sartorius stedim biotech

Operating Instructions
Original Operating Instructions

BIOSTAT STR® 50 to STR® 1000

BIOSTATSTR2
Bioreactor

85037-553-95

Contents

1 About this Document

1.1 Scope

These instructions apply to the device in the following versions:

Device	Type
BIOSTAT STR®	BIOSTATSTR2
Consists of:	
Control / supply unit	TOWERDSTR
Bag holder, 50L	1000023674
Bag holder, 200L	1000023674
Bag holder, 500L	1000023674
Bag holder, 1000L	1000023674

1.2 Accompanying Documents

▶ In addition to these instructions, observe the following documents:
- Operating instructions for DCU4 system user management
- Operating instructions for DCU4 system logbook function
- Operating instructions for DCU4 system parameter import / export
- Technical documentation in the "Technical Documentation" folder, e.g., P&I diagrams, spare parts list, installation plans, etc.
- Documentation of customer-specific modifications (if applicable)
- Sterile Connector OPTA Operating Instructions
- KPC Operating Instructions

1.3 Target Groups

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

Target group	Knowledge / responsibilities
User	The user is responsible for operating the device and for the associated work processes. The user knows the dangers that can occur when working with the device and can avoid these dangers. The user has been trained in the operation of the device.
Operating engineer / laboratory manager	The operating engineer / laboratory manager makes decisions about the use and configuration of the device. The operating engineer / laboratory manager is trained in the operation of the device.
Administrator	The administrator is responsible for integrating the device in the production process. The administrator ensures the reliable functioning of the system and device software. The administrator is trained in the operation of the device.
Electrician	A qualified electrician who has the specialized training, knowledge and experience as well as familiarity with applicable standards to evaluate the work assigned to him or her and identify possible hazards.

Target group	Knowledge / responsibilities
Operator	The operator of the device is responsible for compliance with safety requirements and workplace safety regulations. The operator must ensure that all persons who work on the device have access to the relevant information and have been instructed in work on the device.

1.4 Symbols Used

1.4.1 Warnings

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

⚠ CAUTION
Denotes a danger with risk that moderate or minor injury may result if it is **not** avoided.

NOTICE
Denotes a danger that can result in property damage if the risk is **not** avoided.

1.4.2 Other Symbols

▶ Required action: Describes actions which must be carried out.

▷ Result: Describes the result of the activities carried out.

[ ] Text inside brackets refers to control and display elements.

Figures on the Operating Display

Depending on the device configuration, the figures on the operating display of the device may differ from those described in these instructions. These instructions show operating values and settings that are default values and examples.

2 Safety Instructions

2.1 Intended Use

The scalable bioreactor family BIOSTAT STR® is a range of stirred single-use bioreactors in which cells can be cultivated. For this purpose, the culture medium is stirred in a single-use bag and kept under defined cultivation conditions. The bag must be disposed of after the single use.

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

Do not carry out any processes using biological materials in Safety Classes 3 or 4.

The device may only be used with the equipment and under the operating conditions described in the Technical Data. You may **not** modify the device or make any technical changes.

Any further use beyond this is considered **improper** and is prohibited. These instructions are part of the device. The device is intended exclusively for use in accordance with these instructions.

Modifications to the device

You may **not** modify or repair the device or make any technical changes. Any retrofitting or technical changes to the device are only permitted with prior written permission by Sartorius Stedim Biotech.

2.2 Personnel Qualification

All persons working on the device must possess the necessary knowledge (for a description, see Chapter "1.3 Target Groups," page 8).

The actions described are addressed to the "user" target group. Sartorius Service personnel or other groups may be required to carry out specific actions. These actions may require specific qualifications that will be indicated in the manual.

2.3 Significance of these Instructions

Failure to follow the instructions in this manual can have serious consequences, e.g. exposure of individuals to electrical, mechanical or chemical hazards.

- ▶ Before working with the device: Read the instructions carefully and completely.
- ▶ If the instructions are lost: Request a replacement or download the latest instructions from our website.
- ▶ The information contained in these instructions must be available to all individuals working on the device.

2.4 Maintenance of the Device

Damaged equipment or worn-out parts can cause malfunctions or lead to hard-to-detect hazards.

- ▶ Only operate the device when it is safe and in perfect working order.
- ▶ Observe the maintenance intervals (for intervals and maintenance work, see Chapter "9.2 Maintenance Schedule," page 182).
- ▶ Do not operate a damaged device. Organize the immediate repair of any malfunctions or damages by Sartorius Service personnel.

2.5 Safety Equipment

The safety equipment on the device protects persons who work with the device against the hazards and harms associated with it, e.g. electrical current.

- Do **not** remove or modify the safety equipment (for safety equipment, see Chapter "3.7 Safety Equipment," page 28).

2.6 Access to the Device

Users may be exposed to hazards and must be knowledgeable about the device before being granted access to the device. The user must be familiar with the operation of the device and the associated work processes.

- Allow only trained users access to the device.

2.7 Damage to the Electrical Equipment

Damage to the insulation or individual components can be fatally dangerous. Contact with parts under voltage represents a direct danger to life.

- Check the device for defects such as loose connections or damage to the insulation (for intervals and maintenance tasks, see Chapter "9.2 Maintenance Schedule," page 182).
- If the electrical equipment is defective, immediately switch off the power supply and contact Sartorius Service.
- Keep live parts away from moisture. Moisture can cause short circuits.
- If the electrical equipment catches fire: Fight the fire with CO_2 extinguishers. Do not use other fire extinguishers.

2.8 Working on the Electrical Equipment

Only Sartorius Service personnel may work on or modify the electrical equipment of the device. The device may only be opened by Sartorius Service personnel.

2.9 Gases

The gases used or formed during the fermentation process can be hazardous to health, e.g. lead to the danger of suffocation by escaping nitrogen and carbon dioxide.

All gas lines used in the cultivation process must be regularly inspected for leaks (for intervals, see Chapter "9.2 Maintenance Schedule," page 182).

- Observe the applicable workplace health and safety information to protect against gases, e.g., for information on the handling and storage of gases and what to do in the event of an emergency.
- Ensure that the workplace is well ventilated.
- If required: Connect the exhaust air from the cultivation process to a laboratory exhaust air treatment system.
- If required: Outfit the room with suitable equipment for monitoring the air.

Danger of Fire due to Pure Oxygen (O_2)

Pure oxygen can give rise to chemical reactions that could cause substances to self-combust. Areas where pure oxygen can escape must be ventilated so that the air **cannot** become saturated with pure oxygen up to a critical concentration level.

- ▶ Only use gases free of dust and oil in the cultivation process.
- ▶ When working on the oxygen line: Make sure your work equipment and hands are free from grease and oil.
- ▶ Keep pure oxygen away from combustible materials and ignition sources.
- ▶ Avoid sparks in the vicinity of pure oxygen.

2.10 Accessories, Consumables and Spare Parts

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

- – Risk of injury to persons
- – Damage to the device
- – Malfunctions of the device
- – Failure of the device

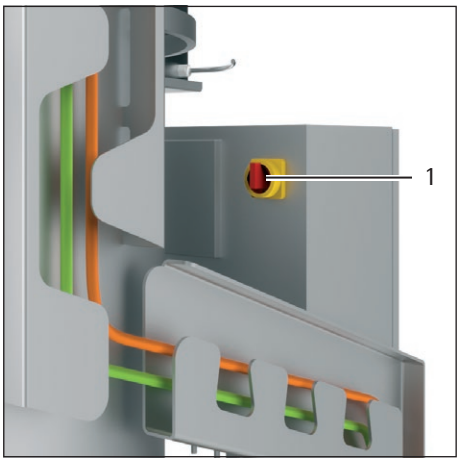
- ▶ You should only use accessories, consumables and spare parts supplied by Sartorius Stedim Biotech. Information on operational quality is available upon request from Sartorius Stedim Biotech.
- ▶ Only use accessories, consumables and spare parts that are in proper working order.

2.11 Conduct in an Emergency

Device malfunctions can lead to injury or material damage. If there is immediate danger of personal injury or equipment damage: Take the device out of operation immediately.

Control / supply unit

- ▶ Turn the main switch (1) to position **0** (Off).
- ▷ The power supply to the device is disconnected and all device operations are turned off.
- ▷ The inlet-side pressures in the gas lines are retained.
- ▷ The pressures on the bag will abate on their own.
- ▶ The motor is off. The enable signal for the control / supply unit is omitted. Have any malfunctions repaired immediately by the Sartorius Service.



Bag holder

- ▶ Turn the main switch (1) to "Off" position.
- ▷ The power supply to the device is disconnected.
- ▷ The pump, temperature control unit and the heating element are off.
- ▷ The cooling valve goes into the de-energized state.
- ▶ Have any malfunctions repaired immediately by the Sartorius Service. All other device functions will remain active (for example: the agitation and gassing).

2.12 Personal Protective Equipment

Personal protective equipment protects against risks arising from the device and the material being processed. If the personal protective equipment is missing or unsuitable: People may be injured.

Protective equipment designation	Explanation / examples
Protective work clothing	Tight-fitting work clothing with low tear resistance, tight sleeves and without any projecting parts. / Protects against being caught by moving parts.
Head covering	Protects hair from being pulled into moving parts.
Safety gloves	Protect against chemicals, heat and injuries.
Safety glasses	Protect against substances leaking under high pressure, splashing fluids.
Safety boots / non-slip shoes	Protect against injuries to the feet caused by mechanical effects. / Protect against slipping on wet surfaces.

- ▶ Wear appropriate personal protective equipment.
- ▶ If the workplace or the process, in which the device is used, requires additional safety precautions: Additionally, wear the appropriate personal protective equipment.

2.13 Components under Pressure

If the bag is subjected to excessive pressure: The bag may burst and result in leakage of the culture medium or gases. This can cause hearing damage. Escaping culture medium can cause scalding and burns.

- ▶ Only use the control / supply unit for gas supply.
- ▶ It is recommended to use the filter heater in the cultivation process. The filter heater protects the exhaust air filter capsule from blockage due to condensation. Always operate the device with the pressure sensor connected to the bag headspace. Gassing will turn off when 50 mbar of pressure is reached.
- ▶ Do **not** exceed the maximum permissible total gas flow rate (see Chapter "15.7 Gas and Compressed Air Supply," page 196).

2.14 Faulty Components

If individual components are damaged, gaseous and liquid materials may escape under high pressure.

- Do not start the device without overpressure valves and pressure reducer or comparable overpressure safety devices.
- Have overpressure valves and the pressure sensor serviced regularly by Sartorius Service (intervals see Chapter "9.2 Maintenance Schedule," page 182).
- When working on components under pressure: Switch off the device and secure it from being turned back on again.
- Regularly check all lines, tubes and connections under pressure for leaks and externally detectable damage (intervals see Chapter "9.2 Maintenance Schedule," page 182).

2.15 Escaping Supply and Culture Media

Escaping supply and culture media can lead to chemical burns and contamination.

- If health-threatening feed and culture media are used: Take special measures to protect the users.
- Only use prescribed tubes.
- Secure all tubing using tube fasteners.
- Empty the feed tubes completely after the process has ended.
- Wear personal protective equipment when loosening tubing connections.

2.16 Hot Surfaces

During operation, parts of the device can heat up, thereby making their surfaces hot. There is a danger of burns to the body parts that touch these surfaces.

- Avoid contact with hot surfaces.
- Before working with the device: Allow heating elements and device equipment to cool.
- Wear personal protective equipment.

2.17 Coupling with Magnetic Drive

The electromagnetic field emitted by the magnet drive can interfere with and damage devices that are sensitive to magnetic fields. There is a danger of injury to people with pacemakers.

- Do not allow people with pacemakers to work on the magnetic drive.
- Keep the magnetic drive away from devices and objects sensitive to effects of magnetic fields, such as data storage media and check cards. Do not store them together.

2.18 Rolling Away of the Device

If the device is accidentally set in motion: The device can injure people.

- Only place the device on level surfaces.
- Secure all transport wheels of the device by applying the parking brake.

2.19 Lockable Castors of the Device

If the lockable castors are operated improperly, e.g., using the hands or by someone wearing unsuitable footwear: Serious injuries can occur.

- ▶ Operate the lockable castors only with your foot.
- ▶ Wear personal protective equipment such as steel toed shoes when moving the device to avoid crushing feet.

2.20 Unintended or Unexpected Startup of the Device

Depending on the control unit / supply unit settings, the device may start again automatically with the configured parameters after a power failure. Device components can be unexpectedly set in motion and injure persons in the immediate vicinity.

- ▶ Note the details on the behavior of the device after a power failure (see Chapter "8.3 Setting the Failtime," page 108).

2.21 Rotating or Moving Parts

If clothing or body parts come into contact with rotating or moving parts:
The clothes and body parts can become caught. This can lead to serious injuries.

- ▶ Wear personal protective equipment.

2.22 Heavy Weight of the Device

The device has a high intrinsic weight. There is a danger of injury when lifting and transporting the device.

- ▶ Get help from additional persons when lifting and transporting objects.
- ▶ Use suitable conveyance devices when covering long transport routes, e.g. forklifts.
- ▶ The device should only be lifted using the designated carrying handles (see Chapter "12.2 Lifting the Bag Holder," page 188).

3 Device Description

3.1 Device Overview

Fig. 1: Control / supply unit with 2 bag holders, 200L (example: Twin System)

No.	Designation
1	Bag holder 1
2	Control / supply unit
3	Bag holder 2

3.2 Control / Supply Unit

The control / supply unit controls the processes in the bag and supplies the culture medium with the supply media, e.g. oxygen, nitrogen. The control / supply unit controls the temperature of the culture medium.

Depending on the configuration of the control / supply unit, 1 or 2 bag holders can be connected.

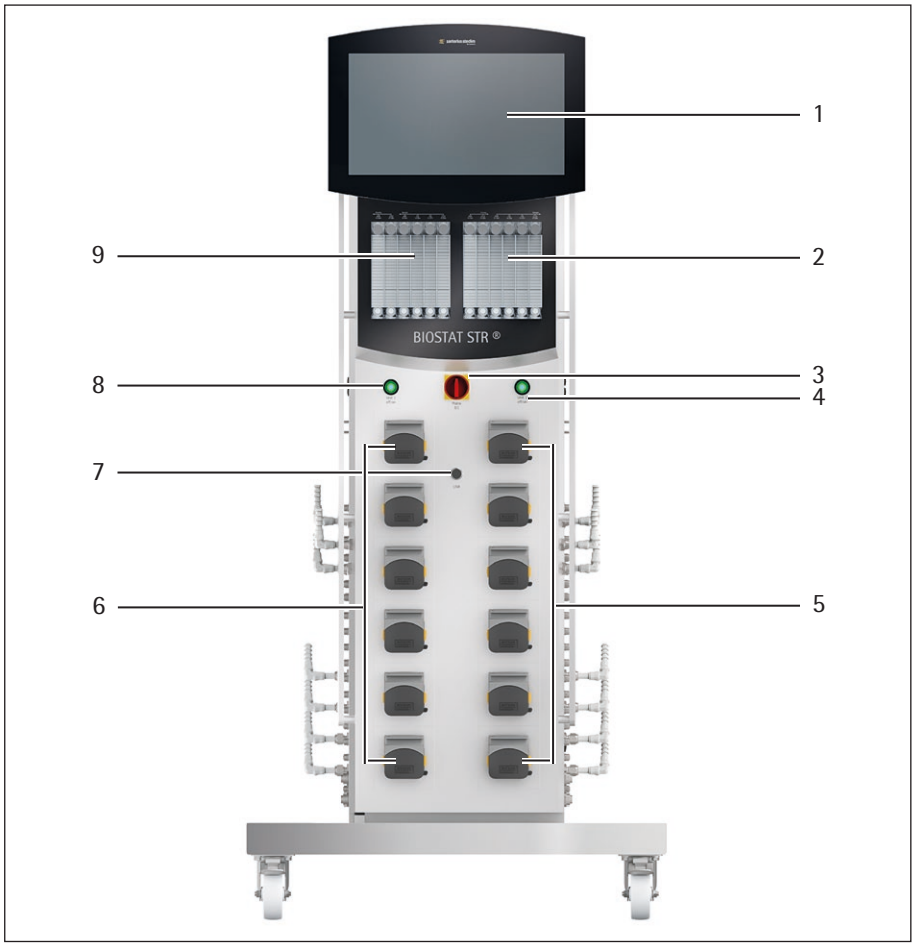


Fig. 2: Control / supply unit for 2 bag holders, front view (example)

No.	Designation	Description
1	Operating display	
2	Variable area flow meter	For bag holder 2
3	Mains I/O	Main switch and emergency power switch.
4	Unit 2 off/on	Switches the measurement and control system for bag holder 2 on and off.
5	Peristaltic pumps	For bag holder 2
6	Peristaltic pumps	For bag holder 1
7	USB connection	Covered with screwable cover.
8	Unit 1 off/on	Switches the measurement and control system for bag holder 1 on and off.
9	Variable area flow meter	For bag holder 1

3.2.1 Connections for Bag Holder 1

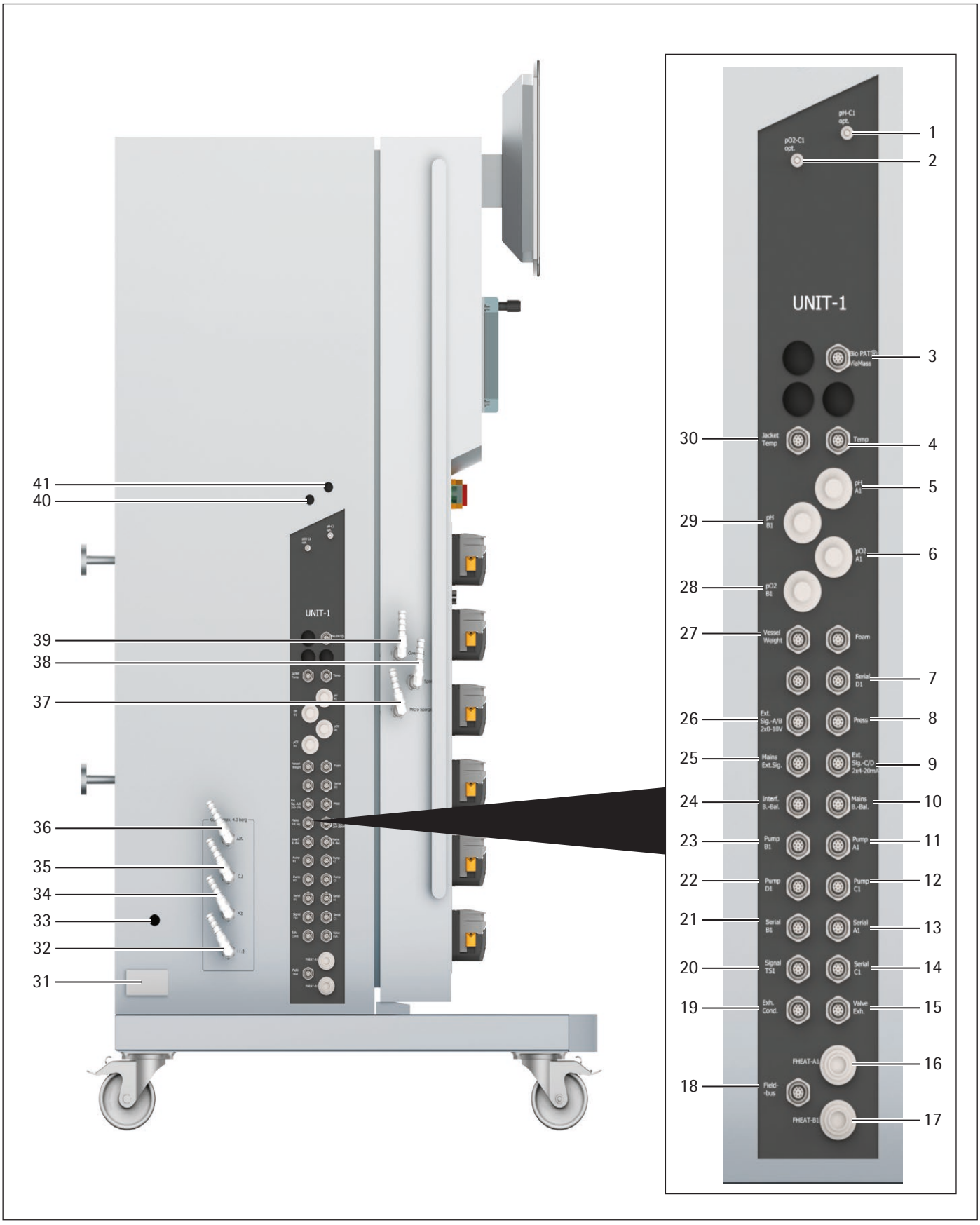


Fig. 3: Control / supply unit, connections for bag holder 1 [UNIT-1]

No.	Designation	Description
1	pH-C1 Opt.	Optical pH sensor
2	pO_2-C1 Opt.	Optical DO (pO_2) sensor
3	BioPat® ViaMass	Biomass sensor (optional)
4	Temp	Temperature sensor, M12 plug connection
5	pH A1	pH sensor A1, VP8 plug
6	pO2 A1	DO (pO_2) sensor A1, VP8 plug
7	Serial D1	Serial D1, M12 plug connection (optional)
8	Press	Pressure sensor, M12 plug connection
9	Ext.Sig-C/D 2x 4-20mA	External signal input C / D, M12 plug connection
10	Mains B.-Bal.	Power supply for the balance of the bag, M12 plug connection
11	Pump A1	Pump A1, M12 plug connection
12	Pump C1	Pump C1, M12 plug connection
13	Serial A1	Serial A1, M12 plug connection
14	Serial C1	Serial C1, M12 plug connection
15	Valve Exh.	Valve exhaust air, M12 plug connection
16	FHEAT-A1	Heater of the exhaust air filter capsule A1, Amphenol 6+PE socket, 24 V_{AC}
17	FHEAT-B1	Heater of the exhaust air filter capsule B1, Amphenol 6+PE socket, 24 V_{AC}
18	Fieldbus	Fieldbus, M12 plug connection
19	Exh. Cond.	Exhaust condenser pump, M12 plug connection
20	Signal TS1	Signal Temperature Control Unit, M12 plug connection
21	Serial B1	Serial B1, M12 plug connection
22	Pump D1	Pump D1, M12 plug connection
23	Pump B1	Pump B1, M12 plug connection
24	Interf. B.-Bal.	Fieldbus for the balance of the bag, M12 plug connection
25	Mains Ext. Sig.	Power supply for external signal input, M12 plug connection
26	Ext.Sig-A/B 2x 0-10V	External signal input A / B, M12 plug connection
27	Vessel Weight	Vessel weight, M12 plug connection
28	pO2 B1	DO (pO_2) sensor B1, VP8 plug (optional)
29	pH B1	pH sensor B1, VP8 plug (optional)
30	Jacket Temp	Temperature sensor for the double wall, M12 plug connection
31	Motor control connection	For operating the bag's stirrer shaft motor
32	CO2	Carbon dioxide supply
33	PA	Grounding connection for potential equalization of the bag holder
34	N2	Nitrogen supply
35	O2	Oxygen supply
36	Air	Compressed air supply
37	Micro Sparger-1	Connection for micro sparger
38	Sparger-1	Connection for sparger
39	Overlay-1	Connection for overlay
40	pO2-D1 Opt.	Optical DO (pO_2) sensor (optional)
41	pH-D1 Opt.	Optical pH sensor (optional)

3.2.2 Connections for Bag Holder 2

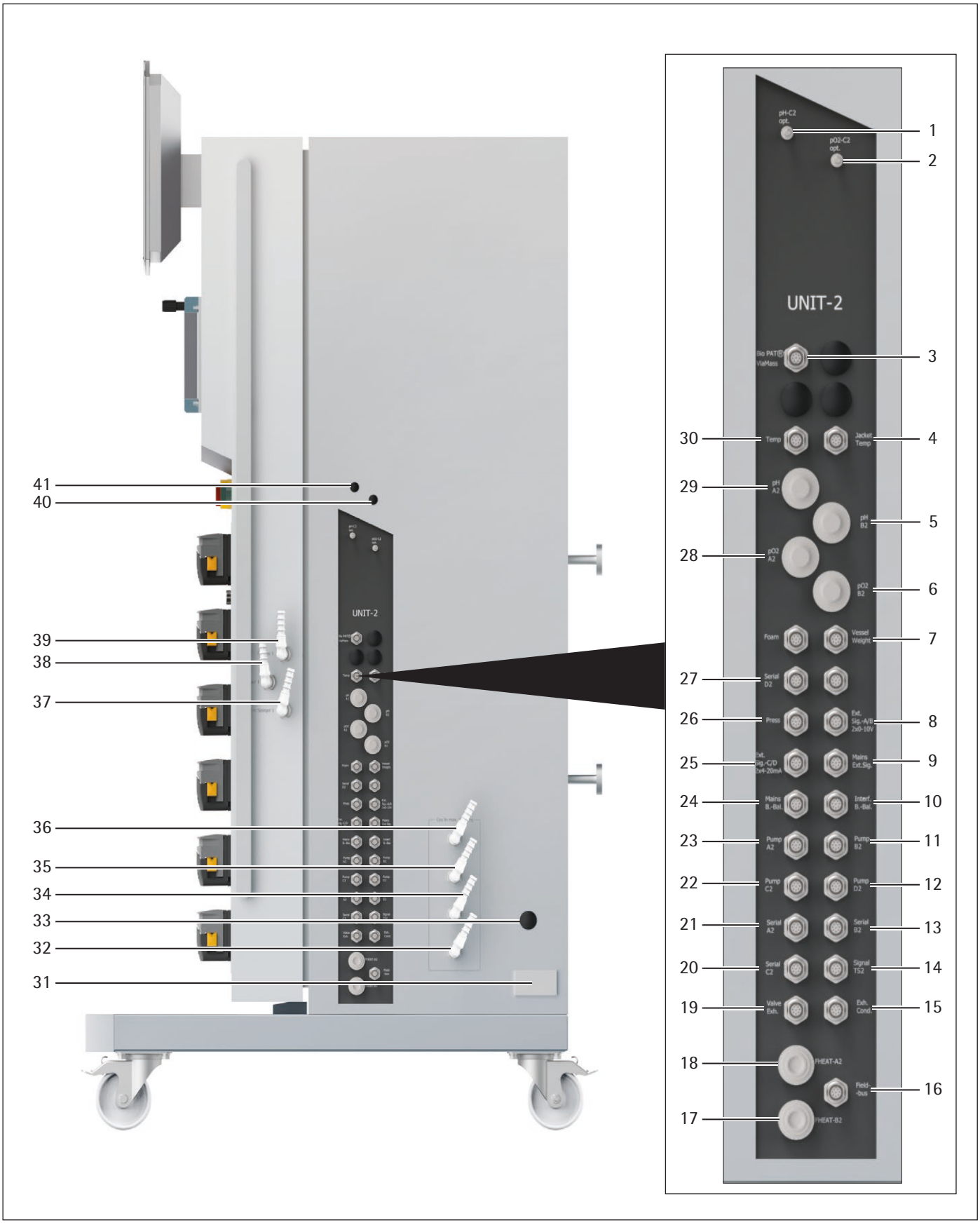


Fig. 4: Control / supply unit for 2 bag holder, connections for bag holder 2 [UNIT-2]

No.	Designation	Description
1	pH-C2 Opt.	Optical pH sensor
2	pO2-C2 Opt.	Optical DO (pO_2) sensor
3	BioPat® ViaMass	Biomass sensor (optional)
4	Jacket Temp	Temperature sensor for the double wall, M12 plug connection
5	pH B2	pH sensor B2, VP8 plug (optional)
6	pO2 B2	DO (pO_2) sensor B2, VP8 plug (optional)
7	Vessel Weight	Vessel weight, M12 plug connection
8	Ext.Sig-A/B 2x 0-10V	External signal input A / B, M12 plug connection
9	Mains Ext. Sig.	Power supply for external signal input, M12 plug connection
10	Interf. B.-Bal.	Fieldbus for the balance of the bag, M12 plug connection
11	Pump B2	Pump B2, M12 plug connection
12	Pump D2	Pump D2, M12 plug connection
13	Serial B2	Serial B2, M12 plug connection
14	Signal TS2	Signal Temperature Control Unit, M12 plug connection
15	Exh. Cond.	Exhaust condenser pump, M12 plug connection
16	Fieldbus	Fieldbus, M12 plug connection
17	FHEAT-B2	Heater of the exhaust air filter capsule B2, Amphenol 6+PE socket, 24 V_{AC}
18	FHEAT-A2	Heater of the exhaust air filter capsule A2, Amphenol 6+PE socket, 24 V_{AC}
19	Valve Exh.	Valve exhaust air, M12 plug connection
20	Serial C2	Serial C2, M12 plug connection
21	Serial A2	Serial A2, M12 plug connection
22	Pump C2	Pump C2, M12 plug connection
23	Pump A2	Pump A2, M12 plug connection
24	Mains B.-Bal.	Power supply for the balance of the bag, M12 plug connection
25	Ext.Sig-C/D 2x 4-20mA	External signal input C / D, M12 plug connection
26	Press	Pressure sensor, M12 plug connection
27	Serial D2	Serial D2, M12 plug connection (optional)
28	pO2 A2	DO (pO_2) sensor A2, VP8 plug
29	pH A2	pH sensor A2, VP8 plug
30	Temp	Temperature sensor, M12 plug connection
31	Motor control connection	For operating the bag's stirrer shaft motor
32	CO2	Carbon dioxide supply
33	PA	Grounding connection for potential equalization of the bag holder
34	N2	Nitrogen supply
35	O2	Oxygen supply
36	Air	Compressed air supply
37	Micro Sparger-2	Connection for micro sparger
38	Sparger-2	Connection for sparger
39	Overlay-2	Connection for overlay
40	pO2-D2 Opt.	Optical DO (pO_2) sensor (optional)
41	pH-D2 Opt.	Optical pH sensor (optional)

3.2.3 Connections for Supply Voltage, Potential Equalization and Ethernet

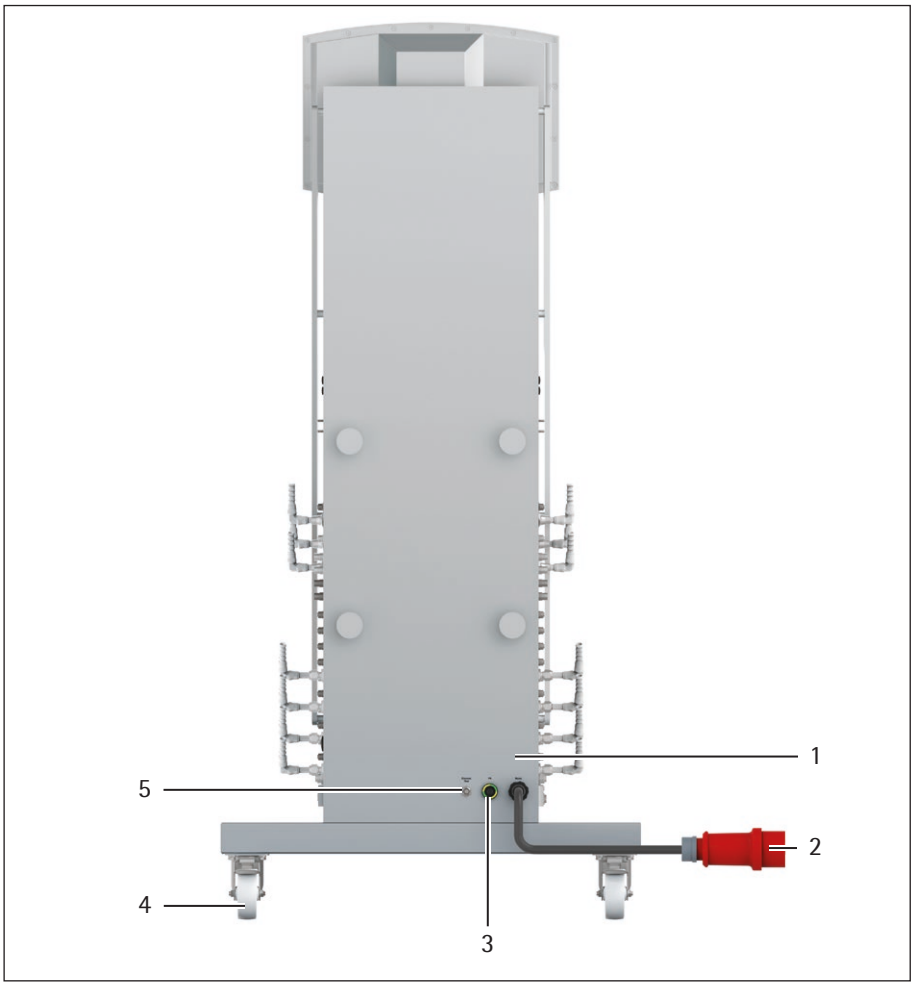


Fig. 5: Control / supply unit for 2 bag holders, rear view (example)

No.	Designation	Description
1	Manufacturer's ID label	Not shown
2	Mains	Main electrical connection with country-specific plug
3	PA	Grounding connection for potential equalization, type: Multi-Contact
4	Locking Castor Wheel	
5	Ethernet host	Ethernet connection for external host system, M12 plug connection

3.3 Bag Holder

The bag holder holds the bag.

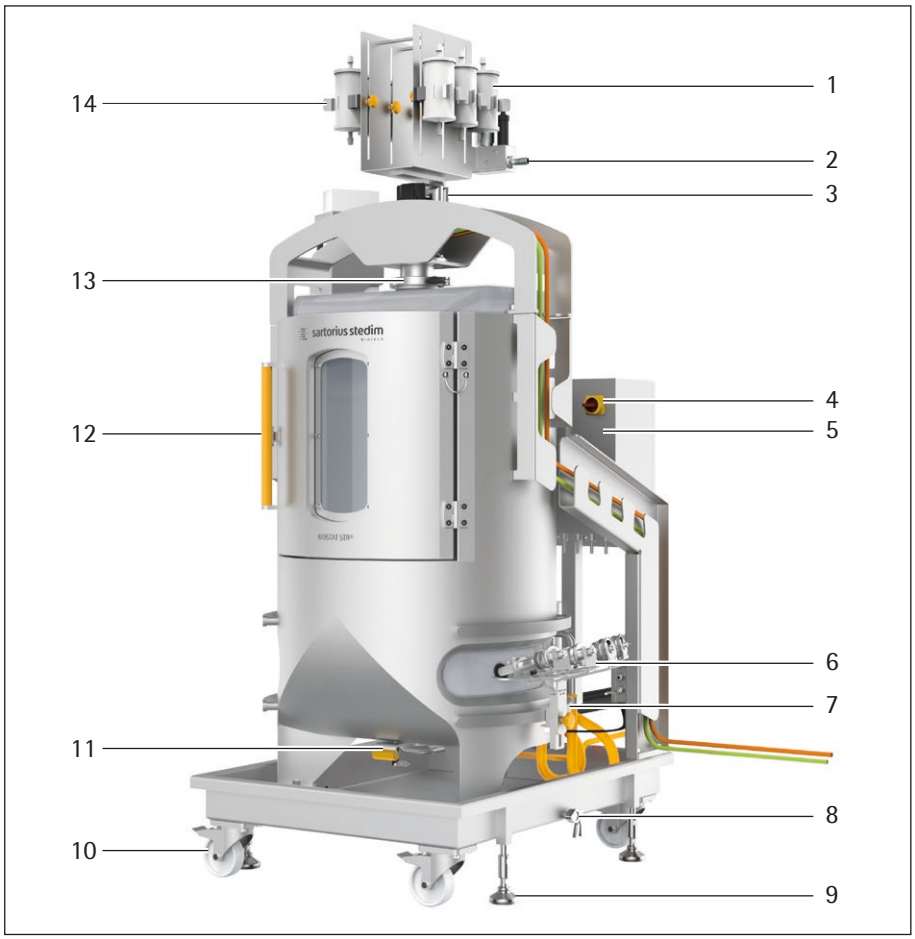


Fig. 6: Bag holder, 200L, front view (example)

No.	Designation	Description
1	Filter capsule	
2	Pressure sensor and pressure safety valve	
3	Motor	
4	Main switch	
5	Manufacturer's ID label	Not shown
6	Lateral ports	Come with the single use bag: Depends on device configuration.
7	Probe holder	
8	Drain connection	Drains liquid from tub.
9	Height-adjustable leveling foot	Levels the bag holder.
10	Locking Castor Wheels	
11	Slider for fixation of drain port	Secures the bag.
12	Door	
13	Magnetic coupling	
14	Filter holder	Accommodates the filter capsules.

3.3.1 Bag Holder Connections

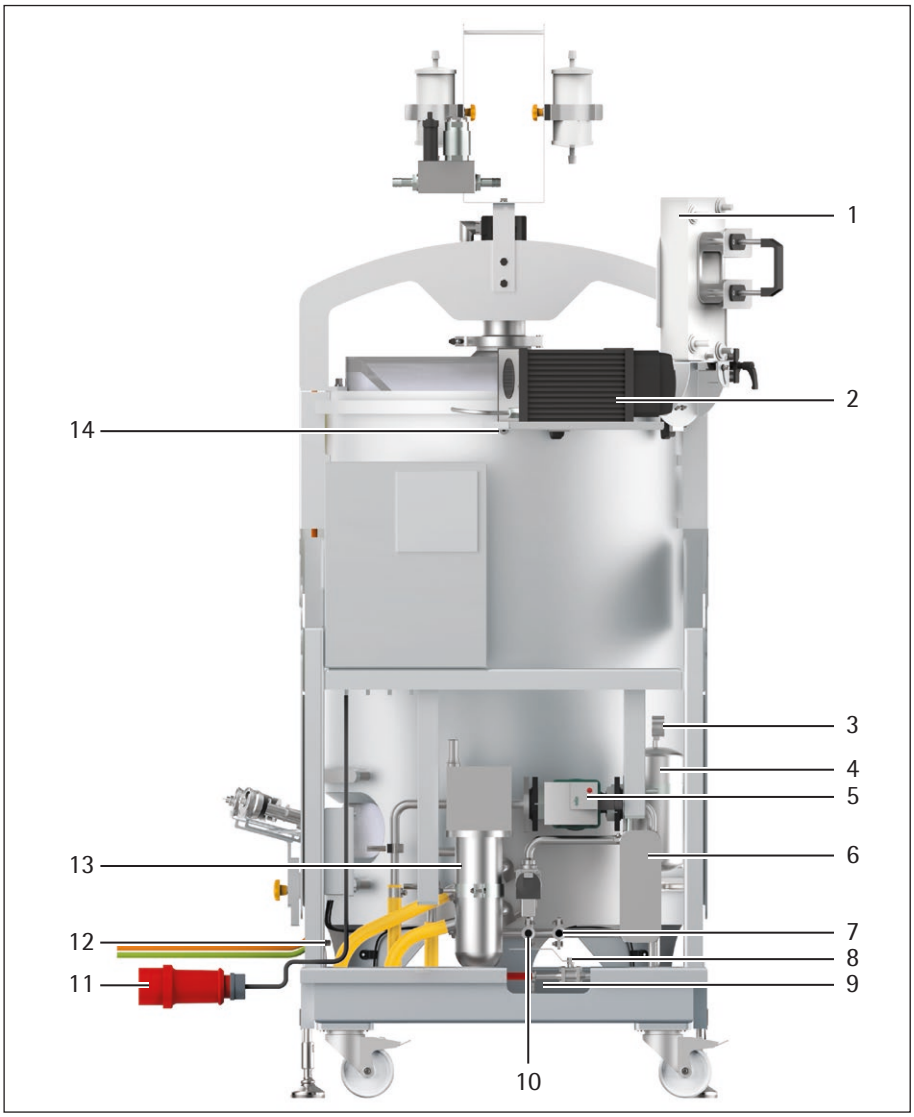


Fig. 7: Bag holder, 200L, connections rear view (example)

No.	Designation	Description
1	Exhaust cooler (optional)	Condenses the moisture from the exhaust air of the bag.
2	Pump for condensation return (optional)	Returns the condensate to the bag.
3	Pressure gauge	Monitors the pressure in the temperature control circuit.
4	Expansion vessel	Compensates for the volume expansion of the heat transfer fluid in the temperature control circuit.
5	Circulation pump	Pumps the heat transfer fluid through the temperature control circuit.
6	Plate heat exchangers	
7	Cooling medium inlet	Conducts cooling medium into the plate heat exchanger.
8	Ball valve	Used to fill the double wall.

No.	Designation	Description
9	Filling and discharging port of the double wall	Connection for filling the double wall with heat transfer fluid and emptying it.
10	Cooling medium outlet	Conducts cooling medium out of the plate heat exchanger.
11	Mains electrical connection	Connection with country-specific plug.
12	Grounding connection for potential equalization	Minimizes disparate electrical potentials.
13	Heating element	Heats the heat transfer fluid.
14	Double wall ventilation	Conducts excess air out of the double wall during filling.

3.3.2 Probe Holders and Autoclave Trays

The probe holders and autoclave trays are designed to hold conventional sensors. The probe holder supports the sensors when installed in the bioreactor. The autoclave tray holds the sensors when they are sterilized in an autoclave.

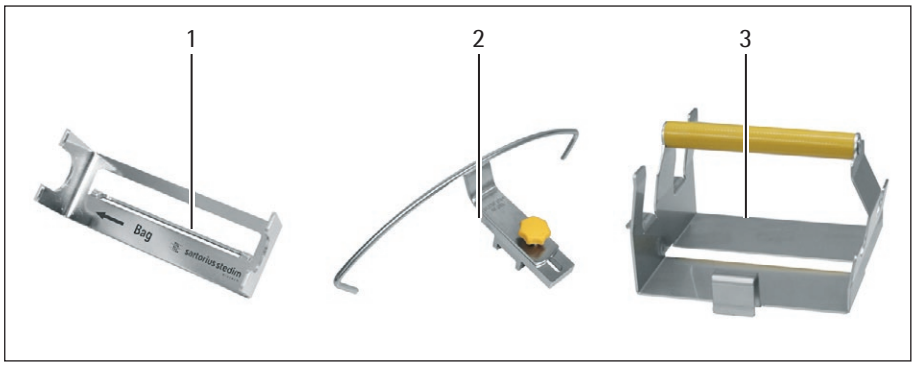


Fig. 8: Probe holders, components

No.	Designation	Description
1	Sensor clamp	Accommodates a sensor.
2	Probe support arm	Accommodates up to 4 sensor clamps. Separate design for bag holders 50 | 200 and bag holders 500 | 1000
3	Autoclave tray	– Accommodates up to 2 sensors that are sterilized in the autoclave. – The autoclave trays can be stacked in the autoclave.

3.4 Gas Flow Controller

3.4.1 Variable Area Flow Meter

The variable area flow meters are used to visualize the aeration rates for cultivation. The variable area flow meters can be used to limit the gas flow in the respective gas line. If mass flow controllers are used to control gas flow rates, these rotameters should be fully opened during operation.

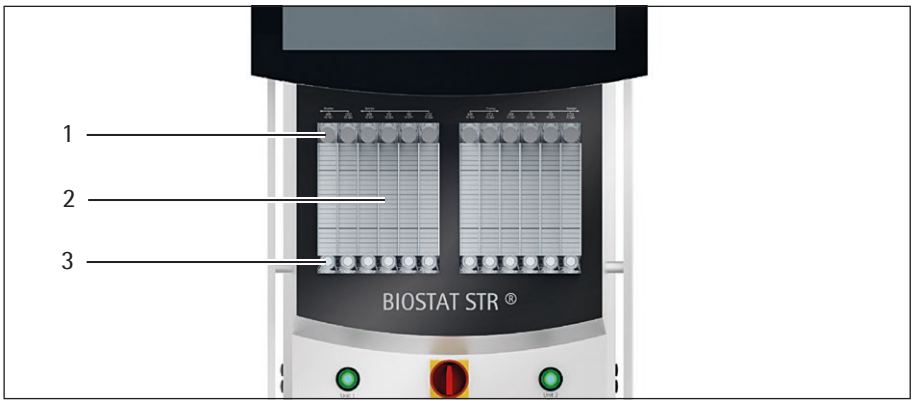


Fig. 9: Variable area flow meter

No.	Designation	Description
1	Control dial	Used to adjust the gas flow manually.
2	Variable area flow meter	Air OV / SP: Air
		O_2 OV / SP: Oxygen
		N_2 OV / SP: Nitrogen
		CO_2 OV / SP: Carbon dioxide
		-OV: Gas to "Overlay" outlet (headspace aeration)
		-SP: Gas to "Sparger" outlet (submerged aeration)
		FI "XYZ": Designation, variable area flow meters according to P&I diagram
3	Ball	Displays the gas flow.

3.4.2 Mass Flow Controller

The mass flow controllers are used to precisely control the gas flow rates for cultivation. The mass flow controllers control the gas flow in the respective gas line.

3.5 Peristaltic Pumps

The peristaltic pumps convey the correction media and nutrient media through tubing into the bag.

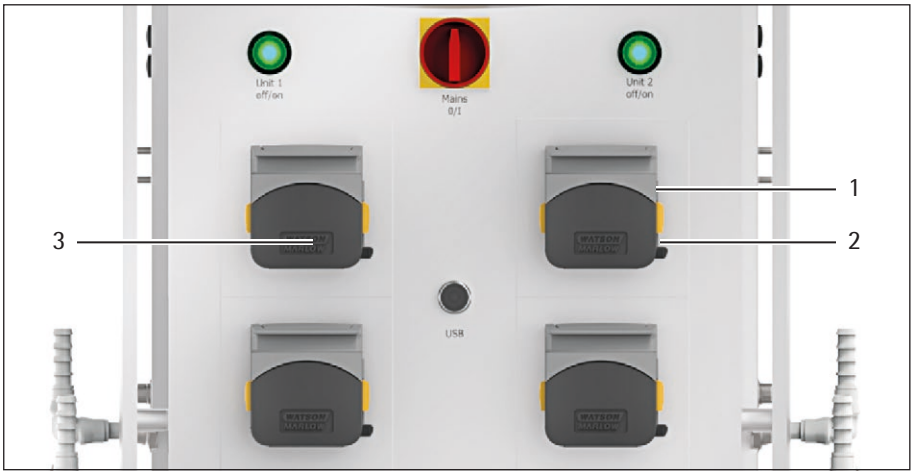


Fig. 10: Peristaltic pump

No.	Designation	Description
1	Flap cover	Closes the tubing in the pump head.
3	Tube uptake	Receives the tubing.
2	Scale	Not shown. Shows the height to be adjusted for the tube clamps depending on tubing size.

3.6 Operation

3.6.1 Temperature Control

The temperature control unit directs the heat transfer fluid into the double wall of the bag holder. The heating element of the bag holder heats the heat transfer fluid to the desired temperature. The heat transfer fluid is cooled by the cooling liquid connected to the heat exchanger. This is how the control / supply unit controls the temperature of the culture medium.

3.6.2 Aeration

Aeration is carried out by the gas flow controllers, variable area flow meters or mass flow controllers. The gas flow control depends on the configuration:

- A gas flow limit can be set for each gas on the respective variable area flow meter.
- Every gas can be regulated using a mass flow controller.
- Both gas flow controllers can be used at the same time.

Additional solenoid valves and function buttons in the DCU system make it possible to switch the aeration from “sparger” to “micro sparger”.

Oxygen Addition

2 / 2-way solenoid valves or mass flow controllers are used for oxygen addition. The solenoid valve and the mass flow controller are controlled by a gas flow controller or by the DO (pO_2) controller of the DCU system.

Addition of CO_2

CO_2 can be added either via a 2/2-way solenoid valve or a mass flow controller. The solenoid valve and the mass flow controller are controlled by a gas flow controller or by the pH controller of the DCU system.

"Advanced Additive Flow – 3 out" Aeration

The "Advanced Additive Flow - 3 out" aeration strategy is suitable for the following applications:

- For pH control
- For DO (pO_2) control

Aeration takes place with up to 4 gases via 3 outputs: [Sparger], [Micro Sparger] and [Overlay]. The gases are added by default as follows:

- Supply of air for "Sparger" or "Micro Sparger" and "Overlay"
- Depletion of the O_2 content by adding N_2 for "Sparger"
- Enrichment by adding O_2 for "Sparger" or "Micro Sparger"
- Adding CO_2 for pH control for "Sparger" and "Overlay"

3.6.3 Stirring System

The stirring system consists of the motor and the stirrer shaft of the STR bag. The motor and drive shaft of the STR bag are connected to each other by a magnetic coupling.

3.7 Safety Equipment

3.7.1 Power Disconnect

Fig. 11: Control / supply unit and bag holder, power disconnect

No.	Designation	Description
1	Mains 0/I	The main electrical switch serves as the main power switch and emergency switch. – Position 0 (horizontal): The device is voltage-free. – Position I (vertical): The device is live.

3.7.2 Overpressure Valves

The overpressure valves monitor the pressure in the bag when installed in line with the bioreactor headspace and in the double wall of the bag holder.

3.7.3 Overheating Protection

The overheating protection limits the maximum permissible temperature for the heat transfer fluid.

3.8 Symbols on the Device

Symbol	Meaning
	During operation, parts of the device can heat up, thereby making their surfaces hot. There is a danger of burns to the body parts that touch these surfaces.
	If body parts come into contact with rotating parts: Body parts can be crushed. This can lead to serious injuries.
	During operation, parts in the device may be live. Only electricians may have access to and work on these parts, such as to perform maintenance and repairs.
	Only authorized persons are allowed to start up the temperature control unit with the medium described in this manual. In the interest of safety, the pump as well as the pump heads and tubing employed should only be used by authorized persons who have previously read and understood these operating instructions and are aware of the possible dangers. Any person involved in the installation or maintenance of this pump must be authorized to carry out such work.
	Do **not** hit the magnetic disk with a hammer. The motor and magnetic disk could be damaged.

4 Operating Design

4.1 User Interface

The user interface provides a graphical overview of the status and characteristics of connected components.

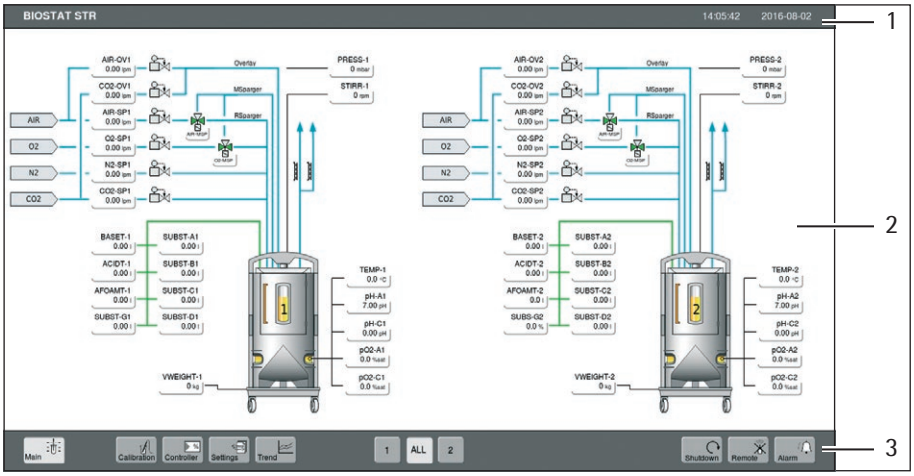


Fig. 12: User interface, [Main] function is activated (example)

No.	Name	Description
1	Header	Displays the following information: – Name of the active process or device configuration – Time in the format [hours:minutes:seconds] – Date in the format [year-month-day]
2	Work area	Displays the control and display elements of the active main function.
3	Footer	Contains the main function keys. If a main function is active: The main function key is highlighted.

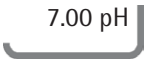
4.2 Display of Control and Display Elements

4.2.1 General information

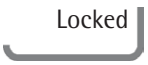
Symbol	Name	Description

		– Indicates the following statuses:
		  – The controller or component is disabled.
		  – If a controller is calibratable: The controller has not been calibrated.
		  – The phase is inactive.
		– Press to display the settings screen of the controller.

		– Indicates the following statuses:
		  – The controller or component is active.
		  – If a controller is calibratable: The controller is calibrated.
		  – The phase is active.
		– Press to display the settings screen of the controller.

		– Displays the activated status of the controller in cascade mode. – Press to display the settings screen of the controller.
		– Displays the activated status of the controller in manual mode. – Automatic control is not possible. – Press to display the settings screen of the controller.
		Displays the calibration.
		– Displays the short name of the controller. – Displays the measurement and control variables.

		– Displays the short name of the controller.
		– Indicates the following calibration statuses:
		  – Inactive
		  – Measure
		  – Calib

		[Locked] indicates that the process input or process output is locked.
		– Indicates the operating mode of the pump. Example: Pump off -> pump in automatic mode. – Press to display the pump operating mode screen.
		– Displays the valve position. Example of a 2/2-way valve: Valve closed -> valve open. – Press to display the valve operating mode screen.
		Press to cancel the input operation. Changes are **not** saved.
		Press to confirm the input.
		Press to cancel the input operation. Changes are **not** saved.

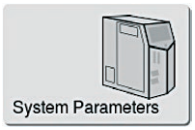
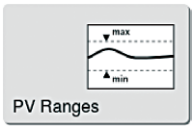
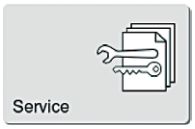
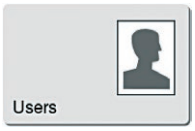
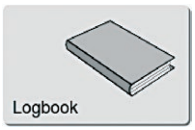
Symbol	Name	Description
		Press to delete the entries in the input field.
		Press to delete the last character entered.
		Press to set the plus or minus sign.
		Press to display the process value selection list.
	Controller setting screen | Advanced controller settings screen	Press to display the controller parameters settings screen.
	Profile Param.	Press to display the setpoint profile settings screen.
	Alarm Param.	Press to display the alarm parameters settings screen.

4.2.2 Footer

Symbol	Name	Description
	Main	Press to display the [Main] function. The [Main] function shows the current configuration with the current process values.
	Calibration	Press to display the main function [Calibration]. Use this function to calibrate the sensors.
	Controller	Press to display the main function [Controller]. Use this function to set parameters and start phases [Phases].
	Settings	Press to display the main function [Settings]. Use this function to configure basic system settings.
	Trend	Press to display the main function [Trend] (trend display). This presents the course of process values graphically.
	1	Press to display UNIT-1 in detail.
	ALL	Press to display the overview of both UNITS.
	2	Press to display UNIT-2 in detail.

