Operating Instructions

Original Operating Instructions

Sterisart® Universal | Gen 4

16421-B | 16421-E | 16421-A
Peristaltic Pump



1000127034

SARTORIUS

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1 About These Instructions

1.1 Validity

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

Device	Item Number
Sterisart® Universal | Gen 4 - Basic, without control unit	16421-B
Sterisart® Universal | Gen 4 - Essential, with control unit (1ZE---0058)	16421-E
Sterisart® Universal | Gen 4 - Advanced, with control unit (1ZE---0058) and extended software (pursuant to 21 CFR, Part 11)	16421-A

1.2 Related Documents

- In addition to these instructions, please refer to the following documents:
  - Instructions for consumables and accessories, e.g., Sterisart® systems, Sterisart® NF.
  - Instructions for installation in the isolator

1.3 Target Groups

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

Target Group	Knowledge and Qualifications
Operator	The operator is familiar with the device and the associated work processes. The operator understands the hazards which may arise when working with the device and knows how to prevent them.*

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

1.4 Symbols Used

1.4.1 Warnings in Operation Descriptions

⚠ WARNING
Denotes a hazard that may result in death or serious 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

Depending on the device configuration, the figures depicting the device and operating display may differ slightly from the supplied device. The variants shown in these instructions are examples.

2 Safety Instructions

2.1 Intended Use

The device is a peristaltic pump and is intended for the even volumetric filling and drainage of 2 sterility test units in a closed system.

Devices without a control unit must be operated with the control button. Only the simple pumping process can be performed in this manner.

Devices with a control unit can also be controlled using the control unit and via remote access with the Sterisart® control software.

The device can be used as a bench-top device in clean rooms and laminar flow units, or integrated into isolators | RABS, e.g., isolators. Integration into the isolator must only be carried out by Sartorius Service or by a partner trained by Sartorius.

The device is intended solely for use in accordance with these instructions. Any other use is considered **improper** and may impair the protection supported by the device, e.g. protection against mechanical dangers.

Operating Conditions for the Device

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

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

2.1.1 Modifications to the Device

If the device is modified: Persons may be put at risk. Device-specific documents and product approvals may lose their validity.

For queries regarding modifications to the device, contact Sartorius.

2.1.2 Maintenance and Repairs on the Device

Device maintenance and repairs may only be carried out by persons with specialized knowledge of the device. If the device is **not** maintained or repaired by a specialist: Persons may be put at risk. Device-specific documents and product approvals may lose their validity.

Only the maintenance tasks described in these instructions should be carried out. For maintenance tasks that need to be carried out by Sartorius Service, contact Sartorius Service.

Sartorius recommends that any repair work, even that carried out after the end of the warranty period, is carried out by Sartorius Service or after consulting with Sartorius Service.

2.2 Qualifications of Personnel

Persons who do not possess adequate knowledge about how to use the device safely may injure themselves and other persons.

If a particular qualification is required for an activity: The target group is specified. If **no** qualification is specified: The activity can be performed by the "Operator" target group.

2.3 Functionality of the Device Parts

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

- If device parts are **not** functioning: Do **not** use the device.
- Comply with the maintenance intervals (intervals and maintenance tasks see Chapter "9.2 Maintenance Schedule", page 69).

2.4 Safety Information on the Device

Symbols, e.g., warnings and safety signs, are safety information for handling the device. 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.
- Replace the symbols if they become illegible.

2.5 Electrical Equipment

2.5.1 Damage to the Device's Electrical Equipment

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

- If the electrical equipment of the device is defective, cut off the power supply and contact Sartorius Service.
- Keep live parts away from moisture. Moisture can cause short circuits.

2.5.2 Power Supply Cable

The use of an **unauthorized** power supply cable may cause life-threatening injuries as a result of electric shocks, for example.

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

2.5.3 Socket at the Installation Site

If the socket at the installation site is **not** grounded: People may suffer life-threatening injury due to electric shock.

- ▶ Ensure that the socket at the installation site is grounded.
- ▶ The device must be connected to a grounded wall socket.

2.6 Accessories and Consumables

The use of unsuitable accessories and consumables can affect the functionality and operating reliability of the device and has the following consequences:

- Risk of injury to persons
- Damage, malfunctions, or failure of the device

- ▶ Only use accessories, consumables, and spare parts that are approved by Sartorius for this device.

2.7 Personal Protective Equipment

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

The following personal protective equipment must be worn:

- Close-fitting clothing
- Latex gloves
- During use in the isolator: Isolator gloves

2.8 Rotating Parts

If items of clothing or body parts come into contact with the clamping bracket or rotor of the device: Items of clothing or body parts can get caught. This can lead to serious injuries.

- ▶ Wear personal protective equipment.
- ▶ Only operate the device alone.
- ▶ Do **not** use the device without a tube inserted.

2.9 Danger of Fire due to Corrosive and Explosive Liquids

If corrosive or explosive liquids are pumped through tubes: People may suffer burning or chemical burns.

- ▶ Do **not** pump any corrosive or explosive liquids.

3 Device Description

3.1 Device Overview



Fig. 1: Sterisart® Universal | Gen 4 bench-top version (with and without control unit, example)

Pos.	Name	Description
1	Control unit	
2	Protective cap	Protects the control unit connection from water and dust.
3	Clamping bracket-Clamp	Clamps the tubes into the sterility test units.
4	Pump head	Contains the rotor.
5	Control button	– Is intended to start and stop the pumping process. – Is intended for scrolling in the parameter list (for devices with control unit only). – Is intended for setting and confirming parameter values (for devices with control unit only).
6	Handle	Is intended for transporting and moving the device.
7	Pump unit	

3.2 Lever

The lever is intended to position the clamping bracket. The lever must be moved manually by the operator.

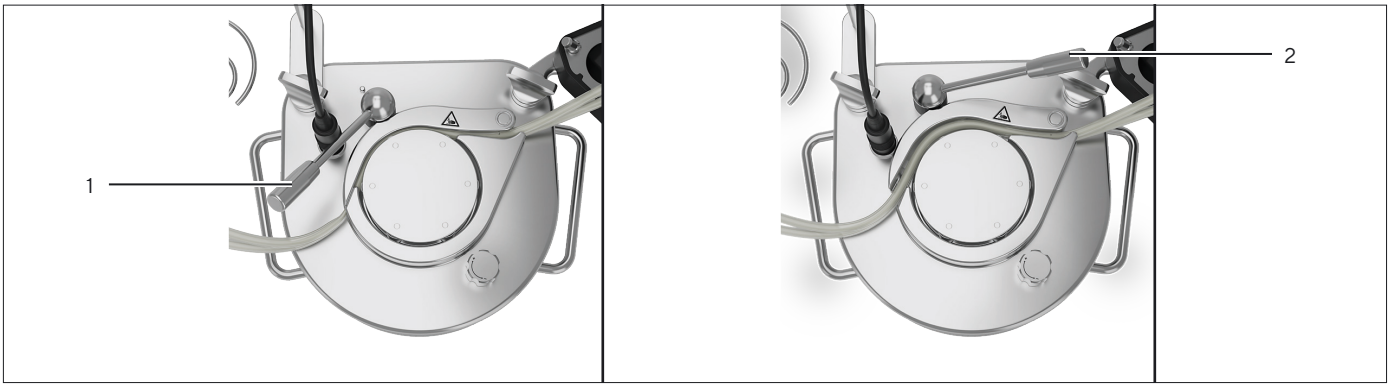


Fig. 2: Lever position (tubing not shown, example)

Pos.	Name	Description
1	Lever closed	The clamping bracket remains on the pump head. This fixes the tubes to the pump head.
2	Lever open	— The clamping bracket is removed from the pump head. This releases the tubes. — For maximum opening of the clamping bracket, the lever can be moved as far as the fixed end stop. — If the lever is opened during a pumping process: The pumping process will be interrupted.

3.3 Stand and Bottle Holder



Fig. 3: Stand and bottle holder, mounted on the pump unit

Pos.	Name	Description
1	Stand	Intended to attach components, e.g. control unit and bottle holder.
2	Bottle holder clamp	– Comprises an inner part with fastening screw. – Fixes the bottle holder to the stand.
3	Stand lug	Connects the stand with the pump unit.
4	Fastening screw	Fixes components to the pump unit.
5	Bottle holder	– Consists of holder arm, bottle holder, and infusion hook. – Is intended to hang up process media.

3.4 Control Unit

The control unit is intended to control the pumping process, e.g. to manually configure and perform pumping processes and generate reports.

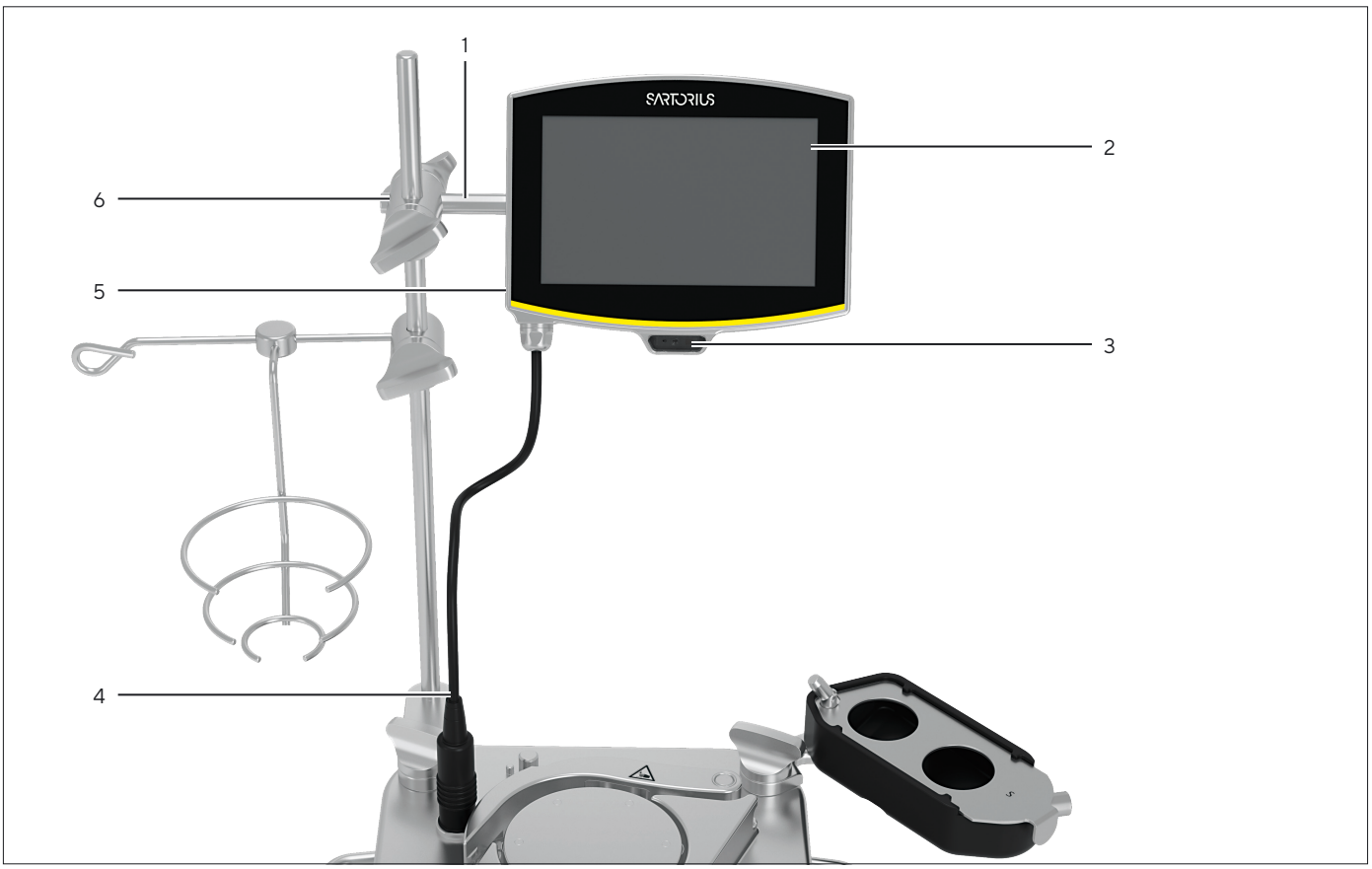


Fig. 4: Control unit, mounted on the stand

Pos.	Name	Description
1	Connection arm	Is intended to attach to the stand.
2	Operating display	
3	1D2D barcode scanner	Is intended to scan codes.
4	Control unit connection cable	— Is intended to connect the control unit to the device. — Is equipped with a protective cover.
5	Manufacturer's ID label	
6	Cross-clamp	— Consists of 1 clamping tube and 2 fastening screws. — Is intended to fix the control unit to the stand.

3.5 Collection Vessel

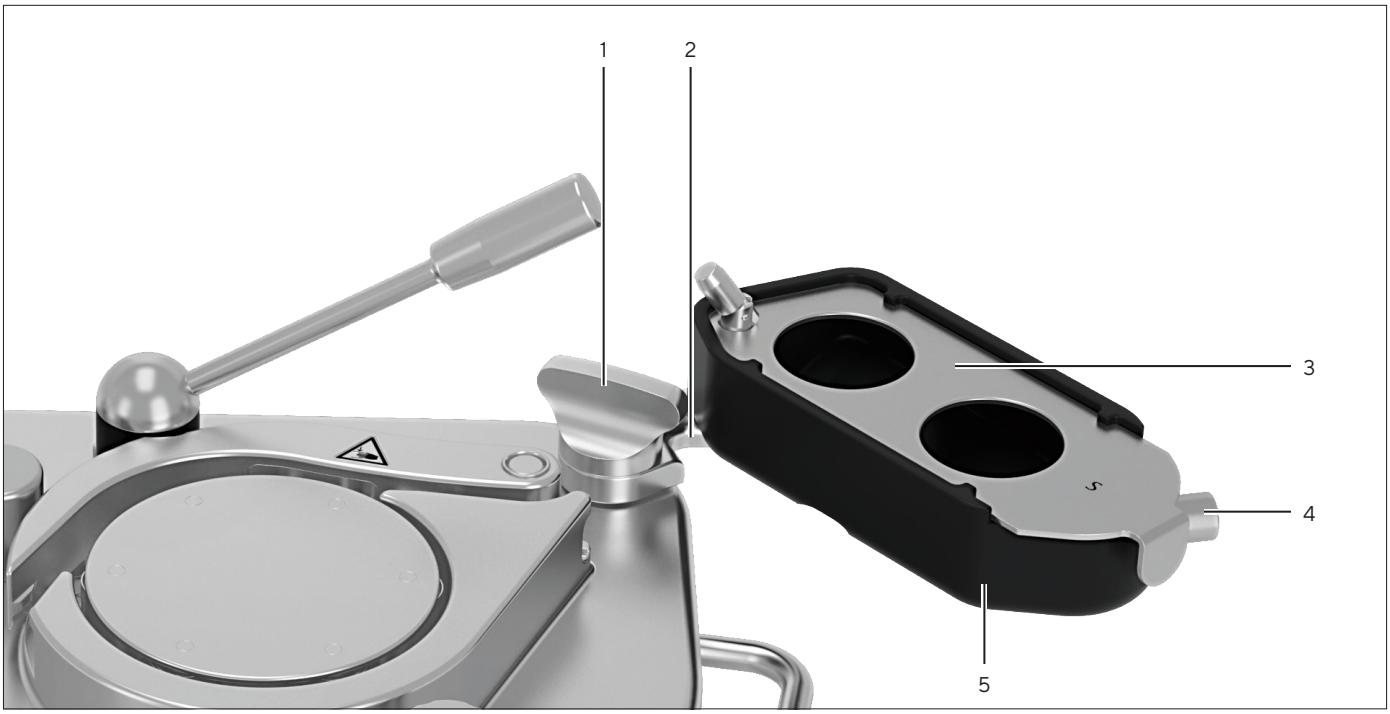


Fig. 5: Run-off vessel, mounted on the pump unit

Pos.	Name	Description
1	Fastening screw	Intended to attach components to the pump unit.
2	Collection vessel lug	– Includes a pin for inserting the collection vessel. – Connects the collection vessel with the pump unit.
3	Cover for collection vessel	Is intended to insert the sterility test units.
4	Waste pipe	– Allows liquids to drain from the vessel, e.g. into a collection vessel or a tube. – Is intended to attach the waste tubing.
5	Pan	Intended for the collection of discharged liquids.

3.6 Pressure sensor

There are 2 pressure sensors installed in the device. The pressure sensor is intended to measure the pressure in the sterility test units. Devices with a control unit include pressure monitoring and pressure control. The pressure threshold and overpressure response can be configured (see Chapter “3.7 Pressure Monitoring and Pressure Control (Only Devices With Control Unit)”, page 16).

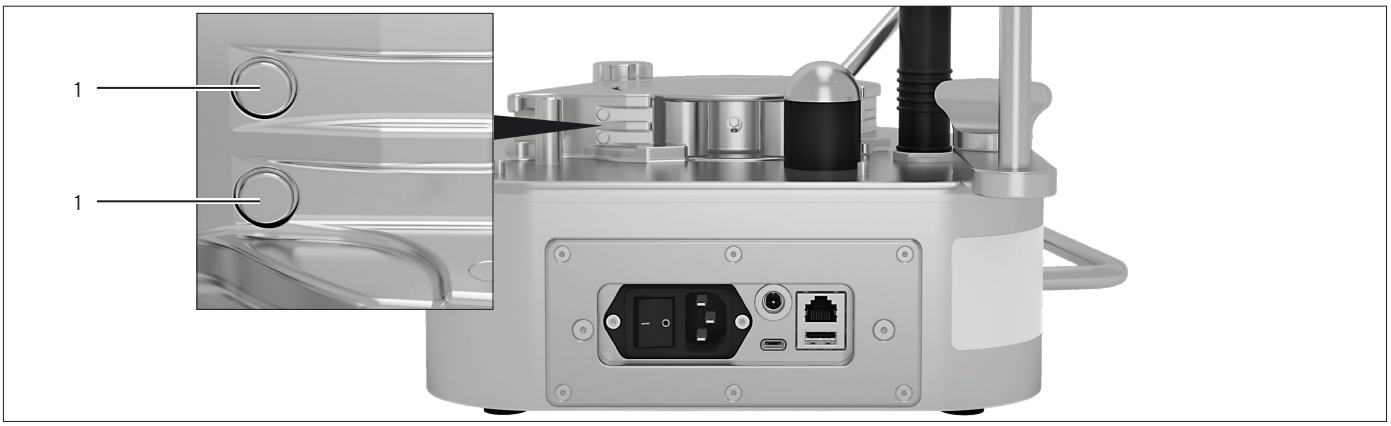


Fig. 6: Pressure Sensor on the Device with Uninstalled Clamping Bracket

Pos.	Name	Description
1	Pressure Sensor	The pressure sensors determine the pressure in the sterility test units. The upper pressure sensor is responsible for measurement in the upper tube and the lower pressure sensor is responsible for measurement in the lower tube.

