sartorius stedim biotech

Operating Instructions
(Translation of the Original Operating Instructions)

# BIOSTAT® B-DCU

Bioreactor | Fermenter

85037-549-98

# Contents

# 1 About These Instructions

## 1.1 Validity

These instructions provide all the information needed to operate the BIOSTAT® B-DCU (referred to as the "device" in the following). These instructions apply to the following versions of the device:

| BIOSTAT® B-DCU device | Type |
|---|---|
| Control unit | 1000012248 |
| Supply unit 2 gas outputs | 1000012304 |
| Supply unit 6 gas outputs | 1000012305 |

These instructions apply to the BIOSTAT® B-DCU in combination with the following components:

| Component | Description |
|---|---|
| UniVessel® Glass, single-walled | 1L, 2L, 5L, 10L |
| UniVessel® Glass, double-walled | 1L, 2L, 5L, 10L |
| UniVessel® SU | 2L |

## 1.2 Accompanying Documents

These instructions provide information for operating the device with the standard equipment intended for this purpose.

▶ In addition to these instructions, observe the following documentation:
- Operating instructions for UniVessel® Glass culture vessels
- Operating instructions for UniVessel® SU culture vessels and associated components, e.g., UniVessel® SU holder, adapter ring, connection box
- Instructions for electrodes, e.g., pH electrode
- Technical documentation in the "Technical Documentation" folder, e.g., P&I diagrams, spare parts list, installation plans, technical drawings, etc.
- Documentation for customer-specific modifications (if applicable)
- Operating instructions for DCU4 system user management
- Operating instructions for DCU4 system logbook function
- Operating instructions for DCU4 system parameter import/export
- Operating instructions for BioPAT Xgas
- Operating instructions for BioPAT Trace
- Operating instructions for BioPAT ViaMass
- Operating instructions for DeltaV connection

## 1.3 Target Groups

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

| Target group | Knowledge \| responsibilities |
|---|---|
| User | The user is familiar with the operation of the device and the associated work processes. He knows the dangers that can occur when working with the device and can avoid these dangers.<br>The user has been trained in the operation of the device. The training takes places within the scope of startup and is performed by the laboratory manager or device operator. |
| 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. The training takes place during startup and is performed by Sartorius Service or the operator. |
| Administrator | The Administrator is responsible for integrating the device in the production process. He ensures the reliable functioning of the system and device software.<br>The administrator is trained in the operation of the device. The training takes place during startup and is performed by Sartorius Service or the operator. |
| Electrician | An electrician has the specialized training, knowledge, and experience as well as familiarity with applicable standards and regulations to evaluate the work assigned to him or her and identify possible hazards. |
| Operator | The device operator is responsible for ensuring compliance with workplace health and safety regulations.<br>The Operator must ensure that anyone working with the device has access to the relevant information and is trained to work with the device. |

## 1.4 Symbols Used

### 1.4.1 Warnings

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

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

**ATTENTION**
Denotes a hazard that may result in material damage if it is **not** avoided.

### 1.4.2 Other Symbols Used

▶ Required action: Describes actions which must be carried out in the order given.

▷ Describes the result of the actions.

[ ] Refers to control and display elements.

**Figures on the Operating Display**

Depending on your device configuration, the figures on the operating display of your device may deviate from those in these instructions.

# 2 Safety Information

## 2.1 Intended Use

The device is used as the control unit for various bioreactor systems in combination with the UniVessel® Glass or UniVessel® SU. This control unit is used to cultivate biological cultures in liquids or aqueous nutrient solutions under controlled and reproducible conditions. For this purpose, the medium is stirred and kept under prescribed cultivation conditions. The device is exclusively designed for this purpose.

The device is **not** suitable for use in potentially explosive environments.

The device may only be used indoors.

These instructions are part of the device. The device is intended exclusively for use in accordance with these instructions.

### Foreseeable Misuse

Any use going beyond the intended use of the device may lead to unknown hazards and falls under the sole responsibility of the operator.

No misuse is reasonably foreseeable.

## 2.2 Qualification of Personnel

All persons working with the device must have the required knowledge to do so (see Chapter “1.3 Target Groups,” page 9).

The activities described in these instructions are intended for the User target group. If individual tasks have to be carried out by other target groups, this is specified in the instructions.

### Sartorius Service

Information with service addresses and services offered can be found on our website (www.sartorius.com).

## 2.3 Significance of These Instructions

These instructions must be read, understood and used by all personnel commissioned to work with the device. Failure to observe these instructions can have serious consequences, such as hazards to personnel from electrical, mechanical, or chemical influences.

- ▶ Before working with the device: Read these instructions carefully and thoroughly.
- ▶ If these instructions are lost: Request a replacement or download the latest version from our website.
- ▶ The information from these instructions must be available to users.

## 2.4 Proper Working Order of the Device

A damaged device or worn parts may lead to malfunctions or cause hazards which are difficult to recognize.

- ▶ 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 Cleaning and Maintenance,” page 157).
- ▶ Have any malfunctions or damage repaired immediately by the Sartorius Service.

## 2.5 Safety Devices

The safety devices of the device protect personnel working with the device from hazards caused by the device, e.g., electrical current.

- Do **not** remove or modify the safety devices (for safety devices, see Chapter 3.2, page 32).

### 2.5.1 Electrical Power

Electrical switching elements are installed in the device. Damage to the insulation or individual components can be fatal. Contact with parts under voltage represents a direct danger of death.

Work on and modifications to the electrical equipment of the device may only be carried out by Sartorius Service personnel. The device may only be opened by Sartorius Service personnel.

- Check the device for defects such as loose connections or damage to the insulation (for intervals and service tasks, see Chapter "9 Cleaning and Maintenance," page 157).
- Keep moisture away from parts under voltage. Moisture can lead to short circuits.
- Switch off the power supply immediately if defects with the electrical equipment are discovered and contact Sartorius Service.
- Do not replace the power supply cable with a power supply cable of insufficient length. Only use the original power supply cable.

### 2.5.2 Energy Release

Power supply lines may be incorrectly dimensioned and **not** protected against impermissible fluctuations and faults. This can lead to energy release, e.g., electrical shock or gas release.

The power supply lines for operating the device must meet the Specifications (see Chapter 13, page 173). Energy connections must be fitted with fully functional safety devices:

- Earth leakage circuit breaker for mains connections (ground fault circuit interrupter)
- Fittings for shutting off water, compressed air or gas supplies

### 2.5.3 Gases

Gases used in the cultivation process or produced by the culture can be dangerous; there is a risk of suffocation due to nitrogen and carbon dioxide, for example.

All gas lines used in the cultivation process must be checked regularly for leaks (Chapter "9 Cleaning and Maintenance," page 157).

- 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.

**Risk of explosion and 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 be saturated with pure oxygen.

The oxygen line from the gas source to the consumption point must be free from grease and oil. The oxygen line comprises all areas where pure oxygen is routed or that are saturated with pure oxygen.

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

## 2.6 Accessories, Consumables, and Spare Parts

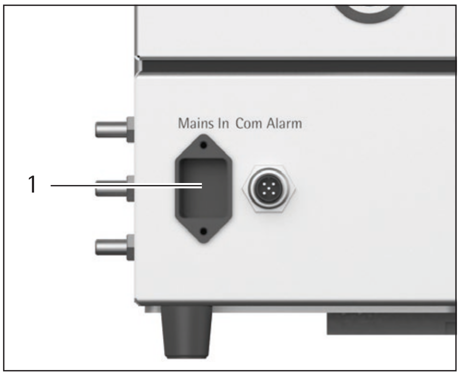
The use of unsuitable accessories, consumables and spare parts can be hazardous and have the following consequences:

- Damage to the device
- Malfunctions of the device
- Device failure

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

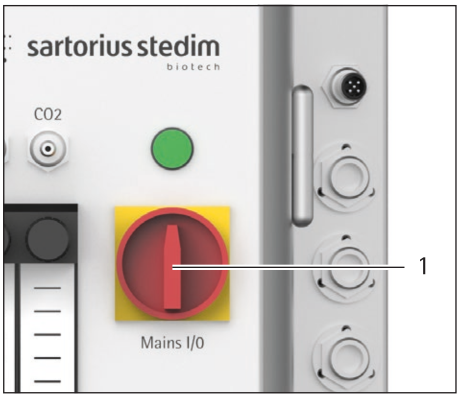
## 2.7 What to Do in the Event of an Emergency

Device malfunctions can lead to injury or material damage.
Immediately decommission the device if there is a direct risk of injury to personnel or damage to the device:




**Control Unit**

▶ Firmly pull out the connection cable from the "Mains In" socket.




**Supply Units**

▶ Turn the main switch (1) to position **0** (Off).
▷ The power supply to the device is disconnected.
▷ The inlet-side pressures in the gas lines are retained.
▷ The pressures to the culture vessel will reduce on their own.

▶ Have faults rectified immediately by Sartorius Service.

## 2.8 Personal Protective Equipment

Personal protective equipment protects against hazards caused by the device or the processed materials.

| Protective equipment | Explanation/examples |
|---|---|
| Protective work clothing | Tight-fitting work clothing with low tear resistance, tight sleeves, and without any projecting parts. / Protects users from getting caught by moving parts. |
| Head covering | Protects the hair from getting pulled into moving parts. |
| Safety gloves | Protect against chemicals, heat and injuries. |
| Safety glasses | Protect against substances leaking under high pressure, splashing liquids. |
| 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.
- ▶ Also follow the instructions posted in the work area pertaining to personal protective equipment.

## 2.9 Components under Pressure

**Bursting of the Glass Culture Vessel**

If the culture vessel is put under excessive pressure, it may burst, e.g., if gas supply equipment from third-party manufacturers is used or if the exhaust filter gets blocked. Damaged or bursting culture vessels can cause cuts and pose a risk of injury to the eyes.

- ▶ Only use the control and supply unit for gas supply. The pressure safety valve installed in the supply unit limits the operating pressure in the glass culture vessel to max. 1 bar.
- ▶ Ensure that the supply lines for compressed air and gas comply with the device specifications.
- ▶ The total volumes of all liquid media to be supplied should be less than the air volumes in the culture vessel.
- ▶ Always use the exhaust cooler in the cultivation process. The exhaust cooler protects the exhaust filter from getting blocked.

**Bursting of the UniVessel® SU Culture Vessel**

If the culture vessel is put under excessive pressure, it may burst, e.g., if gas supply equipment from third-party manufacturers is used or if the exhaust filter gets blocked. Damaged or bursting culture vessels can cause cuts and pose a risk of injury to the eyes.

- ▶ Use the safety valve station when using the UniVessel® SU.
- ▶ Always use the filter heater in the cultivation process. The filter heater protects the exhaust filter from getting blocked.
- ▶ The total volumes of all liquid media to be supplied should be less than the air volumes in the culture vessel.

## 2.10 Escaping Substances

**Faulty Components**

If individual components are damaged, gaseous and liquid substances may escape under high pressure and cause injury to the eyes, for example.

- ▶ Do not start the device without overpressure valves and pressure reducer or comparable overpressure safety devices (such as a burst disk).
- ▶ Have overpressure valves and the pressure reducer serviced regularly by Sartorius Service.
- ▶ When working on components under pressure: Switch off the device and secure it from being turned back on again.
- ▶ Regularly check all lines, hoses, and connections under pressure for leaks and externally detectable damage.
- ▶ Only switch on pump when the pump head is closed.

**Escaping Supply and Culture Media**

Escaping supply and culture media can lead to chemical burns and contamination. Take special measures when working with supply and culture media that pose a health risk.

- ▶ Only use prescribed hoses.
- ▶ Use hose fastenings on connecting pieces.
- ▶ Clear supply hoses.
- ▶ When loosening hose connections: Wear personal protective equipment.

## 2.11 Hot Surfaces

Contact with hot surfaces poses a burn risk.

- ▶ Avoid contact with hot surfaces, such as:
  - Temperature-controlled heating mats
  - Motor housing
  - Culture vessel
  - Heating module.
- ▶ Allow heating elements and device equipment to cool.
- ▶ Wear personal protective equipment.

## 2.12 Unintended or Unexpected Startup of the Device

The device may start up automatically to the preset parameters after a power failure, depending on the settings on the control and supply unit.

- ▶ Observe the information on device behavior after a power failure (see Chapter "4.2 System Start," page 35).

## 2.13 Rotating or Moving Parts

Clothing or body parts can get caught if they come into contact with rotating or moving parts, such as the stirrer shaft of the culture vessel. This can lead to dangerous injury.

- ▶ Wear personal protective equipment.
- ▶ Only start the stirrer drive when it is positioned on and fixed to the stirrer shaft.
- ▶ Only switch on the stirrer drive when the UniVessel® is fully mounted.
- ▶ Only switch on the pump when the pump head is closed.

## 2.14 Danger of Tripping or Slipping

Power supply cables that are too long may present a tripping hazard. Hoses that are too long and not secured may present a tripping hazard. Disconnected hoses may cause the floor to become soiled (hose leakages). This poses a risk of slipping.

Therefore:

- ▶ Ensure that power supply cables are properly laid.
- ▶ Install the reservoir bottles as close as possible to the basic unit.
- ▶ Keep hoses as short as possible.
- ▶ Check hoses before inserting and startup:
  - Check general condition of the hose
  - Ensure hoses are sufficiently fastened to the hose barbs. If necessary, also secure hoses with cable ties.
- ▶ Ensure the hoses are properly laid:
  - No kinks in the hoses.
  - No twists in the hoses.

# 3 Device Description

## 3.1 Device Overview

The device is designed for cultivating microorganisms and cells in discontinuous and continuous processes.

It was designed for cultivating microorganisms and cells at various reactor volumes. The device can be used to conduct studies on developing and optimizing fermentation procedures and to perform limited-volume production fermentation processes in a reproducible way.

The BIOSTAT® B-DCU bioreactor can comprise the following basic units:
- 1 control unit with measurement and control system (DCU system)
- 1 to 6 supply units with connected culture vessel

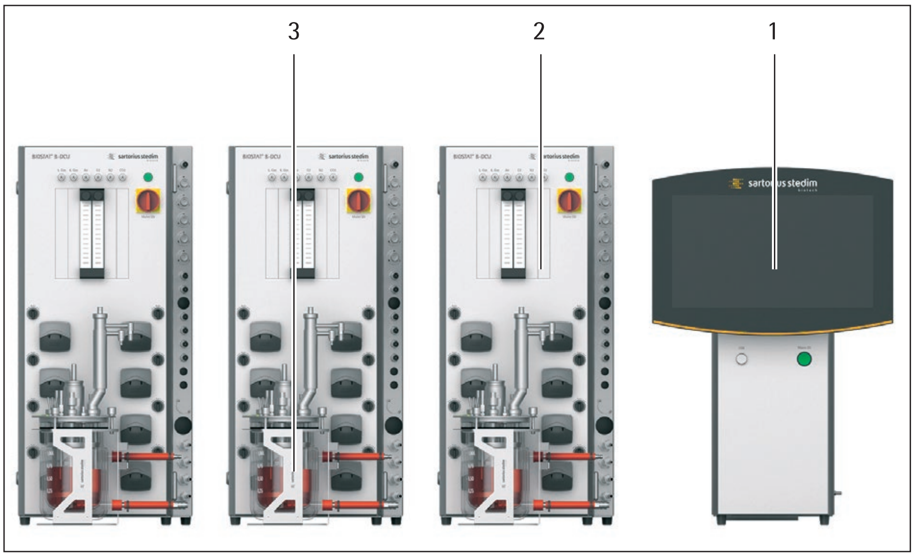



Fig. 3-1: Sample BIOSTAT® B-DCU with three connected supply units and culture vessels

| No. | Description |
|---|---|
| 1 | Control unit with measurement and control system (DCU system) and operating display |
| 2 | Supply unit, in the example: with aeration system, 8 metering pumps, and temperature control module for double-walled culture vessels |
| 3 | Culture vessel |

### 3.1.1 Control Unit

One to six supply units with different culture vessels can be connected to the control unit.

The DCU system of the control unit controls and regulates the connected supply units. The DCU system offers the following functions for each culture vessel connected to a supply unit:

– Online measurement, online control, online analysis of process variables (e.g., temperatures, pH, and DO values)
– Independent monitoring of process sequences

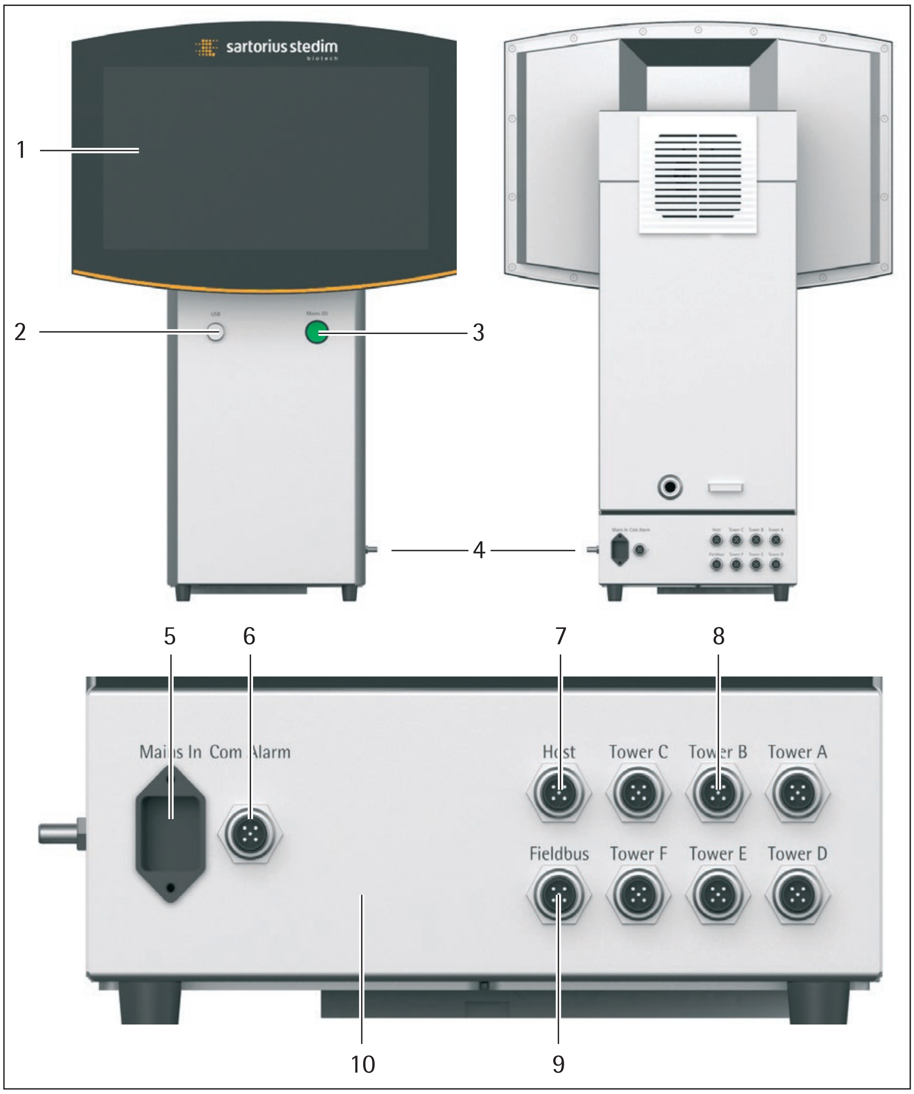



Fig. 3-2: Control unit overview

| No. | Description | Description |
|---|---|---|
| 1 | | Operating display |
| 2 | USB | USB port for peripheral devices<br>(with screwable cover) |
| 3 | Mains I/O | Illuminated push-button<br>– Button: Switches the measurement and control system (DCU system) on<br>– Display:<br>  – Light on: Device is switched on<br>  – Light off: Device is switched off |
| 4 | | Potential equalization |
| 5 | Mains In | Power supply/mains disconnector |
| 6 | Com Alarm | Potential-free alarm contacts (X23)<br>When an alarm triggers (see Chapter 10.3, page 163):<br>– Contact open (break contact)<br>– Contact closed (make contact) |
| 7 | Host | Ethernet port for an external host system<br>e.g., MFCS SCADA |
| 8 | Tower A ... F | Connection of up to 6 supply units<br>Tower A ... F corresponds to supply unit 1 ... 6 |
| 9 | Fieldbus | Port for optional network-compatible components |
| 10 | Manufacturer's<br>ID label | |

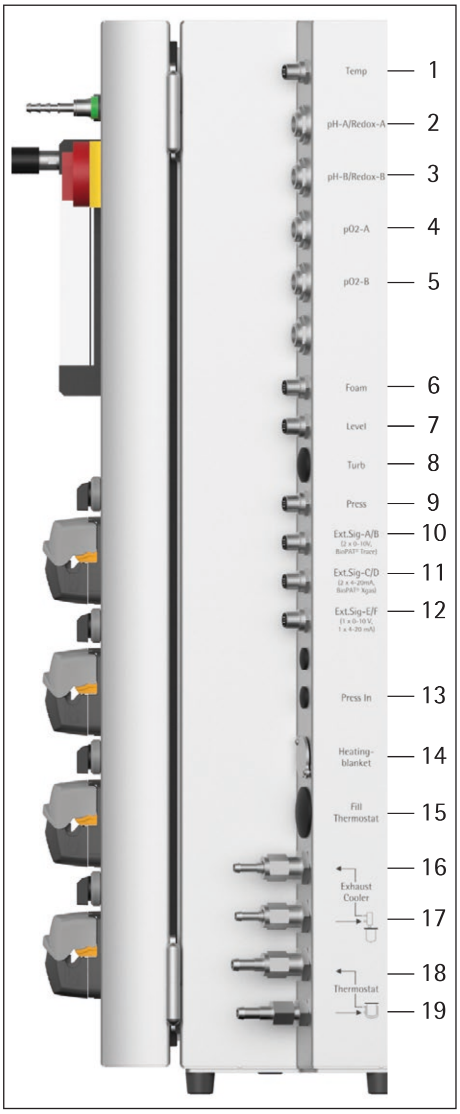
### 3.1.2 Supply Unit

The supply unit provides power, gases, and supply media to the connected culture vessel. It forms the interface between the culture vessel and the measurement and control system (DCU system) of the control unit.

#### 3.1.2.1 Front View (with/without Variable Area Flow Meter)


Fig. 3-3: Front view of supply unit

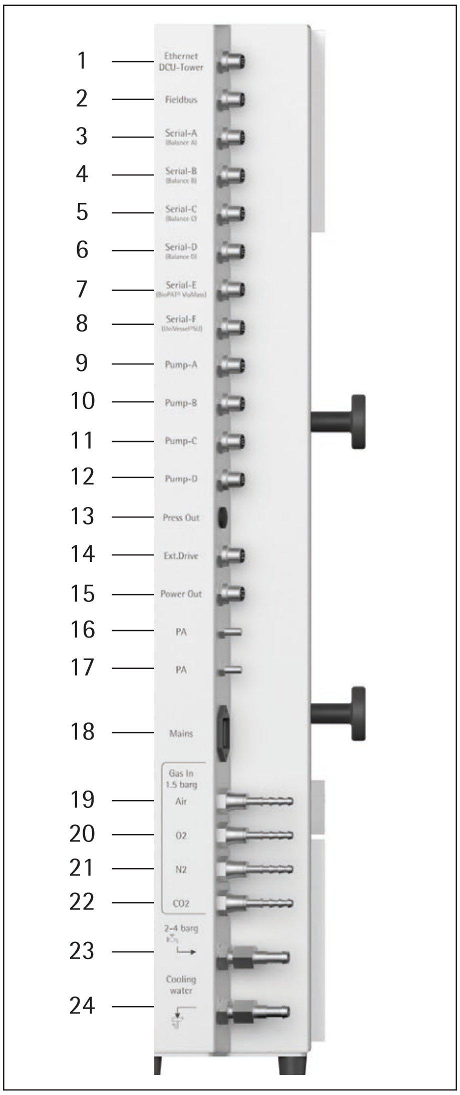
| No. | Description | Description |
|---|---|---|
| 1 | Ready indicator | Illuminates when the power supply is switched on |
| 2 | Mains I/O | Main switch / mains disconnector |
| 3 | Rack | – Cannot be used in conjunction with variable area flow meters<br>– Rack for small parts |
| 4 | | Connection panel |
| 5 | Motor support | Stirrer drive holder |
| 6 | | Up to 8 peristaltic pumps with rotary switch |
| 7 | | Peristaltic pump rotary switch for filling/clearing |
| 8 | | Variable area flow meter (optional)<br>Cannot be used in conjunction with rack |
| 9 | | Aeration system (see Chapter 3.1.3, page 23) |




### 3.1.2.2 Front View of Connection Panel

| No. | Description | Description |
|---|---|---|
| 1 | Temp | Temperature sensor Pt-100, M12 plug connection |
| 2 | pH-A/Redox-A | pH sensor A or pH and Redox sensor A, VP8 plug |
| 3 | pH-B/Redox-B | pH sensor B or pH and Redox sensor B, VP8 plug |
| 4 | DO-A | DO sensor A, VP8 plug |
| 5 | DO-B | DO sensor B, VP8 plug |
| 6 | Foam | Foam sensor, M12 plug connection |
| 7 | Level | Level sensor, M12 plug connection |
| 8 | Turb | Turbidity sensor, Lemo plug |
| 9 | Press | Pressure sensor, M12 plug connection |
| 10 | Ext.Sig-A/B | External signal input A/B, M12 plug connection |
| 11 | Ext.Sig-C/D | External signal input C/D, M12 plug connection |
| 12 | Ext.Sig-E/F | External signal input E/F, M12 plug connection |
| 13 | Press In | Gas inlet for culture vessel pressure control, nozzle, ∅ 6 mm |
| 14 | Heating blanket | – Single-walled culture vessels: heating jacket, Amphenol plug<br>– Double-walled culture vessels: dummy plug |
| 15 | Fill thermostat | – Double-walled culture vessels: rocker switch for filling the thermostat system<br>– Single-walled culture vessels: dummy plug |
| 16 | Exhaust Cooler | Exhaust cooling return, Serto gland ∅ 8 mm |
| 17 | Exhaust Cooler | Exhaust cooling inlet, Serto gland ∅ 8 mm |
| 18 | Thermostat | Temperature control return, Serto gland ∅ 10 mm |
| 19 | Thermostat | Temperature control inlet, Serto gland ∅ 10 mm |

For connector pin assignment, see Chapter 15.1, page 182.




### 3.1.2.3 Rear View of Connection Panel

| No. | Description | Description |
|---|---|---|
| 1 | Ethernet, DCU-Tower | Connection for control unit, M12 plug connection |
| 2 | Fieldbus | Field bus connection, M12 plug connection |
| 3 | Serial-A | Balance A, serial RS-232/M12 plug connection |
| 4 | Serial-B | Balance B, serial RS-232/M12 plug connection |
| 5 | Serial-C | Balance C, serial RS-232/M12 plug connection |
| 6 | Serial-D | Balance D, serial RS-232/M12 plug connection |
| 7 | Serial-E | BioPAT® ViaMass, serial RS-485 / M12 plug connection |
| 8 | Serial-F | UniVessel® SU (optical sensors), serial RS-485 / M12 plug connection |
| 9 | Pump-A | External pump A, M12 plug connection |
| 10 | Pump-B | External pump B, M12 plug connection |
| 11 | Pump-C | External pump C, M12 plug connection |
| 12 | Pump-D | External pump D, M12 plug connection |
| 13 | Press Out | Gas outlet for culture vessel pressure control, nozzle, ∅ 6 mm |
| 14 | Ext. Drive | External stirrer, M12 plug connection |
| 15 | Power Out | Power supply for external components e.g., vessel lighting, M12 plug connection |
| 16 | PA | Potential equalization |
| 17 | PA | Potential equalization |
| 18 | Mains | Power supply |
| 19 | Air | Compressed air supply * |
| 20 | $O_2$ | Oxygen supply * |
| 21 | $N_2$ | Nitrogen supply * |
| 22 | $CO_2$ | Carbon dioxide supply * |
| 23 | Cooling Water | Cooling medium inlet, nozzle ∅ 10 mm |
| 24 | Cooling Water | Cooling medium return, nozzle ∅ 10 mm |
| * | Nozzle ∅ 6 mm or plug-in ether-based polyurethane hose with 6 mm external diameter | |

For connector pin assignment, see Chapter 15.1, page 182.