Symbol	Name	Description
	Shutdown	Press to cause all controller outputs to go into the defined safety position.
	Remote	Press to activate remote operation. The control / supply unit can be controlled from a central computer.
	Alarm	Press to display the alarm overview.

4.2.3 [Settings] Main Menu

Symbol	Name	Description
	System Parameters	Press to configure the system parameters in the [System Parameters] window.
	PV Ranges	Press to configure the measurement ranges in the [Process Value Ranges] window.
	External	Press to display the window [External System]. Use this window to view the statuses of the external equipment, e.g. scales / balances.
	Manual operation	Press to display the window [Manual Operation]. – Use this window to manually set the values of the sensors / process inputs. – Use this window to manually switch actuators / controller outputs on and off and to set values.
	Service	Press to display service and diagnostic interventions. Only accessible to the Sartorius Service.
	Users	Press to display the optional function User Management. This function regulates the access of users to the DCU system. See “User management in DCU4 systems” operating instructions.
	Logbook	Press to display the optional function Logbook. This function records all messages since system startup. No entries can be changed, deleted or added. See the operating instructions titled “Logbook function (“Logbook”) in DCU4 systems”.
	User Parameters	Press to display the [User Parameters] window. The function “Importing / Exporting Parameters in DCU Systems” allows the operator to save and import DCU parameters and user authentication data in a parameter file. See the operating instructions for “Importing / Exporting Parameters in DCU4 Systems”.

4.3 Controller Configuration and Operation

4.3.1 Controller Settings Screen

The settings screen is used to configure a controller. Basic settings can be made in this window. More detailed settings can be made in the advanced setting screen.

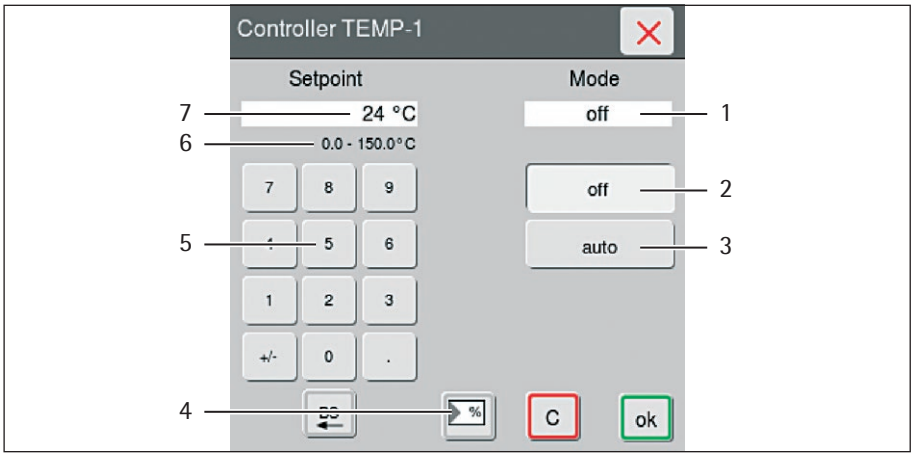


Fig. 13: Controller settings screen for controller TEMP-1 (example)

No.	Name / value	Description
1	Mode	Displays the current operating mode of the controller.
2	off	Press to switch the controller to the operating mode [off].
3	auto	– Press to switch the controller to the operating mode [auto]. – In the operating mode [auto], the controller TEMP-1 is controlled as a slave controller by a higher level controller (master controller).
4		Press to display the advanced controller settings screen.
5	Setpoint	Input field for the setpoint.
6	Setpoint	Displays the setting limits of the controller.
7	Setpoint	Displays the current setpoint of the controller.

4.3.2 Operating Mode Selection Screen

The operating mode selection screen is used to select the operating mode.
The actually available operating modes depend on the controller and the current operating situation.

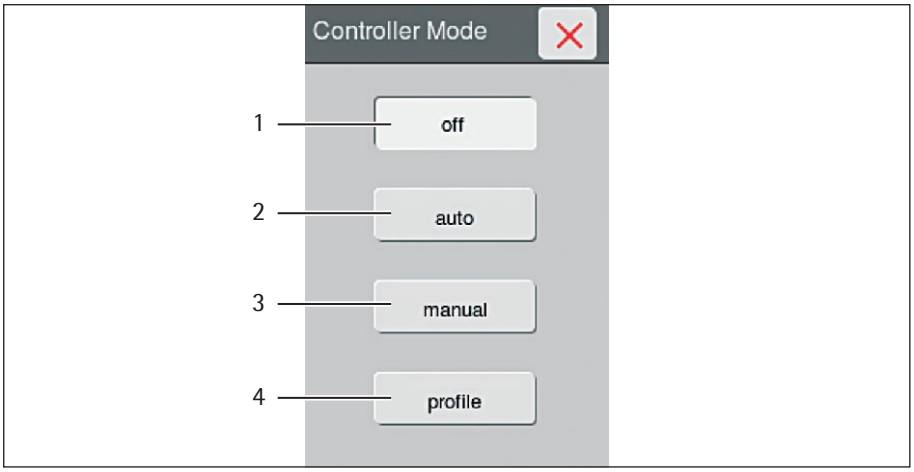


Fig. 14: Operating mode selection screen (example)

No.	Name / value	Description
1	off	Press to switch off the controller.
2	auto	Press to switch the controller to the operating mode [auto]. In the operating mode [auto], the controller TEMP-1 is controlled as a slave controller by a higher level controller (master controller).
3	manual	Press to manually assign values to the controller output.
4	profile	– When a setpoint profile is defined: Press to activate the setpoint profile of the controller. – If no setpoint profile is defined: Press to activate the operating mode [auto].

4.3.3 Advanced Controller Settings Screen

The advanced controller settings screen displays all parameters of the controller. All parameters can be changed and further configuration options can be displayed.

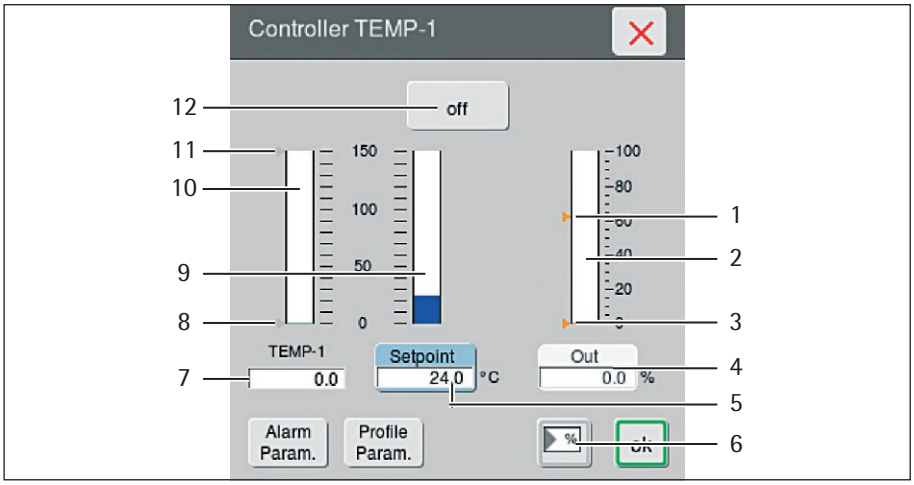


Fig. 15: Advanced controller settings screen for controller TEMP-1 (example)

No.	Name / value	Description
1	▶	Displays the maximum limit of the controller output.
2		Displays the controller output as a bar graph.
3	▶	Displays the minimum limit of the controller output.
4	Out	– Displays the controller output as a numeric value. – Only in [manual] operating mode: Press to display a window for configuring the controller output.
5	Setpoint	– Displays the setpoint of the controller as a numeric value. – Press to open a window for entering the setpoint.
6		Press to display the controller parameters settings screen.
7	TEMP-1	Displays the actual value of the controller as a numeric value.
8	▶	Displays the lower alarm limit of the process value.
9		Displays the setpoint of the controller as a bar graph.
10		Displays the actual value of the controller as a bar graph.
11	▶	Displays the upper alarm limit of the process value.
12	off	– Displays the current operating mode. – Press to display the operating mode selection screen.

4.3.4 Controller Parameters Settings Screen

Use the controller parameter settings screen to set the PID controller parameters.

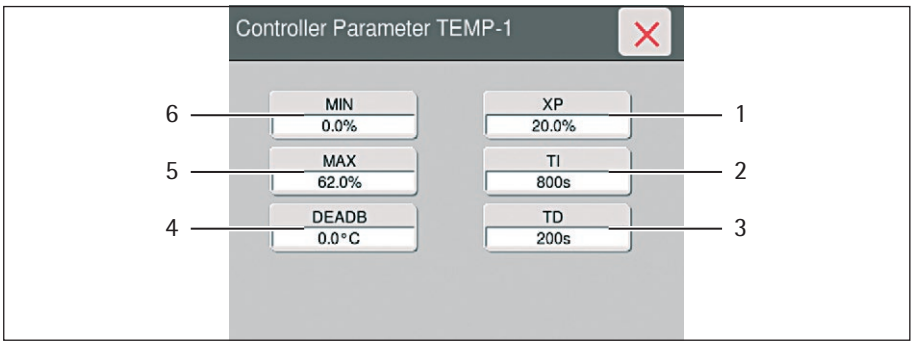


Fig. 16: Controller parameter settings screen for controller TEMP-1 (example)

No.	Name / value	Description
1	XP	– Press to display a window for entering the value XP. – Shows the proportional range in percent. Proportional range: Signal gain of the variable response in proportion to the input signal.
2	TI	– Press to display a window for entering the value TI. – Displays the integral component in seconds. Integral portion: With a higher I portion, control will react more slowly (and vice versa).
3	TD	– Press to display a window for entering the value TD. – Displays the differential component in seconds. Differential portion: Damping, greater D portion, damps the controller response (and vice versa).
4	DEADB	– Press to display a window for entering the value DEADB. – Displays the value for the deadband.
5	MAX	– Press to display a window for entering the value MAX. – Displays the maximum output limit in percent.
6	MIN	– Press to display a window for entering the value MIN. – Displays the minimum output limit in percent.

4.4 Setpoint Profile Settings Screen

The setpoint profile settings screen is used to create a setpoint profile for a controller. Free profile points can be defined. The setpoint profile is executed in the operating mode [Profile].

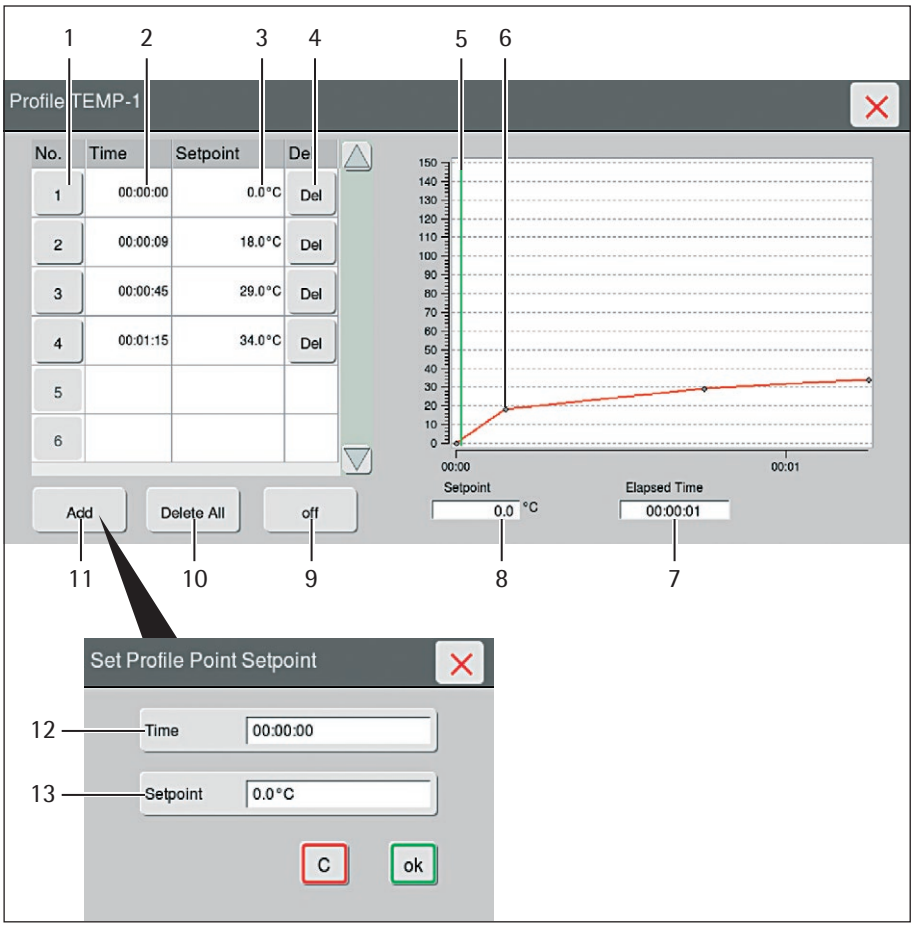


Fig. 17: Setpoint profile settings screen for controller TEMP-1 (example)

No.	Name / value	Description
1	No.	– Press to display the [Set Profile Set Point] window, where you can set the values of the profile point. – Displays the number of profile point.
2	Time	Displays the time of profile point.
3	Setpoint	Displays the setpoint of the profile point.
4	Del	Press to delete the profile point.
5		If setpoint profile is activated: Shows the progress of the profile.
6		Shows profile point no. 2 of the setpoint profile shown.
7	Elapsed Time	Shows the elapsed time after starting the setpoint profile.
8	Setpoint	Displays the current setpoint.
9	off	– Displays the current operating mode. – Press to display the operating mode selection screen.
10	Delete All	Press to delete all profile points.
11	Add	Press to display the [Set Profile Setpoint] window and enter a new profile setpoint.
12	Time	Press to display a window for entering the time of a new profile point.
13	Setpoint	Press to display a window for entering the setpoint of a new profile point.

4.4.1 Pump Operating Mode Selection Screen

The pump operating mode selection screen is used to select the pump operating mode.

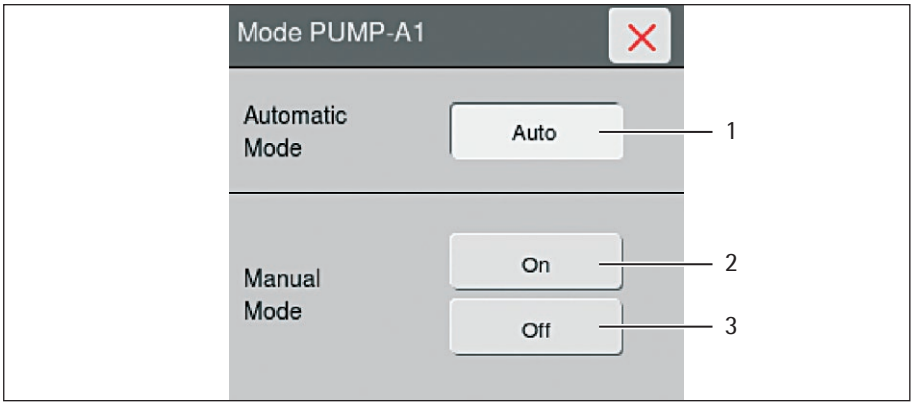


Fig. 18: Pump operating mode selection screen (example)

No.	Name / value	Description
1	auto	Press to switch the pump to the operating mode [auto]. In the operating mode [auto], the pump PUMP-A1 is controlled by a master controller.
2	on	Press to manually switch on the pump.
3	off	Press to manually switch off the pump.

4.4.2 Valve Operating Mode Selection Screen

The valve operating mode selection screen is used to select the valve operating mode.

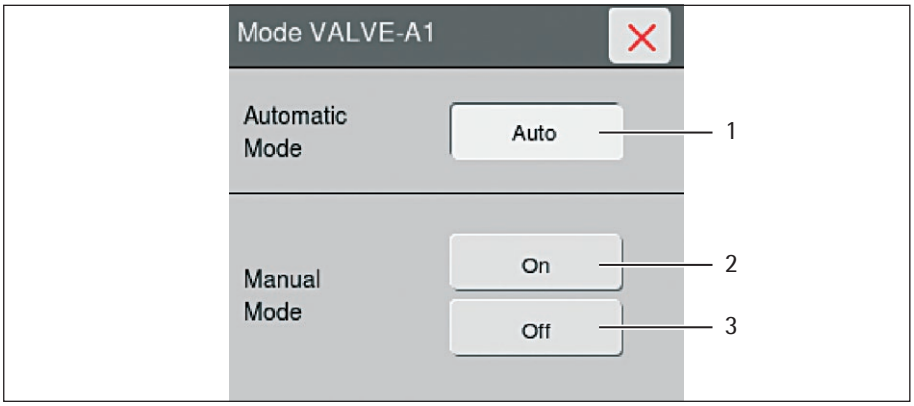


Fig. 19: Valve operating mode selection screen (example)

No.	Name / value	Description
1	auto	Press to switch the valve to the operating mode [auto]. In the operating mode [auto], the valve VALVE-A1 is controlled by a master controller.
2	on	Press to switch the valve on.
3	off	Press to switch the valve off.

4.5 Calibration

In the [Calibration] main function, all calibration actions required for routine operation can be activated:

- Calibration routines for sensors: e.g. pH, pO_2
- Sensor function check: e.g. BioPAT® ViaMass
- Calibration of pump totalizer: e.g. acid, base, substrate
- Calibration of gas totalizer: e.g. N_2, O_2, CO_2

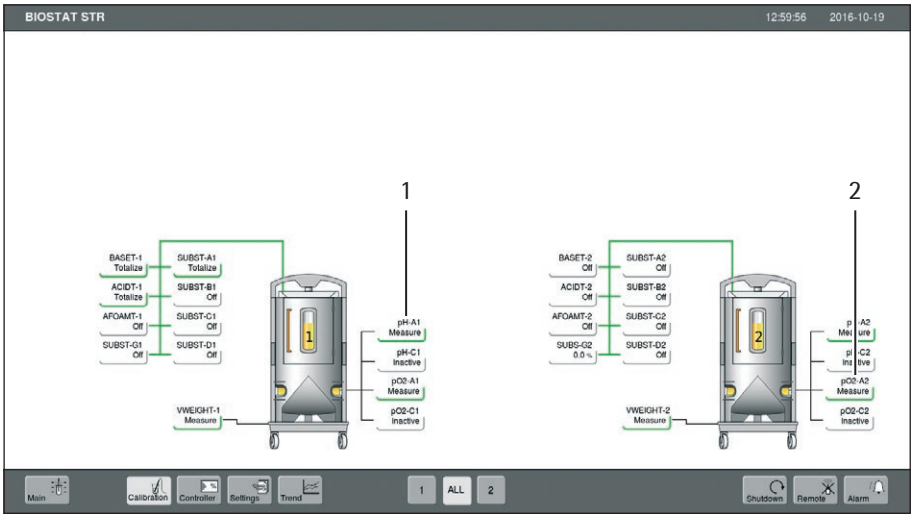


Fig. 20: Overview menu with multiple systems (identifies key calibration functions of both UNITS, example)

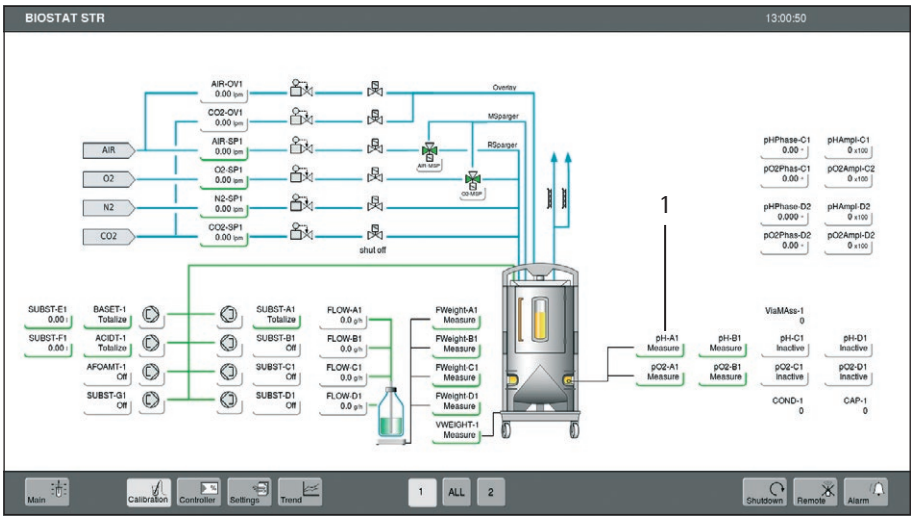


Fig. 21: Overview menu for a single subunit (contains all calibration functions contained in the configuration, example using UNIT-1)

No.	Name / value	Description
1	pH-1	– Displays calibration of the pH sensor [pH-1]: pH sensor [pH-1] is calibrated. – Press to display the calibration mode selection screen.
2	pO2-2	– Displays the calibration status of the DO (pO_2) sensor [pO2-#]: DO (pO_2) sensor [pO2-#] is calibrated. – Press to display the calibration mode selection screen.

The calibration parameters remain stored when the DCU system is switched off. After power is restored, the DCU system uses the saved figures until a new calibration is carried out.

The settings screens and operating menus for calibration of the pH sensors are displayed in the following.

4.5.1 Calibration Mode Selection Screen

The "Calibration pH Select" screen is used to select single or group calibration.

The sequence of single and group calibration is similar. Group calibration additionally allows the following settings:

- Simultaneous calibration of all connected pH sensors. Deselection of individual pH sensors from the group calibration is **not** possible.
- Group calibration is only possible for conventional and digital pH sensors, **not** for optical pH sensors.
- **No** direct input of zero offset and pH sensor slope is possible.
- pH sensors **cannot** be re-calibrated.

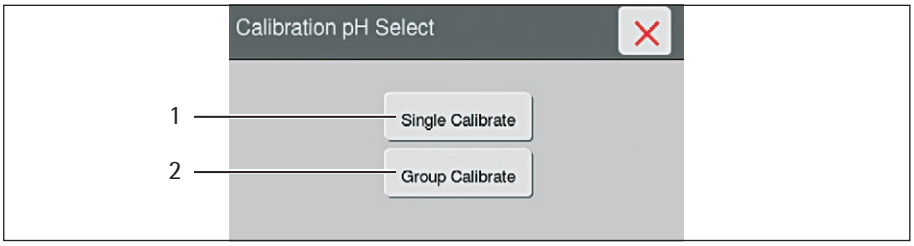


Fig. 22: Single and group pH sensor calibration selection screen

No.	Name	Description
1	Single Calibrate	Press to display the settings screen for pH sensor calibration.
2	Group Calibrate	Press to display the settings screen for group calibration of all pH sensors.

4.5.2 Single Calibration Settings Screen

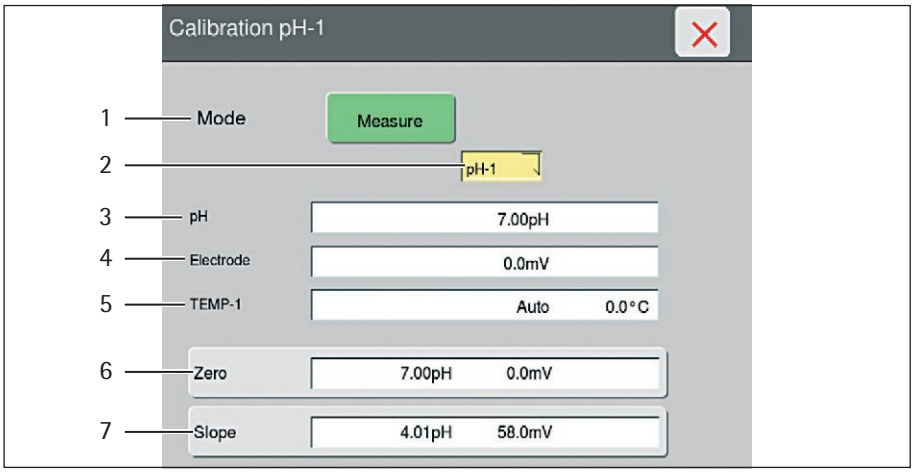


Fig. 23: Settings screen for single calibration of a pH sensor

No.	Name / value	Description
1	Mode	– Press to display the calibration method selection screen. – Automatically switches to pH measurement after the calibration routine has ended.
2	pH-#	Shows the pH sensor to be calibrated as a numeric value.
3	pH	Displays the pH readings as a numeric value.
4	Electrode	Displays the electrode voltages as a numeric value.
5	TEMP-#	Displays the temperature compensation values as numeric values.
6	Zero	– Displays the zero offset values as numeric values. – Press to display the settings screen for input of the zero offset.
7	Slope	– Displays the slope values as numeric values. – Press to display the settings screen for input of the slope.

4.5.3 Calibration Method Selection Screen

This screen is used to select the calibration method.

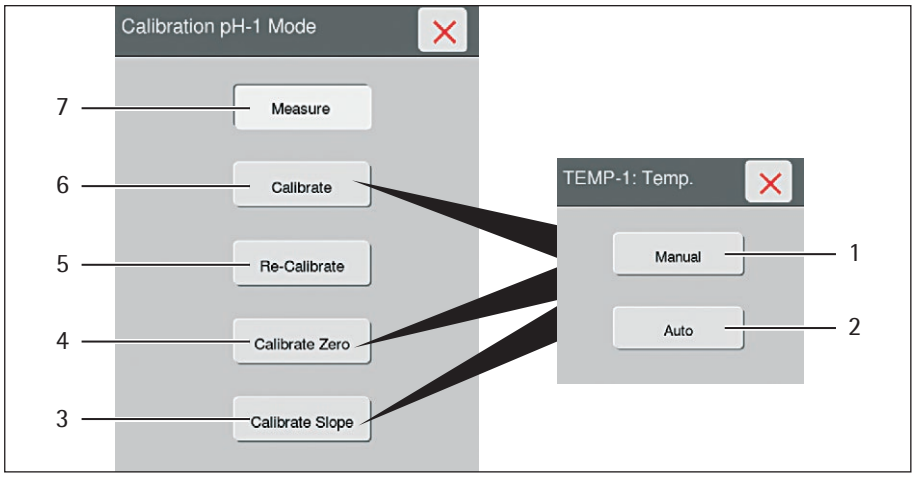


Fig. 24: Calibration method selection screen for pH sensor pH-1 (example)

No.	Name	Description
1	Manual	Press to display the window for entering a reference temperature measured outside the bag.
2	Auto	Press to perform temperature compensation based on the temperature measured by the temperature sensor in the bag.
3	Calibrate Slope	After entering the values, press to perform the slope calibration of the pH sensor as a single step for the following settings: – Temperature compensation – Slope
4	Calibrate Zero	After entering the values, press to perform the zero point calibration of the pH sensor as a single step for the following settings: – Temperature compensation – Zero offset
5	Re-Calibrate	Press to re-calibrate the pH sensor. Recalibration is only possible when calibration mode [Single Calibrate] is selected.
6	Calibrate	After entering the values, press to perform a full calibration of the pH sensor, e.g. for the following settings: – Temperature compensation – Slope
7	Measure	Press to display the settings screen.

4.6 Alarm Message

The following figure shows how an alarm is shown after it occurs.

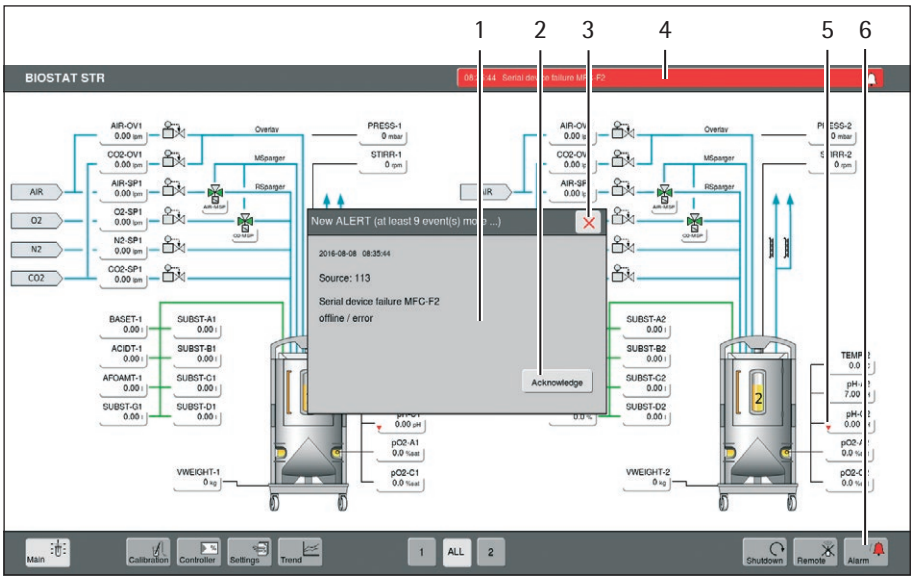


Fig. 25: Alarm message (example)

No.	Symbol	Designation	Description
1		New ALERT	The [New ALERT] window displays information about the alarm. This window overlaps any other windows.
2		Acknowledge	– Press to confirm the alarm. – Closes the [New ALERT] window. – The alarm is saved as confirmed in the alert overview (State: ACK).
3		x	Active alarm message in the header: – Press to close the [New ALERT] window. – The alert is saved as unconfirmed in the alert overview (State: UNACK). – Alarm indicator (4) is retained.
4		Alarm display	– Indicates a triggered alarm. An acoustic signal sounds. – Press to display the alarm overview.
		Time	Displays the time at which the alarm was triggered.
		Alarm message	Displays the error code.
5			Indicates that the process value has exceeded the upper alarm limit.
			Indicates that the process value falls below the low alarm limit.
6		Alarm	– Indicates that there are unconfirmed alarms. – Press to display the alarm overview.
		Alarm	– Indicates that there are no new unconfirmed alarms. – Press to display the alarm overview.

4.7 Alarm Overview

The alarm overview displays the alarms that have occurred and makes it possible to acknowledge and delete alarms.

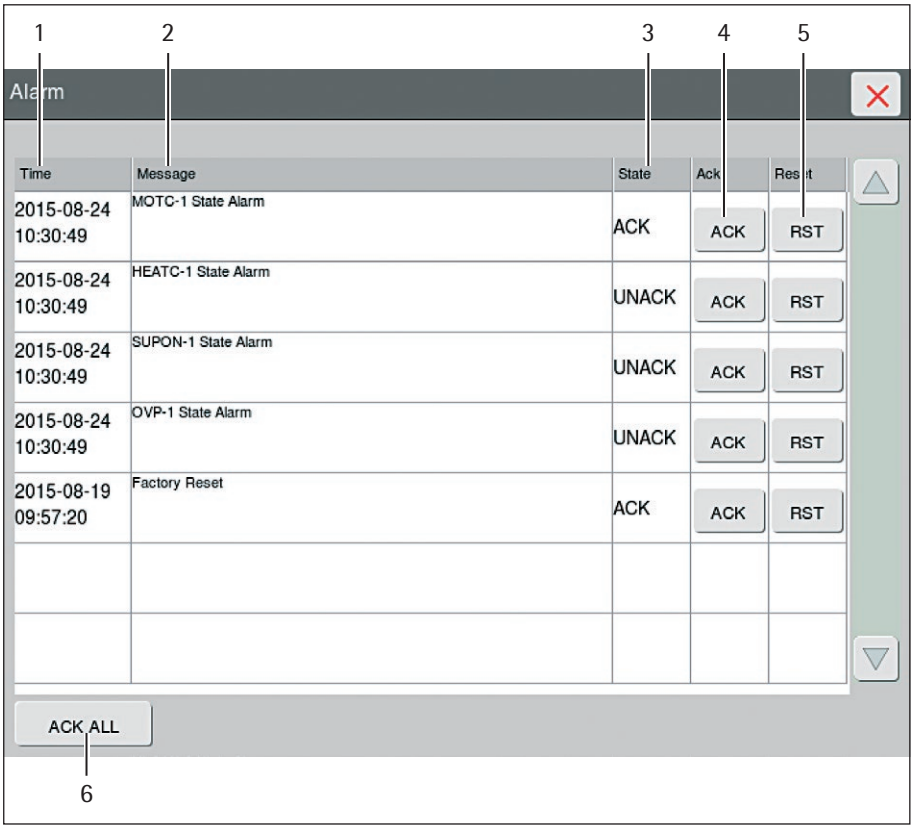


Fig. 26: Alarm overview (example)

No.	Name / value	Description
1	Time	Displays the time at which the alarm was triggered.
2	Message	Shows the message and any additional information pertaining to it.
3	Status	Displays the status of the message: – ACK: Message has been confirmed. – UNACK: Message has not yet been confirmed.
4	ACK	Press to confirm the selected alarm.
5	RST	Press to confirm the selected alarm. The alarm is deleted from the overview.
6	ACK ALL	Press to confirm all alarms that have not yet been confirmed.

4.8 Alarm Parameters Settings Screen

The alarm parameter settings screen sets the alarm parameters for a controller. If the alarm is activated and the alarm limits are exceeded or undershot, an alarm is triggered.

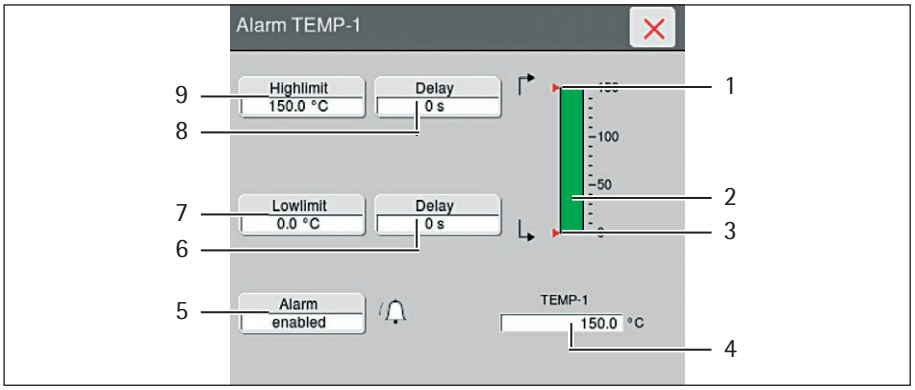


Fig. 27: Alarm parameter settings screen for controller TEMP-1 (example)

No.	Name / value	Description
1	▶	Displays the upper alarm limit of the process value.
2		Displays the actual value of the controller as a bar graph.
3	▶	Displays the lower alarm limit of the process value.
4	TEMP-1	Displays the actual value of the controller as a numeric value.
5	Alarm	
	disabled	– Displays the monitoring status (disabled). – Press to activate monitoring.
	enabled	– Displays the monitoring status (enabled). – Press to disable monitoring.
6	Delay (Lowlimit)	The alarm becomes active when the alarm limits are undershot following the configured delay time. – Press to display a settings screen for setting the delay time. – Displays the delay time for the alarm message.
7	Lowlimit	– Press to display a window for entering the lower alarm limit. – Displays the lower alarm limit of the process value.
8	Delay (Highlimit)	The alarm becomes active when the alarm limits are exceeded following the configured delay time. – Press to display a settings screen for setting the delay time. – Displays the delay time for the alarm message.
9	Highlimit	– Press to display a window for entering the upper alarm limit. – Displays the upper alarm limit of the process value.

4.9 Trend Display

The trend display is a graphical representation of the course of process values (channel). Multiple channels can be displayed. The display of the channels can be individually adapted.

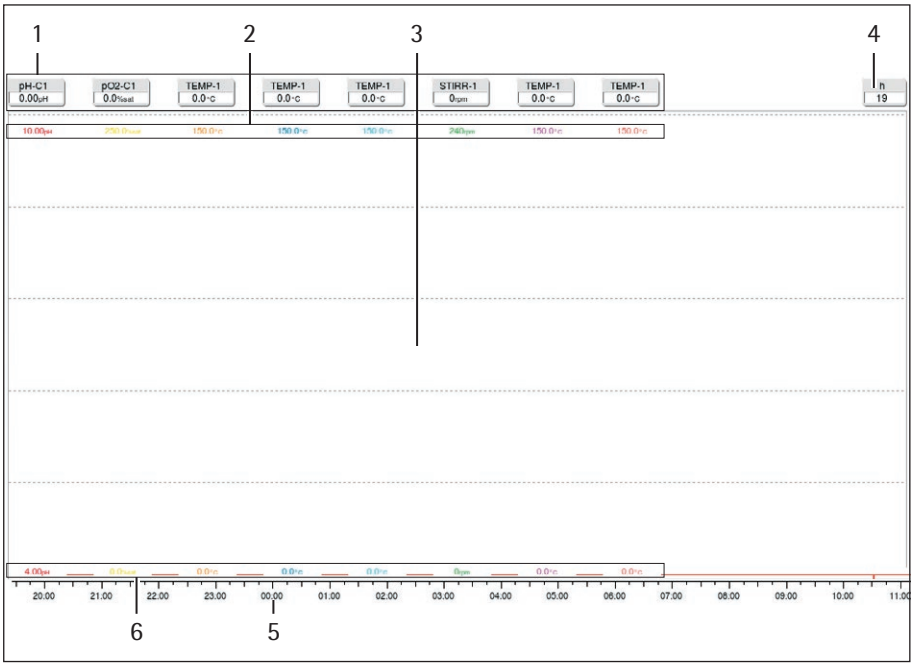


Fig. 28: Trend display overview (example)

No.	Name	Description
1	Channel	– Displays the channels with the assigned process values. – Press to display the channel settings screen.
2	Upper limit	Displays the upper limit of the value range.
3	Trend history	Displays the history of the process values assigned to the channels.
4	Time range	– Displays the user-selected time range of the timeline. – Press to open a window for setting the time range.
5	Timeline	Displays the process time.
6	Lower limit	Displays the lower limit of the value range.

4.9.1 Channel Settings Screen

The channel settings screen is used to configure a channel. The following parameters of a channel can be set:

- Process value
- Upper / lower limit of the value range
- Color

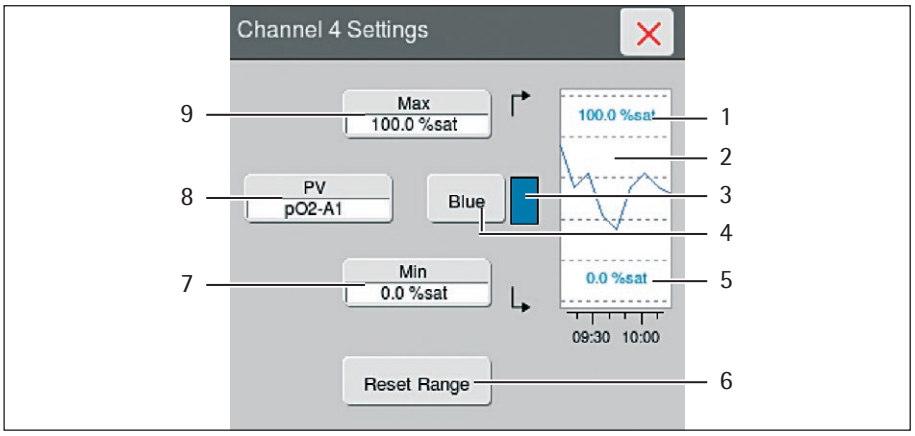


Fig. 29: Channel settings screen (example)

No.	Name	Description
1	100.0 sat%	Displays the current upper limit of the value range.
2		Displays the appearance of the channel in the trend display.
3		Displays the current display color of the channel.
4	Blue	Press to display a window for selecting the display color of the channel.
5	0.0 sat%	Displays the current lower limit of the value range.
6	Reset-Range	Press to reset the current upper / lower limit of the range to the defaults.
7	MIN	– Displays the current lower limit of the value range. – Press to display a window for entering the lower limit of the value range.
8	PV	– Displays the process value assigned to the channel. – Press to display the channel assignment screen.
9	MAX	– Displays the current upper limit of the value range. – Press to display a window for entering the upper limit of the value range.

4.9.2 Channel Assignment Screen

The channel assignment screen is used to assign a process value to the selected channel. All assigned channels are automatically recorded even if not displayed on the trend.

A channel can be assigned to the following types of parameters:

- Process values
- Controller setpoint
- Controller output

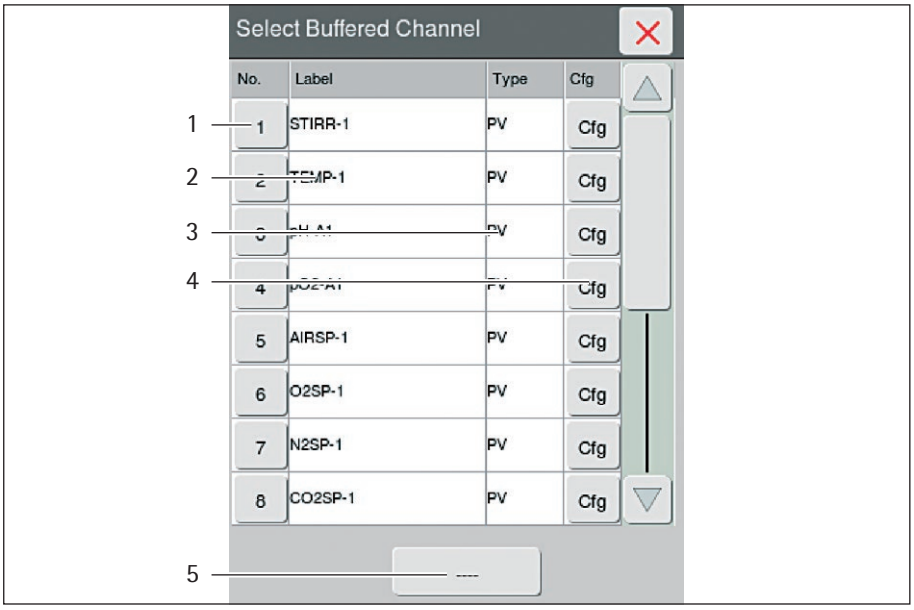


Fig. 30: Channel assignment screen (example)

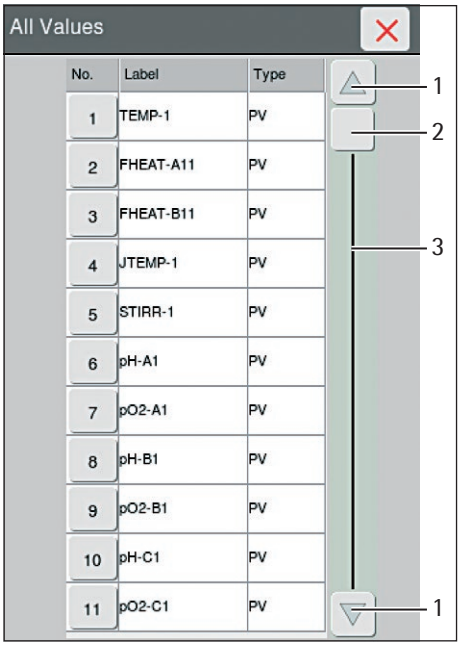
No.	Name	Description
1	No.	Assigns a parameter to the selected channel.
2	Label	Displays the parameter's name.
3	Type	Displays the parameter type.
4	Cfg	Press to assign a different parameter to the channel.
5	[----]	Delete channel assignment.

4.10 Navigating Menus

Scrolling Through Lists

If submenus contain lists of elements, short names or parameters that cannot be displayed in a window: You will see a scroll bar with a cursor. To scroll through long lists: The following options are available:

- Press the arrow keys (1).
- Hold down and move the cursor (2).
- Press directly in the scrollbar at the relative height (3) where the channel tag could be located.



5 Installation

5.1 Equipment Supplied

Item	Quantity	Purpose
Control / supply unit	1	
Bag holder	As specified in the order	
Probe holder	As specified in the order	Fixes the electrodes to the bag holder.
Autoclave tray	As specified in the order	Used to autoclave and transport up to 2 electrodes.
Bag	As specified in the order	
Filter capsule	As specified in the order	
Filter heater	As specified in the order	Heats the exhaust air filter capsule.
Peristaltic pumps	As specified in the order	
Exhaust cooler	As specified in the order	
Installation set	As specified in the order	
Sensors/sensor cables	As specified in the order	
Equipment and accessories (e.g. electrodes, filters)	As specified in the order	
Operating Instructions BIOSTAT STR®	1	

5.2 Prerequisites for Installation

⚠ WARNING

Danger of functional problems and operational malfunctions

Avoid improper installation. Only authorized Sartorius Service technicians may set up the device and carry out the initial startup procedure.

⚠ WARNING

Danger of injury if access to shutdown equipment and shut-off devices is blocked!

Equipment for emergency shutdown and shut-off devices, e.g. for the power supply, water or gas feed, as well as the particular equipment connections, must be kept clear and easily accessible.

- ▶ All of the equipment should be set up at a distance of at least between 100 mm to around 300 mm from any walls to ensure adequate ventilation and convenient access to the connections on the rear.

⚠ WARNING

Risk of personal injury and property damage if the installation location does not meet the set requirements!

- ▶ Sufficient load bearing capacity of the installation location ensures safe installation of the bioreactor.
- ▶ When dimensioning accordingly, observe that the maximal potential weight of the respective medium must be added to the intrinsic weight.
- ▶ The place of installation must meet the following requirements (see Chapter "15 Technical Data," page 194).

⚠ WARNING

Risk of personal injury and property damage due to improper cabling and tubing!

Incorrectly laid cables and tubes present a tripping hazard and injury risk. Ripped out cables and tubes could permanently damage the bioreactor and connected components.

- ▶ Ensure all cables and tubes have been laid so that they do not present a tripping hazard!

⚠ CAUTION

Danger of injury due to insufficient component stability!

- ▶ Follow any other manufacturer's operating instructions for additional components.
- ▶ Follow the construction guidelines required to ensure that the device is stable.

Procedure

- ▶ Make sure that the following conditions are met at the place of installation:

Condition	Features
Ambient conditions	Suitability tested (see ambient conditions Chapter "15 Technical Data," page 194)
Setup surface	– Stable and level surface – Sufficiently dimensioned for the device and the peripheral devices (for device space requirements: dimensions see Chapter "15.12 Dimensions," page 197); peripheral device space requirements, see instructions on the peripheral devices) – Sufficient weight bearing capacity to bear device and peripheral devices, also in a filled state (net weight of the device: Chapter "15.13 Net Weight," page 198; peripheral devices weight, see instructions on the peripheral devices, e.g. exhaust cooler)
Access to operation-relevant parts	Convenient, safe and easily accessible
Tools for bag startup	Scissors for the outer packaging.
Supply media	Check suitability (according to Chapter "15.7 Gas and Compressed Air Supply," page 196).

Condition	Features
Connections	– Make easily accessible. – Install correctly (see Chapter "6 Getting Started," page 54). – Configure according to the Technical Data and make ready for operation (see Chapter "15 Technical Data," page 194).
Cooling water	– Without pressure surges – Particle-free – Check suitability (according to Chapter "15.4 Heat Transfer Fluid Supply," page 195).
Compressed gases	– Without pressure surges – Particle-free – Oil free – Free of condensate
Barriers and emergency shutoffs	– Equip all supply lines used for cooling water, compressed air and gases with suitable fittings

5.3 Unpacking

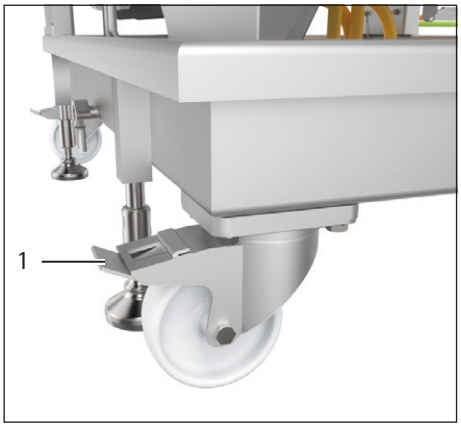
Procedure

- ▶ Do not destroy the packaging and only remove it just before assembly.
- ▶ Unpack device, supplied equipment and accessories.
- ▶ If the device is stored temporarily: Observe the information on storage (see Chapter "13.1 Storage," page 190).
- ▶ **NOTICE** Danger of damage to the device from improper handling! Do **not** lift the device by its base. Only move the device via the locking wheels.
- ▶ Install the device at the intended installation location. To this end, observe the setup plans.

6 Getting Started

6.1 Positioning the Device

▶ ⚠ **CAUTION** Risk of feet being rolled over and crushed when moving the device! Wear personal protective equipment while moving the unit.

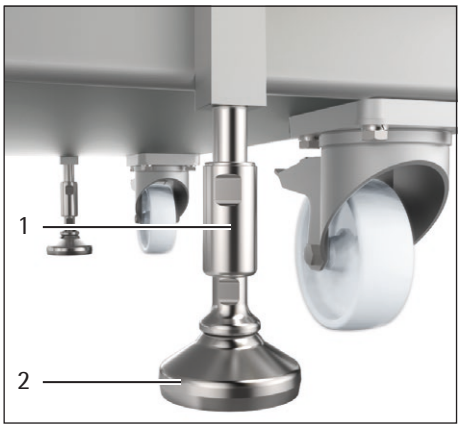


6.2 Securing the Device at the Place of Installation

Lock the castor wheels when at the place of installation to secure the device during leveling.

Procedure

▶ ⚠ **WARNING** Danger of crushing when operating the lockable castors! Operate the lockable castors only with your foot. Wear personal protective equipment.
▶ Press down on the lever with your foot. Do not use hands as pinching can occur.
▷ The device is secured against moving.



6.3 Leveling the Bag Holder at the Installation Location

The leveling feet (2) are used to level the device.

Procedure

▶ ⚠ **CAUTION** Danger of crushing when operating the leveling feet! Wear personal protective equipment.
▶ Observe the maximum setting height of the leveling feet (see Chapter "15.12.4 Leveling the Bag Holder," page 197).
▶ Align the bag holder with the leveling feet (2) horizontally. Then secure the configuration with the lock nuts (1).
▷ The device is horizontally aligned and secured against movement.

6.4 Connecting the Motor

The drive motor rotates the stirrer in the bag.

⚠ CAUTION

Risk of injury when motor is running!

Before mounting or disassembling the motor cable, the control / supply unit on the main switch must be switched off.

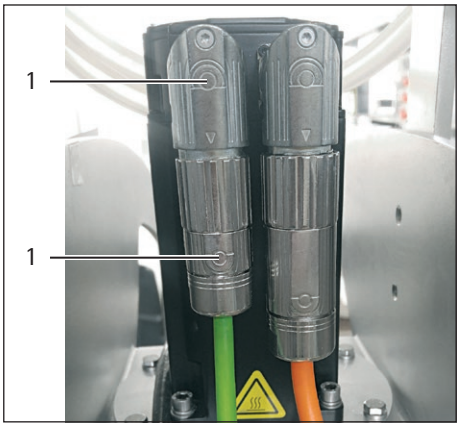
▶ Do **not** reach into the sleeve with your fingers.
▶ Leave the motor control switched off until the bag is attached to the magnetic coupling of the motor.

NOTICE

Danger of damage to the stirrer driver!

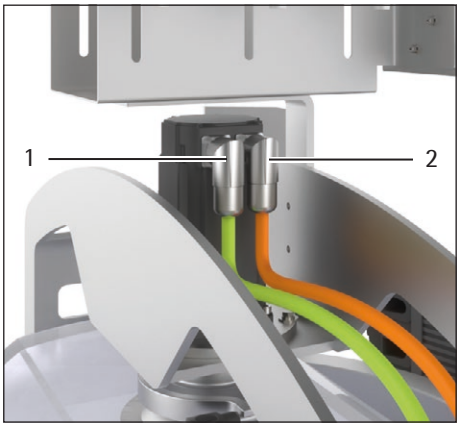
The control / supply unit must be turned off prior to fitting or detaching the motor cable; otherwise there is risk of short circuits and the motor can be damaged.

▶ Make sure the bag is not yet attached to the magnetic coupling.



Procedure

▶ Establish the connections: For the orientation of the respective connector, see the symbols (1) on the connector and the socket.

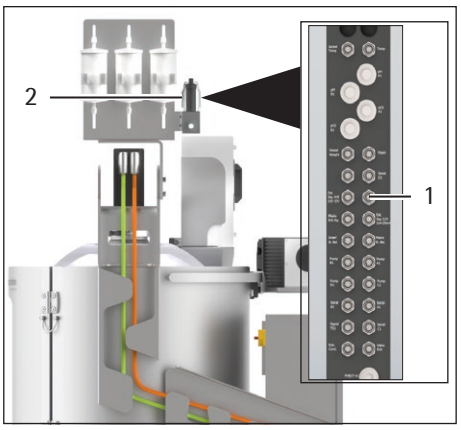


▶ Plug the connection cable into the respective sockets on the motor.
▶ Green connection cable (1): Connect on the left
▶ Orange connection cable (2): Connect on the right

▶ Carefully tighten the plug connection cap nuts by hand.

6.5 Connecting the Pressure Sensor

The pressure sensor monitors the pressure in the bag.

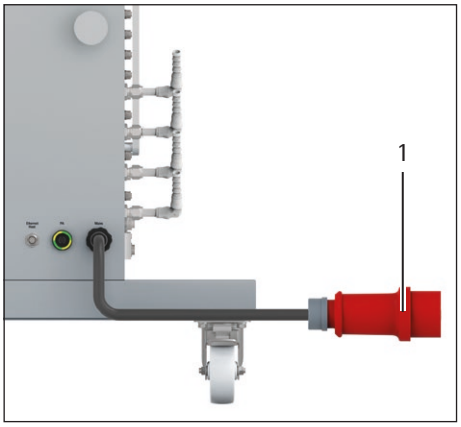


Procedure

▶ Connect the connection cable of the pressure sensor (2) to the [Press] socket (1) of the control / supply unit.

