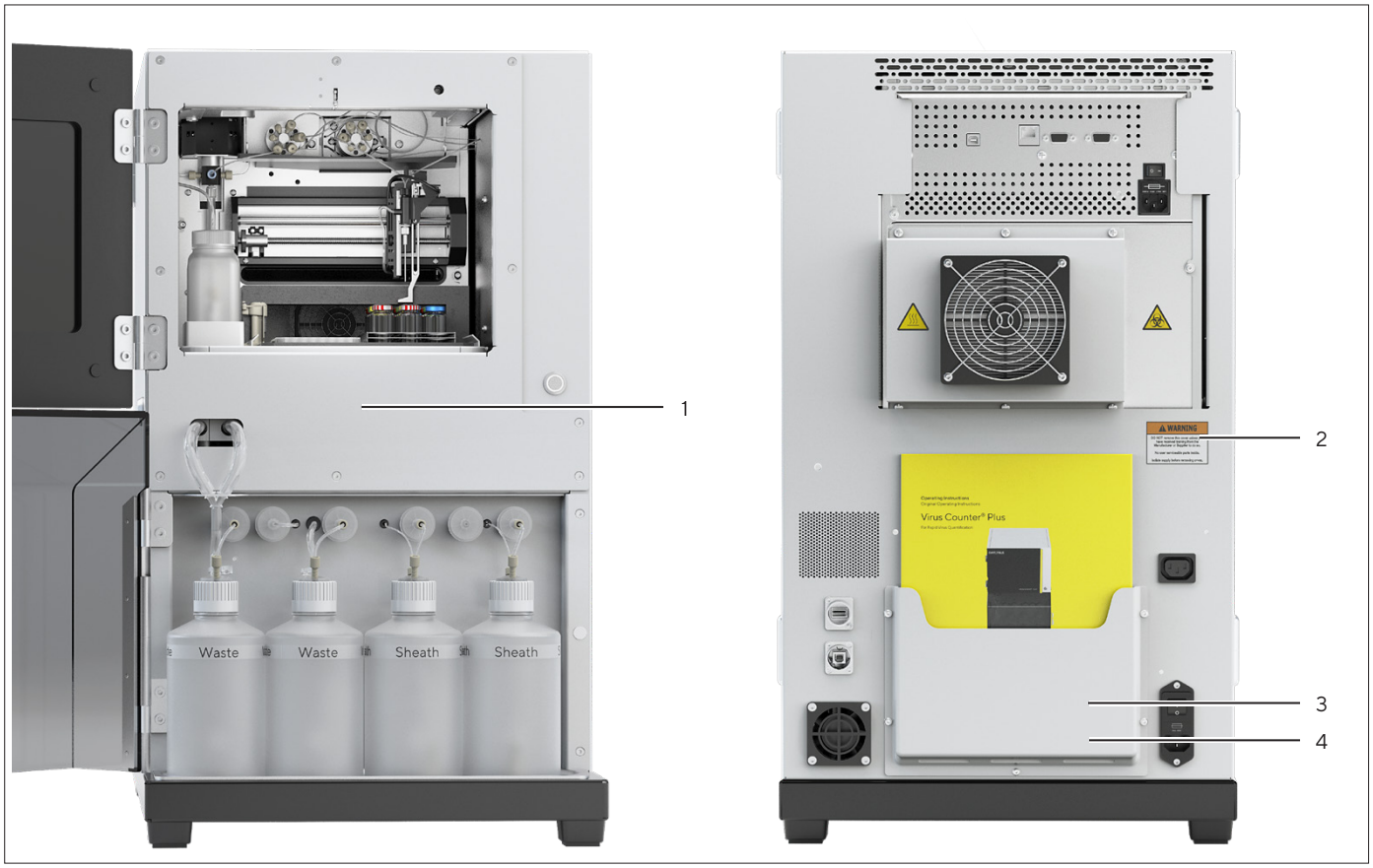


Fig. 10: Positions of the symbols on the front and back of the instrument

Pos.	Symbol	Meaning
1		– Pinch: Risk of trapping fingers or loose clothing from moving parts. Only operate the instrument with the sample bay door fully closed. Appropriate PPE should be worn at all times. – Puncture: Risk of puncture from the sample probe. Only operate the instrument with the sample bay door fully closed. Appropriate PPE should be worn at all times.

Pos.	Symbol	Meaning
2	**WARNING** DO NOT remove this cover unless you have received training from the Manufacturer or Supplier to do so. No user serviceable parts inside. Isolate supply before removing cover.	The inside of the instrument, apart from the fluid and sample bay, does **not** contain any customer-serviceable parts. Only qualified Sartorius Service should ever remove the cover.
3	Complies with FDA performance standards for laser products except for conformance with IEC 60825-1 Ed. 3., as described in Laser Notice No. 56, dated May 8, 2019.	
4	CLASS 1 LASER PRODUCT EN/IEC 60825-1 2014	Product qualifies as Class 1 under all procedures of operation and maintenance. Repair work on the laser is not permitted and may only be carried out by Sartorius Service. The service panels must not be removed from the instrument or opened (see chapter „3.8 Service Panel“, page 21).

3.10.2 Manufacturer’s ID Label

Fig. 11: Manufacturer’s ID Label (example)

4 Installation

4.1 Scope of Delivery

Item	Quantity
Virus Counter® Plus type: VIR-92394	1
Installation kit	1
PC	1
Power supply cable	1
Autosampler power cable, country-specific	1
PC power cable	1
Autosampler USB cable, 1 m	1
PC USB cable, 1 m	1
Sample plate	1
Consumables vial rack	1
Waste bottles	2
Plus® fluid bottles	2
Alcohol hydration bottles	2
Maintenance cleaning bottles	2
EtOH bottle (250 mL)	1
Operating instructions	1

4.2 Selecting an Installation Site

⚠ WARNING!

Risk of injury from falling equipment due to insufficient dimensioned footprint!

- ▶ Install instrument on a stable table to ensure that it cannot lose balance or tip over.

Procedure

- ▶ Ensure that the setup conditions have been met (see chapter “15 Technical Data“, page 74).

4.3 Unpacking and Installing the Instrument

The instrument will be unpacked and installed by Sartorius Service.

Procedure

▶ Please call Sartorius Service.

4.4 Acclimatization

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

Procedure

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

5 Introduction to the Operating Concept

5.1 Main Screen

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

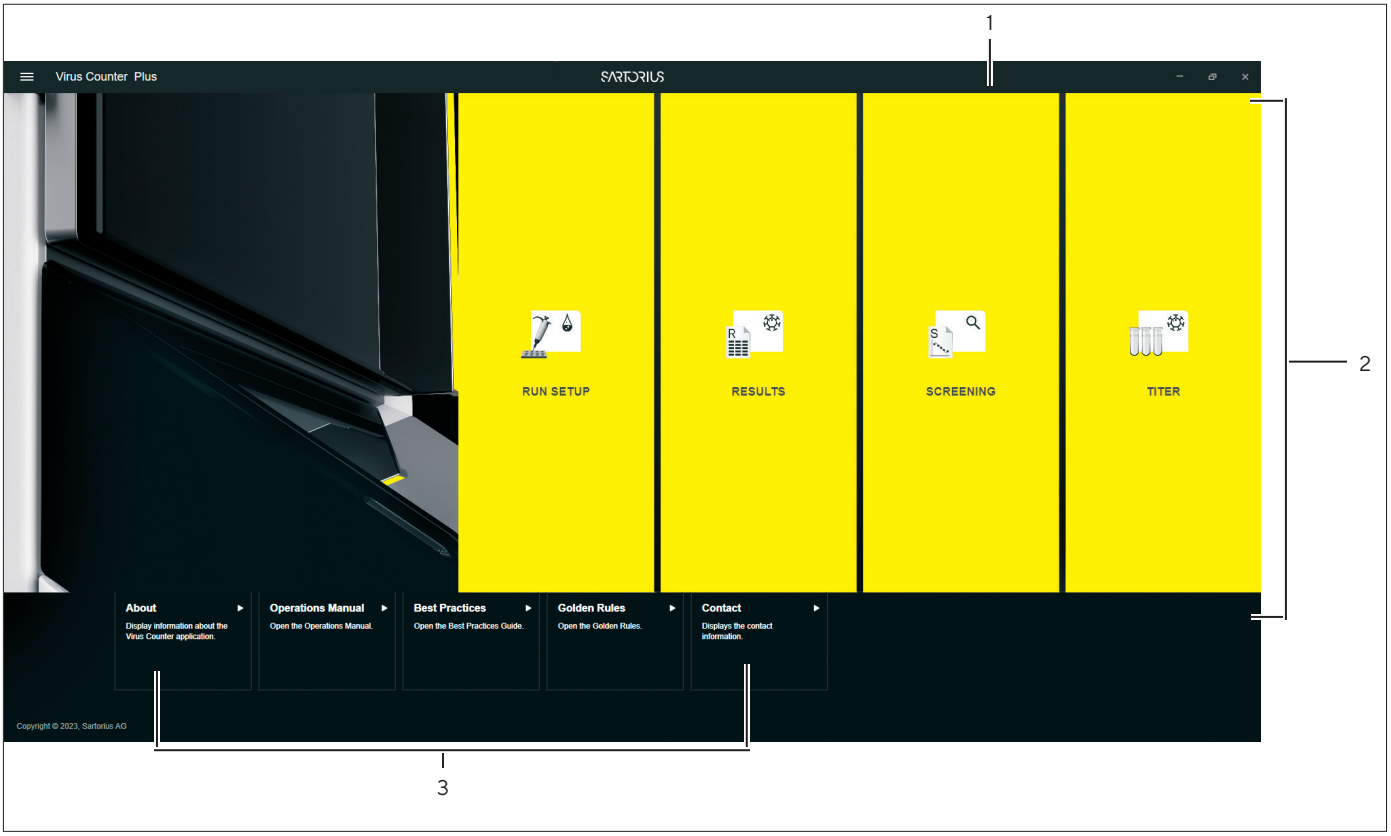


Fig. 12: Main Screen

Pos.	Name	Description
1	Header	Includes drop down menus, e. g. [FILE], [OPTIONS] or [HELP].
2	Action Tiles	Opens other screens, e. g. the [RUN SETUP] screen.
3	Quicklinks	Opens different help menus: – About: Displays a dialog box with information about the current software version. – Operation Manual: Opens a link to the current version of this operating manual. – Troubleshooting: Displays the troubleshooting guide. – Best Practices: Displays the best practices guide. – Golden Rules: Displays the Golden Rules document. – Contact: Displays a dialog box with details on how to contact Sartorius for technical support.