### 3.1.2.4 Rear View

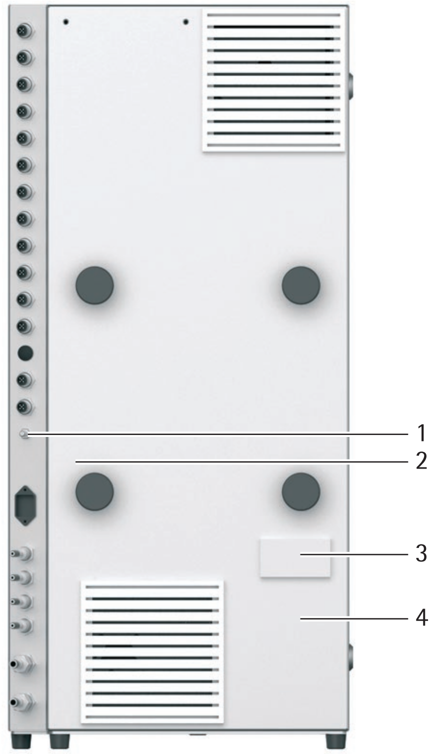



Fig. 3-4: Rear view of the supply unit

| No. | Description |
|---|---|
| 1 | Potential equalization |
| 2 | Manufacturer's ID label |
| 3 | Stirrer connection cable |
| 4 | NRTL marking (for 120 V version only) |

### 3.1.3 Aeration

The supply units are equipped with the following gas flow controllers:

– Variable area flow meter
– Mass flow controller

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.

▶ If the gas flow of a gas or the total aeration rate is regulated using an installed mass flow controller and if no gas flow limit should be set, open the variable area flow meter completely.

#### 3.1.3.1 Variable Area Flow Meter

**Designations on the Variable Area Flow Meter**

To identify the variable area flow meters, these are labeled with a sticker.
The following nomenclature is used:

| Description | Description |
|---|---|
| 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 on variable area flow meters according to P&I diagram |

**Calibration**

For information on calibrating the installed variable area flow meters and mass flow controllers, see "13.9 Dimensions of the Variable Area Flow Meters" on page 177.

### 3.1.3.2 "$O_2$ Enrichment" and "Gasflow Ratio" Aeration Modules

The "$O_2$ Enrichment" and "Gasflow Ratio" aeration modules supply air and enrich it with oxygen, e.g., for microbial cultures.

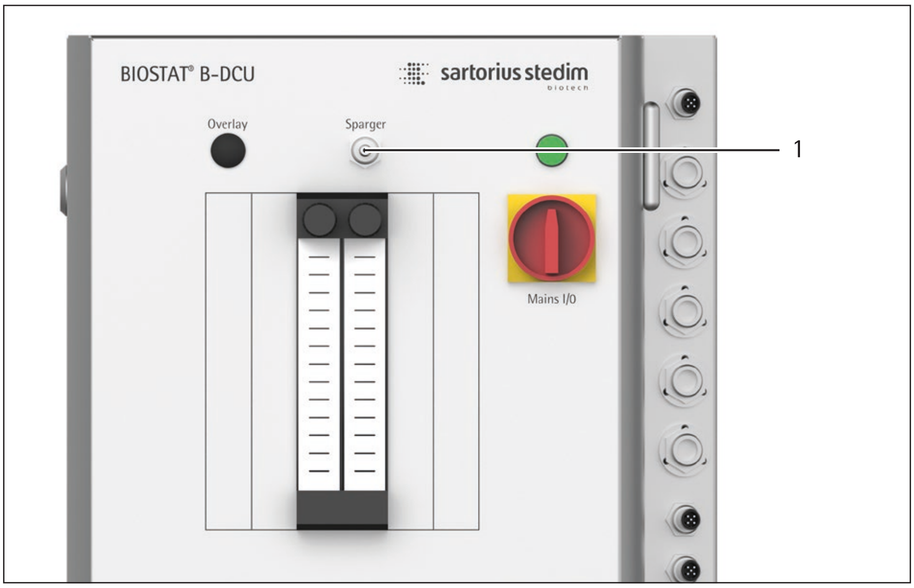



Fig. 3-5: "$O_2$ Enrichment" (one variable area flow meter) and "Gasflow Ratio" (two variable area flow meters) aeration modules with "Sparger" outlet

**"$O_2$ Enrichment" Aeration**

In the "$O_2$ Enrichment" aeration module, aeration is carried out with "Air" as the carrier stream, which can be enriched with oxygen via a solenoid valve.

– Oxygenation takes place via a 3/2-way solenoid valve; the solenoid valve is actuated via the DCU system's gas filling controller/DO controller.
– The mass flow controller is actuated via the DCU system's gas flow controller/ DO controller.
– "Sparger" outlet (1) for culture vessel total aeration rate.

**"Gasflow Ratio" Aeration**

In the "Gasflow Ratio" aeration module, aeration is carried out with air and/or oxygen, each with a mass flow controller.

The mass flow controller is controlled via the DCU system's gas flow controller/ DO controller.

#### 3.1.3.3 "Advanced Additive Flow" Aeration

These aeration modules can supply up to 4 gases and are suitable for cultures with special requirements for the supply of gas (e.g., $CO_2$):

- for pH regulation, e.g., in mammalian cell cultures
- as a carbon source, e.g., in anaerobic bacteria or algae cultures

**"Advanced Additive Flow - 2 out" Aeration**

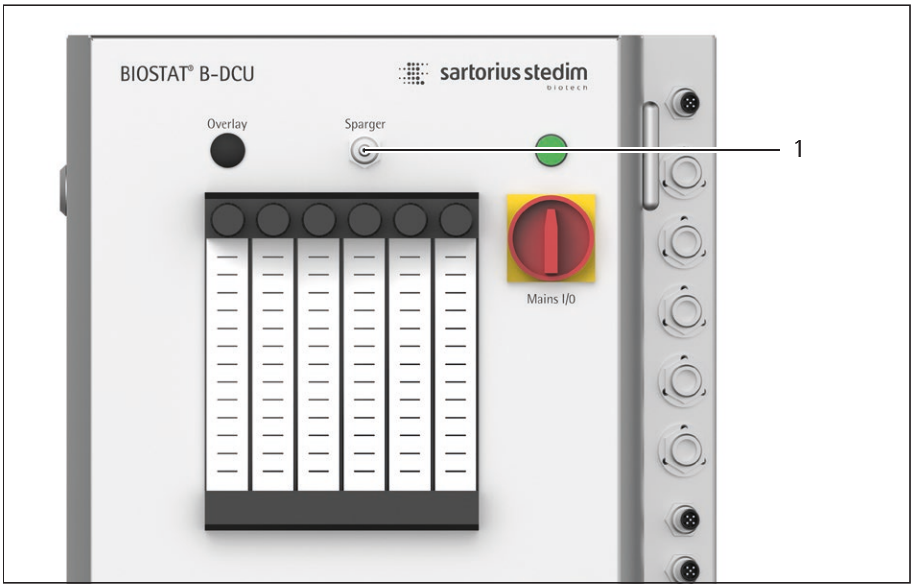



Fig. 3-6: "Advanced Additive Flow - 2 out" Aeration

In the "Advanced Additive Flow - 2 out" aeration module, aeration takes place with up to 4 gases via a "Sparger" and "Overlay" outlet.
These are by default:

- Air supply for "Sparger" and "Overlay"
- Supply of $N_2$ for decreasing the $O_2$ content, or $O_2$ for increasing the oxygen content for the "Sparger"
- Supply of $CO_2$ for pH regulation or as a carbon source for "Sparger" and/or "Overlay"
- A 3/2-way solenoid valve and function key in the DCU system are used to switch between Overlay and Sparger

The aeration rates are set on variable area flow meters. Optionally, they can be regulated via mass flow controllers.

- 2/2-way solenoid valves or mass flow controllers are used for oxygen enrichment/reduction. The solenoid valve/mass flow controller is actuated using the gas filling controller/gas flow controller or via the DCU system's DO controller.
- $CO_2$ is added via a 2/2-way solenoid valve actuated by mass flow controllers. The solenoid valve/mass flow controller is actuated using the gas filling controller/gas flow controller or via the DCU system's pH controller.
- Optional 3/2-way solenoid valves and function keys in the DCU system make it possible to switch gases between "Sparger" and "Overlay."

**"Advanced Additive Flow - 6 out" Aeration**

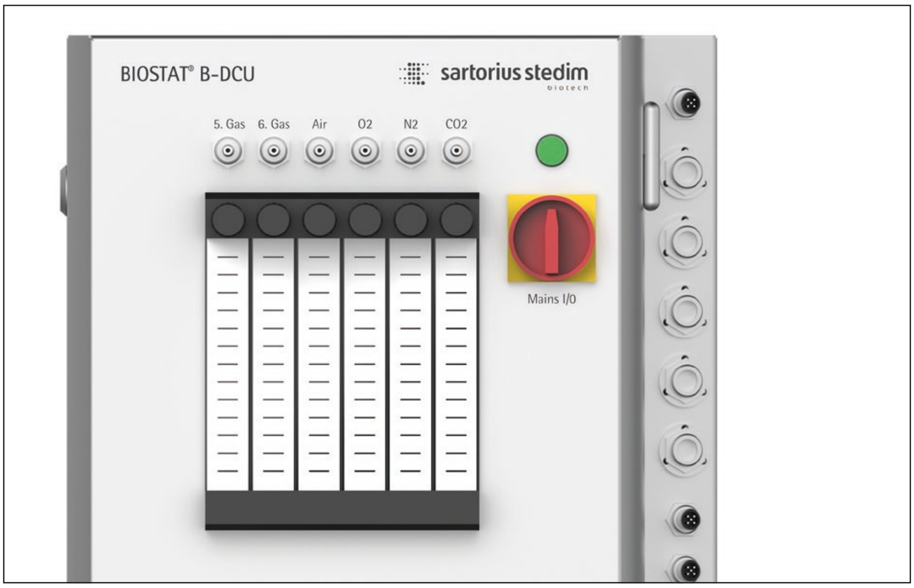


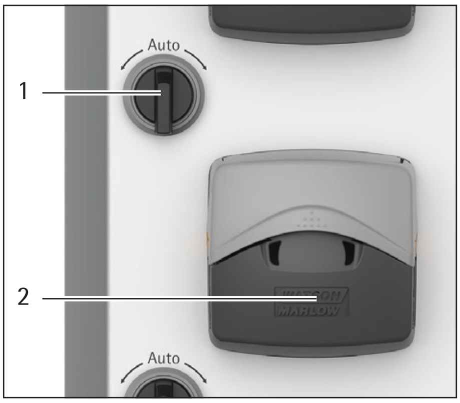

Fig. 3-7: "Advanced Additive Flow - 6 out" Aeration

In the "Advanced Additive Flow - 6 out" aeration module, aeration takes place with up to 4 gases and up to 6 individual gas outlets. These are by default:
- Supply of air
- Supply of $N_2$ for decreasing the $O_2$ content, or $O_2$ for increasing the oxygen content
- Supply of $CO_2$ for pH regulation or as a carbon (C) source

The aeration rates are set on variable area flow meters. Optionally, they can be regulated via mass flow controllers.
- 2/2-way solenoid valves or mass flow controllers are used for oxygen enrichment/ reduction. The solenoid valve/mass flow controller is actuated using the gas filling controller/gas flow controller or via the DCU system's DO controller.
- $CO_2$ is added via a 2/2-way solenoid valve actuated by mass flow controllers. The solenoid valve/mass flow controller is actuated using the gas filling controller/gas flow controller or via the DCU system's pH controller.

### 3.1.4 Peristaltic Pumps

Depending on the configuration, the following peristaltic pumps can be connected or installed for each supply unit:
- Up to 4 digital peristaltic pumps installed (left side)
- Up to 4 analog peristaltic pumps installed (right side)
- Up to 4 external pumps (Pump-A ... D) can be connected as an alternative to the installed peristaltic pumps
- Max. 4 pumps can be analog peristaltic pumps




### 3.1.4.1 Integrated Peristaltic Pumps

The peristaltic pumps (2) on the front side of the supply unit pump the correction and nutrient media through hoses into the culture vessel. Up to eight peristaltic pumps can be installed or connected to each supply unit (depending on the configuration).
A rotary switch (1) can be used to switch on the pump, e.g., for filling or clearing the hoses.

| Rotary switch position | Function |
|---|---|
| Left * | Pump runs with direction of rotation to the left |
| Auto | Pump is controlled by the DCU system |
| Right * | Pump runs with direction of rotation to the right |

* The left or right position takes precedence over the DCU system setting.

The pumps are labeled with stickers to denote their standard function.

**Pump Speed**

The peristaltic pumps can be installed in 4 different specifications in the supply unit:

| Type | Speed [n/min] |
|---|---|
| WM 114 set speed (digital peristaltic pump) | 5 |
| WM 114 set speed (digital peristaltic pump) | 44 |
| WM 114 controlled speed (analog peristaltic pump) | 0–5 * |
| WM 114 controlled speed (analog peristaltic pump) | 5–150 * |

* Speed range can be selected in the DCU system

**Feed Rates**

Hoses with the following dimensions can be operated. The following feed rates per revolution can be achieved.

The hose wall thickness is 1.6 mm.

| | | | | |
|---|---|---|---|---|
| Hose internal diameter (mm) | 0.5 | 0.8 | 1.6 * | 3.2 * |
| Feed rate (mL/revolution) | 0.02 | 0.04 | 0.14 | 0.47 |

* = Silicone hoses supplied as standard

The integrated peristaltic pumps are designed for use with silicone-type hoses. Other hose materials can significantly shorten the life of the peristaltic pumps.

When using hoses other than those provided:
– Only hoses with a wall thickness of 1.6 mm are permitted.
– Follow the instructions on the hose pump data sheet in the “Technical Documentation” folder.

#### 3.1.4.2 External Pumps

Four external pumps can be connected to the supply unit (see Chapter 3.1.2.3, page 22).

WM 120 or WM 323 peristaltic pumps are recommended.
If other pumps are used, the connector pin assignment must be observed (see Chapter 15.1, page 182).

**Maximum Speed of External Pumps**

The control unit can control external pumps in a range of 1:100. The controllable rpm range of the external pump is determined by the maximum speed configured for the pump.

**Example:** The maximum speed of the external pump is set to 50 rpm. The control unit can control the external pump in a range of 0.5–50 rpm.

Set the maximum speed of the external pump so that the minimum required speed is within the control range of the control unit. Notes on setting the speed can be found in the operating instructions for the external pump.

### 3.1.5 Temperature Control Modules

#### 3.1.5.1 Temperature Control Module for Double-Walled Culture Vessels

Ensure that the cooling medium can run off unimpeded. If this is not guaranteed, the double wall of the UniVessel may be damaged.

The temperature control module is designed to control the temperature of the UniVessel and exhaust cooler.
Cooling water is only fed into the temperature control circuit and simultaneously the hot water outlet if necessary in order to cool the vessel.

---

## ATTENTION

**Risk of damage to the double wall!**

Ensure that excess temperature control medium can run off unimpeded and without pressure. If this is not guaranteed, the double wall of the UniVessel® Glass may be damaged.

---

**Structure and Components**

The temperature control module forms a temperature control circuit on the culture vessel together with the double wall and exhaust cooler. The hose system contains an open, unpressurized outlet for excess temperature control media, which ensures operation at ambient pressure.
- Temperature control circuit with circulation pump.
- Electrical heater and cooling water valve controlled by the temperature controller in the DCU system.
- "Thermostat" inlet/outlet for connection to/from the double wall of the culture vessel.

The cooling water supply for the exhaust coolers is supplied from a branch of the cooling water supply line. The cooling water supply line does not form part of the culture vessel circuit. The cooling water will flow into the system at a constant rate as soon as an exhaust cooler ("Exhaust Cooler" inlet/outlet) has been connected and the laboratory supply point has been opened.

**Specifications**

The temperature control module is designed for/fitted with:
- 230 VAC, 50 Hz | 120 VAC, 60 Hz electrical connection
- Thermostat with 1000 W electric heater

### 3.1.5.2 Temperature Control Modules for Single-Walled Culture Vessels

The temperature control modules contain the power supply for the electrical heating jackets of the single wall culture vessels. The internal cooling water circuit supplies and drains away the cooling water for the exhaust cooler and, if fitted inside the culture vessel, operates the cooling finger.

**Structure and Components**

The temperature control modules contain the power supplies for the heating jackets of the culture vessels. The temperature control module for single-walled culture vessels comprises:
- 230 VAC, 50 Hz | 120 VAC, 60 Hz electrical connection
- Heating jacket
- Cooling finger for cooling water supply (controlled flow – optional)
- Cooling water inlet and outlet for exhaust cooler

Operating principle:
- The temperature controller of the control unit activates the power supply for the heating jacket on the culture vessel.
  - The heating jacket must be connected to the female connector on the connection panel on the side.
  - The heating jacket must not be connected to any other power supply.
- The cooling water inlet from the laboratory and cooling water return are connected to the connection panel on the side. The cooling finger and exhaust cooler are connected to the front panel.
- The cooling finger will be supplied with cooling water as regulated by the temperature controller. The cooling water for the exhaust cooler will flow into the system as soon as the exhaust cooler has been connected and the supply point inside the laboratory has been opened.
  - "Exhaust cooler" inlet for connecting the exhaust cooler
  - Outlet for returning the water to the laboratory system

### 3.1.6 Culture Vessels

The following culture vessels can be connected to the supply unit:

- UniVessel® Glass
- UniVessel® SU

All information on operating the culture vessels can be found in the operating instructions for the culture vessel.

### 3.1.6.1 Stirrer Drive

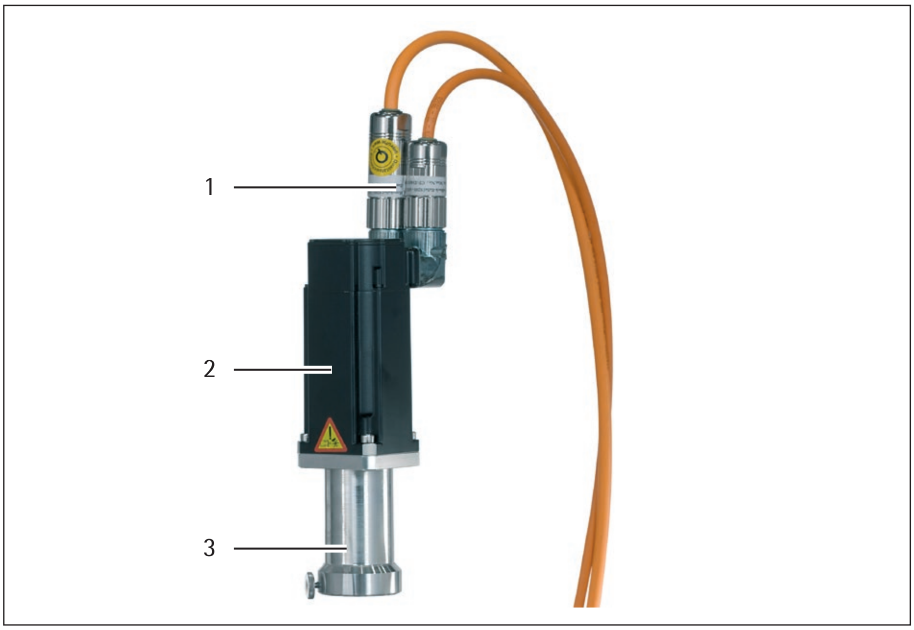



Fig. 3-8: Stirrer Drive

| No. | Description |
|---|---|
| 1 | Power supply/connection cable for the supply unit |
| 2 | Stirrer drive for culture vessel coupling |
| 3 | Motor adapter including motor coupling |

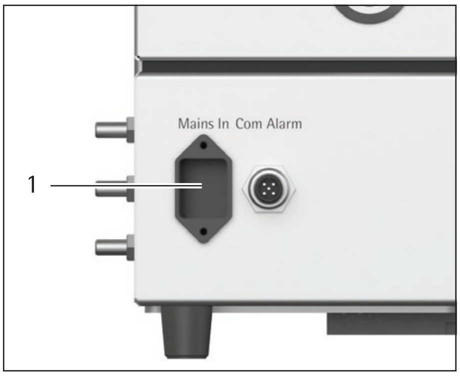
Stirrers/drives have the following functions:

- Top-mounted drive for culture vessels:
- Stirrer shaft in the vessel lid, direct drive with direct coupling, optional magnetic coupling
- Attachable motor
- 6-blade disk impeller for microbial cultures or
  3-blade segment impeller with adjustable blades for cell cultures

Available stirrer drives:
- 200 W motor: for UniVessel® Glass 1–10 L and UniVessel® SU 2 L culture vessels
- 400 W motor: for UniVessel® Glass 10 L culture vessel (for highly viscous applications)

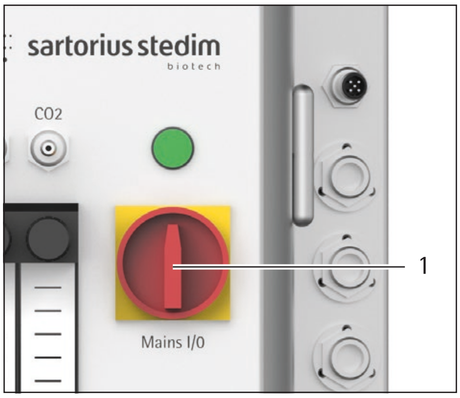
## 3.2 Safety Devices and Protective Systems

### 3.2.1 Mains Disconnector




**Control Unit**

The "Mains In" socket (1) located on the rear side of the control unit is used to connect and disconnect the power supply.




**Supply Units**

The "Mains" switch on the front side of the supply unit switches the device off and disconnects the power supply.

### 3.2.2 Overpressure Valves and Pressure Reducers

#### 3.2.2.1 Aeration Segment Overpressure Valves

Overpressure valves are installed in the aeration segments of the supply unit for sparger and overlay aeration. The pressure in the aeration segments to the UniVessel® Glass culture vessel is limited to max. 1 barg using the overpressure valves.
The overpressure valve opens from 0.8 barg and is opened completely at 1 barg.

**When Using the UniVessel® SU Culture Vessel**

Connect the UniVessel® SU safety valve station to the aeration segments when using the UniVessel® SU culture vessel.
The pressure in the aeration segments to the UniVessel® SU is limited to 0.5 barg with the help of the UniVessel® SU safety valve station.

**Pressure Reducer Cooling System**

The pressure reducer is installed in the temperature control module as a fixed element.
The cooling water for the temperature control and exhaust system is limited to max. 1.2 bar using a pressure reducer.

### 3.2.3 Overheating Protection

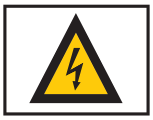
The overheating protection within the device limits the maximum permissible temperature for the temperature control medium. The following temperature control modules can be used:
- Water circulation system temperature control
- Heating jacket temperature control

## 3.3 Symbols on the Device

The following symbols are affixed to the device/connected components:

**Danger of Crushing at the Peristaltic Pump!**

Do not attempt to put your hand inside rotating parts, e.g., a pump head.
The pump must always be switched off before inserting hoses or aligning the pressure rollers.
- ▶ Pump rotary switch to position "Auto".
- ▶ Switch off pump in the DCU system.



**Access to Conductive Parts!**

Only electricians may have access to and work on this equipment, such as to perform maintenance and repairs.

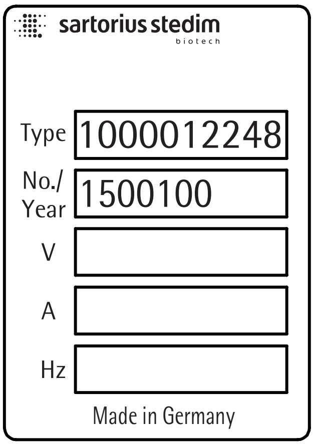
**Danger of Burns!**

Motor and culture vessel equipment becomes hot during operation.
- ▶ Avoid accidental, unintentional contact.
- ▶ Wear personal protective equipment.
- ▶ Prior to removing the motor from the stirrer drive, allow the motor housing to cool down.
- ▶ Let the culture vessel and equipment cool down before carrying out assembly work.

Some of the markings and labels on the equipment were applied by the equipment manufacturers. These may not always match the safety markings conventionally used by Sartorius Biotech.
Please follow the instructions in this manual.

Keep all safety notes and danger warnings on the device in legible condition and replace them as needed.

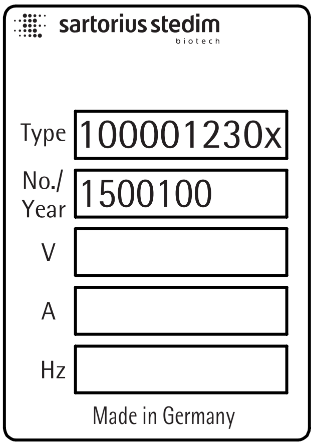
## 3.4 Manufacturer's ID Labels




**Control Unit**

The manufacturer's ID label is located on the right side panel.

| Description | Description |
|---|---|
| Type | Device type: 1000012248 |
| No. / Year | Serial number: 1500100 increasing consecutively |
| V | Mains voltage |
| A | Current consumption |
| Hz | Mains frequency |




**Supply Unit**

The manufacturer's ID label is located on the rear panel of the supply unit next to the "Mains In" socket.

| Description | Description |
|---|---|
| Type | Device type:<br>– 1000012304: two gas outlets<br>– 1000012305: six gas outlets |
| No. / Year | Serial number: 1500100 increasing consecutively |
| V | Mains voltage |
| A | Current consumption |
| Hz | Mains frequency |

# 4 Software

## 4.1 User Information

These instructions show the standard functions of the DCU software. DCU systems can be customized according to the customer's specifications. Therefore, this documentation may describe functions that a delivered configuration does not contain or a system may contain functions that are not described here. Information about the actual scope of functionality can be found in the configuration documents. Additional functions can be described in the technical data sheet in the "Technical Documentation" folder.

Illustrations, parameters, and settings in this documentation are only examples. They do not show the configuration or operation of a DCU system in terms of a particular device, unless they explicitly refer to that device.

### Usage Instructions, Structure, and Functions

The DCU system can be integrated into higher-level automation systems. For example, the industrially tested MFCS/Win system can take on host PC functions like process visualization, data storage, process logging, etc.

These instructions show operating values and settings that are default values and examples. Only if explicitly specified as such will they show settings for the operation of a particular bioreactor.
Information about the settings that are permitted for a bioreactor and the specifications for a customer system can be found in the configuration documentation.

---

**ATTENTION**
Only system administrators or authorized, trained, and experienced users may change the system configuration.

---

## 4.2 System Start

The DCU system is switched on by flipping the main switch "Mains I/O" of the control unit.

After powering on and program start (or restoration of voltage after a power outage), the system starts in a defined basic state:
- The system configuration is loaded.
- Any user-defined parameters from a previous process are stored in a memory (CF card) and can be used for the next process:
  - Setpoints
  - Calibration parameters
  - Profiles (if applicable).
- All controllers are turned off and actuators (pumps, valves) are in stand-by position.

For interruptions in operation, the startup behavior of outlets and system functions that have a direct effect on the associated end device (controllers, timers, etc.) depend on the type and duration of the interruption. There are several different types of interruptions:

– Turning the unit off/on at the main switch of the control unit
– Failure of power supplied from the connection in the laboratory (power outage)

A maximum "Failtime" duration for power interruptions can be set in the "System Parameters" submenu. The "Failtime" indicates the length of time during which the activated controllers automatically restart if the power supply fails:

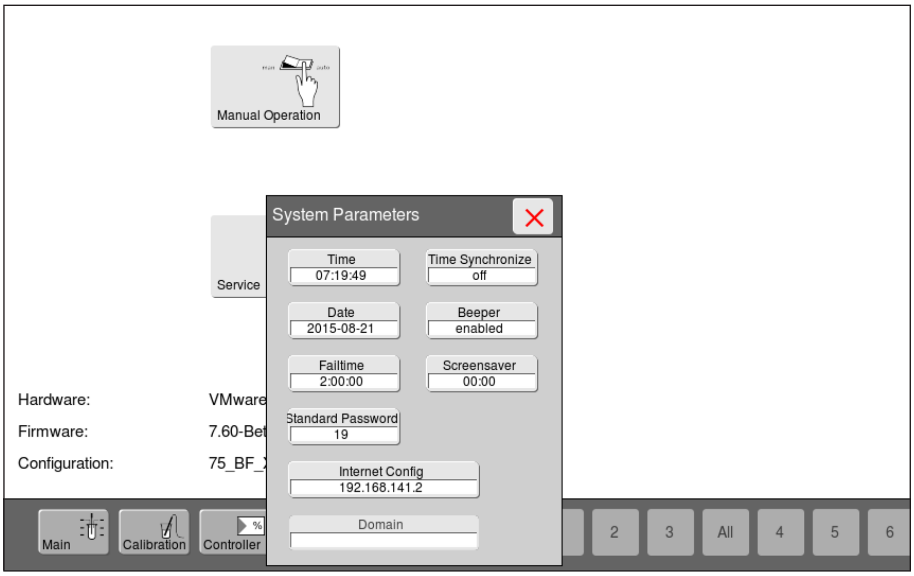



Fig. 4-1: "System Parameters" submenu

If a power outage is shorter than the "Failtime," the system continues as follows:

– A "Power failure" error message shows the outage time.
– Controllers continue to work with the configured setpoint and mode.
– Timer and setpoint profiles continue to be processed.