6.6 Connecting the Power Supply

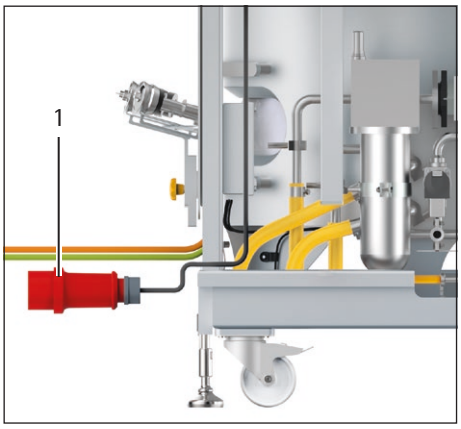
6.6.1 Connection for Control / Supply Unit



Procedure

- ⚠ **WARNING** Severe injuries caused by using defective power cords! Check the power supply connection cable for damage, e.g. cracks in the insulation.
  - If required: Contact Sartorius Service.
- **NOTICE** Device damage due to unsuitable mains plugs. Only use Sartorius Stedim Biotech mains plugs.
- **NOTICE** Damage due to high input voltage! Ensure that the voltage indications on the Manufacturer's ID label match the voltage supply at the installation location.
  - If the input voltage is too high: Do **not** connect the device to the power supply.
  - Contact Sartorius Service.
- Check whether the country-specific mains plug (1) matches the mains connection at the installation location.
  - If required: Contact Sartorius Service.
- Connect the device to the power supply.

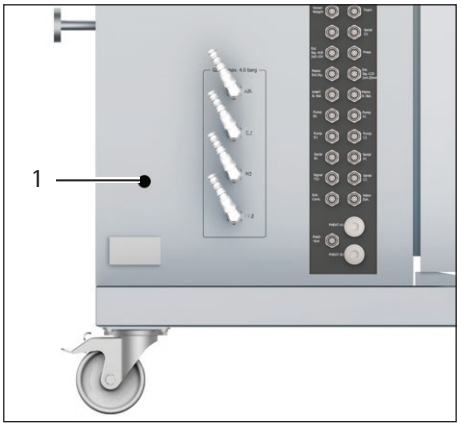
6.6.2 Connection for Bag Holder



Procedure

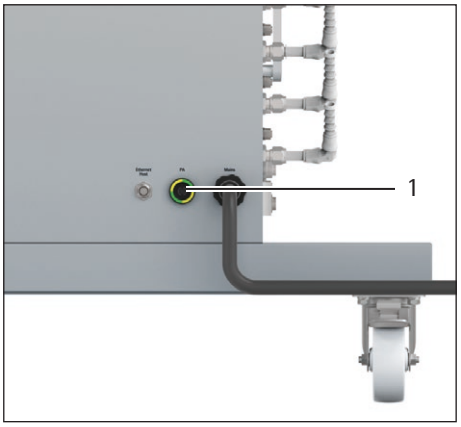
- ⚠ **WARNING** Severe injuries caused by using defective power cords! Check the power supply connection cable for damage, e.g. cracks in the insulation.
  - If required: Contact Sartorius Service.
- **NOTICE** Device damage due to unsuitable mains plugs. Only use Sartorius Stedim Biotech mains plugs.
- **NOTICE** Damage due to high input voltage! Ensure that the voltage indications on the Manufacturer's ID label match the voltage supply at the installation location.
  - If the input voltage is too high: Do **not** connect the device to the power supply.
  - Contact Sartorius Service.
- Check whether the country-specific mains plug (1) matches the mains connection at the installation location.
  - If required: Contact Sartorius Service.
- Connect the device to the power supply.

6.6.3 Establishing Potential Equalization



Procedure

▶ Connect the grounding cable of the bag holder to the port for the grounding cable "PA" PA (1) of the control / supply unit.



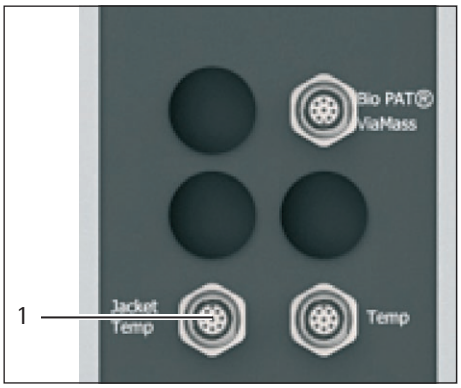
▶ Connect a grounding cable to the grounding port labeled "PA" PA (1) of the control / supply unit and the building's earth ground connection.

6.7 Setting up Temperature Control Circuit

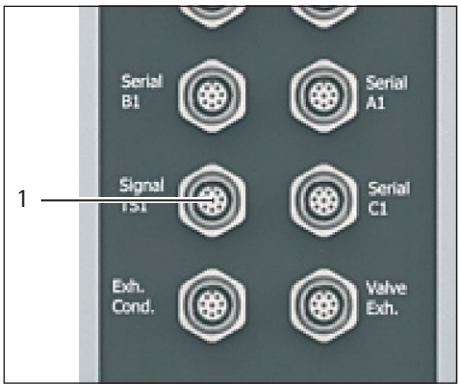
6.7.1 Connecting the Temperature Sensor and the Signal Cable

Bag holder 1 is used as an example in the following chapters to demonstrate how to setup the temperature control circuit.

Procedure



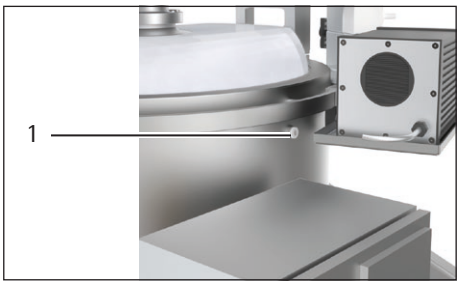
▶ Connect the temperature sensor in the temperature control circuit to the M12 connector Jacket Temp (1) of the control / supply unit.



▶ Connect the signal cable of the temperature control unit to the M12 connector signal TS1 (1) of the control / supply unit.

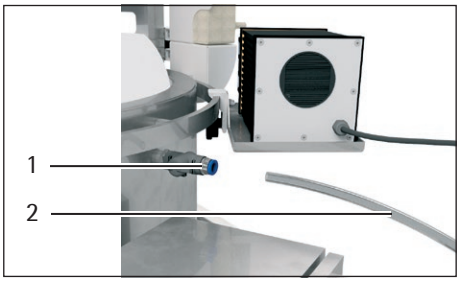
6.7.2 Installing and Preparing the Double-walled Vent Valve

Procedure



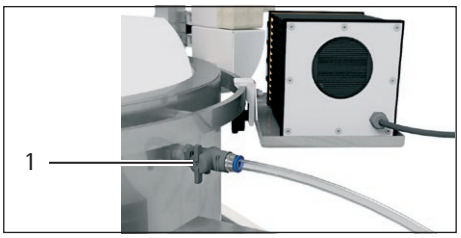
▶ Unscrew the plug (1) from the vent hole.

▶ Screw the double-walled vent valve into the vent hole.



▶ Insert the vent tube (2) into the tube connection (1) of the double-walled vent valve.

▶ Place the open end of the vent tube into a drain or into a vessel.

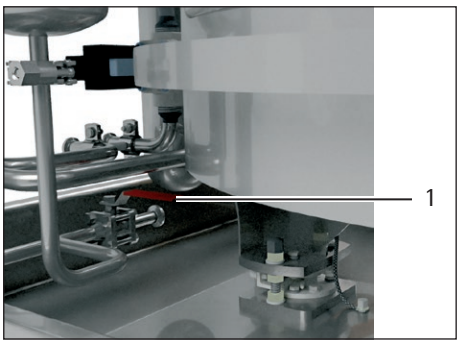


▶ Close the double-walled vent valve (1).

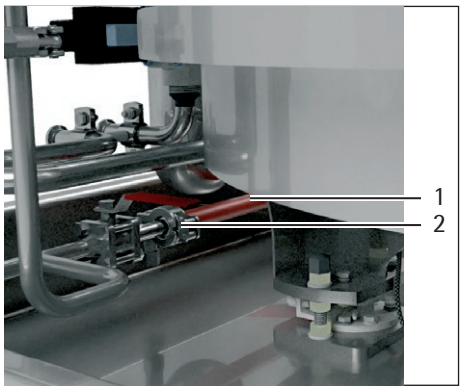
6.7.3 Preparing the Filling Valve

Material: Filling tube for Tri-Clamp connection 25 mm

Procedure

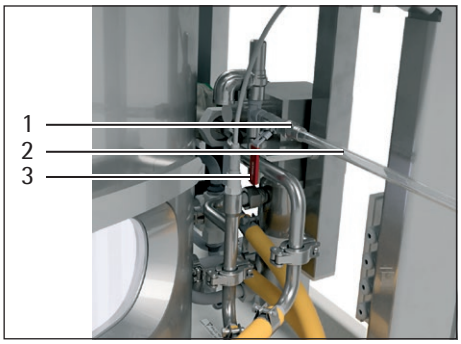


▶ Close the filling valve. Rotate the lever (1) of the filling valve perpendicular to the position of the flow direction.



▶ Connect the filling tube (1) to the connection (2) of the filling valve.

6.7.4 Preparing the Temperature Control Circuit Vent Valve



▶ Insert the temperature control circuit vent tube (2) into the tube connection (1) of the temperature control circuit vent valve.
▶ Place the open end of the temperature control circuit vent tube into a drain or into a vessel.
▶ Close the temperature control circuit vent valve (3).

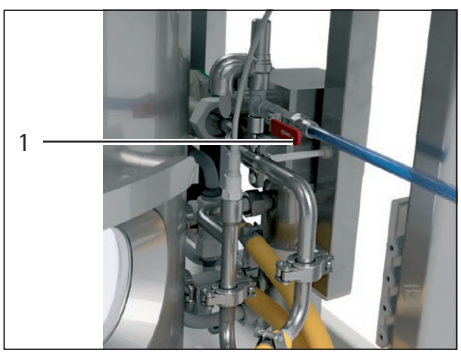
6.7.5 Filling and Venting the Double Wall

Requirements

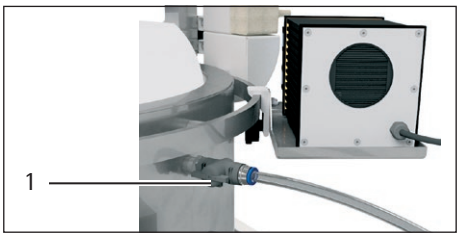
– The bag holder has been set up and leveled.
– The power is off to the bioreactor and temperature controller.

Procedure

▶ **NOTICE** Damage from an unsuitable heat transfer fluid! Contaminated heat transfer fluid can damage the pumps, fittings or sensors, e.g.: Lime deposits, corrosion or algae formation.
  ▶ Use a suitable heat transfer fluid (see Chapter 15.5, page 195).
  ▶ If required: Install a prefilter.
  ▶ Only use suitable tubes, fittings, and fixation materials for laboratory connections.

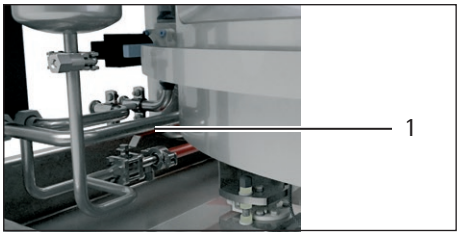


▶ Open the temperature control circuit vent valve (1).

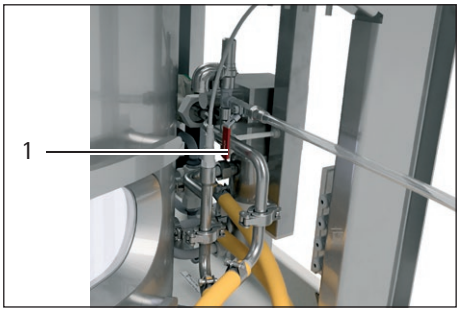


▶ Open the double-walled vent valve (1).

▶ **NOTICE** The system may be damaged due to high pressure on the temperature control circuit! The pressurization of the temperature control circuit must not exceed the maximum value (for max. value, see Chapter "15.5 Heat Transfer Fluid Double Wall," page 195). Check the pressurization using the pressure gauge (1).

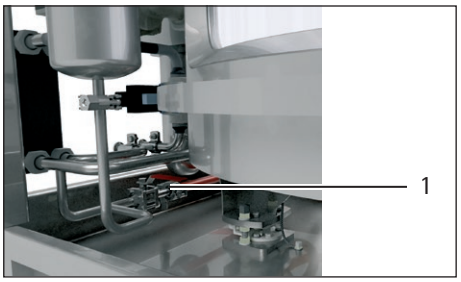


▶ If the device is operated without a pressure controller: Only partially open the filling valve.
▶ To open the filling valve: Rotate the lever (1) slowly parallel to the tube.
▷ The double wall of the bag holder and the temperature control circuit are filled with the heat transfer fluid.



▶ If heat transfer fluid is leaking out of the temperature control circuit vent valve: Close the temperature control circuit vent valve (1).
▷ The double wall continues to fill and vent.

▶ Once air is **no** longer escaping from the double-walled vent valve: Open the temperature control circuit vent valve and close the double-walled vent valve.
▷ The air collected in the TCU is released.
▶ Once air is **no** longer escaping from the temperature control circuit vent valve: Close the filling valve (1) and the temperature control circuit vent valve.
▷ All filling and vent lines from the double wall and temperature control circuit are closed.

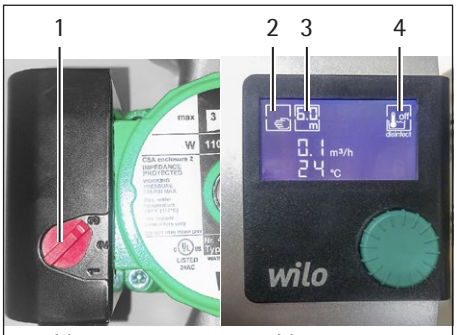


6.7.6 Venting the Temperature Control Circuit

Requirements

- **No** bag is installed.
- The TCU box is switched on.
- The control / supply unit is switched on.
- The switch for the respective unit for the bag holder to be filled is switched on at the control / supply unit.

Procedure

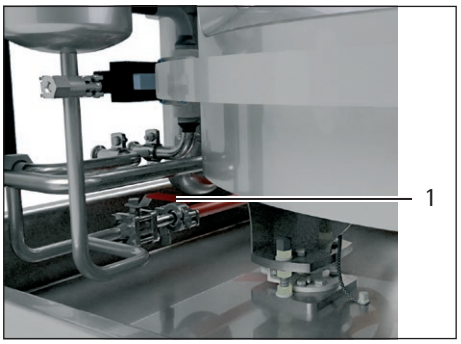


208 V system (example) 400 V system (example)

▶ If a 208 V system is installed: Set the circulation pump for the temperature control circuit to maximum delivery pressure under constant differential pressure (1) (see circulation pump operating instructions).

▶ If a 400 V system is installed:
  ▶ Switch the pump to manual operating mode (2) (see circulation pump operating instructions).
  ▶ Set a constant differential pressure of 6 m (3) (see circulation pump operating instructions).
  ▶ Deactivate thermal disinfection (4) (see circulation pump operating instructions).

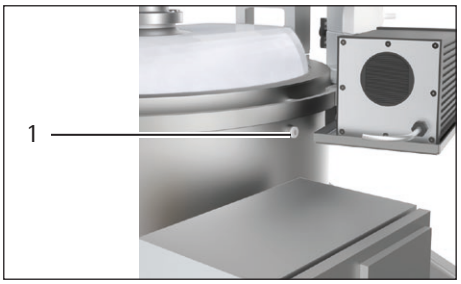
▶ Set the controller [JTEMP] to 10°C on the control / supply unit. The temperature must be lower than the room temperature of the temperature sensor.
▷ The pump pumps at maximum flow rate.
▶ If a 400 V system is installed:
  ▷ A power consumption of 40 W to 45 W is displayed on the pump after approx. 1 – 2 minutes.
  ▶ If the pump keeps on displaying a lower power consumption, e.g. only 15 W or the error E11: There is still air in the system. Repeat venting with the filling valve and vent valve.
▷ The air remaining in the temperature control circuit collects in the upper part of the double wall.
▶ Turn off the controller [JTEMP] at the control / supply unit after approx. 5 minutes.
▶ Open the temperature control circuit vent valve and the double-walled vent valve.
▶ Open the filling valve slowly.
▶ If only heat transfer fluid is emerging from the vent lines without air: Close the filling valve.
▶ Close the temperature control circuit vent valve and the double-walled vent valve.
▶ Set the controller [JTEMP] to 50°C on the control / supply unit.
▶ Heat the system to 50°C.
▶ Set the controller [JTEMP] to 20°C.
▶ Allow the system to cool to 20°C.
▶ If you can hear any noises from air bubbles in the double wall: Fill the double wall and vent the temperature control circuit again.
▶ If you can **no longer** hear any noises from air bubbles in the double wall:



- Close the filling valve (1).
- Turn off the heat transfer fluid supply.
- ⚠ **CAUTION** Risk of injury from pressurized media! Media escaping under pressure can lead to injuries, e.g. eye injuries.
  - Wear personal protective equipment.
  - Close the supply lines.
  - Carefully disconnect the filling tube and supply tubes. Disconnect and hold the tubing ends. Keep the tubing ends away from body orifices.
  - Secure the filling valve and the temperature control circuit venting valve against opening with a cable clip.

6.7.7 Uninstalling the Double-walled Vent Valve

Procedure



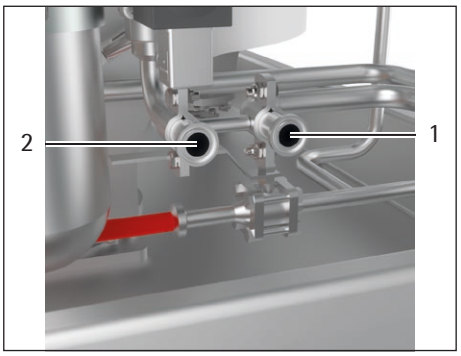
- Remove the double-walled vent valve from the vent hole.
- Screw the plug into the vent hole (1).

6.8 Connecting Coolant Supply

Requirements
Material:
– 1 tube for inlet line of heat transfer fluid
– 1 tube for return line of heat transfer fluid

Procedure

- ⚠ **WARNING** Improperly installed fittings can come off unexpectedly! Avoid improper installation. The startup of the heat transfer fluid supply must be carried out by an authorized specialist.
- **NOTICE** Damage can be caused by an unsuitable heat transfer fluid! Contaminated heat transfer fluid can damage the pumps, fittings or sensors, e.g.: Limescale deposits, corrosion or algae formation. Check the suitability of the heat transfer fluid (suitable heat transfer fluid, see Chapter "15.4 Heat Transfer Fluid Supply," page 195).
  - If required: Install a prefilter.
  - Only use suitable tubes, fittings and fixation materials for laboratory connections.



- Connect the tube for the inlet (1) to the bag holder connection.
- Connect the tube for the outlet (2) to the bag holder connection.
- Secure the connections carefully and ensure they cannot become loose inadvertently.
- Before the inlet is opened: Ensure that the supply pressure is set correctly.
- Connect the tubing without kinks.
- Check regularly to make sure that excess water can run off unimpeded.

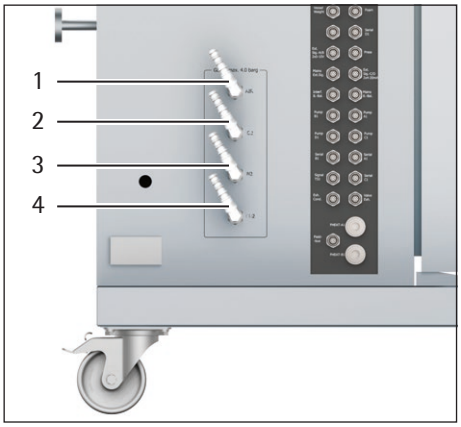
6.9 Connecting Gas and Compressed Air Supply

The startup process for the gas and compressed air supply for bag holder 1 is shown in the following section.

Procedure

- ⚠ **WARNING** Improperly installed fittings can come off unexpectedly! Avoid improper installation. The startup of the gas and compressed air supply must be carried out by an authorized specialist.
- ⚠ **WARNING** The gases are under high pressure. Do not open the gas tubes (maximum pressure allowed, see Chapter "15.7 Gas and Compressed Air Supply," page 196).
- **NOTICE** Damage to the device due to contaminated gases or compressed air! Check the suitability of the gases and compressed air (permissible gases, compressed air and maximum pressure, see Chapter "15.7 Gas and Compressed Air Supply," page 196).
  - If required: Install a prefilter.

- When connecting the tubing, make sure that they are not bent, kinked or stretched.



- Connect the control / supply unit to the gas supply:
  - Gas supply — compressed air [Air] (1)
  - Gas supply — oxygen [O2] (2)
  - Gas supply — nitrogen [N2] (3)
  - Gas supply — carbon dioxide [CO2] (4)

6.10 Inserting Tubing into the Peristaltic Pumps

⚠ WARNING

Danger of limbs being pulled into the rotation pump and crushed!

Only allow qualified personnel to work on the device. Deactivate the associated controller function of the control / supply unit.

NOTICE

If the two tube clamps are in the position for small tubes and larger tubes are used: The flow rate and tubing lifespan are reduced.
If the two tube clamps are in the position for large tubes and smaller tubes are used: There is a risk that the tubing will enter into the pump head and burst.

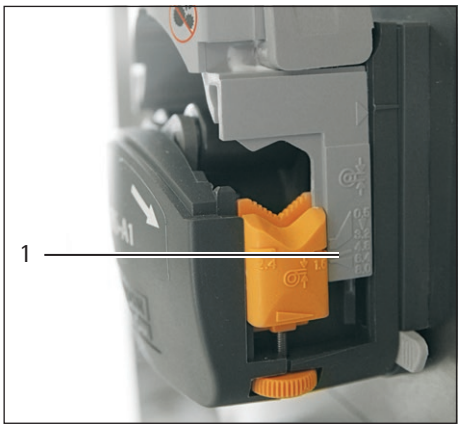
Requirements

Disconnect the pump before installing any tube. It is possible to put tubes with different tube diameters into the peristaltic pump. The tube clamps must be adjusted to the cross-section of the inner tubing used.

Procedure

▶ Open the peristaltic pump: Lift the lid upwards and open it completely.

▶ Adjust the two tube clamps for the tube cross-section used: Adjust the tube clamps to the desired height using the two knurled screws (1).



- ▶ Adjust the height (1) on the housing of the peristaltic pump according to the scale.
- ▶ Given greater suction heights: Tighten the tube clamps until the hose is securely fixed.

- ▶ **NOTICE** Unsuitable tubing material may damage the peristaltic pump!

- ▶ Make sure that there is sufficient hose available for the curvature inside the pump's track. The hose must **not** be twisted or overtensioned.
- ▶ Position the hose between the rotor rollers and the guide track and press it against the inner wall of the pump head.

- ▶ Carefully lower the lid (1) until it locks into the closed position. The hose must not be compressed or stretched in the hose clamps.
- ▷ The track closes automatically and the tubing stretches properly.

- ▶ To remove the tube element, perform the steps in reverse order.

- ▶ Before starting automatic control of the correction medium supply: Fill the tubing with correction medium. To this end, manually activate the peristaltic pumps (see Chapter "4.4.1 Pump Operating Mode Selection Screen," page 39).
- ▶ When the tubing is filled with the correction medium up to the bag end: On the control / supply unit, switch back to automatic control of the correction medium supply.

6.11 Installing the Probe Holder

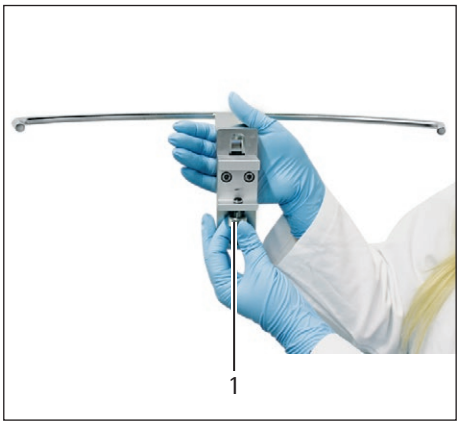
⚠ CAUTION

Danger of injury due to unsuitable probe holder!

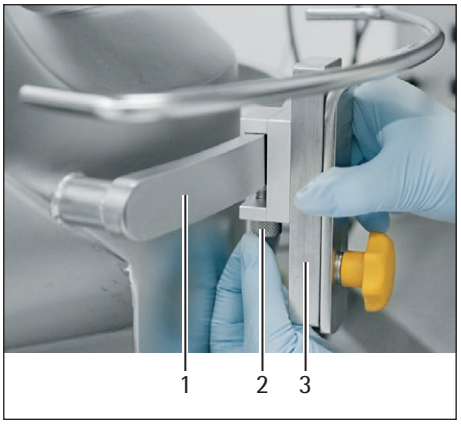
An unsuitable probe holder can lead to leakages between sensor and sensor port. Media may leak out of the bag and cause injury.

▶ Only install the probe holder for the corresponding bag holder.

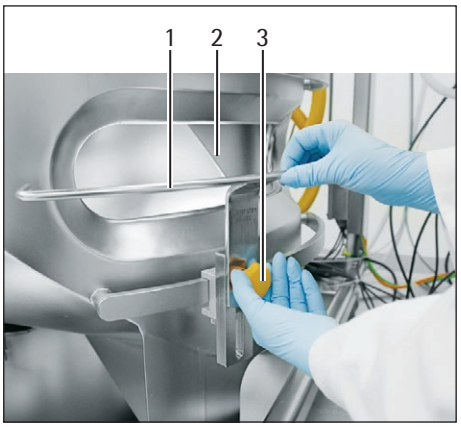
Procedure



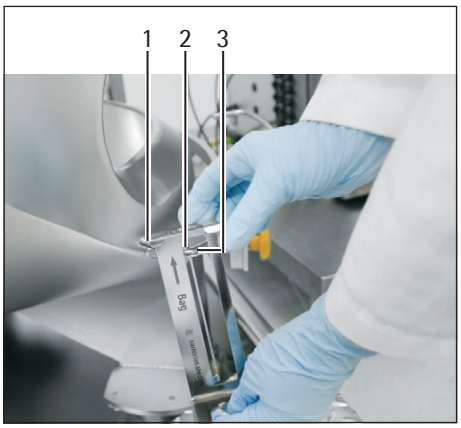
▶ Loosen the knurled screw (1) on the probe support arm.



▶ Place the probe support arm (3) on the lower side of the system rail (1).
▶ To fix the probe support arm: Tighten the knurled screw (2).



▶ Align the probe support arm (1) with the probe window (2):
  ▶ Release the star grip (3).
  ▶ Align the probe support arm vertically.
  ▶ Tighten the star grip.



- ▶ Push the probe clamp (1) with the opening (2) over the probe support arm (3).
- ▷ The arrow on the probe clamp must be aligned with the bag holder.
- ▶ To align the probe clamps for the process: Align the probe clamps after installing the bag and the conventional sensors (for installation of the sensors, see Chapter 7.8.5, page 102).

7 Process Preparation

7.1 Overview of the Process Preparation

The work to be done in order to put the device into operation and prepare for the cultivation process comprise the following key measures:

Assembly steps	Chapter, page
Setting up bag holder	7.3, 69
Unpacking bag	7.4, 73
Installing bag in bag holder	7.5, 81
Installing filter heater	7.6, 93
Installing Tri-Clamp connection on a filter capsule	7.7, 94
Installing sensors on the bag	7.8, 97
Filling the bag	7.9, 105

7.2 Inspecting the Device and Device Equipment

Procedure

▶ Make sure that the following conditions are met at the workplace:

- The device equipment and gaskets have been inspected.
- ⚠ **WARNING** Risk of injury due to damaged tubes and fittings! Damaged tubes and fittings can lead to the uncontrolled escape of heat transfer fluid. Escaping heat transfer fluid can cause scalding.
  - The heat transfer fluid tubes have been tested.
  - The screws and lock nuts have been checked.

7.3 Setting up Bag Holder

⚠ CAUTION

Danger of crushing in the door frame of the bag holder!

Fingers and hands can be crushed when the door of bag holder is closed.

▶ Wear personal protective equipment.

▶ Do **not** touch the door frame of the bag holder when closing the door.

7.3.1 Bag Holder Setup Overview

The work to set up the bag holder includes the following key measures:

Assembly steps	Chapter, page
Preparing drain port holder	7.3.2, 70
Preparing filter holder	7.3.3, 71

7.3.2 Preparing Drain Port Holder

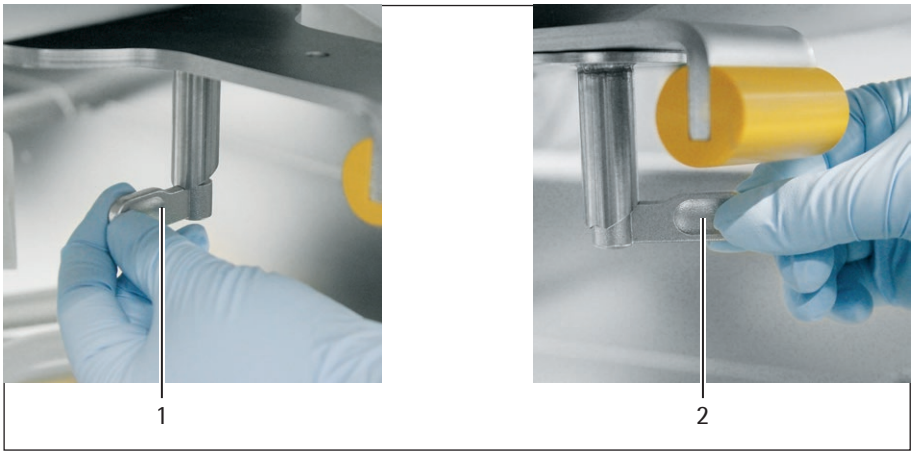
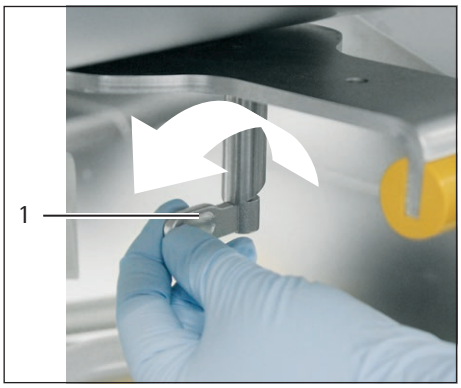


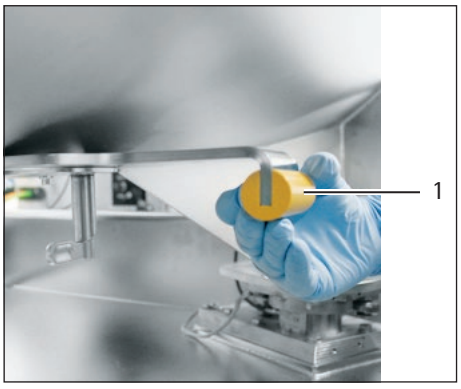
Fig. 31: Unlocking and locking the drain port holder

No.	Designation	Description
1	Lever position in the unlocked position	The drain port holder is unlocked.
2	Lever position in the locked position	The drain port holder is locked.

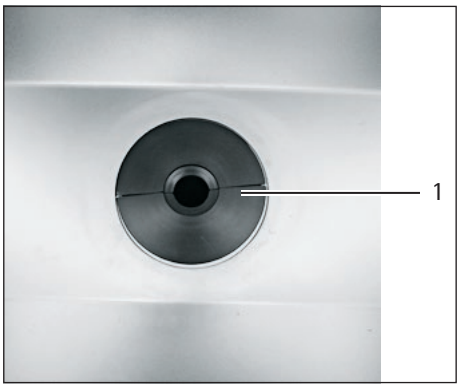
Procedure



▶ To open the drain port holder: Turn the lever (1) to the unlocked position.



▶ Pull the handle (1) towards you.



▶ Remove the fitting cone (1) from the drain port holder.

7.3.3 Preparing Filter Holder

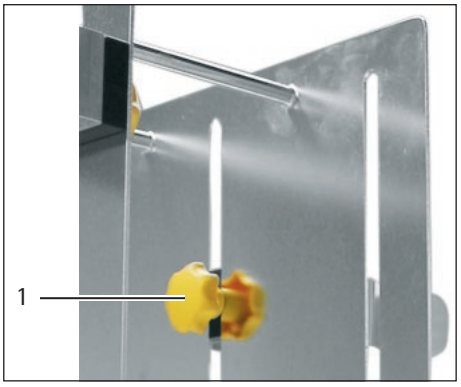
⚠ CAUTION

Danger of crushing by the overhanging filter holder!

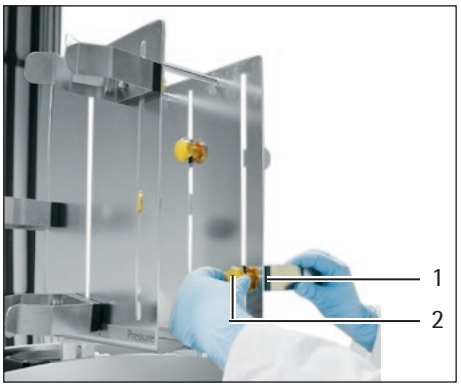
When working in the area of the filter holder, the head striking the filter holder may result in injury.

▶ Wear personal protective equipment.
▶ Remain prudent and focused when working.

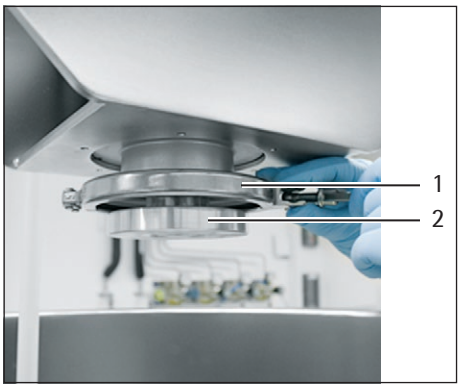
Procedure



▶ Loosen the 6 star screws (1) on the filter holder.



▶ Slide the 6 clips (1) downwards.
▶ To fix the clips: Tighten the star screws (2).



▶ Loosen the Tri-Clamp clip (1) on the magnetic coupling (2) of the motor.

▶ Unlock the bag holder door (1).
▶ Open the door.

7.4 Unpacking the Bag

NOTICE

Damage due to improperly unpacking the bag!

A damaged bag can lead to functional and operational disturbances.

▶ Carefully note the procedure for unpacking the bag.

The procedure for unpacking the bags is presented using the Flexsafe STR® 500 L as an example. Deviations in the procedure for other versions are indicated accordingly.

Personnel:

– Flexsafe STR® 500 L | 1000 L bag	3 persons
– Flexsafe STR® 50 L | 200 L bag	2 persons
Tools:	Scissors

Procedure

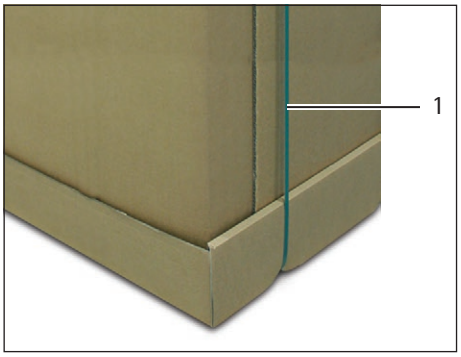
▶ Remove the protective wrapping (1).

▶ **NOTICE** Transportation is unsafe when the bands (1) stretched around the transport packaging (2) are removed. Do not cut the bands.

▶ Cut and remove the bands (3) secured to the pallet.

▶ ⚠ **CAUTION** Cuts from sharp edges on the bands! Do **not** lift the transport packaging by the bands. Lift the transport packaging at the corners and set it down on the ground (for details of the weight of the bag and packaging, see Chapter "15.13.3 Bag," page 198).

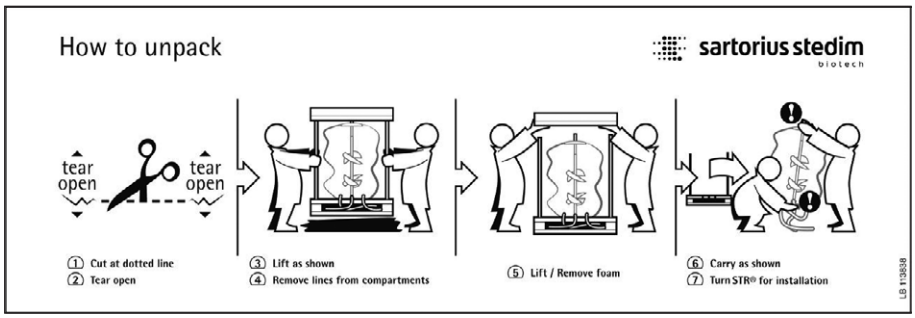
▶ Cut and remove the bands (1).

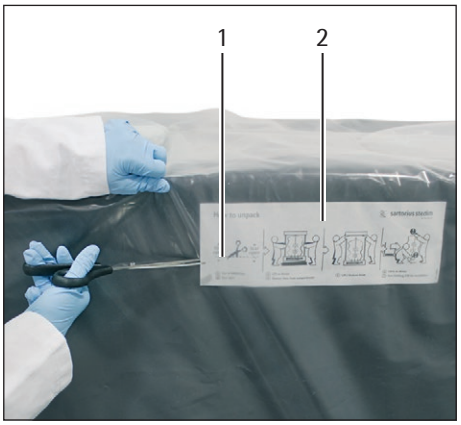


▶ In order to remove the lid (1) from the transport packaging:
  ▶ Flexsafe STR® 50 L | 200 L: Take the lid off of the transport packaging.
  ▶ Flexsafe STR® 500 L | 1000 L: Remove the lid from the transport packaging with a second person.

▶ To remove the lateral packaging (1):
  ▶ Flexsafe STR® 50 L | 200 L: Lift and remove the lateral packaging out from the bottom of the transport packaging.
  ▶ Flexsafe STR® 500 L | 1000 L: Lift and remove the lid of the transport packaging from the bottom of the transport packaging with a second person.

- ▶ To remove the lower part of the transport packaging: Lift the packaged bag at the 4 tube elements (1).
- ▶ Set the packaged bag down next to the transport packaging.
- ▷ On the black bag of the packaging, there is a pictogram showing additional information on how to proceed.





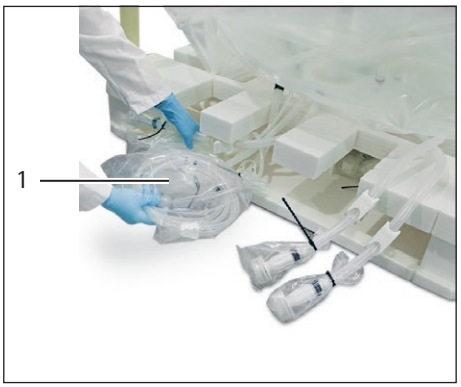
- ▶ Dispose of the transport packaging and the transport pallet.
- ▶ Carefully cut the transparent bag along the mark (1) shown on the pictogram (2).

- ▶ Pull the lower part of transparent bag (1) downwards.
- ▶ Remove the upper part of the transparent bag (2).
- ▶ In order to remove the lower portion of the transparent bag: Lift the packaged bag at the 4 tube elements.
- ▶ Set down the packaged bag.
- ▶ Discard the transparent bag.

- Carefully cut the black bag and the transparent bag underneath it along the mark (1) shown on the pictogram (2).

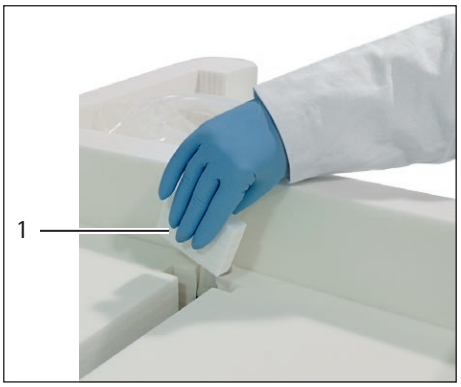
- Pull the lower part of the black and the transparent bag (1) downwards.
- Remove the upper parts of the black and the transparent bag (2).

- To remove the lower portions of the black and the transparent bag: Lift the packaged bag at the 4 tube elements (1).
- Set down the packaged bag next to the black and the transparent bags.
- Discard the black and the transparent bag.



▶ Remove the tubes (1) from the lower foam element.

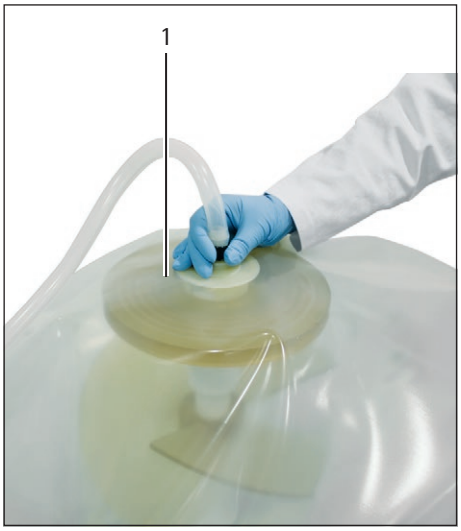
▶ Flexsafe STR® 50 L | 200 L: Remove the drain line (1).



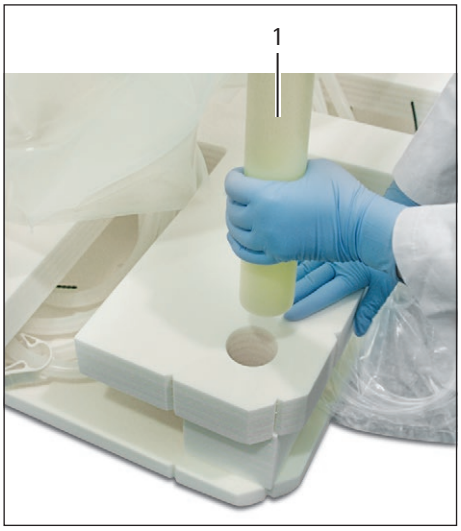
▶ Flexsafe STR® 500 L | 1000 L: Remove the fixing element (1) that is holding the drain line in place..

▶ Flexsafe STR® 500 L | 1000 L: Remove the drain line (1).

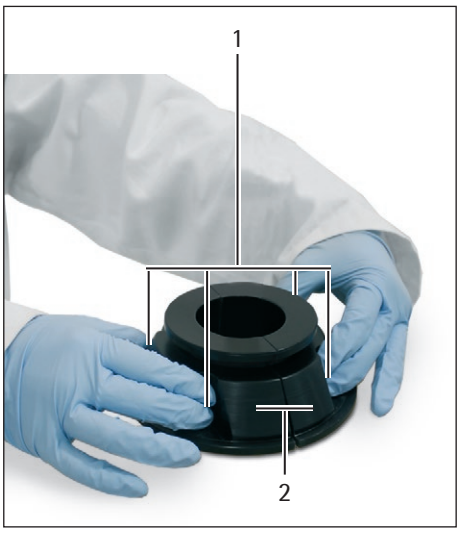
- To remove the upper foam element:
  - Flexsafe STR® 50 L | 200 L: Remove the 2 foam elements.
  - Flexsafe STR® 500 L | 1000 L: Take off and remove the foam element with a second person.



- To remove the 4 tube elements:
  - User 1: Firmly hold the bag at the drain port.

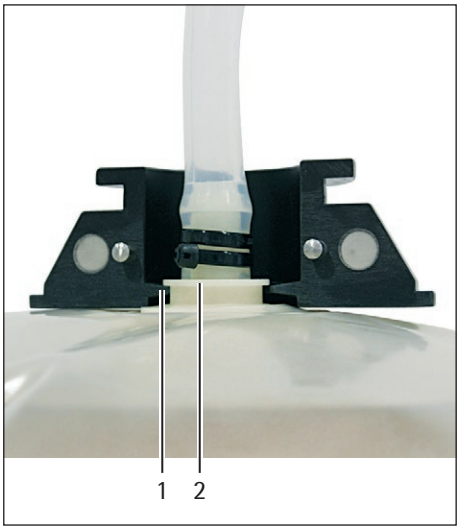


  - User 2: Remove the 4 tube elements from the recesses in the lower foam element.



▶ To prepare the fitting cone for the installation:
  ▶ Place the fingers of your right and left hand in the recessed grips (1) provided on the fitting cone.
  ▶ Pull the two fitting cone elements (2) apart.

▶ ⚠ **CAUTION** Danger of crushing the fingers when securing the fitting cone on the drain port! The contact surfaces of the fitting cone elements are magnetic and join together abruptly when assembled. Hold the fitting cone elements (1) by the recessed grips and lay them around the drain port.



▶ **NOTICE** Damage to the bag if the cone is in the wrong position. Check the position of the fitting cone.
▷ The fitting cone collar (1) must be located below the drain port ring (2).

- ▶ Push the two fitting cone elements (1) together.
- ▶ Remove the drain line tube from the dust bag.

- ▶ To reduce the dead volume in the tube: Position the clip (2) as far as possible on the fitting cone (1).
- ▶ Close the clip.

- ▶ **NOTICE** Damage to the bag by improper lifting and during improper transport. Only lift and transport the bag using the hard plastic elements of the top port (1) and drain port (2).
  - ▶ User 1: Lift the bag at the top port.
  - ▶ User 2: Lift the bag at the drain port.
- ▶ Remove the bag from the lower foam element.
- ▶ Flip the bag.
- ▷ The top port is oriented upwards and the drain port downwards.

7.5 Installing Bag in Bag Holder

⚠ CAUTION

Risk of injury caused by bursting of the bag!

Overpressure in the bag can cause it to rupture.

▶ Observe the following guidelines before aerating the bag:
- The pressure measuring section must be installed.
- The bag must be carefully installed in the bag holder. The film of the bag must **not** be clamped.
- The tubing must **not** be pinched or be kinked.

NOTICE

Functional and operational disturbances from installing unsuitable bags!

The bag holders may only be operated with Sartorius Flexsafe STR® bags.
The Flexsafe STR® bags for the bag holder STR® 50 | 200 are equipped with a telescopic shaft.

▶ Do **not** insert bags without a telescopic shaft in the STR® 50 | 200 bag holder, e.g. STR® 50 | 200 Cultibags.

NOTICE

Functional and operational disturbances from improper bag installation!

An improperly installed bag can be damaged and lead to functional and operational disturbances during the process.

▶ Note the procedure for installing the bag.

7.5.1 Bag Installation Overview

The work to install the bag in the bag holder includes the following key measures:

Assembly steps	Chapter, page
Securing bag in drain port holder	7.5.2, 82
Setting up exhaust air and aeration segment	7.5.3, 84
Inflating bag	7.5.4, 88
Connecting top port with magnetic coupling	7.5.5, 90

The procedure for installing bags is illustrated using the example of the Flexsafe STR® 500 L version. Deviations in the procedure for other versions are indicated accordingly.

7.5.2 Securing Bag in Drain Port Holder

Personnel:

– Flexsafe STR® 500 L | 1000 L bag 3 persons
– Flexsafe STR® 50 L | 200 L bag 2 persons

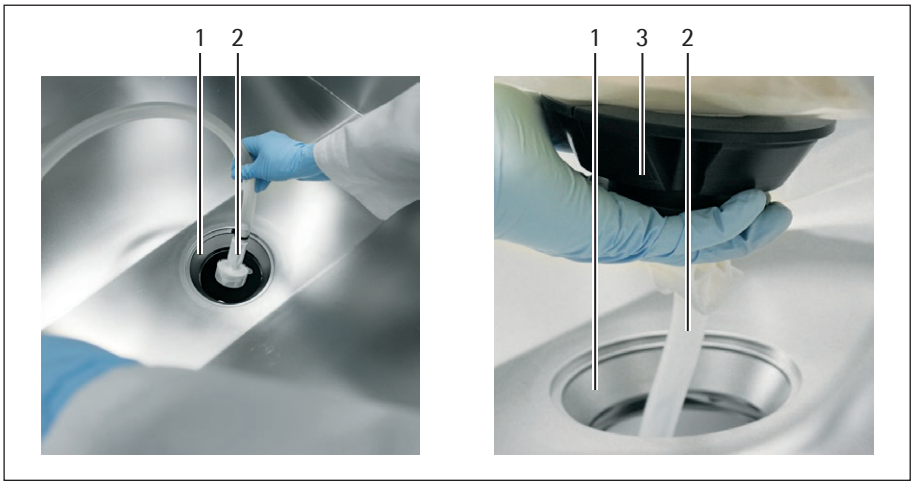


Fig. 32: Drain port holder in the bag holder

No.	Designation	Description
1	Drain port holder	Accommodates the drain port fitting cone.
2	Drain line	Drains media out of the bag.
3	Fitting cone	Connects the drain port and the drain port holder.

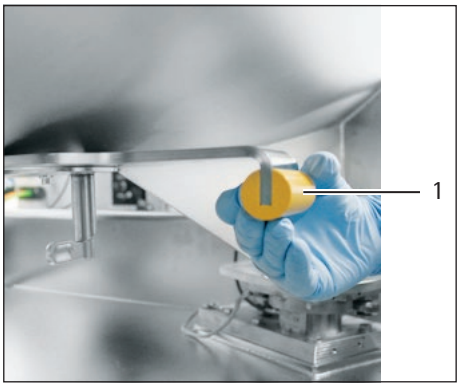
Procedure

▶ Open the bag holder door.
▶ **NOTICE** Damage to the bag due to improper lifting. Lift the bag by the hard plastic elements of the top port and drain port and align in front of the bag holder:
  – The sensor ports for the temperature sensor and for the sampling are aligned with the left sensor window.
  – The tubes inside the bag are aligned with the door opening of the bag holder.

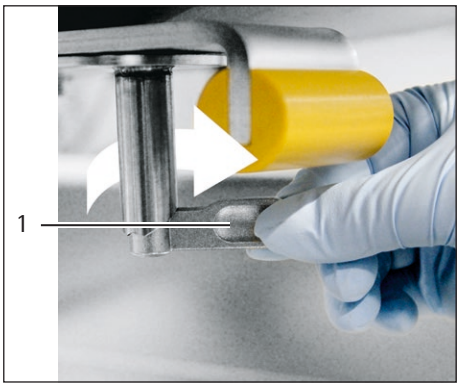
Guiding the Drain Line Through the Drain Port Holder

▶ Flexsafe STR® 500 L | 1000 L Bag: With 3 people, lift the bag over the double outer wall into the bag holder:
  ▶ Person (1) holds the top port. The top port must be held in a vertical position until the magnetic coupling is connected to the top port.
  ▶ Person (2) holds the drain port fitting cone.
  ▶ Person (3) reaches with their left hand through the left sensor window and guides the drain line further through the drain port holder.
  ▶ Person (3) takes the drain port fitting cone from person (2) and puts it into the drain port holder.

- ▶ Flexsafe STR® 50 L | 200 L Bag: With 2 people, lift the bag over the double outer wall into the bag holder:
  - ▶ Person (1) holds the top port. The top port must be held in a vertical position until the magnetic coupling is connected to the top port.
  - ▶ Person (2) holds the drain port fitting cone with their right hand and guides the drain line through the drain port holder.
  - ▶ Person (2) reaches with their left hand through the left sensor window and sticks the drain port fitting cone into the drain port holder.



- ▶ **NOTICE** Damage to the stirrer shaft of the stirring system if the drain port holder is **not** secured. Securing the drain port holder:
  - ▶ To close the drain port holder: Press the handle (1) in the direction of the drain port holder.
  - ▶ The drain port holder cannot be closed: Check the position of the fitting cone, adjust if necessary and repeat the closing process.



  - ▶ To lock the drain port holder: Turn the lever (1) to the locked position.
- ▷ The bag is connected to the drain port.

- ▶ Flexsafe STR® 500 L | 1000 L bag: Setting up the exhaust air and aeration segment (see Chapter "7.5.3 Setting up the Exhaust Air and Aeration Segment," page 84).
- ▶ Flexsafe STR® 50 L | 200 L bag: Connect the top port of the bag with the magnetic coupling (see Chapter 7.5.5, page 90).

7.5.3 Setting up the Exhaust Air and Aeration Segment

Personnel:

- Flexsafe STR® 500 L | 1000 L bag 2 persons
- Flexsafe STR® 50 L | 200 L bag 1 person

Requirements

- The bag is connected to the drain port.
- Flexsafe STR® 500 L | 1000 L bag: The bag is held in a vertical position by one person.
- Flexsafe STR® 50 L | 200 L bag: The top port is connected to the magnetic coupling.

⚠ WARNING

Danger of injury due to escaping compressed gases or pressurized media!

Escaping compressed gases or media escaping under high pressure can lead to injuries, e.g. eye injuries.

▶ Wear personal protective equipment.
▶ Close the supply lines.
▶ Carefully disconnect the supply tubes. Disconnect and hold the tubing ends. Keep the tubing ends away from body orifices.
▶ Follow any other manufacturer's operating instructions for additional components.
▶ Follow the construction guidelines required to ensure that the device is stable

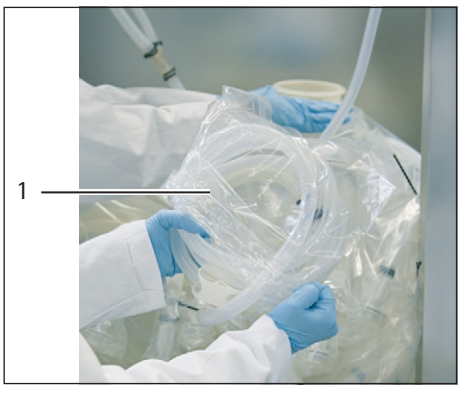
⚠ CAUTION

Danger of crushing by the overhanging filter holder!

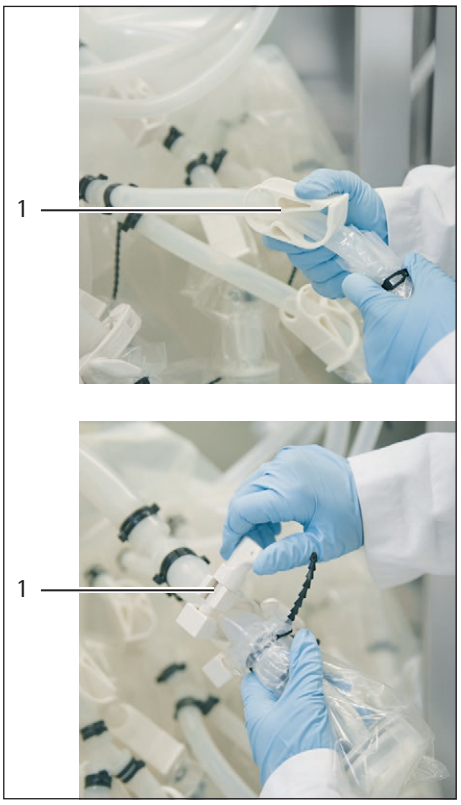
When working in the area of the filter holder, the head striking the filter holder may result in injury

▶ Wear personal protective equipment.
▶ Remain prudent and focused when working.