5.2 [RUN SETUP] Screen and Instrument Control Panel

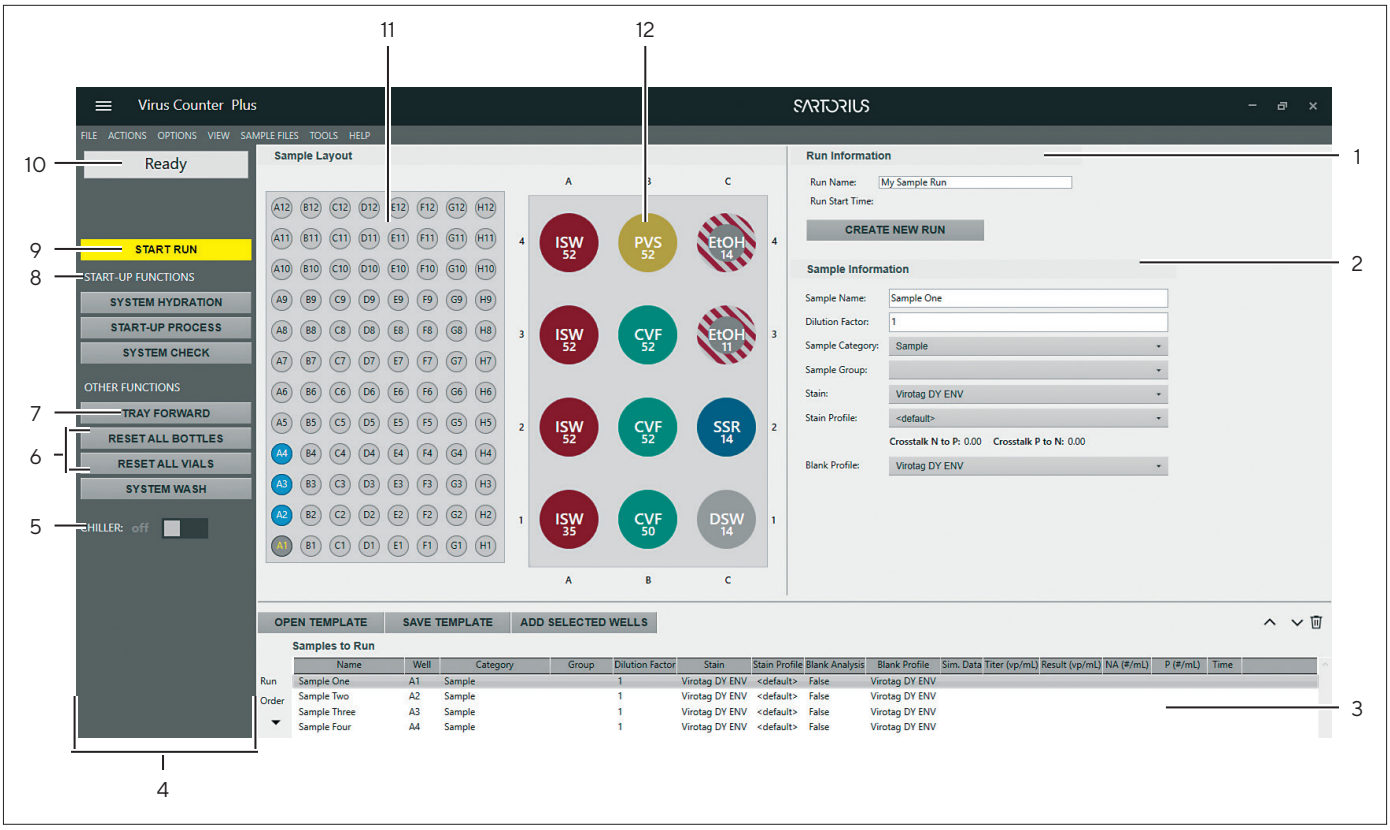


Fig. 13: [RUN SETUP] Screen and Instrument Control Panel

Pos.	Name	Description
1	Run Information	Contains “Run Name“, “Run Start Time“, and [Create New Run].
2	Sample Information	Fields for “Sample Name“, “Dilution Factor“, “Sample Category“ etc.
3	Samples To Run	Lists the samples that are analyzed in a run. This area is updated in real time as samples are selected in the layout area above it.
4	Instrument Control Panel	Includes menus, instrument status indicator, and function control buttons.
5	Chiller	Activates | deactivates the chiller.
6	RESET ALL VIALS | BOTTLES	Resets all vials or bottles to the default state.
7	TRAY FORWARD	Moves the sample | consumable tray in the front position.
8	START-UP FUNCTIONS	Initiates a cycle of different performances, e. g. [SYSTEM CHECK].
9	START RUN	Creates a sample and start analysis with the current settings.
10	Status Bar	Indicates the current status of the instrument and process.
11	Sample Layout	Highlights the samples to be run.
12	Vials Area	Shows the filling level of the reagents.

5.3 [RESULTS] Screen

The [RESULTS] screen displays sample analyses that have been saved to the database, and is searchable and sortable. Data metrics and raw data can be accessed within this action tile.

This area consists of a sortable, searchable table that allows the user to access all sample analyses that have been saved to the database. The table includes important information and metrics for each sample.

Double clicking on the sample will provide additional information for the sample that appears below the sample entry.

Below are explanations of each parameter on the results screen, and following that a range of nominal values that can be expected during runs.

Value	Description
Well	For plates, row, and column designations, e.g. A1-G12.
Results (vp/mL)	Calculated number of viral particles in 1 mL of sample.
Titer (vp/mL)	Will be identical to “Results (vp/mL)“; Reflects the concentration of the original sample when the dilution factor is taken into account. It only changes when dilutions are being factored in.
NA Counts (#/mL)	Vtag1/Nucleic (#/mL); this is the concentration of nucleic acid particles in 1 mL of sample.
P Counts (#/mL)	Protein (#/mL); this is the concentration of protein particles in 1 mL of sample.
S Counts (#)	Shows a count of simultaneous peaks. It is this number that is used to directly calculate results, based on flow rates.
NA Peak Heights (V)	Average height of peaks on the nucleic acid channel, in volts.
P Peak Heights (V)	Average height of peaks on the protein channel, in volts.
NA Peak Widths (µs)	Average width of peaks on the nucleic acid channel, in microseconds.
P Peak Widths (µs)	Average width of peaks on the protein channel, in microseconds.

5.4 [SCREENING] Screen

The [SCREENING] screen graphically displays the results selected from the [RESULTS] screen. Refer to the Data Analysis section for detailed description of the use of the Screening function.

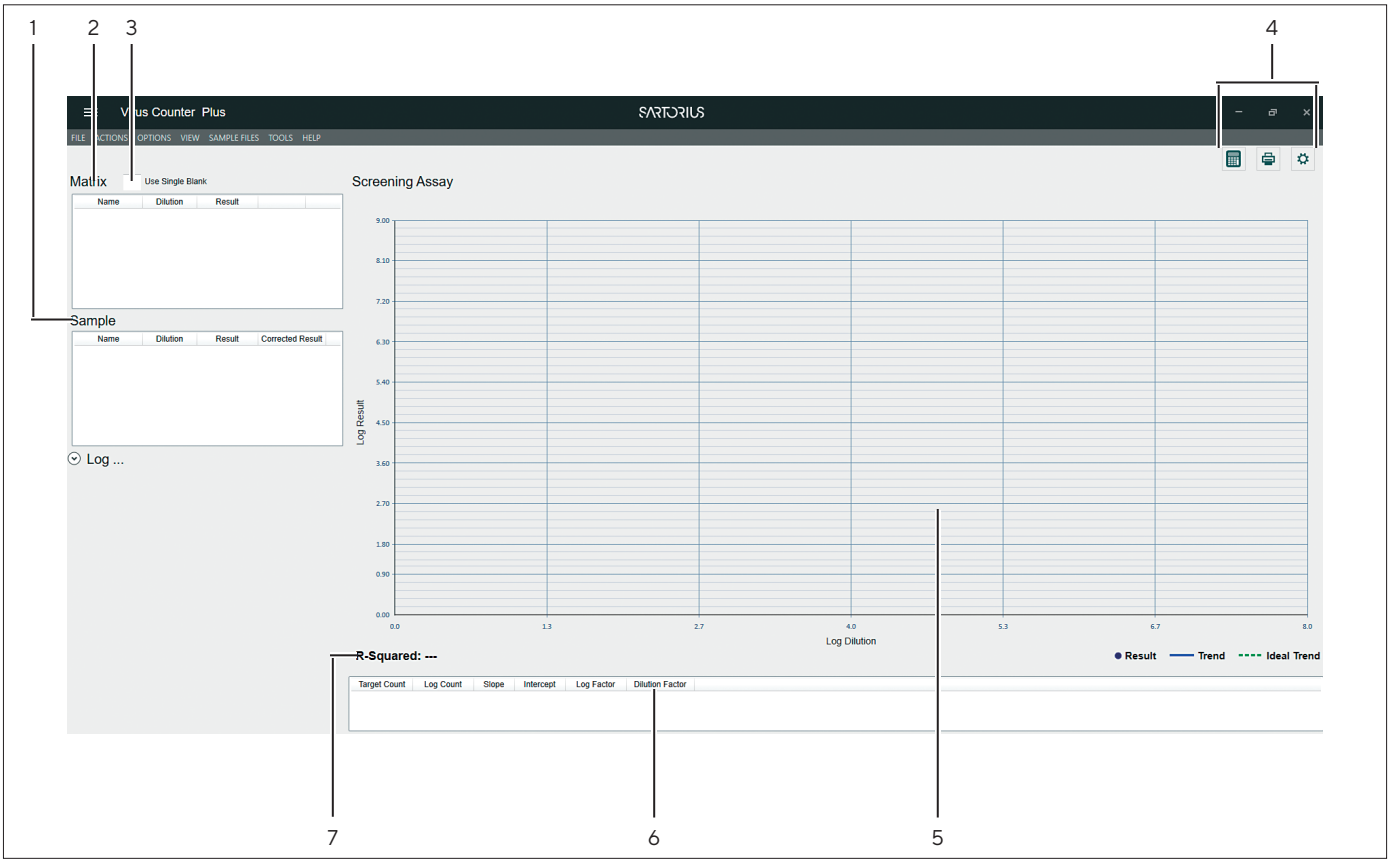


Fig. 14: [SCREENING]

Pos.	Name	Description
1	Sample Table	Populates samples from dilution series.
2	Matrix Table	Populates matrix samples which do not contain virus positive.
3	Single Blank Box	Box to be checked if there is a single matrix to correspond to all samples.
4	Action buttons	– Calculator: To plot the data and fit a linear regression line – Printer: To print out the data received. – Gear: To activate | deactivate the “Ideal Trend”
5	Graphic Area	Shows the trend line (blue) etc.
6	Dilution factor	The factor by which the original sample is diluted in sample dilution buffer.
7	R-Squared	Represents the proportion of the variance for a dependent variable that is explained by an independent variable in the graph.

6 Getting Started

6.1 Checking All Connections and Cables

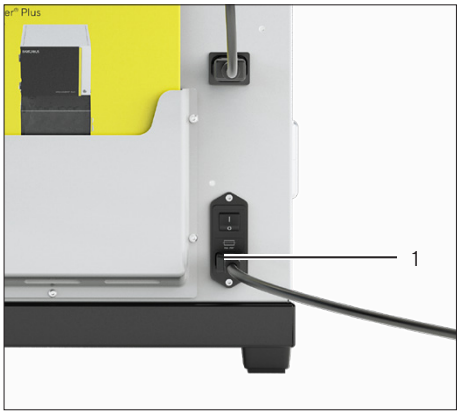
Procedure

- ▶ Check cables for damage, e.g., cracks in the insulation.
  - ▶ If required: Please contact Sartorius Service.

6.2 Connecting the Main 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: Please contact Sartorius Service.
- ▶ **NOTICE** Damage to the instrument due to excessive input voltage! Check whether the voltage specifications on the power supply unit and in technical data match those of the power supply at the installation site.
  - ▶ If the input voltage is too high: Do **not** connect the instrument to the power supply.
  - ▶ Please contact Sartorius Service.
- ▶ Insert the power supply cable firmly into the main power connector on the rear of the instrument (1) and into a mains supply socket on the installation site.



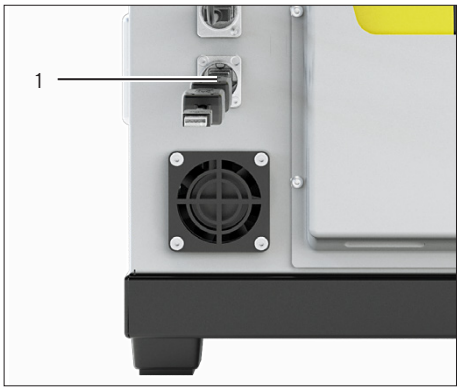
6.3 Connecting the PC

The PC should be connected to the instrument exclusively by attaching the supplied USB-B cable.

NOTICE

Unreliable hardware | software behavior due to additional USB devices!

- ▶ Do not connect any other USB devices to the PC, except for the following:
  - Virus Counter® plus
  - Mouse
  - External keyboard
  - USB drive



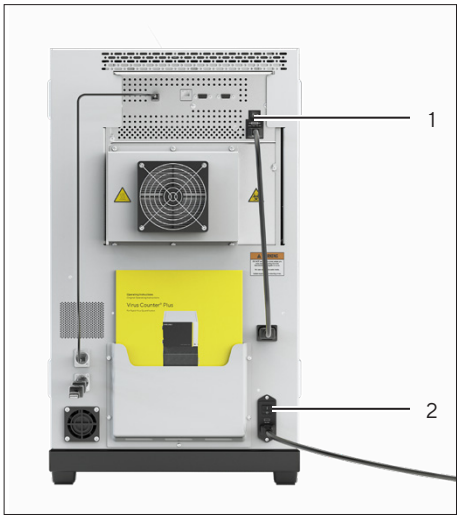
Procedure

- ▶ Connect the power supply cable to the PC and to the power supply at the installation site.
- ▶ If the PC is set up: Connect the USB cable provided to the USB-B connector (1) on the rear of the instrument. The USB cable with black boxes near the connectors is used to connect the instrument to the PC.
- ▶ Connect the other end of the USB cable to the PC.
- ▶ If required: Connect mouse, keyboard, and USB drive to the PC.
- ▶ Follow the set-up procedure according to the instructions in the software manual.