If the power outage lasts longer than the configured "Failtime," the DCU system acts as though the user had turned the unit off normally, that is, it starts in the defined basic state.

After the next restart, an alarm message appears, specifying the date and time at which the power failure occurred.

## 4.3 Principles of Operation

### 4.3.1 User Interface

The user interface offers a graphical overview of the controlled device, with symbols for the culture vessel, components of the gas supply (e.g., valves, MFCs), probes, pumps, filling counters, and if applicable, additional peripheral devices.

The user interface is divided into 3 sections:

– Header
– Work area
– Footer

#### 4.3.1.1 Header



Display of the system status, time, date:
- System (type) display
- Time in format [hh:mm:ss]
- Date in format [yyyy-mm-dd]

Alarm display (area marked in red/bell symbol):
- Time of the triggered alarm
- Type of malfunction
- Alarm triggered
- All alarm messages are shown in the “Alarm” menu

#### 4.3.1.2 Work Area

The work area shows the function elements and submenus of the active main function:

- Preselected process values with current measured value or setpoint
- Pumps or filling counters with process values, e.g., flow rates or filling volumes for correction media and gases
- Controllers, e.g., for temperature, speed, mass flow controller (MFC), with current setpoints
- Probes, e.g., for pH, DO, antifoam, with measured values
- Peripheral devices, e.g., weighing system, with measured values

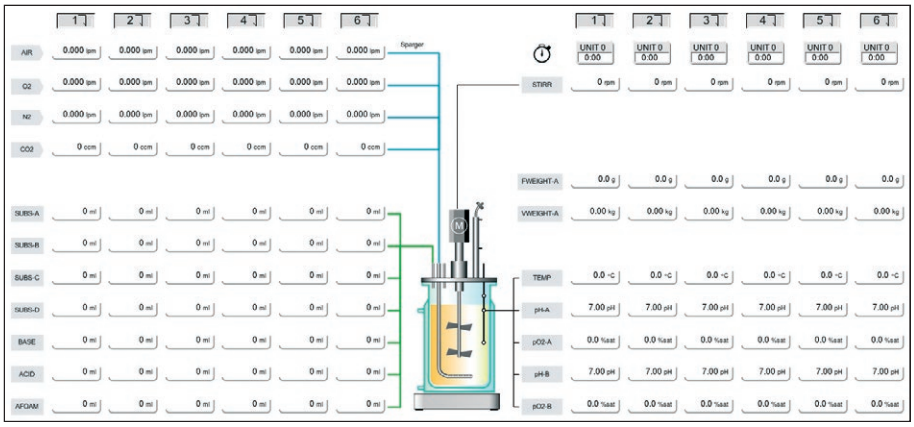


Fig. 4-2: Example: “Controller” main screen for all units

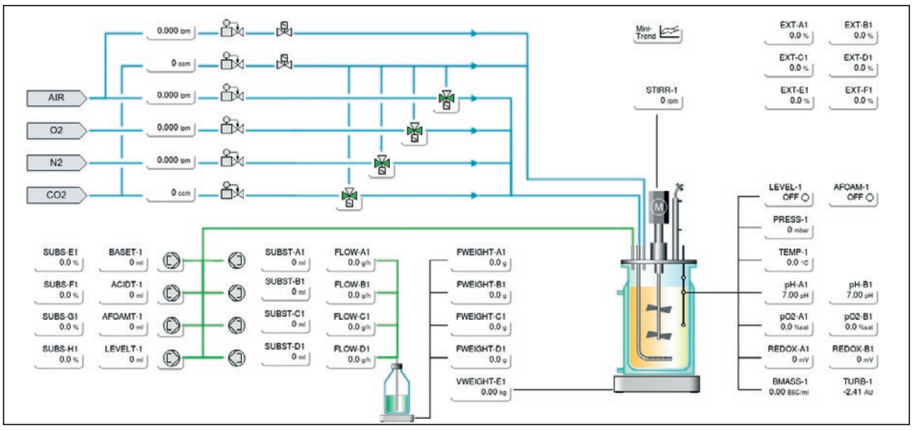



Fig. 4-3: Example: “Controller” main screen for Unit 1

### 4.3.2 Footer


Fig. 4-4: Selecting “Main” using the main function key

The footer shows the main function keys (see Chapter 4.3.4, page 41) for:
- Access to the menus for associated main functions:
  - “Main”
  - “Calibration”
  - “Controller”
  - “Trend”
  - “Settings”
- Switching between the overviews for all units (“All”) and for individual units (“1” to “6”)
- Activation of additional functions:
  - “Shutdown”
  - “Remote” (for receiving setpoints via a host interface)
  - “Alarm” (with an overview of alarms)

**Example**

"Main" and "1:"

- Most important and most frequently used parameters for Unit "1"
- Display of all parameters for Unit "1"

Display:

- Selected main function: light gray key, activated
- Function not selected: dark gray keys, deactivated

**Setting Process Parameters and Monitoring Process Values**

Depending on the configuration, the BIOSTAT® B-DCU can be equipped with up to 6 culture vessels. Operation can be specific to each culture vessel:

- The DCU system is operated directly on the operating display by selecting a main function and the associated submenus. By tapping the function elements in the work area and main function keys in the footer, you can activate the associated submenus, such as for the input of data and setpoints or the selection of modes.
- Available functions, tag names, parameters, and submenus depend on the culture vessel used and the configuration (for example, heating and cooling system, aeration type).
- The available functions, "tag" names, parameters, and submenus depend on the configuration of the controlled device.

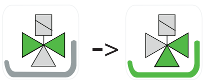
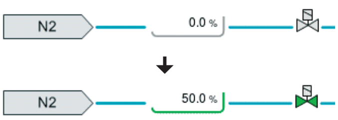
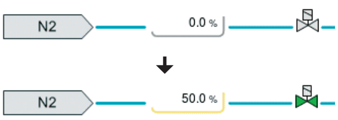
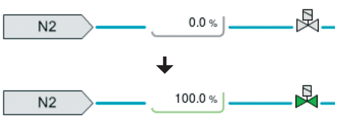

Supply unit 1/Process 1


Overview of all
supply units/processes


Supply unit 5/Process 5

### 4.3.3 Display of Function Elements

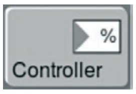
The display of the function elements in the work area shows the current status and the intended use.

| Symbol | Display | Description |
|---|---|---|
| [Tag PV]<br>MV [Unit] | Function element<br>Key with<br>gray underline | Field for short name ("tag") for the function element, e.g., TEMP, STIRR, pH, DO, ACID, SUBST, VWEIGH, BALANCE<br>Field for measured or set value in its physical unit<br>Submenu or function can be selected by tapping it |
| [Tag PV]<br>MV [Unit] | Key with<br>green underline | Measured value collection or output of function element is active, with measured value or set value as shown |
| [Tag PV]<br>MV [Unit] | Key with<br>yellow underline | Display of function if in "Manual" mode; (switched on or off); automatic control not possible |
| [Tag PV]<br>MV [Unit] | No underline | No submenu assigned (function cannot be selected) |
| [△] , [▽]<br>[◁] , [▷] | Arrow key | Move forward or back in specified menu or function |
|  | Pump off -> auto on<br>Line gray -> green | Direct access to submenu to select the mode |
|  | Off -> manual on<br>Line displayed in yellow,<br>pump gray -> green | Submenu to select mode |
|  | Valve off -> auto on<br>Line gray -> green | * Direct access to submenu to select mode,<br>example for 2/3-way valve |
|  | Off -> manual on<br>Line displayed in yellow,<br>flow direction in green | Valve symbol also shows (changed) flow direction<br>* Submenu to select mode |
|  | Line gray -> green | Valve closed -> auto on |
|  | Line gray -> yellow | Valve closed -> manual on |
|  | Line gray -> light green | Valve closed -> controller in cascade |

Examples for function elements, short names (tags), measured values, working values, and submenus that can be accessed by selecting keys.

### 4.3.4 Overview of the Main Function Keys

Main functions can be selected at any time during a running process. The title of the main function shown in the work area is also displayed in the header.

| Key, symbol | Description |
|---|---|
| "Main" function<br> | Start screen with graphical overview of the controlled device:<br>– Display of components of the current configuration<br>– Overview of measured values and process parameters<br>– Direct access to important menus for operating input |
| "Trend" function<br> | Display of process sequences, selection of parameters from:<br>– Process values<br>– Setpoints from control loops<br>– Outputs from controllers |
| "Calibration" function<br> | Menus for calibration functions, for example:<br>– Measurement electrodes for pH, DO<br>– Totalizer for all pumps (ACID, etc.)<br>– Totalizer for aeration rates for valves<br>– Balances (optional, in development) |
| "Controller" function<br> | Operating and configuration menus for controllers, for example:<br>– Temperature regulation TEMP<br>– Speed regulation STIRR<br>– pH and DO regulation<br>– Control of correction medium pumps (e.g., pH, SUBSx)<br>– Aeration rate regulation (valves, or mass flow controllers) |
| "Settings" function<br> | Basic system settings, for example:<br>– Measurement ranges of process values:<br>– Manual operation, e.g., for inlets and outlets, controllers<br>– External communication (e.g., with printers, external computers)<br>– Selection, modification of configurations (password-protected, for Sartorius Service only) |
| "Shutdown" function<br> | Shutdown function:<br>Pressing the "Shutdown" function switches all outlets to the defined safety position. This does not affect any other functional sequences for controllers, timers, profiles, formulations, or sterilization. |
| "Remote" function<br> | Operation with external computer systems (central computer)<br>Pressing the main function key switches to remote operation; instructions on configuration. |
| "Alarm" function<br> | Overview table of alarms that have occurred:<br>– If alarms occur, the symbol changes color and an acoustic signal sounds.<br>– Display red: Table still contains alarms which have not yet been acknowledged.<br>– Pressing the main function key opens an overview menu of all alarm messages. |

### 4.3.5 Overview of Selection Keys

| Button | Description |
|---|---|
|  | Cancel<br>Changes will not be saved |
|  | Confirmation of input |
|  | Further controller parameters |
|  | Cancel<br>Changes will not be saved |
|  | Deleting characters |
|  | Selection of sign when entering a value |
|  | Selection list of process values |

### 4.3.6 Direct Function Keys for Selection of Submenus

The function elements in the work area of the "Main" menu can contain function keys that can be used to directly access submenus for important functions:

– Numerical input of setpoints, pump and flow rates
– Configuration of alarm limits
– Selection of controller modes

The functions which can be reached from the main menu depend on the configuration.

▶ Press the function keys to view the available functions in the supplied configuration.

This chapter shows an example of screens and submenus accessible via direct function keys.

**Example: Input of Temperature Setpoint**

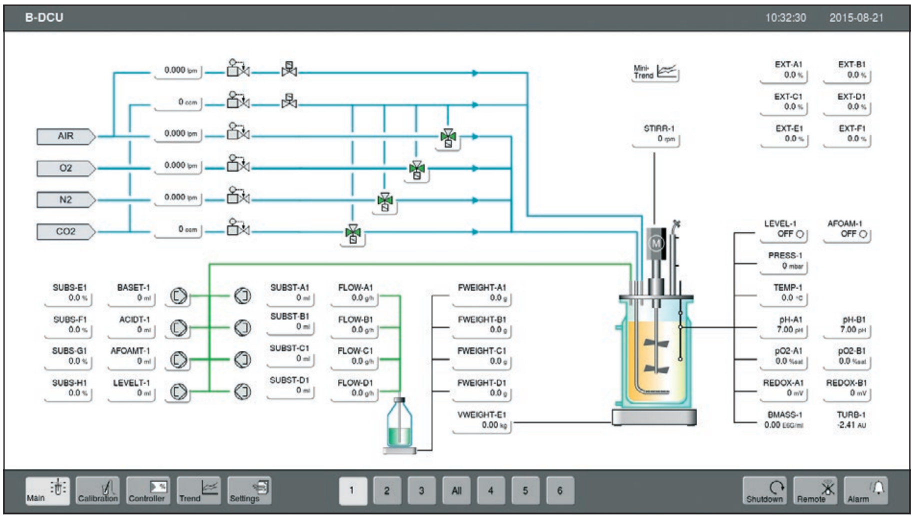
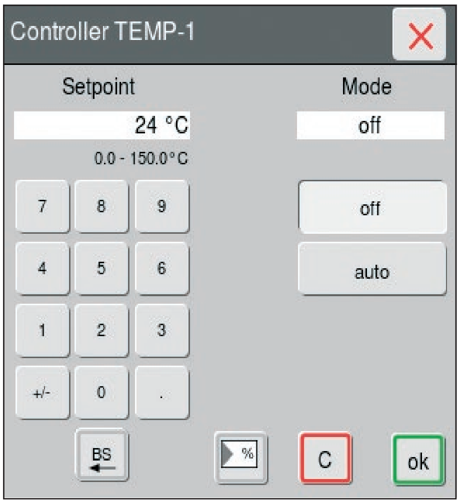



Fig. 4-5: Setpoint input and selection of the "TEMP" controller mode via the "Main" menu




▶ In the work area of the "Main" menu, press the "TEMP" function element or in the work area of the "Controller" menu, select the TEMP controller (TEMP function element).

▷ When the "Main" menu is accessed, a submenu opens with a keypad for data entry and a "Mode" selection field for possible operating modes.

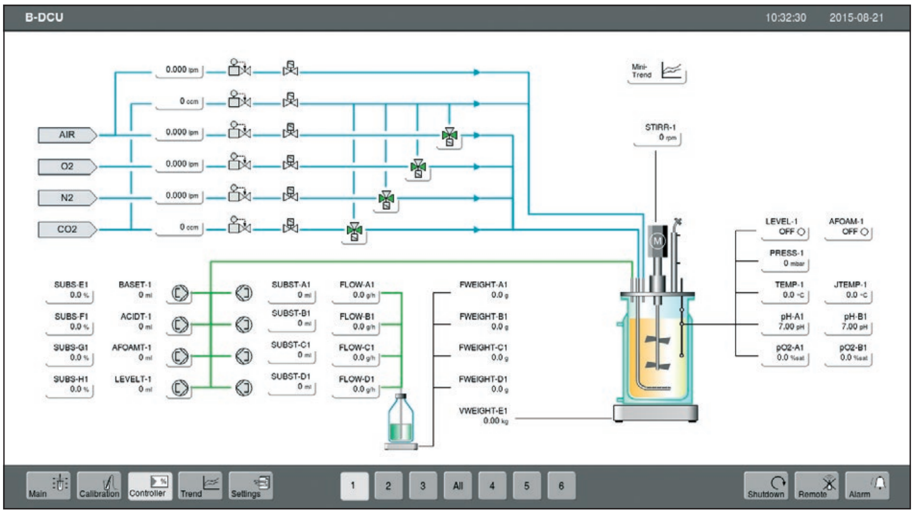
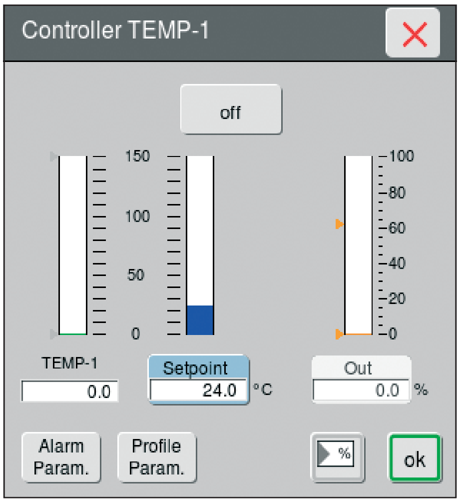


Fig. 4-6: Setpoint input and selection of the “TEMP” controller mode via the “Controller” menu




▷ When the “Controller” menu is accessed, the “Setpoint” key can be used to enter a setpoint (after pressing the key, an on-screen keypad also opens). The “off” key can be used to select the mode.

▶ Enter the new setpoint using the on-screen keypad.
▶ Observe the permissible value range under the input field.
▶ To correct the entered value, press the “BS” (backspace) key.
▶ To discard the entered value and exit the submenu, press the “C” (cancel) key.
▶ To confirm the input, press the “OK” key.
▷ The submenu window closes.
▷ The setpoint is active and displayed.

### Example: Selecting the Controller Mode

▶ In the work area of the main menu, press the “TEMP” function element or select the “Controller” function and then the TEMP controller.
▶ Press the function key for the desired operating mode.
▶ Confirm by pressing the “OK” key.
▷ The function (of the controller) is active and displayed.

▶ To access the full screen of the controller, press the  key.

This is the same as activating the “Controller” function and selecting the TEMP controller on the overview screen.

### 4.3.7 Selection Lists and Tables

If submenus contain lists of elements, short names or parameters that cannot be displayed in a window, a scrollbar with a position marker is displayed:

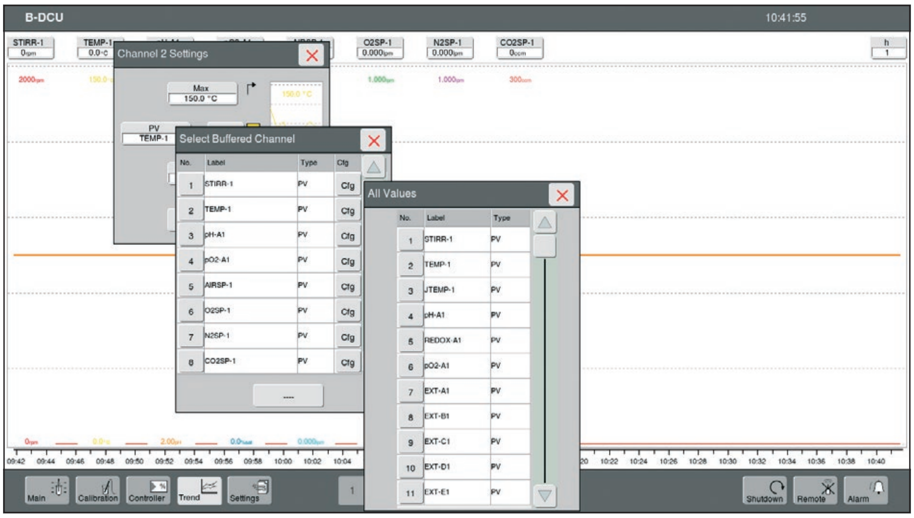


Fig. 4-7: Access to values accessible from the submenu after assigning a channel in the trend display

To page through lists that contain more entries than can be displayed in the window, the following options are available:
- ▶ Press the “s” (down) or “r” (up) arrow keys.
- ▶ Press the position mark (light gray field in the scrollbar) and move it in the desired direction.
- ▶ Press directly in the scrollbar at the relative height where the channel tag could be located.

## 4.4 Password Protection of Individual Functions

Only disclose this information to authorized users or Sartorius Service. If required, remove this page from the manual and keep it in a special place.

Certain system functions and settings that should only be accessible for authorized personnel are protected by a password. These include the settings for the controller parameters in the controller menu, for example, and the following settings in the “Settings” menu:

- – The process value “PV” setting.
- – The interface parameter setting for digital and analog process inlets and outlets or for simulation controllers during manual operation.

The “Service” submenu of the “Settings” menu is only accessible via a special service password. This is only disclosed to authorized Sartorius Service personnel.

When selecting password-protected functions, a keypad is displayed automatically with a prompt to enter the password. The following passwords can be defined:
- – Default password (factory-set: 19)
- – Customer-specific default password[1]
- – Service password

1 The customer-specific password can be set via “Settings->System Parameters-> Standard Password.”

## 4.5 User Management

The user management function regulates the access of users to the DCU system. This function makes it possible to grant or restrict access permissions, to prevent incorrect operation of the DCU system, for example.

▶ Observe the user management operating instructions for DCU4 systems.

## 4.6 Bug Handling and Troubleshooting

If the DCU system should encounter technical problems, contact Sartorius Service.

## 4.7 Locking Functions

Locking functions are permanently configured; the user cannot change them. In the "Settings" menu, locked inlets and outlets are highlighted with a colored marking. The extent of the locking functionalities is system-specific and predefined during configuration. This is documented in the configuration lists supplied with every system.

# 5 Transport

The device will be delivered by Sartorius Stedim Biotech or by a transport company engaged by Sartorius Stedim Biotech.

## 5.1 Inspection upon Acceptance by the Recipient

### 5.1.1 Reporting and Documenting Transport Damage

Upon acceptance of the device by the customer:

- ▶ Inspect the device for visible transport damage.
- ▶ Report transport damage immediately to the delivering office.

### 5.1.2 Checking Completeness of the Delivery

The delivery includes all required fittings, connector elements, lines, hoses, and cables.

- ▶ Check the delivery against the order to ensure it is complete.

Connection lines to supply facilities are not in the scope of delivery.

## 5.2 Packaging

The packaging used for transport and protection of the unit consists primarily of the materials suitable for recycling.

- ▶ Do not dispose of the packaging in the garbage.
- ▶ Dispose of all packaging material in accordance with local regulations.

## 5.3 Shipping Instructions

When moving the device, it is particularly important to do so in a way that will prevent damage by force or careless loading and unloading.

---

**⚠ WARNING**

**Danger of severe injury and material damage due to improper transport!**

- – The packaged device may only be moved by trained forklift drivers.
- – This equipment requires two or more people to transport and set up, or the use of appropriately rated lifting equipment.
- – The load capacity of the lifting equipment (forklift) must in the very least be appropriate for the weight of the device (see Chapter "13 Technical Specifications," page 173).
- – Make sure that the transport routes, such as elevators, are sufficiently large and have adequate load bearing capacity.
- – Wear personal protective equipment.
- – The device 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.
- – Lift the device only at suitable points with lifting accessories.
- – To ensure stability and safety: Always lift the device slowly and carefully.
- – Secure the device from falling during transport.
- – During transport of the device, ensure that no personnel are in its path.

---

## ATTENTION

**Danger of damage due to improper transport!**

▶ Protect the device against:
  - Impact
  - Falls
  - Damage
  - Humidity

### Loading/Unloading

## ATTENTION

**Danger of damage due to improper loading or unloading!**

The device must **not** be unloaded outdoors when it is raining or snowing. The device must also be covered with film, if there is a risk of it getting wet. The device must **not** be placed outdoors. Use only suitable, clean, undamaged load lifting accessories.

### Weight of the Control Unit, Supply Units, Culture Vessels

The exact weight of a supply unit depends on the internal fittings, e.g., whether and how many mass flow controllers it contains.

The exact weight of a UniVessel® culture vessel depends on the vessel equipment and size (see Chapter "13 Technical Specifications," page 173).

# 6 Installation

The device is set up according to the respective contract conditions by:
- Sartorius Service
- Sartorius authorized specialist personnel
- The customer's authorized specialist personnel

Setting up the device involves the following main steps:
- Ensure that the ambient conditions have been fulfilled for the installation location.
- Ensure that there is adequate and suitable work space.
- Ensuring that the laboratory energy sources correspond to the specifications.
- Set up the control unit and supply unit(s), as well as other devices and equipment required for the process.

## 6.1 Ambient Conditions

The device may only be operated under the ambient conditions listed in Chapter 13.7, page 176.

## 6.2 Work Surfaces and Loads

The culture vessels are designed to be setup on a stable laboratory table. The work surface must be big enough for the equipment required for the fermentation process. It must be easy to clean and, where relevant, to disinfect.

---

⚠ **WARNING**

**Danger of injury if access to emergency 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.

---

⚠ **CAUTION**

**Danger of injury due to insufficient component stability!**

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

---

▶ Ensure that the laboratory table is dimensioned sufficiently for the weight of the device, the culture vessels, and the process media in use (see Chapter "13 Technical Specifications," page 173).
▶ Ensure that the laboratory table is level.
▶ Ensure that the workplace is dimensioned in such a way that the device is easily accessible for in-process operation, maintenance, and service work. The space requirements also depend on the peripheral devices to be connected.
▶ Always squat to work on low-lying components; do not bend over.
▶ Carry out work on high components with an upright posture with your back straight.

**Setup Example**

The guide for setup of the device are the installation plans. The actual required space depends on the additional equipment used for the process.

## 6.3 Laboratory Energy Sources

The connections for energy and supply systems must be prepared before installation of the device in the work area. They must be easily accessible, correctly installed, set in accordance with the device's specifications, and ready to operate.

The connections for the supply media are located on the rear panel of the supply units, as well as a voltage connection on the control unit.

The following supply media are connected to the supply unit:
- Power supply, potential equalization
- Cooling water
- Gases:
  - Compressed air (Air)
  - Oxygen ($O_2$)
  - Nitrogen ($N_2$)
  - Carbon dioxide ($CO_2$)

▶ Ensure that the supply lines for electricity, cooling water, compressed air, and gas comply with the device specifications.
▶ Ensure that the supply lines are equipped with suitable fittings for shutting off the lines and emergency shutoff.

### 6.3.1 Electricity

▶ Keep access to the emergency shut-off devices inside the laboratory and the equipment's power connections clear.

---

**NOTICE**

**Risk of damage due to voltage dips and spikes!**

▶ Ensure that the voltage supply data on the manufacturer's ID label (see Chapter 3.4, page 34) matches the laboratory's voltage supply.

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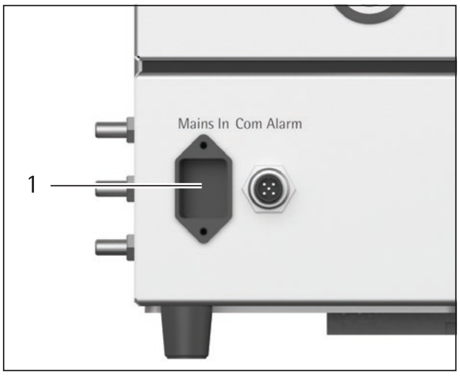
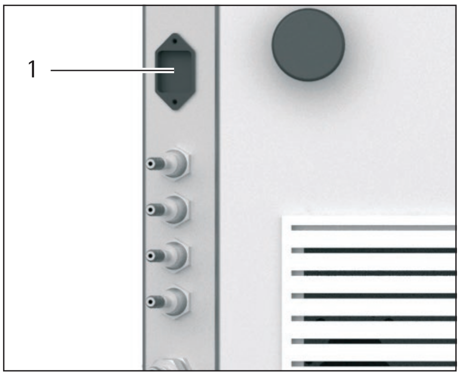



**Control Unit Power Supply**

▶ Only use the supplied mains cable in accordance with your national mains connection regulations and specifications.
▶ Plug the connection cable firmly into the "Mains In" socket (1) until the cable noticeably clicks into place.
▶ Plug the mains cable into the laboratory mains wall outlet fitted with a grounding conductor.




**Supply Unit Power Supply**

- ▶ Only use the supplied mains cable in accordance with your national mains connection regulations and specifications.
- ▶ Plug the connection cable firmly into the "Mains In" socket (1) until the cable noticeably clicks into place.
- ▶ Plug the mains cable into the laboratory mains wall outlet fitted with a grounding conductor.

**Establishing Potential Equalization**

- ▶ Connect potential equalization cable of the supply unit to potential equalization connection of the building firmly and permanently.
- ▶ Connect potential equalization cable of control unit to potential equalization connection of the building.

### 6.3.2 Temperature Control Medium

Water is used as temperature control medium for the supply unit and may contain antifreeze if necessary. Water is used for the following functions:
- Temperature control of a double-walled culture vessel or a UniVessel® SU with heating/cooling jacket
- Cooling liquid for the cooling finger (for single-walled glass vessels)
- Cooling liquid for the exhaust cooler

---

## ATTENTION

**Danger of damage to the heat circulation pump, fittings, and thermostat system!**

Inadequate water quality can affect the functioning of the heat circulation pump and fittings in the thermostat system. The following impairments are possible:
- Formation of scale if water is hard
- Corrosion from distilled or demineralized water
- Faults resulting from contaminants or corrosion residues

---

Malfunctions and damages arising from unsuitable water quality are excluded from the warranty granted by Sartorius Stedim Biotech.

Green microbes inside the double wall are a sign of algae formation caused by organic contaminants in the water. Do not use water contaminated in this way.

Observe the information in Chapter "13.3.1 Cooling Water Supply/Cooling Circuit," page 174, for the cooling circuit.

- ▶ Check whether the water is clean before connecting it to the supply unit.
- ▶ Rinse the laboratory supply lines.
- ▶ If necessary: Install a suitable pre-filter in the laboratory or in the supply line routed to the supply units.
- ▶ Use tap water with max. 12 dH; no distilled or demineralized water.

Using a water hardness of max. 12 dH minimizes the formation of scale deposits in the temperature control circuit and double wall of the culture vessels. To calculate the water hardness, see Chapter 13.8, page 176.

### 6.3.3 Gas Supply

The laboratory gas supplies for each of the gases must be preset (see Technical Specifications). The pressure in the vessel supply lines is limited to max. 1 barg by the safety valves in the gas flow controllers.