3.7 Pressure Monitoring and Pressure Control (Only Devices With Control Unit)

3.7.1 Pressure Monitoring

Pressure monitoring takes place if pressure control is activated (see Chapter “3.7.2 Pressure Control”, page 17). During pressure monitoring, the pressure measurement profile is shown based on visual and acoustic signals(see Chapter “15.9 Visual Signals (for Devices With Control Unit)”, page 80). The pressure threshold can be set in the device settings and applies to all tasks (see Chapter 7.8.1, page 58). The value can be set between 1.5 and 3.0 bar and is set to 3.0 bar as standard upon delivery of the device. If the configured pressure threshold is exceeded: An alarm sounds and a warning line is displayed. If the pressure threshold of 4.5 bar is exceeded, an alarm sounds and the pump head stops.

3.7.2 Pressure Control

There are 2 types of pressure control: Manual and automatic.

If manual pressure control is set: The user is prompted by a status display to reduce the pump speed.

If automatic pressure control is turned on: The device reduces the pump speed independently in case of excess pressure. The reduction is carried out in 2 steps: In the 1st step, the speed is reduced by 40%, and in the 2nd step it is reduced again by 80%. This prevents the pressure threshold from being exceeded and avoids damage to the sterility test units.

If pressure control is turned off: The user does not receive feedback regarding pressure.

The pressure control type can be set as a parameter for each task (see Chapter “7.8 Setting Pressure Control”, page 57).

3.8 Device Connections

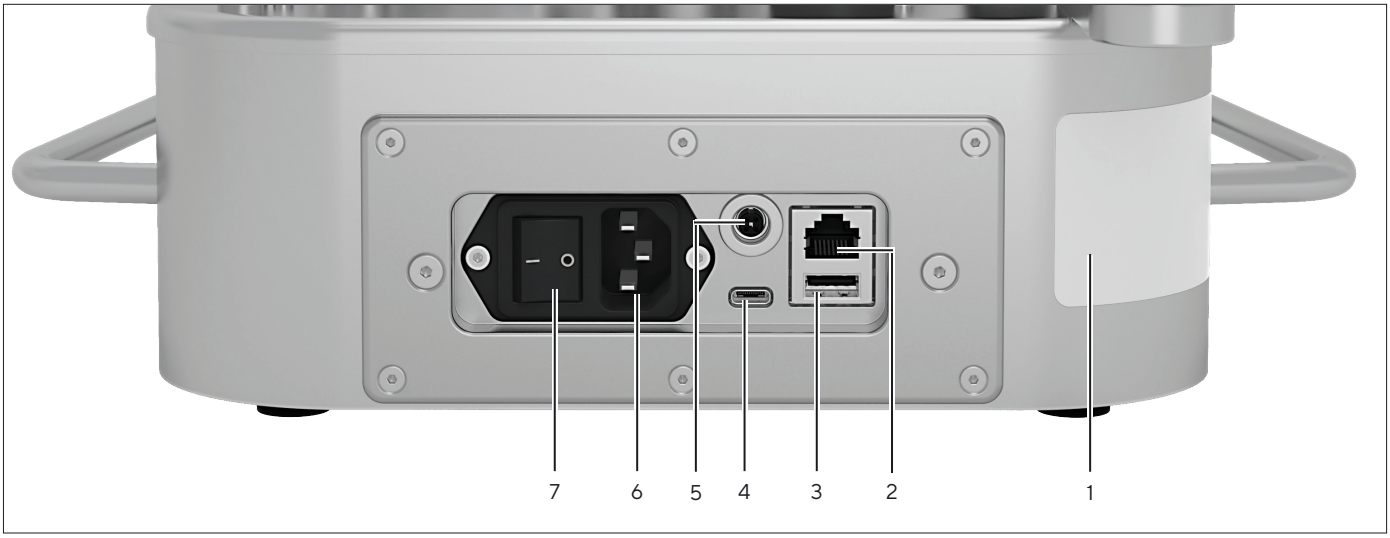


Fig. 7: Connections on the back of the device

Pos.	Name	Description
1	Manufacturer’s ID label	
2	Ethernet RJ45 network connection	For connection to the network
3	USB-A connection	For copying files to and from a USB mass storage device
4	USB-C connection	– For connecting accessories – For copying files to and from a USB mass storage device
5	M9 plug connection	For connecting the foot switch
6	Power supply connection	Intended for the power supply to the device.
7	On / Off switch [O/I]	Switches the device on [I] or off [0].

3.9 Acoustic Signals (for Devices With Control Unit)

The acoustic signals are freely configurable for selected situations. For example, sounds can be set for the following situations: Switching on the device, end of a pumping process.

When the device is delivered, sounds are set as standard for individual situations.

Signal	Meaning
Sound 1	Sounds when the device is switched on.
Sound 2	If a duration has been preset: Signals that the time has lapsed and the pumping process has ended.
Sound 3	— Signals a scanning error. — Signals an internal storage access error.
Sound 4	— Sounds when confirming an entry. — Sounds when touching a button.
Sound 5	General alarm sound

3.10 Accessories

Accessories are available for the device. These allow the device to be tailored to the specific work processes and workplace conditions in the laboratory, e.g. foot switch (see Chapter “16.1 Accessories”, page 84).

3.11 Symbols on the Device

Symbol	Meaning
	Hand injuries: Danger of crushing due to moving parts.

4 Operating Design (Only Devices With Control Unit)

4.1 [Main Menu] Display

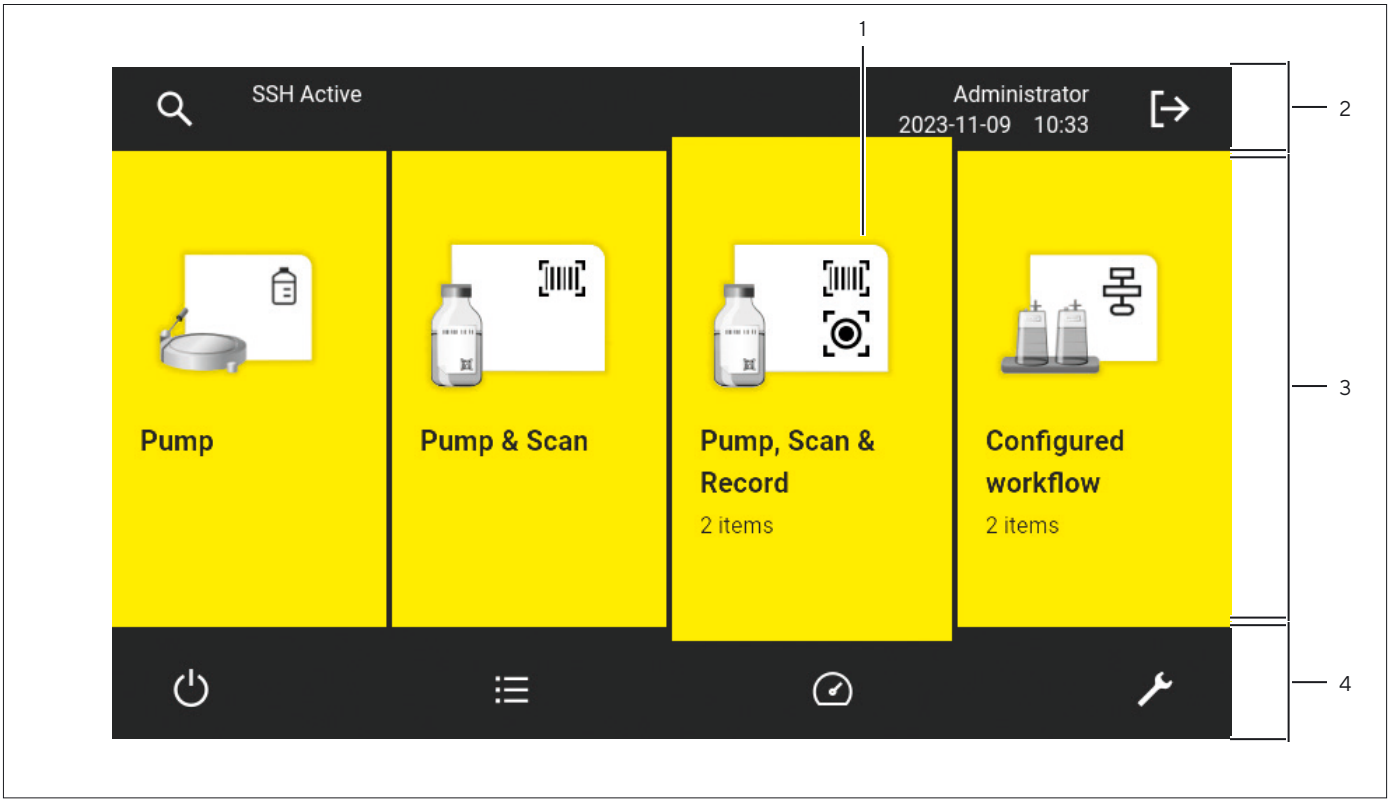


Fig. 8: "Main menu" display for model 16421-A (example)

Pos.	Name	Description
1	Task	If only one task has been created: Opens the described task. If several tasks have been created: Opens the selection menu.
2	Function bar	– Enables logging in and out, as well as navigating and searching in menus and lists. – Indicates the currently logged in user, date, and time.
3	Available tasks	– Displays the available tasks. – For navigation in the main menu with the control button: The selected task is highlighted. – When opening the main menu: The last task performed is highlighted.
4	Function bar	Displays available submenus and operating functions for the current display and current user.

4.2 [Settings Menu] Display

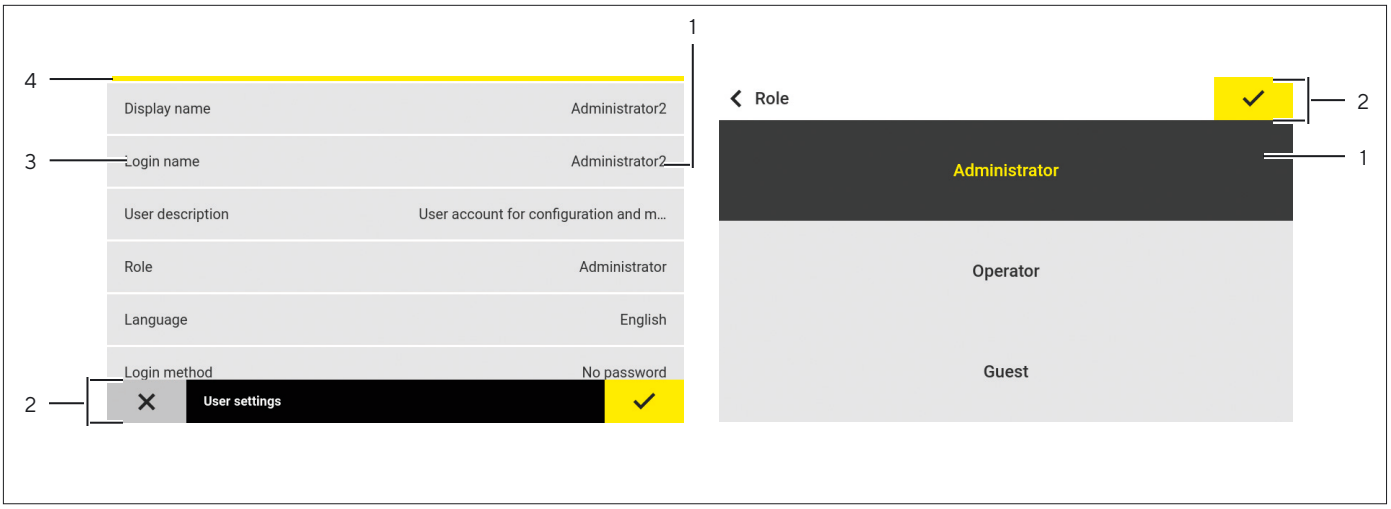


Fig. 9: [Settings Menu] display (example)

Pos.	Name	Description
1	Setting value	– In the “All parameters” view: Displays the selected | entered setting value. – In the “Individual parameters” view: Displays the available setting values for the active parameter.
2	Function bar	– Enables navigation in the display. – Displays the name of the setting menu | parameter.
3	Parameter	Displays the available parameters.
4	Progress bar	

4.3 Display in the Configurator on the Device Website

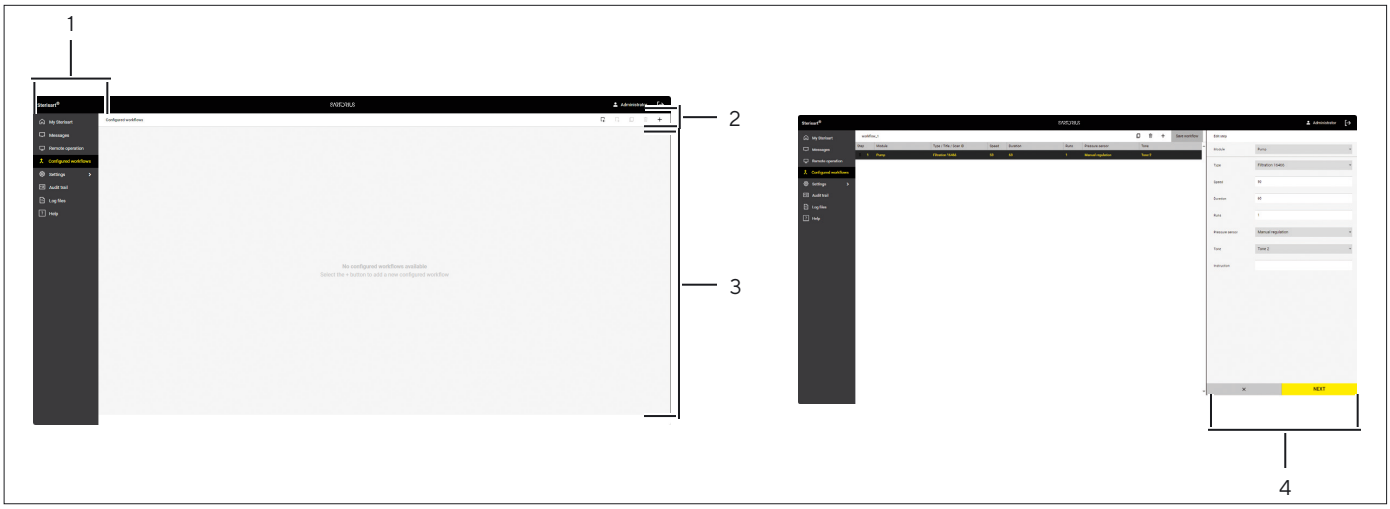


Fig.10: Displays in the configurator on the device website (example)

Pos.	Name	Description
1	Menu bar	
2	Function bar	— Enables navigation in the display. — Enables the addition, selection, export/import, and deletion of workflows. — Displays the name of the menu or workflow.
3	Available workflows and process steps	Displays all available workflows and process steps.
4	[Parameters] display	Displays the available parameters for the selected workflow or process step.

4.4 Operating Elements in [Task Management]

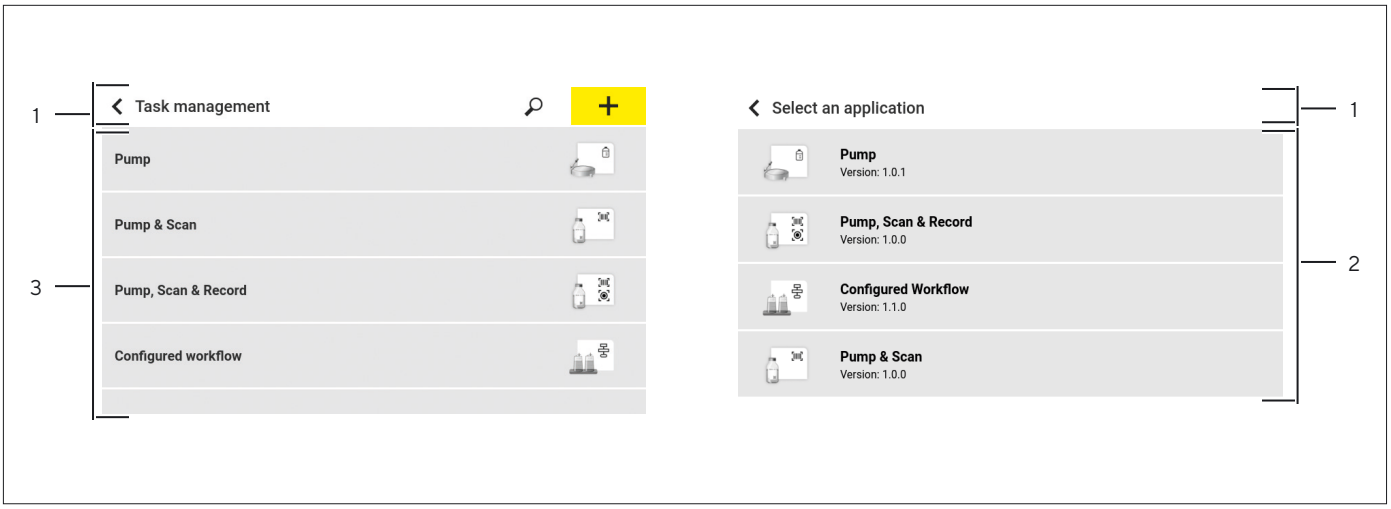


Fig. 11: Operating elements in task management for model 16421-A (example)

Pos.	Name	Description
1	Function bar	– Enables searching and addition of tasks. – Displays the name of the menu or task.
2	Applications	– Displays all available lists of licensed applications. – Intended as a basis for a new task. – Pressing on an application: Opens a display with parameter entries.

3	Available tasks	– Displays all available tasks.
		– Pressing on a task:
		  – Opens a summary of the properties for the displayed task.
		  – Enables the export of the summary as a PDF.
		  – Enables the editing or deletion of a task.