6.4 Powering on the Main Switches

Requirements

- The instrument is connected to the mains supply.
- All cables are securely connected.



Procedure

- ▶ Turn on switch sample bay (1) and switch power supply (2) on the rear of the instrument.
- ▶ Wait 45 min to warm up the instrument (see chapter „15.6 Warm-up Time“, page 75).

7 Process Preparation

The software supplied with the Virus Counter® Plus alongside the software manual supports a fully guided workflow for process preparation and operation of the instrument. Only major steps pertaining purely to the hardware preparation are contained here.

7.1 Switching the Instrument to Active Mode

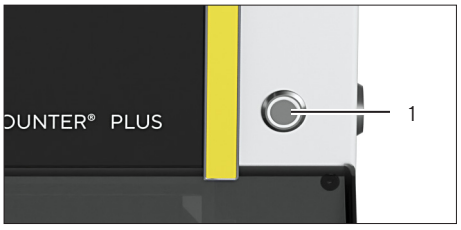
When the [Power on | off button] is not illuminated, the unit is in standby mode. In standby mode, the heater module is supplied with power to maintain the proper temperature.

As long as the instrument is connected to mains power, and the switches on the back of the instrument are turned on, and after the initial warm-up period, the instrument is always ready to perform fluidic startup operations. It is not necessary to wait for the instrument to warm up each day.

Requirements

The instrument is **not** in operation.

Procedure



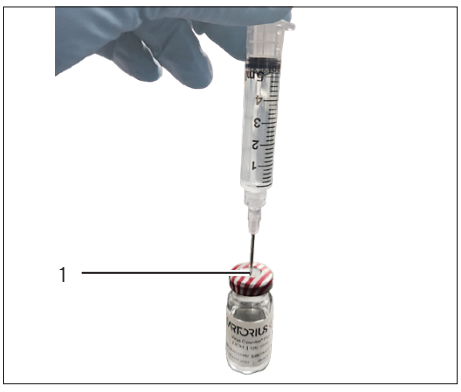
▶ Push the [Power on | off button] on the front of the instrument (1).
▷ The light around the button will illuminate solid white.
▷ The instrument is ready to use with no further delay.

7.2 Refilling the EtOH Vial (Optional)

EtOH vials arrive prefilled. If a refill is needed, follow the procedure below.

The total capacity of the vial is 10 mL.

Material	Unit	Value
EtOH vial	mL	10
EtOH solution	%	≥95
Syringe needle (to be provided by user)	mL	10



Procedure

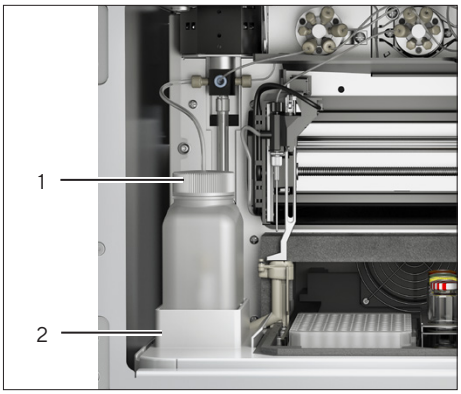
▶ Insert the syringe needle into the top of the EtOH vial (1).

▶ Gently press down onto the syringe plunger until the vial is full (2).

7.3 Filling the 250 mL EtOH Bottle

Material	Unit	Value
EtOH solution	%	≥95

Procedure



▶ Open the fluid bay door.
▶ Unscrew the cap (1) of the 250 mL EtOH bottle and remove the bottle from the sample bay.
▶ Fill the 250 mL EtOH bottle with EtOH solution to the neck of the bottle.
▶ Ensure that the uptake filter remains at the bottom of the bottle.
▶ Place the EtOH bottle in the sample bay container (2) and screw on the cap.

7.4 Emptying the Waste Reservoir (Waste 1 | 2)

The waste reservoir within the fluid bay collects mixed waste. This waste consists of Plus® fluid and anything run through the sample system (e.g., virus samples, standards, Inter-Sample Wash, Cleanliness Verification Fluid). Waste reservoirs should be emptied before a sample run.

Material: Bleach, 100 mL

Requirements

The instrument is in standby mode.

⚠ WARNING

Risk of infection due to contact with waste fluid!

People may come into contact with the waste fluid due to overflowing waste reservoirs or incorrectly connected waste reservoirs. The waste fluid may contain virus components that have not been deactivated.

▶ Ensure that the waste reservoir is correctly connected to waste tube.
▶ Load the waste bottle with 100 mL bleach solution to inactivate viruses as they enter the bottle.
▶ Wear appropriate PPE.

Procedure

- ▶ Open the fluid bay door.
- ▶ Remove the waste reservoir from the fluid bay.
- ▶ Hold the cap of the waste reservoir with one hand. Unscrew the bottle of the waste reservoir with the other hand and carefully remove it downwards.
- ▶ If liquid drips from the silicone tubing: Absorb with a wipe and disinfect with sufficiently strong EtOH (70 %).
- ▶ Dispose of the waste (i.e., pour it into an appropriate waste receptacle).
- ▶ Add 100 mL of bleach to the empty waste reservoir.
- ▶ Screw on the cap of the waste reservoir and insert the waste reservoir into the fluid bay.

7.5 Filling the 1 L Source Fluid Bottles (Sheath 1 | Sheath 2)

The instrument is supplied with 3 sets of 1 L source fluid bottles, which are used for 3 different operations.

- Alcohol bottles: The ethanol bottles are filled with 95% ethanol. The ethanol bottles are used for priming and rehydrating a dry system. The alcohol bottles may also be used for troubleshooting a system suspected of having air in the lines.
- Sheath bottles: The sheath bottles are filled with sheath fluid for normal operation of the system.
- System wash bottles: The system wash bottles are filled with cleaning solution and are used for routine maintenance.

Requirements

The instrument is in standby mode.

⚠ CAUTION

Risk of slipping and falling!

If a fluid-filled tube bursts or becomes unattached, the fluid can spray or splash from the tube, resulting in injuries to people nearby from slipping and falling.

- ▶ Ensure appropriate PPE is worn at all times.
- ▶ Detach the instrument from the mains power supply and clean.

NOTICE

Property damage due to unapproved fluids!

- ▶ Only use the appropriate Virus Counter® Plus sheath fluids.

NOTICE

Property damage and measurement inaccuracies due to missing sheath fluids!

- ▶ Fill the fluid reservoirs to the maximum with sheath fluids before each use.

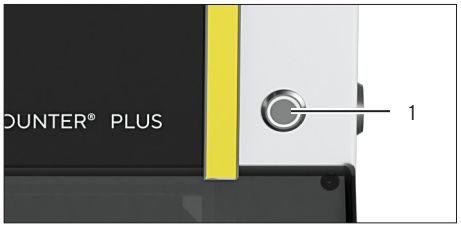
Procedure

- ▶ Open the fluid bay door.
- ▶ Remove the fluid reservoir from the fluid bay.
- ▶ Hold the cap of the fluid reservoir with one hand. Unscrew the bottle of the fluid reservoir with the other hand and carefully remove it downwards.

- ▶ Fill the reservoirs with the appropriate Plus® fluid until the fluid level reaches the nominal level (1). Do **not** overfill.
- ▶ Insert the fluid reservoir into the fluid bay.
- ▶ Ensure that the uptake filter remains at the bottom of the bottle and screw on the cap of the fluid reservoir.

7.6 Turning the Instrument on

Procedure



- ▶ Push the on | off button on the front of the instrument (1).
- ▷ The light around the button illuminates.
- ▶ **NOTICE** Property damage and measurement inaccuracies due to missing sheath fluids! Start the software within 10 min after pushing the [Power on | off button]. If the instrument is switched on for a longer period of time without starting the software, the fluid reservoirs will be overdrained.

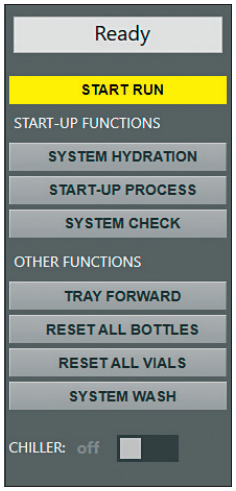
7.7 Opening the Software

Procedure

- ▶ **NOTICE** Unreliable behavior of the hardware and software! Do **not** connect any other USB instruments to the PC, except for the following:
  - the Virus Counter® Plus instrument
  - Mouse
  - External keyboard
  - USB drive

- ▶ Double click the Virus Counter® Plus desktop icon.
- ▶ Click on the [RUN SETUP] tile on the main screen.
- ▷ The startup check box appears on the screen.

- ▶ Select the checkboxes after having verified the activities on the Virus Counter® Plus instrument.
- ▶ On the instrument, visually check for bubbles in the syringe body.
  - ▶ If a volume of air is observed in the syringe body, perform an extra priming.
- ▶ Use the instrumental control panel on the left side of the [RUN SETUP] screen to control the following steps.



7.8 Inserting the Consumables Vial Rack in the Sample | Consumables Tray

These steps must be carried out before running samples.

⚠ WARNING

Risk of injury due to chemical exposure to operator upon reaction of consumables!

Improper mixture of consumables may cause a reaction.

- ▶ The consumables must be placed in the consumables vial rack in the correct order.

Requirements

– The fluid bay has been prepared (waste | Plus® fluid reservoirs have been connected).

Procedure

- ▶ Click on the [RUN SETUP] tile on the main screen.
- ▶ Click on the [TRAY FORWARD] button.

- ▶ Open the sample bay door to load the sample | consumables tray (1).

▶ Place the vials in the corresponding rack positions as shown below.

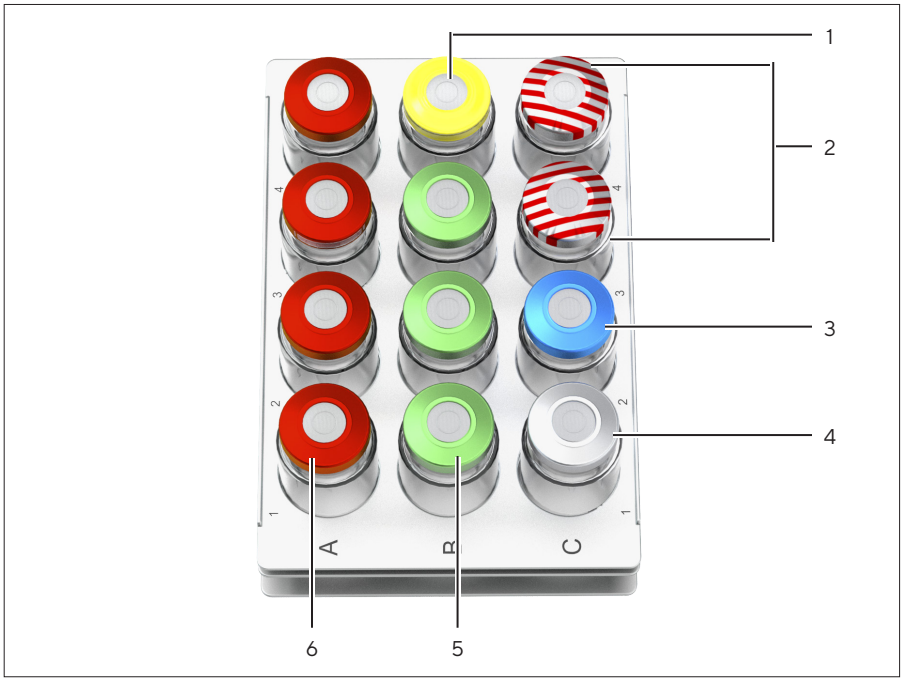
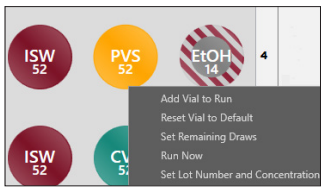


Fig. 15: Arrangement of vials

Pos.	Rack position	Fluids	Meaning
1	B4	PVS	Performance Verification Standard
2	C3, C4	EtOH	≥95 % ethanol solution
3	C2	SSR	Start-up | Shut-down Rinse
4	C1	DSW	Daily System Wash
5	B1, B2, B3	CVF	Cleanliness Verification Fluid
6	A1, A2, A3, A4	ISW	Inter-Sample Wash



▶ In the software, select the vials which are being replaced | refilled.
▶ Right click and select “Reset Vial to Default”.
▶ If replacing the PVS vial, additionally right click the PVS vial icon, select “Set Lot Number and Concentration”, and enter the information from the label on the vial.
▶ Close the sample bay door.