Gas supply comprises the following gases (depending on the integrated aeration module):

**Aeration Modules**

| "$O_2$ Enrichment," "Gasflow Ratio" | "Advanced Additive Flow" |
|---|---|
| Air | Air |
| Oxygen ($O_2$) | Oxygen ($O_2$) |
| | Nitrogen ($N_2$) |
| | Carbon dioxide ($CO_2$) |

## ATTENTION

**Risk of malfunctions and damages to gas-carrying components!**

Contaminants such as oil and dust can adversely affect the functioning of gas supply components and lines.

- When corrosion-causing gases needed for certain processes are used in the gas supply, the gas-carrying components have to be corrosion-resistant (e.g., ammonia can cause corrosion to gas-carrying components made of brass).
- Make sure that the supply gases are dry and free of dirt, oil, and ammonia.
- Install suitable filters, if necessary.
- Malfunctions and damage arising from contaminated gas media are excluded from the warranty granted by Sartorius Stedim Biotech.

# 7 Getting Started

Commissioning the device involves the following essential measures:

| Assembly steps | Chapter, page |
|---|---|
| Connect the supply unit(s) to the control unit | 7.3.1, 54 |
| Connect the control unit to a process control system like MFCS | |
| Connect the laboratory water supply | 7.3.4, 55 |
| Connect the laboratory gas supply | 7.3.5, 55 |
| Connect the stirrer motor to the supply unit | 7.3.6, 56 |
| Connect the UniVessel® SU Holder | 7.3.8, 57 |
| Connect the barcode scanner | 7.3.9, 58 |
| Connect sensor cable | 7.3.3, 54 |
| Connecting the hoses for aeration | 7.3.7, 57 |
| Connect the temperature control | 7.4, 58 |
| Connect the exhaust cooler | 7.5, 62 |
| Connect external pumps | 7.5, 62 |
| Switch on the supply unit(s) and control unit | 7.8, 64 |

## 7.1 Installation Materials

The equipment supplied with the bioreactor includes a connection kit.

- Only use lines and fittings approved for use with the bioreactor or for which suitability has been confirmed in writing by Sartorius Stedim Biotech.
- Only replace damaged components and worn parts with Sartorius Stedim Biotech approved parts.

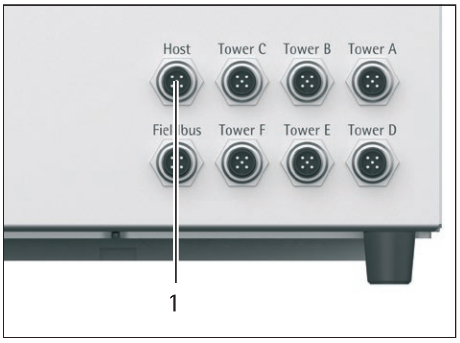
### ATTENTION

**Danger of malfunction and breakdowns!**

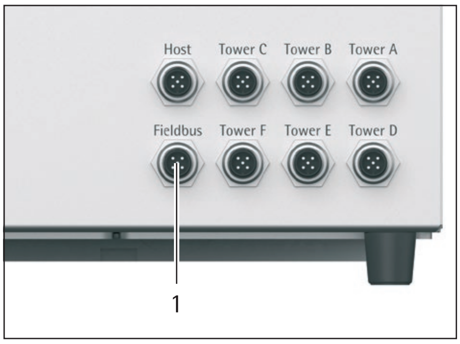
Sartorius Stedim Biotech does not accept any liability for malfunctions and breakdowns related to the use of equipment that has not been approved for use withthe bioreactor, nor any secondary damage arising from this.

## 7.2 Connecting the Control Unit

### 7.2.1 Connecting the Control Unit to an External Host System




▶ Connect the external host system (e.g., MFCS SCADA) to the “Host” port on the rear panel of the control unit.



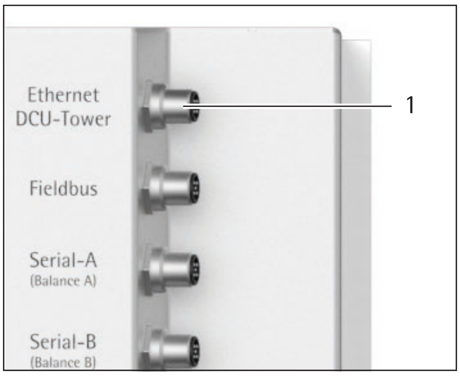

### 7.2.2 Connecting Network-Compatible Components to the Control Unit

▶ Connect components with a network connection to the “Fieldbus” port on the rear panel of the control unit.
▶ Modbus TCP-compatible components can be connected if their driver is supported by the DCU.

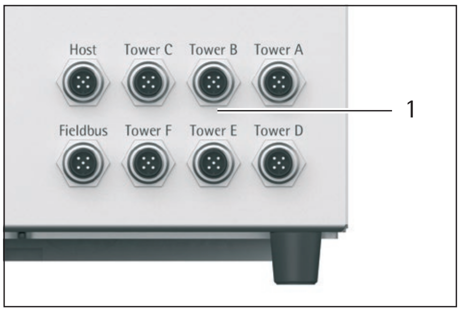
## 7.3 Connecting the Supply Unit

### 7.3.1 Connecting the Supply Unit to the Control Unit

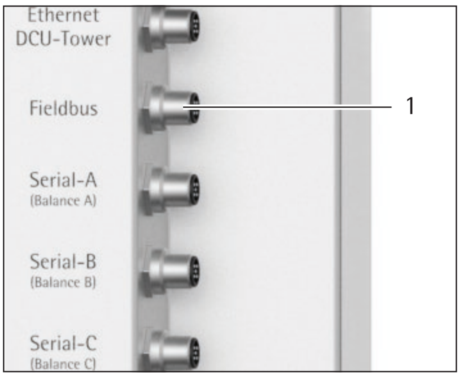
Depending on the scope of delivery, up to 6 supply units (A–F) can be connected to one control unit.




▶ Connect the Ethernet system cable to the “Ethernet DCU-Tower” port on the supply unit.




▶ Connect the Ethernet system cable to the “Tower x” port defined in the system specification and located on the rear panel of the control unit.
Tower A ... F corresponds to supply unit 1 ... 6




### 7.3.2 Connecting Network-Compatible Components to the Supply Unit

▶ Connect components with a network connection (e.g., bag balance) to the “Fieldbus” port on the rear panel of the control unit.

### 7.3.3 Connecting Additional Components/Sensors to the Supply Unit

▶ Connect additional components (e.g., pump, balance) and sensors required for the process to the supply unit (see Chapter 3.1.2, page 20).

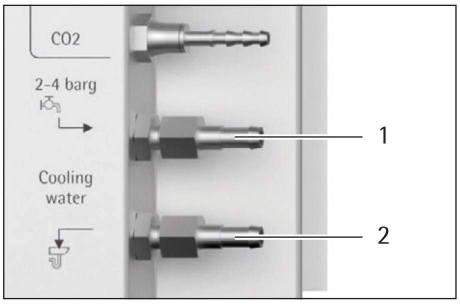
### 7.3.4 Connecting the Laboratory's Water Supply to the Supply Unit

## ATTENTION

**Risk of injury due to bursting culture vessel!**

If the pressure in the temperature control circuit is too high, there is a risk that the double-walled versions of the culture vessels will burst.

- ▶ Ensure the correct connection of the cooling water inlet (1) and cooling water outlet (2) in the "Cooling Water" connection area.
- ▶ Prevent lines from kinking. The water must flow freely into the outlet.
- ▶ When connection to a closed (laboratory) cooling circuit system, the water must not be impeded and apply pressure to the outlet connection.




The water input pressure is limited by a pressure reducer. A flap valve does not allow water to access the system if the water supply was inadvertently connected to the water outlet.

- ▶ For connecting the water supply, use the hose clips, and hoses supplied (or components with equivalent specifications).
- ▶ Only use the supplied or equivalent and matching hoses, fittings, and fastening equipment for connecting the equipment inside the laboratory.
- ▶ Secure the connections carefully and ensure they cannot become loose inadvertently.
- ▶ Before opening the supply line to the supply unit: Ensure that the laboratory preliminary pressure is set correctly.
- ▶ Make sure that there are no kinks in the hose and lay it in such a way that there is no risk that water pockets form.
- ▶ Check regularly to make sure that excess water can run off unimpeded.

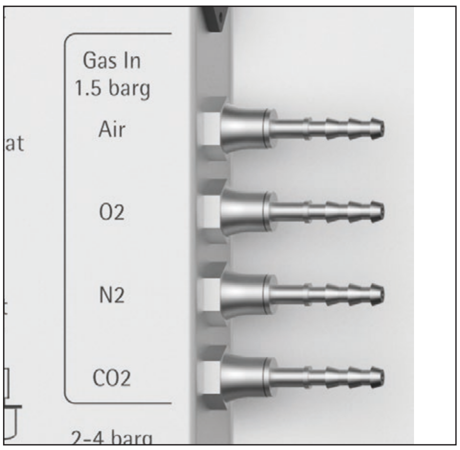
**Connecting External Cooling Equipment**

You can connect a laboratory cooling water circuit or cooling device to the cooling water inlet and outlet. Observe the information in Chapter "13 Technical Specifications," page 173 for the cooling circuit.

Observe the correct arrangement of the inlet and outlet:

- Connect the outlet of the external loop or the cooling device to the inlet of the supply unit (1).
- Connect the outlet of the supply unit (2) to the laboratory return line or the inlet of the cooling device.

### 7.3.5 Connecting the Laboratory's Gas Supply to the Supply Unit




The gases and compressed air supplied inside the laboratory must correspond to the supply unit's specifications. The connections for the gas supply are located on the side panel of the supply unit. The unused inlets for the "$O_2$ Enrichment" and "Gasflow Ratio" aeration modules are sealed with dummy plugs.

- ▶ Observe the information in Chapter "13 Technical Specifications," page 173.
- ▶ Observe the information on the dimensioning of variable area flow meters in Chapter 13.9, page 177.
- ▶ Prepare the laboratory gas supply lines, if necessary, by fitting suitable filters to ensure that the supplied gas is free from oil and grease.
- ▶ Connect the laboratory supply lines to the supply unit(s) using the appropriate adapters (see Chapter 3.1.2, page 20).

### 7.3.6 Connecting Stirrer Drive

## ⚠ CAUTION

**Risk of injury when motor is running!**

When detached, the motor can also be started up for testing by switching on the control unit of the DCU. Reaching into the running drive can cause injuries to the fingers.

- **Do** not reach into the protective sleeve with your fingers.
- Leave the motor controller switched off (except if the power is switched off and you are connecting the drive to perform a function test) until you have fastened the motor to the stirrer shaft.

## ATTENTION

**Danger of damage to the stirrer drive!**

The main switch 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 that the motor is not yet fitted to the stirrer shaft.

The following figures show connection cable plugs and their corresponding female connectors on the stirrer motor.

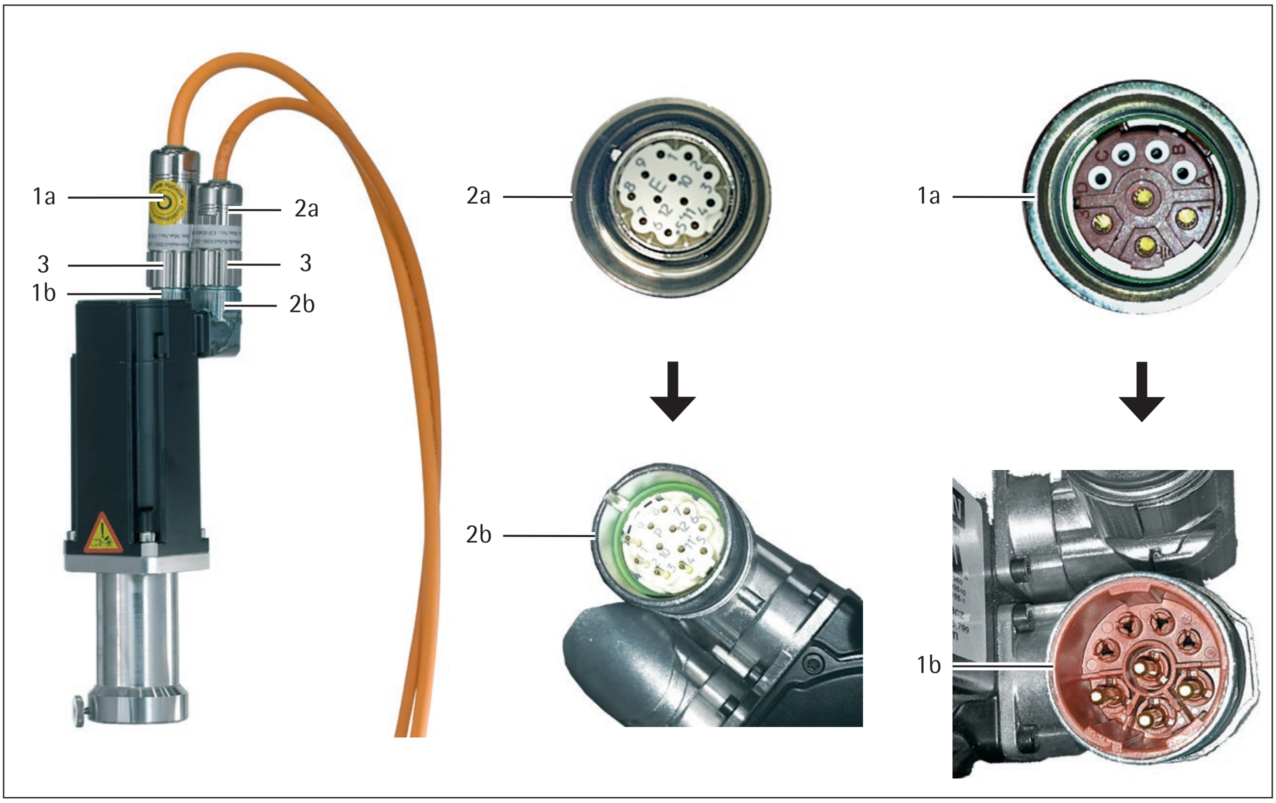



Fig. 7-1: Cap nuts, connection plugs

- Plug the connection cable into the respective sockets on the motor.
- Carefully tighten the plug connection cap nuts (3) by hand.

**Speed Ranges**

## ATTENTION

Depending on the size and equipment of the culture vessels, the permissible speed may be limited, e.g., to max. 300 rpm in vessels with aeration rigs for bubble-free aeration. Operating the stirrer at impermissible high speeds can affect the culture vessel's stability and cause damage to fittings. For information on permissible speeds, see Chapter "13 Technical Specifications," page 173.

### 7.3.7 Connecting the Hoses for Aeration

The supply unit is fitted with aeration modules which have independently controllable spargers, depending on the specifications of the device.

- The "$O_2$ Enrichment" and "Gasflow Ratio" modules only have one adjustable "Sparger" outlet for submerged aeration.
- The "Advanced Additive Flow 2-out" modules have an adjustable "Sparger" outlet for submerged aeration and/or an "Overlay" outlet for headspace aeration.
- The "Advanced Additive Flow 6-out" modules have 6 gas outlets for individual aeration. Depending on the process requirements, hoses can be connected to these.

▶ Connect the hoses for aeration on the front panel of the supply unit (see also Chapter "3.1.3 Aeration," page 23).

### 7.3.8 Connecting the UniVessel® SU Holder

The UniVessel® SU holder is for mounting the UniVessel® SU culture vessel and/or to compile and analyze measurement signals from the optical pH and DO sensors in the UniVessel® SU culture vessel. The holder transmits the measurement signals via the digital interface.

The holder and adapter ring ensure the stability and proper operation of the culture vessel. Furthermore, the process data is exchanged with the control unit via the interfaces.

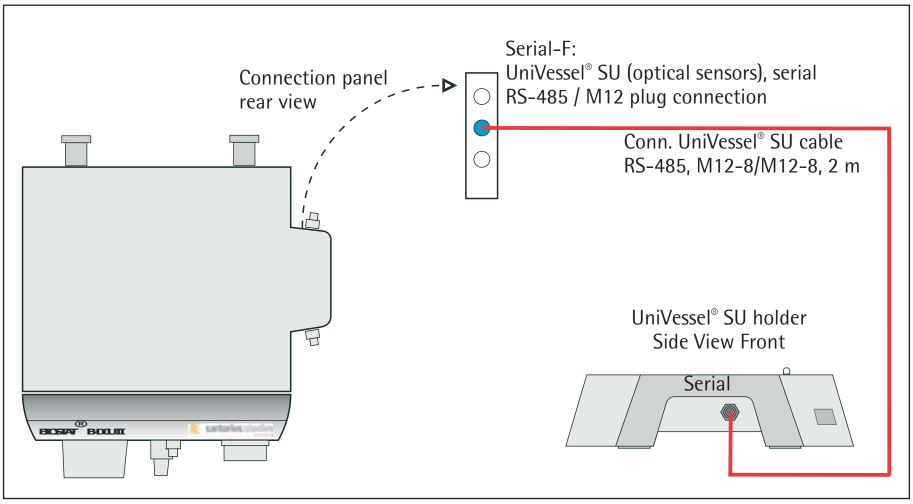



Fig. 7-2: Connecting the UniVessel® SU holder to the supply unit

▶ Connect the holder's data cable to the "Serial" port and to the "Serial-F" port on the rear panel of the supply unit (see Chapter "3.1.2 Supply Unit," page 20).

### 7.3.9 Connecting the Barcode Scanner


The calibration data is determined during production and delivered with the culture vessel for optical single-use pH and DO sensors. The pH and DO calibration data is located on the calibration sticker on the UniVessel® SU cardboard box. The calibration data can either be entered manually or with the barcode scanner and then transmitted to the control unit via the USB port.

▶ Connect the barcode scanner to the (1) USB port on the front panel of the control unit (see Chapter "3.1.1 Control Unit," page 18).

▶ Perform pH and DO calibration before starting the process (see Chapter "8.8 "Calibration" Menu," page 84).

Further information on the UniVessel® SU, UniVessel® SU holder, adapter ring, and barcode scanner can be found in the following instructions:

– UniVessel® SU Culture Vessel Installation Instructions
– UniVessel® SU Holder Operating Instructions
– Adapter Ring Installation Instructions

## 7.4 Connecting the Temperature Control System

### 7.4.1 Double-Walled Culture Vessels/Single-Walled Culture Vessels with Heating/Cooling Jacket

---

⚠ **WARNING**

**Danger of injury from glass splinters!**

Excess pressure can cause the glass culture vessels to break. Bursting glass culture vessels can cause cuts and damage to the eyes.

▶ Make sure that the hose on the return connection leading to the supply unit is not kinked or disconnected.

▶ Excess temperature control medium must be able to drain unimpeded and without pressure.

---

**NOTICE**

**Running the system on dry can damage the circulation pump in the temperature control system!**

▶ Always fill the temperature control circuit **before** activating the temperature controller.

---

To ensure optimal heat transfer, the double wall of the culture vessel must be completely filled. Check the fill level every time before the equipment is sterilized and before starting a process.

### Hose Kits

Hose kits to connect double-walled culture vessels or the UniVessel® SU heating/ cooling jacket are included with the equipment supplied.

The exhaust coolers are supplied with the hose kits needed for connecting to the associated outlet of the supply unit.

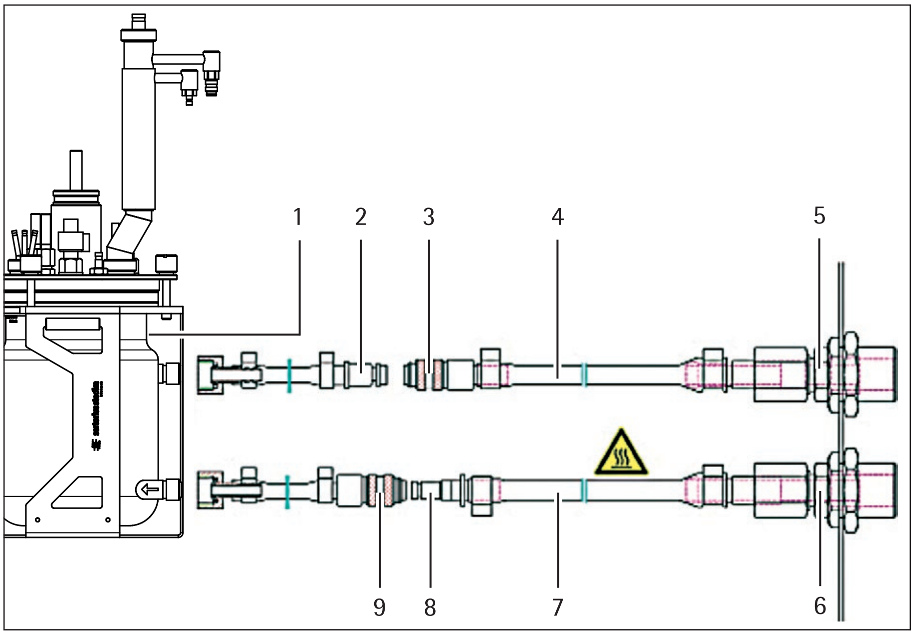



Fig. 7-3: Hose kit, temperature control for double-walled glass culture vessels

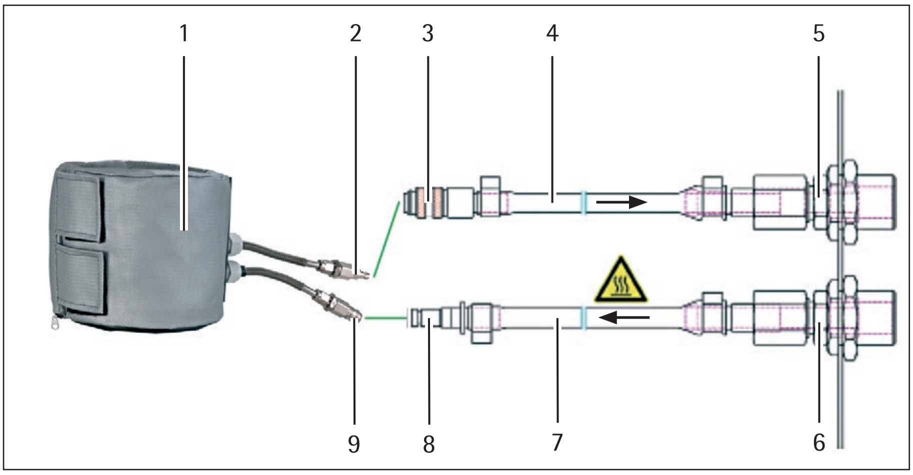
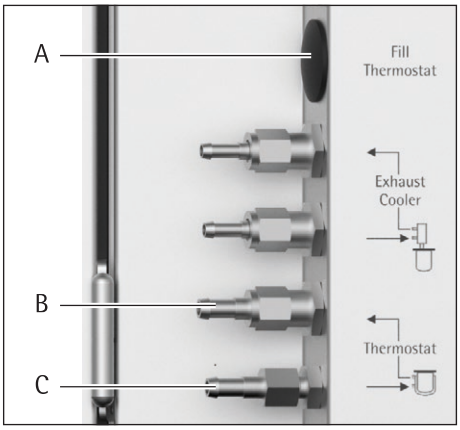



Fig. 7-4: Hose kit, temperature control for UniVessel® SU culture vessels with heating/cooling jacket

| No. | Description |
|---|---|
| 1 | Double-walled culture vessel, heating/cooling jacket |
| 2 | Hose with sealing clip |
| 3 | Sealing coupling |
| 4 | Hose with sealing coupling for return (length 600 mm) |
| 5 | Supply unit connection (return) |
| 6 | Supply unit connection (inlet) |
| 7 | Hose with sealing clip for inlet (length 600 mm) |
| 8 | Sealing clip |

| No. | Description |
|---|---|
| 9 | Hose with sealing coupling |




**Filling the Temperature Control Medium**

The supply unit and control unit must be switched on (see Chapter 7.8, page 64).

▶ Connect inlet hose (7) to supply unit connection (C) and then to connection (9).
▶ Connect the return hose to supply unit connection (B) and then to connection (2).
▶ Hold down the rocker switch (A) on the front panel of the supply unit for approx. 1–2 min. to fill the double wall of the culture vessel or the heating/cooling jacket.
▶ As soon as water flows out of the laboratory outlet: Stop the filling process.

During the process, the cooling water is only fed into the temperature control circuit if the vessel needs to be cooled. The cooling water supply to the exhaust cooler is configured in such a way that, once the laboratory supply point has been opened, there will be a constant flow of fresh water.

**External Cooling Equipment**

The minimum culture vessel temperature is around 8°C above the ambient temperature. The bioreactor can only be operated at temperatures that are lower than those stated above if used with an external cooling system:

– External cooling circuit in the laboratory
– FRIGOMIX® chiller (optionally available from Sartorius Stedim Biotech)

If external cooling equipment is connected, the temperature control circuit must run without pressure (at ambient pressure).

### 7.4.2 Heating jacket

The heating jackets are designed for heating single-walled culture vessels.

**⚠ WARNING**

**Danger to life caused by electric shock if heating jacket is defective!**

The heating jackets must not show any visible signs of damage.
▶ Follow the associated safety instructions.

The power consumption of the heating jacket used may not exceed 780 watts.
▶ Only use the parts specified by Sartorius Stedim Biotech.

Special versions and especially models from other suppliers require the prior written agreement of Sartorius Stedim Biotech.

**ATTENTION**

**Supplying the heating jacket with the wrong kind of voltage will damage the heating jacket.**

The heating jackets must only ever be connected to the female connector on the supply unit – never to a power supply in the laboratory.
The only connection that provides the correct voltage is the “Heating Blanket” connection, which is controlled by the supply unit’s temperature controller.

### Heating Jacket Structure

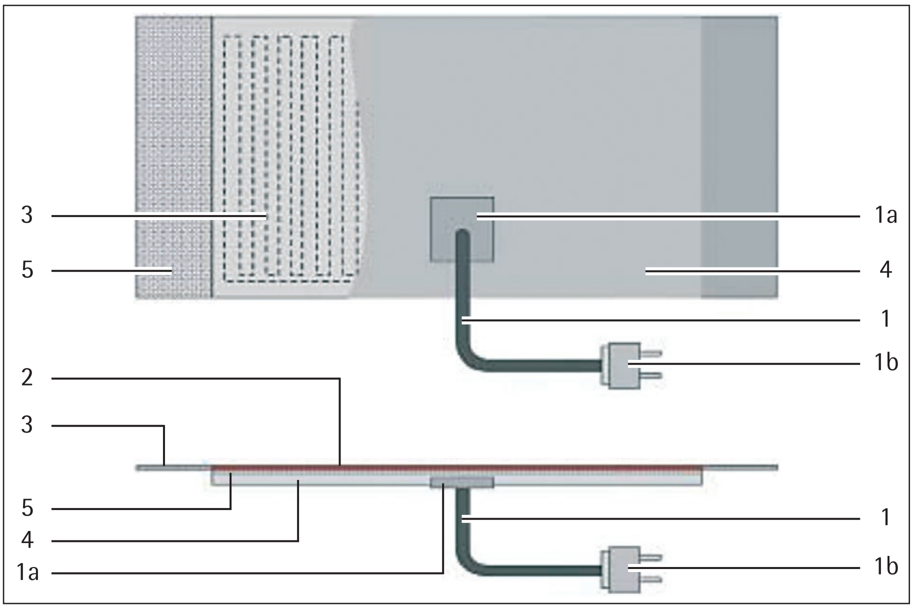



Fig. 7-5: Heating jacket

| No. | Description |
|---|---|
| 1 | Power cord |
| 1a | Cable connection with overheating protection |
| 1b | 6-pin Amphenol power cord |
| 2 | Protective film of heating coil (vessel side) |
| 3 | Heating coil |
| 4 | Silicone foam sleeve |
| 5 | Velcro fastener |

### Connecting the Heating Jacket to the Supply Unit

▶ Ensure that the supply unit has been switched off at the “Mains I/O” main switch.
▶ Plug the heating jacket's connection cable into the “Heating Blanket” connection on the front panel of the supply unit (see Chapter 3.1.2, page 20).
▶ Carefully tighten the plug connection cap nuts by hand.