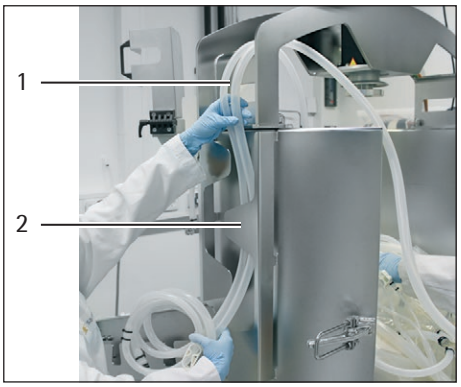
Procedure



▶ Remove the dust covers from the long tubes, e.g. feed tubes and connectors.
▶ Do **not** remove the dust covers from the short tubes, e.g. aeration tubes and exhaust tube.
▷ The caps of the short tubes can fall into the bag holder during setup.



▶ Close all clamps (1) on the tubes.

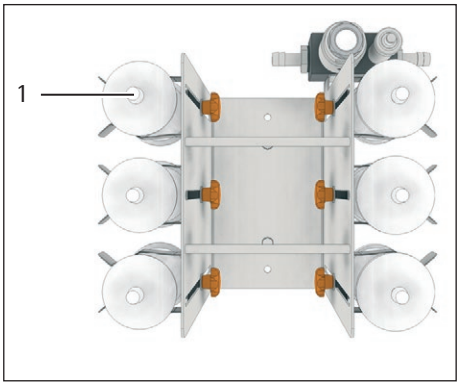


▶ Insert the tubing (1) into the tubing holder (2).

Exhaust Air Segment

Procedure

▶ Remove the dust cover from the exhaust tubing.
▶ Remove the exhaust air filter capsule from the packaging.
▶ Connect the exhaust air filter capsule to the exhaust tubing of the bag via the OPTA coupling (see Chapter 1.2, page 8).
▶ Clamp the exhaust air filter capsule in the position (1) of the filter holder.
▶ Flexsafe STR® 50 | 200 L bag: Adjust the setting height of the filter clamp on the filter holder so that the exhaust tubing is not kinked.
  ▶ Secure the filter clamp.



Headspace Aeration (Overlay) Flexsafe STR® 500 | 1000 L Bag

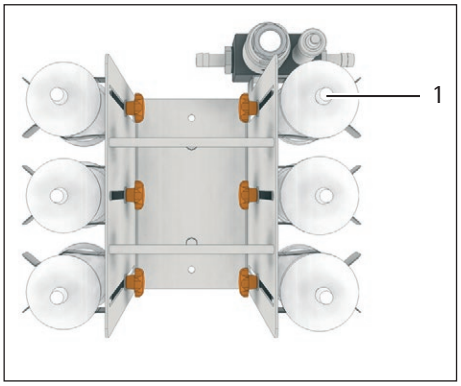
Procedure

- ▶ Setting up the aeration segment for the headspace:
  - ▶ Remove the dust cover from the aeration tube.
  - ▶ Remove the filter capsule from the packaging.
  - ▶ Connect the filter capsule to the aeration segment of the bag via the OPTA coupling (see OPTA Sterile Connector Operating Instructions).
  - ▶ Connect the filter capsule and the control / supply unit with the aeration tube (see Chapter 7.7, page 94).
  - ▶ Do **not** clamp the filter capsule in the filter holder.
  - ▶ Place the aeration tube carefully over the top edge of the bag holder.
- ▶ Set up the pressure sensor segment:
  - ▶ Remove the dust cover on the pressure sensor tubing.
  - ▶ Remove the pressure sensor filter capsule from the packaging.
  - ▶ Connect the pressure sensor filter capsule to the pressure sensor segment of the bag via the OPTA coupling (see OPTA Sterile Connector Instructions).
  - ▶ Connect the pressure sensor filter capsule and the pressure sensor with the aeration tube (see Chapter 7.7, page 94).
  - ▶ Do **not** clamp the pressure sensor filter capsule in the filter holder.
  - ▶ Place the aeration tube carefully over the top edge of the bag holder.

Headspace Aeration (Overlay) Flexsafe STR® 50 | 200 L Bag

Procedure

- ▶ Remove the dust cover from the aeration tube.
- ▶ Remove the filter capsule from the packaging.
- ▶ Connect the filter capsule to the aeration segment via the OPTA coupling (see OPTA Sterile Connector Instructions).
- ▶ Clamp the filter capsule in the position (1) of the filter holder.
- ▶ Connect pressure sensor and the aeration segment (see Chapter 7.7, page 94).
- ▶ Connect the pressure sensor and the control / supply unit with the aeration tube.
- ▶ Adjust the setting height of the filter clamp on the filter holder so that the aeration tube is not kinked.
- ▶ Secure the filter clamp.



Medium Aeration (Sparger)

When using a Combi-sparger (ring sparger and micro sparger), 2 filter capsules must be installed.

Fig. 33: Aeration tubing of the micro sparger, marking

No.	Designation	Description
1	Orange cable tie	Identifies the aeration tubing of the micro sparger.

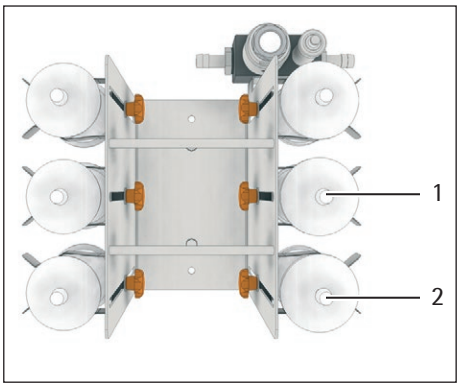
The installation procedure is shown using the example of a filter capsule.

Requirements

Flexsafe STR® 500 L | 1000 L bag:

- The bag is inflated (see Chapter 7.5.4, page 88).
- The top port of the bag is connected to the magnetic coupling of the motor (see Chapter 7.5.5, page 90).

Procedure



- ▶ Remove the dust cover from the aeration tube.
- ▶ Remove the filter capsule from the packaging.
- ▶ Connect the filter capsule to the aeration segment of the bag via the OPTA coupling (see OPTA Sterile Connector Operating Instructions).
- ▶ Clamp the filter capsule in the filter holder:
  - ▶ 1 filter capsule: Clamp the filter capsule in the position (1) of the filter holder.
  - ▶ 2 filter capsules: Clamp the filter capsules in positions (1) and (2) of the filter holder.
- ▶ Connect the filter capsule and the control / supply unit with the aeration tube (see Chapter 7.7, page 94).
- ▶ Open the clamp on the aeration segment.
- ▶ Adjust the setting height of the filter clamp on the filter holder so that the aeration tube is not kinked.
- ▶ Secure the filter clamp.

7.5.4 Inflating Bag

Personnel:

- Flexsafe STR® 500 L | 1000 L bag 2 persons
- Flexsafe STR® 50 L | 200 L bag 1 person

Flexsafe STR® 500 L | 1000 L bag

Requirements

- The bag is connected to the drain port holder of the bag holder.
- The aeration segment is set up for headspace aeration (overlay).
- The bag is held in a vertical position by one person.
- The control / supply unit is connected in the laboratory and switched on.

⚠ CAUTION

Risk of injury caused by bursting of the bag!

Overpressure in the bag can cause it to rupture.

▶ Observe the following guidelines before aerating the bag.
  - The max. permissible pressure for aeration must not be exceeded (pressure for gases, see Chapter 15.7, page 196).
  - Flexsafe STR® 500 L | 1000 L: The pressure sensor filter capsule for headspace aeration must be connected to the pressure sensor and the safety valve.
  - The pressure sensor and the safety valve must be connected to the control / supply unit.
  - The bag must be carefully installed in the bag holder. The film of the bag must not be pinched.
  - The tubing must **not** be pinched or be kinked.
  - The exhaust air filter capsule must be connected.
  - The clamps for the exhaust, overlay and pressure sensor lines must be open.

Procedure

▶ The bag is generally inflated by aerating with air via the headspace aeration segment.

▶ If a Flexsafe STR® 500 L bag is used: The bag should be aerated without pressure. Slowly increase the aeration rate up to the maximum value of 50 l/min until the components in the bag are no longer in contact with the film (max. pressure for switching off aeration, see Chapter "15.7 Gas and Compressed Air Supply," page 196). Afterwards stop the aeration.

▶ If a Flexsafe STR® 1000 L bag is used: The bag should be aerated without pressure. Slowly increase the aeration rate up to the maximum value of 100 l/min until the components in the bag are no longer in contact with the film.

▶ Afterwards stop the aeration.Connect the top port of the bag with the magnetic coupling (see 7.5.5, 90).

Flexsafe STR® 50 L | 200 L bag

Requirements

- The bag is connected to the drain port holder of the bag holder.
- The aeration segments for headspace aeration (overlay) and for media aeration (sparger) are set up.
- The top port of the bag is connected to the magnetic coupling of the bag holder.
- The control / supply unit is connected in the laboratory and switched on.

⚠ CAUTION

Risk of injury caused by bursting of the bag!

Overpressure in the bag can cause it to rupture.

▶ Observe the following guidelines before aerating the bag.
  - The max. permissible pressure for aeration must not be exceeded (pressure for gases, see Chapter 15.7, page 196).
  - Flexsafe STR® 50 L | 200 L: The filter capsule for headspace aeration must be connected to the pressure sensor and the safety valve.
  - The pressure sensor and the safety valve must be connected to the control / supply unit.
  - The bag must be carefully installed in the bag holder. The film of the bag must not be pinched.
  - The tubing must **not** be pinched or be kinked.
  - The exhaust air filter capsule must be connected.
  - The clamps for the exhaust, overlay and pressure sensor lines must be open.

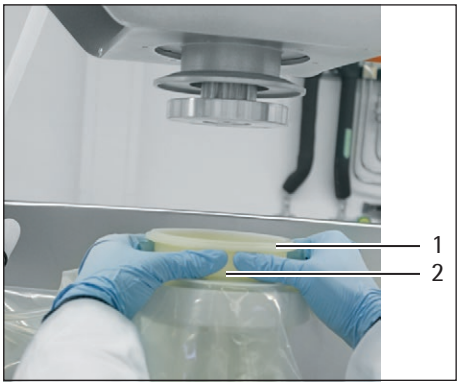
Procedure

▶ The bag is generally inflated by aerating with air via the headspace aeration segment.

▶ Inflating Flexsafe STR® 50 L:
  ▶ Aerate the bag without pressure at a maximum aeration rate of 5 L/min.
  ▶ Stop aeration when the bag has unfolded and is flat against the wall of the bag holder.

▶ Inflating Flexsafe STR® 200 L:
  ▶ Aerate the bag without pressure at a maximum aeration rate of 20 L/min. Slowly increase the aeration rate up to the maximum value.
  ▶ Stop aeration when the bag has unfolded and is flat against the wall of the bag holder.

▶ Aligning the bag in the bag holder:
  ▶ ⚠ **CAUTION** Crushing of fingers and hands when aligning the top port at the magnetic coupling! Grab the top port (2) with both hands below the flange (1).



  ▶ Position the bag so that the sampling port and the sensor ports can be routed through the sensor window.

7.5.5 Connecting Top Port with Magnetic Coupling

⚠ WARNING

Risk of injury due to strong magnetic field!

The magnetic field emitted from the magnetic coupling can interfere with or damage equipment susceptible to magnetic effects. There is a significant danger of injury to people with pacemakers.

▶ Do **not** allow individuals with pacemakers to work on the magnetic coupling.

⚠ CAUTION

Danger of crushing by the overhanging filter holder!

When working in the area of the magnetic coupling, the head striking the filter holder may result in injury.

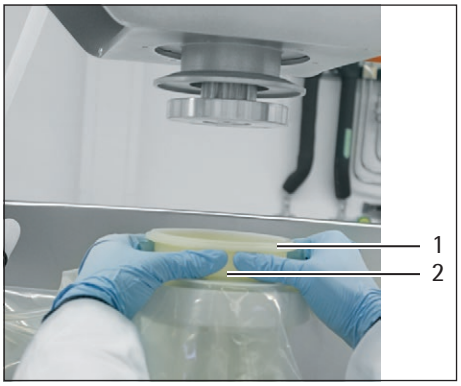
▶ Wear personal protective equipment.
▶ Remain prudent and focused when working.

Flexsafe STR® 500 L | 1000 L bag

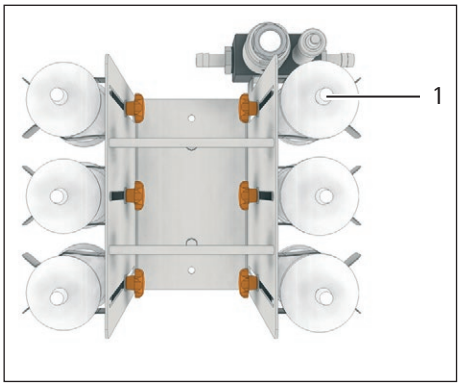
Requirements

– The bag is connected to the drain port holder of the bag holder.
– The aeration segment is set up for headspace aeration (overlay).
– The bag is inflated to the extent that the internal components are no longer in contact with the film.

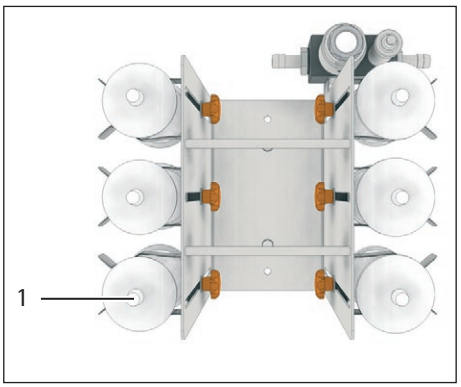
Procedure



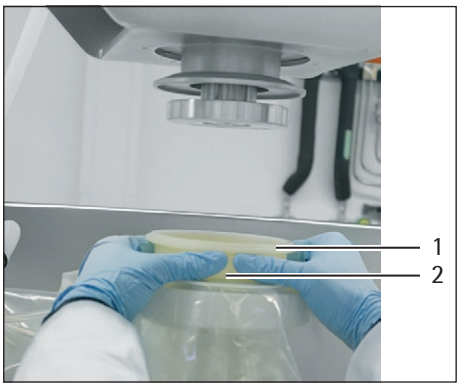
▶ ⚠ **CAUTION** Crushing of fingers and hands when connecting the top port at the magnetic coupling! Grab the top port (2) with both hands below the flange (1).
▶ Pull the top port of the bag towards the magnetic coupling until the top port locks into the magnetic coupling.
▶ Lay the short tubes over the top edge of the bag holder.



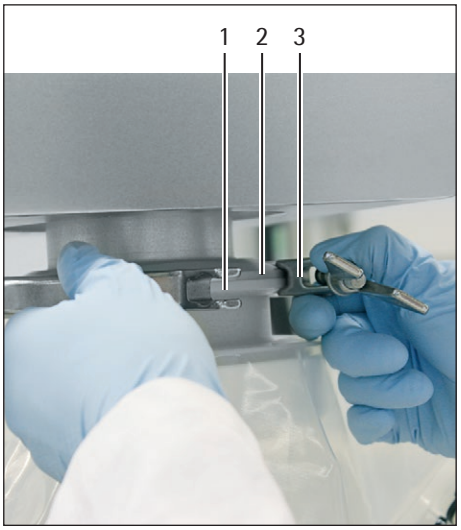
▶ Clamp the filter capsule for headspace aeration in the position (1) of the filter holder.
▶ Adjust the setting height of the filter clamp on the filter holder so that the tubing for pressure measurement is not kinked.
▶ Secure the filter clamp.



- ▶ Clamp the pressure sensor filter capsule for the pressure measurement line in position (1) of the filter holder.
- ▶ Adjust the setting height of the filter clamp on the filter holder so that the aeration tube is not kinked.
- ▶ Secure the filter clamp.
- ▶ Set up the aeration segment for media aeration (see Chapter 7.5.3, page 84).
- ▶ Re-inflate the bag without pressure by aerating with air via the headspace aeration segment (see Chapter "7.5.4 Inflating Bag," page 88).
- ▶ Stop aeration when the bag has unfolded and is flat against the wall of the bag holder.



- ▶ Aligning the bag in the bag holder:
  - ▶ ⚠ **CAUTION** Crushing of fingers and hands when aligning the top port at the magnetic coupling! Grab the top port (2) with both hands below the flange (1).
  - ▶ Position the bag so that the sampling port and the sensor ports can be routed through the sensor window.
- ▷ The weld seam of the bag film is located in the center of the closed door window.
- ▶ Check the positioning of the aeration tubing and correct if necessary:
  - ▶ Adjust the setting heights of the filter clamps on the filter holder so that the aeration tubes are not kinked.
  - ▶ Correct the position of the tubing on the motor bracket.



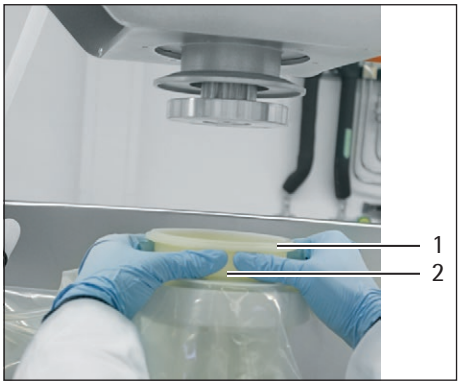
- ▶ Secure the top port (1) and the magnetic coupling (2) with the corresponding Tri-Clamp clip (3).
- ▶ Close the bag holder door.
- ▶ Install the filter heater (see Chapter 7.6, page 93).

Flexsafe STR® 50 L | 200 L bag

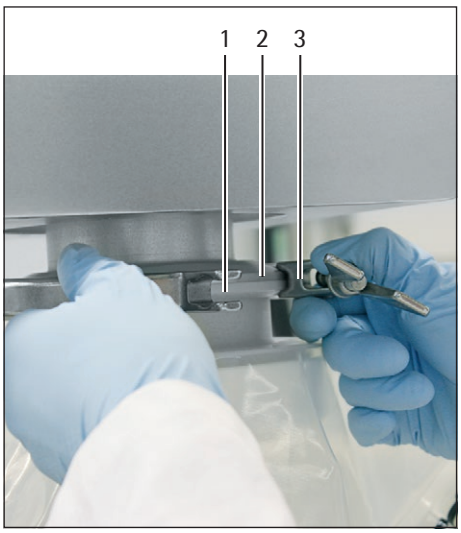
Requirements

The bag is connected to the drain port holder of the bag holder.

Procedure



- ⚠ **CAUTION** Crushing of fingers and hands when connecting the top port at the magnetic coupling! Grab the top port (2) with both hands below the flange (1).
- Pull the top port of the bag towards the magnetic coupling until the top port locks into the magnetic coupling.



- Secure the top port (1) and the magnetic coupling (2) with the corresponding Tri-Clamp clip (3).
- Close the bag holder door.
- Install the filter heater (see Chapter 7.6, page 93).

7.6 Installing Filter Heater

⚠ CAUTION

Danger of injury due to escaping compressed gases or pressurized media!

Escaping compressed gases or media escaping under high pressure can lead to injuries, e.g. eye injuries.

- ▶ Wear personal protective equipment.
- ▶ Close the supply lines.
- ▶ Carefully disconnect the supply tubes. Disconnect and hold the tubing ends. Keep the tubing ends away from body orifices.
- ▶ Follow the manufacturer's operating instructions for additional components.
- ▶ Follow the construction guidelines required to ensure that the device is stable.

⚠ CAUTION

Risk of injury due to installing an unsuitable filter heater!

Improper filter heaters may damage the exhaust air filter capsule. Damaged exhaust air filter capsules can lead to blockage of the exhaust air line. A clogged exhaust air line can cause overpressure in the bag. The bag can burst.

- ▶ Install the filter heater supplied in the scope of delivery.

⚠ CAUTION

Danger of crushing by the overhanging filter holder!

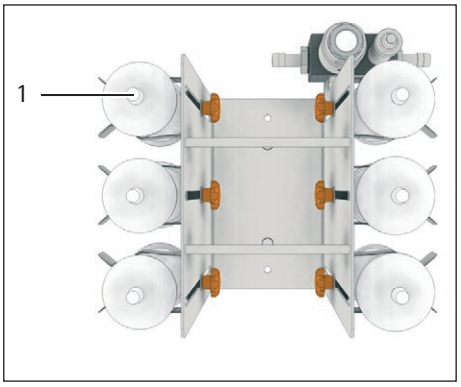
When working in the area of the filter holder, the head striking the filter holder may result in injury.

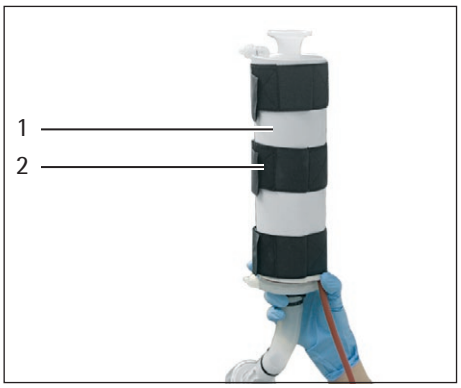
- ▶ Wear personal protective equipment.
- ▶ Remain prudent and focused when working.

Installation of the filter heater is demonstrated using bag holder 1 as an example.

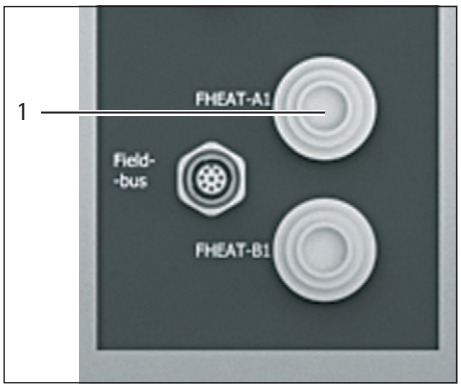
Procedure

- ▶ Remove the exhaust air filter capsule (1) from the filter holder.





- ▶ Lay the filter heater (1) around the exhaust air filter capsule and secure it with the Velcro fastener (2).
- ▶ Clamp the exhaust air filter capsule in the original position of the filter holder.



- ▶ Connect the power supply of the filter heater to the terminal FHEAT-A1 (1) of the control / supply unit.

7.7 Installing Tri-Clamp Connection on a Filter Capsule

To install the Tri-Clamp on a filter capsule, the following components are required:

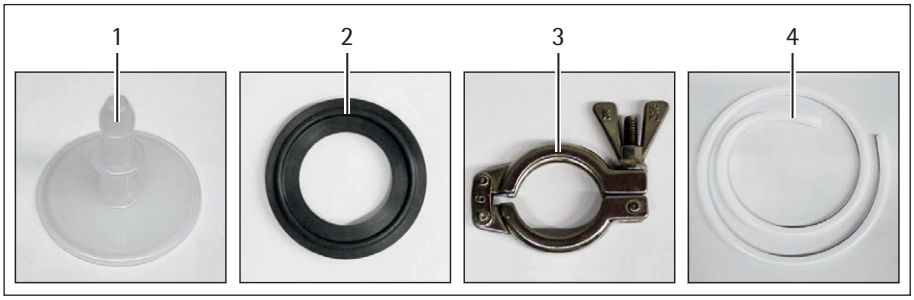


Fig. 34: Components of the Tri-Clamp connection

No.	Designation
1	Tri-Clamp connection with tube hose barb fitting
2	Tri-clamp gasket
3	Tri-Clamp
4	Aeration tube

Requirements

- The filter capsule is secured to the filter holder.
- The aeration tube is connected to the control / supply unit.

⚠ CAUTION

Danger of injury due to escaping compressed air or pressurized media!

Escaping compressed gases or media escaping under high pressure can lead to injuries, e.g. eye injuries.

- ▶ Depressurize the bag holder and disconnect it from the control / supply unit.
- ▶ Wear personal protective equipment.
- ▶ Close the supply lines.
- ▶ Carefully disconnect the supply tubes. Disconnect and hold the tubing ends. Keep the tubing ends away from body orifices.
- ▶ Follow the manufacturer's operating instructions for additional components.
- ▶ Follow the construction guidelines required to ensure that the device is stable.

⚠ CAUTION

Danger of crushing by the overhanging filter holder!

When working in the area of the filter holder, the head striking the filter holder may result in injury.

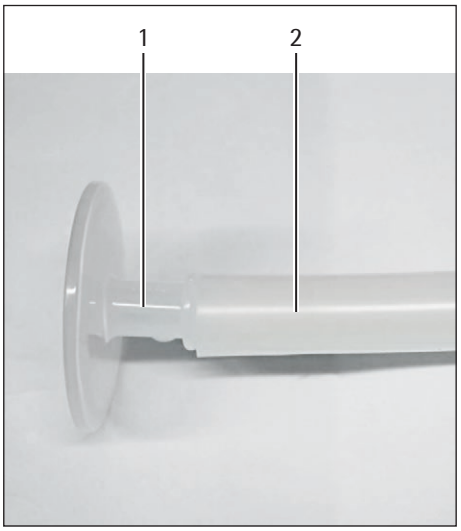
- ▶ Wear personal protective equipment.
- ▶ Remain prudent and focused when working.

NOTICE

Damage to the bag and installed components due to improper installation of the Tri-Clamp connection!

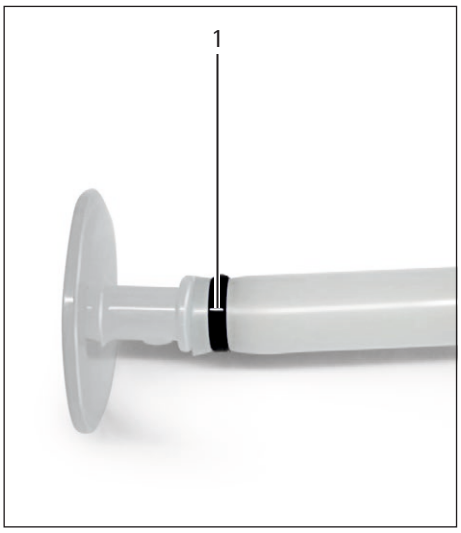
Improper installation of the Tri-Clamp connection can lead to functional and operational disturbances.

- ▶ Carry out the following procedure carefully.



Procedure

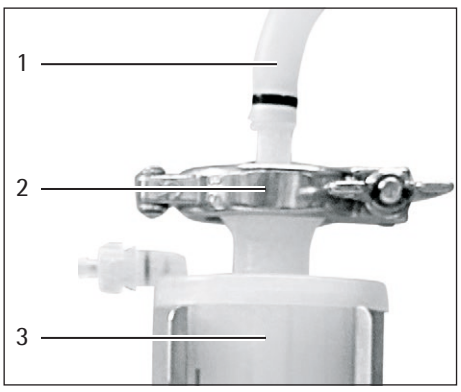
- ▶ Connect the aeration tube (2) onto the hose barb side of the tri-clamp connector (1).



▶ Secure the aeration tube to the tube barb with a cable tie (1).

▶ Place the Tri-Clamp gasket (1) on the Tri-Clamp connection (2) of the filter capsule.

▶ Place the Tri-Clamp connection with tube nozzle (1) on the Tri-Clamp gasket (2).



▶ Lay the Clamp (2) around the Tri-Clamp connection.
▶ Tighten the clamp.
▷ The filter capsule (3) is connected to the aeration tube (1) via the Tri-Clamp connection.

7.8 Installing Sensors on the Bag

NOTICE

Damage to the fiber optic cable and sensor cable through contact with the double wall!

The hot surface of the double wall can cause thermal damage to the fiber optic cables and sensor cables. Functional and operational disturbances can result.

▶ Lay the fiber optic and sensor cables so that there is no contact with the double wall of the bag holder.

7.8.1 Sensor Installation Overview

Depending on the configuration of the bag, optical or conventional sensors can be installed in the sensor window. Depending on the configuration, the work will include the following key measures:

Assembly steps	Chapter, page
Installing temperature sensor	7.8.2, 97
Activating single-use sensor port	7.8.3, 99
Installing and connecting fiber optic cables	7.8.4, 100
Installing and connecting conventional sensors	7.8.5, 102

7.8.2 Installing Temperature Sensor

⚠ CAUTION

Risk of injury due to installing an unsuitable temperature sensor!

An unsuitable temperature sensor can damage the sensor port. A damaged sensor port can cause leaks. Media may leak and cause personal injury.

▶ Install the PT100 temperature sensor supplied in the scope of delivery.

To install the temperature sensor, the following components are required:

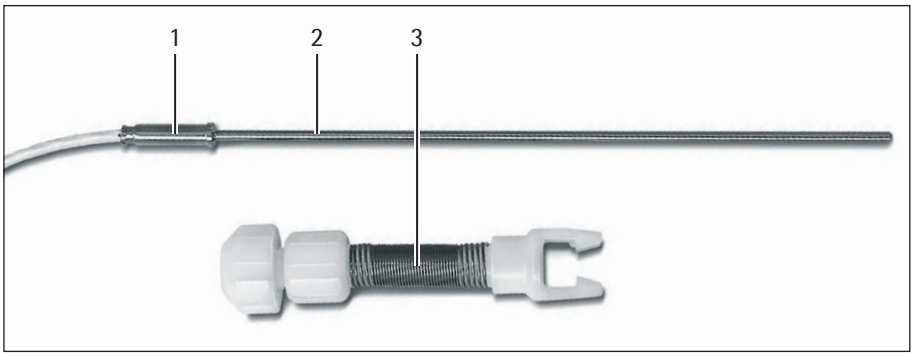


Fig. 35: PT100 temperature sensor, temperature sensor fixture

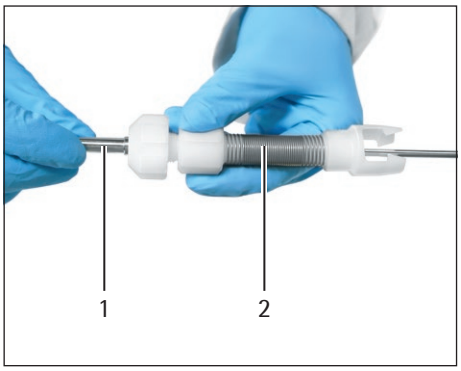
No.	Designation
1	Metal sleeve
2	Temperature sensor, PT100
3	Temperature sensor fixture

Requirements

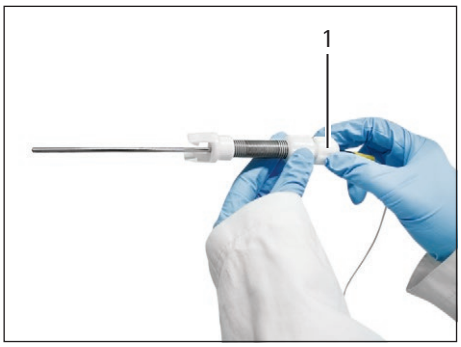
- The bag is installed and aligned in the bag holder.
- The bag is fully inflated.

Procedure

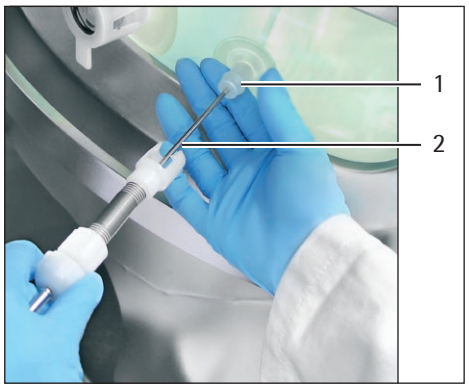
▶ Open the screw (1) of the temperature sensor fixture.



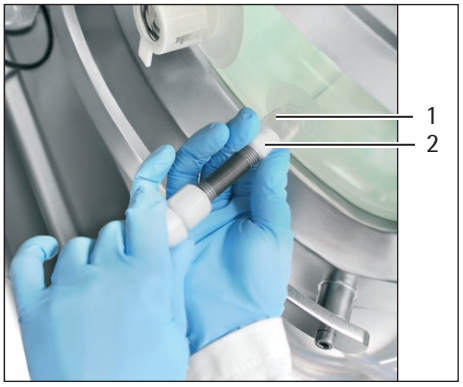
▶ Slide the temperature sensor into the temperature sensor fixture (2) up to the cable metal sleeve (1).



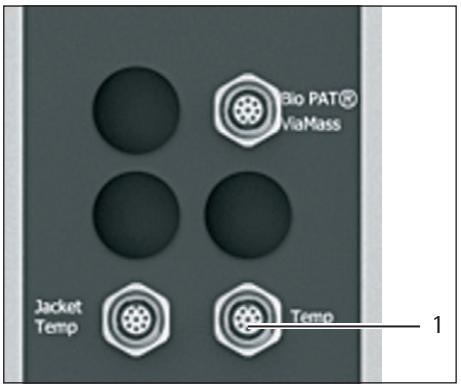
▶ Tighten the screw (1) of the temperature sensor fixture.



▶ Slowly slide the temperature sensor (2) into the sensor port (1).



▶ Attach the temperature sensor fixture (1) to the tube barb (2) on the sensor port.



▶ Connect the signal cable of the temperature sensor to the M12 plug connection Temp (1) of the control / supply unit.

7.8.3 Activating Single-use Sensor Port

Requirements

– The bag is installed and aligned in the bag holder.
– The bag is fully inflated.

Procedure

▶ To activate the single-use sensor port: Twist the knob (1) 90 degrees counterclockwise until it stops.

▷ The knob is in the vertical position. The single-use sensor port is enabled.

7.8.4 Installing Fiber Optic Cable

The installation of the optical fiber is exemplified using the example of bag holder 1.

Requirements

- The bag is installed and aligned in the bag holder.
- The bag is fully inflated.
- The single-use sensor port is activated.

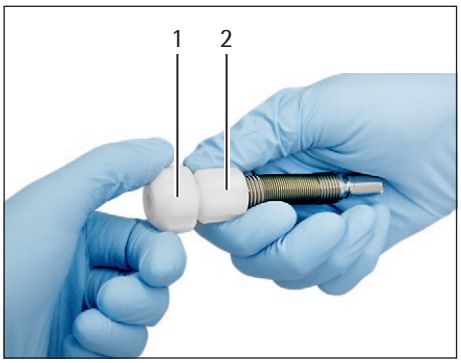
Procedure

NOTICE

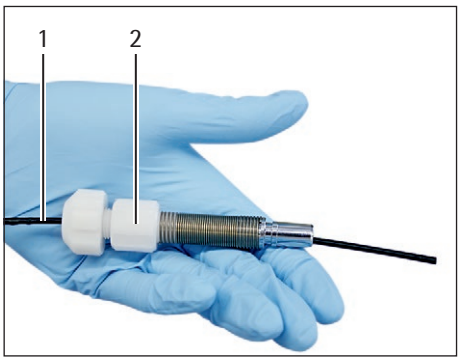
Damage to the fiber optic cable due to incorrect installation!

Laying the fiber optic cable in tight circles can lead to disturbances in the signal transmission.

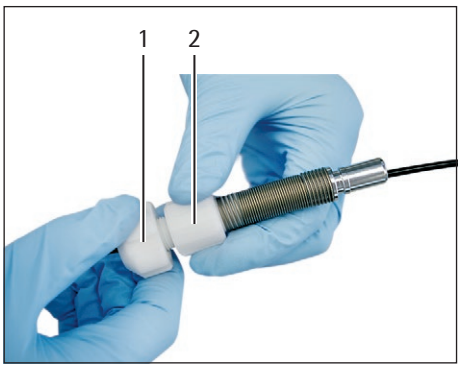
- ▶ Do **not** kink the fiber optic cable when laying it out.
- ▶ Lay out the fiber optic cable in large circles.
- ▶ Lay out the fiber optic cable so as to protect it from accidental contact.



▶ Unscrew the screw (1) on the fiber optic cable fixture (2).



▶ Push the fiber optic cable (1) through the fiber optic cable fixture (2) until the fiber optic cable protrudes 4–5 cm out of the fiber optic cable fixture.



▶ Tighten the screw (1) on the fiber optic cable fixture (2).

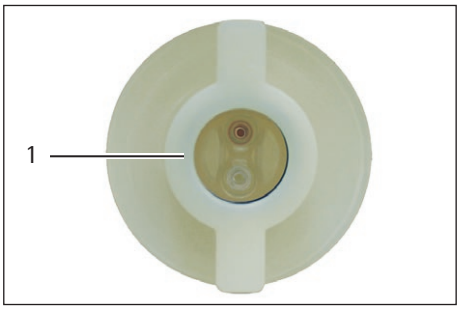
Connecting the Fiber Optic Cable to the Sensor Port

There are sensor ports in the following versions:

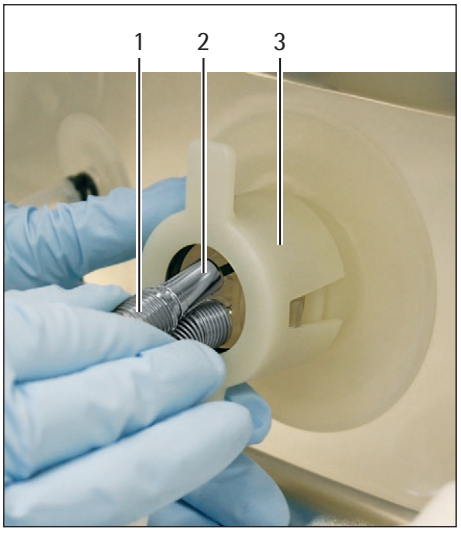
- Single-use sensor port for pH sensor and DO (pO_2) sensor
- Single-use sensor port for two DO (pO_2) sensors

The sensor patches on the bag are marked as follows:

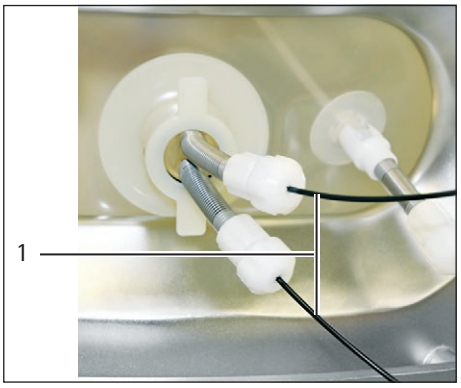
- DO (pO_2) sensor: red marking
- pH sensor: white marking



▶ To connect the optical DO (pO_2) sensor or pH sensor: Push the fiber optic cable of the sensor into the connector of the single-use sensor port (1) marked in red or white.



▶ Hold the knob (3) and pull the spring (1) to the single-use sensor port.
▶ Slide the end piece (2) of the fiber optic cable fixture all the way into the single-use sensor port. A clicking sound indicates that the fiber optic cable is secured in the single-use sensor port.



▶ Connecting the fiber optic cable (1) to the control / supply unit connections. Observe the correct assignment of the fiber optic cable and connections:

	Fiber optic cable	Connection
Use of 1 pH sensor and 1 DO (pO_2) sensor	pH sensor	pH-C1 opt.
	DO (pO_2) sensor	DO (pO_2) C1 opt.
Use of 2 DO (pO_2) sensors	First DO (pO_2) sensor	DO (pO_2) C1 opt.
	Second DO (pO_2) sensor	DO(pO_2) D1 opt.

7.8.5 Installing and Connecting Conventional Sensors

NOTICE

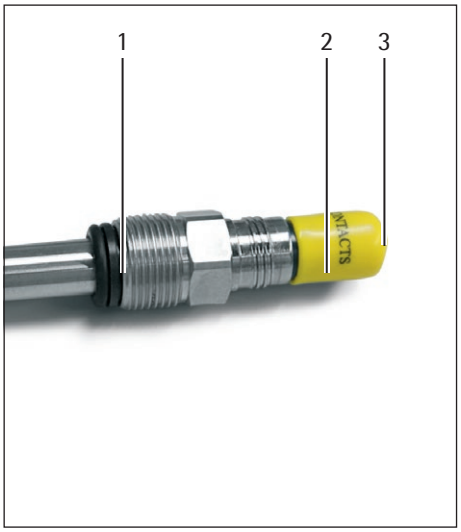
Damage to the bag if sensors are installed after filling!

In ports for conventional sensors, sensors must always be installed prior to filling the bag. Clamping off the tube at this port and inserting sensors after the bag has been filled can result in damage to the bag.

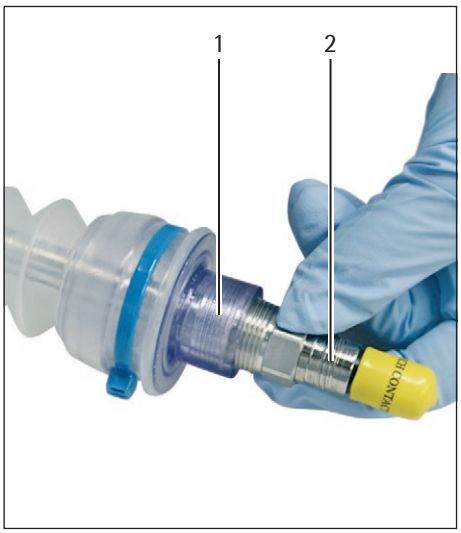
Requirements

- The probe holder is installed.
- Sensors which must be calibrated with external fluids and aerations (and thus **cannot** be calibrated in the bag) must be calibrated prior to autoclaving.

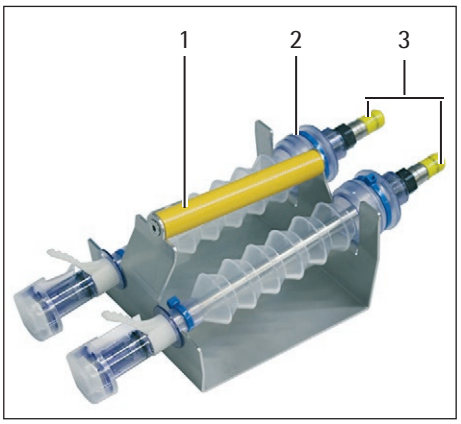
Procedure



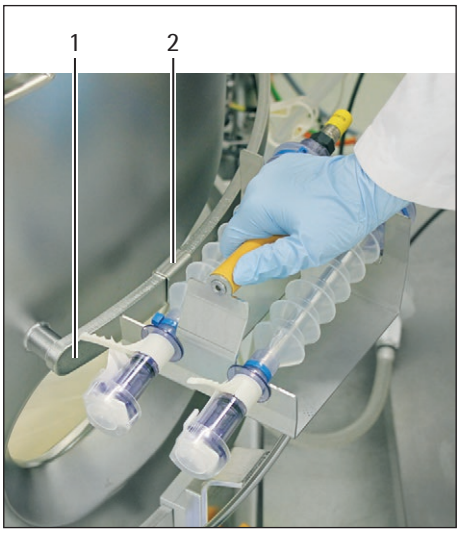
▶ Check that the gasket (1) below the sensor thread is present:
  ▶ If required: Install gasket.
▶ To protect the connection of the sensor during installation: Stick the protective cap (3) on the terminal (2).



▶ Screw the sensor (2) into the sensor adapter (1).

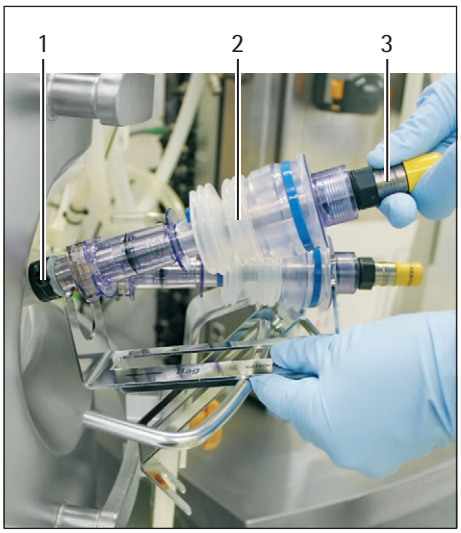


- Insert the sensor adapter (2) into the autoclave tray (1).
- If required: Insert a second sensor adapter into the autoclave tray.
- Remove the protective caps (3).
- Put the autoclaving holder into the autoclave:
  - Autoclave the autoclaving holder, the sensor adapter and sensors in the autoclave.
- **NOTICE** Do not stack the autoclaving holders for transport.
- If more than 2 sensors are sterilized: Stack the autoclaving holders in the autoclave.
- After autoclaving the sensors: Remove the autoclaving holder from the autoclave using the yellow handle.
- Place the protective caps on the sensors.



- Hook the bracket (2) of the autoclaving holder onto the upper system rail (2).

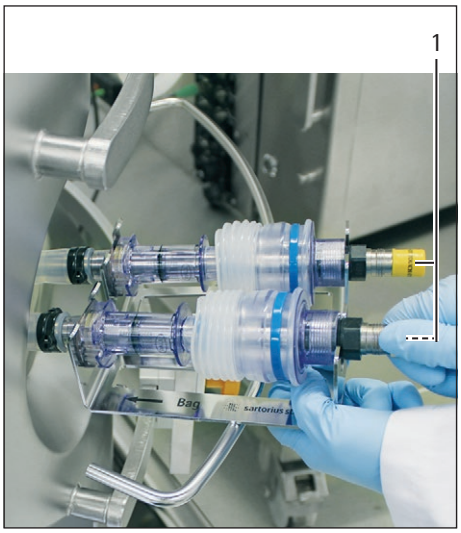
- Remove the sensor adapter from the autoclaving tray.
- Position the sensor adapter in front of the KPC sterile connector.
- Connect the KPC sterile connector to the bag (see KPC operating instructions).



- ▶ Press the sensor (3) into the holder (1) of the KPC sterile connector.
- ▷ The sensor guide (2) on the sensor adapter is compressed in the process.

- ▶ In order to position the sensor in the sensor clamp: Place the terminal (2) of the sensor on the recess (3).
- ▷ The KPC sterile connector (1) is located behind the recess of the sensor clamp.
- ▶ To install additional sensors:
  - ▶ Connect a KPC sterile connector to the appropriate connector on the bag (see step: Connect the KPC sterile connector to the bag).
  - ▶ Carry out the steps that follow this step.

- ▶ In order to ensure tension-free positioning of the sensors:
  - ▶ Adjust the position of the probe support arm (see Chapter 6.11, page 67).
  - ▶ Adjust the sensor clamp distance (see Chapter 6.11, page 67).



- ▶ Remove the protective caps (1) on the sensors.
- ▶ To connect the sensors to the control / supply unit: Connect the sensors on the sensor cables to the appropriate connections of the control / supply unit.

7.9 Filling the Bag

Requirements

The sensors required for the process are installed in the bag.

Procedure

▶ ⚠ **CAUTION** Risk of injury due to bursting of the bag! An improperly filled bag may burst. Escaping media can cause injury. Start the filling process at the control / supply unit according to the process specification.

7.10 Tempering and Stirring Process

To avoid damage, e.g. to the bag or stirrer: Ensure that the following conditions are met when starting the tempering and stirring process.

Tempering Process

– The bag is filled with the minimum volume (see Chapter "15.10 Bag Volume," page 197).
– The temperature sensor is installed (see Chapter "7.8.2 Installing Temperature Sensor," page 97)

Stirring Process

– The bag is filled with the minimum volume (see Chapter "15.10 Bag Volume," page 197).

8 Operation

8.1 Sampling

⚠ WARNING

Danger of contamination and infection!

The samples contain living cells.

▶ Wear personal protective equipment.

▶ Clean and disinfect contaminated objects and surfaces. Laboratory drains and collection vessels must be suited for biological waste water.

Requirements

– Laboratory drains and collection vessels must be suited for biological waste water.

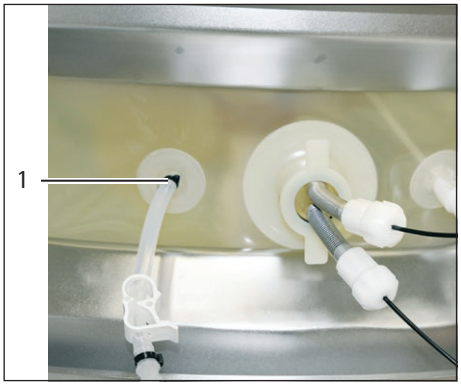
– For safety-critical cells, observe the safety guidelines for the handling of sample residues (e.g. pathogenic cells).

– Use 2 sampling syringes:
  – With the first sampling syringe, remove the dead volume from the sampling tube.
  – With the second sampling syringe, take a representative sample.

Procedure

▶ As needed: Remove the samples from the Flexsafe STR® bag.

▶ Carry out the sterile removal of a sample via the sampling port (1):
  ▶ Remove the cap from the clave connector of the sampling port.
  ▶ Store the cap for the duration of the sampling so that it cannot be contaminated.



▶ ⚠ **CAUTION** When disinfecting the clave connector, make sure that all surrounding and adjacent objects and components of the Flexsafe STR® bag are covered and protected. Spraying the surfaces of surrounding and adjacent objects and components with 70% ethanol solution could damage labeling.

▶ Disinfect the clave connector (1).

- ▶ Use a sterile Luer Lock syringe (e.g. 20 ml, without needle) for sampling.
- ▶ Use 2 sampling syringes:
  - ▶ With the first sampling syringe, remove the dead volume from the sampling tube.
  - ▶ With the second sampling syringe, take a representative sample.
- ▶ Remove the cap from the sterile sampling syringe.
- ▶ Position the syringe and tighten by turning it clockwise until it stops against the sampling port clave connector.
- ▶ ⚠ **CAUTION** Danger of contamination! Never push fluid (air or liquid) into the bioreactor. Always pull out of the bioreactor.
- ▶ Open the tube clamp of the sampling tube.
- ▶ Fill the sampling syringe (20 ml) once to remove the dead volume.
- ▶ Then close the tube clamp on the sampling tube.
- ▶ Turn the sampling syringe counterclockwise and remove.
- ▶ Inactivate the sample syringe, e.g. by heat sterilization, and then dispose of it properly (see Chapter "14.1 Information on Decontamination," page 192).
- ▶ Repeat the procedure with an unused, sterile syringe and remove a representative sample of any volume.
- ▶ Measure samples quickly to minimize the effects of degassing (especially for pH and dissolved gas measurement).
- ▶ End sampling: Put the cap back on the clave connector.

8.2 Switching Control / Supply Unit and Bag Holder On/Off

The device has been properly installed and connected in accordance with the specifications.

- ▶ Ensure that all required supply energies are connected to the control / supply unit.
- ▶ Check to make sure that all connections (cooling water and gas supply lines) are connected to the bag holder.

The DCU system will start after switching on the control / supply unit in the defined default mode. Switch on the control unit first before switching on the bag holder.

The defined default mode means:
- The system configuration is loaded.
- The user-defined parameters from a previous process are stored in a memory (CF card) and can be used for the next process, e.g.:
  - Set values
  - Calibration parameters
  - Profiles (if there are any)
- All controllers are switched off: [off] mode.
- Actuators are in the rest position: Pumps, valves.

Switching on the Control / Supply Unit

Procedure

- ▶ Turn the main switch [Mains I/O] on the control / supply unit to the "I" position.
- ▷ The DCU system will start in the defined default mode.
- ▶ Wait until the main menu appears on the operating display.

Switching on Bag Holder

▶ Turn the main switch [Mains I/O] of the bag holder to the "I" position.
▶ Switch on the bag holder's measurement and control system: To do so, press the switch [Unit 1 off/on] and/or [Unit 2 off/on] on the control / supply unit.
▷ The switch lights up green to indicate that the measurement and control system is switched on.
▶ Wait until realistic process data for the switched-on bag holder appears on the operating display of the control unit.

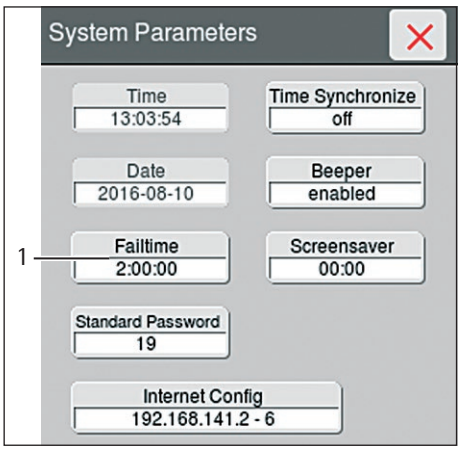
Switching off

▶ If you wish to stop operating the device, switch off this equipment using „Mains I/O" switch first, then disconnect the power cable from the AC power outlet (mains outlet).

8.3 Setting the Failtime

The failtime is the downtime, i.e. the time during which the voltage supply to the control / supply unit is interrupted. The following types of interruptions of the voltage supply are distinguished:

- The time during which the voltage supply is interrupted is shorter than the configured failtime:
  - The DCU system starts automatically after restoring the power supply.
  - A status message [Power Failure ... Power lost at ...] shows the failtime.
  - Controllers continue to work with the configured setpoints and mode.
  - Timer and setpoint profiles continue to be processed.
- The time during which the voltage supply is interrupted is longer than the configured failtime:
  - The DCU system automatically restarts in the defined basic state after restoring the voltage supply. Controllers will not continue to work.
  - A status message [Failure, Process Stopped ... Power lost at ...] appears, specifying the date and time at which the voltage interruption occurred.



Procedure

▶ In the [Settings] main function, press [System Parameters].
▶ In the [System Parameters] window, press [Failtime] (1).
▶ Enter the failtime in the input window [Failtime] and confirm with the [ok] key.

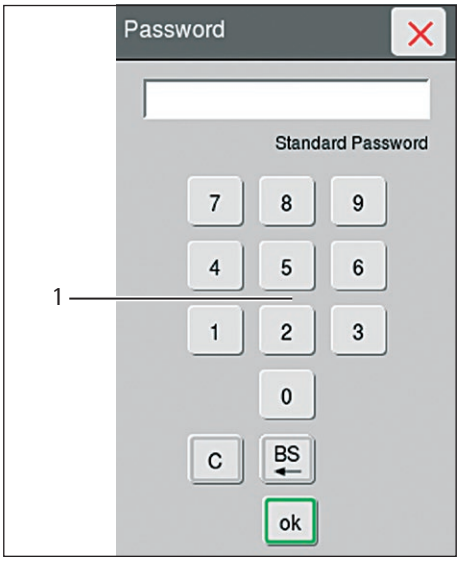
8.4 Accessing Password-protected Functions

8.4.1 Password Protection of Individual Functions

Required qualification: Operating engineer / laboratory manager

In order to protect the device from unintentional input, individual functions are protected by a standard password. These include, for example:

- Configuration of the controller parameters.
- The process value setting "PV".
- Manual operation of the control elements.



When selecting password-protected functions, a key field is displayed automatically with a prompt to enter the password. The standard password is either factory-set at <19> or is preset with a customer-specific password.