7.9 Hydrating the Instrument

If the instrument is being used for the first time after the instrument has been dry, a System Hydration needs to be performed. This applies to a new instrument and when using the instrument after a long-term shutdown.

If the instrument has recently been in regular use, and has not had a long-term shutdown procedure performed since the last use, perform System Startup (see chapter “7.10 Start-up Process“, page 38).

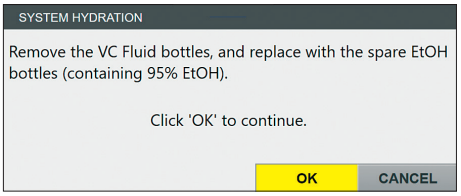
If the instrument is due for routine washing, perform System Wash (see chapter “10.6.1 Performing a System Wash“, page 52).

The system hydration takes about 20 min.

Procedure

- ▶ **NOTICE** Damage to the instrument! Use only ≥ 95% ethanol. Use of other types of alcohol or lower-concentration ethanol may damage the instrument.
- ▶ Ensure 1 L bottles labeled “95% EtOH” and the 250 mL alcohol bottles each contain at least 200 mL of 95% ethanol.
- ▶ Use the instrumental control panel on the left side of the screen and select [SYSTEM HYDRATION].

- ▷ The software will prompt to exchange bottles.



- ▶ Remove the two 1 L sheath bottles from the instrument and set aside. Be careful not to twist or strain the fluid connections.
- ▶ Install the two 1 L ethanol bottles in the two 1 L source bottle positions.
- ▶ Select [OK].
- ▷ A routine will execute which primes the entire instrument with ethanol to remove air.
- ▷ The software will prompt to reinstall the sheath bottles.
- ▶ Remove the two 1 L ethanol bottles and reinstall caps on these bottles.
- ▶ Install the 2 sheath bottles in the two 1 L source fluid positions.
- ▶ Select [READY].
- ▷ A routine will execute which purges the ethanol from the instrument.
- ▷ After completion of system hydration, the instrument is now ready to perform a [SYSTEM CHECK]. It is not necessary to perform a [START-UP PROCESS] immediately after performing system hydration.

7.10 Start-up Process

This procedure takes approximately 20 min.

The start-up process performs a similar function to system hydration. System hydration performs a more complete priming sequence and may be used in place of start-up process if air in the instrument is suspected.

Procedure

- ▶ Ensure the 250 mL alcohol bottle contains at least 200 mL of 95% ethanol.
- ▷ The start up process does not use the 1 L alcohol bottles.
- ▶ **NOTICE** Damage to the instrument! Use only ≥ 95% ethanol. Use of other types of alcohol or lower-concentration ethanol may damage the instrument.

START-UP PROCESS

- ▶ Click on the [RUN SETUP] tile on the main screen.
- ▶ Click on the [START-UP PROCESS] button on the left side of the screen.

- ▷ A routine will execute which performs alcohol priming of the syringe pump system.
- ▷ After completion of the start-up process, the instrument is now ready to perform a system check.

7.11 Running a System Check

The system check can be skipped if one has been run recently. If the system check has not passed within 30 min, it automatically performs when the [START RUN] button is clicked. The system check will add 15 min to the run.

The system check determines if there are enough consumables to run the system check.

Procedure

SYSTEM CHECK

- ▶ Click on the [RUN SETUP] tile on the main screen.
- ▶ Click on the [SYSTEM CHECK] button on the left side of the screen.

Ready

- ▷ If the system check passes: The system is ready to run samples and enters into “ready status”.

- ▶ If the system check fails: See chapter “11.1 Troubleshooting Overview”, page 59.

7.12 Setting the Blank

A blank must be set for each stain type before analysis can be performed. A blank solution consists of the stain being used and sample dilution buffer. The instrument will use the blank analysis to set thresholds in the signal detection algorithm.

Requirements

- — The instrument is ready for operation.
- — The instrument has been primed via the hydration or start-up process.

Procedure for the Verification Stain

- ▶ If manual operations have been performed, such as PVS readings, perform at least 2 ISW operations to ensure the instrument has been flushed.
- ▶ Right click the CVF fluid icon and select “Blank Analysis”.
- ▶ After the instrument performs blank analysis, select whether or not to overwrite the previous settings with the new blank profile.
- ▶ For details on establishing the blank for other stain profiles, reference the product insert of the relevant assay.

7.13 Inserting the Sample Plate in the Sample | Consumables Tray

These steps must be carried out before running samples.

Requirements

- The fluid bay has been prepared (waste | Plus® fluid reservoirs have been connected).
- The sample plate is prepared in accordance with the procedure detailed on the product inserts.
- The sample plate is loaded.

Procedure

▶ Click on the [RUN SETUP] tile on the main screen.
▶ Click on the [TRAY FORWARD] button.

TRAY FORWARD

Fig. 16: Inserted sample plate and consumables vial rack

Pos.	Name
1	Sample	consumables tray

▶ Open the sample bay door.
▶ Carefully insert the sample plate into the left position of the sample | consumables tray and push down gently.
▷ There is a label on the sample tray which indicates proper orientation.
▶ Check if the sample plate is fully seated in the sample | consumables tray.
▶ If required, use the chiller cover.
▶ **NOTICE** Damage to the cooling unit! Always use the chiller cover when the chiller is on.
▶ Close the sample bay door.

8 Operation

8.1 Operating Modes

Operation mode	Description
Standby operation mode	When main power supply is connected to the instrument and the main switches are switched on, the power is supplied to certain internal systems, even if the “Power on | off button” is off. When the “Power on | off button” is not illuminated, the instrument is in standby mode. No fluid is flowing when the instrument is in standby mode. The instrument maintains the optical system at a constant temperature of 31°C. The light around the front panel power button will be off. Standby mode allows for immediate operation of the Virus Counter® Plus and prevents variability in the optical system from environmental temperature changes. Only pressing the “Power on | off” button can take the instrument out of this mode and into system operation mode.
System operation mode	When the “Power on | off” button is depressed, the instrument will be in operation mode. The instrument will wait for a command from the attached PC to commence operation. When in system operation mode, sheath fluid will flow at 50 uL/min during idle periods and at higher flow rates during use and the light around the front panel power button will be on.
Sleep mode	If the instrument completes a programmed sampling sequence or stops due to an error, the instrument will enter sleep mode after an extended period (27 h). In sleep mode the sheath flow will stop. Any command from the PC to perform an operation will take the instrument out of sleep mode.

8.2 Preparing a Run

The software will guide you through operating the instrument.

Note the ambient temperature. Ambient temperatures higher than +25°C | +77°F can interfere with sample cooling and laser performance of the instrument. This can reduce measurement accuracy.

Requirements

- The sample plate and consumables vial rack are inserted into the sample | consumables tray.
- The samples have been prepared in accordance with the instructions provided in the product inserts.
- A system check has been carried out.

⚠ WARNING!

Risk of injury from sample probe which contains biological agents.

- ▶ Do **not** open the sample bay door during operation.
- ▶ Wear suitable protective equipment.

⚠ CAUTION

Risk of trapping or injury by moving parts!

- ▶ Only operate the instrument with the sample bay door firmly closed.

⚠ CAUTION

Puncture hazard due to sample probe!

- ▶ Do **not** open the sample bay door during operation.

Procedure

- ▶ Check that:
  - The waste reservoirs are emptied (see chapter 7.4, page 33).
  - The fluid reservoirs are filled up (see chapter 7.5, page 34).
  - The EtOH bottle is filled up (see chapter 7.3, page 33).
  - The 12 vials on the consumables vial rack are loaded and filled.

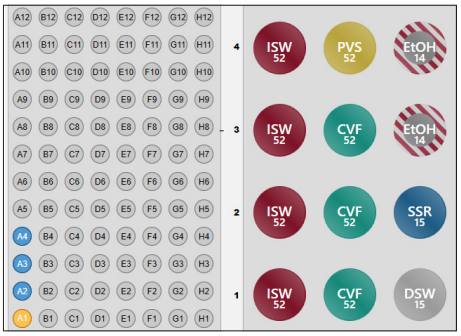
8.3 Running Samples

The analysis of each sample consists of a specific sequence of events automated by the software to allow walk-away operation.

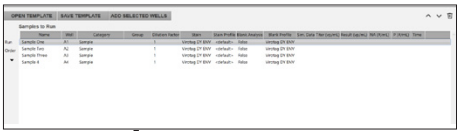
A sample is analyzed, after which ISW and CVF are introduced to ensure no sample-to-sample carryover before analysis of the next sample.

At the end of a run, the system performs a final shutdown rinse sequence and the needle assembly returns to the Home position.

Procedure

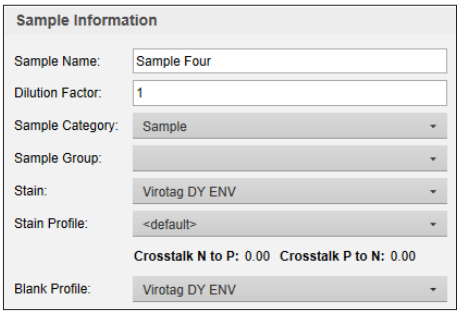


- ▶ Click on the [RUN SETUP] tile on the main screen.
- ▶ Add samples by highlighting the desired wells, right click, and select “Add Wells as Sample”.
- ▷ Multiple samples can be added at the same time.
- ▶ Select the samples that you would like to run and edit them respectively.



- ▶ Samples can be selected in the [Samples To Run] area.
- ▶ Each sample can be selected separately by chosing the respective table row.
- ▶ Multiple rows can be selected at the same time for entering information all at once (e.g., the stain type).

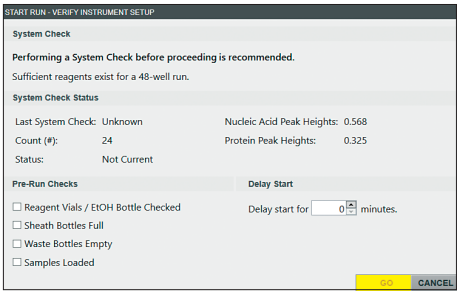
- ▶ Samples can be reordered by clicking and dragging the row to a different position in the list, or by clicking the up | down arrows at the top of the area.
- ▶ Samples can be deleted from the list by clicking the delete button at the top of the area.
- ▶ The sample information such as sample name, dilution factor, stain type, etc., can be changed in the [Sample Information] area.



- ▶ Name the samples. Choose a unique description that helps distinguish samples.
- ▶ Enter the dilution factor. It is used in later calculations.
- ▶ Enter the sample category and sample group designations.
- ▶ Select the corresponding stain type and blank profile from the drop down list depending upon the staining method used.

Process	Stain Type
Virotag DY ENV	Virotag DY ENV
PVS	Verification
Virotag AB	BCVB, VSVG etc.
Virotag DY	Virotag DY

- ▶ Click the [START RUN] button.



- ▶ Verify the instrument setup by ticking the checkboxes.
- ▶ Click the [GO] button.

▷ The run starts.

8.4 Finishing Samples

Requirements

All data has been collected.

Procedure

- ▶ If samples have been run, leave the sample bay door shut for at least 10 min.
- ▶ Once the data has been collected, save your data by highlighting and right-clicking on the sample(s) of interest and selecting “Export” (see chapter „8.8 Exporting and Sending Data“, page 46).

- ▶ To go back to the main screen, click on the button in the upper left corner.

8.5 Removing the Sample Plate

Procedure

- ▶ Bring the sample | consumables tray into the loading position.
- ▶ Open the sample bay door.
- ▶ If required: Remove the chiller cover.
- ▶ Carefully remove the sample plate from the sample | consumables tray.
- ▶ Close the sample bay door.
- ▶ Dispose of any remaining samples according to local regulations.