## 7.5 Connecting the Exhaust Cooling Hoses

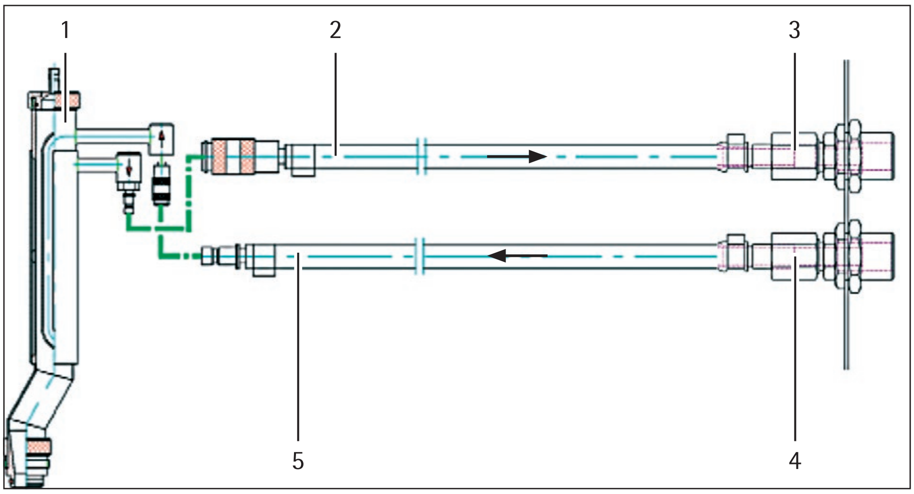
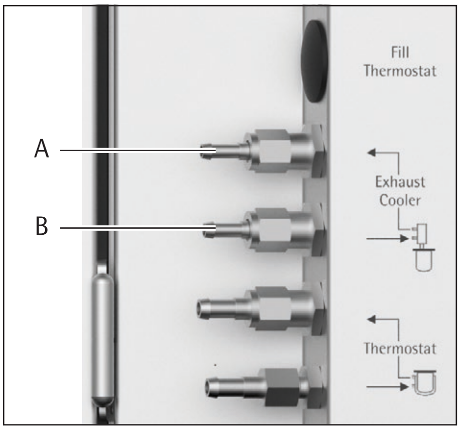



Fig. 7-6: Hose kit, exhaust cooling for culture vessels

| No. | Description |
|---|---|
| 1 | Exhaust cooler |
| 2 | Hose with sealing coupling for return |
| 3 | Supply unit connection (return) |
| 4 | Supply unit connection (inlet) |
| 5 | Hose with sealing clip for inlet |




### Connecting Hoses to the Supply Unit

▶ Connect the supply hose (5) to the supply unit connection (B).
▶ Connect the return hose (2) to supply unit connection (A).

## 7.6 Connecting External Pumps

▶ Connect the external pumps to the supply unit.
  ▶ The connections for the external pumps are located on the rear panel of the supply unit (see Chapter 3.1.2.3, page 22).

▶ Set the maximum speed of the external pump so that the minimum required speed is within the control range of the control unit.
  ▶ Observe the information in Chapter "3.1.4.2 External Pumps," page 29.
  ▶ To configure the speed, observe the operating instructions of the external pump.

## 7.7 Connecting the Balance

If a separate Sartorius balance is available or if a Cubis/Quintix/Secura balance is purchased later, the balance can be connected to the device:

The weight unit of the balance matches the unit set in the DCU system (g or kg) and its measuring range.

**Connecting the Balance**

▶ Connect the M12 plug connection of the supplied cable to the serial signal input on the supply unit defined in the system specification.

▶ Connect the wires on the other end of the cable to the balance.
Observe the connector pin assignment in Chapter 15.1, page 182.

**Configuring the Balance**

▶ Set the following parameters on the balance. Refer to the operating instructions for the balance.
  - Protocol: RS-232 SBI
  - Baud rate: 9600 baud
  - Data bits: 7 bits
  - Parity: even
  - 1 stop bit
  - Software handshake (X-On/X-Off)
  - Print: manual without stability
  - Printout: without ID
  - Power-on mode: "AUTO-ON"

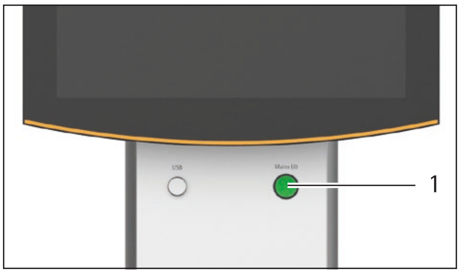
## 7.8 Switching the Control Unit and Supply Unit(s) On/Off

The device must be properly installed and connected in accordance with the specifications.

▶ Ensure that all required energy supplies are connected to the supply unit(s).
▶ Check whether all connections (cooling water and gas supply lines) and the signal cables for the supply unit, control unit, and to the culture vessels are connected.

Switch on the control unit first before switching on the supply unit(s).

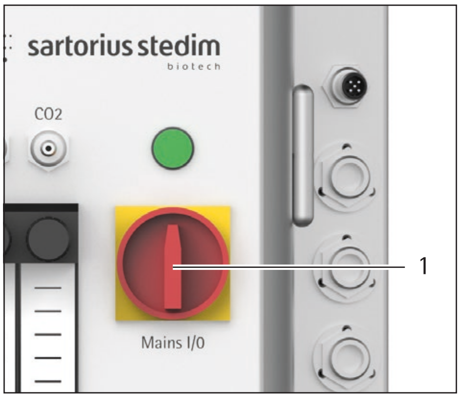
### Switching On the Control Unit




▶ Press the "Mains I/O" main switch (1).
▷ The main switch illuminates green to indicate that it is switched on.

▶ Wait until the main menu appears on the operating display.

### Switching On the Supply Unit




▶ Turn the "Mains I/O" main switch (1) to position **1** (On).
▶ Wait until realistic process data for the supply unit switched on appears on the operating display of the control unit.

### Switching Off the Device

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

# 8 Preparing and Running the Process

## 8.1 Overview

Process preparation of the device during the relevant process includes the following main steps:
- Equipping and changing the equipment of the culture vessels (see UniVessel® Glass operating manual):
- Connecting and installing the UniVessel® SU components (see UniVessel® SU Holder operating manual and installation instructions for the delivered UniVessel® SU components)
- Calibrating the probes
- Autoclaving the UniVessel® Glass culture vessels and the accessories that are to be connected aseptically (see UniVessel® Glass operating manual)
- Connecting the culture vessels and setting up the device at the site designated for the fermentation process
- Performing a process

## 8.2 Preparing the Glass Culture Vessels

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⚠ **CAUTION**

**Risk of injury when handling heavy culture vessels!**

Fully equipped and filled culture vessels are heavy, e.g., a UniVessel® with a maximum volume of 5 liters weighs over 18 kg.
- Handle the culture vessels with care.
- Use suitable transport and lifting equipment.
- Only lift the vessels at the handles provided for this purpose.

---

▶ Equip the culture vessels with the components that are needed for the process (see UniVessel® Glass operating manual).

**General Measures**

Make sure that the vessel equipment is in perfect condition and clean before installing it in the culture vessel.
- Remove all residues, contaminations, or microbes from the previous processes from the culture vessel and its fittings.
- Carefully check all equipment, especially glass culture vessels, sealing gaskets, and silicone hoses, for damage. Replace all damaged and worn parts.

**Measures Required Before Installing and Connecting Certain Parts**

- pH sensor (see operating instructions of the manufacturer):
  - Calibrate the pH sensor before autoclaving the culture vessel.
  - Calibrate the zero point and slope of the sensors using the buffers in accordance with the scheduled measuring range.
- DO sensor (see operating instructions of the manufacturer):
  - Test the sensor as recommended by the manufacturer and service it if required. For example, replace the membrane and the electrolyte for measurement.
  - The DO sensor must be calibrated after the culture vessels have been sterilized in readiness for the fermentation process.
- Redox sensor (optional, where included):
  - Test the sensor as recommended by the manufacturer using reference buffers.

## 8.3 Connecting Transfer Lines

The transfer lines are connected between the correction medium bottle(s) and the culture vessel.

**Transfer Line for UniVessel® Glass, UniVessel® SU**

| Standard designation | Material | Inner diameter of the hose | Wall thickness |
|---|---|---|---|
| 0.8 x 1.6; VMQ 7621; 55° Shore | Silicone hose transparent | 0.8 mm | 1.6 mm |
| 1.6 x 1.6; VMQ 7621; 55° Shore | Silicone hose transparent | 1.6 mm | 1.6 mm |
| 3.2 x 1.6; VMQ 7621; 55° Shore | Silicone hose transparent | 3.2 mm | 1.6 mm |

**Correction Media Bottles**

▶ Prepare the bottles for acid, base, antifoaming agent or nutrient solutions and connect the transfer lines.

Information about setup, equipment, and installation of the corrective media bottles can be found in the UniVessel® Glass operating manual.

**Fitting the Transfer Lines**

⚠ **CAUTION**

**Risk of chemical burns from acids and bases!**

If the hoses are not securely fastened, there is a risk that they will slide off, in which case the correction media will leak out uncontrolled.
▶ Wear personal protective equipment.
▶ Only use the hoses included with the supplied equipment.
▶ Make sure that the hoses are securely fastened.
▶ Only switch on the pump when the pump head is closed.

Each of the culture vessels can be supplied with correction media from up to 3 different bottles.

▶ Fit a piece of silicone hose onto the hose connection on the correction media bottle to which the dip tube is fitted.
▶ Connect the free end of the hose to the inlet on the culture vessel.

The hoses must be long enough to ensure that they can be easily fitted into the associated hose pumps after having been set up at the supply unit.
▶ Secure all of the hose connections with hose clamps.
▶ Before autoclaving, clamp off the hoses connected to the dip tubes using hose clamps. The reason is that when positive pressure builds up in the bottles, media can be forced out of the bottles, and this must be prevented.
▶ Put the corrective media bottles in the bottle holder (rack).

If the bottles need to be connected to the culture vessels at a later time, they can be autoclaved separately. Fit the transfer lines with STT quick release couplings to create a sterile connection to the culture vessel:
– Fit the STT quick release coupling plugs to the transfer line.
– Fit the coupling to the supply line of the culture vessel.

## 8.4 Preparing the Cultivation Process

### ⚠ CAUTION

**Danger of burns due to hot surfaces!**

The premature removal of culture vessels from the autoclave can cause burns.
- ▶ Let the culture vessels cool down inside the autoclave.
- ▶ Wear personal protective equipment.

- ▶ Carefully transport the culture vessels to the work site and place the culture vessels in front of their supply unit in such a way that all of the lines and peripheral devices can be easily connected.
- ▶ Fit the stirrer driver to the stirrer shaft (see Chapter 8.4.1, page 68).

**Temperature Control Circuit – UniVessel® Double-Walled:**

- ▶ Connect the inlet and outlet hoses of the temperature control circuit to the ports on the culture vessel.

**Temperature Control Circuit – UniVessel® Single-Walled/UniVessel® SU (Single Use):**

- ▶ Connect the inlet and outlet hoses of the temperature control circuit to the heating/cooling jacket and fit to the culture vessel.

  or (depending on the equipment)

- ▶ Fit the heating jacket to the culture vessel.

**Exhaust Cooling**

- ▶ Connect the inlet and outlet hoses of the exhaust cooling to the ports of the exhaust cooler at the culture vessel.

**Exhaust Heater – UniVessel® SU (Single Use):**

- ▶ Fit the exhaust filter heater to one of the exhaust filters and connect the plug to the mains supply (see installation instructions “Heater for Exhaust Filter”).

**Sensors**

- ▶ Connect the sensors to the appropriate cables.

**Aeration Modules**

- ▶ Connect the aeration to the culture vessel (see Chapter 8.4.3, page 71).

**Corrective Solution Supply**

- ▶ Place the transfer hoses in the peristaltic pumps on the device (see Chapter “8.4.2 Installing the Heating/Cooling Jacket,” page 70).

**Exhaust Filter Pressure Regulation**

- ▶ Stick a silicone hose on the exhaust filter and connect it to the “Press in” connection on the front panel of the supply unit.

### 8.4.1 Mounting the Stirrer Drive

⚠ **CAUTION**

**Risk of injury when motor is running!**

When detached, the motor can also be started up for testing by switching on the control unit of the DCU.
Reaching into the running drive can cause injuries to the fingers.

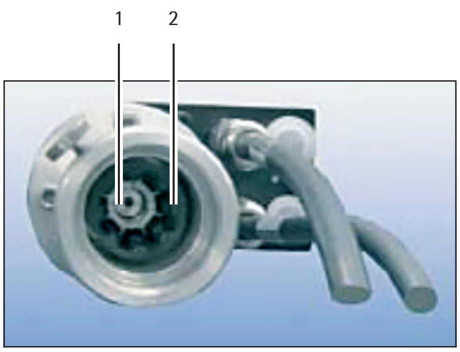
▶ Do not reach into the sleeve with your fingers.
▶ Leave the motor controller switched off (except for function tests) until you have fastened the motor to the stirrer shaft.

⚠ **CAUTION**

**Danger of injury if motor falls!**

If the motor falls, it can cause bodily injury.

▶ Attach the motor to the motor support after removing from the culture vessel.




The figures show possible sleeve and stirrer shaft coupling models. The actual model supplied may differ from the illustration.

The coupling (1) of the motor is equipped with a rubber compensation element (2). The compensation element establishes a positive connection to the coupling of the stirrer shaft, ensuring silent force transmission of the drive.

The stirrer drive motor can be fitted to the following stirrer shafts:

– UniVessel® (single-walled/double-walled)
– UniVessel® SU (with corresponding adapter)

### Installing UniVessel® Culture Vessels

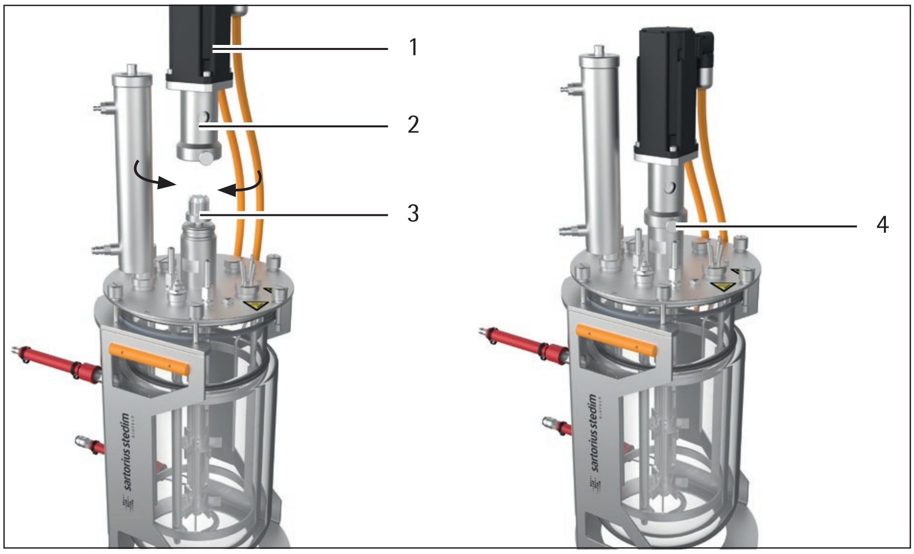



Fig. 8-1: UniVessel® stirrer coupling

| No. | Description |
|---|---|
| 1 | Motor |
| 2 | Sleeve |
| 3 | Coupling |
| 4 | Fastening screw |

⚠ **CAUTION**

**Danger of crushing when positioning the motor!**

There is a danger of crushing when placing the coupling onto the stirrer shaft.
- Only trained personnel are permitted to position the coupling on the stirrer shaft.
- Wear personal protective equipment.

▶ Remove the motor from the motor support.
▶ Place the coupling with sleeve onto the stirrer shaft.
▶ Gently twist the motor housing to the left or right until the motor's coupling and the coupling on the stirrer shaft engage.
▶ In order to fasten the motor securely to the stirrer shaft, tightly screw the fastening screw of the sleeve.

**Installing UniVessel® SU Culture Vessels**

It is not possible to fit the motor for the stirrer shaft directly to the coupling when using UniVessel® SU culture vessels. An adapter is required in order to fit the motor. The adapter is not part of the device's standard equipment.
You can order the adapter with enclosed installation instructions from Sartorius Stedim Biotech.

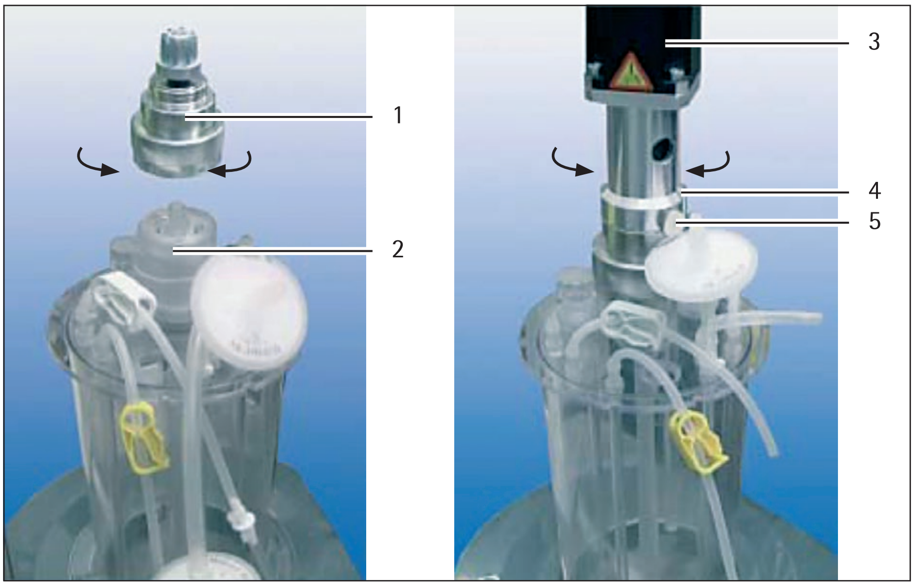



Fig. 8-2: UniVessel® SU stirrer coupling

| No. | Description |
|---|---|
| 1 | Adapter |
| 2 | Stirrer shaft coupling |
| 3 | Motor |
| 4 | Sleeve |
| 5 | Fastening screw |

▶ Fit the adapter to the coupling of the stirrer shaft (see installation instructions for motor adapter).
▶ Remove the motor from the motor support.

⚠ **CAUTION**

**Danger of crushing when positioning the motor!**

There is a danger of crushing when placing the coupling onto the stirrer shaft.
- Only trained personnel are permitted to position the coupling on the stirrer shaft.
- Wear personal protective equipment.

▶ Place the coupling with sleeve onto the adapter.
▶ Gently twist the motor housing to the left or right until the motor's coupling and the coupling on the adapter engage.
▶ In order to fasten the motor securely to the stirrer shaft, tightly screw the fastening screw of the sleeve.

### 8.4.2 Installing the Heating/Cooling Jacket

▶ Install the heating jacket and heating/cooling jacket according to the instructions provided with the jackets.

### 8.4.3 Connecting the Aeration Modules

#### 8.4.3.1 Conducting Preliminary Steps

The culture vessels must be fitted with the equipment needed for submerged aeration (see UniVessel® Glass operating manual):
– Sparger pipe with ring sparger or microsparger
– Aeration rig with silicone hose membrane
– Supply air filter
– Exhaust cooler with exhaust filter
– Supply air filter for headspace aeration when using the "Additive Advanced Flow" aeration module.

**Aeration Hose Overlay/Sparger for UniVessel® Glass, UniVessel® SU**

| Standard designation | Material | Inner diameter of the hose | Wall thickness |
|---|---|---|---|
| 3.2 x 1.6; VMQ 7621; 55° Shore | Silicone hose transparent | 3.2 mm | 1.6 mm |
| 6 x 9; Transparent; 55° Shore | Silicone rubber hose | | |

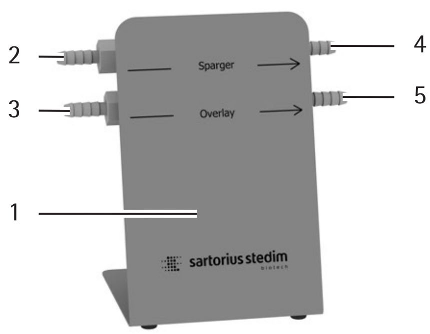
The culture vessels must be autoclaved together with the supply air and exhaust air filters and then set up next to the associated supply unit.
Configure the calibration parameters for the DO sensor and select the aeration mode using the DCU system (see Chapter "8.8 "Calibration" Menu," page 84).

After autoclaving and before aeration with air and oxygen, you can carry out the zero point calibration of the DO sensor with nitrogen.

Observe the instructions for zero point calibration of the DO sensor with nitrogen in vessels with "$O_2$ Enrichment" and "Gasflow Ratio" aeration modules (see Chapter "8.8.5.3 Performing Calibration," page 95).

#### 8.4.3.2 UniVessel® SU Safety Valve Station

The safety valve station ensures that the specified maximum operating pressure of the UniVessel® SU culture vessel is not exceeded.




The safety valve station is interconnected between bioreactor control unit and culture vessel. This prevents inadmissible overpressure in the culture vessel.

▶ Set up the safety valve station on a stable foundation in proximity to the bioreactor control unit.
▶ Set up the safety valve station such that the front panel (1) is facing you.
▶ Connect the hoses on the Overlay and Sparger outlets to the inlets of the safety valve station (2) and (3) (see safety valve station installation instructions).
▶ Connect the outlets of the safety valve station (4) and (5) to the corresponding inlets of the UniVessel® SU culture vessel (see UniVessel® SU operating instructions).

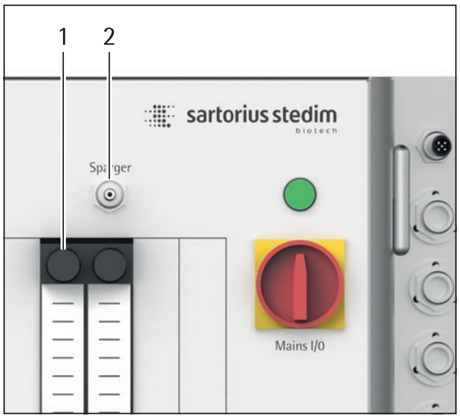
When laying and connecting the hoses, make sure not to bend or stretch them.

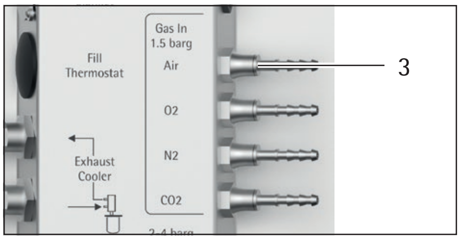
### 8.4.3.3 Connecting the “$O_2$ Enrichment” and “Gasflow Ratio” Aeration Modules

**⚠ WARNING**

**Danger of suffocation due to nitrogen during zero point calibration!**

Never leave the device unattended during zero point calibration.




▶ Connect the hose from the “Sparger” outlet (2) to the supply air filter of the culture vessel.

**Zero Point Calibration**

To calibrate the DO sensor’s zero point by feeding nitrogen into the vessel through the “$O_2$ Enrichment” and “Gasflow Ratio” aeration modules, proceed as follows:

▶ For the zero point calibration, connect the laboratory’s nitrogen supply to the “AIR” (3) connection on the rear panel of the supply unit.

▶ Open the laboratory nitrogen supply and the variable area flow meter at the “Sparger” outlet (1).

▶ Aerate the culture medium with nitrogen and calibrate the zero point (see Chapter “8.8.5.3 Performing Calibration,” page 95).

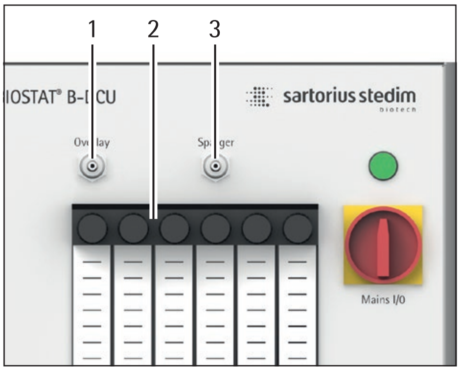
▶ After zero point calibration, remove the laboratory’s nitrogen supply hose from the “AIR” (3) connection.

▶ Connect the laboratory’s air supply to the “AIR” (3) inlet on the supply unit.

▶ Aerate the culture medium with air and calibrate the slope.

▶ Set the gas flow rate that you want to use at the start of the process using the “Sparger” variable area flow meter or the DCU system’s gas flow controller. If the supply unit is fitted with mass flow controllers for the gas supply, set the variable area flow meter for the “Sparger” outlet to the maximum gas flow rate.

### 8.4.3.4 Connecting the “Advanced Additive Flow” Aeration System




▶ Connect the hose from the “Sparger” outlet (3) to the supply air filter for submerged aeration of the culture vessel.

**Zero Point Calibration**

▶ Aerate the culture medium with nitrogen and calibrate the zero point (see Chapter “8.8.5.3 Performing Calibration,” page 95).

▶ Aerate the culture medium with air and calibrate the slope.

▶ Connect the hose from the “Overlay” outlet (1) to the supply air filter for headspace aeration of the culture vessel.

▶ Set the gas flow for your process at the variable area flow meters (2).

If the supply unit is fitted with mass flow controllers for the gas supply, set the variable area flow meter for the “Sparger” and “Overlay” outlet to the maximum gas flow rate.

### 8.4.4 Preparing the Corrective Medium Supply

The supply unit can contain up to 8 WM114 peristaltic pumps for supplying correction media (acid, base, anti-foam agent, or nutrient solution).

**Preliminary Steps:**

The culture vessels must be fitted with the following equipment needed for supplying correction media or media removal (see culture vessel operating manual):
- pH sensor, feed pipe for acid and base
- Anti-foam probe, feed pipe for antifoaming agent
- Harvest pipe for removal of media

The bottles must be prepared (see Chapter "8.3 Connecting Transfer Lines," page 66).

## ⚠ WARNING

**Danger of crushing limbs by being pulled into the rotation pump!**

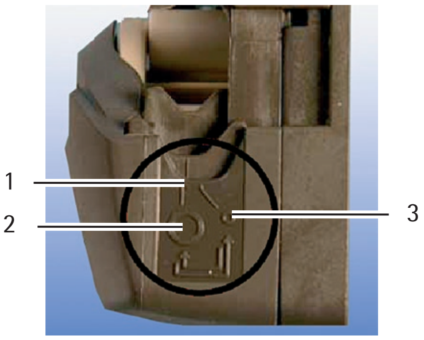
- Allow only qualified technical personnel to work on the unit.
- Keep the associated DCU controller function switched off or switch this controller function off, e.g., anti-foam, pH, or level controller.
- Switch the hose pumps to "off" before inserting the hoses.

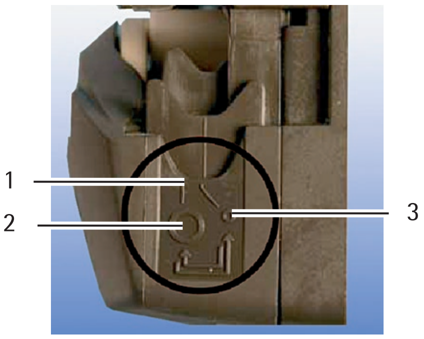
**Configuring the Hose Holder for the Peristaltic Pump**

It is possible to put hoses with different hose diameters into the peristaltic pumps.

The hose holder must be set up according to the used hose diameter.

▶ In order to carry out adjustments, lift up the cover of the peristaltic pump.
The position of the hose holder can be determined with the markings on the hose holder (1) and on the housing (2, 3).




The following table can be used to determine the position of the hose holder depending on the inner diameter of the hose.

| Inner diameter of the hose | 0.5 mm | 0.8 mm | 1.6 mm | 2.4 mm | 3.2 mm | 4.0 mm | 4.8 mm |
|---|---|---|---|---|---|---|---|
| Position of the hose holder | 3 | 3 | 2 | 2 | 2 | 2 | 2 |
| Cross-section | ○ | ○ | ◯ | ◯ | ◯ | ◯ | ◯ |

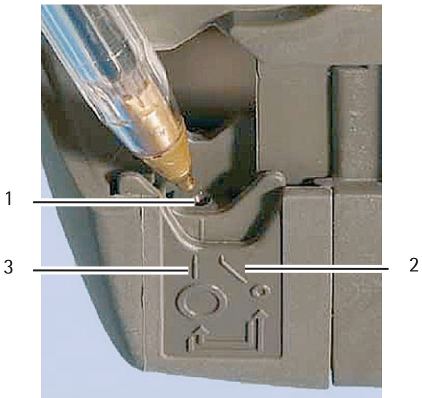
## ATTENTION

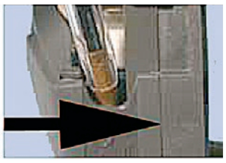
When the hose holder with small hoses (small circle) is located in position (3) and bigger hoses (4.0–4.8 mm internal diameter) are used, this reduces feed volumes and lifespan.

Using smaller hoses (0.5–0.8 mm internal diameter) with the hose holder in position (2) for big hoses (big circle) will increase the risk that the hose will get into the pump head and burst.

### Changing the Position of the Hose Holder

Changing to smaller hose diameter:



Prior to changing the hose holder position, turn off the pump. In order to re-position the lower hose holders on both sides of the pump head, use a pointed object (e.g., a ballpoint pen).