4.5 Operating Elements in Task Display

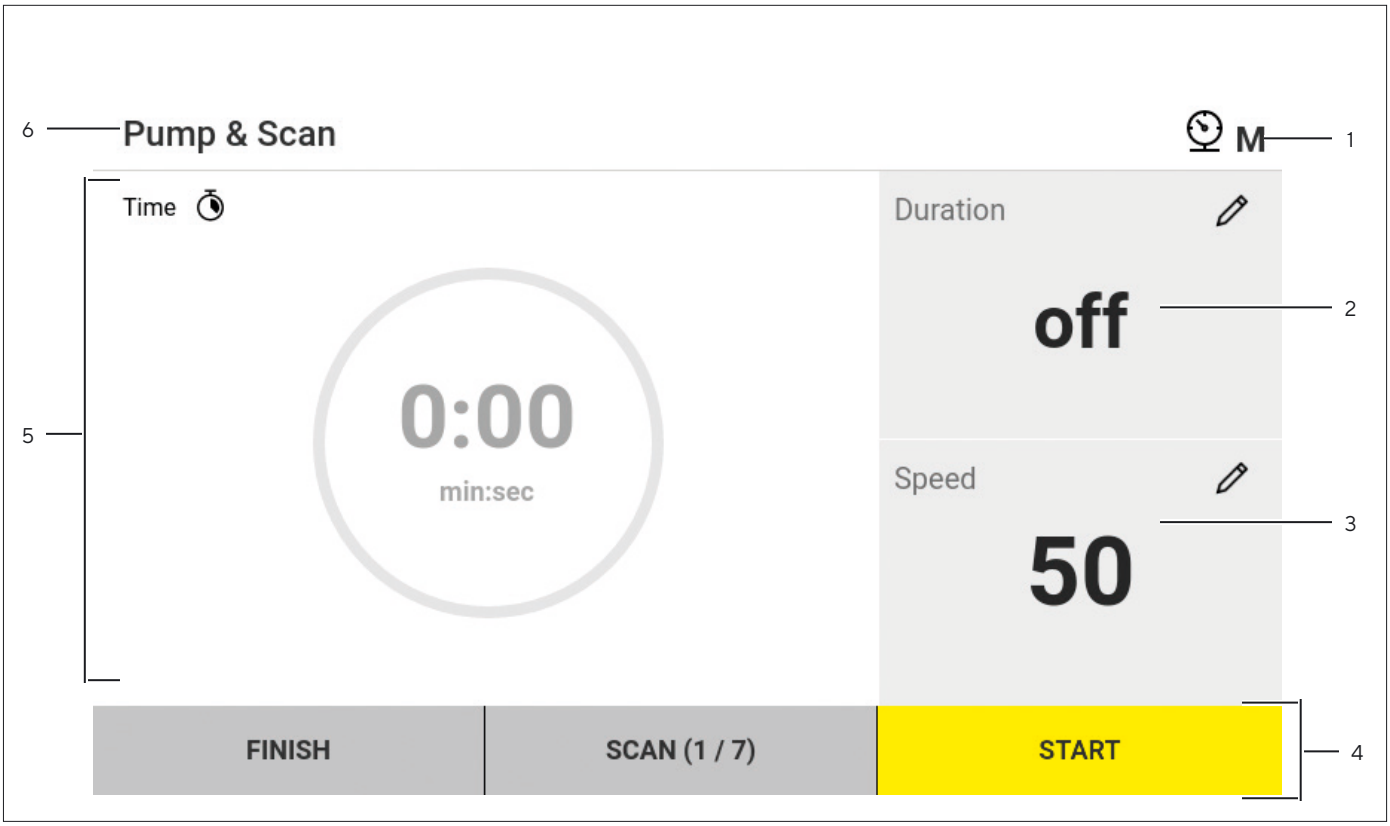


Fig. 12: Display in task mode (example)

Pos.	Name	Description
1	Pressure Control	– Displays the status of the pressure control: – M: Manual, – A: Automatic – If empty: Pressure control is deactivated.
2	Pumping duration	– Can be adjusted before and during the pumping process. – If a pumping duration is set: The pumping process stops automatically after the set time has elapsed. – If the pumping duration is set to “Off”: The operator must stop the pumping process manually or the pumping process stops automatically after 1 hour.
3	Pump speed	– Can be adjusted before and during the pumping process. – If automatic pressure control is set: If the pressure is too high, the pump speed is reduced by the device itself. – The operator has the option to change the pump speed at any time.
4	Function bar	– Displays available operating functions for the current display. – Enables navigation in the task.
5	Task display	Displays information about the current task, e.g., time elapsed in the current pumping run.
6	Task name	Displays the name of the active task.

4.6 Operating Elements in the Configured Workflow

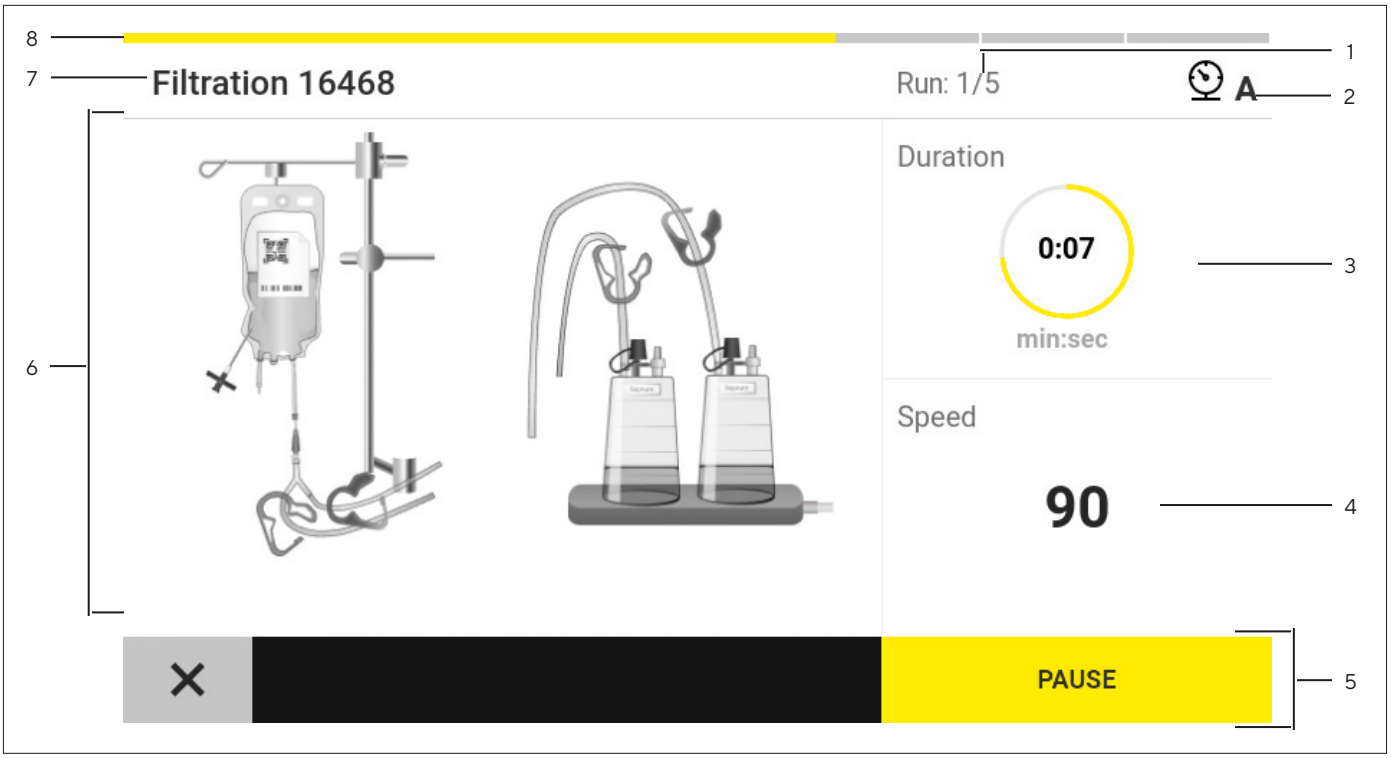


Fig. 13: Display in the configured workflow (example)

Pos.	Name	Description
1	Run	– Displays how many runs in total are set for the active process step. – Displays the number of the current run.
2	Pressure Control	– Displays the status of the pressure control: – M: Manual, – A: Automatic – If empty: Pressure control is deactivated.
3	Pumping duration	– Before the start of the run: Displays the total duration of the active run. – During the run: Displays the time remaining for the active run.
4	Pump speed	Displays the pre-set pump speed for the active run.
5	Function bar	– Displays available operating functions for the current display. – Enables the starting and stopping of the pump, as well as the cancellation of the workflow.
6	Workflow display	Displays information about the current task, e.g., diagrams to assist with processes.
7	Workflow data	Displays the following data: – The name of the current pumping step – The number of the active run – The total number of runs – The overpressure response
8	Progress bar	– Displays the progress of the workflow. – Yellow: Already complete – Gray: To be performed

4.7 User Guide

4.7.1 Help Function

For some menus, additional descriptions for menu or parameter contents can be called up, e.g., user management. The help texts have a full text search and are equipped with links. The help texts can be exported.

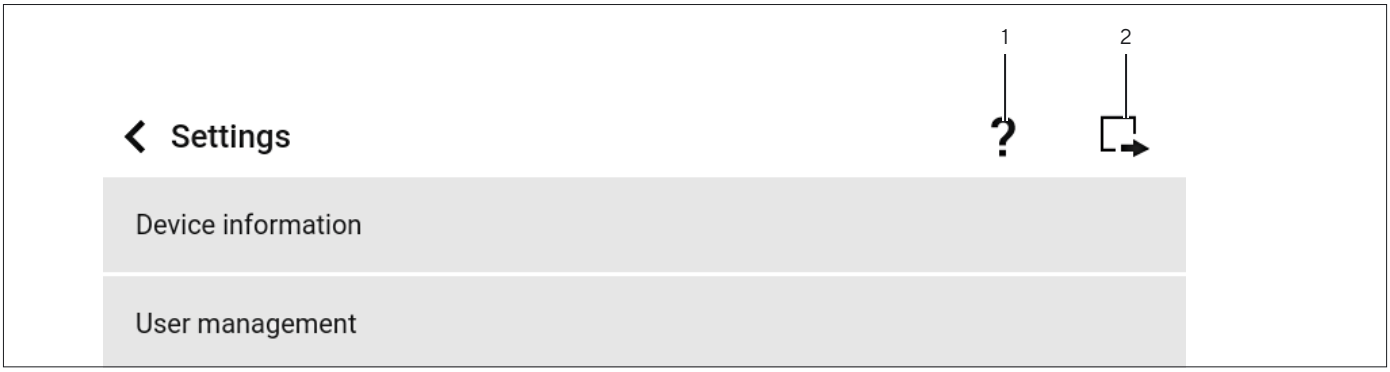


Fig. 14: Help function in the “Settings” menu (example)

Pos.	Name	Description
1	[Help] button	Accesses the help texts.
2	[Export] button	Exports all devices and settings as a PDF to a connector, e.g., USB stick.

4.7.2 Messages

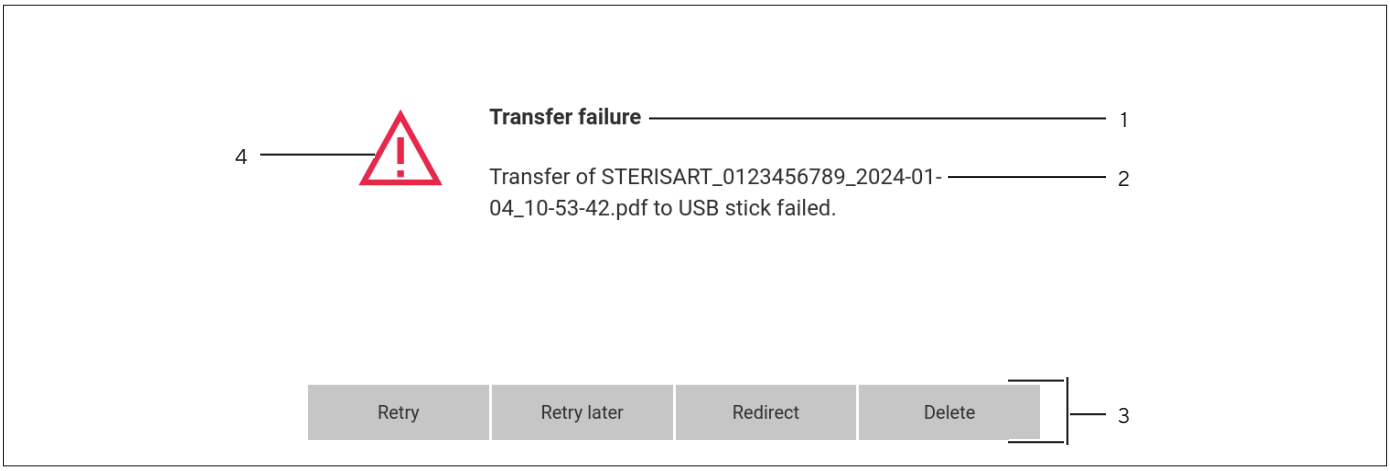


Fig. 15: Error message (example)

Pos.	Name	Description
1	Title	Specifies the type of message.
2	Description	Specifies the cause.
3	Action options	Displays possible options for action.
4	Message type	Indicates that the message is a status message, warning message, or an error message.

4.7.3 Status Center

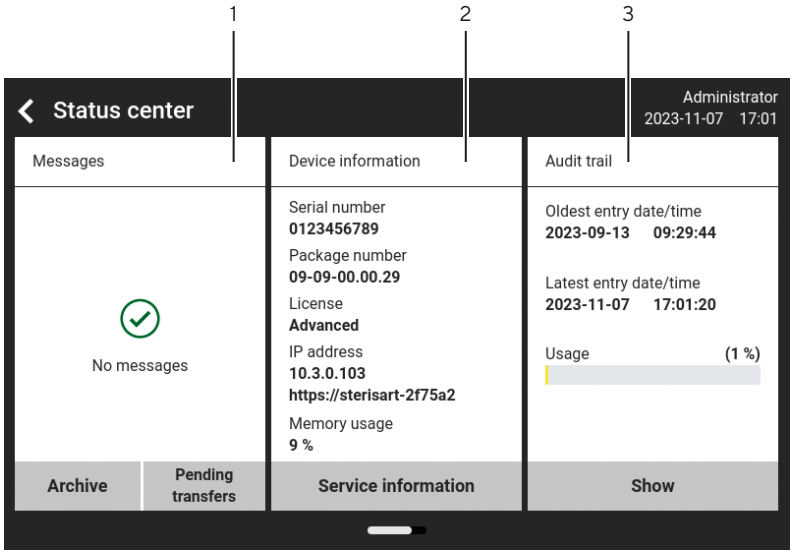


Fig. 16: Status center (example)

Pos.	Name	Description
1	Messages	– Displays information, warning, and error messages, as well as pending transfers. – Enables the resending of pending transfers.
2	Device information	– Displays the general device information. – Displays the license package programmed on the device. – Provides information about the connected IP address. – Has a link to the “Service” menu. – Displays the storage usage for the system as a whole in percent.
3	Audit Trail	Displays the oldest and newest audit trail entry and the memory usage of the audit trail in percent.
4	Calibration (not shown here)	– Displays the time stamp for the last calibration and the user who performed the calibration. – Enables the opening of an overview of all calibration reports.
5	Timer-controlled actions (not shown here)	– If timer-controlled actions are created: Displays the overview of timer-controlled actions. – Enables the editing of timer-controlled actions.

4.8 Keypad

The keypad is intended for entering values in input fields. If an input field is activated: The alphanumeric keypad or numerical keypad is displayed.

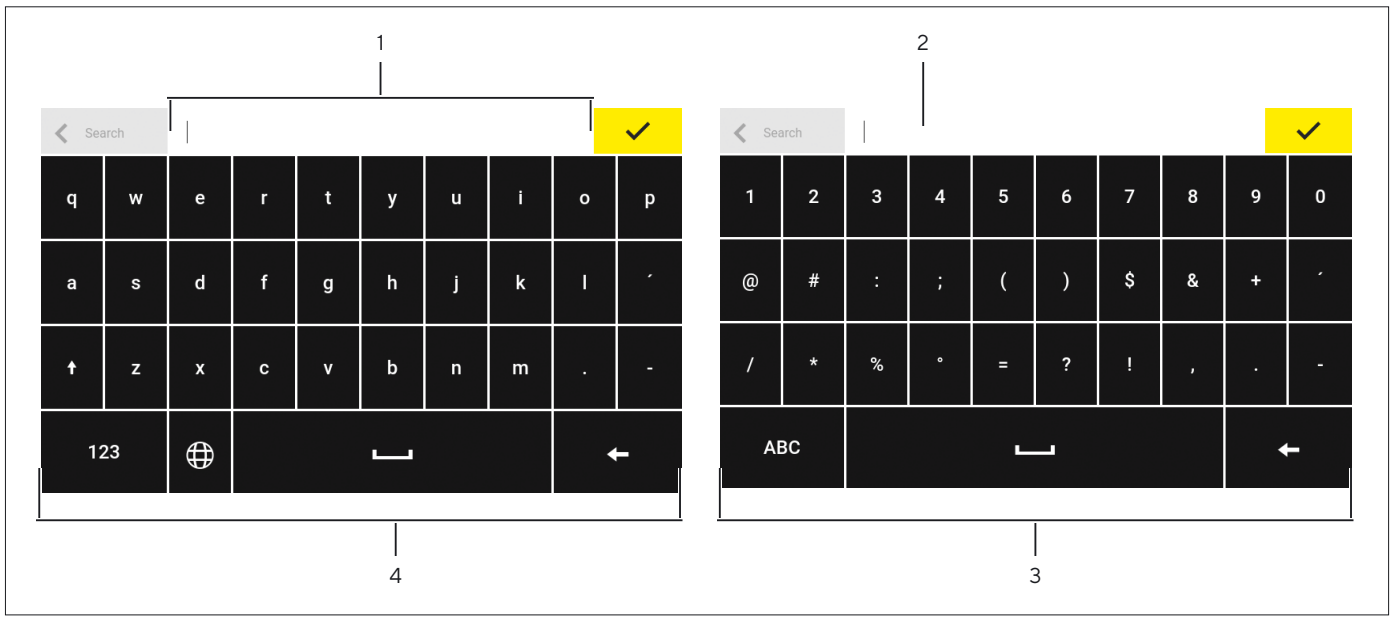


Fig. 17: Alphanumeric keypad and numerical keypad (example)

Pos.	Name
1	Input field
2	Input assistance
3	Numeric keypad
4	Alphanumeric keypad

4.9 Tasks and Workflows

4.9.1 Task

The basic device functions such as pumping and scanning are carried out using tasks. A task is a created, configured application that can be launched by users. Tasks are performed manually. The pumping duration and pump speed can be adjusted before and during a task.