8.6 Opening | Saving Templates

8.6.1 Saving Run Templates

The [SAVE TEMPLATE] button can be used to save an entire run setup so that it can be run again in the future by importing it for use on a different sample set. A sample run setup can be saved as an .csv or .tsv file and opened in any compatible spreadsheet program.

Procedure

- ▶ Click the [SAVE TEMPLATE] button to save the run template for later use.
- ▶ Follow the prompts to save the template to the desired location.
- ▷ Template files can subsequently be opened in any compatible spreadsheet program for editing.
- ▷ In the template, the variables that can be edited display at the top of each column. Each row in the template represents one sample to be analyzed.
- ▶ Enter the sample information as desired (names, well positions, order, etc.) and resave the template as a .csv or .tsv file with the desired name.

8.6.2 Opening Run Templates

The [OPEN TEMPLATE] button can be used as an alternative to populating the “Samples To Run” list. The text strings of the variables shown in the columns of the template are the only variables that can be in the template. Adding columns results in an error and the inability to open the template correctly. However, deleting columns from the template is allowed. Any columns that are deleted from the template are populated with the default value for the deleted variable(s) when the template is opened.

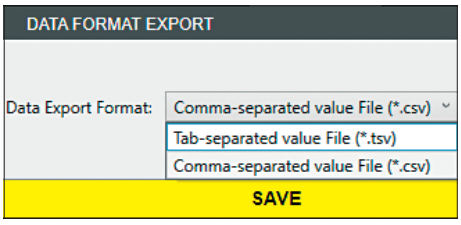
Procedure

- ▶ Click the [OPEN TEMPLATE] button and navigate to the location of the template file you want to load.
- ▶ Click the file to open the template.
- ▷ The “Samples To Run“ area at the bottom is now populated using the template file.

8.6.3 Changing the Export Format

The format can be changed from .csv to .tsv file or vice versa.

Procedure

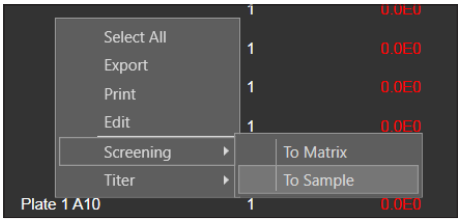


- ▶ In the header, click on the [OPTIONS] drop down.
- ▶ Click on “Data Export Format“.
- ▶ Select the prefered format and click on the [SAVE] button.

8.7 Importing Sample Results Into the [Screening] Screen

Selected results can be mirrored to other menus to keep the amount of information within a limit.

Procedure



- ▶ Click on the [RESULTS] tile on the main screen.
- ▶ Select all sample results to be analyzed.
- ▶ Right click the selection, choose “SCREENING“ and “TO SAMPLE“.

- ▶ Select all matrix results to be analyzed.
- ▶ Right-click the selection, choose “SCREENING“ and “TO MATRIX“.
- ▶ Click on the [SCREENING] tile on the main screen.
- ▷ All results that were sent from the [RESULTS] screen to either MATRIX or SAMPLE populate the table in the [SCREENING] screen.
- ▶ Do **not** include data points that were initially (before correction) below the Instrument Quantification Limit (IQL).
- ▶ If dilution factors need to be edited: Delete the samples from the [SCREENING] screen.
- ▶ Find the sample in the [RESULTS] screen and edit the sample by right-clicking and “EDIT“.
- ▷ Edited samples can be reloaded to the [SCREENING] screen.

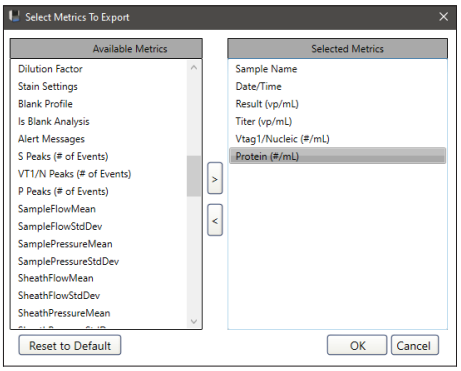
8.8 Exporting and Sending Data

Requirements

A run has been completed.

Procedure

- ▶ Click on the [RESULTS HISTORY] tile on the main screen.
- ▷ In the header, you can select from various filter options to refine individual results and there is also a search field.
- ▶ Double click on the desired run.
- ▷ The system displays the data for that run, with samples in the order they were analyzed.
- ▶ Right click on any sample and select “Select All“ or choose the samples which are to be exported.
- ▶ With the samples highlighted select “Export“.



▷ A menu will pop up and prompt to confirm | change the metrics to be exported.

▶ Name and save the file.

8.9 Working Offline

The [Work Offline] function allows the user to access and process past results without operating the instrument. The offline mode offers the full functionality of the [Results History] Screen.

Procedure

▶ Double click the Virus Counter® Plus desktop icon.

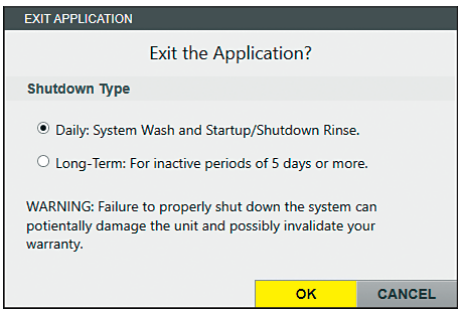
▷ The startup check box appears on the screen.
▶ Select [Work Offline].

8.10 Shutting Down the Instrument

Requirement

The current run has been completed.

Procedure



▶ Click on the [File] drop down menu.
▶ Click on “Exit”.
▶ Choose “Daily”.
▶ Click [OK] to continue.
▶ Once a confirmation that Shutdown is complete appears, click [OK].
▷ The application will be closed.

8.11 Performing a Long-Term Shutdown

If the instrument will not be used for 5 days, a long-term shutdown must be performed.

Requirement

The current run has been completed.

Procedure

- ▶ Click on the [File] drop down menu.
- ▶ Click on “Exit”.
- ▶ Choose “Long-Term”.
- ▶ Click [OK] to continue.
- ▶ Follow the instructions in the dialog.
- ▷ The current step of the Long-Term shutdown procedure is indicated in the status bar.
- ▶ Once a confirmation that Shutdown is complete appears, click [OK].
- ▷ The application will be closed.

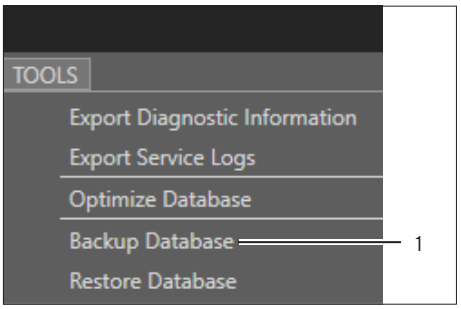
9 Backup | Restore Database

9.1 Backup Database

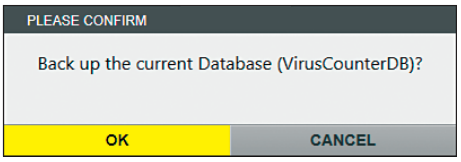
“Backup Database“ allows the user to back up the data used by the Virus Counter® Plus. The files created can then be moved to a network or cloud location for archival purposes.

Procedure

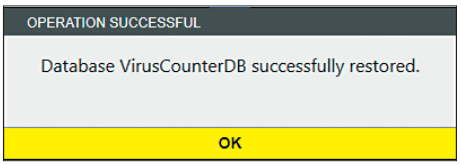
- ▶ In the header, click on the [TOOLS] drop down.
- ▶ Click on “Backup Database“ (1).



- ▶ Confirm to back up the database.



▷ A wait message will appear.
▷ Once the backup is complete, a message will be displayed.
▷ A "Please Wait" message will appear in the launcher window.
▷ When the database has been backed-up, a message will be displayed.



▶ Click [OK] to close the message.

▶ Click the [START] button on the launcher window to start the application.

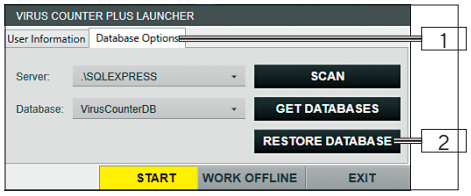
9.2 Restore Database

"Restore Database" allows the user to restore (overwrite) the database from a backup file. This can be useful when wanting to view archived data, or in the case of transferring the application to a new PC.

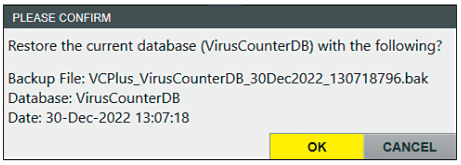
Procedure

▶ Close the application.

▶ Restart the application by double-clicking the Virus Counter® Plus desktop icon.



▶ When the launcher window appears, click on "Database options" (1).
▶ Select the desired database to restore (if different from the default).
▶ Click [RESTORE DATABASE] (2).
▷ A file dialog will appear.
▶ Select the backup file to restore the database from.
▶ Click "Open".
▷ A Confirmation dialog will appear.



▶ Click [OK] to begin the restore process.

10 Cleaning and Maintenance

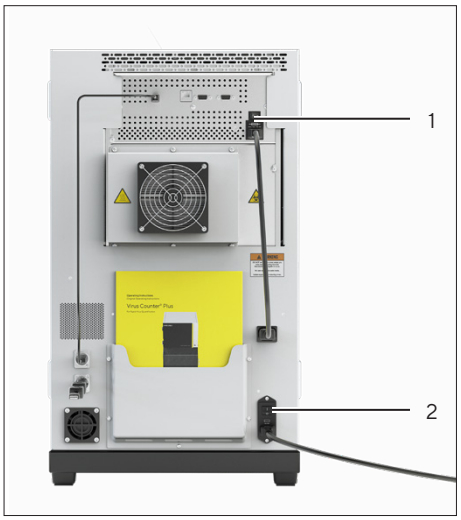
10.1 Powering off the Instrument

The instrument must be powered off before all cleaning work.

Requirements

All processes on the instrument have ended.

Procedure



- ▶ Turn off the sample bay switch (1) and power supply switch (2) on the rear of the instrument.
- ▶ Disconnect the instrument from the mains power supply socket at the installation site.

10.2 Removing the Spill Tray

The spill tray under the bottles can be removed for cleaning.

Procedure

- ▶ Open the fluid bay door.
- ▶ Hold the caps of the reservoirs tight while unscrewing the bottles.
- ▶ Remove the 4 bottles from the fluid bay.
- ▶ If required: Dispose of the waste of the 2 waste reservoirs (i.e., pour it into an appropriate waste receptacle).
- ▶ Remove the spill tray.

10.3 Cleaning

Requirements

— The shutdown process has been completed.
— The instrument is powered off.

Procedure

▶ Do **not** use corrosive, chloride-containing, and aggressive cleaning agents.
▶ Do **not** use cleaning agents that contain abrasive ingredients, e.g., scouring agents, steel wool.
▶ Do **not** use solvent-based cleaning agents.
▶ Do **not** use ethanol or isopropanol agents on the sample bay door.
▶ Only use suitable cleaning agents and follow the product information for the cleaning agent used.
▶ Damage to the instrument from penetrating fluids! Do **not** spray cleaning solution into the ventilation openings.
▶ Wipe the housing with a slightly damp cloth. Use a mild soapy solution or a suitable cleaning agent for more severe contamination.

10.4 Inserting the Spill Tray

Procedure

▶ Open the fluid bay door.
▶ Insert the spill tray.
▶ Insert the 4 bottles into the fluid bay and hold the cap stationary while attaching the bottle to the cap.

10.5 Maintenance Schedule

Interval	Component	Activity	Chapter, page	Target group
At minimum every 2 weeks | after 6 plates	Instrument	Perform system wash	10.6.1, 52	User
6 months	Syringe pump piston	Replace	10.6.5, 56	
6 months	Sample probe	Replace	10.6.3, 54	
6 months	Bottle air filters	Replace	10.6.2, 53	

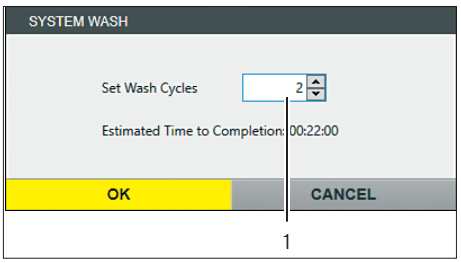
10.6 Maintenance

Maintenance procedures are supported both in the software itself and in the chapter concerning maintenance.