▶ Insert the pointed object into the recess (1) and push the instrument (e.g., a ballpoint pen) downwards.
▶ Push the hose holder's flange towards position (2) until the flange snaps into the new position.
▷ By now, the marking of the hose holder should be covering the marking for the small hose diameter (2).
▶ Reduce the pressure laid on the instrument.
▷ The flange should rise up and be aligned correctly.

If the flange does not rise up, repeat the procedure and maintain downward pressure until release.

▶ The hose holder on the other side of the pump head is adjusted accordingly.

Changing to bigger hose diameter:

Carry out the steps as described in the chapter above. Push the hose holder towards the opposite direction, allowing the flange to snap into position (3).

---

## ATTENTION

Soiling on the peristaltic pump mechanisms.
If no hose is inserted after setting up the hose holder position, the cover of the peristaltic pump must be sealed.
Soiling in the mechanisms can result in malfunctions and decrease the lifespan of the peristaltic pump.

---

### Inserting and Removing Hose

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## ATTENTION

**Unsuitable hose material may damage the peristaltic pump!**

Using hoses not made of silicone can damage the peristaltic pump.
▶ Only use silicone hoses.

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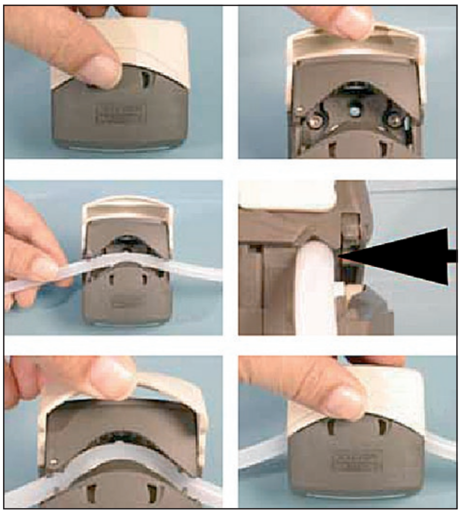
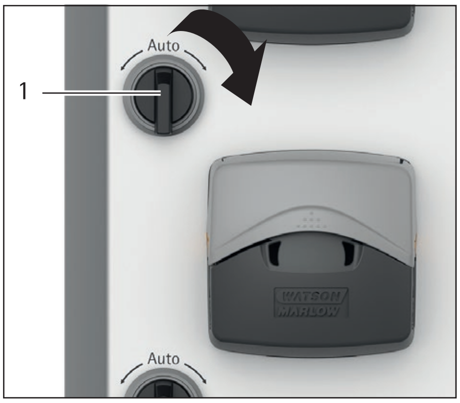


Check if the hose holders on both sides of the pump head are set up according to the used hose size (see Chapter "Changing the Position of the Hose Holder").

▶ Lift up the cover completely.
▶ Make sure that there is sufficient hose available for the curvature inside the pump's track. The hose must be positioned between the rotor-roller and the track; press and hold it towards the inner wall of the pump head. The hose must not be seated to the rolls in a twisted or bent manner.
▶ Push down the cover until it snaps into the closed position.
▷ The track closes automatically and the hose is stretched in the correct manner.
▶ In order to remove the hose element, conduct the steps in reverse order.




Before starting the automatic correction media supply system, the hoses must be filled with correction media.
▶ Activate the peristaltic pumps manually for this purpose: Turn the rotary switch (1) for filling to the right until the hose leading to the culture vessel is filled with correction media right up to where it joins the vessel.

## 8.5 Performing a Process

### NOTICE

**Premature aging of the sensor patches in UniVessel® SU!**

Incoming light causes the optical sensors to age prematurely, if no culture vessel is placed on the UniVessel® SU during initialization.
- Do **not** initialize the UniVessel® SU holder without a culture vessel in place.

### 8.5.1 Setting Up the Measurement and Control System

Carry out the following steps:
- Switch on all peripheral devices (e.g. exhaust filter heater).
- Check for any malfunctioning or failure.
  Error messages from the DCU system are shown on the operating display (see Chapter "10.3 Process-related Faults/Alarms," page 163).
- Select the measurement and control functions and set the parameters required for your process:

### 8.5.2 Guarantee Sterility

**Sterility Test**

Before starting the fermentation process, it is possible to perform a sterility test. The sterility test can be used to establish whether the culture vessels and the connected equipment have been safely sterilized or are contaminated. To perform a sterility test:
- Enter all of the process parameters as specified (temperature, speed, aeration, pH regulation, etc.)
- Leave the bioreactor running for approx. 24 hours and monitor it for signs of error, e.g.:
  - A changed pH value
  - Unexpectedly high oxygen consumption
  - Cloudiness of the medium
  - Unusual odors in the exhaust air

These signs could indicate that the equipment has not been properly sterilized or that germs from the environment have made their way inside through defective or insufficiently tightened connections and sealing gaskets.

**Corrective measures:**
- Sterilize with new medium for longer sterilization times.
  Do **not** increase the sterilization temperature.
- Dismantle all vessel equipment and connections.
- Check sealing gaskets and lines for damage.

### 8.5.3 Alternating Operation between Glass Culture Vessel and UniVessel® SU

The DCU system can be prepared for alternating operation between a glass culture vessel and UniVessel® SU with a heating/cooling jacket. Upon delivery, the system's default settings are configured for cultivation with a glass culture vessel. To alternate between a glass culture vessel and UniVessel® SU, the following parameters must be adjusted:

**Controller Parameters for a Glass Culture Vessel (Double-Walled)**

| | **Maximum controller output** |
|---|---|
| Temperature controller | 62% |
| Speed regulation (STIRR) | |
| – Standard coupling, 1 liter vessel | 100% |
| – Standard coupling, 2 liter vessel | 100% |
| – Standard coupling, 5 liter vessel | 75% |
| – Standard coupling, 10 liter vessel | 40% |
| – Magnetic coupling, 1 liter vessel | 100% |
| – Magnetic coupling, 2 liter vessel | 100% |
| – Magnetic coupling, 5 liter vessel | 40% |
| – Magnetic coupling, 10 liter vessel | 35% |

**Controller Parameters for UniVessel® SU with Heating/Cooling Jacket**

| | **Maximum controller output** |
|---|---|
| Temperature controller | 44% |
| Speed regulation (STIRR) | 20% |

⚠ **WARNING**

**Risk of damage to UniVessel® SU due to high temperature and escaping biological culture!**

The maximum permissible operating temperature for UniVessel® SU is 40°C. Never set the operating temperature for UniVessel® SU to more than 40°C.

**NOTICE**

Before every cultivation, check whether the parameters are set for the right vessel type.

### 8.5.4 Carrying Out the Cultivation Process

▶ Transfer the inoculation culture into the culture vessel.
▶ Perform the required process steps.
▶ Take samples, given this is necessary to monitor the process flow.
▶ On completion of the process, harvest the culture and transfer it to the next point of use (scale-up, processing, etc.).

**Switching Off the Device**

▶ If no other process is running on a supply unit:
Switch off the supply units and the control unit at the end of the process.

## 8.6 "Main" Menu

### 8.6.1 General Information

The "Main" menu opens after the control unit has been switched on.
This is the central starting point for in-process operation.

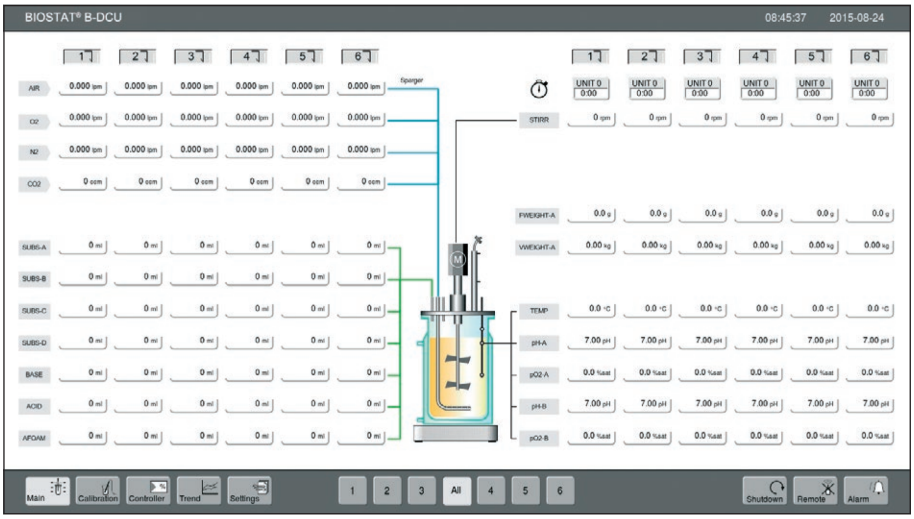



Fig. 8-1: "Main Overview All" screen for a 6-way system

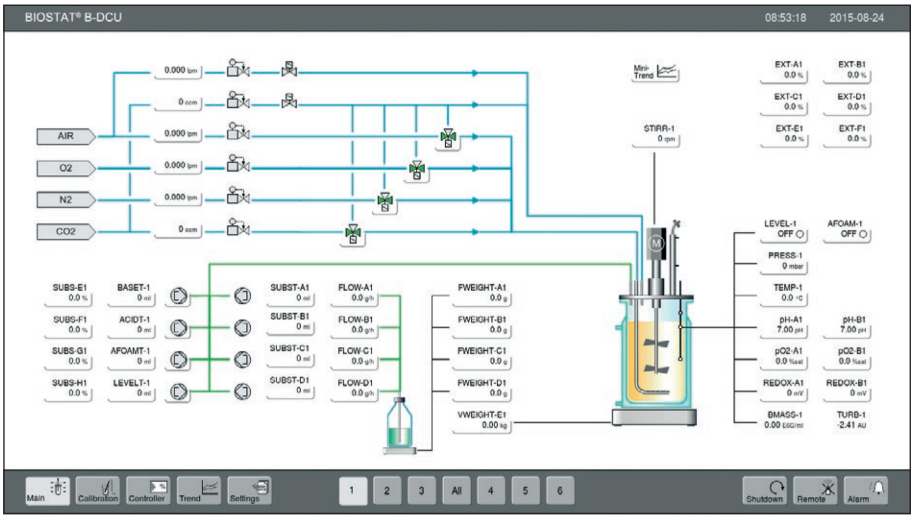



Fig. 8-2: "Main Overview #1" screen for a 6-way system

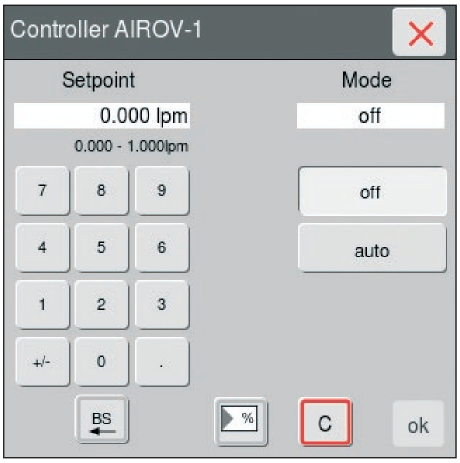
The graphical display of the system structure simplifies the overview of the system components. Pressing the function elements provides access to the submenus for the most important or most frequently used settings. If practical, the function elements also show the currently entered or configured data and settings.

Which function elements are actually shown depends on the configuration of the DCU system, the controlled device, e.g., the type of device, and customer specifications.

### 8.6.2 Process Displays in the "Main" Menu

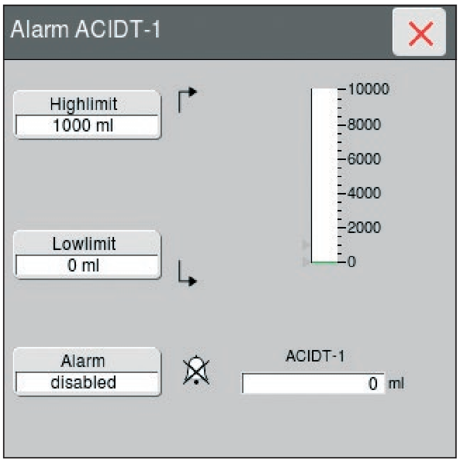
The function elements can display associated process values:
- Values measured by connected probes such as pH, DO, foam, etc.
- Calculated variables like pump filling amounts, calculated values of arithmetic functions, etc.
- Process duration displays.
- Measured data and key figures from external component feedback such as speed control, mass flow controllers, balances, etc.

### 8.6.3 Direct Access to Submenus

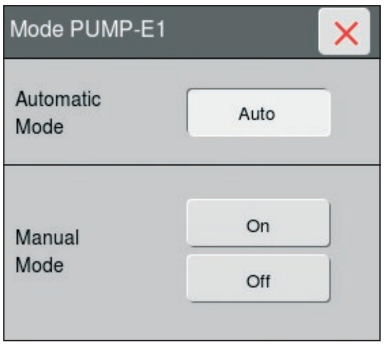



The following menu screens show examples of submenus accessible from the "Main" menu and configuration options for the measurement and control system. Which submenus are available and which parameters can be configured depends on the configuration:

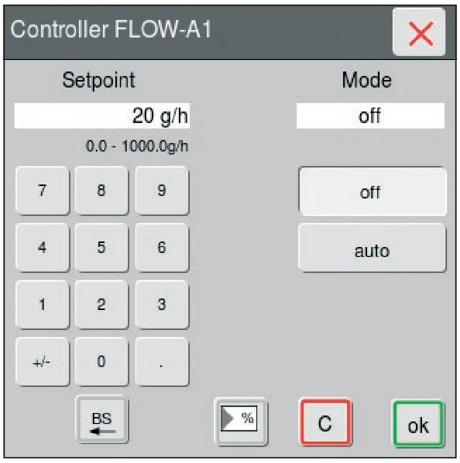
Setpoint specifications and mode selection for headspace aeration (overlay) for air and $CO_2$ and submerged aeration (sparger) for all gases; example "AIR-OV1" menu



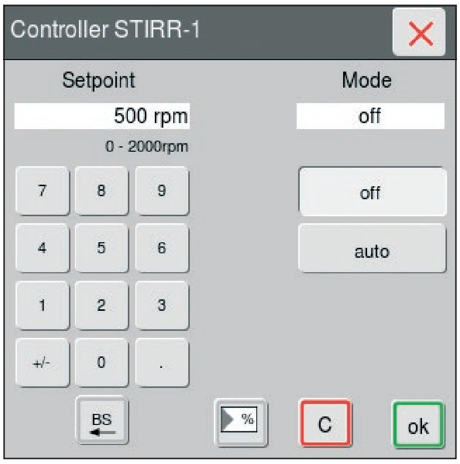

Setting for alarm limits and activation of alarm monitoring for totalizer; example "ACIDT-#"




Mode selection for correction medium pumps, example "PUMP-#1"




Setpoint configuration and mode selection for pumps, example "FLOW-#"




Stirrer speed "STIRR-#"


Pressure measurement, where necessary pressure control (if used) PRESS-#

## 8.7 “Trend” Menu

### 8.7.1 Trend Display

The trend display provides a graphical view of the process value time profiles. 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:

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

Trend displays are not saved. Use a host system (e.g., MFCS) to log this data and permanently document the process values.

▶ To access the trend display: Press the “Trend” main function key.
▷ The trend display appears.


Fig. 8-1: Trend display overview

| No. | Name | Description |
|---|---|---|
| 1 | Channels | Display and configuration of channels 1 to 8 |
| 2 | Time range | Display and configuration of time range for the time bar |
| 3 | Time bar | Display of process time (1 to 72 hours) |
| 4 | Lower limit | Lower limit of the selected value range for each channel |
| 5 | Trend time profile | Display of process values for the selected channels |
| 6 | Upper limit | Upper limit of the selected value range for each channel |

### 8.7.2 Changing the Settings for a Channel

▶ To change the configuration of a channel: Press the desired channel in the trend display, e.g., Channel 4 "DO-#."

▷ The "Channel # Settings" window opens.

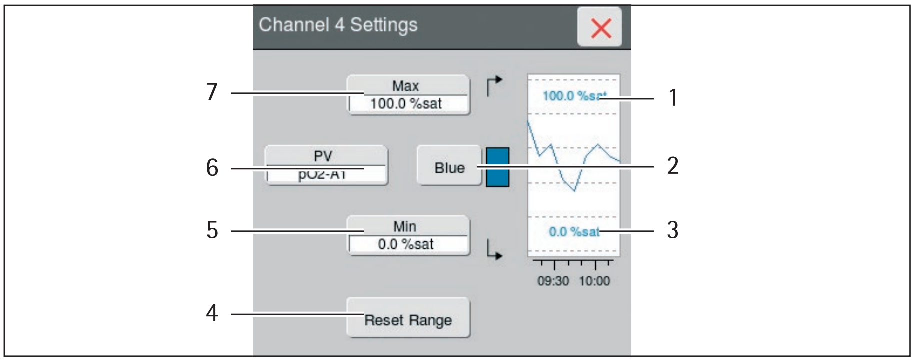



Fig. 8-2: "Channel # Settings" window

| No. | Name | Description |
|---|---|---|
| 1 | 100.0 sat% | Display of current upper limit of value range |
| 2 | Blue | Display and configuration of display color of channel |
| 3 | 0.0 sat% | Display of current lower limit of value range |
| 4 | "Reset-Range" | Reset upper/lower limit of value range to default values |
| 5 | "Min" | Change lower limit of value range |
| 6 | "PV" | Assign process value to channel |
| 7 | "Max" | Change upper limit of value range |

### 8.7.2.1 Assigning a Process Value to a Channel

▶ In the "Channel # Settings" window: Press the "PV" key.
▷ The "Select Buffered Channel" window appears, where a parameter can be assigned to a channel.
▶ To display all parameters in the configuration: Press "Cfg."

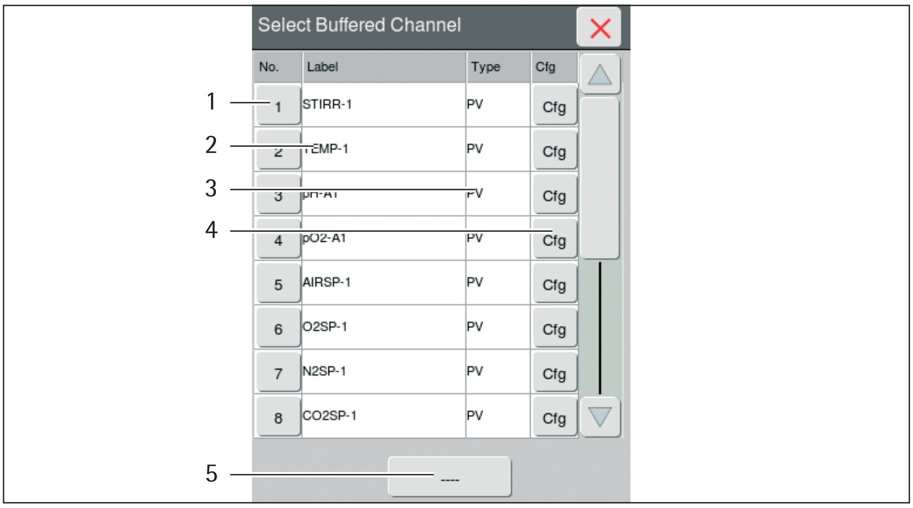



Fig. 8-3: "Select Buffered Channel" window

| No. | Name | Description |
|---|---|---|
| 1 | No | Assign the parameter to the channel |
| 2 | Label | Name of parameter |
| 3 | Type | Type of parameter |
| 4 | Cfg | Assign another parameter to the channel |
| 5 | [ ---- ] | Delete the assignment of the parameter to the channel |

A channel can be assigned the following parameters:
– Process values
– Controller setpoint
– Controller output

## 8.8 "Calibration" Menu

### 8.8.1 General Information

In the "Calibration" menu, all calibration actions required for routine operation can be activated:

- Calibration routines for sensors: e.g., pH, DO ($pO_2$), turbidity
- Sensor function test: e.g., REDOX
- Calibration of pump filling counter: e.g., acid, base, substrate
- Calibration of gas filling counter: e.g., $N_2$, $O_2$, $CO_2$

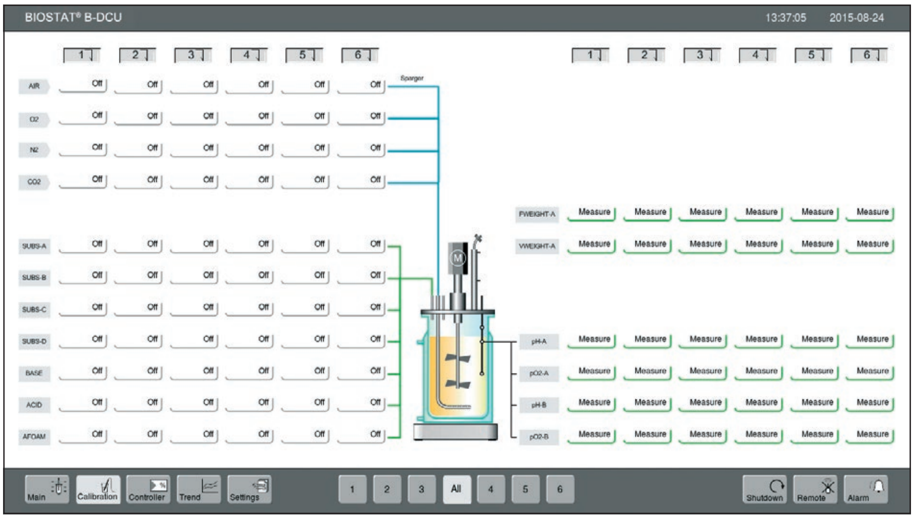



Fig. 8-1: Overview menu for multiple systems (shows the most important calibration functions for all systems)

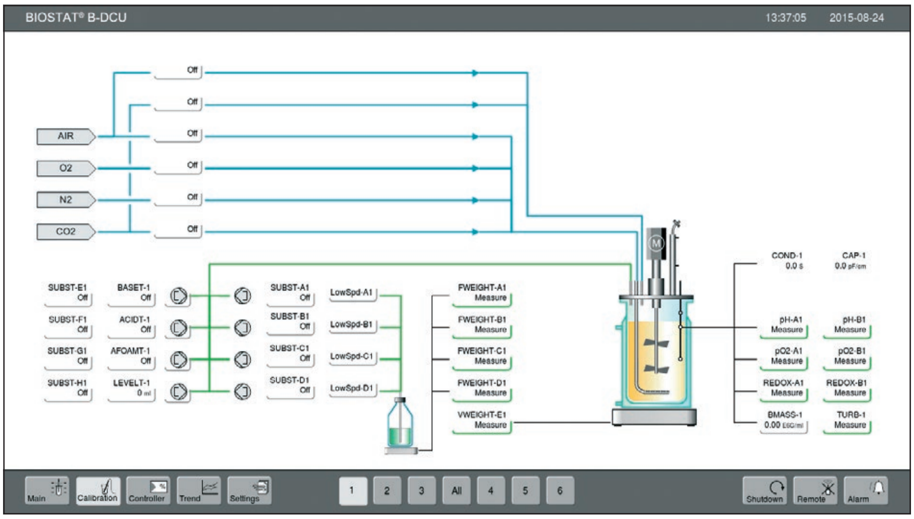



Fig. 8-2: Overview menu for the individual subunit (shows all calibration functions included in the configuration)

After pressing the "Calibration" main function key, the calibration menu opens. Operating displays show the status of the associated calibration functions and open the associated submenu in order to carry out calibration routines. Operating instructions on the individual steps and required entries on the operating display lead the user through the menus.

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.

### 8.8.2 Group or Single 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, so the process is not described in detail a second time. Please observe the following notes on group calibration, however:

– Allows for simultaneous calibration of all connected pH sensors or DO ($pO_2$) sensors.
– All sensors are calibrated each time; it is not possible to carry out group calibration on a selected group of sensors.
– Group calibration is only possible for conventional and digital sensors, not for optical sensors.
– No direct input of zero point offset and sensor slope is possible.
– Sensors cannot be recalibrated.

#### Selecting the Calibration Type

▶ Press the key for the sensor to be calibrated (e.g., "pH-#") in the "Calibration" menu.
▷ A selection for the type of calibration appears.

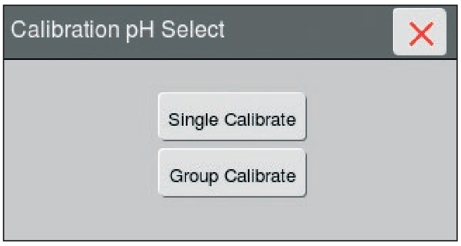



Fig. 8-3: Single or group calibration selection menu (example for pH sensors)

| Field | Function, input required |
|---|---|
| Single Calibrate | Calibration of a pH sensor |
| Group Calibrate | Simultaneous calibration of all pH sensors |

▶ Select the type of calibration.
▷ When "Single Calibrate" is selected, the "Calibration pH-#" submenu appears.
▷ When "Group Calibrate" is selected, the "Group Calibration pH" submenu appears:

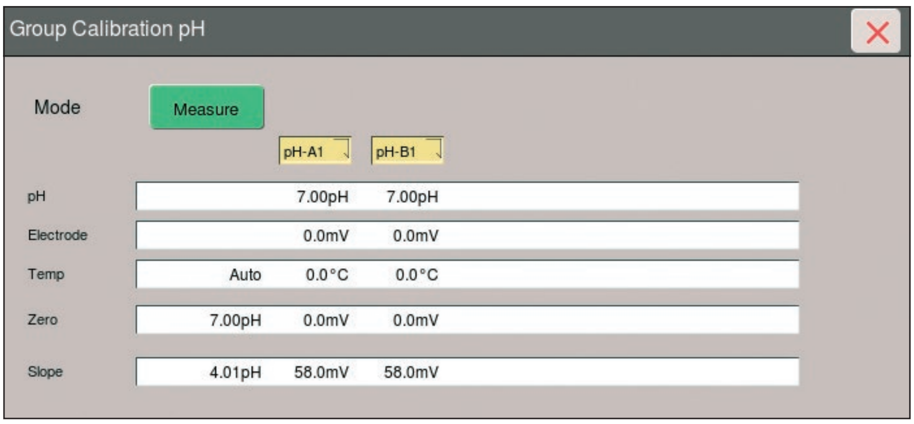



Fig. 8-4: Overview menu of all connected sensors (in this example, conventional pH sensors)

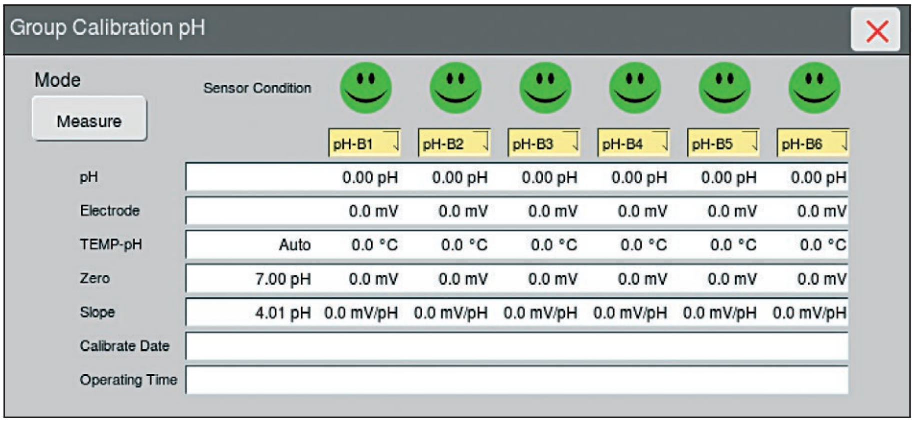



Fig. 8-5: Overview menu of all connected sensors (in this example, digital pH sensors)

Detailed information on calibrating individual sensors can be found in the following chapters.

### 8.8.3 pH Calibration (Conventional Sensor)

#### 8.8.3.1 General Information on pH Sensors

Conventional pH sensors are calibrated using a two-point calibration with buffer solutions. During pH measurement, the system calculates 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 you can enter the reference temperature manually; during pH measurement temperature compensation is carried out automatically based on the temperature measurement value in the bioreactor.

Sensors are calibrated before installation at the point of measurement, e.g., in the culture vessel.
Sterilization can alter the sensor zero point. To recalibrate the pH sensors, you can measure the pH value externally in a sample taken from the process and enter the value into 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. Test 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. Information on reordering is available on request.
– If the "zero offset" and "slope" values are known and the process allows, you can also enter these values directly into the relevant fields.
– The sensor's service life is limited and depends on the in-process working and operating conditions. Whenever a function check or calibration points to a malfunction, the pH sensor 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 measuring range (pH 2.00 pH–12.00 pH) when the sensor is sterilized, replaced, or ages. If this occurs, calibrate the sensor again or check the quality of the sensor.