NOTICE

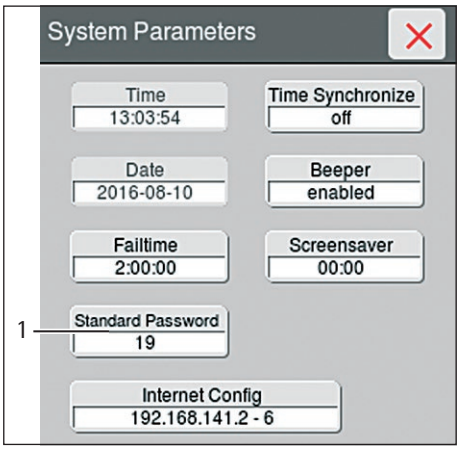
Incorrect system settings and inappropriate controller parameters can lead to unpredictable device damage! Provide passwords only to authorized users, e.g. system administrators, service engineers, Sartorius Service.

Password Input

Procedure

▶ When the [Password] window appears: Enter the standard password using the keypad (1) and confirm with the [ok] key.

Changing the Standard Password



Procedure

▶ In the [Settings] main function, press [System Parameters].
▶ In the [System Parameters] window, press [Standard Password] (1).
▶ Enter the new password in the input window [Standard Password] and confirm with [ok].

8.4.2 Password Protection of the Service Menu

The submenu [Service] of the main function [Settings] is only accessible with a special service password. This is only provided to Sartorius Service technicians.

8.5 Locked Controller Inputs or Controller Outputs

The DCU system can lock certain process inputs and outputs, e.g. when alarms occur. Locked inputs and outputs are identified by the label "Locked". Locking functions are part of the permanent configuration and cannot be changed. The scope of the locks depends on the system configuration (see the configuration lists in the "Technical Documentation" folder).

8.6 Showing Trend Display and Modifying Display Options

8.6.1 Showing Trend Display

The trend display can be used to graphically display the progress of process values. The trend display gives, for example, a quick impression as to whether the process is running as expected or whether irregularities or disruptions are present.

The trend display offers the following functions:

- Display of up to 8 time profiles (channels)
- Time frame of 1 to 72 hours (freely selectable)

Trend readouts are **not** saved. To permanently store process values, the data must be recorded using a host system, e.g. BioPAT® MFCS.

Procedure

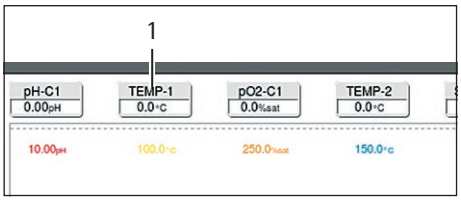
▶ Press the [Trend] main function key.
▷ The trend display appears.

8.6.2 Modifying Channel Display

The display of the channels can be adapted:

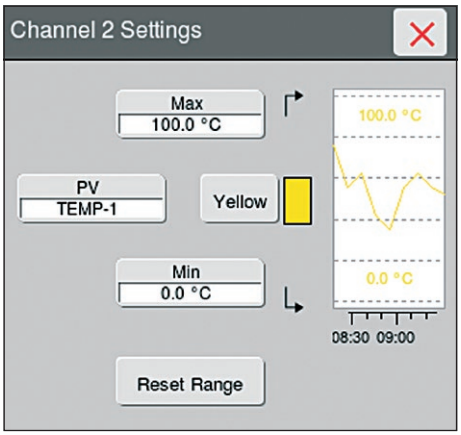
- Selecting process values
- Upper/lower limit of the value range
- Color

Procedure

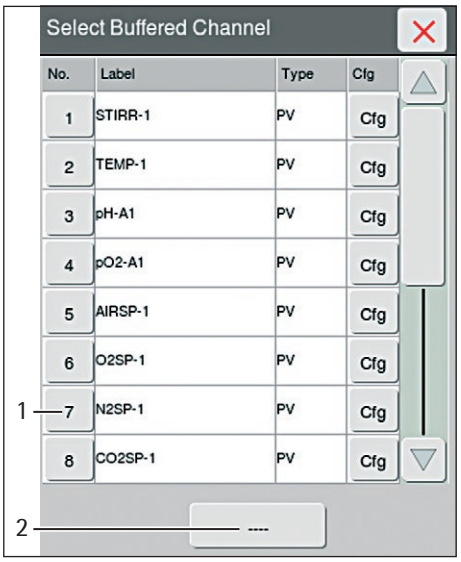


▶ In the trend display, press the corresponding channel (1), e.g. channel 2 [TEMP-1].

▷ The channel settings window [Channel 2 Settings] is displayed.
▶ Change the channel 2 settings, such as max value or color.



8.6.3 Changing or Deleting Channel Assignment to the Parameter



Procedure

▶ In the channel settings window [Channel 2 Settings]: Press the [PV] key.
▷ The [Select Buffered Channel] window is displayed.

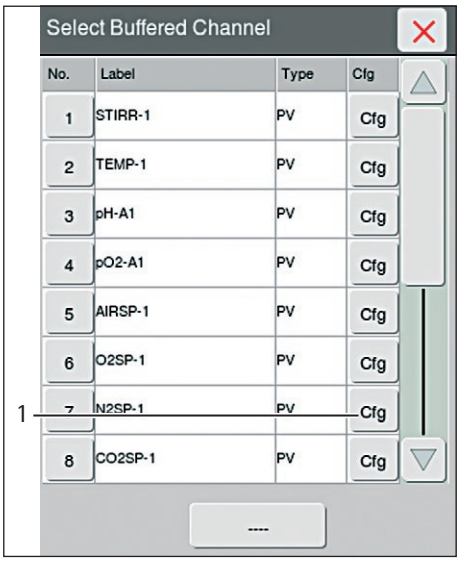
▶ To assign a parameter to Channel 2: Press the parameter from the selection list, e.g. [7] (1).
▷ Channel 2 is assigned to the parameter N2SP-1.

▶ To delete the assignment of TEMP-1 to Channel 2: Press the [----] (2) key.
▷ No more parameters are assigned to Channel 2. Channel 2 is **no longer** displayed on the trend display until a new parameter is assigned.

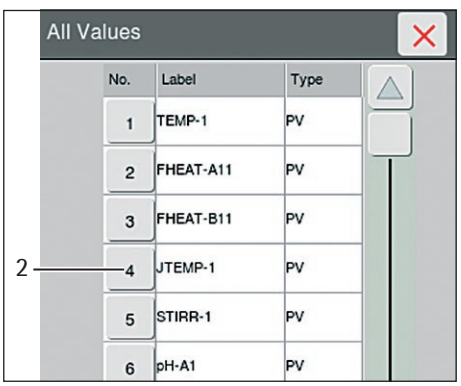
8.6.4 Changing the Parameters of the Selection List

Additional parameters can be assigned to the selection list. If the desired parameter is not present in the list, each channel can me modified to select the desired variable. All variables in the "select buffer channel" list are recorded even if they are not displayed.

Procedure



▶ To display all parameters in the configuration: Press the [Cfg] key (1).
▷ The selection screen [All Values] is displayed.



▶ Press the key corresponding to the desired parameter from the selection list, e.g. [4] (2).
▷ The [All Values] window closes.
▷ The selection list in the [Select Buffered Channel] window is assigned to parameter JTEMP-1.
▷ Channel 2 is assigned the parameter JTEMP-1.

8.7 Confirming and Configuring Alerts

Faults in the operating sequence are displayed as alerts on the operating display. The DCU system distinguishes between:

- Process messages (process-related alerts)
- Status messages (system-related alerts)

8.7.1 Confirming Single Alerts

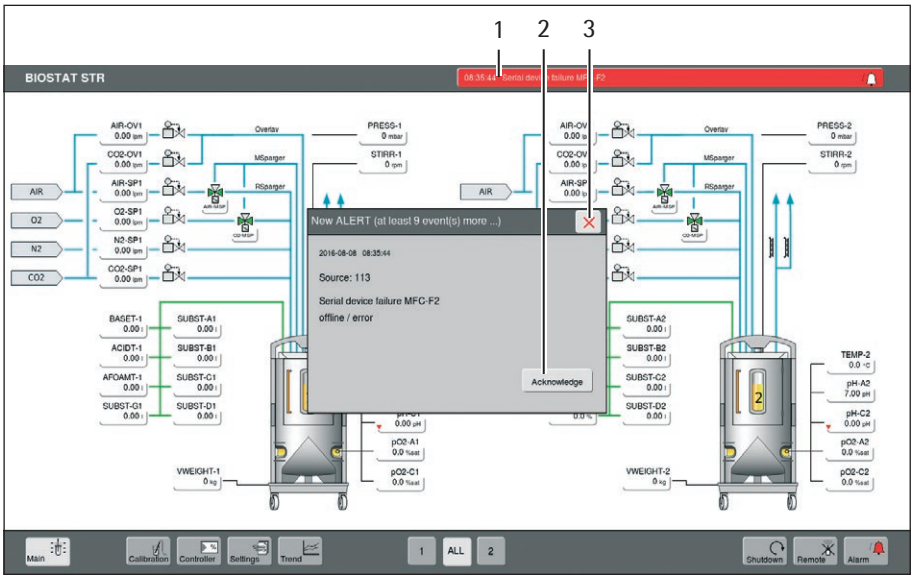


Fig. 36: Single alert [New Alert] (example)

No.	Designation	Description
1		Active alert message in the header.
2	Acknowledge	– Press to confirm the alarm. – Closes the [New ALERT] window. – The alarm is saved as confirmed in the alert overview (State: ACK).
3	x	– Press to close the [New ALERT] window. – The alert is saved as unconfirmed in the alert overview (State: UNACK). – The alert message remains in the header.

Procedure

- ▶ Confirm the alert by pressing the [Acknowledge] key or close the [New ALERT] window by pressing the [X] key.
- ▶ Eliminate the cause of the alarm, e.g.:
  - ▶ Check the functionality of the component that supplies the input signal.
  - ▶ Check the corresponding connections and, if necessary, the controller settings.
- ▷ If several alerts have occurred: After confirming the active alarm window [New ALERT], the next still-unconfirmed alarm appears.

8.7.2 Confirming the Alarm in the Alarm Overview

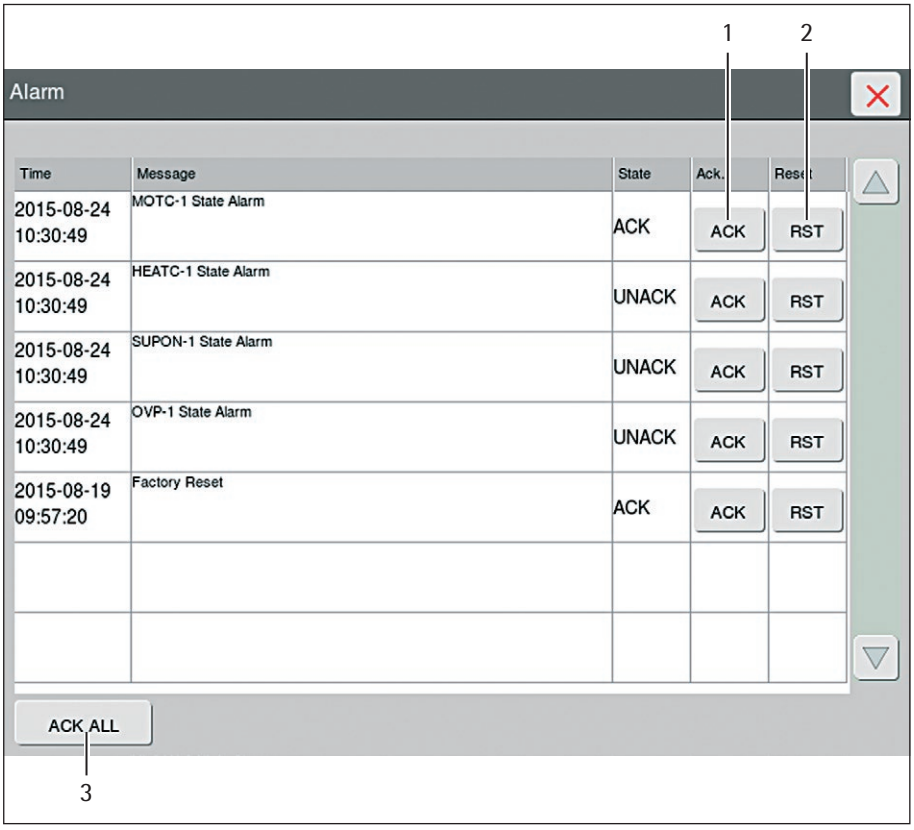


Fig. 37: Alarm overview (example)

No.	Designation	Description
1	ACK	Press to confirm the selected alarm.
2	RST	Press to confirm the selected alarm and reset the alarm status. Alarm is deleted from the overview.
3	ACK ALL	Press to confirm all pending alarms.

Procedure

- ▶ Call up the alarm overview:
  - ▶ Press the alarm message in the header or
  - ▶ Press the main function key [Alarm].
- ▶ Eliminate the cause of the alarm, e.g.:
  - ▶ Check the functionality of the component that supplies the input signal.
  - ▶ Check the corresponding connections and, if necessary, the controller settings.
- ▶ Confirm the corresponding alarm with the [ACK] key.
- ▶ If necessary, delete the corresponding alarm from the alarm overview with the [RST] key.

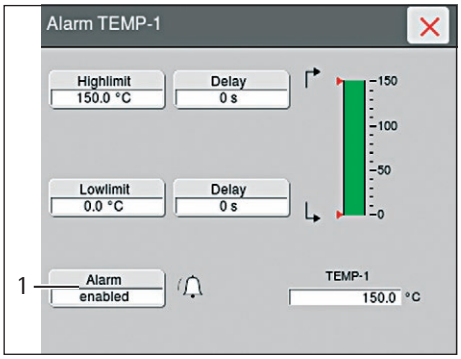
8.7.3 Enabling or Disabling Monitoring

Monitoring of the following values can be individually activated or deactivated:

- Process values (measured values and calculated process values).
- Digital inputs, e.g. limit contacts (antifoam | level sensors), motor protection switches or automatic circuit breakers.

Procedure

▶ Call up the extended setting window for the process value controller, e.g. TEMP-#.
▶ In the [Controller TEMP-#] window: press [Alarm Param.].
▶ Configure monitoring to the requirements:



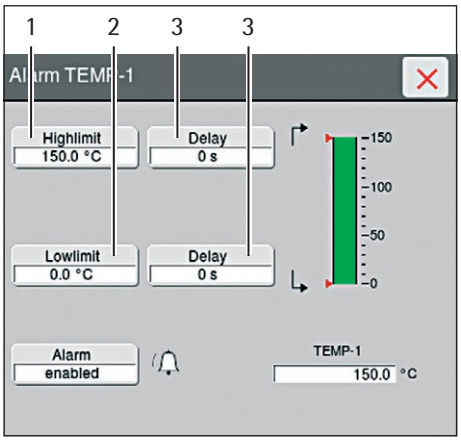
No.	Name	Description
1	Alarm disabled	Monitoring for process value is disabled. Press to activate monitoring.
	Alarm enabled	Monitoring for process value is activated. Press to disable monitoring.

8.7.4 Setting Alert Limits for Process Values

The DCU system monitors process values (measured values and calculated process values) for compliance with limits (Highlimit | Lowlimit). The limits can be specified individually for each process value. The alarm limits must be within the measurement range limits.

Procedure

▶ Call up the extended setting window for the process value controller, e.g. TEMP-#.
▶ In the [Controller TEMP-#] window: press [Alarm Param.].
▶ Configure the alarm limits to the requirements:



No.	Name	Value	Description
1	Highlimit	°C	Displays the upper alarm limit of the process value.
2	Lowlimit	°C	Displays the lower alarm limit of the process value.
3	Delay	s	Displays the delay time for the alarm message.

▶ To set the upper alarm limit: Press the [Highlimit] key.
▶ To set the lower alarm limit: Press the [Lowlimit] key.
▶ To set the delay time: Press the [Delay] key.
▶ Enter the value in the displayed input field.

8.8 Creating and Starting a Setpoint Profile

Most control loops can be operated with time-dependent setpoint profiles (Control Loop Profiles). The following settings are possible for a setpoint profile:

- Jumps and ramps are possible in the setpoint profile.
- Profiles can be started and stopped at any time. The elapsed time is displayed for started profiles.

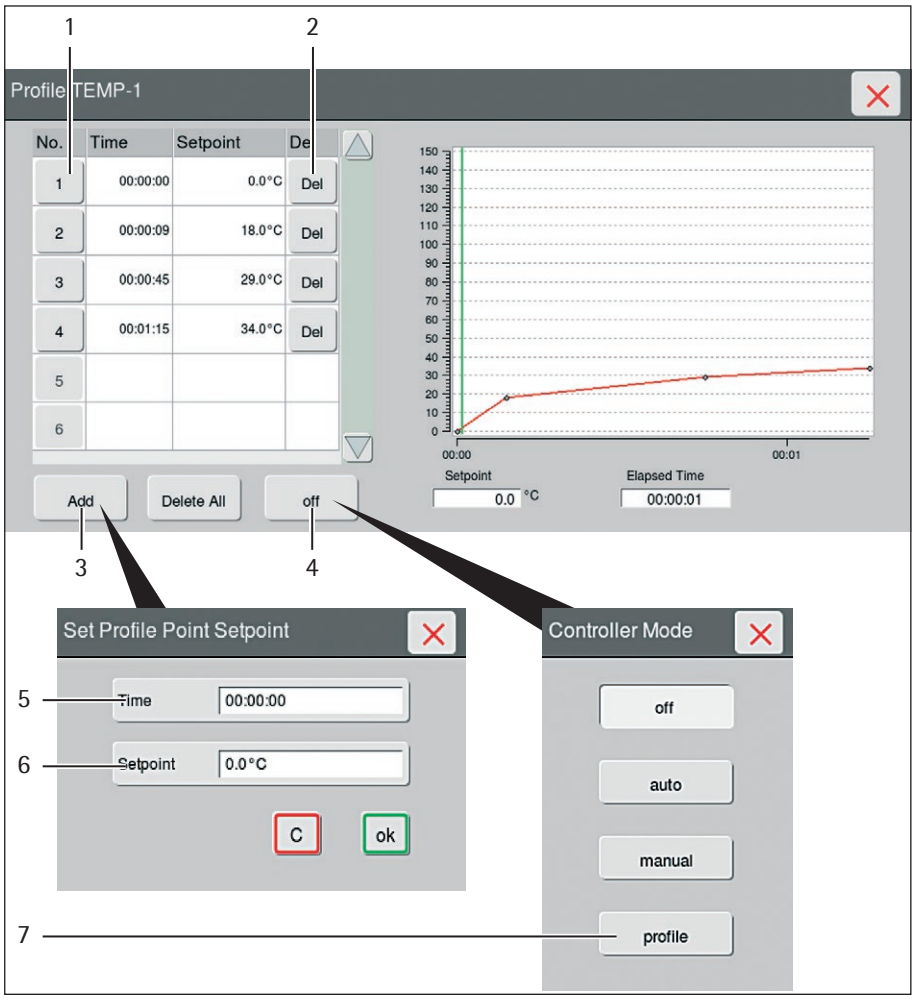


Fig. 38: Controller TEMP-1, set the setpoint profile (example)

No.	Name	Description
1	No.	Press to display the [Set Profile Set Point] window, where you can set the values of the profile point.
2	Del	Press to delete the profile point.
3	Add	Press to display the [Set Profile Set Point] window and enter an additional profile set point.
4	off	– Displays the current operating mode. – Press to display the operating mode selection screen.
5	Time	Press to display a window for entering the value Time.
6	Setpoint	Press to display a window for entering the value Setpoint.
7	Profile	Press to start the setpoint profile.

Creating a Setpoint Profile

Requirements

– A profile sketch with profile point and associated target values has been created. The times and target values to be programmed can be read from the profile points entered on the sketch.
– The setpoint profile configuration window appears.

Procedure

▶ To add a profile point: Press the [Add] key.
▶ Enter the time [Time] and the setpoint [Setpoint] of the profile point in the input window.
  ▶ If the zero time "00:00" is not entered for the first profile point: The system uses the current setpoint as the start time after profile start.
▶ Confirm inputs with [ok] key.
▷ The profile point has been added.
▶ Add the additional profile points according to the profile sketch.
▶ To change the values of a profile point: In the [No.] column, press the corresponding number of the profile point.
▶ To delete a profile point: Press the [Del] key of the corresponding profile point.

Starting a Setpoint Profile

Requirements

The setpoint profile must have at least one profile point with a time other than zero.

Procedure

▶ To start setpoint profile: Press the key of the operating mode.
▷ The operating mode selection screen is displayed.
▶ In the operating mode selection screen, press the [profile] key.
▷ The setpoint profile is started.

8.9 Calibrating Sensors

8.9.1 Selecting the Type of Calibration

When using multiple pH and DO (pO_2) probes for parallel measurements, the calibration of the probes can be carried out as a single or a group calibration. Single calibration is described in detail in the following chapters.

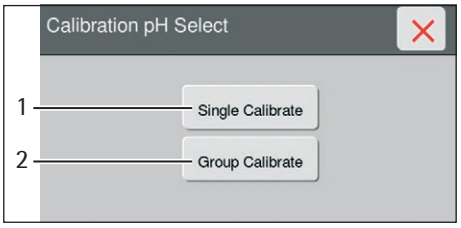
There is, in principle, no difference between group calibration and single calibration therefore this is not described in detail.

The following instructions must be observed for group calibration:

- Simultaneous calibration of all connected pH sensors. Deselection of individual pH sensors from the group calibration is **not** possible.
- Group calibration is only possible for conventional sensors, **not** for optical pH sensors.
- **No** direct input of zero offset and pH sensor slope is possible.
- Sensors **cannot** be recalibrated.

Procedure

▶ Press the key for the sensor to be calibrated, e.g., [pH-#], in the [Calibration] main function.
▷ The selection screen for the type of calibration is displayed.
▶ Select the type of calibration.
  ▶ To select single calibration: Press the [Single Calibrate] key (1).
  ▷ The [Calibration pH-#] window appears.
  ▶ To select group calibration: Press the [Group Calibrate] key (2).
  ▷ The [Group Calibration pH] window appears:



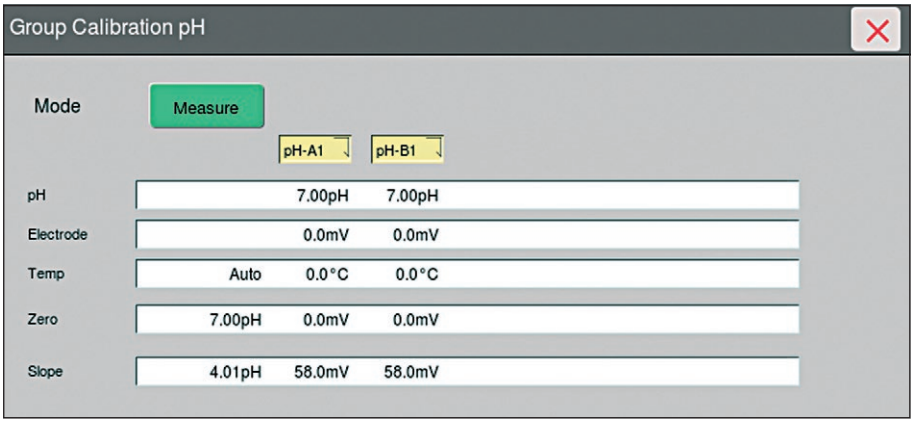


Fig. 39: Group calibration overview of all connected pH sensors (example)

8.10 Calibrating pH Sensor (Conventional Sensor)

8.10.1 General Information on the pH Sensor

Conventional pH sensors are calibrated using a two-point calibration with buffer solutions. During pH measurement, the system adjusts the pH value based on the sensor potential according to the Nernst equation while taking zero point deviation, slope and temperature into consideration.

During calibration, the reference temperature can be entered manually. For pH measurement, temperature compensation takes place automatically according to the temperature reading from temperature sensor of the bioreactor.

The pH sensors must be calibrated prior to installation in the bag. Sterilization can alter the sensor zero point. To recalibrate the pH sensors, the pH value can be measured externally in a process sample and entered in the calibration menu. The calibration function compares the pH value measured online with the one determined externally, calculates the resulting zero offset and displays the corrected process value.
The effects of heat during sterilization and reactions of the diaphragm or electrolytes with components of the medium can influence the measurement properties of the pH sensors. Be sure to check and calibrate the pH sensors before each use.

- Whenever possible, use buffer solutions manufactured by the sensor manufacturer as contained in the equipment supplied with the pH sensor.
- If the "zero offset" and "slope" values are known and the process allows for it, you can also enter these values directly into the relevant fields.
- The lifespan of the sensors is limited. It depends on the use and operating conditions in the process. Whenever a function check or calibration points to a malfunction, the pH sensors should be serviced and replaced as needed.
- The process values are calculated from the raw signal from the sensor using the sensor-specific calibration parameters. The calculated process value may fall outside the defined measurement range (2.00 pH–12.00 pH) when the sensor is sterilized, replaced or ages. In this case, recalibrate or check the quality of the sensor.
- The pH sensor must be serviced or replaced if one of the following values is outside of the working range*:
  - Zero offset ([Zero])
  - Slope

* Refer to the pH sensor manufacturer's documentation for details on the workspace.

8.10.2 Checking Functionality of the pH Sensor

The functionality of a pH sensor can be checked using the following values in the [Calibration pH-#] menu:

- pH reading
- Electrode voltage
- Sensor parameters:
  - Zero offset
  - Slope

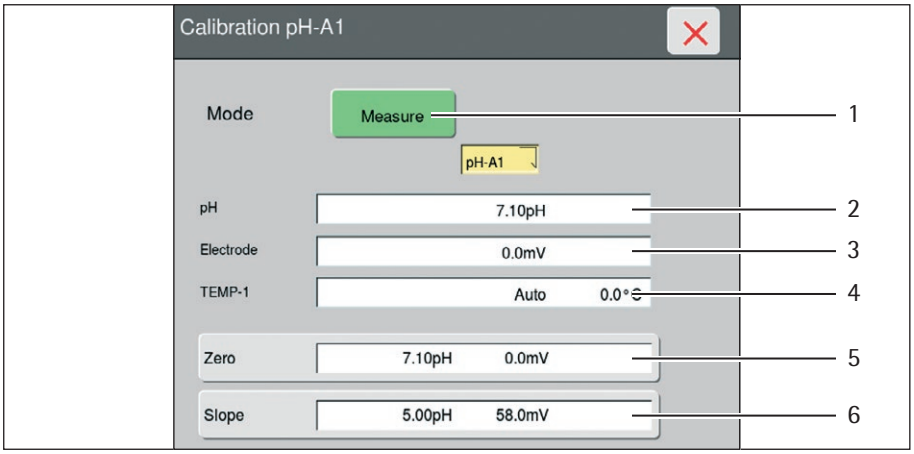


Fig. 40: Calibration Screen Overview [Calibration pH-#]

No.	Parameter	Value	Description
1	Mode	Measure	Press to display the selection screen [Calibration pH-# Mode].
2	pH	pH	Displays the pH reading.
3	Electrode	mV	Displays the value of the measurement chain voltage (raw signal).
4	TEMP-1	°C	Displays the temperature value for temperature compensation.
5	Zero	pH | mV	– Displays the pair of values for the zero offset. – Press to display the window for entering the zero offset.
6	Slope	pH | mV	– Displays the pair of values for the slope. – Press to display the window for entering the slope.

Procedure

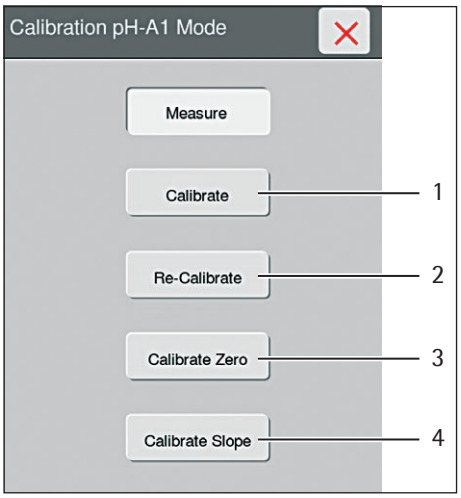
▶ Press the [pH-#] key for the sensor to be calibrated in the [Calibration] main function.
▷ The [Calibration pH-#] window appears.
▶ Check the functionality of the sensor based on the displayed values.

8.10.3 Selecting Calibration Method for the pH Sensor

This chapter describes the selection of the calibration method for the pH sensor as a single calibration.

Procedure

▶ Press the key for the sensor to be calibrated [pH-#] in the [Calibration] main function.
▷ The [Calibration pH Select] window appears.
▶ Press the [Single Calibrate] key.
▷ The [Calibration pH-#] window appears.
▶ Press the [Off] / [Measure] key.
▷ The selection screen [Calibration pH-# Mode] appears.
▶ Select the calibration method:
  ▶ To perform full calibration (two buffer calibration): Press the [Calibrate] key (1).
  ▶ To perform recalibration: Press the [Re-Calibrate] key (2).
  ▷ This recalibrates the current display to an entered value by shifting the offset of the calibration.
  ▶ To perform the zero point calibration as a single step: Press the [Calibrate Zero] key (3).
  ▶ To perform the slope calibration as a single step: Press the [Calibrate Slope] key (4).



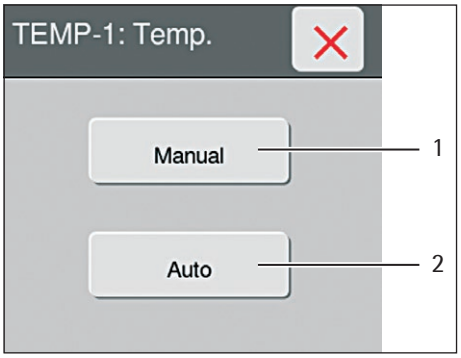
8.10.4 Fully Calibrating the pH Sensor

Requirements

– Two buffer solutions with different pH values are available.

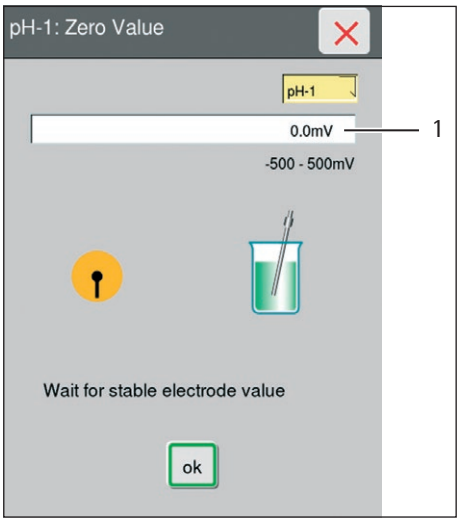
Procedure

▶ In the calibration method selection screen, press the [Calibrate] key.
▷ The [TEMP-#: Temp.] window to select the temperature compensation is displayed.
▶ Select the type of temperature compensation:
  ▶ To manually enter the temperature compensation: Press the [Manual] key (1).
  ▷ The [TEMP-#: Temp. Comp.] window appears.
  ▶ In the [TEMP-#: Temp. Comp.] window, enter the temperature compensation value.
  ▶ To select automatic temperature compensation: Press the [Auto] key (2).



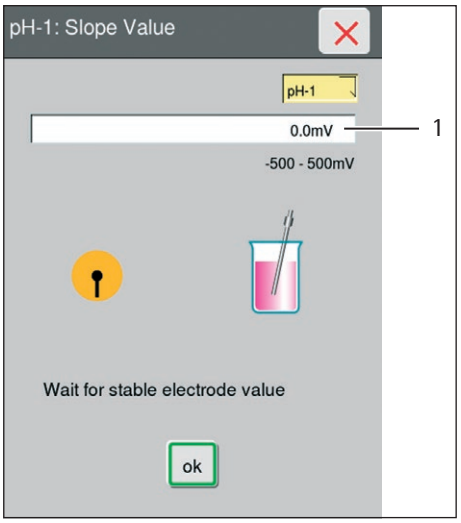
▷ The input window [pH-#: Zero Buffer] for zero point calibration is displayed.

▶ Hold the pH sensor in the buffer solution (usually a buffer solution with pH 7.00).
▶ In the input window [pH-#: Zero Buffer] input the pH value of the buffer solution.
▷ The window [pH-#: Zero Value] will appear.



- ▶ Observe the measured value displayed (1).
- ▶ Confirm the measurement with [ok] as soon as the display value is stable.
- ▷ The window [pH-#: Slope Buffer] for the slope calibration is displayed.

- ▶ Rinse the pH sensor with the second buffer and then hold the pH sensor in the second buffer solution.
- ▶ In the input window [pH-#: Slope Buffer] input the pH value of the second buffer solution.
- ▷ The window [pH-#: Slope Value] will appear.



- ▶ Observe the measured value displayed.
- ▶ Confirm the measurement with [ok] as soon as the display value is stable.

- ▷ The pH sensor is calibrated.

8.10.5 Recalibrating pH Sensor

Requirements

A calibrated pH measuring device is available.

Procedure

- ▶ Take a sample from the process.
- ▶ Quickly measure the pH of the sample with the calibrated pH measuring equipment.
- ▶ Press the [Re-Calibrate] key in the [Calibration pH-# Mode] window.
- ▷ The input window [pH-#: Re-Calibrate] will appear.
- ▶ Enter the pH value measured with the calibrated measuring equipment.
- ▷ The DCU system adjusts the zero offset and displays the corrected pH value.

8.10.6 Direct Entry of the Zero Point Offset

Procedure

- ▶ In the submenu [Calibration pH-#], press the [Zero] key.
- ▶ In the input window [pH-#: Zero Buffer], input the pH value.
- ▶ In the input window [pH-#: Zero Value], input the measured value for the zero offset.

8.10.7 Direct Input of the Slope

Procedure

- ▶ In the submenu [Calibration pH-#], press the [Slope] key.
- ▶ In the input window [pH-#: Slope Buffer], input the pH value.
- ▶ In the input window [pH-#: Slope Value], input the measured value for the slope.

8.10.8 Performing Zero Point and Slope Calibration as Individual Steps

Procedure

- ▶ Select the type of calibration:
  - ▶ To perform the zero point calibration: In the [Calibration pH-# Mode] window, press the [Calibrate Zero] key.
  - ▶ To perform the slope calibration: In the [Calibration pH-# Mode] window, press the [Calibrate Slope] key.
- ▷ The [TEMP-#: Temp.] window to select the temperature compensation is displayed.
- ▶ Select the type of temperature compensation:
  - ▶ To manually enter the temperature compensation: Press the [Manual] key (1).
  - ▷ The [TEMP-#: Temp. Comp.] window appears.
  - ▶ In the [TEMP-#: Temp. Comp.] window, enter the temperature compensation value.
  - ▶ To select automatic temperature compensation: Press the [Auto] key (2).
- ▷ The input window [pH-#: Zero Buffer] / [pH-#: Slope Buffer] for the zero point calibration / slope calibration is displayed.
- ▶ In the window [pH-#: Zero Buffer] / [pH-#: Slope Buffer] input the pH value.
- ▷ The window [pH-#: Zero Value] / [pH-#: Slope Value] will appear.
- ▶ Observe the measured value displayed.
- ▶ Confirm the measurement with [ok] as soon as the display value is stable.
- ▷ The zero point calibration or slope calibration has been completed.

8.11 DO (pO_2) Calibration (Conventional Sensor)

8.11.1 General Information on the DO (pO_2) Sensors

Calibration of the DO (pO_2) sensor is based on a two-point calibration. Measurement is performed in [% oxygen saturation]. Calibration determines the sensor parameters zero current [Zero] and slope [Slope]. The reference value for [Zero] is the oxygen-free medium in the culture vessel. Air-saturated medium can be defined as "100% saturated" and can be used as a basis for determining the [Slope]. Since you will be calibrating the sensors after sterilization, be sure to consider changes in the measuring properties that can result from heat exposure or effects of the medium during sterilization.

The DO (pO_2) sensor must be polarized before first use or if it has been disconnected from the power supply (measurement amplifier) for longer than 5 to 10 min. Polarization can take up to 6 hours (less time when the sensor was only disconnected from the measurement amplifier for a few minutes). This does not apply to optical DO (pO_2) sensors (e.g. VISIFERM, Hamilton). Observe the indications from the sensor manufacturer.

The process values are calculated from the raw signal from the sensor using the sensor-specific calibration parameters. The calculated process value may fall outside the defined measurement range (0.0–100.0 %sat) when the sensor is sterilized, replaced or ages. In this case, recalibrate or check the quality of the sensor.

8.11.2 Checking Functionality of the DO (pO_2) Sensor

The functionality of a DO (pO_2) sensor can be checked in the calibration window based on the readings.

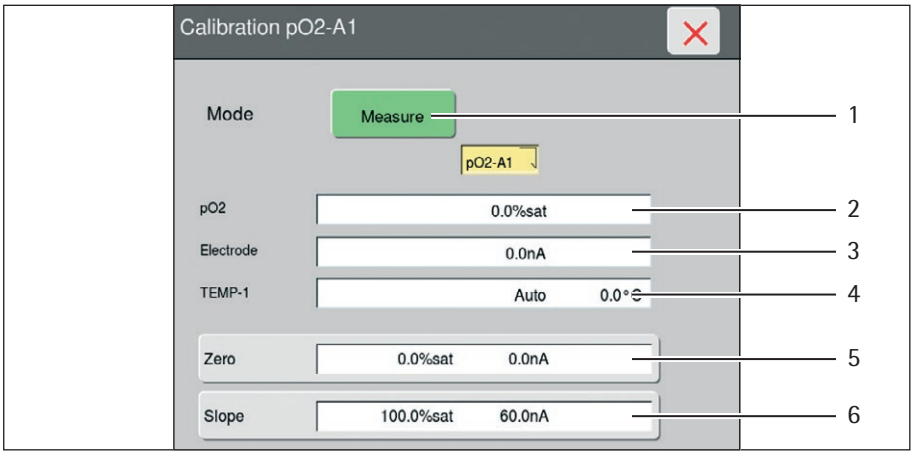


Fig. 41: Calibration Window Overview [Calibration pO_2-#]

No.	Field	Value	Description
1	Mode	Measure	Press to display the selection screen [Calibration pO2-# Mode].
2	pO_2	%sat	Displays the DO (pO_2) saturation.
3	Electrode	nA	Displays the value of the measurement current (raw signal).
4	TEMP	°C	Displays the temperature value for temperature compensation.
5	Zero	%sat | nA	– Displays the pair of values for the zero offset. – Press to display the window for entering the zero offset.
6	Slope	%sat | nA	– Displays the pair of values for the slope. – Press to display the window for entering the slope.

Procedure

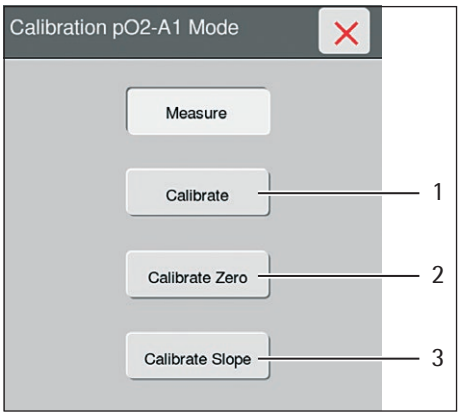
▶ Press the [pO2-#] key for the sensor to be calibrated in the [Calibration] main function.
▷ The [Calibration pO2-#] window appears.
▶ Check the functionality of the sensor based on the displayed values.

8.11.3 Selecting Calibration Method for the DO (pO_2) Sensor

This chapter describes the selection of the calibration method for the DO (pO_2) sensor as a single calibration.

Procedure

▶ Press the key for the sensor to be calibrated [pO2-#] in the [Calibration] main function.
▷ The [Calibration pO2 Select] window appears.
▶ Press the [Single Calibrate] key.
▷ The [Calibration pO2-#] window appears.
▶ Press the [Off] / [Measure] key.
▷ The selection screen [Calibration pO2-# Mode] appears.
▶ Select the calibration method:
  ▶ To perform full two point calibration: Press [Calibrate] key (1).
  ▶ To perform the zero point calibration as a single step: Press the [Calibrate Zero] key (2).
  ▶ To perform the slope calibration as a single step: Press the [Calibrate Slope] key (3).



8.11.4 Fully Calibrating the DO (pO_2) Sensor

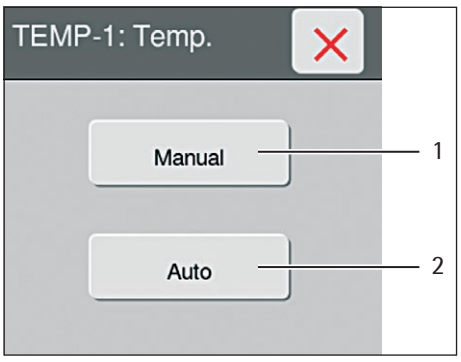
Depending on your choice, only the zero point (Calibrate Zero) or the slope (Calibrate Slope) is calibrated, or a full calibration (Calibrate) is carried out.

The DO (pO_2) sensor must be serviced if one of the following values is outside of the working range*:
– the zero point (window [pO2-#: Zero Value]),
– the sensor current at maximum aeration with air (window [pO2-#: Slope Value]).

* Refer to the DO (pO_2) sensor manufacturer's documentation for details on the workspace.

Procedure

▶ In the selection screen [Calibration pO2-# Mode], press the [Calibrate] button.
▷ The [TEMP-#: Temp.] window to select the temperature compensation is displayed.
▶ Select the type of temperature compensation:
  ▶ To manually enter the temperature compensation: Press the [Manual] key (1).
  ▷ The [TEMP-#: Temp. Comp.] window appears.
  ▶ In the [TEMP-#: Temp. Comp.] window, enter the temperature compensation value.
  ▶ To select automatic temperature compensation: Press the [Auto] key (2).



▷ The input window [pO2-#: Zero Buffer] for zero point calibration is displayed.

The zero point calibration for the DO (pO_2) sensor can, for example, be performed in the following ways:

– On the laboratory table in a gel sample (0% oxygen saturation).
– In pure nitrogen gas environment,
– In medium gassed with nitrogen (as described in the following).

▶ Mount the DO (pO_2) sensor on the bag.
▶ Fill the bag and condition to the desired temperature.
▶ Set the [N2] aeration to 100%. Set all other aerations to 0%.
▶ Set the stirrer (STIRR) to approximately 80%–100% of the maximum permissible speed.
▶ In the input window [pO2-#: Zero Buffer], enter the DO (pO_2) value (generally 0%).
▷ The window [pO2-#: Zero Value] will appear.

▶ Wait until the oxygen dissolved in the medium has been displaced. When the raw electrode signal stabilizes near the 0 nA value, the oxygen saturation is approaching the minimum.
▶ Observe the measured value display in the window [pO2-#: Zero Value]. Once the display is stable, confirm the measurement with [ok].

The slope calibration of the DO (pO_2) sensor can be performed in the following ways:

– on the laboratory table in the ambient air,
– in medium gassed with air (as described in the following):

▶ Set the [AIR] aeration to 100%. Set all other aerations to 0%.
▶ Set the stirrer (STIRR) to approximately 80%–100% of the maximum permissible speed.
▶ In the input window [pO2-#: Slope Buffer], enter the DO (pO_2) value (generally 100%).
▷ The window [pO2-#: Slope Value] will appear.

▶ Observe the measured value display in the window [pO2-#: Slope Value]. The raw electrode signal stabilizing near the max. value of the DO (pO_2) sensor is an indication that the oxygen saturation is approaching maximum (see manufacturer's documentation on the DO (pO_2) sensor for max. value specifications).
▶ Once the display is stable, confirm the measurement with [ok].
▷ DO (pO_2) sensor is calibrated.

8.11.5 Direct Entry of the Zero Point Offset

Procedure

▶ Press the [Zero] key in the [Calibration pO2-#] submenu.
▶ In the input window [pO2-#: Zero Buffer], input the DO (pO_2) value.
▶ In the input window [pO2-#: Zero Value], input the measured value for the zero offset.

8.11.6 Direct Input of the Slope

Procedure

- ▶ Press the [Slope] key in the [Calibration pO2-#] submenu.
- ▶ In the input window [pO2-#: Slope Buffer], input the DO (pO_2) value.
- ▶ In the input window [pO2-#: Slope Value], input the measured value for the slope.

8.11.7 Performing Zero Point and Slope Calibration as Individual Steps

Procedure

- ▶ Select the type of calibration:
  - ▶ To perform the zero point calibration: In the [Calibration pO2-# Mode] window, press the [Calibrate Zero] key.
  - ▶ To perform the slope calibration: In the [Calibration pO2-# Mode] window, press the [Calibrate Slope] key.
- ▷ The [TEMP-#: Temp.] window to select the temperature compensation is displayed.
- ▶ Select the type of temperature compensation:
  - ▶ To manually enter the temperature compensation: Press the [Manual] key.
  - ▷ The [TEMP-#: Temp. Comp.] window appears.
  - ▶ In the [TEMP-#: Temp. Comp.] window, enter the temperature compensation value.
  - ▶ To select automatic temperature compensation: Press the [Auto] key.
- ▷ The input window [pO2-#: Zero Buffer] / [pO2-#: Slope Buffer] for the zero point calibration / slope calibration is displayed.
- ▶ In the window [pO2-#: Zero Buffer] / [pO2-#: Slope Buffer] input the DO (pO_2) value.
- ▷ The window [pO2-#: Zero Value] / [pO2-#: Slope Value] will appear.
- ▶ Observe the measured value displayed.
- ▶ Confirm the measurement with [ok] as soon as the display value is stable.
- ▷ The zero point calibration or slope calibration has been completed.

8.12 Calibrating Optical Single-use pH Sensors

Information on Calibration of Optical Single-use pH Sensors

The patches age when they are exposed to light. The measured value drifts by approx. 0.13 pH based on 10,000 measurements. To compensate for this drift, enhanced DCU configurations provide a [Re-calibration] function. Measurements should therefore be taken as seldom as possible during the process. Additionally, the acceptable measurement accuracy for the process and the possible number of resulting measurements (measurement cycle duration) can be determined empirically.

During typical pH calibration, reference values for zero point and slope are measured in calibration buffers. This is not possible with the optical single-use pH sensors that are pre-sterilized and installed in the BIOSTAT STR®. Instead, a method was developed that determines the typical measured values pH0/ pH and phase-angle f(min) / f(max) for a batch of sensors. These data are supplied with the Flexsafe STR® bag (label stickers with calibration parameters) and entered in the pH calibration menu.

Basic Calibration Procedure

Calibration with the calibration parameters found on the label sticker must be kept at process temperature. Only under these conditions can the optical single-use pH sensors be calibrated correctly.

Requirements

- The optical single-use pH sensors are in the medium for at least two hours.
- The medium has reached the process temperature.

Procedure

▶ If necessary, wait until the medium has reached the process temperature. Immerse the probes in the medium for at least 2 hours.
▶ Enter the initial calibration information on the calibration label sticker ("Enter the initial calibration data").
▶ After reaching the process temperature and conditions, draw an offline sample and recalibrate to the offline pH value.
▶ If necessary, change the measurement cycle.

Calibration Screen Overview [Calibration pH-#]

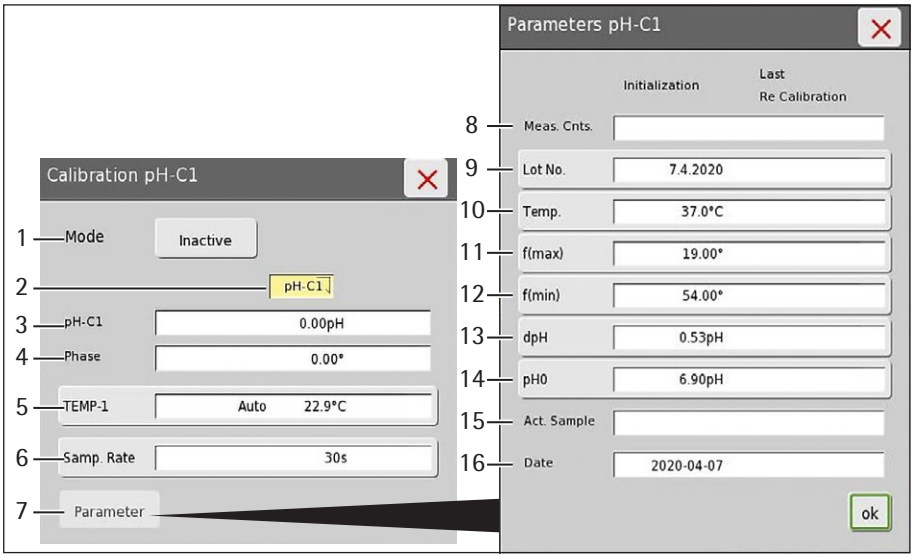


Fig. 42: Calibration screen overview [Calibration pH-#]

No.	Parameter	Value	Description
1	Mode		– Displays the current operating mode. – Press to display the operating mode selection screen.
	– Inactive		Appears after commissioning, before the first calibration.
	– Calibrate		Appears when going through the calibration steps.
	– Measure		Indicates that the measurement is active in process.
	– Hold		Indicates that the in-process measurement has been paused.
	– Re-Calibration		Appears during in-process re-calibration.
2	pH-#		Displays the selected sensor.
3	pH-#	pH	Displays the pH reading.
4	Phase		Measurement phase angle.

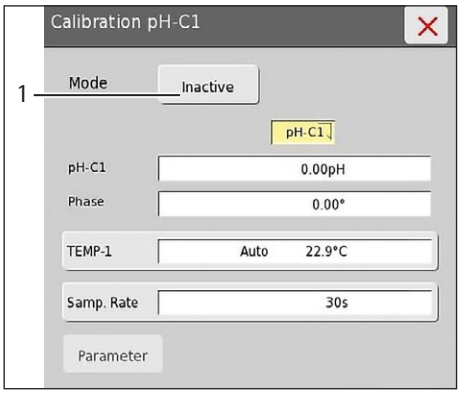
No.	Parameter	Value	Description
5	TEMP-#	°C	Type of temperature compensation; switch between: – Automatic compensation for pH measurement in-process – Manual compensation to calibrate the pH electrode (do not use during normal operation)
6	Samp. Rate	s	Measurement cycle (waiting time between individual measurements) – Setting range: 5 s to 3600 s – Choose a measurement cycle that produces a maximum number of measurements at acceptable frecuency.
7	Parameter		View and change the calibration parameters.
8	Meas. Cnts.		Number of measurements performed.
9	Lot-No.		Manufacturer reference for released batch of sensors.
10	Temp	°C	Reference temperature for calibration.
11	f (max)	°	Phase reference, reference pH (reference measurement deviating from the zero point).
12	f (min)	°	Phase reference, zero point pH (during reference measurement for "zero point").
13	dpH	pH	Reference pH for sensor batch (typical deviation).
14	pHO	pH	Typical pH zero point for batch of sensors.
15	Act. Sample		Displays sampling value of the last re-calibration.
16	Date		Displays the date of last calibration (Initialization) or re-calibration (Last Re-Calibration).

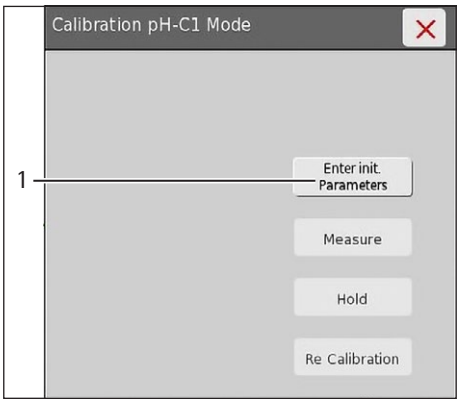
Entering Initial Calibration Data

The calibration data to be entered are printed on the Flexsafe STR® bag. These data must be entered, as no (valid) pH measurement is possible beforehand.

Procedure

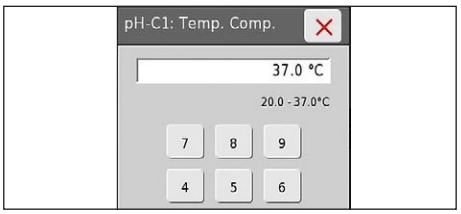
▶ Press the key of the sensor to be calibrated [pH-#].
▷ The submenu [Calibration pH-#] opens.
▶ Press the [Inactive] key (1).
▷ The window [Calibration pH-# Mode] appears.



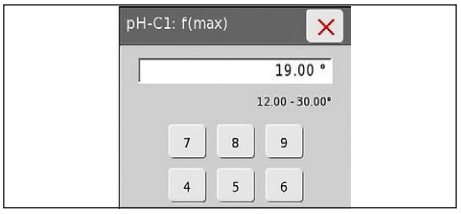


▶ Press the [Enter init. Parameters] key (1).

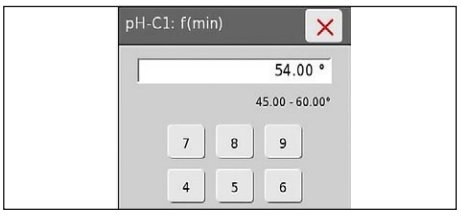
▷ The window [pH-# Lot.No.] appears.
▶ Enter the parameters and confirm with the [Enter] key.



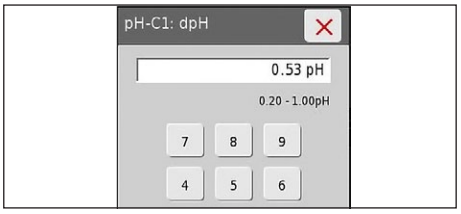
▷ The window [pH-# Temp.Comp.] appears
▶ Enter the parameters and confirm with the [ok] key.



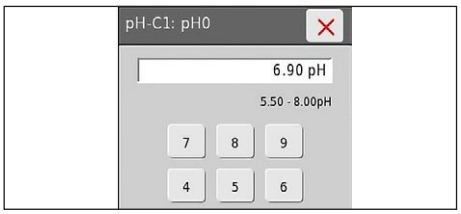
▷ The window [pH-# f(max)] appears
▶ Enter the parameters and confirm with the [ok] key.