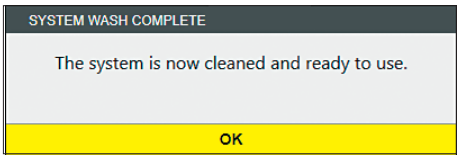
10.6.1 Performing a System Wash

Procedure

- ▶ Prepare the two 1 L bottles labeled “Sys Wash” with ≥ 200 mL of cleaning agent.
- ▶ In the instrument control panel, select [SYSTEM WASH].



- ▶ Select the number of desired wash cycles (1), then follow the on-screen prompts. The “Estimated Time to Completion” will change depending on the number of Cycles selected.
- ▶ Click [OK].



- ▷ The software will display a message stating that cleaning is complete.

10.6.2 Changing the Filters

Removing the Filter

Requirements

The instrument is **not** in operation and is safely powered off (see chapter „10.1 Powering off the Instrument“, page 50).

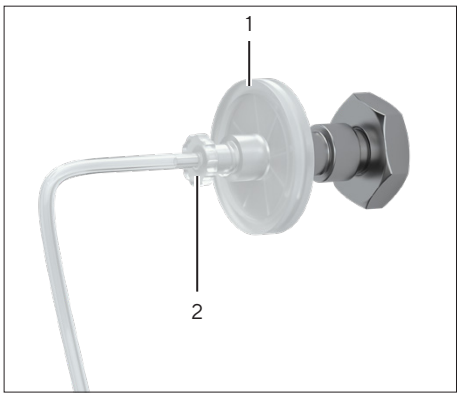
⚠ CAUTION

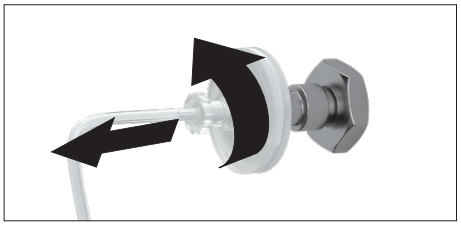
Risk of injury due to exposure to hazardous substances.

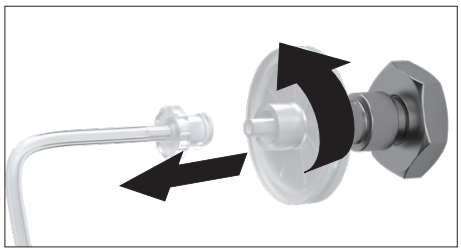
- ▶ Ensure appropriate PPE is worn at all times.
- ▶ Ensure appropriate care is taken.
- ▶ Ensure only qualified personnel perform this action.

Procedure

- ▶ Vent bottles to relieve pressure.
- ▶ Disconnect the fluid line from the bottle by rotating the connector (2) to the filter (1) in an counter-clockwise direction until the fluid line comes free from the filter.



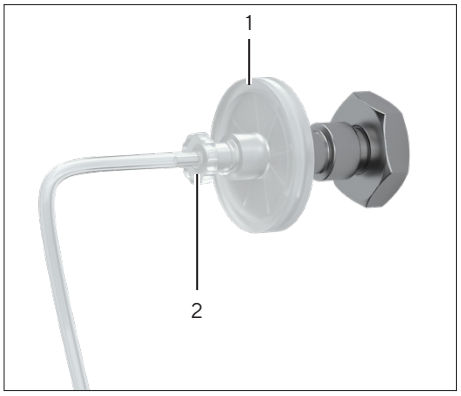




- ▶ Rotate the filter counter-clockwise and pull gently away from the device until the filter comes free.

Replacing the Filter

Material:	Replacement filter 0.2 µm PTFE Luerlock - VC-3100-5046



Procedure

- Insert the filter (1) pushing gently towards the instrument.
- Rotate the filter in a clockwise direction until securely in place.
- Do **not** use excess force when replacing the filter to avoid any potential damage to the filter or instrument thread.
- Push the fluid line onto the male connector (2) on the filter (1).
- Rotate the connector clockwise until secured.

10.6.3 Replacing the Uptake Filter

Procedure

- Open the fluid bay door | sample bay door.
- Remove the cap of the bottle.
- Unscrew the filter element (2) from the filter housing (1).
- Install a new filter to the filter housing.
- Insert the filter back into the bottle and screw the cap onto the bottle.

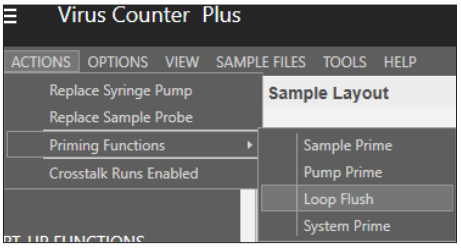
10.6.4 Replacing the Sample Probe

Requirements

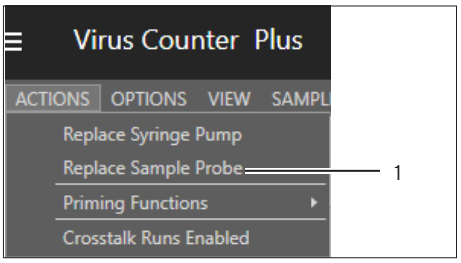
- The instrument is powered on.
- The instrument is **not** in operation.
- The PC is attached and the software is running.
- The sample bay is empty of both samples and consumables.

Procedure

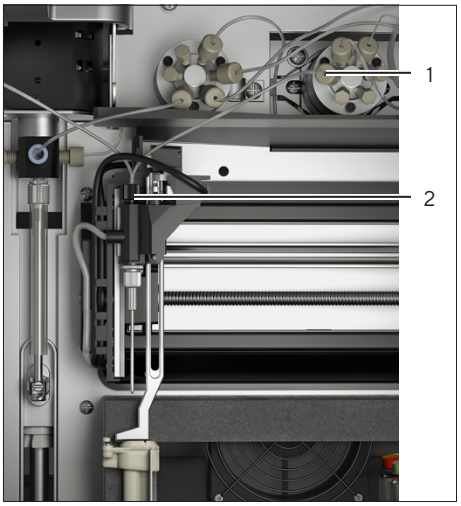
To remove the sample probe:



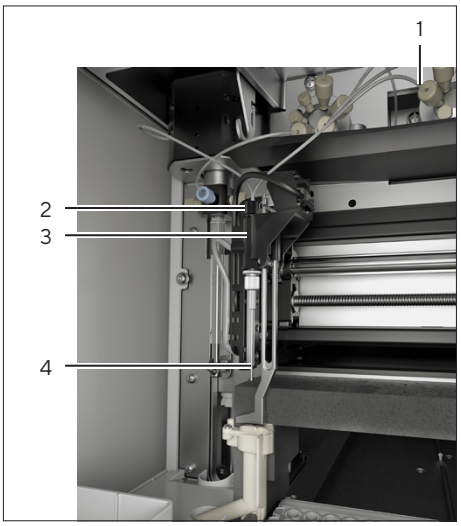
▶ In the header, click on the [ACTIONS] drop down.
▶ Select “Priming Functions”, then click on “Loop Flush”.



▶ Click on “Replace Sample Probe“ (1).
▷ The sample probe moves to a replacement position.



▶ Open the fluid bay door.
▶ Loosen the adaptor fitting (1) of the injection valve.
▶ Loosen the connection fitting (2) of the sample probe.
▶ Gently slide the sample probe upwards and outwards.



To install the sample probe:

- ▶ Carefully insert the sample probe from above into the sample probe holder (3).
- ▶ Check if the the new sample probe goes through the bottom hole of the vial stripper assembly (4).
- ▶ Tighten the connection fitting of the sample probe (2).
- ▶ Connect the other end of the sample probe connection tubing to the injection valve (1).
- ▶ Close the fluid bay door.
- ▶ Test with a [LOOP FLUSH] by selecting it from the instrumental control panel on the left side of the screen.

10.6.5 Replacing the Syringe Pump Piston

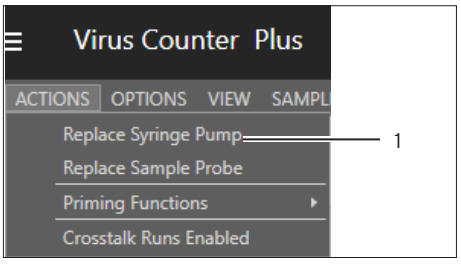
Material:
- — Syringe pump piston
- — Screwdriver

Requirements

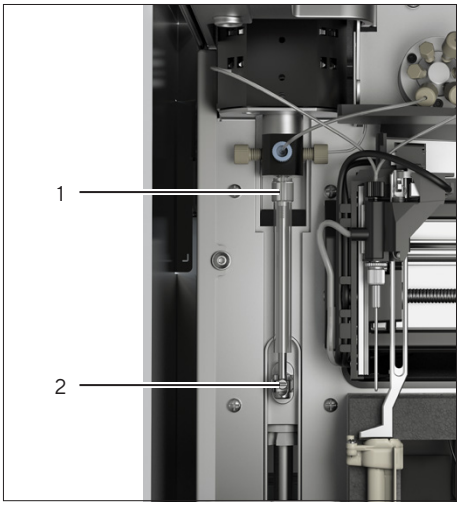
- — The instrument is powered on.
- — The instrument is **not** in operation.
- — The PC is attached and the software is running.
- — The sample bay is empty of both samples and consumables.

Procedure

To remove the syringe pump:

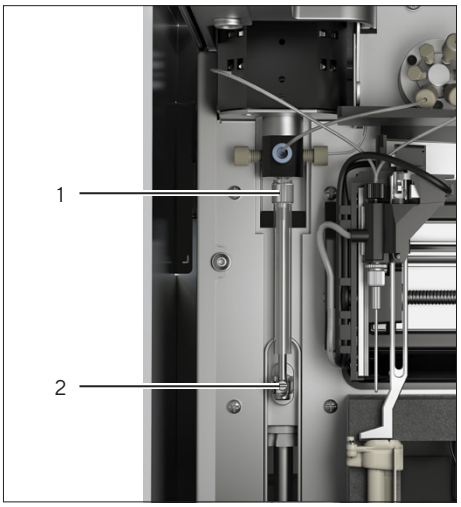


- ▶ Open the fluid bay door.
- ▶ Click on “ACTIONS” and “Replace Syringe Pump” (1).
- ▶ Wait for the syringe pump to move downwards.



- Loosen the hand screw (1) on the top of the syringe pump.
- Use a flathead screwdriver to loosen the bottom screw (2).
- Slide the pump outwards towards the user to remove.

To install the syringe pump:



- Install the new syringe pump carefully at the fittings (1) and then (2).
- Tighten the hand screw (1) at the top first.
- Tighten the flathead screw (2) at the bottom.
- Make sure the plunger is fully seated within the clip.
- Close the fluid bay door.
- Complete with a [LOOP FLUSH] by selecting it from the instrumental control panel on the left side of the screen.

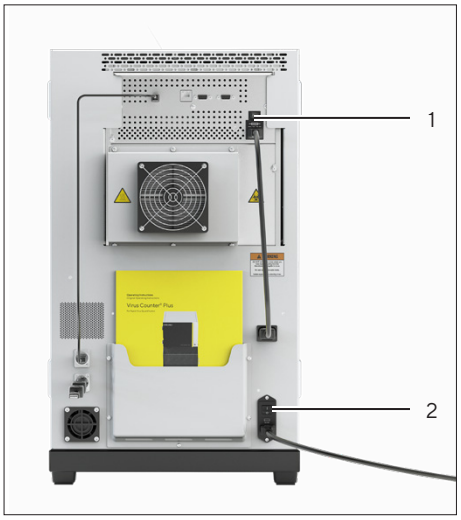
10.7 Restarting

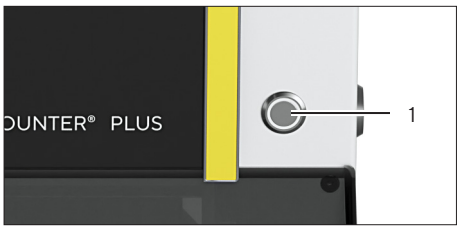
Requirements

– Ensure all fluid reservoirs are connected and closed securely.
– Ensure the sample bay is free from obstacles and that the sample bay door is securely shut.