- The pH sensors must be serviced or replaced when the following values are outside the specified range*:
  - Zero point offset ("zero") outside -30 to +30 mV
  - Slope is outside the range of 56 ... 59 mV/pH.
- Depending on the type and design of the sensors supplied, the menus, sequence, and operation of the calibration function can differ from the information provided herein. Please refer to the configuration documents or to the function specifications of the device, if available.

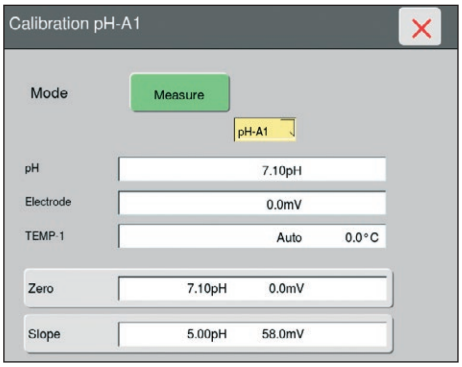
* These values apply to pH sensors from the manufacturers Hamilton and Mettler Toledo. If you use other manufacturers' products, please refer to the manufacturer's documentation.

#### 8.8.3.2 "Calibration pH-#" Submenu

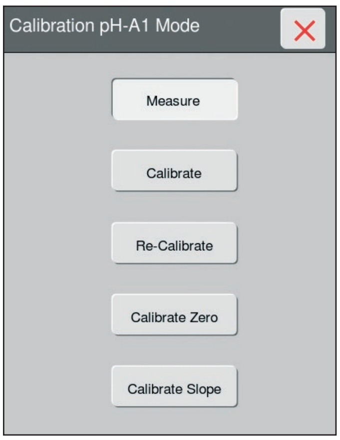
The "Calibration pH-#" submenu shows both the pH value and the measurement chain voltage of the sensors, as well as the zero offset ("zero") and slope sensor parameters. That allows you to easily check the functionality of the pH sensors.

▶ Press the key for the sensor to be calibrated ("pH-#") in the "Calibration" menu.

▷ The "Calibration pH-#" submenu opens:




| Field | Value | Function, input required |
|---|---|---|
| Mode | Measure | – Open the "Calibration pH-# Mode" submenu<br>– Automatic switch to pH measurement after calibration routine is completed |
| | Calibrate | – Perform full calibration |
| | Recalibrate | – Perform recalibration (for Single Calibrate only) |
| | Calibrate Zero | – Perform zero point calibration as a single step |
| | Calibrate Slope | – Perform slope calibration as a single step |
| pH | pH | Display of pH measured value |
| Electrode | mV | Combination electrode voltage (raw signal) |
| TEMP | °C | Temperature value for temperature compensation |
| Zero | mV | Display/input of the zero point offset |
| Slope | mV/pH | Display/input of the slope |
| Manual | | Temperature compensation with entry of a temperature measured manually outside the culture vessel |
| Auto | | Temperature compensation with the temperature measured in the culture vessel (DCU system) |



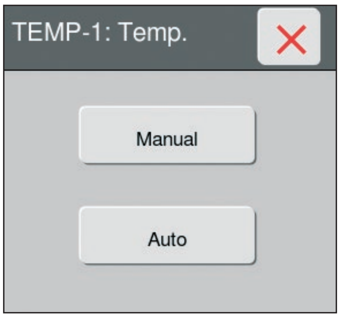

▶ Press the "Measure" key in the "Calibration pH-#" submenu.

▷ The "Calibration pH-# Mode" submenu opens.

### 8.8.3.3 Performing Calibration

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

**Selecting/Entering Temperature Compensation**




- ▶ Press the "Calibrate" key in the "Calibration pH-# Mode" submenu.
- ▶ Select the type of temperature compensation.
- ▶ If "Manual" is selected: Enter the value for temperature compensation.
- ▷ The input window "pH-#: Zero Buffer" for zero point calibration is displayed.

**Zero Point Calibration**


- ▶ Hold the pH sensor in a buffer solution (generally 7.00 pH).
- ▶ In the input window "pH-#: Zero Buffer," input the pH value of the buffer solution.
- ▶ Observe the measured value display in the window "pH-#: Zero Value." Once the display is stable, confirm the measurement with "OK."

**Slope Calibration**


- ▶ 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.
- ▶ Observe the measured value display in the window "pH-#: Slope Value." Once the display is stable, confirm the measurement with "OK."
- ▷ The pH sensor is calibrated.

#### 8.8.3.4 Direct Input of the Zero Offset and Slope

**Zero Offset**

▶ Press the “Zero” key in the “Calibration pH-#” submenu.
▶ 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.

**Slope**

▶ Press the “Slope” key in the “Calibration pH-#” submenu.
▶ 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.

#### 8.8.3.5 Perform recalibration

By following the operating steps described below, you can adapt the calibration of a pH sensor to changed measuring conditions after a sterilization cycle in the autoclave or during the process as needed:


▶ Take a sample from the process.
▶ Measure the pH value of the sample with a calibrated pH measurement device.
▶ Press the “Re-Calibrate” key in the “Calibration pH-# Mode” submenu.
▶ Enter the pH value measured with the measurement device.

▷ The DCU system calculates the zero offset and displays the corrected pH value.

### 8.8.4 pH Calibration (Digital Sensor)

#### 8.8.4.1 General Information on pH Sensors

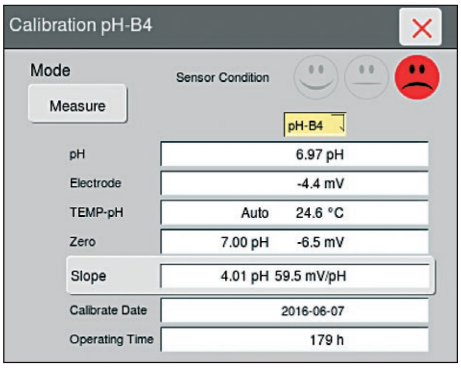
The digital pH sensor uses the same measurement principle as the conventional pH sensor. The electronics integrated in the sensor head save all relevant sensor data, such as the compensated measurement signals, calibration data, and other diagnostic information. This sensor data is read out by the DCU system and further processed.

### 8.8.4.2 "Calibration pH-B#" Submenu

The "Calibration pH-B#" submenu shows both the pH value and the measurement chain voltage of the sensors, as well as the zero offset ("zero") and slope sensor parameters. That allows you to easily check the functionality of the pH sensors.

▶ Press the key for the sensor to be calibrated ("pH-B#") in the "Calibration" menu.

▷ The submenu "Calibration pH-B#" opens:

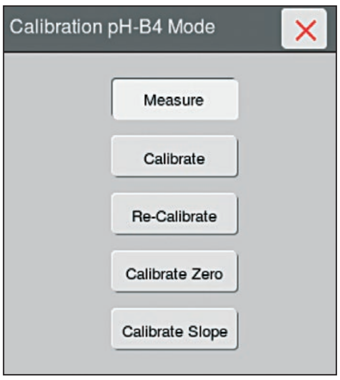



| Field | Value | Function, input required |
|---|---|---|
| Sensor Condition * |  | Sensor condition excellent;<br>further cultivation with sensor possible |
| |  | Sensor condition moderate;<br>approx. 80% of sensor service life reached. A new sensor should be kept in reserve or procured to replace the sensor currently in use |
| |  | Sensor condition poor;<br>No further cultivation with sensor possible |
| Mode | Measure | – Open the "Calibration pH-B# Mode" submenu<br>– Automatic switch to pH measurement after calibration routine is completed |
| | Calibrate | – Perform full calibration |
| | Recalibrate | – Perform recalibration<br>(for Single Calibrate only) |
| | Calibrate Zero | – Perform zero point calibration as a single step |
| | Calibrate Slope | – Perform slope calibration as a single step |
| pH | pH | Display of pH measured value |
| Electrode | mV | Combination electrode voltage (raw signal) |
| TEMP | °C | Temperature value for temperature compensation |
| Zero | mV | Display of the zero offset |
| Slope | mV/pH | Display/input of the slope |
| Calibrate Date | | Time of the last calibration |
| Operating Time | | Operating duration of the sensor |

* The sensor condition is calculated from the following factors:
- Zero offset and slope
- Calibration interval
- Change of the measured value due to recalibration and wear (a function of the operating time and temperature)

▶ Press the "Measure" key in the "Calibration pH-B#" submenu.

▷ The submenu "Calibration pH-B# Mode" opens.



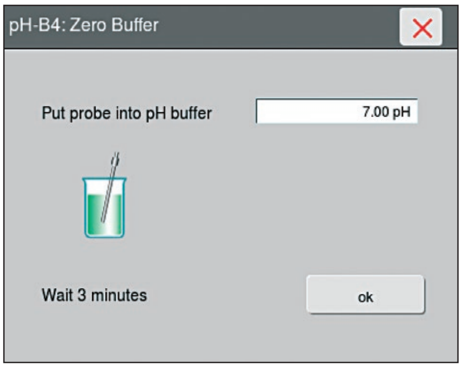
### 8.8.4.3 Performing Calibration

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

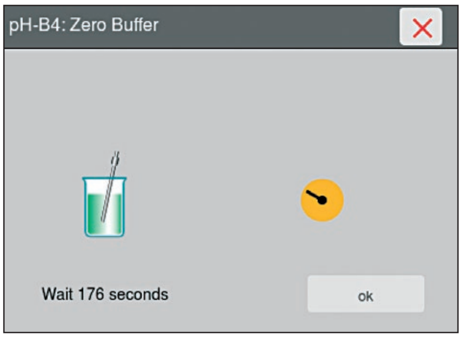
▶ Press the "Calibrate" key in the "Calibration pH-B# Mode" submenu.

**Zero Point Calibration**

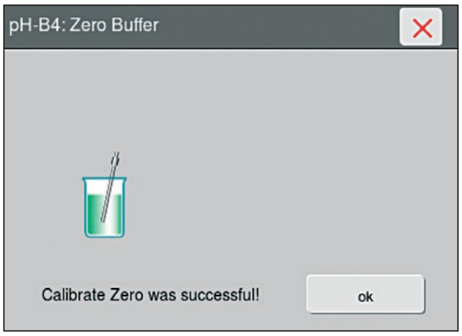
▷ The input window "pH-B#: Zero Buffer" for zero point calibration is displayed.
▶ Hold the pH sensor in a buffer solution (generally 7.00 pH).
▶ Start the calibration with "OK."




▷ Wait for the zero point calibration to take place (approx. 3 minutes).

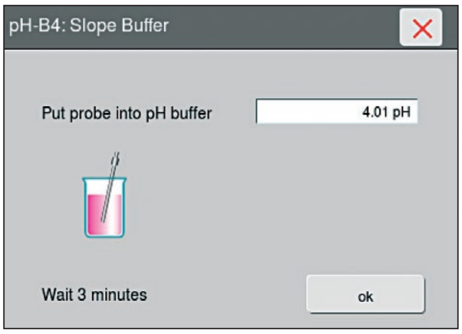


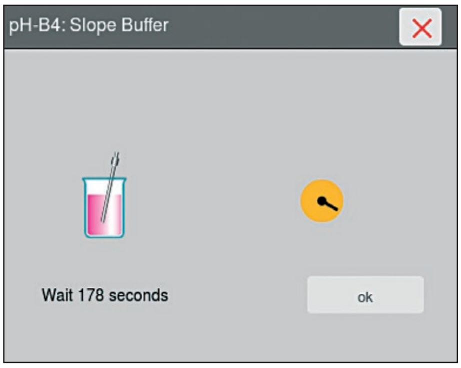

▶ Confirm the zero point calibration by pressing "OK."



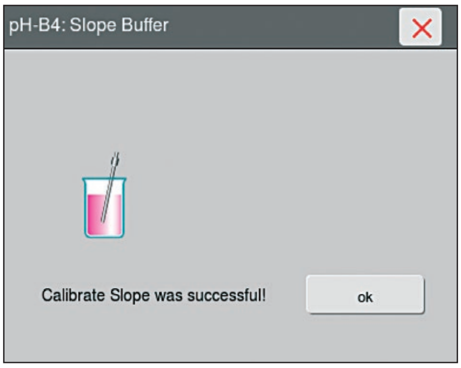

**Slope Calibration**

▶ Hold the pH sensor in the second buffer solution.
▶ Start the calibration with "OK."






▷ Wait for the slope calibration to take place (approx. 3 minutes).




▷ Confirm the slope calibration with "ok."

▷ The pH sensor is calibrated.

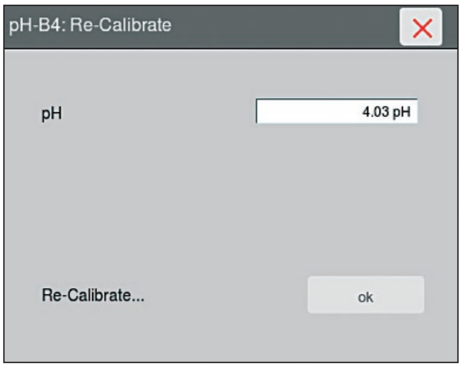
### 8.8.4.4 Direct Input of the Slope

▶ Press the "Slope" key in the "Calibration pH-B#" submenu.
▶ In the input window "pH-B#: Slope Buffer," input the pH value.

### 8.8.4.5 Perform recalibration

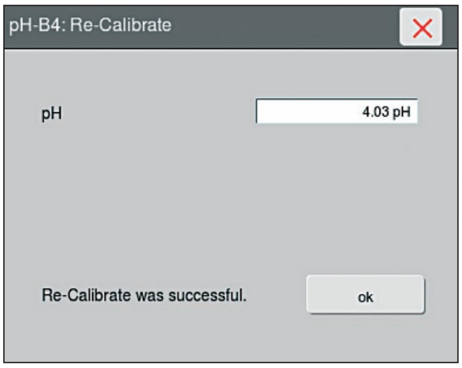
By following the operating steps described below, you can adapt the calibration of a pH sensor to changed measuring conditions after a sterilization cycle in the autoclave or during the process as needed:

▶ Take a sample from the process.
▶ Measure the pH value of the sample with a calibrated pH measurement device.
▶ Press the "Re-Calibrate" key in the "Calibration pH-B# Mode" submenu.
▶ Enter the pH value measured with the measurement device.




▶ Wait for recalibration to take place.

▷ The DCU system calculates the zero offset and displays the corrected pH value.

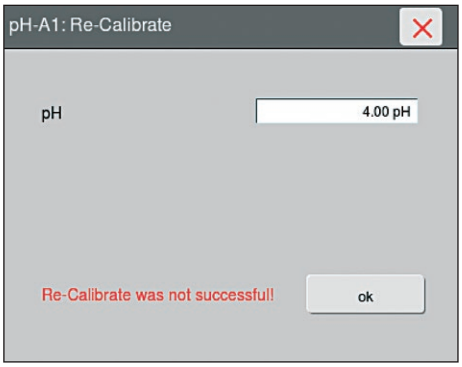



▶ Confirm the recalibration with "ok."

The sensor status display may change after a recalibration if it differs too greatly from the initial calibration.

Possible causes for this can include:

– Wear to the probe (aging)
– Damage to the probe (in particular to the glass)
– Errors when performing the calibration (erroneous reference measurement, operating errors, etc.)




Should the recalibration differ from the initial calibration by more than ± 2 pH, the recalibration will be rejected by the system. In this case, the alarm message ["Recalibration not successful"] will appear.

### 8.8.5 DO ($pO_2$) Calibration (Conventional Sensor)

#### 8.8.5.1 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 the basis for determination of the slope. Since you will be calibrating the sensor after sterilization, changes in the measuring properties that can result from heat exposure or effects of the medium during sterilization should be taken into consideration.

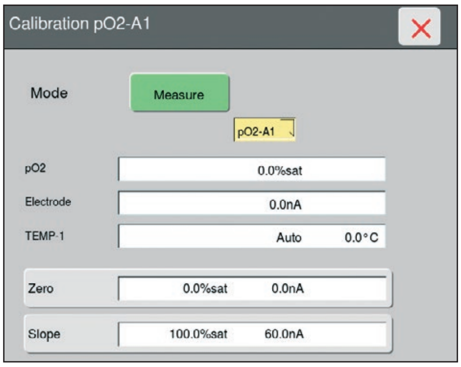
Prior to first use or whenever the DO ($pO_2$) sensor has been disconnected from the power supply (measurement amplifier) for longer than 5 to 10 min., it has to be polarized. Polarization can take up to 6 hours (less time when the sensor was only disconnected from the measurement amplifier for a few minutes). This does not apply to optical DO ($pO_2$) sensors (e.g. VISIFERM, manufactured by Hamilton). Follow the sensor manufacturer's instructions.

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 measuring range (0.0–100.0%sat) when the sensor is sterilized, replaced, or ages. If this occurs, calibrate the sensor again or check the quality of the sensor.

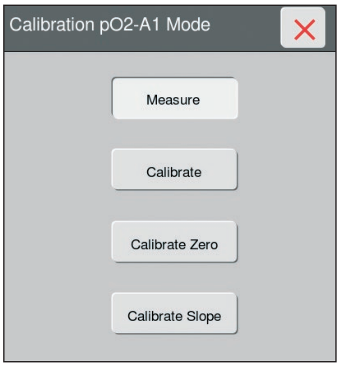
#### 8.8.5.2 "Calibration $pO_2$-#" Submenu

In addition to DO ($pO_2$) saturation, the "Calibration pO2-#" submenu also shows the current sensor current as well as the zero current and slope with calibration conditions. This enables easy regulation of the sensor's functions.

▶ Press the key of the sensor to be calibrated ("pO2-#") in the "Calibration" menu.
▷ The "Calibration pO2-#" submenu opens:




| Field | Value | Function, input required |
|---|---|---|
| Mode | Measure | – Open the Mode submenu<br>– Automatic switch to DO ($pO_2$) measurement after calibration routine is completed |
| | Calibrate | – Perform full calibration |
| | Calibrate Zero | – Perform zero point calibration as a single step |
| | Calibrate Slope | – Perform slope calibration as a single step |
| DO ($pO_2$) | %sat | Display of DO ($pO_2$) saturation |
| Electrode | nA | Measurement chain current (raw signal) |
| TEMP | °C | Temperature value for temperature compensation |
| Zero | %sat/nA | Display/input of the zero point offset |
| Slope | %sat/nA | Display/input of the slope |
| Manual | | Temperature compensation with entry of a temperature measured manually outside the culture vessel |
| Auto | | Temperature compensation with the temperature measured in the culture vessel (DCU system) |

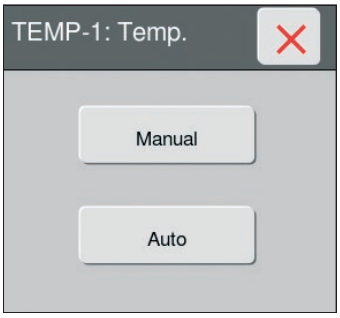



▶ Press the “Measure” key in the “Calibration pO2-#” submenu.
▷ The “Calibration pO2-# Mode” submenu opens.

#### 8.8.5.3 Performing Calibration

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:
– the zero point is not within the range of 0 … +10 nA (“pO2-#: Zero Value” window),
– the sensor current at maximum aeration with air is lower than 30 nA (“pO2-#: Slope Value” window).




**Selecting/Entering Temperature Compensation**

▶ Press the “Calibrate” key in the “Calibration pO2-# Mode” submenu.
▶ Select the type of temperature compensation.
▶ If “Manual” is selected: Enter the value for the temperature compensation and confirm the entry with “OK.”

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


**Zero Point Calibration**

Zero point calibration of the DO ($pO_2$) sensor can be performed as follows:
– on the laboratory table in a gel sample (0% oxygen saturation),
– in medium gassed with nitrogen (as described in the following):
▶ Install the DO ($pO_2$) sensor on the culture vessel.
▶ Set the “$N_2$” aeration to 100%, all other aeration to 0%.
▶ Set the stirrer speed (STIRR) to approx. 80% to 100% of the maximum permissible speed.
▶ In the input window “pO2-#: Zero Buffer,” input the DO ($pO_2$) value (typically 0%).
▶ 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.”


**Slope Calibration**

Slope calibration of the DO ($pO_2$) sensor can be performed as follows:
- on the laboratory table in the ambient air,
- in medium gassed with air (as described in the following):

▶ Set the "AIR" aeration to 100%, all other aeration to 0%.
▶ Set the stirrer speed (STIRR) to approx. 80% to 100% of the maximum permissible speed.
▶ In the input window "pO2-#: Slope Buffer," input the DO ($pO_2$) value (typically 100%).
▷ When the raw electrode signal stabilizes near the 60 nA value, the oxygen saturation is approaching the maximum (this value is only applicable to Hamilton sensors).
▶ Observe the measured value display in the window "pO2-#: Slope Value." Once the display is stable, confirm the measurement with "OK."
▷ DO ($pO_2$) sensor is calibrated.

#### 8.8.5.4 Direct Input of the Zero Offset and Slope

**Zero Offset**

▶ 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.

**Slope**

▶ 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.

### 8.8.6 DO ($pO_2$) Calibration (Digital Sensor)

#### 8.8.6.1 General Information on the digital DO ($pO_2$) Sensors

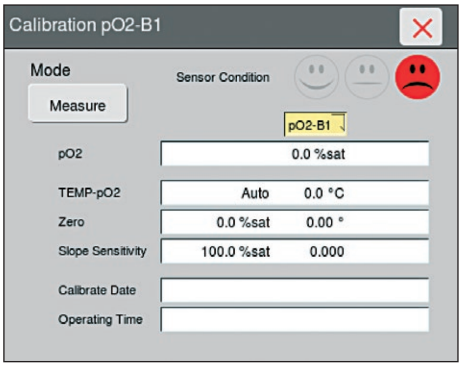
The entire measurement and evaluation of the measurement signal take place in the sensor head. The electronics integrated in the sensor head save other relevant sensor data, such as the calibration data and diagnostic information. This sensor data is read out by the DCU system and further processed.

### 8.8.6.2 "Calibration $pO_2$-B#" Submenu

In addition to DO ($pO_2$) saturation, the "Calibration pO2-B#" submenu also shows the zero current and slope sensitivity with calibration conditions. This enables easy regulation of the sensor's functions.

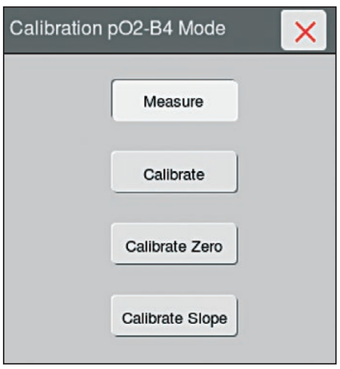
▶ Press the key of the sensor to be calibrated ("pO2-B#") in the "Calibration" menu.

▷ The "Calibration pO2-B#" submenu opens:




| Field | Value | Function, input required |
|---|---|---|
| Sensor Condi-tion * |  | Sensor condition excellent; further cultivation with sensor possible |
| |  | Sensor condition moderate; approx. 80% of sensor service life reached. A new sensor should be kept in reserve or procured to replace the sensor currently in use |
| |  | Sensor condition poor; No further cultivation with sensor possible |
| Mode | Measure | – Open the Mode submenu<br>– Automatic switch to DO ($pO_2$) measurement after calibration routine is completed |
| | Calibrate | – Perform full calibration |
| | Calibrate Zero | – Perform zero point calibration as a single step |
| | Calibrate Slope | – Perform slope calibration as a single step |
| DO ($pO_2$) | %sat | Display of DO ($pO_2$) saturation |
| Electrode | nA | Measurement chain current (raw signal) |
| TEMP-pO2 | °C | Temperature value for temperature compensation |
| Zero | %sat/x.xx° | Display/input of the zero point phase shift |
| Slope Sensitivity | %sat/x.xxx | Display of the slope sensitivity |
| Calibrate Date | | Time of the last calibration |
| Operat-ing Time | | Operating duration of the sensor |

* The sensor condition is calculated from the following factors:
- Zero offset and slope
- Calibration interval
- Change of the measured value due to wear (a function of the operating time and temperature)




▶ Press the "Measure" key in the "Calibration pO2-B#" submenu.

▷ The "Calibration pO2-B# Mode" submenu opens.

#### 8.8.6.3 Performing Calibration

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

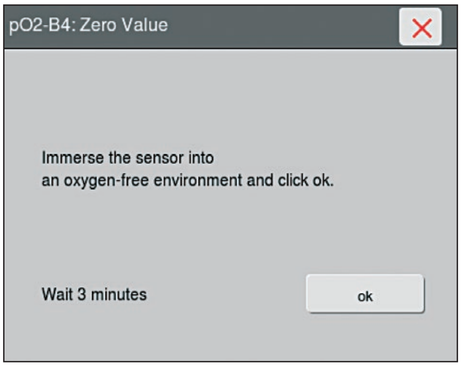
The DO ($pO_2$) sensor must be serviced:

– after every sterilization.
– before the start of each cultivation process.

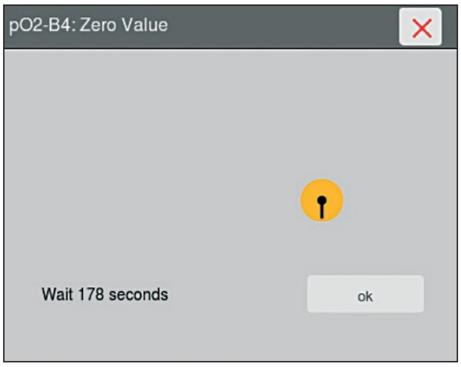
▶ Press the "Calibrate" key in the "Calibration pO2-B# Mode" submenu.

**Zero Point Calibration**

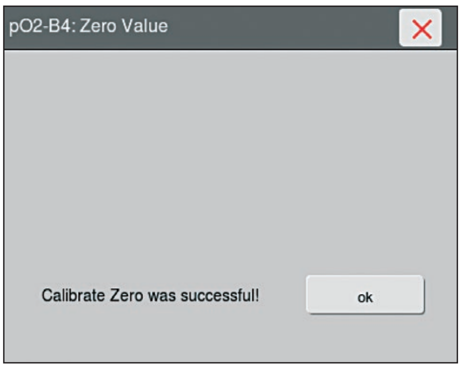
Zero point calibration of the DO ($pO_2$) sensor can be performed as follows:
– on the laboratory table in a gel sample (0% oxygen saturation),
– in medium gassed with nitrogen (as described in the following):



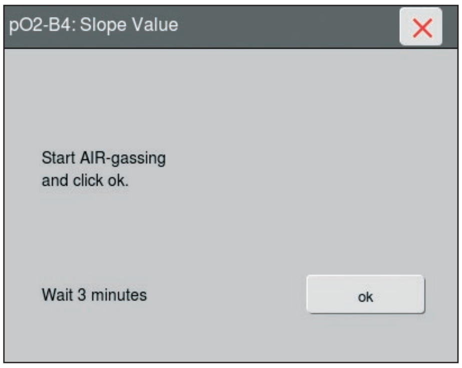

▶ Install the DO ($pO_2$) sensor on the culture vessel.
▶ Set the "$N_2$" aeration to 100%, all other aeration to 0%.
▶ Set the stirrer speed (STIRR) to approx. 80% to 100% of the maximum permissible speed.
▶ Wait until the oxygen dissolved in the medium has been displaced.
▷ When the zero point phase shift stabilizes near the 0.00° value, the oxygen saturation is approaching the minimum.
▶ Observe the measured value display in the window "pO2-B#: Zero Value." Once the display is stable, confirm the measurement with "OK."
▶ Start the zero point calibration with "OK."




▷ Wait for the zero point calibration to take place (approx. 3 minutes).

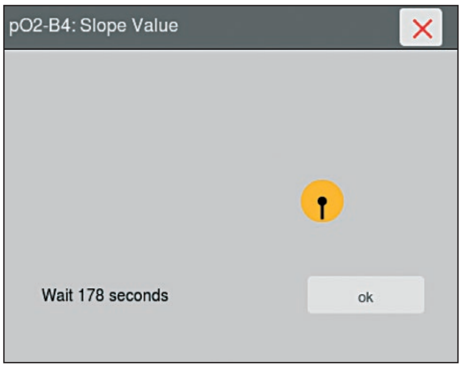



▶ Confirm the zero point calibration by pressing "OK."

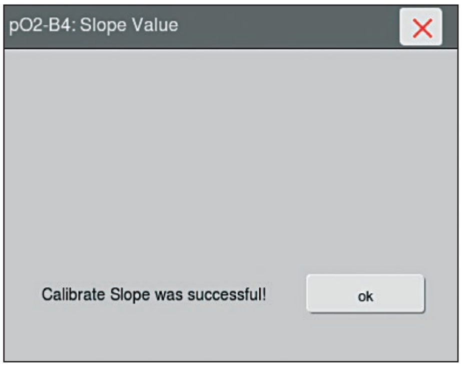



### Slope Calibration

Slope calibration of the DO ($pO_2$) sensor can be performed as follows:
– on the laboratory table in the ambient air,
– in medium gassed with air (as described in the following):
▶ Set the “AIR” aeration to 100%, all other aeration to 0%.
▶ Set the stirrer speed (STIRR) to approx. 80% to 100% of the maximum permissible speed.
▶ Observe the measured value display in the window “pO2-B#: Slope Value.” Once the display is stable, start the calibration with “OK.”