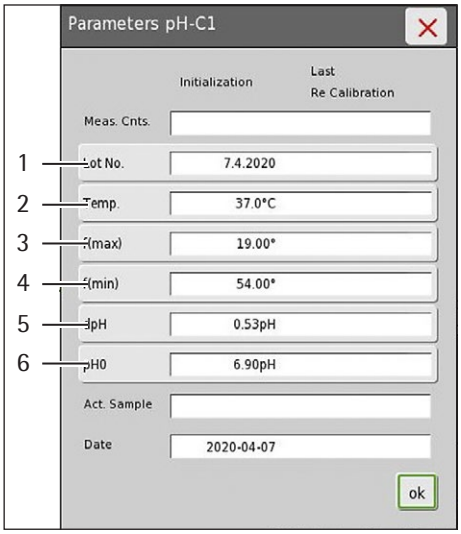
▷ The window [pH-# f(min)] appears
▶ Enter the parameters and confirm with the [ok] key.



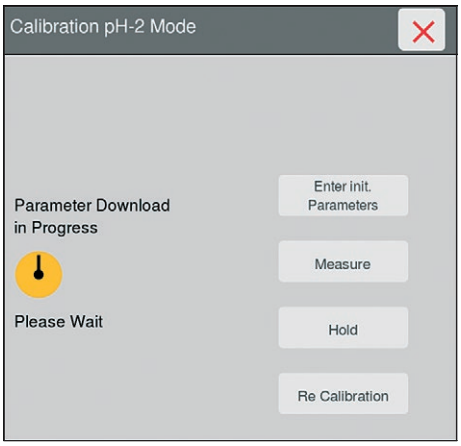
▷ The window [pH-# dpH] appears
▶ Enter the parameters and confirm with the [ok] key.



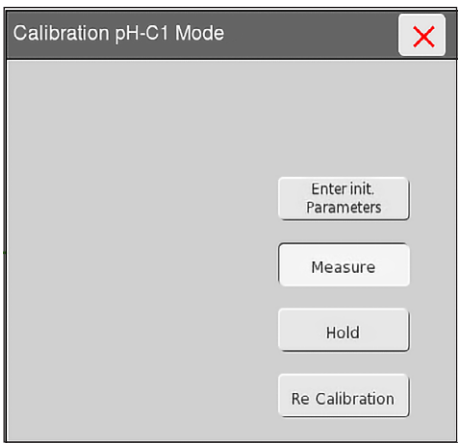
▷ The window [pH-# pH0] appears
▶ Enter the parameters and confirm with the [ok] key.



▶ Check the displayed parameters.
▶ If required: Change the parameters. Do this by pressing the respective key (1) to (6) and enter the correct parameters.
▶ Confirm the changed parameters with the [ok] key.
▷ The data is transferred to the DCU system.



▶ Wait for the parameters to be transmitted.
▷ The initial calibration of the pH sensor is now complete.

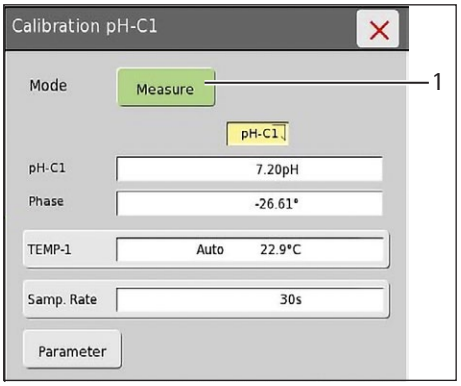


▶ Close the window [Calibration pH-# Mode].

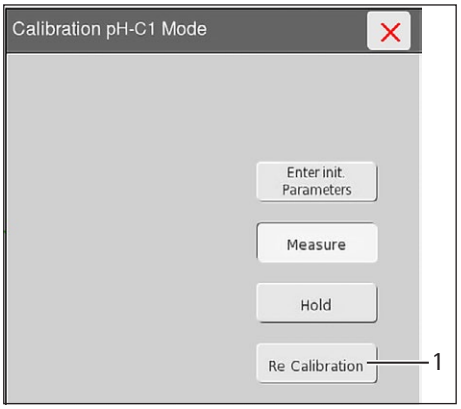
Performing Recalibration

Procedure

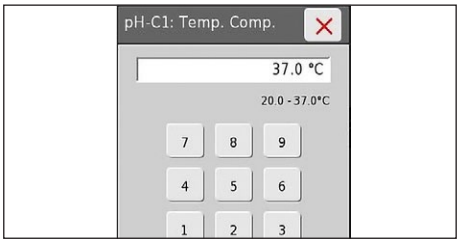
▶ Press the key of the sensor to be calibrated [pH-#].
▷ The submenu [Calibration pH2-#] opens.
▶ Press the [Measure] key (1).



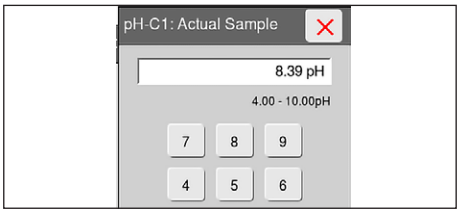
▷ The window [Calibration pH-# Mode] appears.
▶ Press the [Re-Calibration] key (1).



▷ The window [pH-# Temp.Comp.] appears
▶ Enter the parameters and confirm with the [ok] key.



▷ The window [pH-# Actual Sample] appears



▶ Take a sample from the process.
▶ Measure the pH of the sample taken with a calibrated pH measuring equipment.
▶ In the input window [pH-#: Actual Sample], enter the pH value measured.
▷ The DCU system adjusts the zero offset and displays the corrected pH value.

Configuring the Measurement Cycle for pH Measurement

Optical single-use pH sensors show decay of the indicator dyes, e.g. photo bleaching. This degradation depends on the amount of light and increases with the pH value (for alkaline media).

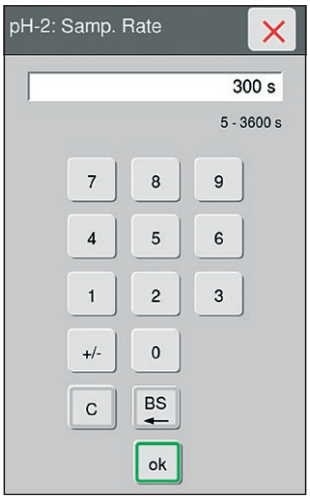
The single-use pH sensors used in the Flexsafe STR® bag are designed for 20,000 measurement points. The measurement cycle can be configured so that 20,000 measurements are possible over the total process time.

Example of calculation specifications:
- Overall process time = 666 hours (approx. 28 days)
- Maximum number of measurements = 20,000

Calculation:
20,000 measurement cycles / 666 hours = 30 measurement cycles / hour
= one 120-second measurement cycle per measurement

Procedure

▶ In the [Calibration pH-#] window, press the [Samp. Rate] key.
▶ Calculate the measurement cycle of the pH measurement according to the above calculation.
▶ In the input window [pH-#: Samp. Rate], enter the measurement cycle.



▷ The measurement cycle of the pH measurement has been changed.

8.13 Calibrating Optical Single-use DO (pO_2) Sensors

Information on Calibration of Optical Single-use DO (pO_2) Sensors

The patches age when they are exposed to light. The typical measured value at 0% DO (pO_2) and 100% DO (pO_2) is determined for a batch of sensors. These data are supplied with the Flexsafe STR® bag (label stickers with calibration parameters) and entered in the DO (pO_2) calibration menu.

Basic Calibration Procedure

Requirements

– The medium has reached the process temperature.
– The probes are immersed in the medium for at least 2 hours.

Procedure

Perform the following steps to calibrate optical single-use DO (pO_2) sensors:

▶ Enter the initial calibration data.
▶ Take an offline sample.
▶ Perform recalibration.
▶ If necessary, change the measurement cycle.

Calibration Screen Overview [Calibration pO2]

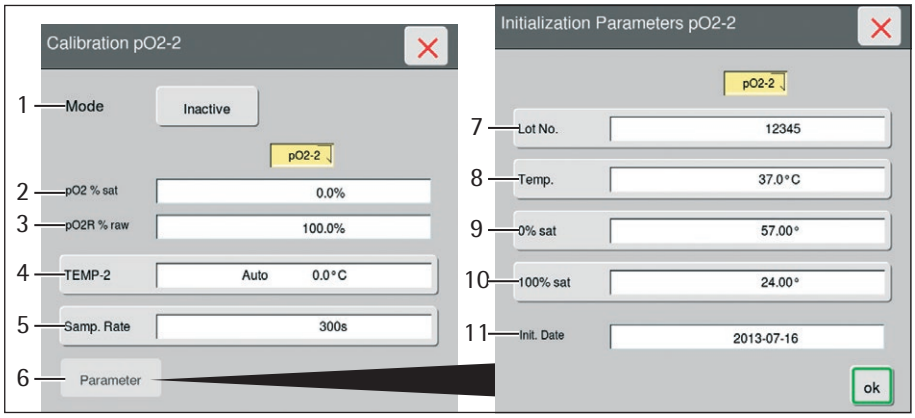


Fig. 43: Calibration Screen Overview [Calibration pO2]

No.	Parameter	Value	Description
1	Mode		– Displays the current operating mode. – Press to display the operating mode selection screen.
	– Inactive		Appears after commissioning, before the first calibration.
	– Calibrate		Appears when going through the calibration steps
	– Measure		Indicates that the measurement is active in process.
	– Hold		Indicates that the in-process measurement has been paused.
	– Re-Calibration		Appears during in-process re-calibration.
2	pO2	% sat	Displays current DO (pO_2) measurement.
3	pO2R%raw		Displays current raw calibration value from the amplifier in %.

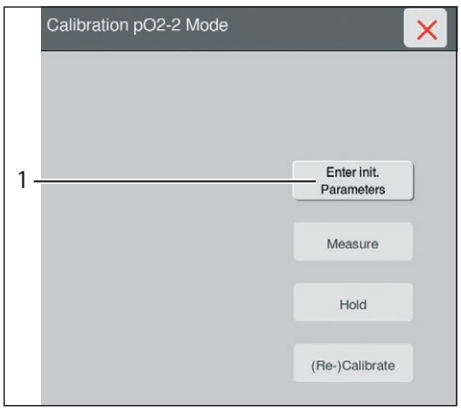
No.	Parameter	Value	Description
4	TEMP-#	°C	Type of temperature compensation; switch between: – Automatic compensation for DO (pO_2) measurement in-process. – Manual compensation to calibrate the DO (pO_2) electrode (do not use during normal operation).
5	Samp. Rate	s	Measurement cycle (waiting time between individual measurements) – Setting range: 5 s to 600 s – Choose a measurement cycle that produces a maximum number of measurements at acceptable frecuency.
6	Parameter		Displays window to display and input the initial calibration parameters.
7	Lot-No.		Manufacturer reference for released batch of bags.
8	Temp	°C	Reference temperature for calibration.
9	0 % sat	%	Typical reference zero point (zero DO (pO_2)) of the batch.
10	100 % sat	%	Typical reference slope (slope DO (pO_2)) of the batch.
11	Init. Date		Displays the date of the initial calibration.

Entering Initial Calibration Data

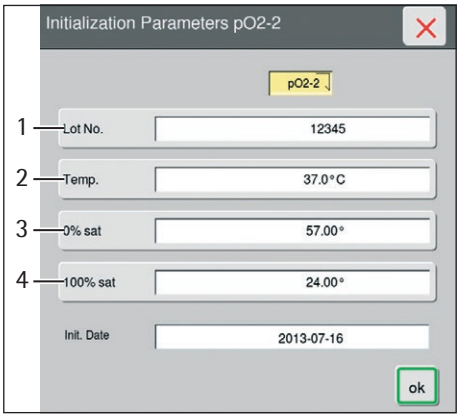
The calibration data to be entered are printed on the Flexsafe STR® bag. These data must be entered, as no (valid) DO (pO_2) measurement is possible beforehand.

Procedure

▶ Press the key of the sensor [pO2-#] to be calibrated.
▷ The submenu [Calibration pO2-#] opens.
▶ Press the [Inactive] key.
▷ The screen [Calibration pO2-# Mode] appears.
▶ Press the [Enter init. Parameters] key (1).

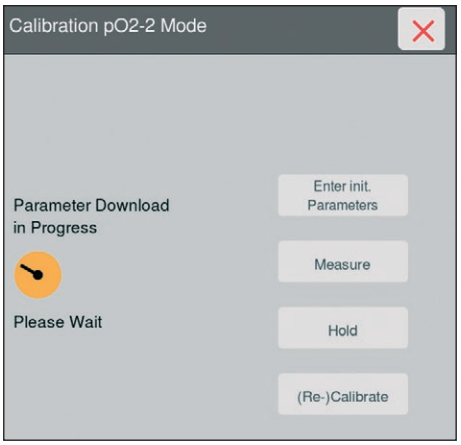


▶ Enter the parameters (8) to (12) from the bag label one after another in the respective input window and confirm by pressing [Enter] and [ok].



▶ Check the displayed parameters.
By pressing the respective key (1) to (4), the corresponding parameter can be modified as necessary.

▶ Confirm input with [ok] key.
▷ The data are transferred to the DCU system.



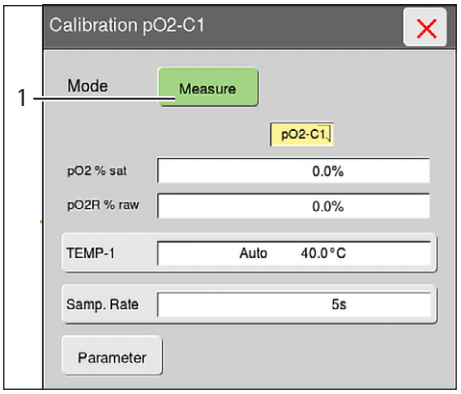
▶ Wait for the parameters to be transmitted.

▷ The initial calibration of the DO (pO_2) sensor is now complete.
▶ Close the window [Calibration pO2-# Mode].

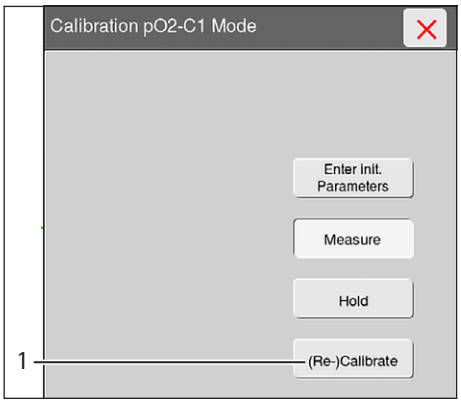
Performing Recalibration

Procedure

▶ Press the key of the sensor [pO2-#] to be calibrated.
▷ The submenu [Calibration pO2-#] opens.
▶ Press the [Measure] (1) key.



▷ The screen [Calibration pO2-# Mode] appears.



▶ Press the [Re-Calibrate] key (1).

▶ Press the [% sat] key.
▶ Take a sample from the process.
▶ Measure the DO (pO_2) value of the sample taken with calibrated DO (pO_2) measuring equipment.
▶ In the input window [pH-#: Actual Sample], enter the DO (pO_2) value measured.
▷ The DCU system adjusts the zero offset and displays the corrected DO (pO_2) value.

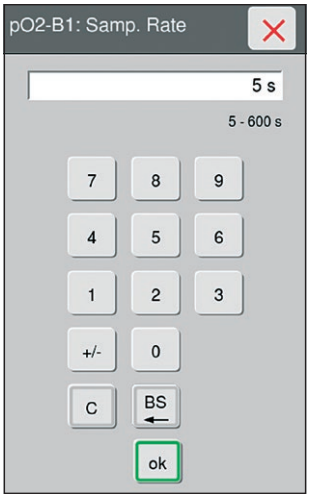
Configuring Measurement Cycles for DO (pO_2) Measurement

Optical DO (pO_2) sensors show decay of the indicator dyes, e.g. photo bleaching. The measurement cycle can be configured so that 200,000 measurements are possible over the total process time.

Example of calculation specifications:
– Overall process time = 666 hours (approx. 28 days)
– Maximum number of measurements = 200,000
Calculation:
200,000 measurement cycles / 666 hours = 300 measurement cycles / hour
= five measurement cycles / minute

Procedure

▶ In the [Calibration pO2-#] window, press the [Samp. Rate] key.
▶ Calculate the measurement cycle of the DO (pO_2) measurement according to the above calculation.



▶ In the input window [pO2-#: Samp. Rate] enter the measurement cycle.

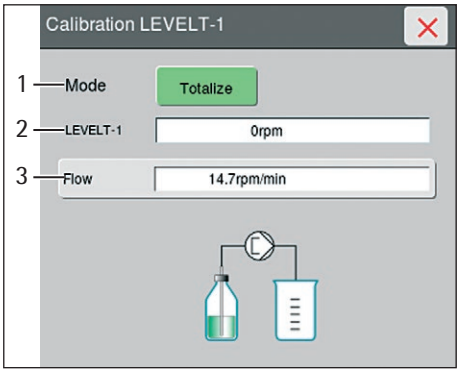
▷ The measurement cycle of the DO (pO_2) measurement has been changed.

8.14 Resetting Totalizer for Pumps and Valves

For documenting the correction medium consumption, the DCU system adds up the running times of the pumps or solenoid valves. It calculates the feed volumes from the running times, taking the specific flow rates into account. You can determine unknown pump feed rates using the calibration menus of the pumps or solenoid valves. Depending on the tubing and pumps used, known specific addition rates can be entered directly into the calibration menu.

The totalizer is reset after calibration. The totalizer is automatically activated after switching on the pump or the associated controller.

The calibration and totalizer functions (Totalize) are the same for all pumps and solenoid valves. Calibration is described using the example [LEVELT-#].



No.	Parameter	Value	Description
1	Mode		– Displays the active operating mode. – Press to display the window [LEVELT-# Mode].
		Calibrate	Press to start calibration.
		Totalize	After [Calibrate] ends, the system automatically switches to [Totalize] mode.
		Reset	Press to set the dose counter back to zero.
2			Display the volume of liquid being pumped for:
	LEVELT-#	rpm/min	Level pump (typically a digital pump)
	FOAMT-#	ml	Antifoam pump (typically a digital pump)
	ACIDT-#	ml	Acid pump (typically a digital pump)
	BASET-#	ml	Base pump (typically a digital pump)
	SUBST-A1... D1	ml	Substrate pump A to D (typically an analog pump)
3	Flow	ml/min	Press to directly enter the specific pump delivery rate or flow of the solenoid valve (if known).

Fig. 44: Calibration screen overview [Calibration LEVELT]

Performing the Calibration

Requirements

– When calibrating pumps, always use the same type of tubing with the same dimension as will be used for the process.
– It is preferable to use an appropriate balance because this method is more accurate than volumetric calibration.

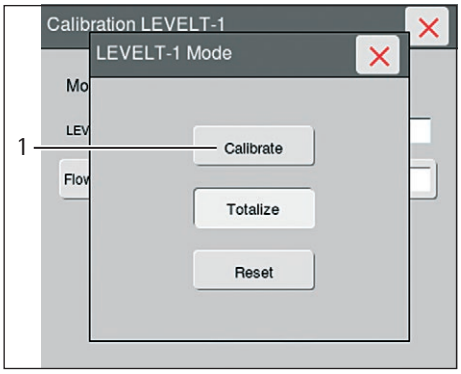
Procedure

▶ Prime the tubing before calibration:
  ▶ Insert the hose into the pump.
  ▶ Hang the hose end from the pump inlet into a media filled beaker.
  ▶ Hang the hose end from the pump outlet into a measuring cup that you can use to measure the feed rate.

The analog pumps must be controlled by the Subs controller.

▶ Activate the pump with [on].
▷ Leave the pump activated until the hose is completely filled.
▶ Once the tubing is primed, turn off the pump.
▶ Press the key of the pump to be calibrated [LEVELT-#].

Before the first calibration, the [Off] mode is displayed.



▶ Press the [Mode] key in the [Calibration LEVELT-#] window.
▶ Press the [Calibrate] key (1) in the [LEVELT-# Mode] window.
▷ The [LEVEL-#: Calibration Start] window appears.

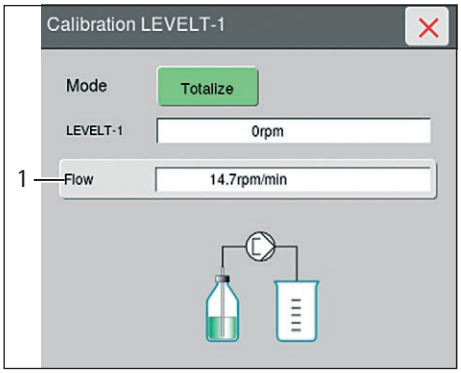
▶ Start pump calibration with [ok].
▷ The [LEVEL-#: Calibration Stop] window appears. The pump pumps the medium.
▶ Wait until a sufficient volume has been pumped.
▶ Stop the calibration by pressing [ok].
▶ Record the total pumped volume.
▶ In the [LEVELT-#: Volume] input window, enter the pumped volume and confirm with [ok].
▷ The totalizer is reset and the display mode changes to [Totalize].

The DCU system adjusts the feed rate automatically from the internally registered pump run time and the feed volume calculated. The feed rate is displayed in the [Calibration LEVELT-#] submenu in the [Flow] field.

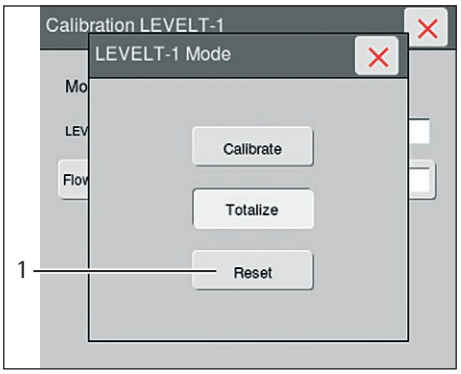
Direct Entry of the Feed Rate

Procedure

If you know the feed rate as a function of the hoses and pumps used: The feed rate can be entered directly:



▶ Press the [Flow] key (1) in the [Calibration LEVELT-#] submenu.
▷ The input window [LEVELT-#: Flow] appears.
▶ In the [LEVELT-#: Flow] window, enter the feed rate and confirm by pressing [ok].

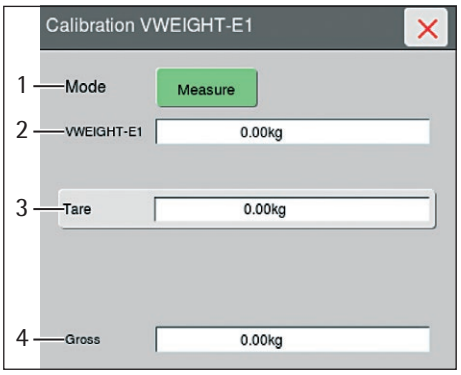


Resetting the Totalizer

▶ Press the [Mode] key in the [Calibration LEVELT-#] window.
▶ Press the [Reset] key (1) in the [LEVELT-# Mode] window.
▷ The totalizer is reset.

8.15 Taring Balances

The weight of bags, feed bottles or media and harvest containers can be measured on weighing platforms or load cells.
Any tare corrections required, e.g. after re-equipping the culture vessel or refilling a holding bottle, can be made during running operations. For this purpose, the net weight must be determined and the tare weight adjusted to the change in weight from different equipment.



No.	Parameter	Value	Description
1	Mode		– Displays the active operating mode. – Press to display the window [VWEIGHT-# Mode].
	– Measure		Indicates that in-process measurement is active.
	– Tare		Press to perform zero-taring.
	– Hold		Indicates that in-process measurement has been paused.
2			Display net weight (WEIGHT = gross tare):
	FWEIGHT-A#/B#	g/kg	Weight of substrate or harvest container
	VWEIGHT-#	g/kg	Vessel (bioreactor) weight
	BWEIGHT-#	g/kg	Weight of the media or correction media bag
3	Tare	g/kg	– Displays the tare weight of the DCU system. – Press to open a window for entering the tare weight.
4	Gross	g/kg	Gross weight display (measured value of the scale)

Fig. 45: Calibration screen overview [Calibration VWEIGHT]

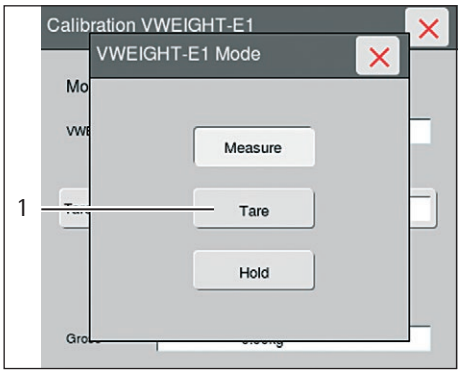
Changing the Tare Weight via Direct Entry

Procedure

▶ Press the [Tare] key in the [Calibration VWEIGHT-#] window.
▷ The input window [VWEIGHT-#: Tare] appears.
▶ In the [VWEIGHT-#: Tare] window, enter the new weight.
▶ Confirm the weight change with [ok].
▷ The tare weight in the DCU system and the [Tare] display is set to the input value. The gross weight [Gross] (measured value of the balance) remains unchanged.

Zero-taring Using the Example of Scale / Vessel weight

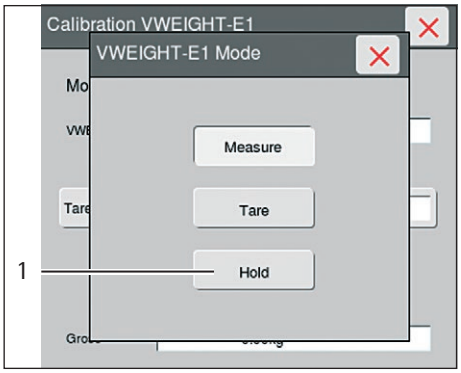
Procedure



- ▶ Press the [Mode] key in the [Calibration VWEIGHT-#] window.
- ▶ Press the [Tare] key (1) in the [VWEIGHT-# Mode] window.
- ▷ The tare weight in the DCU system and the [Tare] display is set to zero. The gross weight [Gross] remains unchanged.

Tare Correction During Running Operations

Procedure



- ▶ Press the [Mode] key in the [Calibration VWEIGHT-#] window.
- ▶ Press the [Hold] key (1) in the [VWEIGHT-# Mode] submenu.

- ▷ The [Tare] display is frozen.
- ▶ Make changes to the equipment: for example, re-equipping the bag or refilling a holding bottle.
- ▶ Quit tare correction by pressing the [ok] key.
- ▷ Despite changing the gross weight, the [Tare] display remains unchanged.

8.16 Configuring Controllers (General)

8.16.1 Controller Operation

The controllers in the DCU system work as PID controllers, target value generators or two-point controllers. They are adapted to their individual control circuits. Depending on the control task, PID controllers are parameterizable. The controller outputs control their control elements either continuously or using pulse-width modulation. Single-sided and split range controls are implemented.

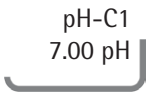
The operation of the controllers includes the configuration of setpoints, alarm limits and selecting of the operating mode. In the control parameters settings screen, the following additional settings can be set:

– Assignment of the controller output, given a controller can control multiple outputs.
– Controller settings that are not necessary for routine operation.

Displaying Controller Window

Procedure

▶ Press the main function key [Main] or the main function key [Controller].
▶ Press the corresponding controller key, e.g. controller pH-C1.



8.16.2 Setting Controller Parameters

To optimize the controllers to the respective controlled loop, the controller parameters can be adjusted in the controller parameters settings screen. DCU systems are configured at the factory with parameters that ensure the stable operation of the control circuits in the device. Factory-set control parameters can be taken from the customer-specific configuration documentation. In "Remote" operation, the host PC defines the target values and operating modes.

As a general rule, it is not required to change the control parameters. The exceptions are controlled loop paths, the behavior of which is strongly influenced by the process, e.g. pH control loops.

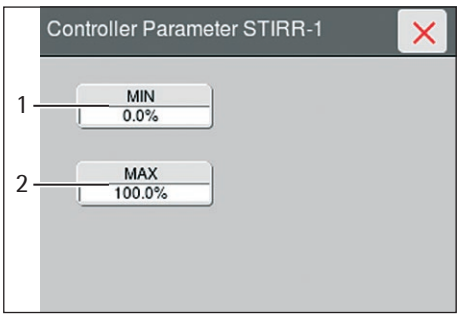
Output limits, deadband and PID parameters can be modified. The PID controller can be optimized this way.

Procedure

▶ Call up the advanced controller settings screen for the respective controller.
▶ Press the symbol key.
▷ The controller parameters settings screen will be displayed.

Setting Output Limits

The controller output for setpoint generators and PID controllers can be assigned a lower and an upper limit. This limitation prevents large actuating of the control elements. In cascade controls, the setpoint range of the slave controller can be limited.



Procedure

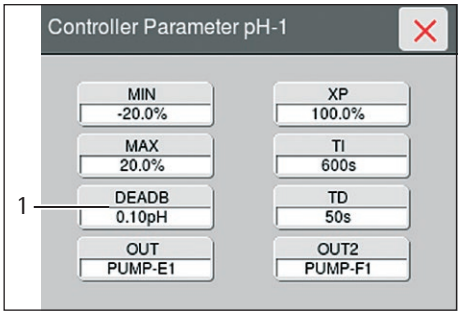
▶ To configure the full range of a unilateral controller output:
  ▶ Press the [MIN] key (1) and enter the value [0].
  ▶ Confirm input with [ok] key.
  ▶ Press the [MAX] key (2) and enter the value [100].
  ▶ Confirm input with [ok] key.

▶ To configure the full range of a split-range controller output: Do the following:
  ▶ Press the [MIN] key (1) and enter the value [-100].
  ▶ Confirm input with [ok] key.
  ▶ Press the [MAX] key (2) and enter the value [100].
  ▶ Confirm input with [ok] key.

Setting the Deadband

A deadband can be set up for PID controllers. Given control fluctuations within the deadband, the controller output is maintained at a constant value. For pH regulators, the value is set to zero, when the output crosses into the deadband. Given fluctuating actual values, setting a deadband enables more stable control with minimized actuating element movements. For controllers with split-range outputs, this prevents oscillation of the controller output, e.g. constantly changing acid / alkaline proportioning on the pH controller.

The adjustment of the deadband is exemplified using the pH controller. The setpoint of the pH controller is set to the value [6.0 pH].

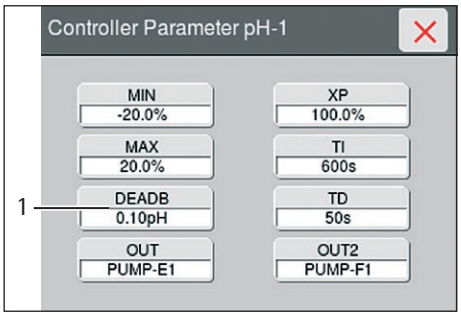


Procedure

▶ Press the [DEADB] key (1) and enter the value 0.1 pH.
▶ Confirm input with [ok] key.
▷ The deadband set is ± 0.1 pH.
▷ In that case, the control loop is inactivated at nominal values between 5.9 pH and 6.1 pH.

Setting the PID Controller Structure

The PID controllers can be optimized using the PID parameters XP, TI and TD.
The implemented digital controllers run according to the position control algorithm. The controller structure (P, PI, PD, PID) can be configured by setting individual PID controller parameters to zero. The PID controller parameters can be changed during operation.



Procedure

▶ To set the controller structure of a P-controller. Do the following:
  ▶ Press the [TI] key and enter the value 0.
  ▶ Confirm input with [ok] key.
  ▶ Press the [TD] key and enter the value 0.
  ▶ Confirm input with [ok] key.
▶ To set the controller structure of a PI-controller:
  ▶ Press the [TD] key and enter the value 0.
  ▶ Confirm input with [ok] key.
▶ To set the controller structure of a PD-controller:
  ▶ Press the [TI] key and enter the value 0.
  ▶ Confirm input with [ok] key.
▶ To set the controller structure of a PID-controller. Do the following:
  ▶ Press the [TI] key and enter the value >0.
  ▶ Confirm input with [ok] key.
  ▶ Press the [TD] key and enter the value >0.
  ▶ Confirm input with [ok] key.

Optimizing PID Controller

Knowledge of control theory is a prerequisite for optimum adjustment of a PID controller and can be obtained from tried and tested configuration rules in the relevant literature, e.g. Ziegler Nichols.

In the optimization of a PID controller, the following basic guidelines should be followed:

- Only switch on the D portion (TD) if the actual values are relatively stable. For actual values with a lot of noise, the D portion makes fast, large changes to the output. This causes unstable control.
- Configure TI:TD should preferably be set to 4:1.
- To counteract periodic oscillations of the control loop: Increase the values for [XP] or [TI] / [TD].
- To speed up adjustment following setpoint changes and given actual value drift: Decrease the values for [XP] or [TI] / [TD].

8.16.3 Customer-specific Adjustment of Controllers

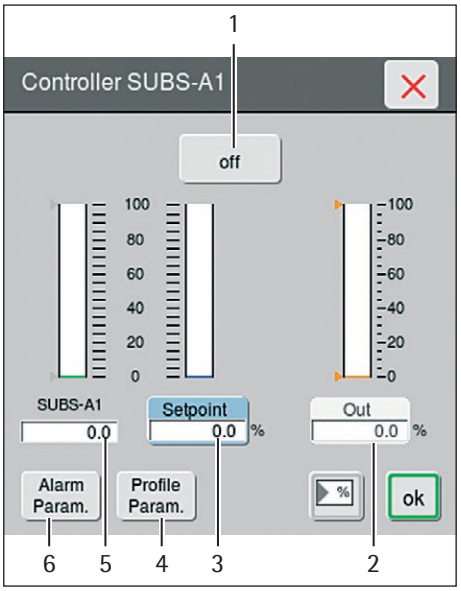
Any pre-installed DCU systems can be retrofitted with control functions by changing the configuration. Moreover, control blocks available in the software can also be used to configure special controllers. These configuration changes may only be carried out by Sartorius Service.

8.17 Configuring Filling Pump Controllers [SUBS] and [FOAM]

To introduce nutrient solution or correction media, the filling pump controller can control an internal or external pump. The filling pump controller works as a setpoint generator, handles control and emits an analog setpoint signal for the pump.

Procedure

▶ Adjust the controller to the requirements, e.g.:

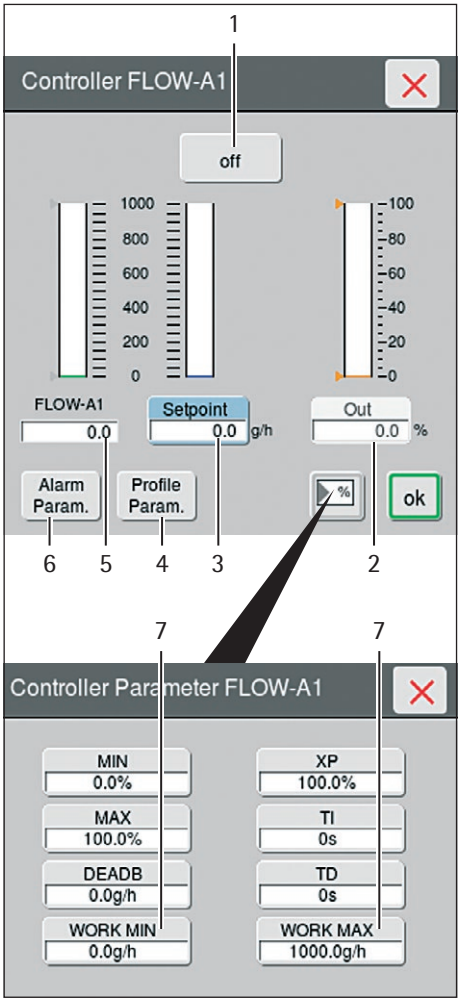


No.	Parameter	Value	Description
1	Operating mode		Displays the operating mode selection screen:
		off	Switch off dosing pump control.
		auto	Adjust the dosing pump to a dosing value using the [Setpoint] key.
		manual	Set the dosing pump to a constant pump speed (pump runs constantly) using the [Out] key.
		profile	Have the dosing pump controlled by a configured dosing profile.
		cascade	Filling pump controller is controlled by a master controller.
2	Out	%	Only in [manual] operating mode: Set controller output (pump speed) to a constant pump speed.
3	Setpoint	%	Enter dosing value.
4	Profile Param.		Create a dosing profile.
5	SUBS-A1	rpm	Displays the actual speed of the dosing pump.
6	Alarm Param.		Setting the alarm parameters.

8.18 Setting Gravimetric Filling Pump Controller [FLOW]

The gravimetric filling pump controller works with a weighing system and a variable-speed dosing pump. The controller works directly with the weight measured by the scale as the input signal. This allows for precise dosing over days and weeks.
The following points must be observed when configuring the controller:

- The feed rate of the filling pump has an important influence on the control loop path. That is why the pump throughput must be adapted to the required flow.
- For accurate proportioning, the working range of the controller output [Out] must lie in the range from 5 to 90%. To this end, the pumping range of the pump must be adjusted to the working range of the controller. For example, hoses of different diameters can be used to provide the required pumping range. Alternatively, the controller can be adapted to the pumping range of the pump.



Procedure

▶ Adjust the controller to the requirements, e.g.:

No.	Parameter	Value	Description
1	Operating mode		Displays the operating mode selection screen:
		off	Switch off gravimetric dosing pump control.
		auto	Adjust the dosing pump to a dosing value using the [Setpoint] key.
		manual	Set the dosing pump to a constant pump speed (pump runs constantly) using the [Out] key.
		profile	Have the dosing pump controlled by a configured dosing profile.
		cascade	Filling pump controller is controlled by a master controller.
2	Out	%	Only in [manual] operating mode: Set controller output to a constant pump speed.
3	Setpoint	g/h kg/h	Enter dosing value.
4	Profile Param.		Create a dosing profile.
5	FLOW	g/h kg/h	Displays the dosing quantity.
6	Alarm Param.		Setting the alarm parameters.
7	WORK MIN / WORK MAX		Optimally adapt the controller to the pump / hose combination: – Configure the quantity pumped at minimum pump speed [WORK MIN] in combination with a specific hose size. – Configure the quantity pumped at maximum pump speed [WORK MAX] in combination with a specific hose size.

▶ Tare scale | balance to zero.
▶ Place the vessel on the scale.
▶ Enter the desired dosing value by pressing [Setpoint] key.
▶ Set the operating mode to [auto].
▷ A negative weight readout on the balance or on the DCU indicates the feed volume which has already been added.

8.19 Setting the Gravimetric Level Regulator [VWEIGHT]

With gravimetric leveling, a specific medium volume can be maintained in the bag. The pump speed is automatically controlled according to the change in weight of the bag. When controlling the medium volume, we distinguish between:

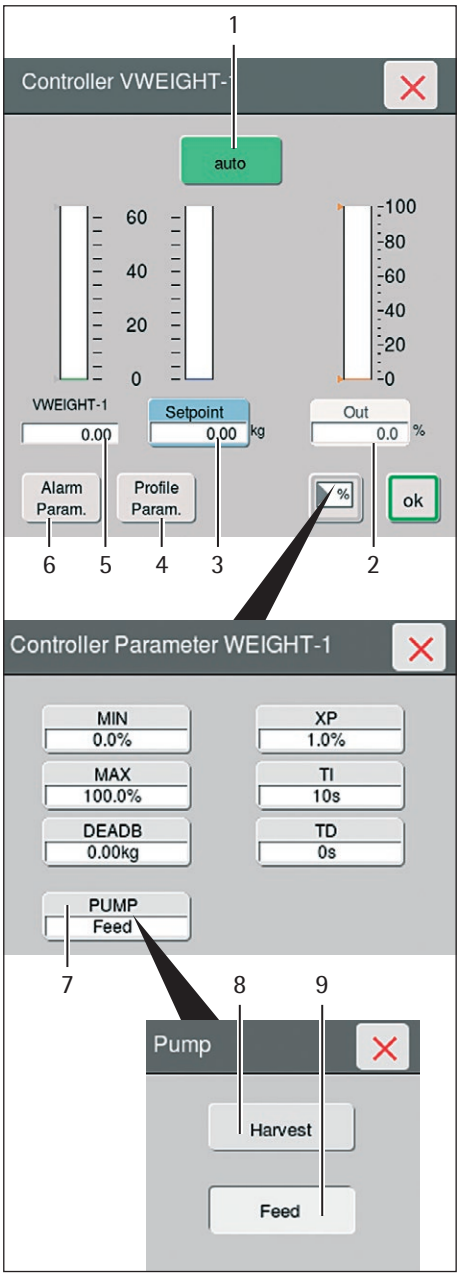
– Addition Operation
– Harvesting Operation

Addition Operation

If the weight of the bag falls below the setpoint: A variable speed (analog) adding pump is activated. The substrate is added to the culture vessel until the setpoint is reached again.

Harvesting Operation

If the weight of the bag exceeds the setpoint: A variable speed harvesting pump is activated. The medium is harvested until the setpoint is reached again.



Procedure

▶ Adjust the controller to the requirements, e.g.:

No.	Parameter	Value	Description
1	Operating mode		Displays the operating mode selection screen:
		off	Switch off gravimetric level control.
		auto	Adjust the media volume to a weight using the [Setpoint] key.
		manual	Set the adding / harvesting pump to a constant pump speed (pump runs constantly) using the [Out] key.
		profile	Have the media volume controlled by a configured weight profile.
		cascade	Gravimetric level control is controlled by a master controller.
2	Out	%	Only in [manual] operating mode: Set controller output (adding pump / harvesting pump) at a constant pump speed.
3	Setpoint	kg	Enter weight.
4	Profile Param.		Create a weight profile.
5	VWEIGHT	kg	Displays current weight: Medium with bag.
6	Alarm Param.		Setting the alarm parameters.
7	PUMP		Shows the selection screen [Pump] to select the pump operating mode.
8	Harvest		Activate the harvesting operation.
9	Feed		Activate the adding operation.

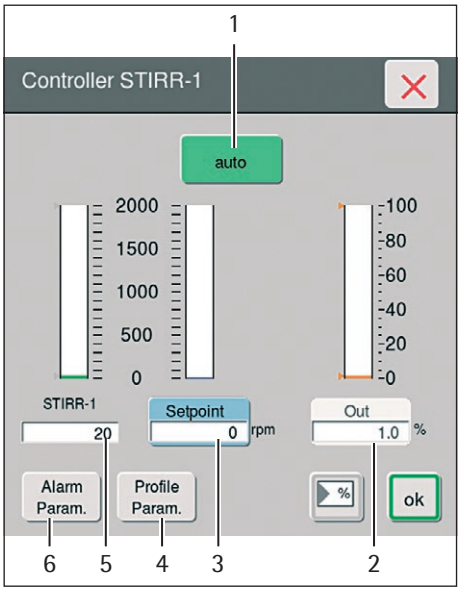
8.20 Setting the Stirrer Speed [STIRR]

The speed controller works like a target value generator for an installed motor controller, which controls the speed of the stirrer motor. In addition to its function as a single controller, the speed controller can also be used as a slave controller in DO (pO_2) control.

NOTICE

High speeds may damage built-in components!

Depending on the bag size and equipment, only a certain maximum stirrer speed may be achieved. Higher stirrer speeds can damage the bag or its equipment, e.g. a hose aeration system.



Procedure

▶ Adjust the controller to the requirements, e.g.:

No.	Parameter	Value	Description
1	Operating mode		Displays the operating mode selection screen:
		off	The speed is regulated down to 0 rpm.
		auto	The rotational speed is adjusted to the target rotational speed.
		manual	The speed is adjusted manually to a fixed motor speed by pressing the [Out] key.
		profile	The speed is controlled by the configured setpoint profile.
		cascade	Speed is controlled by a master controller.
2	Out	%	Only in [manual] operating mode: Set controller output to a constant value.
3	Setpoint	rpm	– Displays the target rotational speed in the operating mode "auto". – Displays a window for entering the target rotational speed for the stirrer.
4	Profile Param.		Create a speed profile.
5	STIRR-1	rpm	Displays the actual speed.
6	Alarm Param.		Setting the alarm parameters.

Switching off Speed Controller

NOTICE Risk of damage to the stirrer due to abrupt stopping!

▶ To turn off, set the target rotational speed of the stirrer to 0 rpm.
▶ Wait until the actual speed has reached 0 rpm.
▶ Toggle the speed controller to the operating mode [off].

Switching on Speed Controller

▶ Set the desired target speed with the [Setpoint] key.
▶ Put the speed controller in the required operating mode.
▷ The speed is automatically and slowly increased to the target speed.

Each additional setpoint change is also adjusted with a delay to avoid damage to the agitator.

8.21 Setting Gas Controllers

Gas controllers control gas supply for the corresponding gas segment, e.g., [AIROV-#], [AIRSP-#], [O2SP-#], [N2SP-#], [CO2OV-#] or [CO2SP-#] and introduce gases into the [Overlay], [Sparger] or [Micro Sparger] aeration segments.

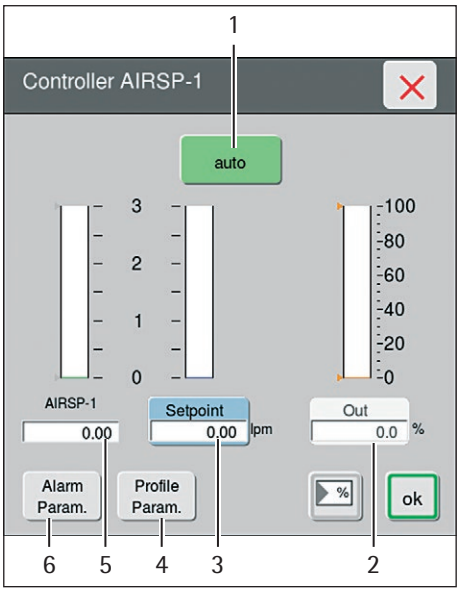
The gas controllers are controlled by the master controller in the DO (pO_2) control or pH control. If the master controllers are off (operating mode [off]), the gas controllers can be used as setpoint generators. If the gas controllers are being controlled by the master controllers, the gas slave controller automatically go into the operating mode [cascade].

The following points must be observed when configuring the controller:

- MIN | MAX output limits are entered in % of the control range of the gas feed. When directly configuring the controller output [Out], take into account the respective measurement range for the aeration rate.
- If the gas controller is controlled by a master controller: The MIN | MAX values must be entered in the controller parameters settings screen of the DO (pO_2) controller. The settings will then act as a switching criterion for cascade control.
- If the gas controller (operating mode [off]) is switched off or after emergency shutdown due to inadmissible overpressure, the control valve in the mass flow controller closes.
- Note the specifications for the measurement / control range of the aeration rates of the device. With a device operated with overpressure, the counter-pressure might cause the maximum aeration rate not to be reached.

Procedure

▶ Adjust the controller to the requirements, e.g.:



No.	Parameter	Value	Description
1	Operating mode		Displays the operating mode selection screen:
		off	Stop the aeration.
		auto	Adjust the aeration rate to a setpoint using the [Setpoint] key.
		manual	Adjust the aeration to a constant gas flow using the [Out] key.
		profile	Have the aeration controlled by a configured aeration profile.
		cascade	Gas controller is controlled as a slave controller by the master controller of DO (pO_2) or pH control.
2	Out	%	Only in [manual] operating mode: Set gas controller to a constant gas flow.
3	Setpoint	lpm / ccm / %	Set aeration rate.
4	Profile Param.		Create aeration profile.
5	AIRSP-1	lpm / ccm / %	Shows the current total gas flow in the gas segment AIRSP.
6	Alarm Param.		Setting the alarm parameters.

8.22 Setting the Temperature

The temperature is controlled by means of cascade control by a master and slave controller. The master controller [TEMP-#] uses the measured temperature in the bag as a reference value for the slave controller [JTEMP-#]. The slave controller uses the temperature measured in the double wall / temperature control circuit as a reference variable and controls the actuators associated with split-range operation.

Associated control elements can include:

- Valves of the cooling water intake(s) in the temperature control circuit.
- Electrical heaters in the temperature control circuit.
- Pump in the temperature control circuit.

The following points must be observed when configuring the controller:

- In the [auto], [manual] and [profile] operating modes of the master controller, the JTEMP slave controller automatically switches to the operating mode [cascade]. In the [off] operating mode of the master controller, the slave controller is automatically switched to [off].
- The output limits required for safe operation are preset in the system configuration. User-defined output limits that deviate from this must be reset after a system reset.
- On certain systems, which do not allow higher temperatures, a setpoint limit must be parameterized for the JTEMP slave controller using the [MAX] output limit of the TEMP master controller.

The output limitation on master controller ([MAX] = 40%) specifies the setpoint limit for the slave controller ([Setpoint] = 60.0 ° C).

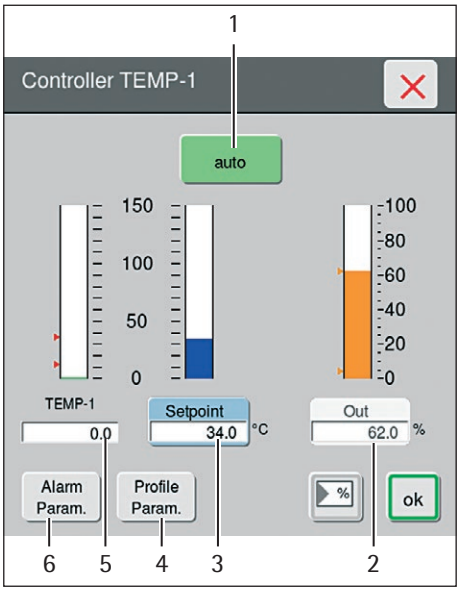
NOTICE

The maximum process temperature in the BIOSTAT STR® bag is 40 °C.

8.22.1 Configuring Master Controller [TEMP-#]

When the value approaches the setpoint, the guide controller [TEMP-#] switches the controller structure from [PD] (starting condition) to [PID], preventing overshoot. In the temperature control circuits, like those in bioreactors, a digital output also switches off the circulating pump as well as the heating when the temperature controller is switched off.

The temperature cascade control must be set on the master controller. Setpoints, operating modes and alarm limits can only be changed on the master controller. The slave controller [JTEMP- #] goes into the [cascade] operating mode. All operations of the slave controller are triggered automatically.



Procedure

▶ Adjust the controller to the requirements, e.g.:

No.	Parameter	Value	Description
1	Operating mode		Displays the operating mode selection screen:
		off	Turn off temperature control.
		auto	Set and control the temperature of the medium to a setpoint defined by pressing the [Setpoint] key.
		manual	Adjust the controller output to a constant value using the [Out] key.
		profile	Have the temperature of the medium controlled by a configured temperature profile.
		cascade	Master controller [TEMP-#] is controlled by a superordinate master controller.
2	Out	%	Only in [manual] operating mode: Set controller output to a constant value.
3	Setpoint	%	Set the target temperature of the medium. When approaching the setpoint temperature, the control structure is switched from [PD] to [PID].
4	Profile Param.		Create a temperature profile for the medium.
5	TEMP-1	°C	Shows the actual temperature of the medium.
6	Alarm Param.		Setting the alarm parameters.

8.22.2 Setting the Slave Controller [JTEMP-#]

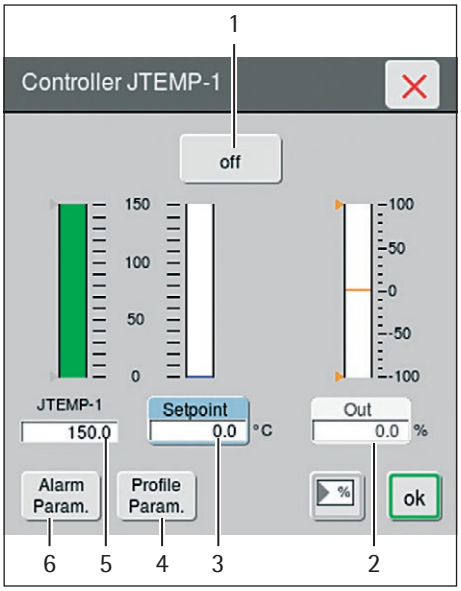
There are direct settings possible for heating and cooling with the slave controller [JTEMP-#], e.g. for testing purposes.

Requirements

The master controller [TEMP-#] is in [off] mode.

Procedure

▶ Adjust the controller to the requirements, e.g.:



No.	Parameter	Value	Description
1	Operating mode		Displays the operating mode selection screen:
		off	The slave controller [JTEMP-#] is off.
		auto	Set and adjust the temperature in the temperature circuit by pressing the [Setpoint] key.
		manual	Adjust the heat output to a constant value using the [Out] key.
		profile	Have the temperature in the temperature circuit controlled by a configured temperature profile.
		cascade	The slave controller [JTEMP-#] is in the [cascade] operating mode. Control takes place via the master controller [TEMP-#].
2	Out	%	Only in [manual] operating mode: Set controller output to a constant value.
3	Setpoint	°C	Set the target temperature in the temperature circuit. When approaching the setpoint temperature, the control structure is switched from [PD] to [PID].
4	Profile Param.		Create a temperature circuit temperature profile.
5	JTEMP-1	°C	Shows the actual temperature in the temperature circuit.
6	Alarm Param.		Setting the alarm parameters.

Settings for Testing Purposes

For testing purposes, the cascade control can be separated. To do this:

Procedure

▶ Switch the slave controller [JTEMP-#] to the operating mode [auto].
▶ Press the [Out] key and specify a target value for the actuators.

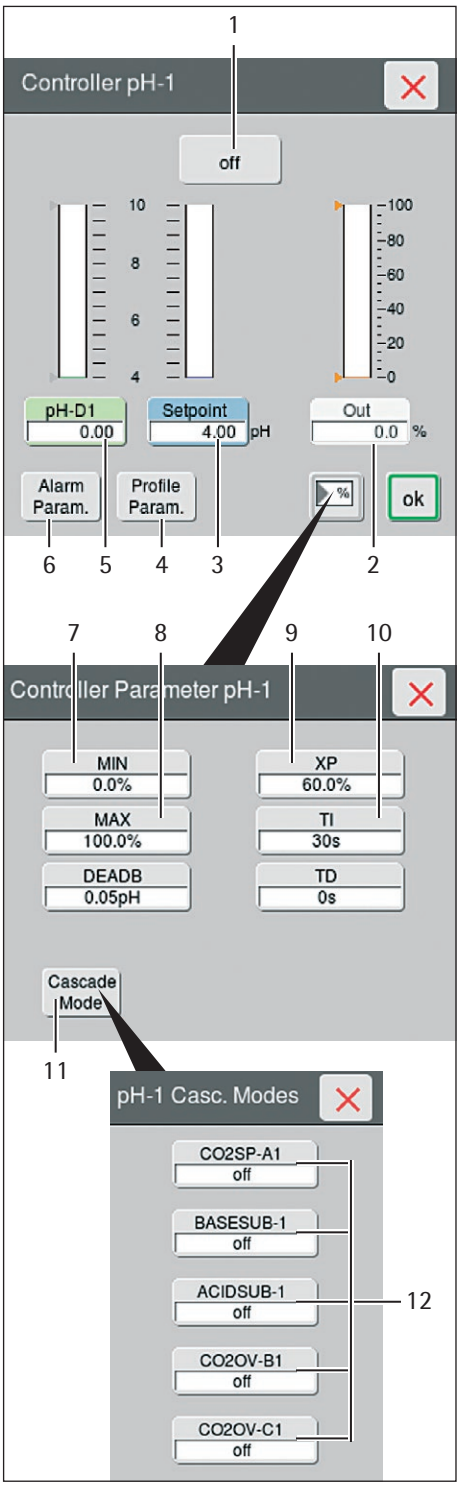
8.23 Configuring pH Controllers

The pH is regulated by controlling the following slave controllers:

– Filling pump controller [SUBS] for addition of acid and alkali.
– Gas controller or dosing valves for the addition of CO_2.