Procedure

▶ Connect the instrument to the mains power supply socket.
▶ Turn on the sample bay switch (1) and power supply switch (2) on the rear of the instrument.





▶ Push the on | off button (3) on the front of the instrument.

11 Troubleshooting

Should any error messages remain after troubleshooting please call Sartorius Service.

11.1 Troubleshooting Overview

Error	Message	Cause	Remedy
Sample bay (autosampler) Error	1001 Autosampler access door open	– The sample bay door of the instrument is open. – The sample bay door sensor is blocked.	▶ Close the sample bay door. ▶ Make sure that the sample bay door sensor is not blocked. ▶ If the error cannot be resolved: Contact Sartorius Service.
	2001 Autosampler syringe aspirate error	Unable to complete aspiration operation.	▶ Check for any obstructions near the moving portion of the syringe pump. ▶ Restart the instrument.
	298 Autosampler Tray position unknown	The tray forward | backward actuator is unable to return to the home position.	▶ Check for any obstruction. ▶ Restart the instrument.
	304 Autosampler Horizontal home sensor not reached!	The needle left | right actuator is unable to return to the home position.	▶ Check for any obstruction. ▶ Restart the instrument.
	308 Needle Position Check Error	Indicates that the needle movement system may be malfunctioning.	▶ Check for any obstruction. ▶ Restart the instrument.
	312 Vertical Position Unknown	Indicates that the needle movement system may be malfunctioning.	▶ Check for any obstruction. ▶ Restart the instrument.
	317 Sample bay (autosampler) missing plate/vial	Sample plate and | or consumables vial rack are missing.	▶ Make sure that the sample plate and consumables vial rack are inserted (see chapter 7.8, page 36 and chapter 7.13, page 40). ▶ Make sure that the sample plate and consumables vial rack are positioned correctly. ▶ Check that there are no obstructions in the sample bay | syringe pump area.

Error	Message	Cause	Remedy
Air in syringe		Use of incorrect alcohol.	▶ Use only ≥ 95% ethanol.
		Low or empty source fluid bottles.	▶ Ensure alcohol in 250 mL EtOH bottle and sheath fluid in sheath bottles cover the uptake filters.
		Air accumulates due to outgassing during aspiration. If the bubble has grown slowly over time, outgassing may be the cause.	▶ Perform start-up process (see chapter 7.10, page 38) or system hydration (chapter 7.9, page 38).
		Leak at connection allows air introduction during aspiration.	▶ Check for loose connections and tighten as appropriate. Connections potentially related to leaking air into the syringe are: – All 3 fittings at the syringe valve – All tube connections (see chapter 11.2, page 69) – The connection between the glass syringe barrel and the syringe valve. Tighten at the knurled metal piece
		Poor seal between syringe piston and glass barrel.	▶ Replace syringe pump piston (chapter 10.6.5, page 56).
		Clog restricts flow, causing fluid cavitation during aspiration. If a large bubble appears during each aspiration event from a particular fluid circuit, that circuit may be clogged.	▶ Perform start-up process (chapter 7.10, page 38). ▶ Replace uptake filter at the bottom of the bottles (chapter 10.6.3, page 54). ▶ Replace sample probe (see chapter 10.6.4, page 55).

Error	Message	Cause	Remedy
Air in syringe		– Fluid uptake tube is blocked. – The end of the uptake tube inside the sheath uptake filters is pressing against the inside of the filter element. – The end of the tubing is supposed to be cut with a sharp razor blade to prevent the tube end from being pinched shut. – Filter at the bottom of the bottles are clogged.	▶ The uptake tube inside the sheath inlet filters should be cut at a 45 degree angle with a sharp razor blade. ▶ Replace uptake filter in the bottles (see chapter 10.6.3, page 54).
		Incorrect sample plate. If non-standard sample plates are used, the inlet hole of the sample aspiration needle may be above the liquid.	▶ Only use sample plates that have been approved by Sartorius.
Sample bay (autosampler) power light off		No power to sample bay (autosampler).	▶ Verify "On | off switch sample bay" and "On | off switch power supply" at rear side of the instrument are on (see chapter 6.4, page 31). ▶ Make sure the main power supply is connected (see chapter 6.2, page 30).
Blank fails		The software will attempt to identify blanks which are suspected to contain contamination or aggregates, and therefore should not be used for the setting filters.	▶ Retry setting the blank (see chapter 7.12, page 39).
CVF too high		Source bottles are contaminated. For example: if the waste bottles were accidentally used as source bottles, this will contaminate the system.	▶ Replace the uptake filters in the 1 L bottles (see chapter 10.6.3, page 54). ▶ Replace the 1 L bottles with new parts.

Error	Message	Cause	Remedy
CVF too high after high-concentration sample		The sample concentrations are not suitable for the operating range of the instrument.	▶ Dilute samples to match instrument operational range.
CVF too high during system check		If the CVF reading is orders of magnitude higher than usual, it suggests the blank is not set correctly, and the system is counting noise peaks as particles. There could also be an obstruction.	▶ Verify blank is set correctly. ▶ Set new blank. ▶ If contaminated fluids are suspected, replace contaminated fluids. ▶ If contaminated components are suspected, replace contaminated components.
Status LED sample bay: Flashing green		Hardware failure at sample bay (autosampler)	▶ Check if there is an obstruction on the deck of the sample bay (autosampler) which may interfere with movement of the needle assembly. ▶ Ensure that the sample plate, consumables vial rack, and all vials are fully-seated. ▶ Restart the instrument.
No response of the sample bay (autosampler).		Communication failure between sample bay (autosampler) and PC	▶ Verify the status LED sample bay is illuminated green. ▶ Verify “On | off switch sample bay” and “On | off switch power supply” at rear side of the instrument are on. ▶ Make sure the main power supply is connected. ▶ Verify USB cable is connected at rear side of the instrument. ▶ Verify USB cable is connected between instrument and PC.

Error	Message	Cause	Remedy
No sheath flow		Sheath flow is controlled by air pressure in the headspace of the sheath bottle. A leak in the air system will prevent proper flow.	▶ Verify cap is sealed on sheath bottle. ▶ Check for loose fittings on sheath cap. ▶ Check for kinks in sheath bottle air line. ▶ Replace Plus® fluid filter (see.chapter 10.6.2, page 53).
No sheath flow		Waste bottle is full and | or waste exhaust air filter is plugged.	▶ Empty the waste bottle. ▶ Replace the waste exhaust air filter.
Peak voltage too low		Air bubble in flow cell causes temporary misalignment.	▶ Ensure system is fully primed prior to operation. ▶ Perform a long-term shutdown (see chapter 8.11, page 48) followed by system hydration (see chapter 7.9, page 38).
Peak voltage too low		Air bubble in flow cell causes temporary misalignment.	▶ See causes | remedies in the “Air in syringe” error description.
Peak voltage too low		The instrument is not warmed up.	▶ Ensure the instrument is warmed up.
PVS too high		The blank is set incorrectly. For example: If the blank is established when the system is not primed or not in alignment, the filters may be lower than ideal.	▶ If the blank was established when the instrument was in a non-ideal condition, reset the blank. E.g., if the blank is established at startup, then the system fails system check, reset the blank after passing system check.
		Excessive carryover will raise the reported counts.	▶ See causes | remedies in the “CVF too high” error description.

Error	Message	Cause	Remedy
PVS too low		The instrument is not warmed up at installation.	▶ Ensure the instrument is warmed up before the first run.
		Incorrect blank.	▶ Verify that an appropriate blank was used. ▶ Reestablish a new blank and try again.
		PVS bottle fluid level is too low. The system cannot access all of the fluid in a vial. The aspiration hole is on the side of the needle, and the needle tip is set to a safe distance above the bottom to ensure safe operation. A vial is effectively empty when the fluid level is approximately 12 mm from the bottom.	▶ Replace the PVS vial.
PVS too low		Air bubble in flow cell causes temporary misalignment.	▶ Ensure system is fully primed prior to operation. ▶ Perform a long-term shutdown (see chapter 8.11, page 48) followed by system hydration (see chapter 7.9, page 38). ▶ See causes | remedies in the “Air in syringe” error description.
Sample concentration is lower than expected.		Sample concentration is too high. If the sample concentration is above the instrument operation range, sample signals run together and can not be parsed by the signal detection system.	▶ Dilute samples to match instrument operational range.

Error	Message	Cause	Remedy
Sample flow error, sample flow high		The waste bottle is pressurized to prevent spontaneous sample flow due to the hydrostatic head pressure caused by the sample bay (autosampler) being higher than the flow cell. If the waste bottle is not pressurized, sample flow will be too high, and sample pressure will be lower than normal.	▶ Verify cap is sealed on waste bottle. ▶ Check for leaks at waste bottle air connections. ▶ Replace the waste exhaust air filter (see chapter 10.6.2, page 53).
Sample flow error, sample flow low		If there is air in the sample line, the flow sensor will read zero flow when the air bubble is at the flow sensor.	▶ Check for air in syringe. Air indicates a possible leak at a syringe connection. Ensure the knurled nut at the top of the glass syringe barrel is finger tight to the syringe block above it. ▶ A clog in the sample bay (autosampler) needle may cause cavitation (air in line) during aspiration. Replace needle and prime system. ▶ If sample flow is normal during some operations and low during other operations, the low-sample-flow operations may be associated with aspirating from an empty well or container. ▶ Verify vials, sheath bottles, 250 mL EtOH bottle and target wells contain adequate fluid. ▶ Verify sample plate is in correct orientation.

Error	Message	Cause	Remedy
Sample flow error, sample flow low		A clog or obstruction in the sample air line will restrict flow. Failure to perform a long term shutdown prior to extended idle periods may result in drying of the fluidic system and formation of crystals.	▶ If the system was idle for an extended period without performing a long-term shutdown, contact Sartorius Service. Operating the system while clogged may overpressurize the system. ▶ Replace sample air filter (chapter 10.6.2, page 53).
Sample flow restricted		If air is in the sample line at the sample flow sensor, the system will increase sample pressure because no flow is detected. The most common cause for air in the sample line is: — Accidentally aspirating from the wrong vial — An empty consumables vial A leak may allow air introduction during aspiration.	▶ Verify sample plate is in correct orientation. ▶ Verify that wells selected for the run contain adequate fluid. ▶ Verify vials, 250 mL EtOH bottle, and 1 L sheath bottles contain adequate fluid. ▶ Check for leaks. ▶ Prime system by using the start-up process (see chapter 7.10, page 38) or the system hydration (see chapter 7.9, page 38).
		This is statistically possible to a small degree (~1% of the time) under normal circumstances. If this is happening more often, it suggests either air in the system, or a problem with fluidic hardware. Build-up inside the fluid system will interfere with flow control. Special cleaning and | or replacement of tubing and other wetted components may be required, especially if routine cleaning or maintenance has been neglected.	▶ Prime system by using the start-up process (see chapter 7.10, page 38) or the system hydration (see chapter 7.9, page 38). ▶ Check connections for leaks. ▶ Check for obstructions such as kinked or pinched tubing, damaged barb fittings, etc. ▶ Perform a system wash.

Error	Message	Cause	Remedy
Sample pressure lower than expected		The waste bottle is pressurized to prevent spontaneous sample flow due to the hydrostatic head pressure caused by the sample bay (autosampler) being higher than the flow cell. If sample pressure is low, and sample flow is high, suspect a problem in the waste bottle pressurization circuit. If sample pressure is low, and sample flow is low, suspect a problem in the sample air circuit.	▶ Verify cap is sealed on waste bottle. ▶ Check for leaks at waste bottle air connection. ▶ Check for leaks at internal waste bottle air lines. ▶ Check for leaks in sample air circuit.
Sampling holes in sample plate or vials are off center		— The sample needle has been bent. — The vial is in the wrong position. — The needle movement system is not operating correctly.	▶ Verify sample plate is in correct orientation. ▶ Verify consumables vial rack is fully-seated. ▶ Check if sample needle is bent. ▶ Replace needle if necessary (see chapter 10.6.4, page 55).
Sheath flow restricted		Triggers when sheath pressure is higher than normal. May indicate a clog.	▶ Replace sheath uptake filter (see chapter 10.6.3, page 54). ▶ Replace waste exhaust air filter (see chapter 10.6.2, page 53).
Sheath pressure lower than expected		The waste bottle is pressurized to prevent spontaneous sample flow due to the hydrostatic head pressure caused by the sample bay (autosampler) being higher than the flow cell. Unusually, low sheath pressure may indicate an air leak at the waste bottle.	▶ Verify cap is sealed on waste bottle. ▶ Check for leaks at waste bottle air connections.