Devices with the essential version of the software are delivered with 2 pre-installed tasks:

- Pump
- Pump & Scan

Devices with the advanced version of the software have an additional task pre-installed:

- Pump, Scan & Record

All other tasks can be newly created and individually configured based on these 3 tasks.

Tasks are visible to all users who have the required role to perform the task. Roles are assigned for all tasks.

4.9.2 Workflows

Workflows are applications with a guided work process. Based on a workflow, tasks can be created comprising scanning steps, messages, and pumping steps, such as the following:

- Diluting
- Dissolving
- Pre-wetting
- Filtration
- Rinsing
- Media filling
- Sealing of vessels

Workflows can only be created, modified, and deleted in the web browser. Workflows created in the web browser are automatically transferred to the control unit and can be executed under the “Configured workflow” task. Using the [Export] and [Import] buttons, workflows can be transferred to other control units.

4.10 Printout

The print options for the device are dependent on the software version.

With the essential version, reports can only be printed as text. With the advanced version, you can also print QR codes, barcodes, and codabars in PDF format.

4.11 Licensed Device Functions (CFR Part 11)

All device functions are activated in the advanced version of the software. Devices with the essential version of the software have a limited range of functions. Model 16421-A is supplied with the advanced version and the basic and essential versions can only be upgraded to the advanced version by Sartorius Service. Only the advanced version provides 21 CFR Part 11 conformity and other licensed functions:

- Extended recording
- Audit Trail
- Electronic signature
- Higher number of scans (30)
- Configured workflows
- User Management
- Remote Control in the Web Browser

4.12 Status Display of the Buttons

Symbol	Name	Description
	Predominant button	Indicates that this function is the next logical step in the display and can be executed. The button is highlighted yellow.
	Secondary button	– In function bars: Indicates that the function can be executed. The button is highlighted white or gray. – In lists: If the function is highlighted white: The button is inactive and signals the end of the list.
Service contact	Inactive button	Indicates that the function **cannot** be executed. The button is grayed out.

4.13 Buttons in Operating Displays

4.13.1 Buttons for Navigation or Organization in Displays

Symbol	Name	Description
	[Back] button	– Returns to the previous display. – If the button is pressed for a prolonged time: Returns to the main menu.
	[Next] button	Accesses the next display, e.g., the next processing step for a wizard.
	[Search] button	– Enables searching in menus and tasks. – If the button has been pressed: Shows the keypad for entering the search term.
	[Active search] button	Displays an active search for tasks or list elements.
	[Filter] button	Displays options for filtering tasks and list elements.
	[Active filter] button	Displays an active filter for tasks or list elements.
	[Sort] button	Displays options for sorting tasks and list elements.
	[Sort ascending] button	Sorts tasks or list elements in ascending order.
	[Sort descending] button	Sorts tasks or list elements in descending order.
	[10 positions forward] button	Jumps forward 10 positions in list elements.
	[10 positions right] button	Jumps 10 positions to the right in list elements.

Symbol	Name	Description
	[Help] button	Displays descriptions of the menu and parameter contents, e.g., printing concept, user management.
	[Info] button	– Opens a display with additional information about the current menu. – In the help text view: Opens an outline of the selected help text.
	[Info] button	
	[Details] button	Shows additional information about an element.
	[Error] button	– In the status center: Opens the associated error message. – Is highlighted in red.
	[Warning] button	In the status center: Opens the associated warning message.
	[User logout] button	Logs the currently active user out and accesses the login display.
	[User login] button	Logs the selected user in.
	[Standby] button	Switches the operating display to standby mode.
YES	[YES] button	Executes the function described in the message.
NO	[NO] button	Cancels the function described in the message and returns to the previous display.
	[iCloud] button	Triggers a connection test of the selected connector.
	[WLAN] button	

4.13.2 Buttons for Operation and Navigation in Task Mode

Symbol	Name	Description
START	[START] button	Starts the pumping process.
END	[END] button	Ends the task and opens the “Report” display.
PAUSE	[PAUSE] button	Halts the pumping process.
RESUME	[RESUME] button	Continues the pumping process.

Symbol	Name	Description
	[Cancel] button	In task mode: Ends the active task and returns to the main menu.
BACK	[BACK] button	Returns to the previous display.
NEW TEST	[NEW TEST] button	Initiates the report backup being canceled without saving and the display returns to task mode.
SAVE REPORT	[SAVE REPORT] button	Starts the printing process, generates the report, and sends the file to the set connector.
Retry	[Retry] button	If report backup has failed: Repeats the report backup process.
Retry later	[Retry later] button	Saves the report in the archive.
Redirect	[Redirect] button	Opens the display for selection of a redirection target.
Delete	[Delete] button	Deletes the current file.
QUIT	[QUIT] button	Exits the active task without saving and returns to the main menu.
SKIP	[SKIP] button	Skips the test result and moves on to the next process step.
OVERVIEW	[OVERVIEW] button	Creates an overview of the process characteristics for the active task.

4.13.3 Buttons for Opening Menus

Symbol	Name	Description
	[Task management] button	Opens the task management.
	[Status center] button	Opens the status center.
	[Setup] button	Opens the “Settings” menu.
Service information	[Service information] button	Opens the “Settings” / “Device settings” / “Device information” / “Service” menu.
Archive	[Status archive] button	Opens an overview of all status messages, warning messages, and error messages.
Pending transfers	[Pending transfers] button	Opens an overview of transfers that have failed and are to be performed later.
View	[View] button	Opens the associated overview.

Symbol	Name	Description
SCAN	[SCAN] button	Opens the “Scan” display. The red laser pointer of the scanner is switched on.
	[Lock] button	Opens the input field to change a user’s password.

4.13.4 Buttons for Editing or Managing Entries

Symbol	Name	Description
	[New] button	Launches a wizard for creating new entries, e.g., a new task, a new print profile, or a user.
	[Edit] button	Accesses the Adjustment Wizard for editing the displayed element, e.g., for setting the parameters for a task.
	[Delete] button	Deletes the selected element.
	[Up] button	— For setting values: Increases the displayed value. — In lists: Moves the selected element further up.
	[Down] button	— For setting values: Decreases the displayed value. — In lists: Moves the selected element further down.
	[On-Off] button	Activates or deactivates the function.
	[Cancel] button	Cancels the current process without saving the changed settings or values.
	[OK] button	Saves a selection or entry.
	[Keypad] button	Shows the keypad.
	[Select character set] button	Switches over the keypad character set for the language version.
	[More] button	Shows the keypad for entering a user-defined value.
	[Select all] button	Selects all elements of a list.
	[Deselect all] button	Deselects the selection for all elements of a list.
	[Lock] button	Locks the selected element.
	[Unlock] button	Unlocks the selected element.

4.13.5 Buttons for Printing and Export Functions

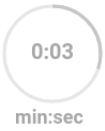
Symbol	Name	Description
	[Duplicate] button	Duplicates the selected user profile.
	[Export] button	– Creates files depending on the context. – Releases the exported files, e.g., PDF or HTML files, via a connected mass storage device. – Enables the export of a workflow from one device to another.

4.14 Display Elements in Operating Displays

Symbol	Name	Description
	[Successfully completed] display	– Indicates that the selected command was completed successfully. – In the archive: Indicates that there are **no** unread messages.
	[Diagnostic file] display	Displays information and prompts to take action associated with the diagnostic file.
	[Error] display	Indicates that an error occurred while performing the command.
	[Safety Information | Process-related Information] Display	Displays safety information | process-related information, e.g. wearing of personal protective equipment or the materials required for the process.
	[Action query] display	Indicates that an action query is involved that either can or cannot be performed.
	[Load] display	Indicates that processes are being executed in the background.
	[Time] display	Displays the course of the pumping process in terms of time.
	[Progress] display	– Indicates that the active task consists of several work steps. – Displays the progress of the active task | the active processing step.

	[Pressure control] display	– Displays whether automatic or manual pressure control is selected:
		  – If “M” is shown: Automatic pressure control is deactivated. The pressure must be controlled manually.
		  – If “A” is shown: Automatic pressure control is activated.

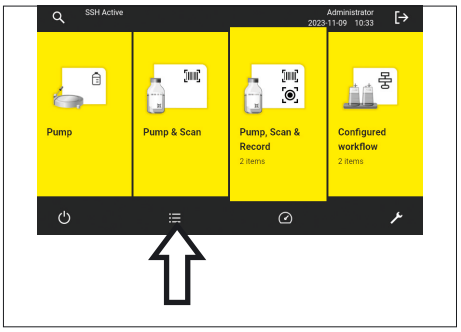
	[Pressure control] display	If the type of pressure control is selected: Indicates that the pressure in the sterility test units is below 3.4 bar.

Symbol	Name	Description
	[Pressure control] display	If the type of pressure control is selected: Indicates that the pressure in the sterility test units is too high (3.4 bar) and must be reduced.
	[Process step time] display	— Displays the time for the current process step. — If the process step is being executed: Displays the time remaining.
	[Locked] display	Indicates that the user profile cannot be edited.

4.15 Navigation

4.15.1 Navigating the Menus

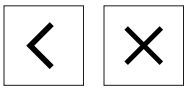
Procedure



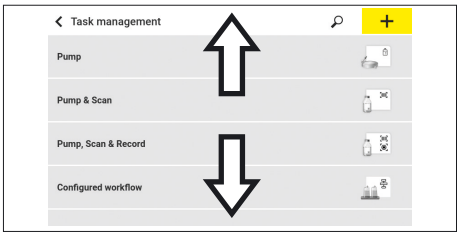
- ▶ To open a menu: Press the button for the preferred menu, e.g., the [Task management] button.
- ▷ The menu is opened and the name of the open menu is opened in the function bar.



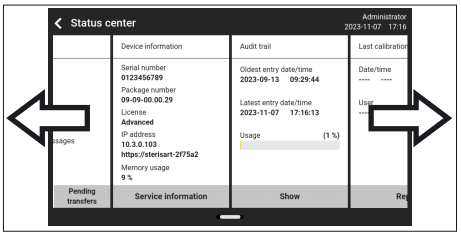
- ▶ To return to the main menu from other menus: Press on the [Back] button until the [Main menu] display is opened.



- ▶ To exit a display: Press the [Back] or [Cancel] button.



- ▶ To scroll through the lists in a menu: Swipe the list downwards or upwards.

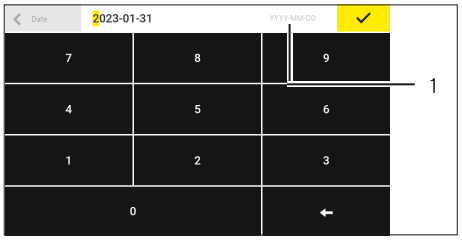


- ▶ To display the previous page in a display with several pages: Swipe the display to the left or right.

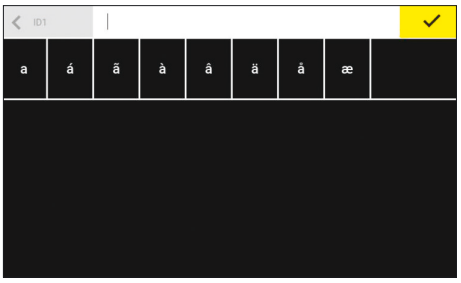
- ▶ If a value needs to be selected from a list:
  - ▶ Scroll to the preferred value in the display. To do this, swipe the display upwards or downwards.
  - ▶ Press the preferred value.
  - ▶ To confirm the selection: Press the [OK] button.
- ▷ The selected value is saved and the list closes.



- ▶ If elements from a display need to be filtered or a display needs to be browsed:
  - ▶ Press the [Search] or [Filter] button.
  - ▷ The keypad is displayed.
  - ▶ Type the search value or value to be filtered into the input field (1) using the keypad.
  - ▶ Press the [OK] button.



- ▶ To close the input field for searching and filtering without starting a search or filter operation: Do **not** enter a value in the input field or delete the entered value.
  - ▶ Press the [OK] button.



- ▶ To display language-specific characters: Press and hold a letter on the keypad.
- ▷ If language-specific characters are available for the letter: All language-specific characters are displayed.
- ▶ To select a language-specific character: Press the desired language-specific character.
- ▷ The character is adopted and the full keypad is displayed again.

4.15.2 Navigating in Task Display

Navigation in the task display is via the buttons. There are 2 ways to actuate buttons: With a finger (touch function) or with the control button.

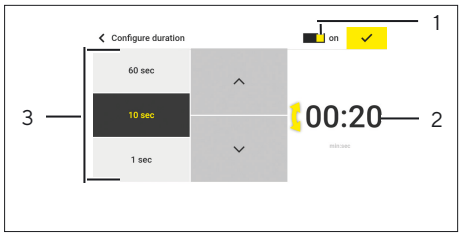
Procedure



- ▶ If a button needs to be actuated with the control button:
  - ▶ Turn the control button to the left or to the right until the desired button is highlighted in yellow.
  - ▶ Push the control button.



- ▶ If a parameter needs to be changed, activated, or deactivated, e.g., “Duration”:
  - ▶ Press the [Edit] button.
  - ▷ The [Configuration] display is opened.
  - ▷ The current value is displayed (2).
  - ▶ To change the unit: Press the button for the unit (3) and select the desired unit.
  - ▶ Set the value using the [Up] and [Down] buttons or set by turning the control button.
  - ▶ To save the selection and return to the task display: Press the [OK] button.
- ▶ To activate or deactivate the “Term” parameter: Press the [On-Off] (1) button.





- ▶ To adjust the speed during the pumping process: Turn the control button to the left or right according to the marking.

4.16 Menu Structure

4.16.1 Main Menu

▶ Navigating the menus (see Chapter “4.15 Navigation”, page 35).

Level 1	Level 2	Level 3	Description
Task management	Available tasks		Displays all available tasks. Opens a summary of the properties for the displayed task.
	Select an application		Displays all available application templates for creating a new task.
Status center			Display information on the device status, e.g., service information, audit trail information, calibration or message information.
Settings	Device information		
	User management		
	Access management		
	Timer-controlled actions		
	Print profiles		
	Connections		
	Device settings		
	Device maintenance		

4.16.2 “Settings” Menu

▶ Navigating the menus (see Chapter “4.15 Navigation”, page 35).

Level 1	Level 2	Level 3	Description
Device Information	General device information		Displays general device information, e.g., model name, serial number.
	Service		Displays general information about service-related topics, e.g., telephone number, last maintenance, or maintenance cycle.
	View audit trail		If advanced licensing is present. Display, sort, browse, or export the contents of the audit trail memory.
	Software licenses		Display the software module used.
User management			Display or edit the 4 standard user profiles, e.g., password, language. For the advanced version only: Create or edit additional user profiles, user roles, and rules.
Access management*	Role management		Display or edit the 4 standard user roles. Create or edit additional user roles.
	Login rules		Define the rules for automatic login, automatic logout, after inactivity, and for failed attempts at password entry.
	Local password rules		Define the permissible characters, length, and validity time for the password.
	LDAP server configuration		Configure the data for device communication with an LDAP server.
Timer-controlled actions			Display the created timer-controlled actions, e.g., “Start task”. Create new timer-controlled actions.
Print profiles	PDF		Display and manage the saved print profiles.
	CSV		
	Web service report		
	Data file		

* Available with advanced licensing only

Level 1	Level 2	Level 3	Description
Connections	Connectors	USB	Display and manage the saved connectors, e.g., a USB stick.
		FTP	The connection to the FTP or FTPS servers facilitates file transfer using the FTP or FTPS protocol.
		FTPS	
		Network printer	Display and manage the saved network printers.
		SMB	The connection to a Windows file server facilitates file transfer using a Server Message Block (SMB protocol).
		HTTP	Create the connection to a server in order to enable exports of files, e.g., data file export.
		HTTPS	
	Network	General settings	Define the device host name.
		Ethernet	Display and manage settings for the device's Ethernet or Wi-Fi connection.
		Wi-Fi	
		Diagnostics	Performs a network test to check the connection.
	Website / web services	Website access	Determines the settings for the display of the website for the device. Depending on the settings for the website access, a user log-in may be required. The user has the same access rights for the website as on the device.
		Web service password	Define the password for the web services.
	Certificates	Trusted certification authorities	Display and export the trusted certification authorities (CA).
		Device certificates	Display and export the device certificates.
		Trust unknown certificate authorities	Specifies the security for unknown certification authorities.

* Available with advanced licensing only

Level 1	Level 2	Level 3	Description
Device settings	Date and time	NTP configuration	Activate or deactivate time synchronization via NTP.
		Set date and time	Enter a date and time. Determine the time zone.
	Device ID	Device ID 1	Determine the device identifier.
		Device ID 2	
		Group ID	
	Pressure Control	Pressure unit	Define the unit for the pressure value: bar or psi.
		Overpressure regulation	Define the excess pressure value from which the automatic pressure control engages and controls the pump.
	Internal scanner	Operating mode	Activate or deactivate the internal scanner. Switch on the additional light. With essential licensing, up to 10 different scans can be saved per task. With advanced licensing, up to 30 different scans can be saved per task.
	Foot switch	Operating mode	Activate or deactivate the foot switch. Defining the operating mode: “Tactile” or “Switching”.
	Electronic signature*	Sign report	Activate or deactivate the electronic signature.
	Start-up behavior	Automatic login	Activate or deactivate automatic login for the administrator or user when starting the device.
		Service user identification	Activates a user identification for the service.
		Automatic start of task	Activate or deactivate automatic start of the last task or the selected task when starting the device.
	Display settings	Display brightness	Define the brightness of the operating display.
	Sound (loudspeaker)	Touch sounds	Activate or deactivate the acoustic signal when operating a button.
		Message sounds	Activate or deactivate the acoustic signal for messages.
		Scan sound	Select the sound during scanning.
		Volume	Set the volume for all sounds.