The controller output (OUT: 50% - 0%) acts on the acid pump or CO_2 supply. The controller output (OUT: 50% - 100%) acts on the alkaline pump. Only when the controller deviation is outside the set deadband [DEADB]: The pH controller activates the slave controller.

When activating the operating modes [auto] or [manual], the dose counters (e.g. [ACIDT-1]) are automatically switched into the operating mode [Totalize].



Procedure

▶ Adjust the controller to the requirements, e.g.:

No.	Parameter	Value	Description
1	Operating mode		Displays the operating mode selection screen:
		off	The pH controller is switched off. Slave controllers can be set individually.
		auto	Use the [Setpoint] key to set and adjust the pH.
		manual	Adjust the controller outputs to a constant value using the [Out] key.
		profile	Have the pH value controlled by a configured pH profile.
2	Out	%	Only in [manual] operating mode: Set controller output to a constant value (split-range).
3	Setpoint	pH	Adjust pH value.
4	Profile Param.		Create pH profile.
5	pH-##	pH	Displays which pH probe is currently controlling the pH control loop. Press to set the controlling probe. Displays the pH value.
6	Alarm Param.		Setting the alarm parameters.

Setting the PID Controller Parameters

The parameter TI must be greater than 0. Starting with firmware V 7.8, the pH regulator no longer uses split-range operation, but starts at OUT = 50%.

Procedure

▶ To get the same control behavior as in split-range operation (up to firmware V 7.7): Convert the PID controller parameters as follows::

No.	Parameter	Calculation based on parameters in the split-range operation
7	MIN	= (100% - absolute value of $MIN_{Splitrange}$) / 2
8	MAX	= (100% + absolute value of $MAX_{Splitrange}$) / 2
9	XP	= $XP_{Splitrange}$ x 2
10	TI > 0	TI > 0

Valid Value Range of PID Controller Parameters

Parameter	Unit	Value
MIN	%	0 ... 100
MAX	%	0 ... 100
XP	%	0.1 ... 1000
TI	s	1 ... 10000
TD	s	0 ... 1000

Selecting Slave Controller for pH Control

If the master controller is disabled: The slave controller can be used for other purposes:

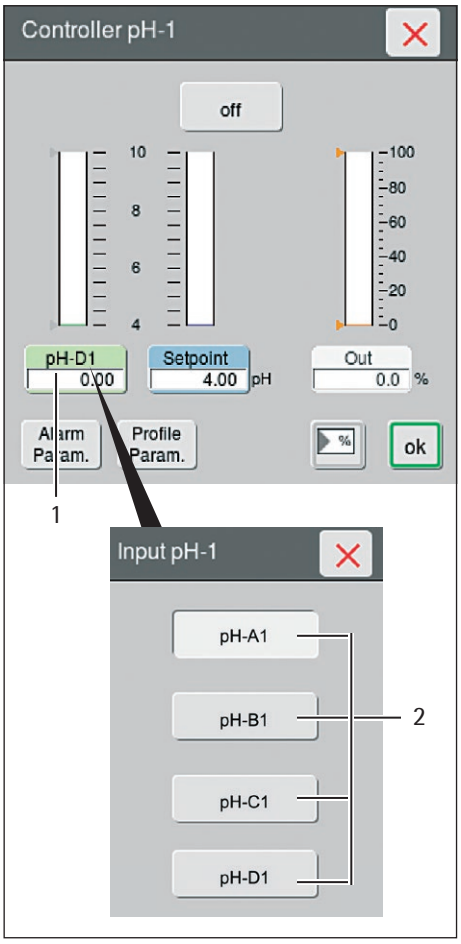
– The CO_2 gas controller can be used as an independent setpoint controller.
– The acid or base pump (ACID / BASE) can be used as a substrate controller.

Procedure

▶ In the control parameter settings screen, press the [Cascade Mode] key (11).
▶ Use the (12) key to enable or disable the corresponding slave controller for pH control.

Changing Process Value Source

Several pH sensors of different types can be installed on the device (conventional, optical, single-use). One of these sensors can be selected as a process value source for pH control.



Procedure

▶ Press the [pH-A1] key (1) in the advanced settings screen.
▷ The [Input pH-1] selection screen appears.

▶ Press the [pH-##] key (2) to select the appropriate process value source:

Name / process value source	Type of pH sensor
pH-A1	Classic pH sensor
pH-B1	Classic pH sensor (optional dual measurement)
pH-C1	Optical single-use pH sensor
pH-D1	Optical single-use pH sensor (optional double measurement)

▶ Confirm the entry in the extended settings screen by pressing [ok] key.

8.24 Setting DO (pO_2) Controller CASCADE (Cascade Controller)

The DO (pO_2) control works like a cascaded regulation. The output of the DO (pO_2) controller (master controller) controls the setpoint input of the slave controller, which then acts on the actuator (e.g. the valves or mass flow controllers for N_2 or O_2 or the stirrer). The following control strategies are possible:

- 1-stage control cascade, i.e. the DO (pO_2) control only affects one of the available setting variables.
- Up to four-stage simultaneous control cascade, during which the DO (pO_2) regulation is controlling up to four setting variables according to their priority.

A range (MIN / MAX) can be defined in the DO (pO_2) controller, in which the DO (pO_2) controller defines the target value for each slave controller. In multi-stage cascaded regulation, the output of the DO (pO_2) controller modulates the slave controllers in sequence as follows:

- The DO (pO_2) controller acts on the slave controller with the priority 1 (Cascade 1) and defines its setpoint. The slave controller 2 receives the setpoint defined in the DO (pO_2) controller as [MIN].
- If the preset setpoint of the first slave controller (Cascade 1) reaches its maximum, the output of the DO (pO_2) controller switches to the setpoint input of the second slave controller (Cascade 2) after an adjustable delay time [Hyst] and defines the following setpoints:
  - Slave controller (cascade) 1: with defined maximum
  - Slave controller (cascade) 2: controlled output of the DO (pO_2) controller
- This sequence continues for the other actuators according to the predefined priority [Cascade #].
- If the need for oxygen drops, the controllers cascade to lower outputs in reverse order until they are off.

In this way, the control can regulate the in-process DO (pO_2) value, even if there are considerable fluctuations in the need for oxygen in the culture. In order to still be able to optimally adapt the control to the behavior of the controlled loop path, the PID parameters of the slave controller are parameterizable independently of one another.

The following points must be observed when setting the DO (pO_2) cascade controller:

- In operating modes [auto] and [profile] of the DO (pO_2) controller, the selected slave controllers are automatically switched to [cascade] mode.
- In the [off] mode of the DO (pO_2) controller, the selected slave controllers remain in the cascade last reached and may need to be switched off individually.
- Switching from slave controller 1 to the downstream controller and vice versa is not done until the respective output limit for the time span defined in the [Hyst] field of the parameterization screen has been over or undershot. After this time has elapsed, check the switch conditions once again and only switch back if they have been met.
- An inverted control direction for slave controllers, such as the substrate controllers, can be achieved by inverting the setpoint limit (MIN > MAX).
- The DO (pO_2) master controller always uses the MIN/MAX limits of the respective slave controller as the working range.
- The difference between MIN and MAX must always be greater than 2% of the specific measurement range.

Setting the Master Controller

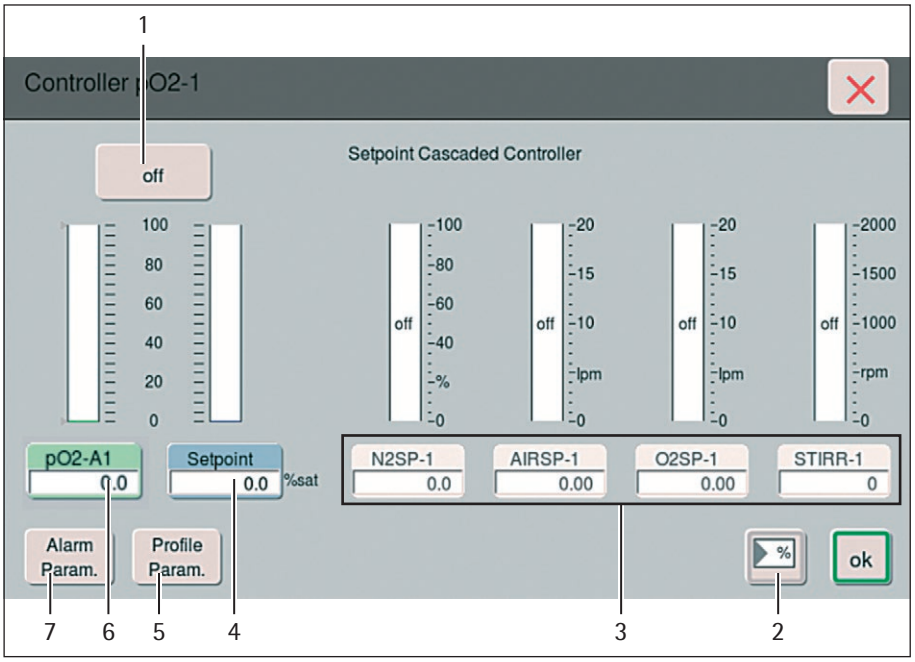


Fig. 46: DO (pO_2) cascade controller advanced settings screen (example)

Procedure

▶ Adjust the master controller to the requirements, e.g.:

No.	Parameter	Value	Description
1	Operating mode		Displays the operating mode selection screen:
		off	The DO (pO_2) controller is switched off. Slave controllers can be set individually.
		auto	Use the [Setpoint] key to adjust the DO (pO_2) setpoint.
		manual	Adjust the controller outputs to a constant value using the [Out] key.
		profile	Have the DO (pO_2) value controlled by a configured DO (pO_2) profile.
2			Setting the parameters of the slave controller.
3			Setpoint for slave controller in the cascade control. Order corresponds to the priority configured in the settings screen.
4	Setpoint	%sat	Set DO (pO_2) value. Relative in %sat for control range 0 ... 100%
5	Profile Param.		Creating DO (pO_2) profile.
6	pO_2-##	pO_2	Changing process value source. Displays the DO (pO_2).
7	Alarm Param.		Setting the alarm parameters.

Setting the Slave Controllers

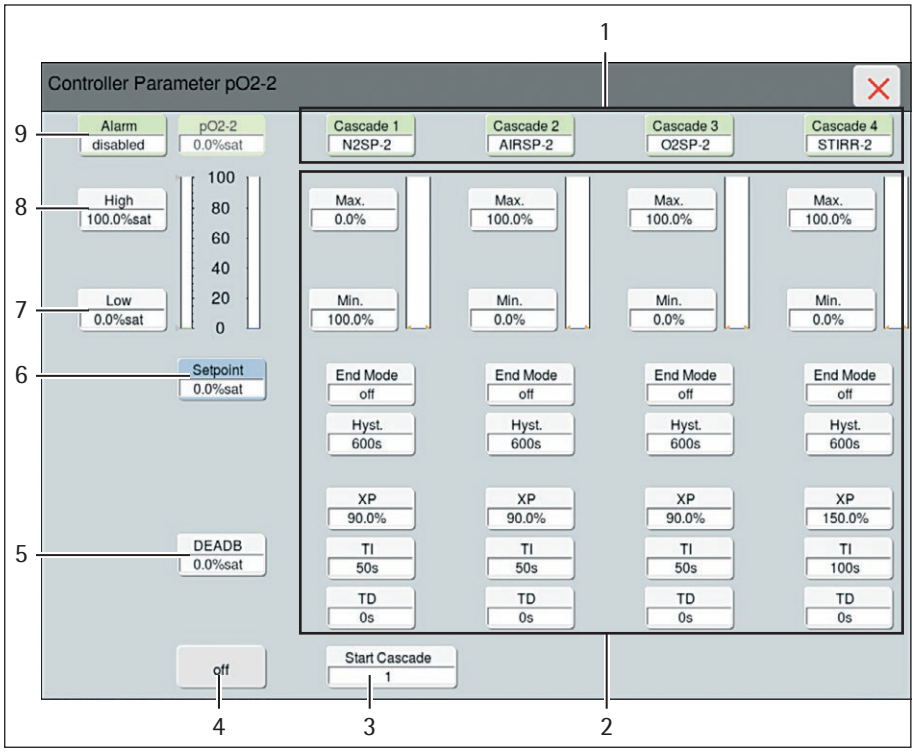


Fig. 47: Overview of parameterization of the slave controllers (example)

Procedure

▶ Adjust the slave controllers to the requirements, e.g.:

No.	Parameter	Value	Description
1	Cascade #		Press to determine order of slave controllers.
5	DEADB	%	Set the deadband.
2			Set controller parameters
	MIN, MAX	%	Set minimum and maximum controller setpoint limit for selected slave controllers.
	XP, TI, TD	%	PID controller parameters
	End Mode		Selecting the operating mode of the slave controller when the master controller is [off] or [disabled]
	Hyst.	m:s	Delay time for switching between the slave controllers.
3	Start Cascade		Configure which master controller starts the cascade control.
4	Operating mode		Displays the operating mode selection screen:
		off	The DO (pO_2) controller is switched off. Slave controllers can be set individually.
		auto	Use the [Setpoint] key to set and adjust the DO (pO_2).
		profile	Have the pO_2 value controlled by a configured DO (pO_2) profile.
7	Setpoint	%sat	Set DO (pO_2) value. Relative in %sat for control range 0 ... 100%
8	Low	%	Set the lower limit of the DO (pO_2) value.

No.	Parameter	Value	Description
9	High	%	Set the upper limit of the DO (pO_2) value.
10	Alarm		Setting the alarm parameters.

8.25 Setting ADVANCED DO (pO_2) Controller (Polygon Controller)

The advanced DO (pO_2) controller acts as the master controller during DO (pO_2) control. In comparison to the conventional DO (pO_2) cascade controller, the advanced DO (pO_2) polygon controller supports the parallel operation of the slave controllers, that is, all actuators are controlled simultaneously.

The master controller works as a PID controller with configurable control behavior. It uses the DO (pO_2) measured at a measuring point as the actual value. In case of deviation from the setpoint, the master controller sends an output signal to the slave controllers.

8.25.1 Notes on Setting the Controller

The slave controllers work as long as the master controller is active, that is, in [auto] or [Manual] mode. After the master controller is turned off ([off]), the slave controllers can be operated manually, either individually or together in the selected combination.

The behavior of the master controller is based on sampled settings for the delay time and switching hysteresis. These settings are determined internally and not accessible for user modification. If necessary, they must be changed in the configuration.
The following settings are saved for the master controllers and slave controllers:

- The set value
- The settings for alarm monitoring
- The PID controller parameters of the master controller
- The settings of the slave controllers in relation to the output of the master controller profile parameters

As a result, these settings then become available again after a power outage or after the DCU system or the controlled end device is turned off. They will be restored for the next process after power returns or the controller is switched back on.

A reset of the DCU system ([Settings] main menu) restores the factory settings.
The process or user-specific settings must thus be recorded before the reset if they are to be used later.

After loading a new system configuration, the DCU system initially starts up with the factory settings. The process or user-specific settings must be re-entered here as well.

8.25.2 Setting Polygon Controller

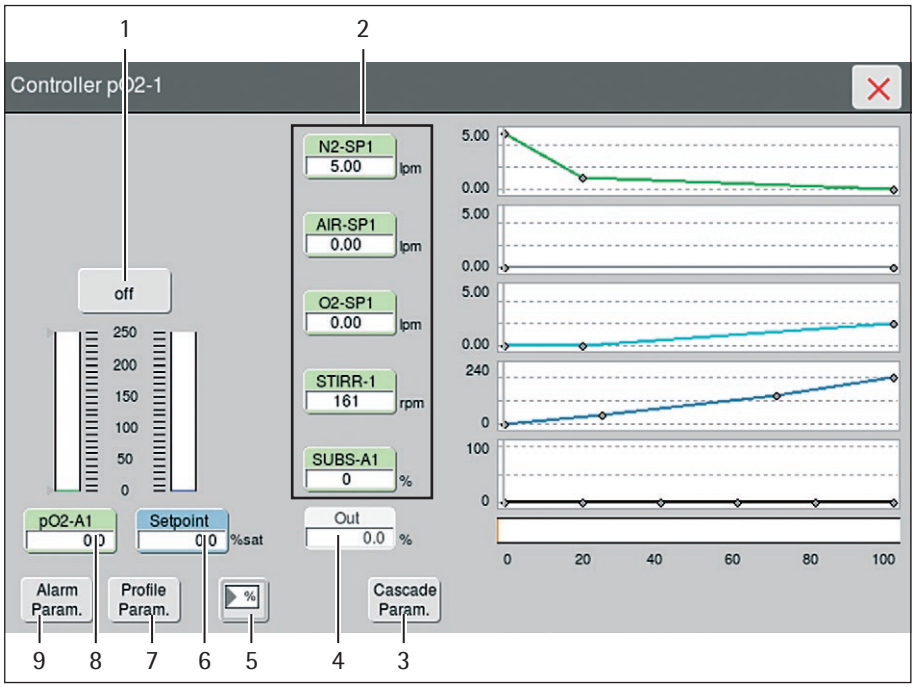


Fig. 48: Advanced DO (pO_2) polygon controller settings screen (example)

Procedure

▶ Adjust the controller to the requirements, e.g.:

No.	Parameter	Value	Description
1	Operating mode		Displays the operating mode selection screen:
		off	The DO (pO_2) controller is switched off. Slave controllers can be set individually.
		auto	Turns on the control of DO according to controller set up. Use the [Setpoint] key to set and adjust the DO (pO_2).
		manual	Adjust the controller outputs to a constant value using the [Out] key.
		profile	Have the DO (pO_2) value controlled by a configured DO (pO_2) profile.
2			Set the polygon curve of the respective slave controller.
3	Cascade Param		Press to select slave controllers.
4	Out	%	Only in [manual] operating mode: Set controller output to a constant value. Relative in % for control range 0 ... 100%.
5			Setting the PID controller parameters.
6	Setpoint	%sat	Set DO (pO_2) value. Relative in %sat for control range 0 ... 100%
7	Profile Param.		Creating DO (pO_2) profile.
8	pO_2-##	pO_2	Changing process value source. Displays the DO (pO_2).

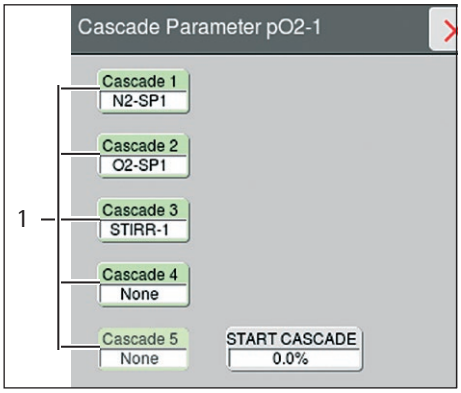
No.	Parameter	Value	Description
9	Alarm Param.		Setting the alarm parameters.

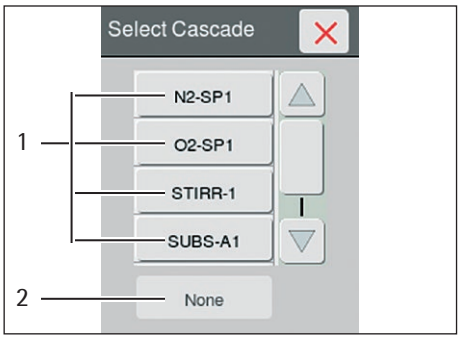
8.25.3 Selecting Slave Controllers for DO (pO_2) Control

Depending on the configuration, up to six slave controllers are available. From these six slave controllers, five can be simultaneously selected for the polygon controller.

Procedure

- ▶ In the advanced controller settings screen, press the [Cascade Param.] key.
- ▷ This opens the selection screen [Cascade parameters pO2-1].
- ▶ Select the slave controllers to be configured using the (1) keys.





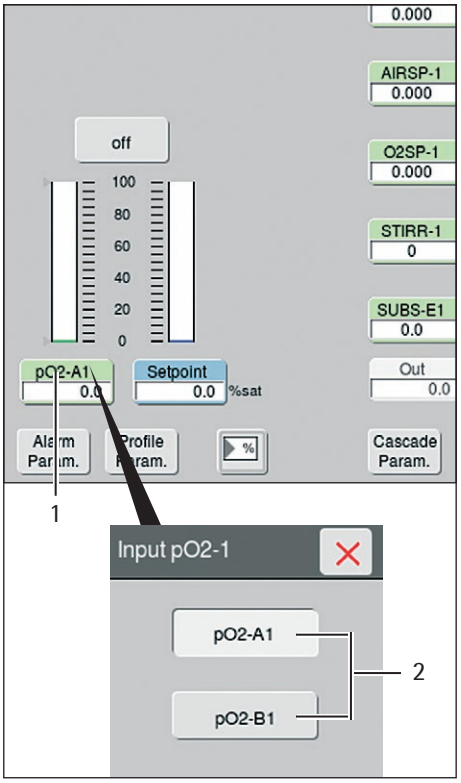
- ▶ In the [Select Cascade] selection list, select a controller (1).
- ▶ If no controller is to be assigned to this slave controller: Press [NONE] (2).

Changes to a controller [Cascade #] delete the subsequent selection. All of the following controllers must be re-assigned. Since the slave controllers control their actuators simultaneously, the order of the controllers has no effect on the control.

- ▶ Where appropriate, specify the starting controller output of the master controller: Do this by pressing [START CASCADE] (1).
- ▶ Enter the starting point in the input window.

8.25.4 Changing Process Value Source

Several DO (pO_2) sensors of different types can be installed on the device (conventional, optical, single-use). One of these sensors can be selected as a process value source for DO (pO_2) control.



Procedure

▶ Press the [pO2-A1] key (1) in the advanced controller settings screen.
▷ The [Input pO2-1] selection screen appears.

▶ Press the [pO2-##] key (2) to select the appropriate process value source:

Designation	Type of pH sensor
pO_2-A#	Conventional DO (pO_2) sensor (amperometric or optic e.g. Visiferm, made by Hamilton)
pO_2-B#	Conventional DO (pO_2) sensor (optional second sensor, amperometric or optical, e.g. Visiferm, made by Hamilton)
pO_2-C#	Optical single-use DO (pO_2) sensor
pO_2-D#	Optical single-use DO (pO_2) sensor (optional second sensor)

▶ Confirm the entry in the extended settings screen by pressing [ok] key.

8.25.5 Setting the Polygon Curves of the Slave Controller

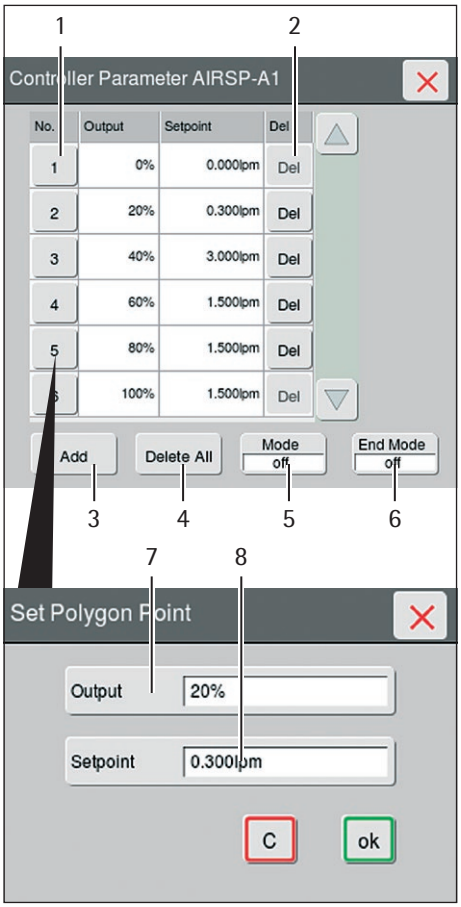
The description uses the example of the slave controller [AIRSP].

Requirements

The slave controller [AIRSP-#] is selected for the DO (pO_2) control.

Procedure

▶ Press the [AIRSP-#] key of the slave controller in the advanced controller settings screen.
▷ The window [Controller Parameter AIRSP-1] appears.
▶ Configure the polygon curve of the slave controller to the requirements, e.g.:



No.	Parameter	Description
1	No.	Press to display the [Set Profile Set Point] window, where you can set the values of the polygon point.
2	Del	Press to delete the polygon point.
3	ADD	Press to display the [Set Polygon Set Point] window and enter an additional polygon point.
4	Delete All	Press to delete all polygon points.
5	Mode	Press to display a window for activation / deactivation of the slave controller.
6	End Mode	Selecting the operating mode of the slave controller when the master controller is [off] or [disabled].
7	Output	Press to open a window for entering the value Output; Output is between 0-100% based on the DO (pO_2) controller output.
8	Setpoint	Press to display a window for entering the value Setpoint.

▷ After closing the submenu with [ok] the setpoints are graphically displayed as a polygonal curve above the output [Out] of the master controller.
▶ Configure the polygon curves of further slave controllers.

8.25.6 Setting the PID Controller Parameters

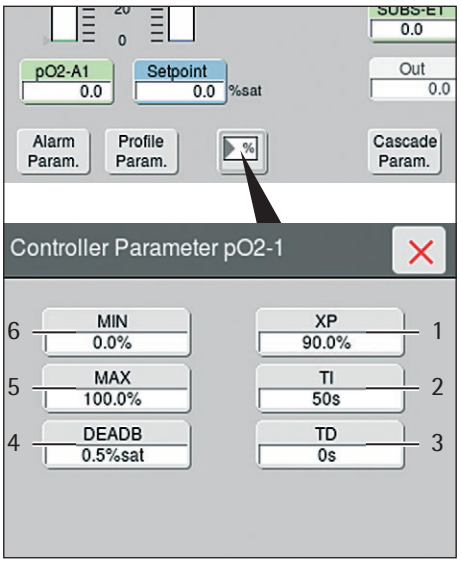
Required qualification: Operating engineer / laboratory manager

Depending on the process (e.g. stability of gas intake or actuator), it may be necessary to change the PID parameters to adapt control behavior. To this end, check the following conditions:

- If the DO (pO_2) measured value (process value) oscillates around the setpoint and does not stabilize: Increase the proportion of "P".
- If the actual value only very slowly approaches the setpoint or does not reach it: Reduce the proportion of "P".
- With a low "I" portion, the controller will react more quickly; as the "D" portion falls, it will react more strongly to setpoint deviations. However, this can induce the controller to tend to overshoot.
- By increasing the "I" portion, we make the controller react more slowly, and by increasing the "D" it will react more weakly to deviations in actual value. This will make the controller response (the control behavior) more sluggish.

Procedure

▶ Check the PID controller parameters according to your requirements and adjust them:



No.	Name	Unit	Value	Description
1	XP	%	0.1 ... 1000	P portion (proportional range); signal amplification of the control response proportional to the input signal; in % of the measurement range.
2	TI	s	1 ... 10000	Integral portion; time function of the control response. With a higher I portion, the controller will react more slowly (and vice versa).
3	TD	s	0 ... 1000	Differential portion; damping of the controller. With a greater D portion, the controller response is reduced (and vice versa).
4	DEADB	%	0.5	Deadband; DO controller output regulation remains inactivate as long as DO (pO_2) deviates from the setpoint by less than DEADB.
5	MAX	%	0 ... 100	Maximum output, 0 to 100% of the control range.
6	MIN	%	0 ... 100	Minimum output, 0 to 100% of the control range.

8.25.7 Configuring Aeration Strategies

By selecting the slave controller and adjusting the polygon curves, any number of aeration strategies can be realized. A sample of two aeration strategies is listed in the following.

Aeration Strategy 'O_2 Enrichment' (Air, O_2)

In this aeration strategy, air is first used for the enrichment of the medium. If this is not sufficient, the air is then continuously enriched with pure oxygen in order to ensure a sufficiently high content of oxygen of the medium.

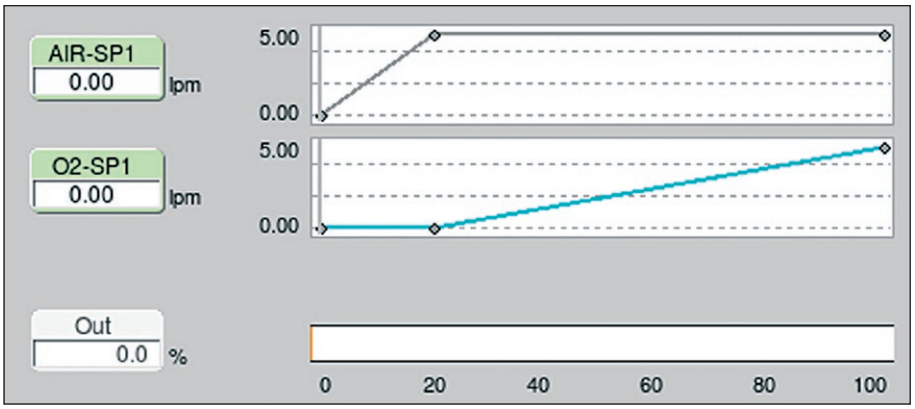


Fig. 49: Setting the slave controller for the aeration strategy O_2 Enrichment (example)

Procedure

- ▶ Select the slave controllers [AIRSP-1] and [O2SP-1] for DO (pO_2) control.
- ▶ Adjust the polygon curves of the slave controllers as follows:
  - Slave controller [AIRSP-1]:
    - ▶ In [Out] = 0%, set a minimum setpoint.
    - ▶ In the control range [Out] = 20 ... 100%, set a maximum setpoint.
  - Slave controller [O2SP-1]:
    - ▶ In the control range [Out] = 0 ... 20%, set a minimum setpoint.
    - ▶ In the control range [Out] = 20 ... 100%, set a setpoint rising to 100%.
- ▷ This aeration strategy initially leads to an increased air sparge rate in the control range [Out] = 0 to 20 %. Then, as the control range [OUT] increases from 20 to 100 %, the oxygen concentration in the sparged gas is continuously increased via the addition of O2, while air flow remains at the specified maximum value.

Aeration Strategy "Gasflow Ratio" (Air, O_2)

In this aeration strategy, the bag is supplied with a constant flow rate of gases.

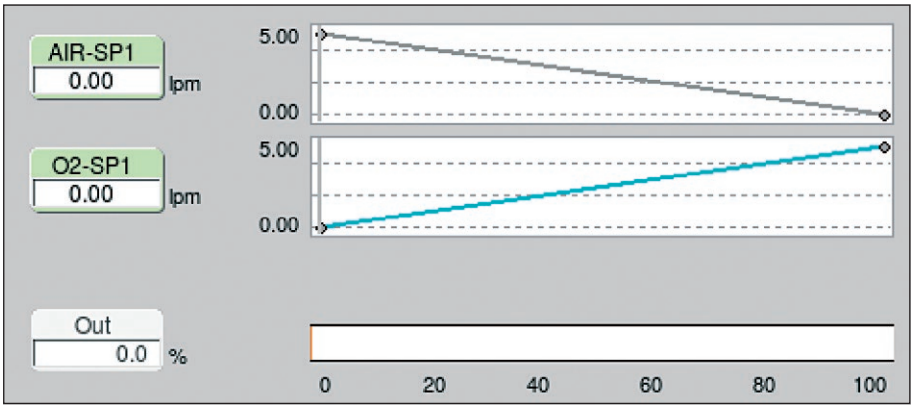


Fig. 50: Setting the slave controller for the aeration strategy Gasflow Ratio (example)

Procedure

- ▶ Select the slave controllers [AIRSP-1] and [O2SP-1] for DO (pO_2) control.
- ▶ Adjust the polygon curves of the slave controllers as follows:
  - Slave controller [AIRSP-1]:
    - ▶ In [Out] = 0%, set a maximum setpoint.
    - ▶ In [Out] = 100%, set a minimum setpoint.
  - Slave controller [O2SP-1]:
    - ▶ In [Out] = 0%, set a minimum setpoint.
    - ▶ In [Out] = 100%, set a maximum setpoint.

▷ In this aeration strategy, only air is supplied when the control output [Out] = 0%. As the controller output increases, the supply of air is continuously reduced and the supply of O_2 is proportionally increased until solely oxygen is supplied when the control output [Out] = 100%.

Further Aeration Strategies

Other aeration strategies, such as Exclusive Flow, can be realized by selecting and configuring the slave controllers.

8.26 Changing System Settings

In the [Settings] main function, the DCU system provides various functions for system maintenance and troubleshooting:

- General settings like date, time, Failtime [Failtime], password-protected screen saver, parameter settings for communicating with external devices [Internet Configuration].
- Defining process values and their ranges or limits [PV Ranges].
- Manual operation of digital and analog inputs and outputs or simulation controllers, for example.
- Service function, e.g., for resetting the system (Reset) or to select the system configuration on multiple configurations.

NOTICE

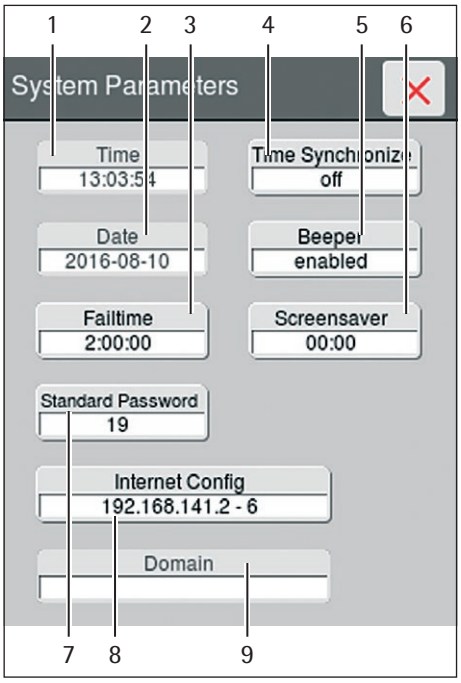
Danger of malfunctions and unsafe operating states due to impermissible settings.

Malfunctions that have unforeseeable impacts on safe operation can result from settings that are not permissible or are unsuited for a certain terminal device. Settings that impact safe operation are password-protected. Only trained and experienced persons may change these settings.

Changes to the [Date] and [Time] will only take effect in the first 5 minutes after the control unit is turned on.

Procedure

▶ Adjust the system settings to the requirements, e.g.:



No.	Parameter	Value	Description
1	Time	hh:mm:ss	Displays the current time.
2	Date	yyyy-mm-dd	Enter the current date.
3	Failtime	hh:mm:ss	Enter power outage time to tell system how to behave after a power failure (see Chapter "8.2 Switching Control / Supply Unit and Bag Holder On/Off," page 107).
4	Time Synchronize	Synchronize:	Enable and disable time synchronization.
		IP Address	Enter the IP address of the time server.
		Time Zone	Specification of the time zone.
5	Beeper	enabled / disabled	Turns acoustic signals on / off, e.g. alarm tones.
6	Screen saver	hh:mm	Enter the time of inactivity after which the screen saver will be turned on (00:00 = switched off).
7	Standard password	xx	Standard password: Preset at <19> or with a customer-specific password.
8	Internet Config		IP address of the DCU system in the network.
9	Domain		Domain name (only in connection with the user administration function for DCU4 systems).

8.27 Setting Measurement Range

Required qualification: Operating engineer / laboratory manager

Process value ranges can be changed for all process values. Measurement ranges configured specifically to devices or customer specifications are factory-set in the device.

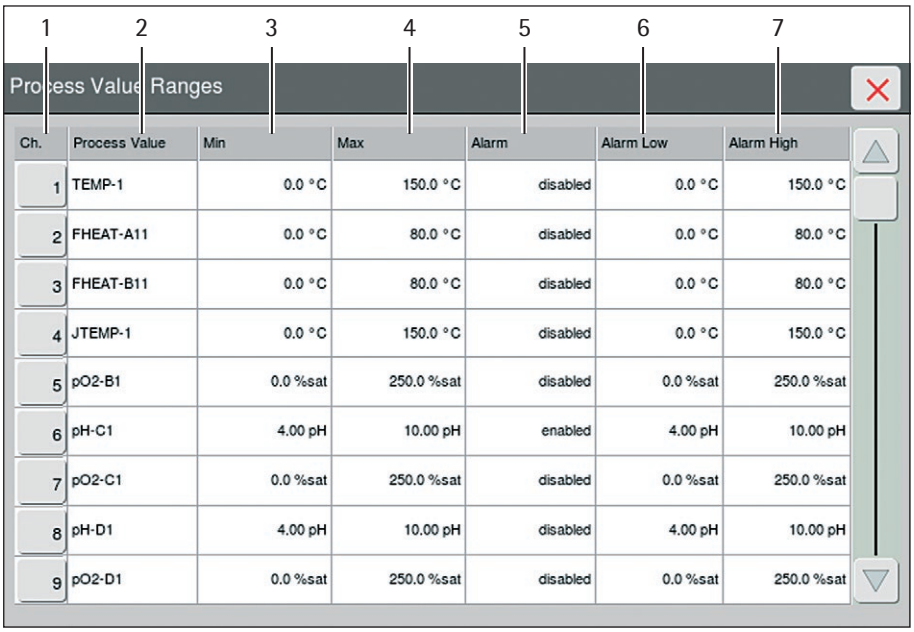


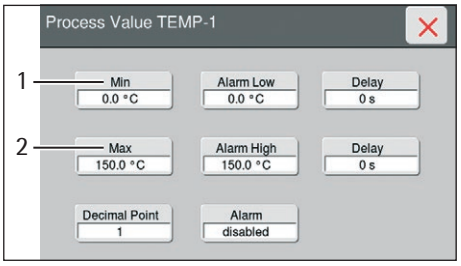
Fig. 51: Overview of the process value measurement ranges (example)

No.	Name	Description
1	Batch	Displays the channel as a numeric value.
2	Proc. Value	Displays the name of the process value.
3	Min	Displays the lower measurement range value of the process value.
4	Max	Displays the upper measurement range value of the process value.
5	Alarm	
	enabled	Displays the monitoring status (enabled).
	disabled	Displays the monitoring status (disabled).
6	Alarm Low	Displays the lower alarm limit of the process value.
7	Alarm High	Displays the upper alarm limit of the process value.

Procedure

The settings are shown using the example of the [TEMP-1] control (channel 6).

- ▶ Press [PV Ranges] in the main function area [Settings].
- ▷ The [Process Value Ranges] window is displayed.
- ▶ In the [Ch.] Column, press the key corresponding to the process value.
- ▷ The [Process Value TEMP-1] window is displayed.



- ▶ **NOTICE** Unsuitable measurement range settings can lead to unpredictable device damage. To set the measurement range value: Press the key corresponding to the measurement range value (1, 2).
- ▷ The window for entering the measurement range value is displayed.
- ▶ Enter the measurement range value and confirm with the [ok] key.
- ▶ If necessary, set further values of the controller [TEMP-1].

8.28 Switch or Simulate Inputs or Outputs in Manual Mode

8.28.1 Starting Manual Operation

Required qualification: Operating engineer / laboratory manager

When starting up operations and troubleshooting, all analog and digital process inputs and outputs as well as DCU internal inputs and outputs can be switched to manual operation [Manual Operation].

- Inputs can be disconnected from the external signal sources.
- Input values can be specified to simulate the measuring signals.
- Outputs can be separated from the DCU internal functions and controllers can be directly influenced in a settings window, e.g. to test the effect of certain configurations.

Settings during manual operation have the highest priority; their effects on the inputs and outputs of the DCU system supersede those of other functions.

Color displays of the inputs and outputs

Color display	Description
The [Value] column is green	An input or output is in the operating mode [Auto]
Only for controllers: The [Setpt] column is highlighted in green	A controller is located in cascade control
The [Value] column is highlighted in turquoise	A phase affects an output
The [Value] column is highlighted in yellow	An input or output is in the operating mode [Manual]
The [Value] column is highlighted in violet	An input or output is locked
All outputs in the [Value] column are highlighted in red	The process triggered an emergency stop
The [Value] column is highlighted in gray	No function accesses an input or output
The [Value] column is highlighted in white	The process control system accesses an output

Procedure

▶ Press the [Manual Operation] key in the main function [Settings].
▷ The [Manual Operation] window is displayed.
▶ For manual operation of the individual functions, follow the instructions in the following sections.

8.28.2 Simulating Digital Inputs

Required qualification: Operating engineer / laboratory manager

In manual mode, the digital inputs can be decoupled and simulated by the physical signal transmitter.

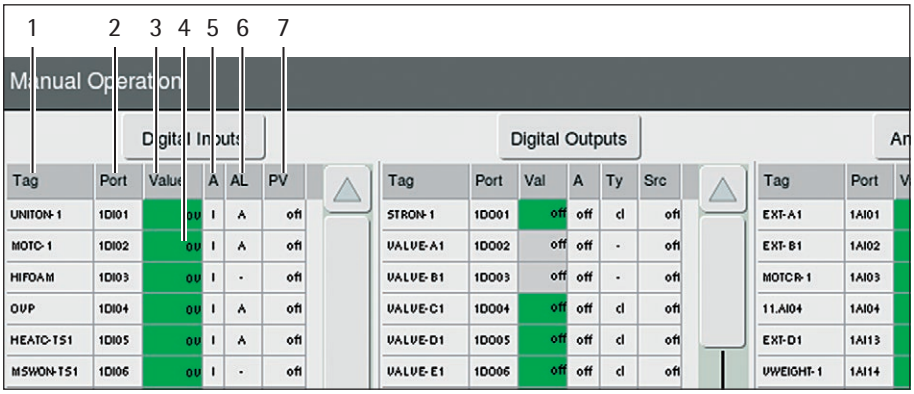
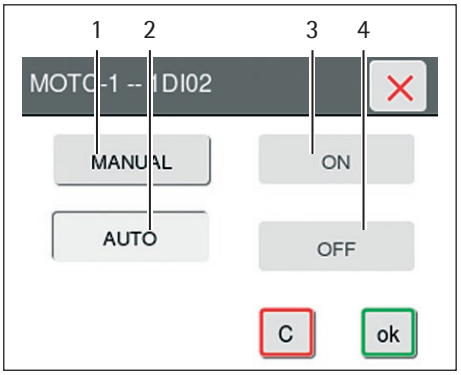


Fig. 52: Overview of manual operation of digital inputs (example)

No.	Name / value	Description
1	Tag	Displays the name of the digital input.
2	Port	Displays the hardware address of the digital input.
3	Value	
	V	Displays the signal level of the digital input. Press to open the window for manual operation of the digital input.
4	0 V	– Press to simulate digital input MOTC-1.
5	A	Displays the physical state of the digital input:
	I	– Digital input is active (active high).
	N	– Digital input is active (active low).
	off	– Digital input is inactive.
6	AL	Displays the alarm status of the digital input:
	A	– Alarm is activated.
	-	– Alarm is **not** activated.
7	PV	Displays the logic state of the digital input:
	on	– Digital input is active.
	off	– Digital input is inactive.



Procedure

- ▶ In the Value column, press the digital input MOT-C1.
- ▷ The setting screen [MOTC-1] is displayed.
- ▶ Switch the digital input to simulation mode: To do so, press the [MANUAL] key (1).
- ▶ Use the [ON] (3) and [OFF] (4) keys to simulate the input signal.
- ▶ Switch the digital input to the DCU operating mode: To do so, press the [AUTO] key (2). Otherwise, the function of the DCU system in simulation mode would be restricted.

8.28.3 Directly Switching Digital Outputs

Required qualification: Operating engineer / laboratory manager

In manual mode, the digital outputs can be controlled directly. Internally, several functions can have an effect on a digital output; the respectively active function is displayed in "Mode". If several functions are active, e.g. for controller outputs, the following priority applies:

Highest priority	Shut down
	Manual operation (manual level)
	Locking
	Controllers, timers, sensors, scales / balances
Lowest priority	Operating state (OPS)

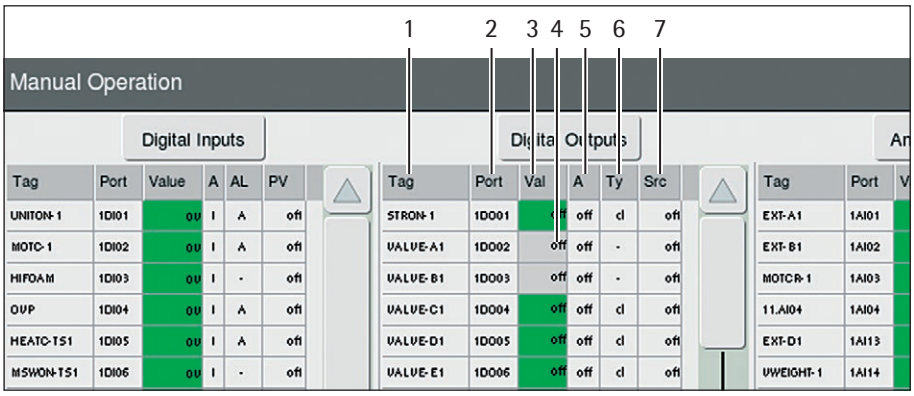
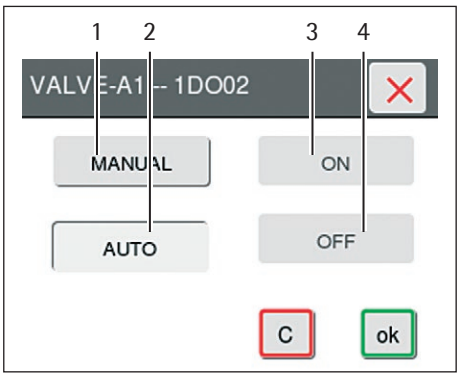


Fig. 53: Overview of manual operation of digital outputs (example)

No.	Name / value	Description
1	Tag	Displays the name of the digital output.
2	Port	Displays the hardware address of the digital output.
3	Val	Displays the logic state of the digital output:
	on	– Digital output (static) is active.
	%	– Digital output (pulse width modulated) is active. The relative duty cycle is displayed or specified. The cycle time is defined in the specific configuration. Example: – Cycle time 10 sec, pulse-duration modulated output 40%: – Digital output 4 sec on and 6 sec off.
	off	– Digital output is inactive.
		Press to open the window for manual operation of the digital output.
4	off	Press to simulate digital output VALVE-A1.
5	A	Displays the physical state of the digital process output (DOP, DO):
	off	– Signal level is 0 V.
	on	– Signal level is 24 V.
6	Ty	Displays the upstream function:
	CL	– Controller function
	-	– No function
7	SRC	Displays the output of the upstream controller.

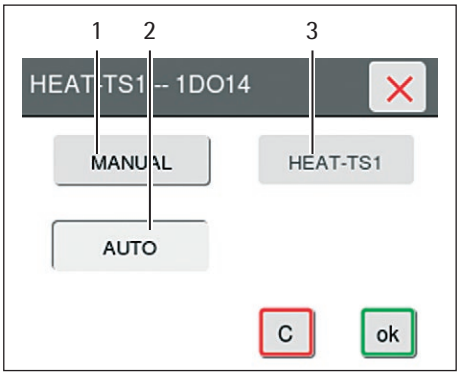


Static output

Procedure

- ▶ In the Value column, press the digital output VALVE-A1.
- ▷ The setting screen [VALVE-#] is displayed.
- ▶ Switch the digital output to simulation mode: To do so, press the [MANUAL] key (1).
- ▶ Use the [ON] (3) and [OFF] (4) keys to simulate the output signal.
- ▶ Switch the digital output to DCU operating mode: To do so, press the [AUTO] key (2). Otherwise, the function of the DCU system in simulation mode would be restricted.

Pulse width modulated output



Procedure

- ▶ In the Value column, press the digital output HEAT-TS.
- ▷ The setting screen [HEAT-#] appears.
- ▶ Switch the digital output to simulation mode: To do so, press the [MANUAL] key (1).
- ▶ Press the [HEAT-TS1] key (3).
- ▶ In the input window, enter the duty ratio in [%].
- ▶ Switch the digital output to DCU operating mode: To do so, press the [AUTO] key (2). Otherwise, the function of the DCU system in simulation mode would be restricted.

8.28.4 Simulating Analog Inputs

Required qualification: Operating engineer / laboratory manager

In manual mode, all analog inputs can be decoupled from the external circuitry, e.g. a measuring amplifier, and simulated by entering a process value.

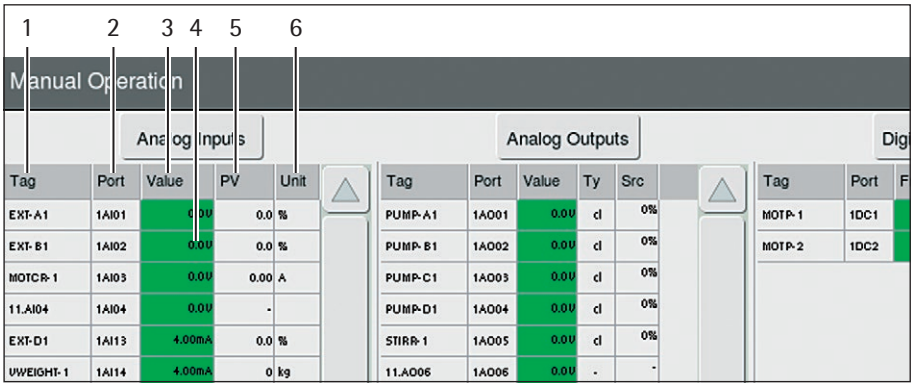
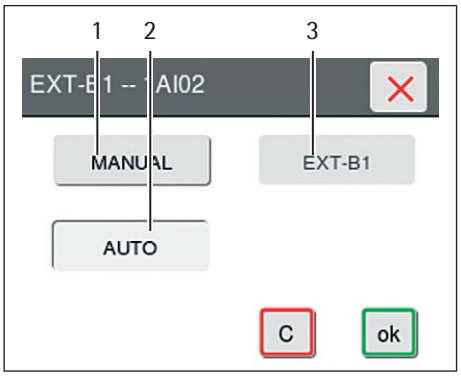


Fig. 54: Overview of manual operation of analog inputs using [PRESS-1] (simulation for input pressure test) as an example

No.	Name / value	Description
1	Tag	Displays the name of the analog input.
2	Port	Displays the hardware address of the analog input.
3	Value	
	PV	Displays the physical input signal. Press to show the window for manual operation of the analog input.
4	0.0 V	Press to simulate analog input EXT-B1.
5	PV	Displays the process value.
6	Unit	Shows the physical unit of the process value.



Procedure

- ▶ In the Value column, press the analog input EXT-B1.
- ▷ The setting screen [EXT-#] appears.
- ▶ Switch the analog input to simulation mode: To do so, press the [MANUAL] key (1).
- ▶ Press the [EXT-B1] key (3).
- ▶ Enter the signal level in the input window:
  - For internal analog inputs (AIM), the physical signal level is always 0 ... 10 V (0 ... 100 %).
  - For external analog inputs (AIP), the signal level can be configured between:
    - 0 ... 10 V (0 ... 100%)
    - 0 ... 20 mA (0 ... 100%)
    - 4 ... 20 mA (0 ... 100%)
- ▶ Switch the analog input to DCU operating mode: To do so, press the [AUTO] key (2). Otherwise, the function of the DCU system in simulation mode would be restricted.

8.28.5 Simulating Analog Outputs

Required qualification: Operating engineer / laboratory manager

During manual operation, you can disconnect analog outputs from the internal DCU functions and influence them directly using signals with a relative level (0 ... 100%). Output signals have the following priorities:

Highest priority	Shut down
	Manual operation (manual level)
	Locking
Lowest priority	Controller

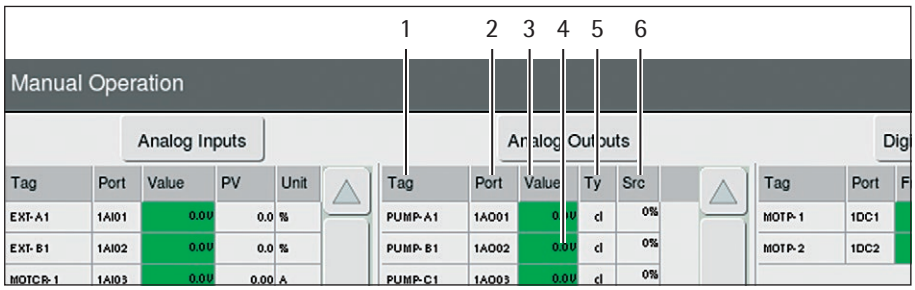
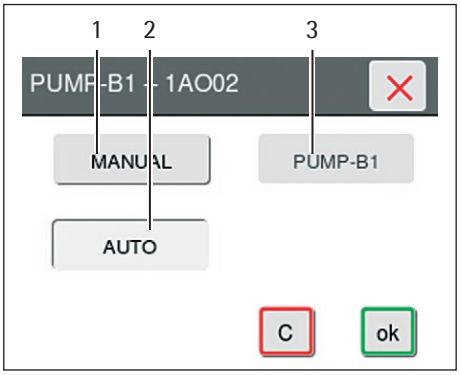


Fig. 55: Overview of manual operation of analog outputs using [PUMP-1] (signal for pump control) as an example

No.	Name / value	Description
1	Tag	Displays the name of the analog output.
2	Port	Displays the hardware address of the analog output.
3	Value	
	PV	Displays the physical output signal. Press to open the window for manual operation of the analog output.
4	0.0 V	Press to simulate analog output PUMP-B1.
5	Ty	Displays the upstream function:
	CL	– Controller function.
	expr	– Logical function.
	-	– No function.
6	Src	
	nn %	Displays the output value of the upstream controller.