Error	Message	Cause	Remedy
Software says “disconnected” in uppper left corner.		The software running on the PC is unable to communicate with the sample bay (autosampler).	▶ Verify the status LED sample bay is illuminated green. ▶ Verify “On | off switch sample bay” and “On | off switch power supply” at rear side of the instrument are on. ▶ Make sure the main power supply is connected. ▶ Verify USB cable is connected at rear side of the instrument (see chapter 6.3, page 31). ▶ Verify USB cable is connected between instrument and PC.
Instrument does not turn on.			▶ Verify “On | off switch sample bay” and “On | off switch power supply” at rear side of the instrument are on. ▶ Make sure the main power supply is connected.
Power on | off button is flashing white.		PC-to-instrument communication lost System crash	▶ Assess USB cabeling. ▶ Power off the instrument. ▶ Disconnect the instrument from the mains supply. ▶ Wait for approximately 10 seconds. ▶ Power on the instrument. ▶ Turn on the instrument. ▶ Restart the software.

11.2 Checking Tube Connections

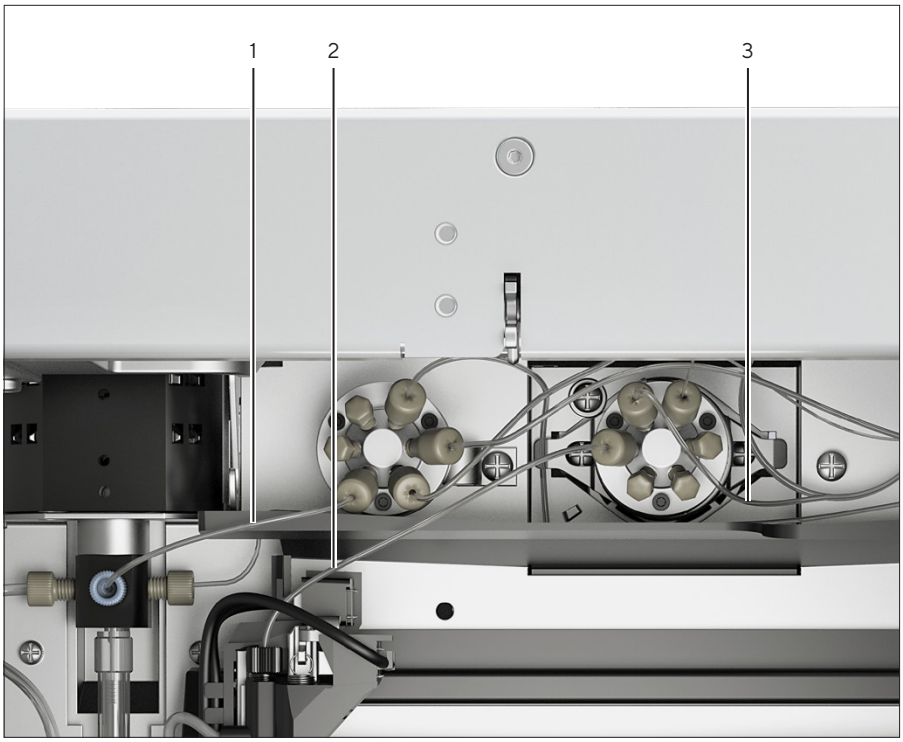


Fig. 17: Overview tube connections

Pos.	Name	Description
1	Syringe connection	Tube assembly that connects the syringe to valve 2
2	Sample needle connection	Tube assembly that connects the sample needle to valve 1
3	Sample loop	

Procedure

- ▶ Check the connections of the sample loop, the sample needle connection, and the syringe connection for tightness.
- ▶ If required: Tighten the connections.

11.3 Repairs

Procedure

- ▶ For repairs please contact Sartorius Service.

12 Decommissioning, Transport

12.1 Decommissioning

Requirements

The instrument is powered off.

Procedure

- ▶ Remove the sample plate and consumables vial rack (see chapter 8.5, page 44).
- ▶ Empty the waste and fluid reservoirs and dispose of all fluids according to local regulations.
- ▶ Disconnect the main power cable at the installation site.
- ▶ Disconnect the USB cable to the PC.
- ▶ Clean the instrument (see chapter "10.3 Cleaning", page 51).
- ▶ Perform a long-term shutdown (see chapter "8.11 Performing a Long-Term Shutdown", page 48).

12.2 Transporting the Instrument

Personnel: 2 persons, user

Requirements

The instrument is decommissioned.

⚠ CAUTION

Danger of injury due to the heaviness of the instrument.

- ▶ Get help from additional persons when lifting and transporting the instrument. Do **not** lift and carry the instrument by yourself.
- ▶ Use suitable conveyance instruments, e.g., trolleys.

Procedure

- ▶ Hold the bottom of the instrument when lifting and transporting it. Do **not** lift or carry the instrument holding it by individual components, e.g., sample bay door, fluid bay door.
- ▶ Do **not** tilt forward the instrument. The autosampler is **not** fixed in the instrument and can fall out.
- ▶ For long transport routes contact Sartorius Service.
- ▶ Transport the instrument to the desired installation location.

13 Storage and Shipping

13.1 Decontaminating the Instrument

The instrument does **not** contain any hazardous materials that would necessitate special disposal actions. If the instrument has come into contact with hazardous substances: Steps must be taken to ensure proper decontamination and declaration.

Procedure

- ▶ For decontaminating the instrument: Please contact Sartorius Service.
- ▶ The operator of the instrument is responsible for adhering to local government regulations on the proper decontamination and declaration for transport and disposal.

13.2 Storage

Requirement

- — The instrument is decontaminated.
- — The instrument has been decommissioned.

Procedure

- ▶ Perform a long-term shutdown (see chapter 8.11, page 48).
- ▶ Clean the instrument (see chapter „10.3 Cleaning“, page 51).
- ▶ Store the instrument according to the ambient conditions (see chapter „15.2 Ambient Conditions“, page 74).

13.3 Returning the Instrument and Parts

Defective instruments or parts can be returned to Sartorius. Returned instruments must be clean, decontaminated, and properly packed.

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

Procedure

- ▶ Decommission the instrument.
- ▶ Contact Sartorius Service for instructions on how to return equipment or parts (please refer to our website at www.sartorius.com for return instructions).
- ▶ Pack the instrument and its parts properly for return.

13.4 Shipping

Instruments contaminated with hazardous materials, e.g., harmful biological or chemical substances, will **not** be accepted for repair or disposal. The instruments must be decontaminated before shipping (see chapter „13.1 Decontaminating the Instrument“, page 71).

14 Disposal

The instrument does **not** contain any hazardous materials that would necessitate special disposal measures.

Contaminated samples and consumables used during the process that could cause biological or chemical hazards are potentially hazardous substances.

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

Procedure

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

Disposing of the Instrument and Parts

The instrument and the instrument accessories must be disposed of properly using the proper disposal facilities.

Requirements

The instrument has been decontaminated.

Procedure

- ▶ Dispose of the packaging in accordance with local government regulations.
- ▶ Dispose of samples, fluids, and consumables in accordance with local government regulations.
- ▶ Dispose of the sample probe and syringe pump in accordance with local government regulations on proper disposal.

15 Technical Data

15.1 Dimensions and Weights

	Unit	Value
Dimensions (LxWxH)	Inches mm	33 x 18 x 29 816 x 443 x 729
Weight, fully loaded	lbs kg	~140 ~63.5

15.2 Ambient Conditions

	Unit	Value
Conventional laboratory rooms, max. height above sea level	m	2000
Pollution level according to IEC 61010-1		2
Temperature		
Temperature during operation	°C °F	+15 – +25 +59 – +77
Relative humidity		
At temperatures up to 35°C, non-condensing	%	20 – 80
Not for use in potentially explosive atmospheres		

15.2.1 Space Requirement

	Unit	Value
Space: Allow service access to side doors and front doors both for opening and closing (relevant for Sartorius Service).	m	0.5

15.2.2 Setup

Surface : Vibration free environment on a flat surface

15.3 Electrical Data

	Unit	Value
Overvoltage category		II
Protective class according to IEC 61140		I

15.3.1 Power Supply Instrument and PC

	Unit	Value
Voltage	V_{AC}	100 – 240 (±10 %)
Frequency	Hz	50/60
Max. current	A	4

15.4 Protection Class

	Unit	Value
Protection class according to EN 60529		IP20

15.5 Laser

	Unit	Value
Wavelength	nm	532
Output power	mW	80
Laser class according to IEC 60825-1:2014, EN 60825-1:2014/ A11:2021		Class 1

15.6 Warm-up Time

	Unit	Value
After starting: **Not** necessary. The instrument is constantly powering thermal control boards within the instrument when power is supplied.		
After restarting, disruption or installation	min	45

15.7 Connection of the Instrument

Connection: One standalone PC connected by USB-2.0. Contact Sartorius Service if a network connection is required.

16 Consumables

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

Reagent	Quantity	Order number
VC PLUS DY ENV KIT (200 ASSAYS)	1	VIR-K1000
VC PLUS BCVB KIT (200 ASSAYS)	1	VIR-K2000
VC PLUS INVA KIT (200 ASSAYS)	1	VIR-K2200
VC PLUS INVB KIT (200 ASSAYS)	1	VIR-K2300
VC PLUS VSVG KIT (200 ASSAYS)	1	VIR-K2400

17 Sartorius Service

Sartorius Service is available for queries regarding the instrument. 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 instrument information, e.g., serial number, close at hand. This information can be found on the manufacturer's ID label.

18 Conformity Documents

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

SARTORIUS

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

Analysegerät zur schnellen Virusquantifizierung
Analytical instrument for rapid virus quantification

Baureihe
Type series

Virus Counter® Plus

Modell
Model

VIR-92394

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 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
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:

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The Automation Partnership (Cambridge) Limited, Royston, 2023-06-15

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19 Appendix

19.1 List of Abbreviations

Abbreviation	Meaning
ISW	Inter-Sample Wash
CVF	Cleanliness Verification Fluid
PVS	Performance Verification Standard
SSR	Startup | Shutdown Rinse
DSW	Daily System Wash
EtOH	95 % ethanol solution
IQL	Instrument Quantification Limit

19.2 Descriptions of the Washing Solutions

Washing Solution	Description
Inter-Sample Wash	The Inter-Sample Wash (ISW) effectively removes buildup of proteins and dyes in the sample system and reduces sample carryover. The instrument automatically runs ISW between samples, unless running vials manually. ISW will automatically be followed by an analysis of CVF to evaluate the effectiveness of the wash.
Startup | Shut-down Rinse	The Startup | Shutdown Rinse (SSR) solution is a special combination of consumables designed to condition the instrument's sample fluidics system during startup and shutdown procedures and to prevent salt build-up. The SSR solution should always be the first and last component through the sample system. Failure to shut down the instrument properly can result in damage to the fluidics system that may require service. SSR should be stored at room temperature.
Daily System Wash	The Daily System Wash (DSW) is a solution designed to remove any build-up of protein or other contaminant from the sample fluidic path.
Ethanol	Is an instrument priming reagent of 95 % Ethanol which allows easier priming and fluidic maintenance of the instrument.

19.3 Descriptions of the Consumables

Consumables	Description
Cleanliness Verification Fluid	Is analyzed to verify that the instrument is clean and that there is no carryover from the previous sample. The Virus Counter® Plus software indicates the result of the CVF which must measure less than 5 × 10^5 vp/mL (virus particles per mL) to pass, which is indicated as less than Instrument Quantification Limit or "<IQL". If the CVF does not pass, consult the Troubleshooting section.
Performance Verification Standard	Is analyzed to verify working order of the instrument. The PVS sample must demonstrate measured concentration within tolerance of the value listed on the vial and have average peak heights greater than 0.30 V (nucleic channel) and 0.25 V (protein channel), respectively. PVS should be stored at room temperature as freezing causes irreversible damage. PVS should be protected from light when not in use.

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

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