* Available with advanced licensing only

Level 1	Level 2	Level 3	Description
Device maintenance	Update firmware	List of connectors followed by list of firmware versions	Starts a firmware update.
	Overpressure sensor test	Start test	Starts the pressure sensor test.
		Print profile	Selects the print profile for the pressure sensor test report.
	Backup device settings	List of connectors	Saves the device data on the selected connector.
	Restore device settings	List of connectors	Loads saved device data from the selected connector.
	Export device settings	Configured workflow tasks Print profiles Connectors Device settings User Roles Timer-controlled actions Certificates	Saves the preferred parameters from the displayed submenus on the selected connector.
	Import device settings	List of connectors for import	Also loads the device data, incl. role and user management, e.g., from a server or connected USB stick.
	Languages	Import language	Imports the language, e.g., from a connected USB stick
		Delete imported languages	Deletes all imported languages.
	Reset to factory settings	Restore factory settings	— Resets the device to factory settings and deletes all configurations. — Audit trail remains intact.
	Create diagnostic file		Save information about the device configuration and the ongoing operation on a connected USB stick.

* Available with advanced licensing only

5 Installation

5.1 Scope of Delivery

Item	Quantity
Pump unit	1
Clamping bracket	1
Lever	1
Control button	1
Country-specific power supply cable type EU according to IEC 60884, CEE type 7/7	1
Stand with stand lug	1
Bottle holder	1
Collection vessel with cover for Sterisart® sterility test systems	1
Lug with pin for the collection vessel	1
Fastening screw	2
Protective cap for the control unit connection	1
Only for devices with a control unit:	
Control unit with connection arm and connection cable	1
Cross-clamp to attach and align the control unit	1
Operating Instructions	1

5.2 Selecting an Installation Site

Procedure

▶ Ensure that the installation conditions have been met (see Chapter “15.4 Installation Conditions”, page 77).

5.3 Unpacking

The device is packed in multilayer foam packaging. The device components, e.g., collection vessel, are inserted into the foam packaging.

The individual layers of the foam packaging must be removed one after the other.

Procedure

- ▶ Remove the top layer of foam packaging.
- ▶ Remove the foam packaging with the device components.
- ▶ For devices with a control unit: Remove the control unit.
- ▶ Holding both handles, lift the device from the packaging.
- ▶ Place the device down on a stable, completely flat surface (see Chapter “15.4.1 Installation Site”, page 77).
- ▶ Sartorius recommends removing the individual components from the foam packaging one after the other.
- ▶ Sartorius recommends keeping the original packaging to return the device appropriately, e.g., for repairs.

5.4 Mounting components to the pump unit

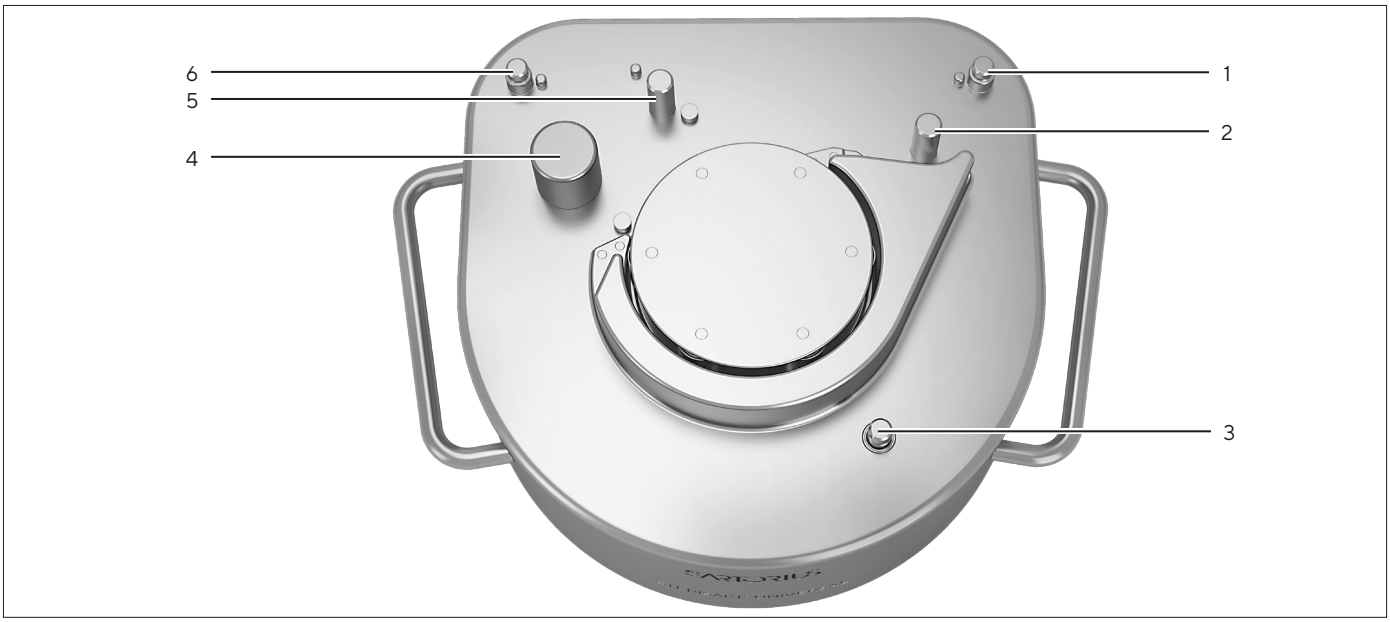


Fig. 18: Fastening elements on the pump unit (example)

Pos.	Name	Description
1	Collection vessel bolt	Intended to secure the collection vessel.
2	Clamping bracket pin	For attaching the clamping bracket
3	Control button sleeve	For attaching the control button
4	Control unit connection	— Is supplied with a pre-installed protective cap. — For connecting the control unit
5	Lever pin	— For attaching the lever
6	Stand bolt	For securing the stand

5.4.1 Securing the Stand to the Pump Unit

The stand can be attached to the pump unit in 2 positions.

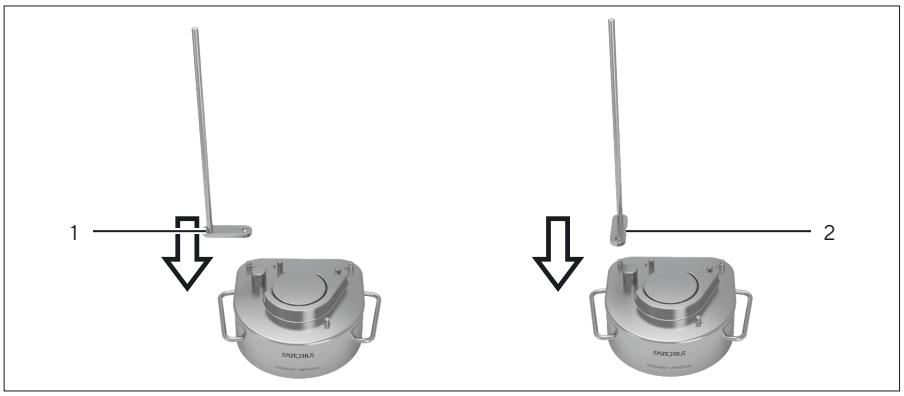
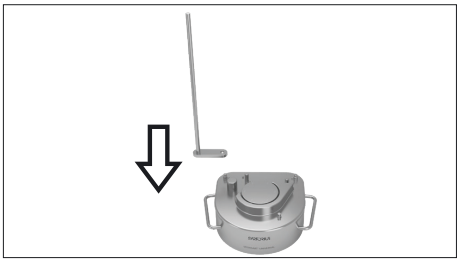


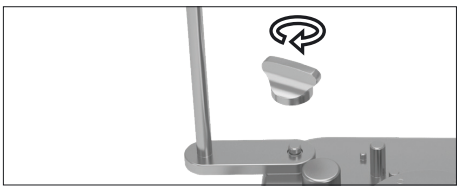
Fig. 19: Stand in possible positions 1 and 2

Pos.	Name	Description
1	Position 1	Stand lug horizontally aligned
2	Position 2	Stand lug vertically aligned

Procedure



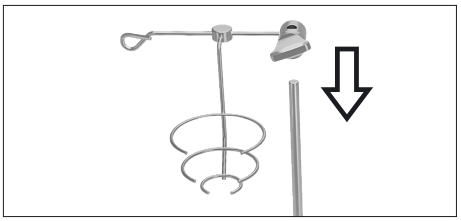
- ▶ Align the stand according to desired position (1).
- ▶ Place the stand on the bolt intended for this purpose.



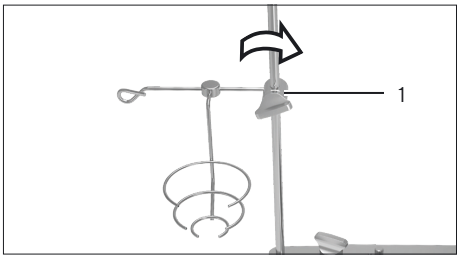
- ▶ Place a fastening screw on the bolt and tighten clockwise by hand.
- ▶ Check that the stand is securely seated. To do this, jiggle the stand.

5.4.2 Securing the Bottle Holder to the Stand

Procedure



- ▶ Pull the bottle holder onto the stand arm and align it according to the desired height and position.

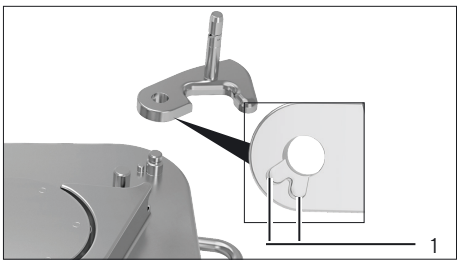


▶ To fix the position: Hold the bottle holder still and tighten the fastening screw (1) clockwise by hand.

5.4.3 Securing the Collection Vessel to the Pump Unit

The collection vessel lug can be attached in 2 positions. The choice of positions is determined by the two indentations on the back of the lug. The collection vessel can be aligned in 2 different positions.

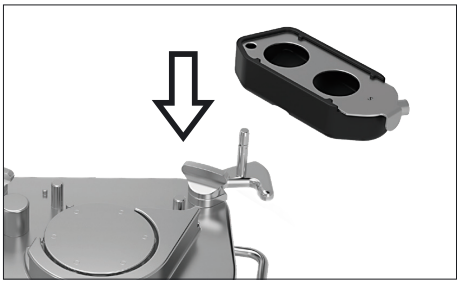
Procedure



▶ Align the lug with the preferred indentation (1) and place on the bolt intended for this purpose.



▶ To secure the lug: Place a fastening screw on the bolt and tighten clockwise by hand.



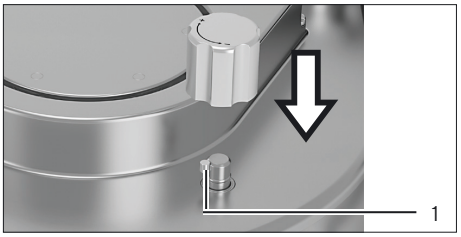
▶ Place the collection vessel on the finger of the lug (2) and align it.



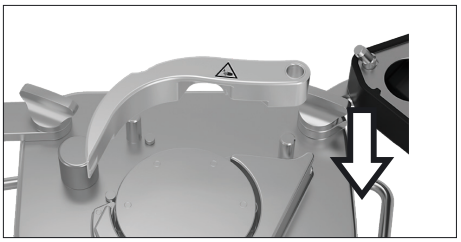
▶ To secure the collection vessel: Snap off the tip (3) of the finger.

5.4.4 Securing Control Button, Clamping Bracket, and Lever

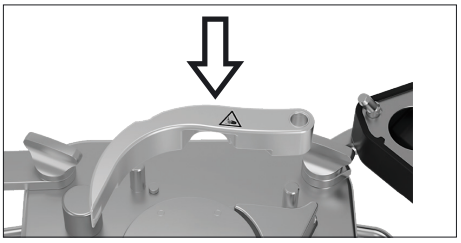
Procedure



- ▶ Place the control button onto the sleeve intended for this purpose, with the control button aligned with the longitudinal pin (1).
- ▷ There is a gap of approx. 2 mm between the control button and the pump housing.



- ▶ Place the clamping bracket on the pin intended for this purpose.

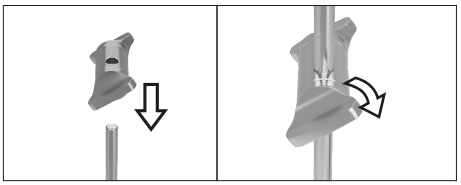


- ▶ Place the lever on the pin intended for this purpose, with the lever pointing to the right.

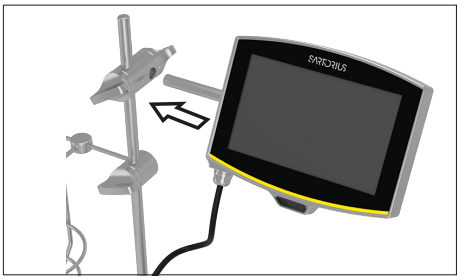
5.4.5 Securing the Control Unit to the Stand (Only for Devices With a Control Unit)

Procedure

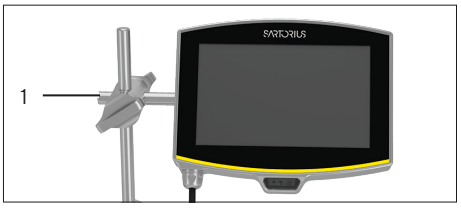
- ▶ Remove the cross-clamp from the foam packaging. To do this, proceed as follows:
  - ▶ Remove the cross-clamp as a complete unit.
  - ▶ To prevent the fastening screw from falling out: Always keep the cross-clamp horizontal.



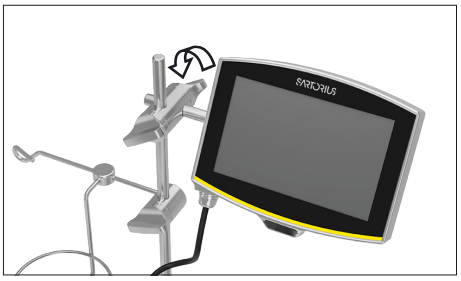
- ▶ Secure the cross-clamp to the stand. To do this, proceed as follows:
  - ▶ Pull the cross-clamp through one of the holes on the arm of the stand.
  - ▶ Align the cross-clamp according to the preferred height and position.
  - ▶ To fix the position: Firmly tighten the appropriate fastening screw by turning clockwise.



- ▶ Push the connector arm on the control unit through the free hole in the cross-clamp.



▷ The connector arm protrudes a little way on the other side (1).
▶ Hold the control unit and tilt to the preferred angle.



▶ To fix the position: With the other hand, tighten the corresponding fastening screw.

5.5 Securing Waste Tubing

The waste tubing is intended to allow larger amounts of water to drain from the collection vessel into a larger vessel, e.g., a collecting tank or sink. This prevents the collection vessel from overflowing. Waste tubing must be secured to the collection vessel.

Procedure

▶ **NOTICE** Potential for the collection vessel to overflow due to insufficient height difference between the collection vessel and the collecting tank! An insufficient height difference will result in the backflow of liquids into the collection vessel.
  ▶ Ensure that the vessel used is at least 5 cm lower than the collection vessel.
  ▶ Make sure that waste tubing is pointing downwards.
▶ Insert one end of the waste tubing into the waste pipe.
▶ Place the other end in the vessel used.

5.6 Placing the Device in the Isolator

Installation into the isolator must be performed by a qualified Sartorius Service engineer. To do this, the instructions for installation into the isolator must be followed. The instructions are included with the isolator installation kit.

6 Commissioning

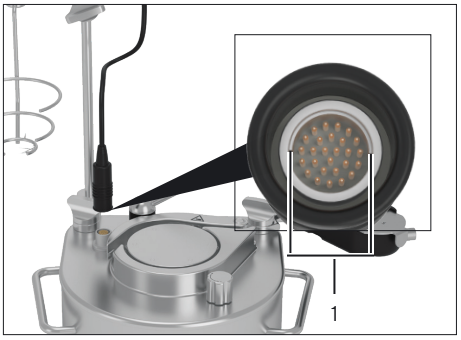
6.1 Connecting the Control Unit to the Device (Only Devices With Control Unit)

Procedure

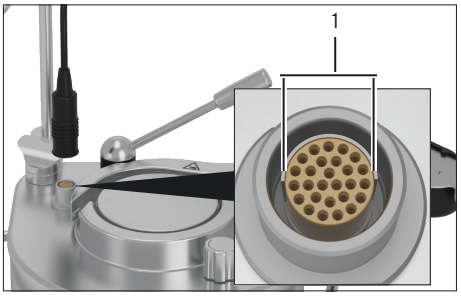


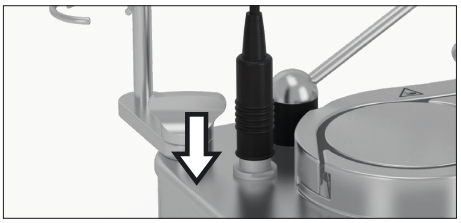
▶ To expose the control unit connection: Remove the protective cap.

▶ **NOTICE** Improper connection may damage the device! If the device is connected to the control unit: The device must be disconnected from the power supply. Ensure that the device is disconnected from the power supply.



▶ Align the control unit connection plug with the device connection. The two inner casings (1) must form a circle.





▶ Place the plug on the connection and plug it in slightly. It must be possible to press down on the plug easily.

▶ If the plug **cannot** be pressed down easily:
  ▶ Turn the plug slightly to the left and to the right on the connection until you feel no more resistance in turning.
  ▶ Insert the plug.

▶ Ensure that the protective cover of the plug is pulled down fully.

6.2 Connecting the Foot Switch

A foot switch can be connected to the device. The foot switch can only be used to start and end the pumping process.

Requirements

The foot switch must be suitable for the device (see instructions for the foot switch).

Procedure

- ▶ **NOTICE** Improper connection may damage the device! If the device is connected with electronic components, e.g., foot switch: The device must be disconnected from the power supply. Ensure that the device is disconnected from the power supply.
- ▶ Connect the foot switch to the foot switch connection.

6.3 Connecting the Device to the Power Supply

Procedure

- ▶ ⚠ **WARNING** Serious injuries caused by using defective power supply cables! Check the power supply cable for damage, e.g., cracks in the insulation.
  - ▶ If required: Contact Sartorius Service.
- ▶ Check whether the country-specific power plug matches the power supplies at the installation site.
  - ▶ If required: Contact Sartorius Service.
- ▶ Connect the plug of the AC adapter to the device's power supply connection.
- ▶ Connect the mains plug of the power supply cable to the wall outlet at the installation site.

6.4 Switching the Device On or Off

When the device is switched on for the first time or after restoring factory settings: The Setup Wizard is opened. All steps in the Setup Wizard must be completed.