Procedure

- ▶ In the Value column, press the analog output PUMP-B1.
- ▷ The setting screen [PUMP-#] appears.
- ▶ Switch the analog output to simulation mode: To do so, press the [MANUAL] key (1).
- ▶ Press the [PUMP-B1] key (3) .
- ▶ In the input window, enter the physical signal level. The signal level of the analog outputs (AO) can be configured between:
  - – 0 ... 10 V (0 ... 100%)
  - – 0 ... 20 mA (0 ... 100%)
  - – 4 ... 20 mA (0 ... 100%)
- ▶ Switch the analog output to DCU operating mode: To do so, press the [AUTO] key (2). Otherwise, the function of the DCU system in simulation mode would be restricted.

8.28.6 Simulate Controllers (Control Loops)

Required qualification: Operating engineer / laboratory manager

In manual mode, controllers can be simulated by entering a setpoint.

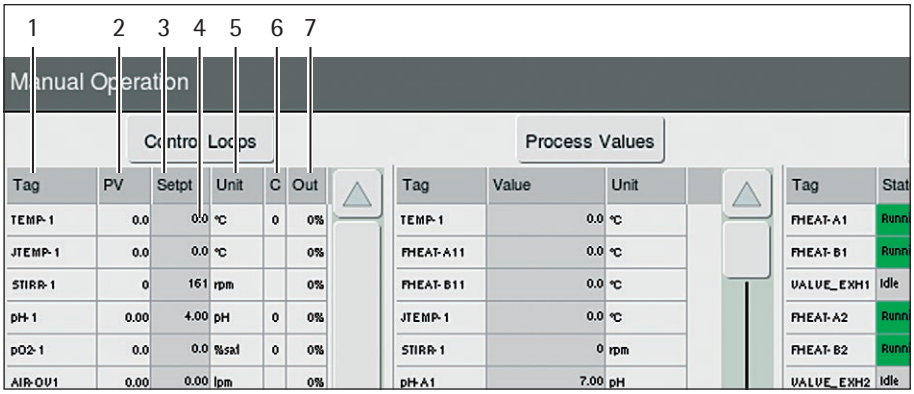
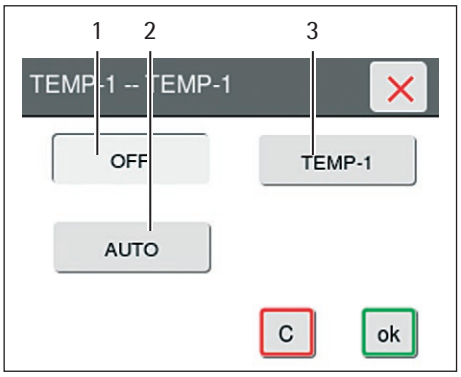


Fig. 56: Manual configuration of controller, example [TEMP-1] (simulation of control signal of temperature controller)

No.	Name / value	Description
1	Tag	Displays the name of the controller.
2	PV	Displays the process value of the controller.
3	Setpt	Displays the setpoint of the controller.
4	0.0	Press to specify the setpoint for TEMP-1.
5	Unit	Shows the physical unit of the process value.
6	C	Displays the active cascade:
	0	– no cascade
	1 ... n	– corresponding cascade of cascade control
7	Out	Displays the calculated output value.



Procedure

- ▶ In the column Setpt, press the controller TEMP-1.
- ▷ The setting screen [TEMP-#] appears.
- ▶ Use the [OFF] (1) and [AUTO] (2) keys to select the operating mode of the controller.
- ▶ Press the [TEMP-1] key (3).
- ▶ Enter the setpoint in the input window:
- ▶ Switch the controller to DCU operating mode: To do so, press the [AUTO] key (2). Otherwise, the function of the DCU system in simulation mode would be restricted.

8.28.7 Manually Controlling Sequences (Phases)

Required qualification: Operating engineer / laboratory manager

In manual mode, sequences can be simulated, e.g. during commissioning.

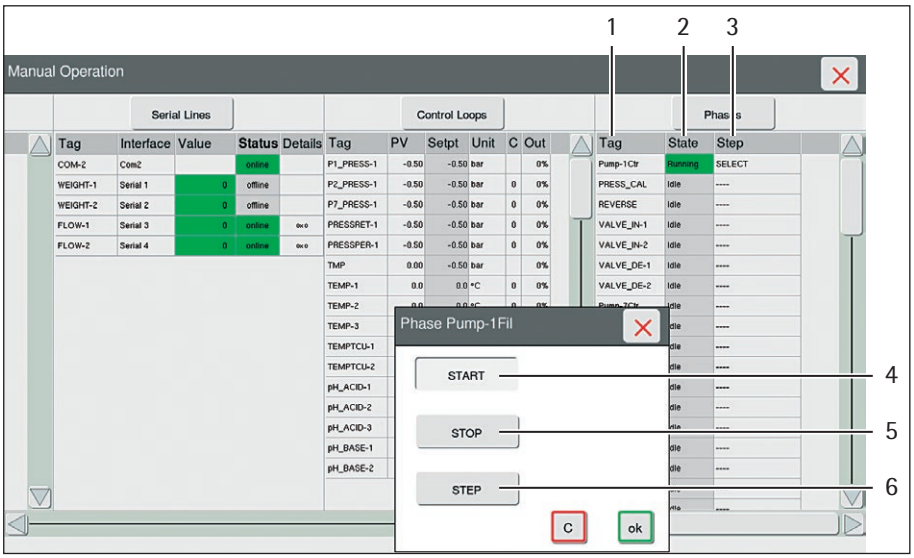


Fig. 57: Overview of operating sequences (phases) using [Pump-1Fil] as an example

No.	Name / value	Description
1	Tag	Displays the name of the sequence.
2	State	– Displays the status of the sequence. – Press to display [Phase Pump-1Fil] window for sequence control.
3	Step	Displays the current sequence step.
4	START	Press to start the sequence.
5	STOP	Press to stop the sequence.
6	STEP	Press to switch to the next sequence step.

Type and number of sequence steps of individual sequences depends on the configuration of your system.

Procedure

▶ In the State column, press the sequence [Pump-1Fil].
▷ The [Phase Pump-1Fil] window appears.
▶ Use [START], [STOP] and [STEP] to manually control the sequence.
▶ After working in manual mode: Stop all sequences. Otherwise, the function of the DCU system would be restricted.

8.29 Configuring External Devices

Required qualification: Operating engineer / laboratory manager

The [External] main function can be used to view and set the status of externally connected units (e.g. scales). In addition, the alarm function for each externally connected device can be activated and deactivated.

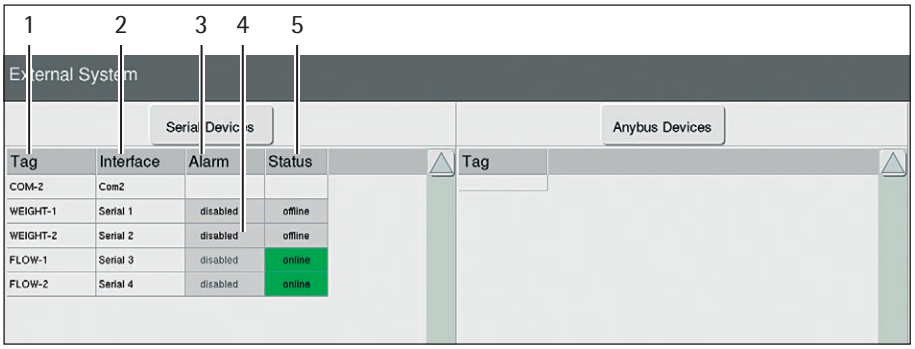


Fig. 58: Overview of externally connected devices (example)

No.	Name / value	Description
1	Tag	Displays the external device connection.
2	Interface	Displays the external device interface.
3	Alarm	– Displays the alarm status:
	enabled	– Alarm function is activated.
	disabled	– Alarm function is disabled.
		– Press to change the alarm status.
4	disabled	Press to activate the alarm function of the external device WEIGHT-2.
5	Status	Displays the status of the connected external device:
	offline	– The device is **not** connected. – The device is switched off.
	online	– The device is connected and switched on.

Procedure

▶ Press the [Manual Operation] key in the main function [External].
▷ The [External System] window appears.
▶ Switch the alarm function on or off by pressing on the [alarm] field of the corresponding external device.

8.30 Uninstalling Bags

⚠ CAUTION

Crushing due to improper uninstallation!

Improperly removing bags from the bag holder may cause body parts to be crushed. Avoid crushing of body part in the doors when opening and closing.

▶ Wear personal protective equipment.

⚠ CAUTION

Risk of injury and damage to the bag!

The improper removal of bags from the bag holder can damage the bag. Media may leak and cause personal injury.

▶ Wear personal protective equipment.
▶ Carefully note the procedure for uninstalling bags.

The procedure for uninstalling bags is illustrated using the example of the Flexsafe STR® 500 L version. Deviations in the procedure for other versions are indicated accordingly.

Personnel:

– Flexsafe STR® 500 L | 1000 L bag	3 persons
– Flexsafe STR® 50 L | 200 L bag	2 persons

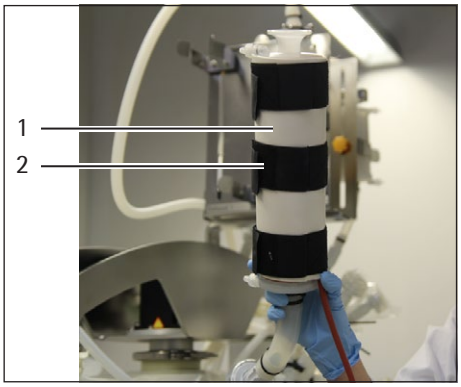
Requirements

The control / power supply unit is switched on.

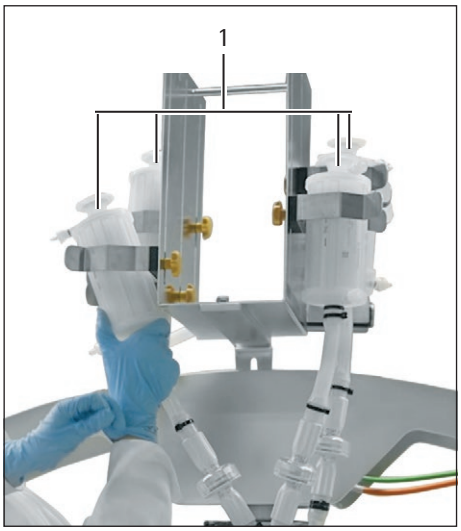
Procedure

▶ The bioreactor contents must be emptied: Connect the drain line at the drain port to the required transfer line.
▶ Switch off all peristaltic pumps (operating mode [off], see Chapter 8.16, page 141).
▶ Open the drain line clamp at the drain port to begin removal of bioreactor contents.
▶ When the bag contents are below the minimum filling volume:
  ▶ **NOTICE** Damage to the agitator could occur if controller [STIRR- #] is switched from auto to off. Adjust the speed of the stirrer [STIRR-#] to 0 rpm (see Chapter 8.20, page 146).
  ▶ Wait one minute until the stirrer has stopped.
  ▶ When 0 RPM is reached, turn off the stirrer controller [STIRR #] by turning the operating mode to [OFF], see Chapter 8.20, page 146).
▶ Stop the aeration:
  ▶ To deactivate the DO (pO_2) cascade: change the DO operating mode from [AUTO] to [OFF], see Chapter 8.21, page 147).
  ▶ Switch off the remaining mass flow controllers.
▶ To switch off temperature control: change the TEMP# operating mode from [AUTO] to [OFF], see Chapter 8.22, page 148).
▶ To switch off pH control: change the pH operating mode from [AUTO] to [OFF], see Chapter 8.23, page 151).
▷ The bag is emptied. After emptying, a small residual volume may be left in the bag.
▶ Close the drain line clamp at the drain port.
▶ Switch off the control / supply unit.
▶ Disconnect all feed and buffer tube lines from the STR Bag.

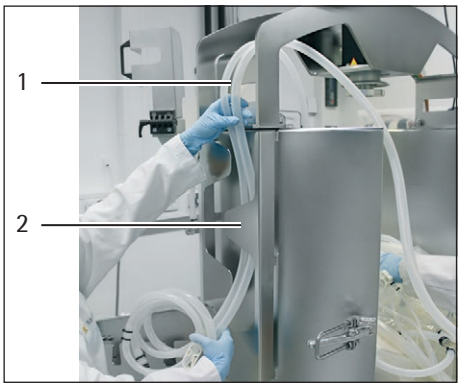
- ▶ Disconnect the drain line from the transfer assembly to the downstream vessel. The remaining attached line must be able to fit through the drain port.
- ▶ Remove the PT100 temperature sensor from the port.
- ▶ If optical sensors are installed on the bag: Remove the fiber optic cables from the ports.
- ▶ If conventional sensors are installed on the bag:
  - ▶ Remove the sensor cable.
  - ▶ Place the caps on the connections of the sensors.
  - ▷ The sensors can be autoclaved with the empty bag.
- ▶ Flexsafe STR® 500 L | 1000 L bag: Remove the aeration tubes.
  - ▶ Remove the pressure sensor tube on the non-sterile side of the filter capsule.
  - ▶ Remove the aeration tube on the non-sterile side of the filter capsule.
- ▶ Flexsafe STR® 50 L | 200 L bag: Remove the aeration tube on the non-sterile side of the filter capsule.
- ▶ Uninstall the filter heater:
  - ▶ Disconnect from the control / supply unit.
  - ▶ Uninstall the filter heater (2) from the filter capsule (1) .



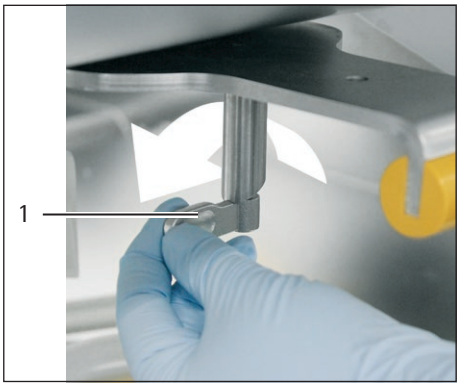
- ▶ Remove the filter capsules (1) from the filter holder.



- ▶ Remove the tubing (1) from the tubing holder (2).
- ▶ Open the bag holder door.

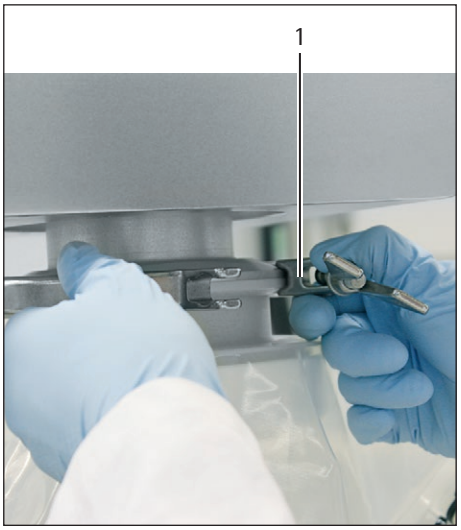


▶ ⚠ **WARNING** Risk of injury due to strong magnetic field! The magnetic field emitted from the magnetic coupling can interfere with or damage equipment susceptible to magnetic effects. There is a significant danger of injury to people with pacemakers.
  ▶ Do **not** allow individuals with pacemakers to work on the magnetic coupling.



▶ To open the drain port holder: Turn the lever (1) to the unlocked position.

▶ **NOTICE** Damage to the sensors due to improper uninstallation! If conventional sensors are installed on the bag:
  ▶ Carefully remove the sensors (1) from the probe clamps (2).
  ▶ Carefully guide the sensors through the probe window and deposit them in the interior of the bag holder.



  ▶ Open the Tri-Clamp clip (1).
  ▶ Remove the Tri-Clamp clip.

- ▶ Push the top port down with both hands.
- ▶ Flexsafe STR® 500 L | 1000 L bag: Remove the bag from the bag holder.
  - ▶ User (1): Step onto the tread surface and hold the bag at the top port.
  - ▶ User (2): Hold the bag at the fitting cone of the drain port.
  - ▶ User (3): Guide the drain line lead through the drain port holder.
  - ▶ Lift the bag out of the bag holder.
- ▶ Flexsafe STR® 50 L | 200 L bag: Remove the bag from the bag holder.
  - ▶ User (1): Hold the bag at the top port and at the fitting cone of the drain port.
  - ▶ User (2): Guide the drain line lead through the drain port holder.
  - ▶ Lift the bag out of the bag holder.

- ▶ **NOTICE** Impairment of the functionality of the fitting cone! The functionality of the fitting cone will be impaired if autoclaved. Remove the fitting cone from the bag before autoclaving it:
  - ▶ Place the fingers of your right and left hand in the recessed grips provided on the fitting cone.
  - ▶ Pull the two fitting cone elements (1) apart.
- ▶ To autoclave the bag in a suitable autoclave:
  - ▶ Observe the dimensions of the bag when selecting the autoclave (see Chapter 15.12.3, page 197).
  - ▶ Place the bag in the autoclave.
  - ▶ Autoclave the bag.
- ▶ Remove the bag from the autoclave after autoclaving.
- ▶ **NOTICE** Damage to the sensors due to improper uninstallation! If conventional sensors are installed on the bag: Carefully remove the sensors from the bag.
- ▶ Dispose of the bag (see Chapter "14 Disposal," page 192).

8.31 Emptying the Double Wall and Temperature Control Unit

⚠ CAUTION

Risk of injury from pressurized media!

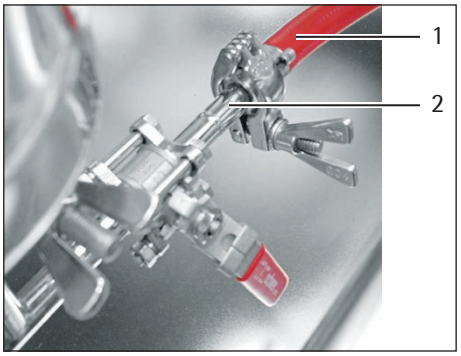
Escaping compressed gases or media escaping under high pressure can lead to injuries, e.g. eye injuries.

- ▶ Wear personal protective equipment.
- ▶ Close the supply lines.
- ▶ Carefully disconnect the supply tubes. Disconnect and hold the tubing ends. Keep the tubing ends away from body orifices.
- ▶ Follow the manufacturer's operating instructions for additional components.
- ▶ Follow the construction guidelines required to ensure that the device is stable.

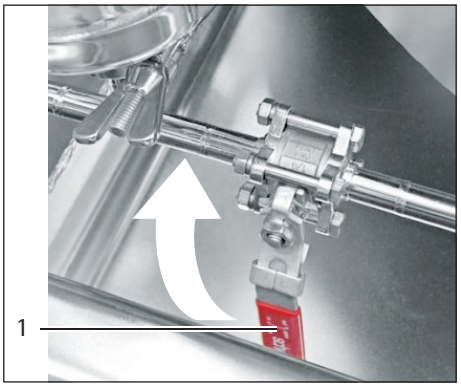
Requirements

- The process is ended.
- The control / power supply unit is switched off.

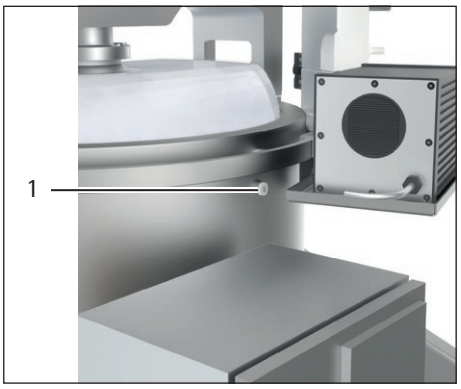
Procedure



- ▶ Connect the tube (1) to the drain valve terminal (2).
- ▶ Lead the open end of the tubing into a drain or collection vessel.
- ▶ To release the lock preventing accidental opening of the drain valve: Remove the cable clip on the drain valve.



- ▶ To open the drain valve: Rotate the lever (1) of the drain valve parallel to the position of the flow direction.



- ▶ Unscrew the plug (1) from the vent hole.
- ▷ The double wall is emptied.

- ▶ To empty the supply and return tubes:
  - ▶ Loosen the TC connections of the supply and return tubes at the Temperature Control Unit.
  - ▶ Place the open ends of the supply and return tubes in a container.
  - ▷ The supply and return tubes are drained.
- ▶ After emptying: Connect the supply and return tubes to the Temperature Control Unit.
- ▶ Firmly tighten the TC connectors.
- ▶ Push the plug into the vent hole (1).
- ▶ Close the drain valve.
- ▶ Remove the tubing from the drain connection.

9 Cleaning and Maintenance

9.1 Cleaning Device Surfaces

⚠ WARNING

Danger of injury due to escaping compressed air or pressurized media!

Escaping compressed air or media escaping under high pressure can lead to serious injuries, e.g. eye injuries.

- ▶ Depressurize the bag holder and disconnect it from the control / supply unit.
- ▶ Always wear the required personal protective equipment when performing all cleaning and maintenance work.
- ▶ Follow any other manufacturer's operating instructions for additional components.
- ▶ Follow the construction guidelines required to ensure that the device is stable.

Requirements

- ▶ The cultivation process has ended.
- ▶ Close all connected aeration segments.
- ▶ Turn all electrical switches to the off position and carefully disconnect the power cables from the device. Keep the tubing ends away from the body when doing this.
- ▶ When working on the oxygen line: Ensure your tools and hands are clean (grease- and oil-free).
- ▶ Turn off all laboratory supply media (water and gas supply lines).
- ▶ The connections and tubes must be depressurized.

Procedure

- ▶ ⚠ **CAUTION** Danger of burns to the hands and body from touching hot surfaces! Allow the device to cool down.
- ▶ **NOTICE** Danger of corrosion or damage to the device due to unsuitable cleaning agents!
  - ▶ Do not use corrosive, chloride-containing or aggressive cleaning agents.
  - ▶ Do not use cleaning agents that contain abrasive ingredients, e.g. scouring agents, steel wool.
  - ▶ Do not use solvent-based cleaning agents.
- ▶ Wipe the outsides of the device surfaces and accessories with a wet cloth. In the case of particularly heavy contamination, use mild soapy water.

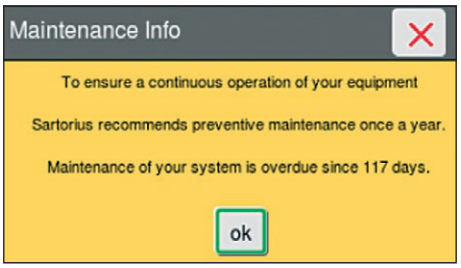
9.1.1 Maintenance Info

The service cycle (365 days) is activated when the device is started up. If this info window appears, the device should be serviced by Sartorius Service in order to ensure its continuous operation.

Requirements

The device is equipped with the "Maintenance Info" function (from firmware V 7.8).

Procedure



- ▶ Confirm the window with the [ok] key.
- ▶ Inform Sartorius Service.

The service cycle is reset after a service is carried out.

9.2 Maintenance Schedule

Interval	Components	Action	Chapter, page
Before every cultivation process	Aeration tubes	Check whether gas is escaping from the tubes. Inspect the aeration tubes for damage, e.g. hairline cracks, pressure sites or porous surfaces. If required: Replace the aeration tubes.	7.5.3, 84
	Bag holder: Temperature control circuit	Check whether heat transfer fluid escapes at all tubing and hose connections on the temperature control unit.	
		Inspect the tubing for damage. If required: Replace the tubing.	6.10, 65
	Filter heater	Check the filter heater for damage. If required: Replace the filter heater.	7.6, 93
	Magnetic coupling	Check for damage and dirt. If required: Clean magnetic coupling.	
	Sensors	Check the sensors for damage.	
		When using pH and DO (pO_2) probes: Calibrate the sensors (for calibration, see instructions on the sensors).	8.9, 117
	Supply air and exhaust filter capsules	Perform integrity test on the filter elements.	
Annually	Seals and gaskets on device equipment (O-rings, gaskets)	When the device equipment comes with separate instructions: Follow the instructions pertaining to the device equipment. Inspect seals and gaskets annually.	
	Device	Maintenance and functional test according to maintenance report. Maintenance and functional testing must be performed by Sartorius Service.	
	Mass flow controller	Calibrate the mass flow controllers – contact Sartorius Service for calibration services.	

9.3 Cleaning and Inspecting Accessories

9.3.1 Filter Heater

Removing Filter Heater

Procedure

- ⚠ **WARNING** Electrical shock from moisture on conductive parts! If splashing water or media escape or are spilled during the cultivation process: Wipe up the fluids and dry any wet equipment. Only remove the filter heater once all equipment is dry.
- ⚠ **CAUTION** Danger of burns to hands and body parts from touching hot filter heater! Allow the filter heater on the device to cool down.
- Unplug the connection cable on the filter heater from the control/supply unit or the power supply.
- Remove the filter heater from the exhaust filter capsule.
- **NOTICE** Danger of damage to connection cable from improper handling! Do **not** hold heating jacket by its connection cable.
- **NOTICE** Danger of damage to the filter heater from folding! Subjecting the filter heater to extreme bending may damage the heating coils inside the filter heater. Do **not** fold the filter heater.
- Spread the filter heater out on the benchtop or a similar surface.
- **NOTICE** Danger of damage to the filter heater from sharp objects! **Never** place any objects on the filter heater. This can result in damage to the filter heater and cause short circuits during operation.

Inspecting the Filter Heater for Damage

⚠ **WARNING**

Electrical shock from damaged filter heater!

Damage to the connection cable, the heating coils or insulation can be life-threatening. Contact with parts under voltage represents a direct danger of death.

- The filter heater must be inspected for damage every time before operation.
- Do **not** use a damaged filter heater.
- Do **not** perform repairs on the filter heater, connection cable or adapter.

Procedure

- Check whether the following damage is detectable on the filter heater and connection cable:
  - Breakage sites on the connection cable and plug
  - Porous sites on the connection cable and plug
  - Kinks in the heating mat
  - Discolorations on the heating mat
  - Wear to the fastening straps
- When damage is detectable on the filter heater and the connection cable: Replace the filter heater.

Cleaning the Filter Heater

- **NOTICE** Danger of damage to the silicone foil from solvents! Solvent-based cleaning agents can cause the silicone foil of the filter heater to become brittle and cracked. When using solvent-based cleaning agents: Avoid contact with the silicone foil.
- **NOTICE** Danger of damage to the filter heater from using sharp-edged tools or assistive devices! Do **not** use sharp-edged objects.
- Wipe the filter heater with a wet cloth and mild soapy water.

9.4 Re-starting the System

⚠ WARNING

Danger of injury due to escaping compressed air or pressurized media!

Escaping compressed air or media escaping under high pressure can lead to serious injuries, e.g. eye injuries.

- When retrofitting and after maintenance or servicing, check the proper connection to energy supply lines as well as the layout and correct functionality of the safety equipment.
- Prevent the danger of functional problems, operational malfunctions and defects caused by improper installation.
- Follow any other manufacturer's operating instructions for additional components.
- Follow the construction guidelines required to ensure that the device is stable.

Procedure

- Prepare the device for the fermentation process (see Chapter "7 Process Preparation," page 69).
- ⚠ **CAUTION** Prevent the danger of functional problems, operational malfunctions and defects caused by improper installation: Have Sartorius Service re-start the system.

10 Malfunctions

10.1 Malfunctions of bioreactor cooling

Malfunctions	Cause	Correction
The cooling water is not being fed into the system.	The laboratory supply line is blocked or the valves of the cooling water supply are defective.	Check the valves. If all other potential causes can be excluded (see below), contact Sartorius Service.
	The cooling water supply valve does not work because of particulate contaminants in the cooling water or scale deposits.	Check the water hardness (max. water hardness, see Chapter "15 Technical Data," page 194). Feed clean cooling water into the system. If required: Install a pre-filter.
The cooling power is insufficient.	The flow rate is too low. Cooling water temperature too high.	The minimal operating temperature (see Chapter "15 Technical Data," page 194). If required: Install a separate upstream cooling device.

10.2 Malfunctions due to Aeration and Ventilation

Malfunctions	Cause	Correction
The air inlet line is blocked.	The inlet air filter is blocked.	Check the inlet air: Dry, oil- and dust-free. If required: Install a pre-filter.
The gas or air supply is blocked or decreases suddenly.	A tube is kinked. A tube is clamped off.	Inspect the tube.
	The exhaust filter capsule is blocked, e.g. as a result of moist air, condensation or foam back flow.	Inspect the tube and filter. If required: Connect a new sterile exhaust air filter capsule.
Gases do not flow	Exhaust heater not installed. There is an interlock on the exhaust heater and the gassing.	Install exhaust heater.

10.3 Malfunction in heating or cooling performance in temperature control circuit

Malfunctions	Cause	Correction
Heating or cooling performance is reduced. 400 V system: Error E11 in pump display or pump throughput displayed is significantly below 40 W. 208 V system: Air noises in temperature control circuit.	Reduced pump throughput as the result of air in the temperature control circuit.	Vent the temperature control circuit and/or refill heat transfer fluid (see Chapter "6.7 Setting up Temperature Control Circuit," page 58).

10.4 Noises During Operation

Malfunctions	Cause	Correction
Occasionally, squeaking noises (< 70 dB) may occur during operation.	Flexsafe STR® Bag: The upper bearing inside the magnet body is designed to operate without lubricant.	The function of the bioreactor is not impaired and the noise cannot be avoided.

10.5 Process Messages

The following table gives an overview of possible alarm messages (process-related alarms):

Process message	Cause	Correction
"Name" state alarm	An alarm was triggered at the "Name" digital input.	Check the process. Confirm the message with [ACK] key.
"Name" low alarm	The process value "Name" exceeded its lower alarm limit.	Check the process. Confirm the message with [ACK] key.
"Name" high alarm	The process value "Name" exceeded its upper alarm limit.	Check the process. Confirm the message with [ACK] key.
Jacket heater failure	The overheating protection in the temperature circulation of the double wall has been triggered.	Re-fill the temperature control circuit. If problem persists contact Sartorius Service.
Motor failure	The overheating protection of the motor has reacted.	Allow the motor to cool down.
OVP	The overvoltage protection has reacted.	Contact Sartorius Service to replace the overvoltage protection.

10.6 Status Messages

The following table gives an overview of possible status messages (system-generated alarms):

Status message	Cause	Correction
Factory reset	The system was re-started with the changed configuration. The system has been reset to factory settings.	Confirm the message with [ACK] key.
Power failure Power lost at [yyyy-mm-dd hh:mm:ss]	A power failure with the date and time.	Confirm the message with [ACK] key.
Power failure, process stopped System in standby Power lost at [yyyy-mm-dd hh:mm:ss]	A power failure with the date and time; the permissible duration of the power failure (System Parameters -> Failtime) was exceeded.	Confirm the message with [ACK] key.
Shut down unit #	The supply unit number # has been switched off at the main switch "Mains I/O".	Confirm the message with [ACK] key.

11 Decommissioning

11.1 Decommissioning the Device

Requirements

The process has ended properly.

Procedure

- ▶ Turn the device off.
- ▶ Depressurize the device.
- ▶ Disconnect the device from the power supply and all other supply systems. To do this, disconnect all cables and tubes.
- ▶ Disconnect all accessories from the device.
- ▶ If the bag is full: Empty the bag.
- ▶ Remove the bag from the bag holder (see Chapter "8.30 Uninstalling Bags," page 175).
- ▶ Clean the device (see Chapter "9 Cleaning and Maintenance," page 180).

12 Transportation

12.1 Transporting

The device will be delivered by Sartorius Stedim Biotech or by a transport company engaged by Sartorius Stedim Biotech.

⚠ WARNING

Danger of injury due to the high weight of the device!

There is a danger of injury when lifting and transporting the heavy device.

- ▶ Get help from additional persons when lifting and transporting heavy devices.
- ▶ Use suitable conveyance devices when covering long transport routes, e.g. forklifts.
- ▶ The load capacity of the lifting system (forklift) must in the very least be appropriate for the weight of the device (see Chapter "15.13 Net Weight," page 198).

NOTICE

Danger of damage due to improper transport!

- Protect the device against:
  - Impact
  - Falls
  - Damage
  - Humidity

Procedure

- Decommission the device.
- **NOTICE** Danger of damage to device from improper handling! Do **not** lift the bagholders by the housing. Lift the device only at suitable points with lifting accessories, e.g. forklifts.
- Make sure that the transport routes, such as elevators, are sufficiently large and have adequate load bearing capacity.
- Wear personal protective equipment.
- **NOTICE** The unit may only be transported with the transport locks in place. To install the transport locks, contact Sartorius Service if necessary.
- Transport locks may only be removed at the place of installation.
- During transport of the device, ensure that no personnel are in its path.

Empty double wall of the bag holder for transport

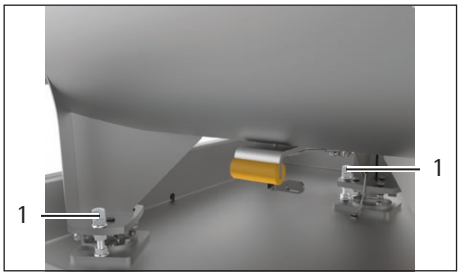
Emptying the double wall is not necessary for transport to another laboratory on the fastening rollers.

- Empty the double wall when preparing for further transport by truck or during temporary decommissioning (see Chapter "8.31 Emptying the Double Wall and Temperature Control Unit," page 178).

12.2 Lifting the Bag Holder

Procedure

- Remove the following parts before lifting:
  - Filter holder
  - Probe holder
  - Holder for exhaust cooler
  - Holder for condensation return pump
  - Remove the bag from the bag holder.



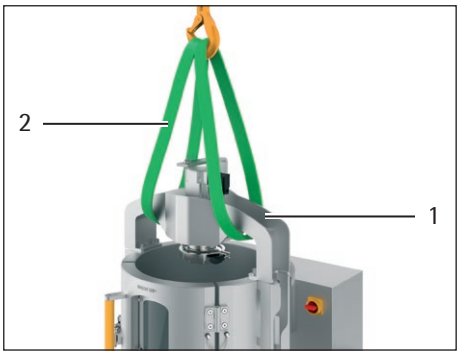
- **NOTICE** Damage to weigh cells due to absence of transport lock! Secure the weigh cells with the screws (1) before lifting them.
- Screw in the bolts (1) until they make contact with the floor pan and secure with the lock nuts.

NOTICE

Danger if center of gravity of the bag holder is behind the center axis!

When lifting, the bag holder tilts backwards slightly.

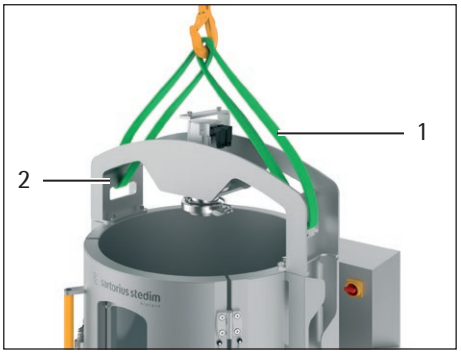
▶ Ensure there is sufficient space around the bag holder.



Bag Holder: Size 50 L

▶ Hook the carry belts (2) into the recesses in the motor support bracket (1).

▶ Lift the bag holder with a suitable crane.



Bag Holder: Sizes 200 L, 500 L and 1000 L

▶ Hook the carry belts (1) into the lateral fixation points (2) of the motor support bracket.

▶ Lift the bag holder with a suitable crane.

13 Storage and Shipping

13.1 Storage

Upon Delivery (Temporary Storage)

▶ Observe the transport conditions for the device (see Chapter "15.2 Ambient Conditions," page 194).

After Use

Procedure

▶ If the device is in operation:
  ▶ Decommission the device.
  ▶ Clean the device.
▶ Store the device according to the ambient conditions (see Chapter "15.2 Ambient Conditions," page 194

13.2 Storage Conditions

13.2.1 Bioreactor

– Dry building
– Do not expose to UV radiation and direct sunlight
– No areas where solvents, chemicals, acids, and fuels are stored
– Observe ambient conditions (see Chapter "15.2 Ambient Conditions," page 194)

13.2.2 Flexsafe STR® Bag

– Store in original packaging
– Do not expose to UV radiation and direct sunlight
– Maintain temperature range (see Chapter "15.2 Ambient Conditions," page 194)
– Maintain relative humidity (see Chapter "15.2 Ambient Conditions," page 194)
– Store only until expiration date has been reached

13.3 Shipping-related Tasks/Returns

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

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

⚠ WARNING

Danger of injury due to contaminated equipment!

Devices contaminated with hazardous materials (Nuclear, biological, or chemical (NBC)) will not be accepted for repair or disposal.

- ▶ Observe the information on Decontamination (see Chapter "14.1 Information on Decontamination," page 192).

13.3.1 Returning Device

Procedure

- ▶ Decommission the device.
- ▶ Complete the Decontamination Declaration. Use the forms available on our website (www.sartorius.com). Contact Sartorius Service to receive a return authorization number. The device will not be accepted by Sartorius without authorization.
- ▶ Enclose the Decontamination Declaration with the delivery documents. The recipient must be able to inspect the completed Decontamination Declaration before removing the device from the packaging.
- ▶ Pack the device and its parts properly.
- ▶ Return the device to Sartorius Service. The service addresses for returns can be found on our website (www.sartorius.com).

13.3.2 Returning Consumables

The consumables are intended for single use. Used consumables may **not** be returned to Sartorius Stedim Biotech for disposal (e.g. the bag).

Used consumables may **only** be sent to Sartorius Stedim Biotech for testing, e.g. in case material damage is suspected.

Procedure

- ▶ Observe the information on Decontamination (see Chapter "14.1 Information on Decontamination," page 192).
- ▶ Sterilize and decontaminate the consumables properly.
- ▶ Returning the consumables (see Chapter "13.3.1 Returning Device," page 191).

14 Disposal

14.1 Information on Decontamination

The device does **not** contain any hazardous materials that would necessitate special disposal measures. The cultures and media (e.g. acids, bases) used during the processes are potentially hazardous materials that could cause biological or chemical hazards.

According to the EU directives (European directive on hazardous substances), the owner of devices that come into contact with hazardous substances is responsible for properly disposing of those devices and for declaring such devices when transporting them.

⚠ WARNING

Danger of injury due to contaminated equipment!

Devices contaminated with hazardous materials (NBC contamination) will **not** be accepted for repair or disposal.

14.2 Disassembly

⚠ WARNING

Danger of severe injury due to ejected or falling parts!

When disassembling the unit, pay particular attention to those components that contain parts under mechanical tension that could spring out during disposal, leading to injury. There is also danger due to moving parts and falling objects.

– The unit may only be disassembled by qualified technical personnel.
– Wear personal protective equipment.

Requirements

The device has been taken out of operation. Drain the system completely.
Switch off the system and secure it to prevent it being turned back on again.
Block and keep the entire system physically separated from all energy and media supply lines.
Discharge the accumulated residual energy. Remove the operating and auxiliary materials and dispose of them in an environmentally friendly way.

Procedure

Required qualification: Operator

▶ Disassemble the device until all parts have been assigned to a material group and can be appropriately disposed of.

14.3 Disposing of Device and Parts

14.3.1 Information on Disposal

The device and its accessories do **not** belong in your regular household waste, since they are made of high-grade materials which can be recycled and reused. All parts must be disposed of properly by disposal facilities.

The packaging is made of environmentally friendly materials that can be used as secondary raw materials.

14.3.2 Disposal

Requirements

The device has been decontaminated.

Procedure

- ▶ Dispose of the device. Follow the disposal instructions on our website (www.sartorius.com). When return and disposal of the device is carried out by Sartorius Stedim Biotech: Send the device or parts to Sartorius Stedim Biotech (see Chapter "13 Storage and Shipping," page 190).
- ▶ In countries that are not members of the European Economic Area (EEA) or where no Sartorius subsidiaries or dealerships are located: Contact the local authorities or the local waste management company.
- ▶ Dispose of the bag in accordance with local government regulations.
- ▶ Dispose of the packaging in accordance with local government regulations.

15 Technical Data

15.1 Power Supply

15.1.1 Control / Supply Unit

	Unit	208 V version	400 V version
Voltage	V	208 V (±10%)	400 V (±10%)
Frequency	Hz	60	50
Power consumption	A	12	10
Power plug		20A, NEMA L21-20P	16A, CEE plug

15.1.2 Bag Holder

	Unit	208 V version	400 V version
Voltage	V	208 V (±10%)	400 V (±10%)
Frequency	Hz	60	50
Power consumption	A	16	13
Power plug		20A, NEMA L21-20P	16A, CEE plug

15.2 Ambient Conditions

	Unit	Value
Installation location: Usual laboratory rooms	m above sea level	< 2000
Temperature range	°C	+5 – +40
Relative humidity		
For temperatures up to 31 °C	%	< 80
Decreasing linearly at temperatures from 31 °C to 40 °C thereafter	%	< 50
Storage conditions for Flexsafe STR® bags	%	< 85
Protection class according to EN 60529		IP44
Acoustic emission, max. sound pressure level	dB (A)	< 70
Impurities		
Pollution level according to IEC 61010-1		2

15.3 Permissible Stirrer Speed

Volume of the bag	Unit	Size 50 L	Size 200 L	Size 500 L	Size 1000 L
Rotational-speed range	1 / min	0 – 240	0 – 150	0 – 110	
Bag with 2 three-blade segment impellers	1 / min				0 – 90
Bag with 6-blade segment impeller (below) + 3-blade segment impeller (above)	1 / min				0 – 70

15.4 Heat Transfer Fluid Supply

	Unit	Value
Heat transfer fluid		
Water or water-coolant mixture (coolant must not be toxic, flammable under operating conditions or harmful to human tissue)		
Supply rate, min.	L/min	15
Water pressure, max.	barg (psig)	6
Water hardness	mmol / L earth alkaline ions	0.7 – 1.5
Temperature range	°C	1 – 40
Connection using Tri-clamp		
For BIOSTAT STR® 50 | 200 L		TC25
For BIOSTAT STR® 500 | 1000 L		TC50.5
Water quality		
Free of corrosion residues and deposits from the supply lines		
No distilled, demineralized or chloride-containing water		

15.5 Heat Transfer Fluid Double Wall

	Unit	Value
Heat transfer fluid		Water
Pressure, max.	bar	0.5
Water hardness	mmol / L earth alkaline ions	0.7 – 1.5
Temperature range	°C	1 – 60
Water quality		
Free of corrosion residues and deposits from the supply lines		
No distilled, demineralized or chloride-containing water		

15.6 Process Temperature

	Unit	Value
Temperature range higher than temperature of heat transfer fluid	°C	8 – 40

15.7 Gas and Compressed Air Supply

Volume of the bag	Unit	Size 50 L	Size 200 L	Size 500 L	Size 1000 L
Supply pressure					
Compressed air [AIR], preset, max.	barg (psig)	1.5 – 2.0	1.5 – 2.0	2.5 - 4.0	2.5 – 4.0
Oxygen [O_2], regulated, max.	barg (psig)	1.5 – 2.0	1.5 – 2.0	2.5 - 4.0	2.5 – 4.0
Nitrogen [N_2], regulated, max.	barg (psig)	1.5 – 2.0	1.5 – 2.0	2.5 - 4.0	2.5 – 4.0
Carbon dioxide [CO_2], regulated, max.	barg (psig)	1.5 – 2.0	1.5 – 2.0	2.5 – 4.0	2.5 – 4.0
Compressed air [AIR], preset, max.	psi	22 – 29	22 – 29	36 – 58	36 – 58
Oxygen [O_2], regulated, max.	psi	22 – 29	22 – 29	36 – 58	36 – 58
Nitrogen [N_2], regulated, max.	psi	22 – 29	22 – 29	36 – 58	36 – 58
Carbon dioxide [CO_2], regulated, max.	psi	22 – 29	22 – 29	36 – 58	36 – 58
Gas flow rate per gas line, max.	vvm	0.1	0.1	0.1	0.1
	L / min	5	20	50	100
Total gas flow rate in bag, max.	vvm	0.2	0.2	0.2	0.2
	L / min	10	40	100	200
Total gas flow rate in					
micro sparger, max.	vvm	0.1			
ring sparger, max.	vvm	0.2			
Purity					
Gases: Dry, grease-free, oil-free, particle-free					
Supply media					
Equip with emergency shutoff					

15.8 Peristaltic Pumps for the Control / Supply Unit

Possible built-in types	Unit	Value
WM 314 set speed, digital	1 / min	6
WM 314 set speed, digital	1 / min	60
WM 314 controlled speed, analog	1 / min	1-200
Max. number of peristaltic pumps per bag holder integrated, for the use of silicone-like tubing		6
Inner diameter of the tube	mm	1.6 – 8.0
Tubing wall thickness	mm	1.6

15.9 External Pumps

	Value
Max. number of external pumps that can be connected	4

15.10 Bag Volume

Volume of the bag	Unit	Size 50 L	Size 200 L	Size 500 L	Size 1000 L
Max. working volume	L	50	200	500	1000
Total volume	L	68	280	680	1280
Minimum volume	L	12.5	50	125	250

15.11 Calibration Values for the Variable Area Flow Meter

Volume of the bag	Unit	Size 50 L	Size 200 L	Size 500 L	Size 1000 L
Absolute pressure	bar	1.21	1.21	1.21	4.0
Gas type		Air	Air	Air	Air
Temperature	°C	20	20	20	20

15.12 Dimensions

15.12.1 Control / Supply Unit

	Unit	Value
Dimensions (W + D + H)	mm	800 × 850 × 1708

15.12.2 Bag Holder

Volume of the bag	Unit	Size 50 L	Size 200 L	Size 500 L	Size 1000 L
Dimensions (W + D + H)	mm	588 × 880 × 1952	788 × 980 × 1978	1033 × 1380 × 2312	1225 × 1380 × 2692

15.12.3 Required Autoclave Size for the Bag

Volume of the bag	Unit	Size 50 L	Size 200 L	Size 500 L	Size 1000 L
Dimensions (W + D + H)	mm	250 × 250 × 770	350 × 350 × 1150	815 × 815 × 1200	1000 × 1000 × 1400

15.12.4 Leveling the Bag Holder

Volume of the bag	Unit	Size 50 L	Size 200 L	Size 500 L	Size 1000 L
Adjustment height leveling feet, min. – max.	mm	104 – 150	104 – 150	108 – 158	144 – 205

15.13 Net Weight

15.13.1 Control / Supply Unit

	Unit	Value
Net weight, approx.	kg	180

15.13.2 Bag Holder

Volume of the bag	Unit	Size 50 L	Size 200 L	Size 500 L	Size 1000 L
Net weight, approx.	kg	185	285	570	765

15.13.3 Bag

Volume of the bag	Unit	Size 50 L	Size 200 L	Size 500 L	Size 1000 L
Weight of the bag, including packaging	kg	12 – 15	16 – 19	28 – 31	32 – 35

16 Accessories, Consumables, Spare Parts

This table contains an excerpt of parts that can be ordered. For information on other products, contact Sartorius Stedim Biotech.

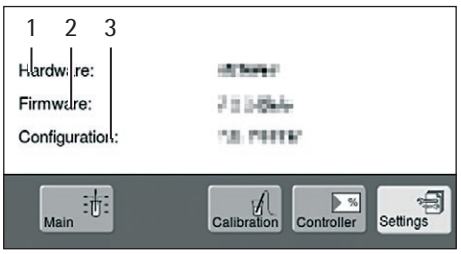
Item	Quantity	Order number
Filter heater		
For sizes 50 L and 200 L, 24 V	1	BB-8804087
For sizes 500 L and 1000 L, 24 V	1	BB-8804260
Filter holder		DZ-----S2FHO
Probe holder		
For sizes 50 L and 200 L	1	DZ200L-S2PHA
For sizes 500 L and 1000 L	1	DZ001K-S2PHA
Probe clamp	1	DZ-----S2PHC
Autoclave tray	1	1ZG---0034
Temperature sensor PT100	1	BB-8804037
Clamp for temperature sensor PT100	1	BB-8804030
Pressure sensor	1	BB-8804062
Cable for pressure sensor, 3 m	1	
For sizes 50 L and 200 L	1	BB-8804093
Cable for pressure sensor, 5 m	1	
For sizes 500 L and 1000 L	1	BB-34147652
Pressure safety valve	1	1000018936
Fiber-optic cables	1	DS-------GF
Clamp for fiber-optic cable	1	BB-8804039
Clamp for temperature sensor PT100	1	BB-8804030
Clamp for tri-clamp flange		
For sizes 50 L and 200 L	1	BB-34163290
For sizes 500 L and 1000 L	1	BB-34163075
Exhaust cooler		
Holder, complete	1	DZ-----S2ECH
Pump	1	BB-34161837
Installation kit	1	BB-34161835
Ethernet cable, 5 m	1	BB-34147260
Clamp for tri-clamp on filter	1	BB-34165008
Tri-clamp plate with filter tubing sleeve	1	BB-34163455
Tri-clamp gasket	1	BB-39125033
pH sensor		
225/12-VP-HM	1	BB-8848656
225/12-VP-MT	1	BB-8848692
VP6-VP6 pH cable, 2m	1	BB-8848614

Item	Quantity	Order number
DO (pO_2) sensor		
225/12-VP-HM-Clark	1	BB-8848663
220/12-VP-MT-Clark	1	BB-8848676
225/12-VP-HM-Optical	1	BB-8848670
DO (pO_2) optical Cable VP8-VP8-2m		BB-8848618
Fitting cone for drain port		
For sizes 50 L and 200 L	1	DZ200L-S2CDP
For sizes 500 L and 1000 L	1	DZ001K-S2CDP

17 Sartorius Service

The Sartorius Service is at your disposal for queries regarding the device.
For information about the service addresses, services provided or to contact a local representative, please visit the Sartorius website (www.sartorius.com).

For inquiries about the system or when contacting Sartorius Service in the event of a malfunction, please always state the serial number of the device and information displayed in the "Settings" main function:



No.	Parameter	Value	Description
1	Hardware	Microbox	Version of the DCU hardware
2	Firmware	X.YY	Version of the system's firmware
3	Configuration	XX YY_ZZ	Version of installed configuration

18 Licensing Information

GNU Licensing

The software code of the DCU systems is partly subject to the license terms of the "GNU General Public License (GPL)" or "GNU LESSER General Public License (LGPL)".

If applicable, the licensing terms and conditions of the GPL and LGPL as well as information about the options for access to GPL code and LGPL code used in this product are available upon request.

The GPL code and LGPL code contained in this product are published without any guarantee and subject to the copyright of one or more authors. You can find detailed information in the documentation about the enclosed LGPL code and in the GPL and LGPL licensing terms and conditions.

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 Stedim Systems GmbH**
Robert-Bosch-Strasse 5 - 7, 34302 Guxhagen, Germany

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

Geräteart / *Device type*: **BIOSTAT STR®: Bioreaktor | Fermenter**
BIOSTAT STR®: Bioreactor | Fermenter

Baureihe / *Type series*: **BIOSTATSTR2**

Modell / *Model*: TOWERDSTR; 1000023674

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

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

2014/30/EU — Elektromagnetische Verträglichkeit
Electromagnetic compatibility
EN 61326-1:2013

2011/65/EU / *2011/65/EU* — Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHS)
Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)
EN 50581:2012

2006/42/EG / *2006/42/EC* — Maschinen
Machines
EN ISO 12100:2010, EN 61010-1:2010, EN 61010-2-010:2014, EN 61010-2-081:2015

Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen:
The person authorised to compile the technical file:

Sartorius Lab Instruments GmbH & Co. KG
International Certification Management
D-37070 Goettingen, Germany

Jahreszahl der CE-Kennzeichenvergabe / *Year of the CE mark assignment:* **17**

Sartorius Stedim Systems GmbH
Guxhagen, 2017-05-10

i.V.

Dr. Susanne Gerighausen
Director of Quality Engineered Systems & Instruments

i.V.

Dr. Dieter Klausgrete
Head of International Certification Management

Diese Erklärung bescheinigt die Übereinstimmung mit den genannten EG- und EU-Richtlinien, ist jedoch keine Zusicherung von Eigenschaften. Bei einer mit uns nicht abgestimmten Änderung des Produktes verliert diese Erklärung ihre Gültigkeit. Die Sicherheitshinweise der zugehörigen Produktdokumentation sind zu beachten.

This declaration certifies conformity with the above mentioned EC and EU Directives, but does not guarantee product attributes. Unauthorised product modifications make this declaration invalid. The safety information in the associated product documentation must be observed.

Doc: 2058357-01 SSS16CE009-01.de,en 1 / 1 PMF: 2058356 OP-113_fo1_2015.10.12

ZERTIFIKAT • CERTIFICATE • 認証書 • СЕРТИФИКАТ • CERTIFICADO • CERTIFICAT

America

CERTIFICATE

No. U8 17 04 73361 071

Holder of Certificate: **Sartorius Stedim Systems GmbH**
Robert-Bosch-Str. 5 - 7
34302 Guxhagen
GERMANY

Production Facility(ies): 73361

Certification Mark:

C US

Product: **Laboratory equipment**

Model(s):
BIOSTAT STR2
TOWERDSTR (control unit)
1000023674 (temperature control unit)

Parameters:

TOWERDSTR (Control unit)

Rated voltage:	208 V	400 V
Rated frequency:	60 Hz	50 Hz
Rated current:	12 A	10 A
Protection class:	I	I
IP-Protection:	20	20

1000023674 (Temperature control unit)

Rated voltage:	208 V	400 V
Rated frequency:	60 Hz	50 Hz
Rated current:	16 A	13 A
Protection class:	I	I
IP-Protection:	20	20

Tested according to:
UL 61010-1:2012/R2015-07
UL 61010-2-010:2015-01
UL 61010-2-081:2015-08
CAN/CSA-C22.2 No. 61010-1:2012 +
UPD No. 1:2015-07 + UPD No. 2:2016-04
CAN/CSA-C22.2 No. 61010-2-010:2015-01
CAN/CSA-C22.2 No. 61010-2-081:2015-11

The product was voluntarily tested according to the relevant safety requirements noted above. It can be marked with the certification mark above. The mark must not be altered in any way. This product certification system operated by TÜV SÜD America Inc. most closely resembles system 3 as defined in ISO/IEC 17067. Certification is based on the TÜV SÜD "Testing and Certification Regulations". TÜV SÜD America Inc. is an OSHA recognized NRTL and a Standards Council of Canada accredited certification body.

Test report no.: 028-713096025-000

Date, 2017-05-03

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

Phone: +49.551.308.0
www.sartorius.com

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

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