If the device is switched on after the Setup Wizard is complete and **no** passwords have been assigned for the user profiles: The user profile for the last user to be logged in is loaded.

Procedure

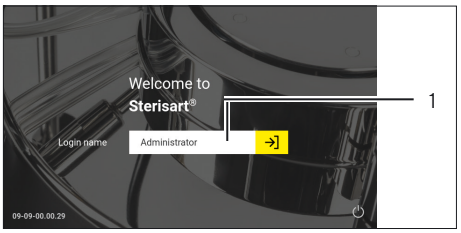
- ▶ To switch the device on: Set the On/Off switch to [I].
- ▷ An acoustic signal sounds.
- ▷ The system will start up.
- ▷ The login display will be displayed.
- ▶ To switch the device off: Set the On/Off switch to [0].

7 System Settings (Only for Devices With a Control Unit)

7.1 Logging Users In or Out

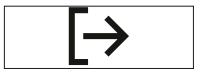
To operate the device, the user must log on. A password must be set in order to use some functions, e.g. electronic signature.

For devices with the advanced version, automatic logout can be set. If automatic logout after inactivity is activated: The user is logged out of the application according to the configured time.



Procedure

- ▶ If the name of the preferred user profile is displayed in the input field (1) of the login display: Press the [Login] button.
- ▶ If the name of the preferred user profile is **not** displayed in the input field of the login display:
  - ▶ Press the input field in the login display.
  - ▷ The user selection is opened.
  - ▶ Press the name of the preferred user profile.
- ▶ If a password has been assigned for the preferred user:
  - ▷ A password prompt is displayed.
  - ▶ Enter the password in the input field and press the [OK] button.
- ▷ The user profile is opened and the main menu is opened.
- ▶ To log out the active user profile from the device: Press the [Logout] button.



- ▷ The login display will be displayed.

7.1.1 Setting Automatic Logout

Procedure

- ▶ Open the “Settings / Access management / Role management” menu.
- ▶ Select the preferred time interval for the “Autom. logout after inactivity” parameter.
- ▷ Automatic logout after inactivity is activated.

7.2 Performing System Settings

Default settings can be adjusted for the device and the applications in order to align with the individual ambient conditions and operating requirements of the facility.

The following settings are recommended for operation of the device:

- Setting Pressure Control
- For the advanced version only: Create role profiles (see Chapter "7.4.5 Creating a User Role", page 53)

The following settings are required for remote operation of the device:

- The device is connected to the configurator on the web browser.
- The role rights "Remote view" and "Remote view and control" are activated for the enrolled user profile:

7.3 Using the Help Function

If help texts are available in a menu: The [Help] button is displayed.

Procedure



▶ Press the [Help] button.
▷ The help topics are displayed.
▶ Select the desired help topic.
▷ The help text is opened.
▶ To navigate through the help text: Swipe the text downwards or upwards.



▶ If the full text search is to be used:
  ▶ Press the [Search] button and enter or scan a search term.



  ▷ The [Active search] button is displayed. The search hits are highlighted in yellow.



  ▶ To switch between the search hits: Press the [Next] and [Back] buttons.



▶ To obtain an outline of the help text: Press the [Info] button.

▶ To obtain additional information on a current menu: Press the [Info] button.

7.4 Managing User Data (Only for Advanced Version)

7.4.1 Assigning a Password

Requirements

The “User management” role right is activated for the enrolled user profile.

Procedure

- ▶ Open the “Settings / User management” menu.
- ▶ Select the user profile.
- ▷ An overview of the settings is displayed.
- ▶ Press the [Edit] button.
- ▶ For the “Login method” parameter, select the value “Local password” and confirm with the [OK] button.

7.4.2 Changing a Password

Requirements

The “User management” role right is activated for the enrolled user profile.

Procedure



- ▶ Open the “Settings / User management” menu.
- ▶ Select the desired user profile.
- ▶ Press the [Edit password] button.
- ▷ The “Change password” dialog box is opened.
- ▶ Confirm the prompt with the [Yes] button.
- ▶ Enter the preferred password in the input field and confirm with the [OK] button.
- ▶ Enter the selected password again and confirm with the [OK] button.

7.4.3 Changing a User Profile or User Role

Requirements

The following role rights are activated for the enrolled user profile:

- User management
- Access settings menu
- Access management
- Role management

Procedure

- ▶ To change a user profile: Open the “Settings / User management” menu.
- ▶ To change a user role: Open the “Settings / Access management / Role management” menu.
- ▷ An overview of the saved user profiles or user roles is displayed.
- ▶ Press the desired user profile or user role.
- ▷ An overview of the settings is displayed.



- ▶ Press the [Edit] button.
- ▷ The “User settings” or “Role parameters” display is opened.
- ▶ Change the preferred settings or parameters.
- ▶ Confirm the changes with the [OK] button.

7.4.4 Creating a User Profile

Requirements

The “User management” role right is activated for the enrolled user profile.

Procedure

- ▶ Open the “Settings / User management” menu.
- ▷ An overview of the saved user profiles is displayed.



- ▶ Press the [New] button.
- ▷ The “User settings” display is opened.
- ▶ Enter or modify the preferred settings.
  Note: The “Display name” and “Login name” settings are mandatory fields.
- ▶ Confirm the entries. To do this, press the [OK] button.
- ▷ An overview of the settings is displayed.

7.4.5 Creating a User Role

Requirements

The following role rights are activated for the enrolled user profile:

- Access settings menu
- Access management
- Role management

Procedure

- ▶ Open the “Settings / Access management / Role management” menu.



- ▶ If a new user role needs to be created: Press the [New] button.
- ▷ The “Role parameters” display is opened.
- ▶ Enter or modify the preferred parameters.
  Note: The “Role name” parameter is a mandatory field.
- ▶ Confirm the entries with the [OK] button.

7.5 Managing Tasks

7.5.1 Editing Tasks

Requirements

The “Task management“ role right is activated for the enrolled user profile.

Procedure



- ▶ Open the “Task management” menu.
- ▶ Press the desired task.
- ▶ To edit the parameters for the task: Press the [Edit] button.
- ▶ To change a parameter: Press the parameter and select the preferred value.
- ▶ If the editing of the parameters is complete: Press the [OK] button.
- ▷ An overview of the parameters is displayed.
- ▶ To save the changes: Press the [OK] button.
- ▷ The display returns to “Task management“ menu.

7.5.2 Deleting Tasks

Requirements

The “Task management“ role right is activated for the enrolled user profile.

Procedure



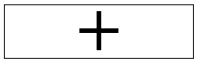
- ▶ Open the “Task management” menu.
- ▶ Press the desired task.
- ▶ To delete the task: Press the [Delete] button.

7.5.3 Creating Tasks

Requirements

The “Task management“ role right is activated for the enrolled user profile.

Procedure



- ▶ Open the “Task management” menu.
- ▶ Press the [New] button.
- ▷ A list of available applications for use as a template is displayed.
- ▶ Select an application. To do this, press the application.
- ▷ The wizard for creating a new task starts.
- ▶ Follow the wizard’s instructions in the operating display.

7.6 Opening the Device Website in the Web Browser (Only for Advanced-Version)

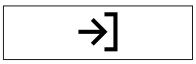
Requirements

The following role rights are activated for the enrolled user profile (see Chapter “7.4.3 Changing a User Profile or User Role”, page 52):

- Access device settings
- Access connections
- Remote view
- Remote view and control

Procedure

- ▶ Connect an Ethernet cable to the Ethernet network connection on the device.
- ▶ Open the “Settings” / “Connections” / “Website / web services” menu.
- ▶ Set the “Website access” parameter to “Enabled, with authentication”.
- ▶ Find the IP address. There are 2 options for doing this:
  - ▶ In the “Status Center” menu in the “Device information” column.
  - ▶ In the “Settings” / “Connections” / “Network” / “Ethernet” menu
- ▶ On the PC, enter the IP address in the web browser, e.g. https://10.3.0.106/remote.
- ▷ The Sterisart® control software can be viewed in the browser.
- ▶ Click on the [User login] button.



- ▶ Enter the login details of the preferred user profile.

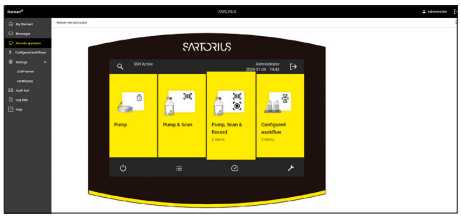
7.6.1 Control the device via remote access

Requirements

- The device website is opened in the web browser.
- The role rights “Remote view“ and “Remote view and control“ are activated for the enrolled user profile:

Procedure

- ▶ In the menu bar, select the “Remote operation” menu.
- ▷ The operating display of the device can been seen in the control software.



7.7 Managing Configured Workflows

7.7.1 Creating a Configured Workflow in the Web Browser

Configured workflows can be used to create work processes that go beyond the simple tasks in the control unit.

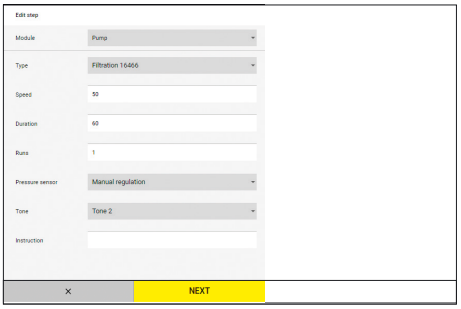
There are individually customizable parameters based on the modules, e.g., runs or instructions. The parameters can only be adjusted in the web browser and not during the execution of the workflow.

Requirements

– The following role rights are activated for the enrolled user profile (see Chapter “7.4.3 Changing a User Profile or User Role”, page 52): Managing Configured Workflows
– The device website is opened in the web browser.

Procedure

▶ Open the “Configured workflow overview“ in the web browser.
▶ Create a new workflow. To do this, proceed as follows:
  ▶ Click on the [New] button.
  ▶ Fill out the parameters and confirm with the [SAVE] button.
▷ The created workflow is displayed in the menu.
▶ To configure the workflow: Select the workflow and click on the [EDIT] button.
▶ To add a process step: Click on the [New] button.
▶ Fill out the parameters for the process step.
▶ To create further process steps click on the [NEXT] button.
▶ Once all of the preferred process steps have been created: Click on the [Cancel] button.



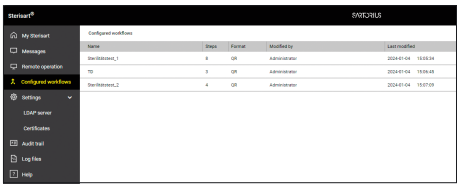
▶ Save the workflow.
▷ The workflow is automatically visible and ready for use on the control unit.

7.7.2 Editing Configured Workflows

Requirements

– The following role rights are activated for the enrolled user profile (see Chapter “7.4.3 Changing a User Profile or User Role”, page 52): Managing Configured Workflows
– The device website is opened in the web browser.

Procedure



▶ Open the “Configured workflow overview“ in the web browser.
▶ Select the preferred workflow and click on the [EDIT] button.
▷ The process steps display is opened.
▶ Select the preferred process step and click on the [EDIT] button.
▶ Enter the preferred changes and save.
▶ If an additional process step needs to be created:
  ▶ Click on the [New] button.
  ▶ If required: Drag the process step to the preferred point in the workflow.



▶ If an existing process step needs to be deleted:
  ▶ Select the preferred process step.
  ▶ Click on the [Delete] button.



▶ Save the workflow.

7.7.3 Deleting Configured Workflows

Requirements

– The following role rights are activated for the enrolled user profile (see Chapter “7.4.3 Changing a User Profile or User Role”, page 52): Managing Configured Workflows
– The device website is opened in the web browser.

Procedure

▶ Open the “Configured workflow overview” in the web browser

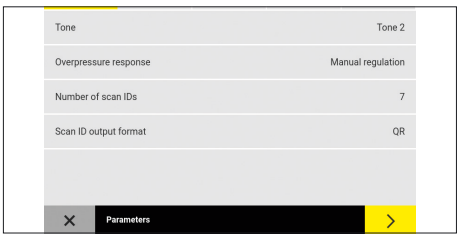


▶ To delete one or more workflows: Select the workflows and click on the [Delete] button.

7.8 Setting Pressure Control

When creating a new task or editing the settings for an existing task, pressure control can be set to manual or automatic.

The pressure control is based on the pressure threshold. This is set to 3.0 bar by default and applies to all tasks and workflows executed on this device.



Requirements

The operating display displays the editing mode for a task (see Chapter “7.5 Managing Tasks”, page 54).

Procedure

▶ Search for the “Overpressure response” parameter in the task settings.
▶ Select the preferred value: “Manual control” or “Automatic control”
▶ Save the settings.
▷ The selected pressure control is set for the task.

7.8.1 Setting the Pressure Threshold

Requirements

The following role rights are activated for the enrolled user profile (see Chapter “7.4.3 Changing a User Profile or User Role”, page 52):
– Access settings menu
– Access device settings

Procedure

▶ Open the “Settings” / “Device settings” / “Pressure control” / “Overpressure regulation” menu.
▶ Select the preferred value or enter manually with the keypad.
▷ The value for overpressure regulation is saved.

7.9 Activating Electronic Signature

Electronic signatures are only included with the advanced version of the software and can only be activated by users for whose user profile a password has been set up.

Requirements

The following role rights are activated for the enrolled user profile (see Chapter “7.4.3 Changing a User Profile or User Role”, page 52):
– Access settings menu
– Access device settings

Procedure

▶ Open the “Settings” / “Device settings” / “Electronic signature”/ “Sign report” menu.
▶ Activate the electronic signature.

8 Operation

8.1 Opening and Closing the Lever

⚠ CAUTION

Danger of crushing due to clamping bracket!

Fingers may become trapped in the clamping bracket when closing the lever.

▶ When closing the lever, ensure that **no** fingers are between the clamping bracket and the pump head.

Procedure

▶ To close the lever: Move the lever to the left to the lock-in position.
▶ To open the lever: Move the lever all the way to the right.

8.2 Inserting and Removing Sterility Test Units Into/From the Device

Consult the operating instructions for the system for information about the sterility test unit used and how to handle it.

8.2.1 Inserting the Sterility Test Unit

Requirements

– The sterility test unit is unpacked (see sterility test unit instructions).
– The pump lever is open.

NOTICE

Liquid spillage may result in damage to the device!

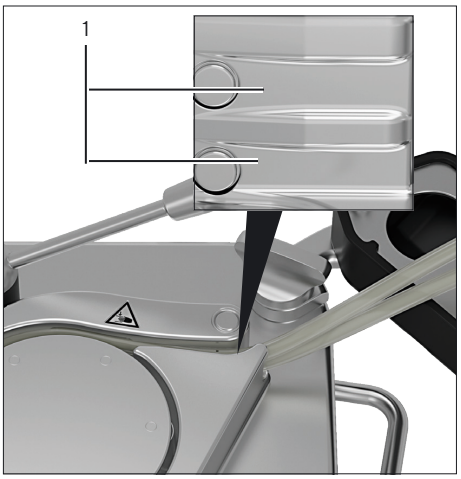
The bottle holder is only designed for bottles up to a maximum of 1 liter. Bottles larger than 1 liter may tip over and spill the medium that they contain. As a result, the device may be damaged and the process may be distorted.

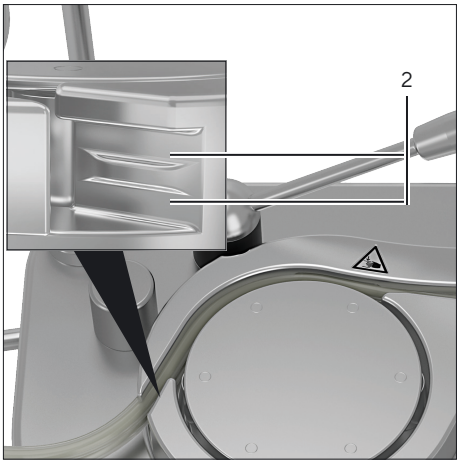
▶ **Do not** insert bottles larger than 1 liter into the bottle holder.

Procedure

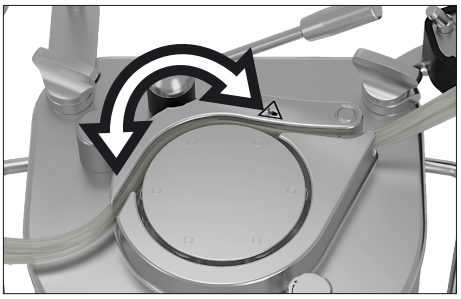
▶ Place both sterility test units in the collection vessel.

- ▶ Insert the sterility test unit tubes into the pump unit. To do this, proceed as follows:
  - ▶ With one hand, snap the tubing outlet side (right) into the C-shaped tube guide (1).





- ▶ With the other hand, lay the tubing inlet side (left) in the guides around the pump head (2).
- ▶ Ensure that the tubes are inserted in the guides on both sides.



- ▶ To ensure that the hoses are positioned correctly: Slide the tubing from left to right and from right to left. The tubes should move smoothly and freely.
- ▶ With your left hand, hold the tubes outside of the clamping bracket at the inlet side.
- ▶ ⚠ **CAUTION** Risk of injury due to trapped limbs. Fingers may be trapped when closing the lever.
  - ▶ Tubes must only be inserted and secured by one person at a time.
  - ▶ If there are **no** fingers within reach of the clamping bracket: Close the lever with your right hand.
- ▷ The clamping bracket will move forwards and press the tubes firmly against the pump head.
- ▷ The tubes are secured.

8.2.2 Removing the Sterility Test Unit

Requirements

- The process is complete.
- The tubes have been disconnected from the sterility test units.

Procedure

▶ To release the tubes: Open the lever.
▷ The clamping bracket will move backwards and release the tubes.
▶ Remove the tubes from the pump unit.
▶ Remove the sterility test units from the collection vessel.

8.3 Pumping Only (Devices Without Control Unit)

Requirements

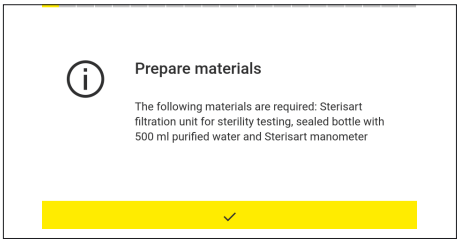
- The sterility test unit is inserted (see Chapter "8.2 Inserting and Removing Sterility Test Units Into/From the Device", page 59).
- The lever is closed.
- The process is prepared (see sterility test unit instructions).

Procedure

▶ To start the process: Push the control button.
▶ To change the pump speed: Turn the control button clockwise or counterclockwise.
  ▶ If the speed needs to be reduced: Turn the control button clockwise.
  ▶ If the speed needs to be increased: Turn the control button counterclockwise.
▶ To stop or end the process: Push the control button.

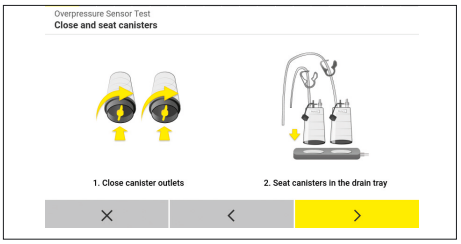
8.4 Performing an Overpressure Sensor Test (Only Devices with Control Unit)

Material
- Pressure sensor calibration kit
- Bottle filled with 500 mL ultrapure water
- Pressure gauge



Procedure

- ▶ Open the “Settings” / ”Device maintenance” / ”Overpressure sensor test” menu.
- ▶ Press the [Start test] button.
- ▷ An information message regarding the required materials is displayed.
- ▶ Prepare the required materials and confirm the information message.



- ▶ Follow the wizard’s instructions in the operating display.

The overpressure sensor test is passed

Procedure

- ▶ Generate report.
- ▷ The [Open menu] display is opened.
- ▶ To return to the main menu: Press the [YES] button.

The overpressure sensor test is failed

Procedure

- ▶ Repeat the overpressure sensor test.
- ▶ If the overpressure sensor test is failed again: Contact Sartorius Service.

8.5 Importing and Exporting Settings (Only Devices With Control Unit)

Requirements

A connector is attached to the device, e.g., USB stick.

Procedure

- ▶ To export settings: Open the “Device maintenance” / “Device settings” / “Export settings” menu.
- ▶ To import settings: Open the “Device maintenance” / “Device settings” / “Import settings” menu.

8.6 Performing Simple Tasks (Only Devices With Control Unit)

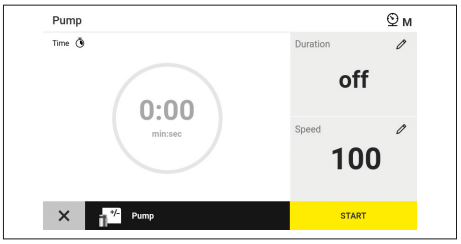
A sterility test unit is required to perform a task. The selection of the sterility test unit will depend on the test requirements. We recommend using Sterisart® sterility test units (see Chapter “16.2 Consumables”, page 84).

8.6.1 Performing the “Pump” Task

Requirements

– The sterility test unit is inserted (see Chapter “8.2 Inserting and Removing Sterility Test Units Into/From the Device”, page 59).
– The lever is closed.
– The process is prepared (see sterility test unit instructions).

Procedure



▶ In the main menu, open the “Pump” task.
▷ The task display is opened.
▶ If required: Set the pump duration and pump speed.
▶ To start the pumping process. Press the [START] button or press the control button.
▶ To stop the pumping process: Press the [STOP] button or press the control button:
▶ If a duration is set: The pumping process ends automatically after time has lapsed.
  ▷ If the sound is switched on: An acoustic signal sounds to indicate the end of the pumping process.
  ▷ The pump head stops turning.
▶ To manually end the pumping process: Press the [Cancel] button.
▷ The pump head stops turning.
▶ To end the task: Press the [Cancel] button.

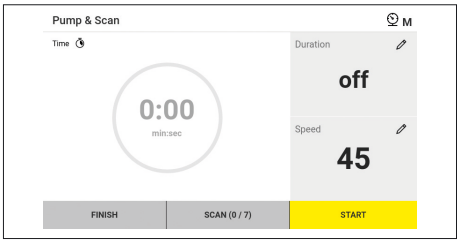


▶ Open the lever.
▶ Remove the sterility test units (see Chapter 8.2.2, page 61).

8.6.2 Performing the “Pump & Scan” Task

Procedure

▶ In the main menu, open the “Pump & Scan” task.
▷ The task display is opened.



Scanning Product Data

Procedure

- ▶ Ensure that a permissible barcode type is used (codes that can be scanned see Chapter “15.11 Scanner”, page 81).
- ▶ Press the [SCAN] button.
- ▷ The red LED of the scanner is activated.
- ▶ Scan the product data of the sterility test system. To do this, proceed as follows:
  - ▶ Hold the code in the scanner beam and wait until the code is read.
  - ▶ If required: Move the code a little closer to the scanner.
  - ▷ If the sound is activated: A confirmation signal sounds.
  - ▷ The scanned code is displayed.
- ▶ If required: Scan further codes.
- ▷ If all available scan places have been used: The display returns automatically to task mode.
- ▶ If not all available scan places have been used: Press the [OK] button.
- ▷ The display returns to task mode.

Preparing the Pumping Process

Procedure

- ▶ Insert the sterility test system (see Chapter 8.2.1, page 59).
- ▶ If required, set a pumping duration and pump speed.

Performing the Pumping Process

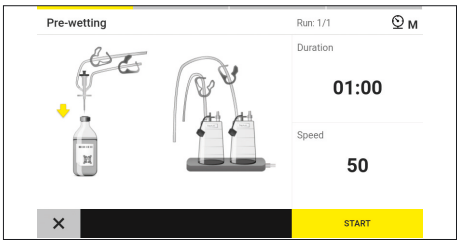
Procedure

- ▶ Start the pumping process. There are two options for doing this:
  - ▶ Press the [START] button.
  - ▶ Push the control button.
- ▶ To pause the pumping process: Press the [STOP] button or press the control button.
- ▶ If a duration is set: The pumping process ends automatically after time has lapsed.
  - ▷ If the sound is activated: An acoustic signal sounds to indicate the end of the pumping process.
- ▶ To manually end the pumping process: Press the [STOP] button.

Ending the Task

- ▶ To end the task: Press the [END] button.
- ▷ The [Report] display is opened.
- ▷ To save a report: Press the [SAVE REPORT] button (see Chapter 8.8, page 65).
- ▶ To start a new test: Press the [NEW TEST] button.
- ▶ To return to the main menu: Press the [QUIT] button.
- ▷ The [Open menu] display is opened.
- ▶ Press the [YES] button.

8.7 Performing a Configured Workflow (Only for Advanced Version)



Requirements

There are configured workflows available in the control unit (see Chapter “7.7.2 Editing Configured Workflows”, page 57).

Procedure

▶ In the main menu, press the “Configured workflow” task.
▷ If there is only 1 configured workflow available: The workflow is started.
▷ If there are several configured workflows available: A list of the configured workflows is displayed.
  ▶ Select the preferred configured workflow.
  ▷ The workflow is started.
▶ Perform the workflow. To do this, follow the instructions in the operating display.

8.8 Creating a Report (Only Devices With Control Unit)

8.8.1 Creating a Simple Report

A report can be created for the following applications:

– “Pump & Scan“ and “Pump, Scan & Record” tasks
– Workflows
– Pressure sensor test

If the report is configured as an integral part of a workflow: The report is automatically created after the last step of the workflow.

In all other cases, the report is created after the applications are ended and can be saved.

Requirements

– The pumping process is complete and the task has ended.
– The [Report] display is visible.

Procedure

▶ Attach a connector to the device, e.g., USB stick.
▶ To save the report: Press the [SAVE REPORT] button.
▷ The “Print process” display is opened.
▶ To close the display: Press the [OK] button or press the control button.

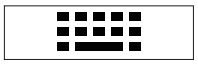
8.8.2 Creating a Report With an Electronic Signature (Only for Advanced Version)

For workflows, electronic signatures can be set for reports in accordance with 21 CFR Part 11.

Requirements

- The electronic signature is activated (see Chapter 7.9, page 58).
- A password is assigned for the enrolled user profile.
- A signature field is included in the GLP of the print profile.
- The pumping process is complete and the task has ended.
- The display [Report] is visible.

Procedure



▶ Attach a connector to the device, e.g., USB stick.
▶ To save the report: Press the [SAVE REPORT] button.
▷ The [Electronic signature] display is opened.
  ▶ The display name and the login name are displayed.
▶ Authorize the signature. To do this, enter the login password.
▷ The report is saved on the attached connector.

9 Cleaning and Maintenance

9.1 Cleaning Device Surfaces

The device follows the hygienic design principle. This means that the surfaces can be cleaned easily and avoids secondary contamination during the sterility test.

Material	– Lint-free soft cloth – Suitable Cleaning and Disinfecting Agents

Requirements

– The process has been completed.
– All consumables have been removed.

NOTICE

Potential for damage to the device due to fluid in the pump head and control unit connection!

If liquids enter the pump head and the control unit connection, this may result in the failure of the device.

▶ Make sure that **no** liquids get into the vicinity of the pump head.
▶ Make sure that **no** liquids get into the vicinity of the control unit connection.
▶ Keep the control unit connection covered at all times:
  ▶ For devices without control unit: Apply the supplied protective cap.
  ▶ For devices with control unit: Pull down the connector grommet.

Procedure

▶ Switch off the device.
▶ ⚠ **WARNING** Risk of injury due to electrical current! Disconnect the device from the power supply before cleaning work.
▶ If an accessory is connected to the device: Disconnect the accessory from the device (see instructions for the accessory).
▶ Only use suitable cleaning agents and cleaning procedures and observe the product information for the cleaning agent used (cleaning agents see Chapter “15.16 Cleaning Agents and Cleaning Procedures”, page 82).
▶ Prewet the cloth with a suitable cleaning agent and use it to wipe all surfaces of the device.
▶ Disinfect stainless steel surfaces with a suitable disinfectant.
▶ If required: Wipe wet surfaces dry with a cloth.

9.1.1 Preparing for VHP Sterilization (Only for Devices Integrated Into an Isolator)

Requirement

The device is installed in the operating plate of an isolator.

NOTICE

Potential for damage to the device due to open connections on the rear of the device!

If the connections come into contact with gaseous or powdered disinfectant, e.g., peracetic acid or hydrogen peroxide, when using a sterilization method: The device may be damaged.

- ▶ If the device is not installed in the operating plate of the isolator: Do not use sterilization methods with gaseous or powdered disinfectants.

Procedure

- ▶ **Use only** approved disinfectants (see Chapter "15.16 Cleaning Agents and Cleaning Procedures", page 82).

9.1.2 Autoclaving Components

Some components of the device can be autoclaved (see Chapter "15.16.2 Approved Cleaning Procedures", page 83). Other device components must **not** be autoclaved.

Procedure

- ▶ **NOTICE** Improper breaking of connections may result in damage to the device! If connection cables are pulled out when the device is switched on: The device may be damaged. Switch off the device first, then remove connection cables from the connections on the device.
- ▶ If individual components need to be autoclaved: Remove the desired components (component removal see Chapter "13.1 Dismantling the Device", page 72).
- ▶ Place the removed components in autoclave bags and autoclave (settings see Chapter "15.16.2 Approved Cleaning Procedures", page 83).

9.2 Maintenance Schedule

Interval	Component	Action	Chapter, Page
12 to 24 months, depending on operating conditions	Device	Contact Sartorius Service.	
Every 6 months	Device	Perform pressure sensor test.	Chapter 8.4, page 61

9.3 Recommissioning

Requirement

All components are mounted (see Chapter “5.4 Mounting components to the pump unit”, page 43).

Procedure

- ▶ Connect the desired accessories (see accessories instructions).
- ▶ Connect the device to the power supply (see Chapter “6.3 Connecting the Device to the Power Supply”, page 49).
- ▶ To switch the device on: Set the On/Off switch to [I].

10 Malfunctions

10.1 Malfunctions on the Device or Control Unit

Malfunction	Cause	Solution	Chapter, Page
The device and the operating display do not turn on.	The plug connection between the control unit and the device is loose.	Check the control unit plug connection.	
		If required: Connect the control unit to the device.	6.1, 48
	The device is disconnected.	Check whether the AC adapter is connected to the device and to the power supply at the installation site.	
		If required: Connect the AC adapter.	6.3, 49
	The power supply unit primary fuse (internal) is defective.	To have the power supply unit (internal) replaced: Contact Sartorius Service.	
The rotor does not turn.	The lever or the clamp is open.	Close the lever.	3.2, 12
	If a foot switch is used: The foot switch is not properly connected.	Check the foot switch connection.	
		If required: Connect the foot switch to the device (see instructions for the foot switch).	
Bar codes are not recognized.	An unknown bar code format is being used	Check whether the bar code format used is supported.	15.11, 81
The pressure sensor measurements are inaccurate.	The pressure sensor is not properly calibrated.	Contact Sartorius Service.	
		To proceed with the workflow: Deactivate the pressure sensor.	7.8, 57

11 Decommissioning

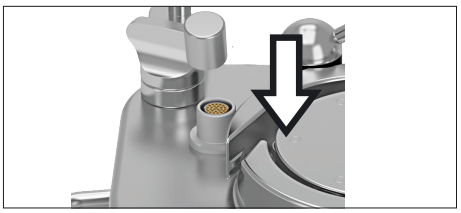
11.1 Decommissioning

Requirements

- The process has been completed.
- All consumables have been removed.
- The waste tubing has been disconnected from the drainage pipe.

Procedure

▶ **NOTICE** Improper breaking of connections may result in damage to the device! If connection cables are pulled out when the device is switched on: The device may be damaged. Switch off the device first, then remove connection cables from the connections on the device.
▶ Disconnect the device from the power supply and all supply systems.
▶ For devices with a control unit: Disconnect the control unit plug connector from the control unit connection on the device.
  ▶ Place the protective cap on the control unit connection.



12 Transport

12.1 Transporting the Device

Materials: Trolley for longer transport routes

Requirements

- The process has been completed.
- All consumables have been removed

Procedure

▶ Disconnect the device from all connections at the installation site.
▶ Use both hands when transporting the device and setting it down. To do this, grasp the handles on the left and right of the device with both hands.
▶ Use a trolley for longer transport routes

13 Storage and Shipping

13.1 Dismantling the Device

Requirements

- The device has been decommissioned.
- The lever is open.

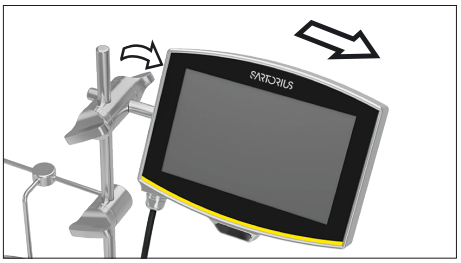
13.1.1 Dismounting Lever, Clamping bracket and Control Button

Procedure

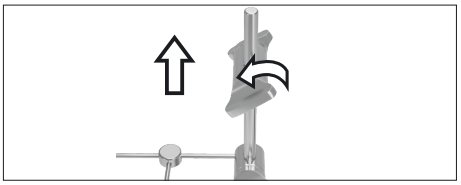
▶ Pull the following components upwards:
- Lever
- Clamping bracket
- Control Button

13.1.2 Dismounting the Control Unit

Procedure



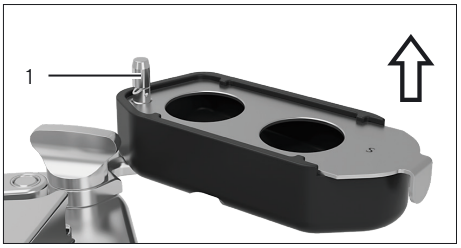
▶ Release the control unit from the stand. To do this, proceed as follows:
- ▶ Hold the control unit steady with one hand.
- ▶ With the other hand, undo the fastening screw directly on the connection arm by turning counterclockwise.
- ▶ Remove the connecting arm together with the control unit from the cross-clamp.



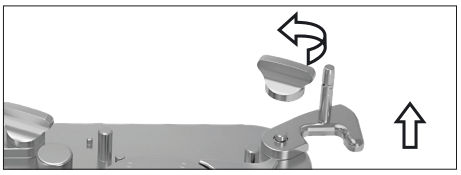
▶ Dismount the cross-clamp from the stand. To do this, proceed as follows:
- ▶ Hold the cross-clamp steady with one hand.
- ▶ With the other hand, undo the wing nut by turning counterclockwise.
- ▶ To prevent the locking nuts from falling out: Always hold the cross clamp horizontally.
- ▶ Pull the cross-clamp upwards to remove.

13.1.3 Dismounting the Collection Vessel

Procedure



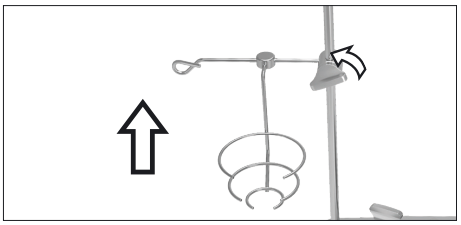
▶ Straighten the tip of the finger (1) and lift the collection vessel upward and away.



▶ Turn the fastening screw counterclockwise and remove the collection vessel plug.

13.1.4 Dismounting the Bottle Holder

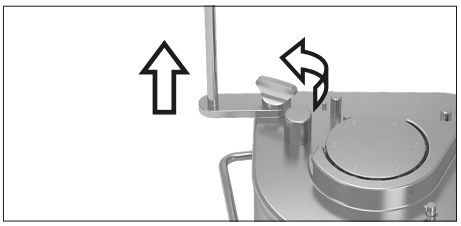
Procedure



▶ Release the bottle holder from the stand: To do this, proceed as follows:
  ▶ Hold bottle holder steady with one hand.
  ▶ With the other hand, undo the fastening screw by turning counter-clockwise.
  ▶ To prevent the locking nuts from falling out: Always hold the cross clamp horizontally.
  ▶ Remove the bottle holder from the stand.

13.1.5 Dismounting the Stand

Procedure



▶ Turn the fastening screw counterclockwise to undo.
▶ Remove the lug together with the stand.

13.2 Storage

Requirement

The device has been decommissioned.

Procedure

▶ Store the device according to the ambient conditions (see Chapter 15.3, page 77).

13.3 Returning the Device and Parts

Defective devices or parts can be returned to Sartorius. Returned devices must be clean and packed in their original packaging.

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

Devices contaminated with hazardous materials, e.g., harmful biological or chemical substances, will **not** be accepted for repair or disposal.

⚠ CAUTION

Risk of injury due to contaminated devices!

Devices contaminated with hazardous materials, e.g., nuclear, biological or chemical substances, may pose a hazard to health in case of contact.

- ▶ Decontaminate contaminated devices before returning them.
- ▶ Do **not** return contaminated devices for repair or disposal.

Procedure

- ▶ Decommission the device.
- ▶ Contact Sartorius Service for instructions on how to return devices or parts (see www.sartorius.com).
- ▶ Pack the device and its parts in their original packaging for return.

14 Disposal

14.1 Disposing of the Device and Parts

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

1 lithium cell battery is installed inside the device. Batteries must be disposed of properly by disposal facilities.

Requirement

The device has been decontaminated.

Procedure

- ▶ Dispose of the device in accordance with local government regulations. Inform the disposal facility that there is 1 lithium cell battery installed inside the device.
- ▶ Dispose of the packaging in accordance with local government regulations.
- ▶ Dispose of the consumables in accordance with local government regulations.

15 Technical Data

15.1 Dimensions

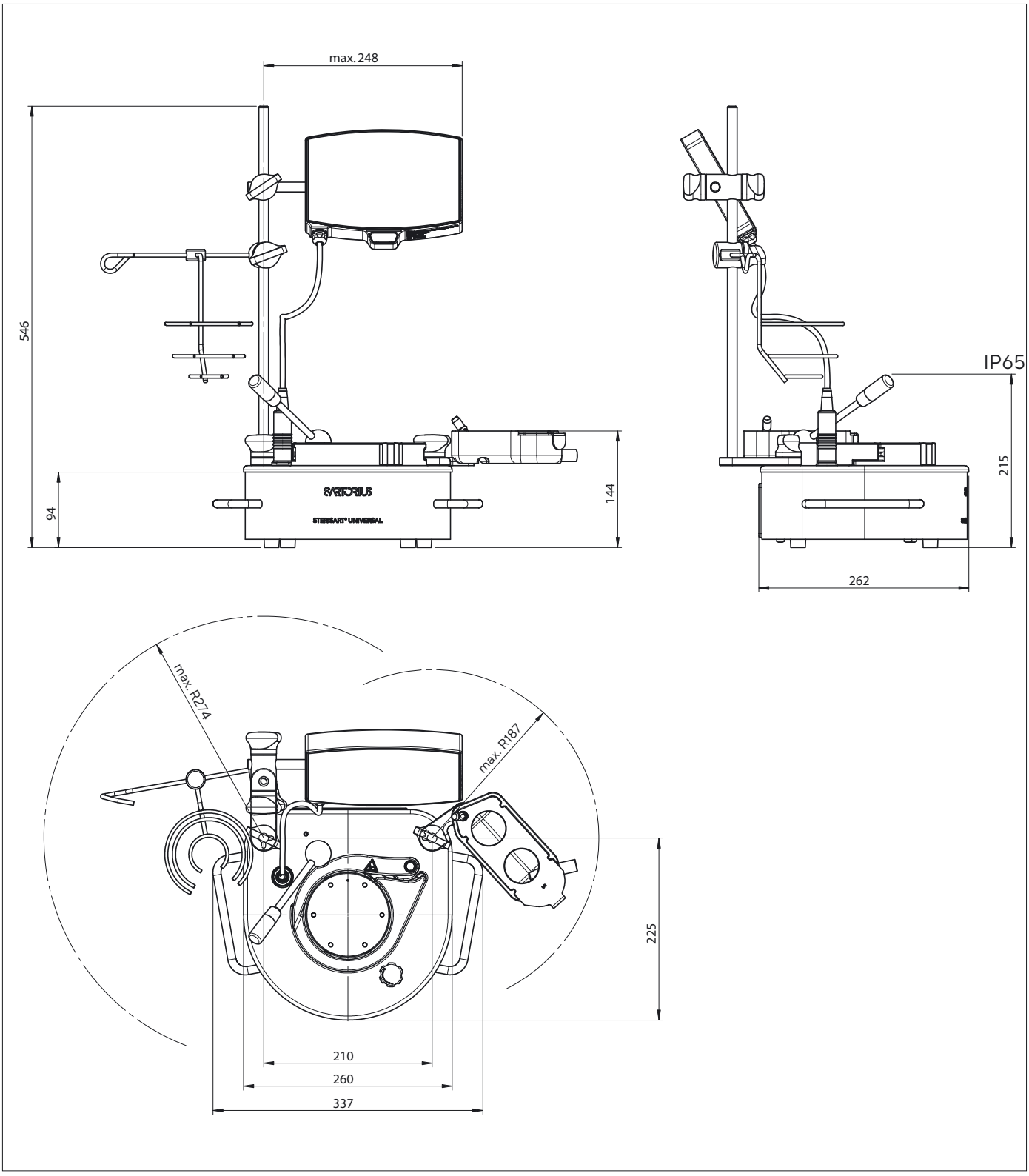


Fig. 20: Device dimensions in mm

	Unit	Value
Control unit dimensions	Inch	7

15.2 Weights

	Unit	Value
Weight of device without components	kg	11.5
Weight of device with stand, bottle holder and collection vessel	kg	13.2
Weight of control unit	kg	2.1

15.3 Ambient Conditions During Storage and Transport

	Unit	Value
Temperature		
During storage and transport	°C	-20 – +55
Storage duration under both extreme values, maximum	h	12
Storage, dry		

15.4 Installation Conditions

15.4.1 Installation Site

	Unit	Value
Height above sea level, maximum	m	2000
No potentially explosive atmospheres		
Clean room with clean room class according to DIN EN ISO 14644		A
Pollution level according to IEC 61010-1		II
Suitable for protection class		
Device protection class as bench-top device, according to EN/IEC 60529-1		IP21
Device protection class integrated into an aseptic preparation unit with isolator integration kit and with connected control unit or attached protective cap, according to EN/IEC 60529-1		IP65
Protection class of the control unit when connected		IP65
Access to operation-relevant parts is guaranteed		
Space requirements		
Suitable for the dimensions of the device and the associated components		

	Unit	Value
Setup surface		
Stable, even, low vibrations		
Suitable for the weight of the device and the associated components		
Additional properties		
No heat from heating systems or direct sunlight		
No direct drafts from open windows, AC systems, or doors		
No vibrations		
No “heavy traffic” areas (personnel)		
No electromagnetic fields		

15.4.2 Equipment at the Installation Site

Residual current circuit breaker (RCCB) present at the installation site

15.4.3 Ambient Conditions at the Installation Site

	Unit	Value
Temperature		
In operation	°C	+ 10 – + 40
Relative humidity, in operation		
Non-condensing	%	90
Air pressure	hPa	700 – 1050

15.5 Electrical Data

15.5.1 Power Supply

	Unit	Value
AC voltage	V_{AC}	100 – 240 (± 10%)
Frequency	Hz	50 – 60
Current consumption, maximum	A	1
Power consumption, typical	VA	110
Power supply only permitted via the power supply cable supplied by Sartorius		
Protection class according to IEC 61010-1		
Device		I
Control unit		I

	Unit	Value
Overvoltage category according to IEC 61010-1		
Device		II
Control unit, installed		I

15.5.2 Safety of Electromagnetic Equipment

Safety requirements according to DIN EN/IEC 61010-1, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

15.5.3 Electromagnetic Compatibility

Electromagnetic compatibility according to DIN EN 61326-1: Electrical equipment for measurement, control, and laboratory use – EMC requirements – Part 1: General requirements (IESC 61326-1:2013)
Interference immunity: Suitable for use in industrial areas (Table 2 of the standard)
Transient emissions: Class B: Suitable for use in residential areas and areas that are directly connected to a low voltage network that (also) supplies residential buildings

15.6 Approved Software

Web browser, for network connection and operation of the device via the internal web server

15.7 IT Connection of the Device

15.7.1 Using the IT Connection

Possible IT Connection	Needed for Working on the Device	Required Duration
Ethernet network	– Operation – Creation of procedural processes – Data transfer	For access to the device

15.7.2 Requirements for IT Connection and Access to Software

Possible IT Connection	Required Hardware	Required Configuration	Access to Device Software
Ethernet network	Connection cable	Setting up the Ethernet interface	– Control unit of the device – Ethernet network

15.8 Operating Modes and Connection Types

Operation according to usage type
As bench-top device
As integrated device in isolators | RABs
Operation without control unit
Pumping process is controlled with the control button
Control unit can be added
Operation with control unit
Pumping process is controlled with the buttons on the control unit and with the control button
Connection of the control unit to the device with a connection plug
Connection to the WiFi router or corporate network via a network connection cable
Operation with remote access via the web browser
Operation with mouse and keypad when control unit is switched on
Connected with a PC via a network (Ethernet connection cable or WiFi)

15.9 Visual Signals (for Devices With Control Unit)

	Unit	Value
Yellow arrow: Pressure in the sterility test units during the pumping process	bar	1 – 3
	psi	14.5 – 43.5
Yellow arrow and note: Pressure in the sterility test units during the pumping process	bar	3 – 3.4
	psi	43.5 – 49.31
Red arrow: Pressure in the sterility test units during the pumping process	bar	> 3.5
	psi	> 49.31

15.10 Pump

	Unit	Value
Type: Peristaltic pump		
Number of rotors		1
Flow rate, dependent on system	mL/min	70 – 650
Speed (rpms)	rpm	27 – 175
Speed		0 – 100
Timer switch for pump operation	min	0 – 60
Pressure during pumping at 20°C, in operation, maximum	psi	50.76

15.11 Scanner

Type: Integrated 1D / 2D barcode scanner
Codes that can be scanned
Code 39 | CODABAR | Code 128 | DataMatrix barcodes | QR code
Other scanners that can be connected
External USB barcode scanners from third-party providers

15.12 Integrated Clock

	Unit	Value
Permissible time deviation in the month (RTC)	s	30

15.13 Backup Battery

	Unit	Value
Lithium battery, type CR2032		
Service life at room temperature	Years	10

15.14 Interfaces

	Unit	Value
M9 plug, 4-pin		
Communication: With accessories, e. g., foot switch and tip drive		
USB connection		
USB-A | USB-C		
Communication: File transfer to USB mass storage		
Round connection, 27-pin		
Communication: With control unit		
Ethernet connection		
Transmission rate	Mbps	100

15.15 Materials

Housing | Plug insert | Control unit housing | Stand | Bottle holder | Protective cap | Base plate | Lever | Clamping bracket | Pump head | Rotor | Collection vessel cover | Control button | Handles | Clamps | Fastening screws | Lugs
Polished stainless steel AISI 316L (1.4404 or 1.4435)
Sealing insert for screw connection (control unit): Thermoplastic polyurethane (TPU), resistant to vaporized hydrogen peroxide (VHP)
Operating display: Natural quartz glass
Connection cable: PVC, resistant to vaporized hydrogen peroxide (VHP)
Control unit connection plug: Nickel-plated brass with matted chrome coating
Connector grommet: TPE
Collection vessel: Polypropylene, high temperature resistance (PP-HT)
Lever casing: PEEK
Clamp friction bearing: PEEK, Iglidur X
Lever friction bearing: Iglidur X
Seals
Static seals: FPM, NBR
Rotating seals: Fluorinated rubber
Operating display seal (adhesive): Silicone

15.16 Cleaning Agents and Cleaning Procedures

15.16.1 Approved Cleaning and Disinfecting Agents

Alcohol solution: Up to 76% ethanol, 70% isopropanol,
Quaternary ammonium compounds (10%) and phenolic compounds
Extran® (2%)
Sodium hypochlorite solution (5%)
Bleach (2.5%)
Phenolic: Vesphene and LpH
Chloroxylenol 3%
Oxivir® Five 16 SmartDose™, dilution 1:16
Virosil 5% (hydrogen peroxide – 10% w/v; dilute silver nitrate solution (AgNo3) – 0.01% w/v)
Formaldehyde and glutaraldehyde
For cleaning in the isolator
Peracetic acid (H_2O_2 and acetic acid 2.5%)

15.16.2 Approved Cleaning Procedures

	Unit	Value
Wipe stainless steel components off with a moistened cloth | dab dry		
Never use abrasive cleaning agents, e.g., steel wool		
VHP sterilization in the aseptic processing system | Isolator (vapor-phase hydrogen peroxide H_2O_2)		
Duration	h	5
Cycles		30
Autoclaving		
Approved components: Bottle holder, control button, lever, collection vessel, stand		
Autoclaving temperature, maximum	°C	121
Permissible overpressure	bar	1
Duration, maximum	min	30

16 Accessories and Consumables

16.1 Accessories

This table contains a selection of the accessories that can be ordered. For information on other products, contact Sartorius.

Article	Quantity	Order Number
Ampoule breaker	1	1ZW---0002
Waste tubing	1	1ZA---0002
Foot switch	1	1ZE---0033
Collecting tank	1	1ZG---0028
Cover for collection vessel for Millipore™ sterility test units	1	1ZG---0024
Control unit with connection cable	1	1ZE---0058
Long connection cable for control unit, 2.9 m	1	1EE---0015
Clamp for control unit	1	1ZF---0016
External barcode scanner	1	1EE---0010
Isolator installation kit	1	1ZE---0050
Transport trolley	1	1ZE---0039
Clampin bracket	1	1ZS---0006
Lever	1	1ZF---0015
Stand arm	1	1ZF---0013
Bottle holder	1	1ZGL--0033
Cover for collection vessel for Sterisart® sterility test units	1	1ZG---0023
Fastening knob	1	1ZF---0008
Collection vessel lug with pin	1	1ZG---0028
Clamp for control unit	1	1ZF---0016

16.2 Consumables

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

Article	Quantity	Order Number
Sterisart® system for liquids in closed, large-volume vessels*	10	16466--------GBD
Sterisart® system with septum for liquids in closed, large-volume vessels	10	16466--------GSD
Sterisart® CA with septum for liquids in closed, large-volume vessels	10	16466-----CA-GSD
Sterisart® system for liquids in open vessels*	10	16467--------GBD
* Suitable for use in isolators		

Article	Quantity	Order Number
Sterisart® system with septum for liquids in open vessels	10	16467--------GSD
Sterisart® CA with septum for liquids in open vessels	10	16467-----CA-GSD
Sterisart® one-connector system for liquids in vessels with Luer connection*	10	16468--------GBD
Sterisart® system for pre-filled syringes *	10	16469--------GBD
Sterisart® system with septum for pre-filled syringes	10	16468--------GSD
Sterisart® system for dilution of liquids and low-solubility lyophilisates in closed vessels*	10	16470--------GBD
Sterisart® system for the transfer of liquids from a closed vessel into an open vessel	10	16472--------GBD
Sterisart® system for lyophilisates in closed vessels	10	16475--------GBD
Sterisart® system with septum for lyophilisates in closed vessels	10	16475--------GSD
Sterisart® system for liquids in closed small-volume vessels*	10	16476--------GBD
Sterisart® system with septum for liquids in closed small-volume vessels	10	16476--------GSD
Sterisart® system for liquids in plastic vessels with blow-fill seal*	10	16477--------GBD
Sterisart® two-connector system for liquids in vessels with Luer connection*	10	16478--------GBD
* Suitable for use in isolators		

17 Sartorius Service

For inquiries about the system or when contacting Sartorius Service in the event of a malfunction, ensure that you have the device information, e.g., serial number, hardware, firmware, configuration, close at hand so you can pass it on to Sartorius Service. To do this, refer to the information on the manufacturer's ID label and in the "INFO" menu.

18 Trademark Information

18.1 Millipore™

Millipore™ is a registered trademark of Merck KGaA, Darmstadt, Germany, or its subsidiaries.

18.1.1 Extran®

Extran® is a registered trademark of Riedel Brands B.V., or its subsidiaries.

18.1.2 Oxivir®

Oxivir® is a registered trademark of Diversey, Inc., or its subsidiaries.

19 Conformity Documents

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

Original

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

Hersteller
Manufacturer

Sartorius Lab Instruments GmbH & Co. KG
37070 Goettingen, Germany

erklärt in alleiniger Verantwortung, dass das Betriebsmittel
declares under sole responsibility that the equipment

Geräteart
Device type

Sterisart® Universal | Gen 4

Modelle
Models

16421-B | 16421-E | 16421-A

in der von uns in Verkehr gebrachten Ausführung allen einschlägigen Bestimmungen der folgenden Europäischen Richtlinien entspricht und die anwendbaren Anforderungen folgender harmonisierter Europäischer Normen einschließlich deren zum Zeitpunkt der Erklärung geltenden Änderungen erfüllt:

in the form as delivered fulfils all the relevant provisions of the following European Directives and meets the applicable requirements of the harmonized European Standards including any amendments valid at the time this declaration was signed listed below:

	EMV | EMC	RoHS	Maschinen | Machines
Richtlinie *Directive*	2014/30/EU	2011/65/EU	2006/42/EG 2006/42/EC
Norm(en) *Standard(s)*	EN 61326-1:2013 EN IEC 613261-1:2021	EN IEC 63000:2018	EN ISO 12100:2010 EN 61010-1:2010 +A1:2019 +AC2014-04

Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen:
The person authorised to compile the technical file: Sartorius Lab Instruments GmbH & Co. KG
Electronics & Product Compliance
37070 Goettingen, Germany

Sartorius Lab Instruments GmbH & Co. KG
Goettingen, **2024-03-13**

Mario Hespe
Managing Director

Halil Yildirim
Product Compliance Manager (SLI)

*: angewandte, jedoch für Maschinen nicht harmonisierte Norm /
applied standard, which however is not harmonized for machines

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Original

UK Declaration of Conformity

Manufacturer Sartorius Lab Instruments GmbH & Co. KG
37070 Goettingen, Germany

declares under sole responsibility that the equipment

Device type **Sterisart® Universal | Gen 4**

Models **16421-B | 16421-E | 16421-A**

in the form as delivered fulfils all the relevant provisions of the following British Regulations and meets the applicable requirements of the British Designated Standards including any amendments valid at the time this declaration was signed listed below:

The Electromagnetic Compatibility Regulations 2016
UK Statutory Instruments 2016 No. 1091

BS EN 61326-1:2013; BS EN IEC 61326-1:2021

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012; UK Statutory Instruments 2012 No. 3032

BS EN IEC 63000:2018

The Supply of Machinery (Safety) Regulations 2008
UK Statutory Instruments 2008 No. 1597

BS EN ISO 12100:2010, BS EN 61010-1:2010+A1:2019*)

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Sartorius Lab Instruments GmbH & Co. KG
Goettingen, **2024-03-13**

Mario Hespe
Managing Director

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*: applied standard, which however is not harmonized for machines

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Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote all genders.

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