▷ Wait for the slope calibration to take place (approx. 3 minutes).




▷ Confirm the slope calibration with “ok.”

▷ DO ($pO_2$) sensor is calibrated.

### 8.8.7 Optical pH and DO ($pO_2$) Sensors

Sartorius Stedim Biotech's optical sensor technology makes it possible to measure the pH and dissolved oxygen values non-invasively. The sensors are integrated into various systems. On the UniVessel® SU, the sensor patches are located on the bottom of the single-use vessels where they are read off directly via free-space optoelectronics. All systems are evaluated for the cultivation of cell culture and microbial fermentations with scalability ranging from the process development to the production scale.

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## NOTICE

**Sunlight or long exposure to daylight damages the optical pH sensors.**

The optical pH sensors are useless if they are exposed to approximately 8 days of daylight or 2 hours of direct sunlight.

– Calibrate the optical pH sensor just before inoculation and after setting up the UniVessel® SU.

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#### 8.8.7.1 Signal Quality of the Optical Probes

Good contact between the free-space optoelectronics and the sensor is a prerequisite for accurate measurement. The amplitude of the signal is indicative of the signal quality.
In the "Calibration" menu (see Fig. 8-6), the values for the pH and DO ($pO_2$) amplitudes are displayed (without dimensions). You can accept values between 0 and >50,000.

The value is displayed in steps of 1000.
Example: The display value "31" represents an amplitude value of 31,000.

– The PV "pO2_Ampl" shows the signal strength (amplitude) of the DO ($pO_2$) sensor.
– The PV "pH_Ampl" shows the signal strength (amplitude) of the pH sensor.

For precise measurement, the "pO2_Ampl" and "pH_Ampl" values should be greater than 10,000 units after the sensors have been wettened for at least 2 hours. If the value is less than 10,000 units, this indicates a fiber optic cable was not correctly installed.

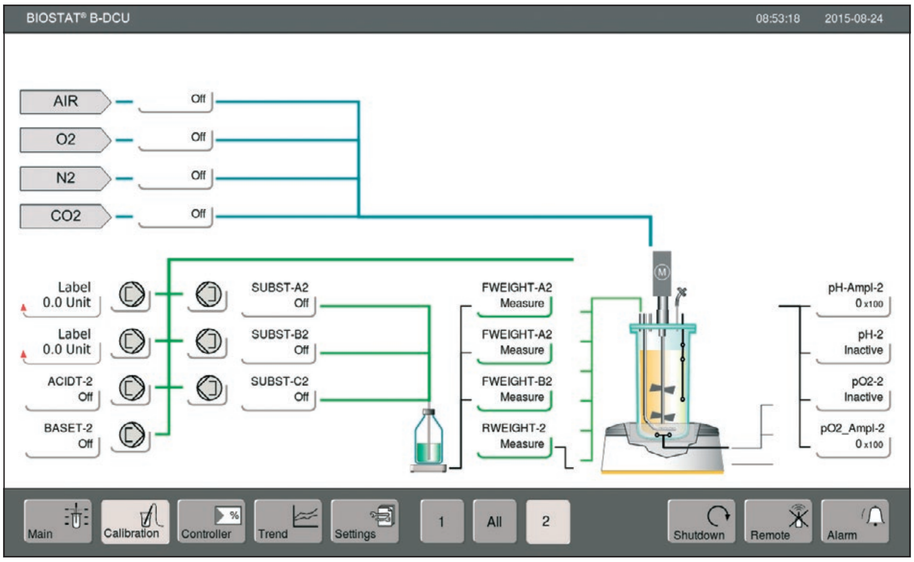



Fig. 8-6: "Calibration 2" main menu with display of the optical probe signal quality

### 8.8.7.2 Notes on Calibration

The indicator strip for the measured value sensors decays when 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 "recalibration" 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.

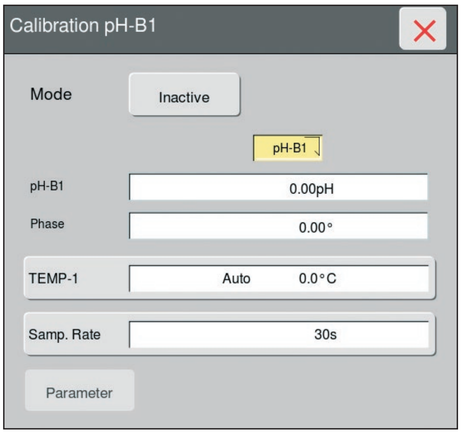
– pH sensor:
  During typical pH calibration, reference valuesfor zero point and slope are measured in calibration buffers. This is not possible with disposable optical pH sensors, as they are pre-sterilized before incorporation into the UniVessel® SUs. Instead, a method was developed that determines the typical measured values pH0/pH and phase-angle f(min)/f(max) for a batch of sensors. This information is provided with the UniVessel® SUs (label sticker with calibration parameters) and entered in the pH calibration menu (see Chapter "8.8.8 pH Calibration (Optical Sensor)," page 101).
– DO ($pO_2$) sensor:
  The typical measured value at 0% and 100% DO ($pO_2$) is determined for a batch of sensors. This information is provided with the UniVessel® SUs (label sticker with calibration parameters) and entered in the DO ($pO_2$) calibration menu (see Chapter "8.8.9 DO (pO2) Calibration (Optical Sensor)," page 106).

## 8.8.8 pH Calibration (Optical Sensor)

To calibrate optical pH sensors, proceed as follows:
▶ Enter the initial calibration data (see Chapter 8.8.8.2, page 103).
▶ Wait until the medium has reached the process temperature.
  Let the probes soak in the medium for at least 2 h.
▶ Take an offline sample and perform a recalibration
  (see Chapter 8.8.8.3, page 104).

It is recommended to recalibrate the pH sensors daily. A recalibration is also necessary if the ionic strength of the medium is changed by adding feed etc.

#### 8.8.8.1 "Calibration pH-#" Submenu

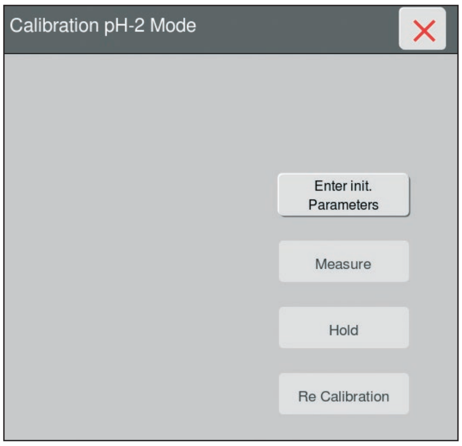



| Field | Value | Function, input required |
|---|---|---|
| Mode | | Display of the active operating mode: Measure, Calibrate, Recalibrate |
| – Inactive | **[Inactive]** | Appears after commissioning, before the first calibration |
| – Calibrate | **[Calibrate]** | Appears when going through the calibration steps |
| – Measure | **[Measure]** | Indicates that the measurement in process is active |
| – Hold | **[Hold]** | Indicates that the measurement in process has been paused |
| – Re-Calibration | **[Re-Calibration]** | Appears during recalibration in process |
| pH | pH | Current pH measured value |
| TEMP | °C | Type of temperature compensation; switch between:<br>– Automatic compensation for pH measurement in process<br>– Manual compensation to calibrate the pH sensor (do not use during normal operation) |
| Samp. Rate | s | Measurement cycle (waiting time between individual measurements)<br>– Setting range: 5 to 3600 s; recommended (default value) 30 s<br>– Choose a measurement cycle that produces a maximum number of measurements at acceptable accuracy (see Chapter "8.8.8.4 Configuring the Measurement Cycle for pH Measurement," page 105) |
| Lot-No. | | Manufacturer reference for released batch of culture vessels |
| Temp Comp | °C | Reference temperature for calibration |
| f (max) | ° | Phase reference, reference pH (reference measurement deviating from the zero point) |
| f (min) | ° | Phase reference, zero point pH (during reference measurement for "zero point") |
| dpH | pH | Reference pH for sensor batch (typical deviation) |
| pHO | pH | Typical zero point for pH sensor batch |
| Meas. Cnts. | | Number of measurements performed |
| Act. Sample | | Recalibration reference value |
| Parameter | | Display of the calibration parameters |

▶ Press the key of the sensor to be calibrated ("pH-B#").
▷ The "Calibration pH-B#" screen opens.

### 8.8.8.2 Entering Initial Calibration Data

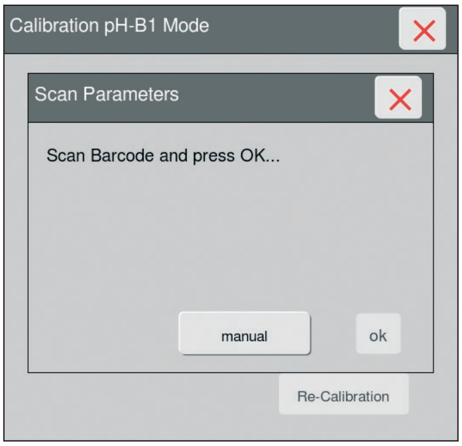
The calibration data to be entered is printed on the UniVessel® SU used. This data must be entered, as no (valid) pH measurement is possible beforehand. (When using the UniVessel ® SU, the calibration data can also be scanned in using the barcode scanner).



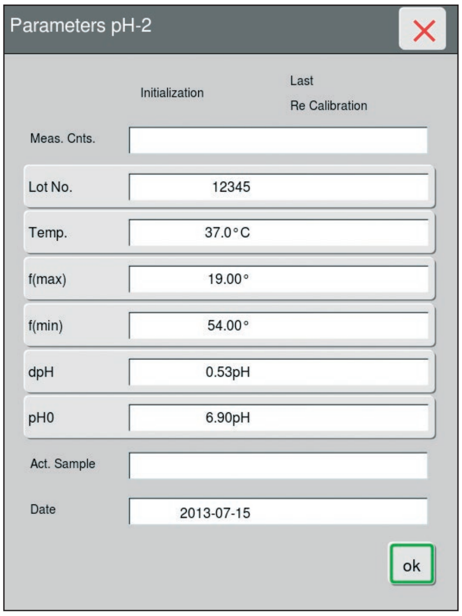

▶ Press the "Inactive" key to open the "Calibration pH-# Mode" window.

**Entering the Parameters**

▶ Press the key "Enter init. parameters" to enter the parameters.
Parameters can be entered in two ways:
– Scanning of the parameters with the barcode scanner
– Manual entry of the parameters

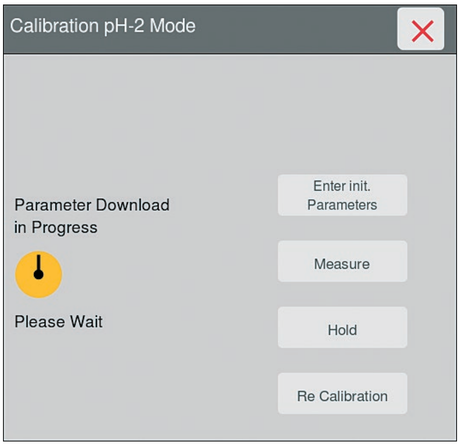



▶ Scan the parameters from the culture vessel label.
▷ Wait until "OK" is active.
▶ **"Manual"**:
Check the scanned parameters or enter the following parameters from the culture vessel label successively into the respective input window and confirm the entry with **"Enter"** or **"OK."**
  – "Lot-No."
  – Temperature compensation
  – "pH f (max)"
  – "pH f (min)"
  – "pH dpH"
  – "pH pHO"
▶ **"OK"**: Confirm the parameters.




▶ Check the parameters displayed.
▶ By pressing the respective key, the corresponding parameter can be modified as necessary.

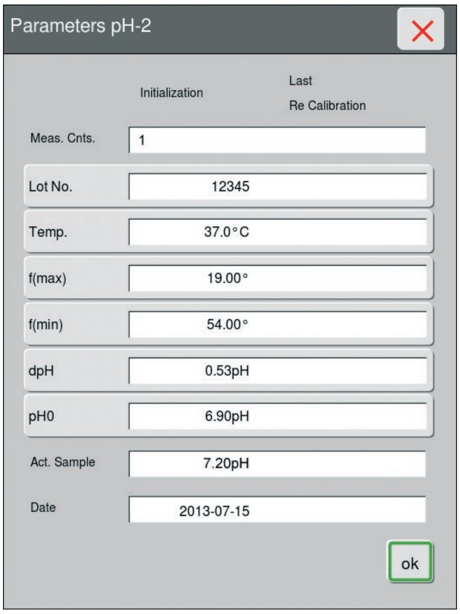
▶ Confirm the manually entered or scanned parameters with **"OK."**




### Transferring the Parameters

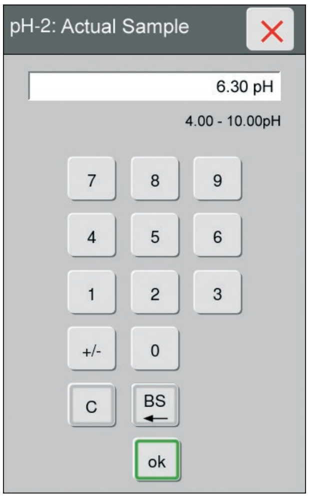
▷ The data is transferred to the DCU system.
▶ Wait until the parameters have been transferred.

▷ The initial calibration of the pH sensor is now complete.




### 8.8.8.3 Performing Recalibration

▶ Press the "Inactive" key to open the "Calibration pH-# Mode" window.
▶ Press the "Re-Calibrate" key to begin recalibration.
▶ Press the key "Act. Sample."
▶ Take a sample from the process.
▶ Measure the pH value of the sample taken with a calibrated pH measurement device.




▶ Enter the pH value measured with the measurement device.
▷ Confirm the input with **"OK."** The DCU system calculates the zero offset and displays the corrected pH value.

Depending on the operating mode, the device switches to **"Measure"** mode automatically or must be manually switched to **"Measure"** mode.
– After successful initialization/calibration, the system switches to **"Measure"** mode automatically.
– After **"Hold"** mode, the device must be switched to **"Measure"** mode manually.

#### 8.8.8.4 Configuring the Measurement Cycle for pH Measurement

Optical 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 pH sensors used in culture bags are designed for 20,000 measurement points.

**Calculating the Measurement Cycle**

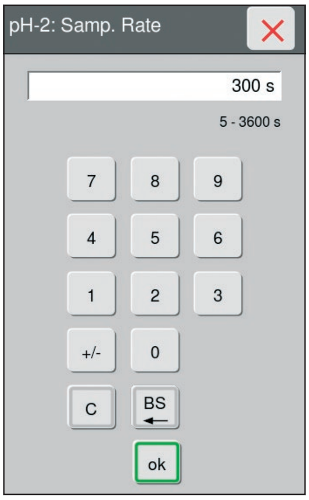
The measurement cycle can be configured so that 20,000 measurements are possible over the total process time.
Example of calculation specifications:
- Overall process time = 666 hours (approx. 28 days)
- Maximum number of measurements = 20,000

Calculation:

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

**Changing the Measurement Cycle**

▶ In the "Calibration pH-#" submenu, press the key "Samp. Rate" to modify the measurement cycle.




▶ Change the value for the pH measurement cycle according to the above calculation.

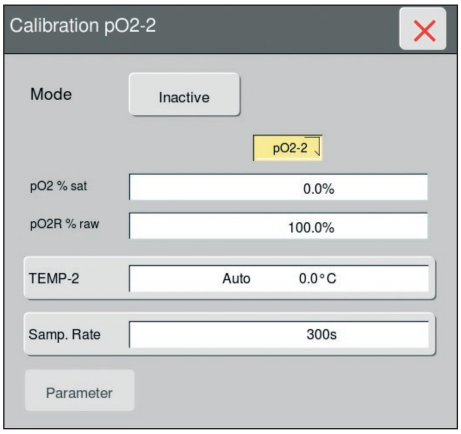
▶ Confirm the input with **"OK."**

### 8.8.9 DO ($pO_2$) Calibration (Optical Sensor)

To calibrate optical DO ($pO_2$) sensors, proceed as follows:

▶ Enter the initial calibration data (see Chapter 8.8.9.2, page 107).
▶ Wait until the medium has reached the process temperature.
Let the probes soak in the medium for at least 2 h.
▶ Take an offline sample and perform a recalibration
(see Chapter 8.8.9.3, page 108).

#### 8.8.9.1 "Calibration pO2-#" Submenu



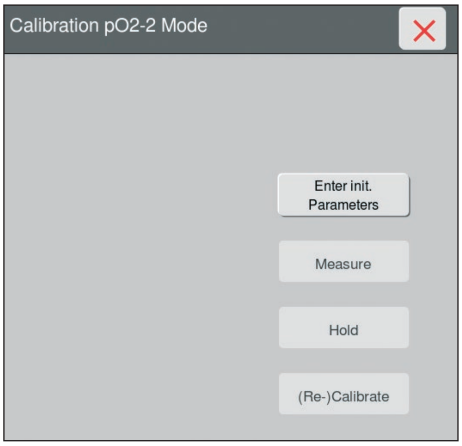

| Field | Value | Function, input required |
|---|---|---|
| Mode | | Display of the active operating mode: Measure, Calibrate, Recalibrate |
| – Inactive | **[Inactive]** | Appears after commissioning, before the first calibration |
| – Calibrate | **[Calibrate]** | Appears when going through the calibration steps |
| – Measure | **[Measure]** | Indicates that the measurement in process is active |
| – Hold | **[Hold]** | Indicates that the measurement in process has been paused |
| – Re-Calibration | **[Re-Calibrate]** | Appears during recalibration in process |
| DO ($pO_2$) | % | Current DO ($pO_2$) measured value |
| TEMP | °C | Type of temperature compensation; switch between:<br>– Automatic compensation for DO ($pO_2$) measurement in process<br>– Manual compensation to calibrate the DO ($pO_2$) electrode (do not use during normal operation) |
| Samp. Rate | s | Measurement cycle (waiting time between individual measurements)<br>– Setting range: 5 to 3600 s; recommended (default value) 5 s<br>– Choose a measurement cycle that produces a maximum number of measurements at acceptable accuracy (see Chapter 8.8.9.4, page 108) |
| Lot-No. | | Manufacturer reference for released batch of culture vessels |
| Temp Comp | °C | Reference temperature for calibration |
| 0% sat | % | Typical reference zero point (zero DO/$pO_2$) of the batch |
| 100% sat | % | Typical reference slope (slope DO/$pO_2$) of the batch |
| Meas. Cnts. | | Number of measurements performed |
| Act. Sample | | Recalibration reference value |
| Parameter | | Display of the calibration parameters |

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

### 8.8.9.2 Performing Initial Calibration

The calibration data to be entered is printed on the UniVessel® SU used. This data must be entered, as no (valid) DO ($pO_2$) measurement is possible beforehand. (When using the UniVessel ® SU, the calibration data can also be scanned in using the barcode scanner).

▶ Press the key of the sensor to be calibrated ("pO2-B#").
▶ Press the "Inactive" key to start initial calibration.

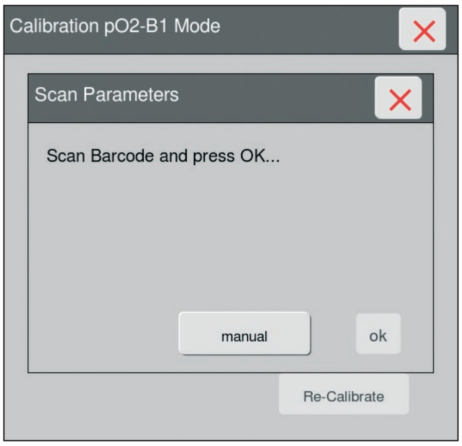



**Entering the Parameters**

▶ Press the key "Enter init. parameters" to enter the parameters.

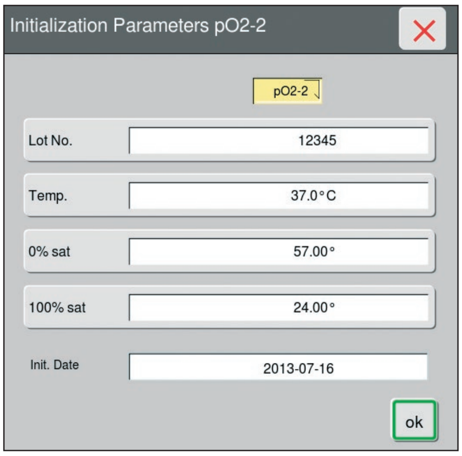
Parameters can be entered in two ways:

– Scanning of the parameters with the barcode scanner
– Manual entry of the parameters



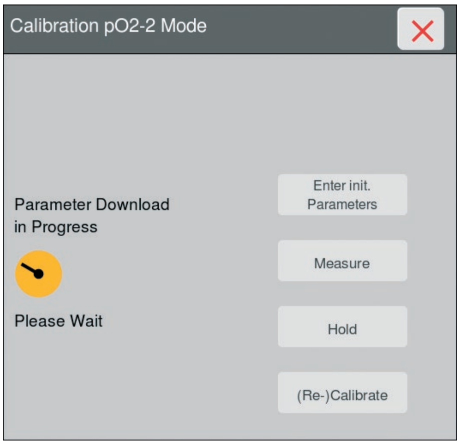

▶ Scan the parameters from the culture vessel label.
▷ Wait until "OK" is active.
▶ **"Manual"**:
Check the scanned parameters or enter the following parameters from the culture vessel label successively into the respective input window and confirm the entry with **"Enter"** or **"OK**."
  – "Lot-No."
  – Temperature compensation
  – "$pO_2$ 0%"
  – "$pO_2$ 100%"

▶ **"OK"**: Confirm the parameters.




▶ Check the parameters displayed.
▶ By pressing the respective key, the corresponding parameter can be modified as necessary.

▶ Confirm the manually entered or scanned parameters with **"OK.**"



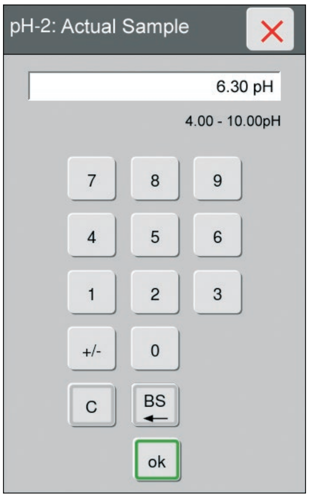

**Transferring Parameters**

▷ The data is transferred to the DCU system.
▶ Wait until the parameters have been transferred.

▷ The initial calibration of the DO ($pO_2$) sensor is now complete.

### 8.8.9.3 Performing Recalibration

▶ Press the "Inactive" key to open the "Calibration pH-# Mode" window.
▶ Press the "Re-Calibrate" key to begin recalibration.
▶ 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.
▶ Enter the DO ($pO_2$) value measured with the measurement device.
▶ Confirm the input with "OK."
▷ The DCU system calculates the zero offset and displays the corrected DO ($pO_2$) value.




Depending on the operating mode the device switches to "Measure" mode automatically or must be manually switched to "Measure" mode.

- After successful initialization/calibration, the system switches to "Measure" mode automatically.
- After "Hold" mode, the device must be switched to "Measure" mode manually.

### 8.8.9.4 Configuring Measurement Cycles for DO ($pO_2$) Measurement

Optical DO ($pO_2$) sensors show decay of the indicator dyes, e.g., photo bleaching.

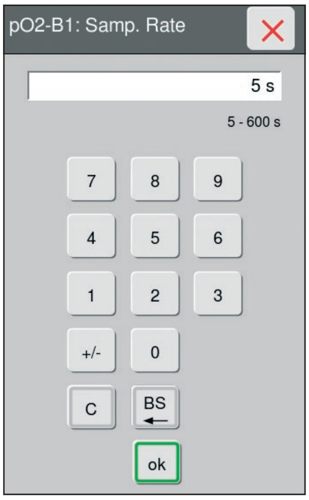
**Calculating the Measurement Cycle**

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 = 1666 hours (approx. 69 days)
- Maximum number of measurements = 200,000

Calculation:
200,000 measurement cycles/1666 hours = 120 measurement cycles/hour
= two measurement cycles/minute

**Changing the Measurement Cycle**

▶ In the "Calibration pO2-B#" submenu, press the key "Samp. Rate" to modify the measurement cycle.




▶ Change the value for the DO ($pO_2$) measurement cycle according to the above calculation.

▶ Confirm the input with "OK."

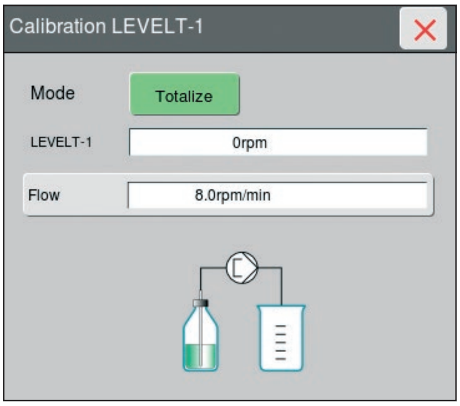
### 8.8.10 Totalizer for Pumps and Valves

**Function**

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 hoses and pumps used, known specific production rates can be entered directly into the calibration menu.

The calibration and filling counter functions are the same for all pumps and solenoid valves. Calibration is described using the example "LEVELT-#."

**Submenu**




| Field | Value | Function, input required |
|---|---|---|
| Mode | Calibrate | – Start calibration |
| | Totalize | – After completion of "Calibrate," the system automatically switches to "Totalize" |
| | Reset | – Reset the filling counter to zero |
| | | Display the volume of liquid being pumped for: |
| LEVELT-# | ml | 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) |
| Flow | ml/min | Directly enter the specific feed rate of the pump or the flow rate of the solenoid valve, if known |

**Preparing for Pump Calibration**

Always use the same type of hose with the same dimensions to calibrate or pump media.
To calibrate, it is recommended that a suitable balance be used, as this is more accurate.

Prior to calibration, the hose must first be filled:

▶ Insert the hose into the pump.
▶ Hang the hose end from the pump inlet into a water-filled beaker.

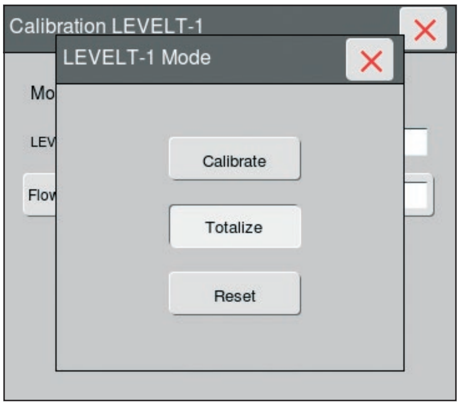
▶ Hang the hose from the pump outlet into a measuring cup that you can use to measure the feed rate.

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.
▶ Deactivate the pump or fill the hose using the rotary switch of the peristaltic pumps (manual, clockwise).

**Performing Calibration**

▶ Press the key of the pump to be calibrated ("LEVELT-#").
Before the first calibration, the "Off" mode is displayed.




▶ Press the "Calibrate" key in the "LEVELT-# Mode" submenu.
▷ The "START calibration with OK" menu is displayed.
▶ Start pump calibration with "OK."

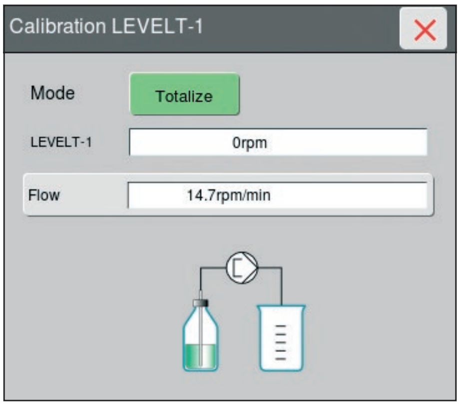
▷ The "STOP calibration with OK" menu is displayed. The pump pumps the medium.

▶ Wait until a sufficient volume has been pumped.
▶ Stop the calibration by pressing "OK."
▶ Read off the feed volume on the measuring beaker.
▶ In the "LEVELT-#: Volume" input window, enter the feed volume and confirm with "OK."
▷ The filling counter is reset and the display mode changes to "Totalize."

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

**Direct Input of the Feed Rate**

If the feed rate as a function of the hoses and pumps used is known, the feed rate can also be entered directly.




▶ Press the "Flow" key in the "Calibration LEVELT-#" submenu.

▶ In the "LEVELT-#: Flow" input window, enter the feed rate and confirm with "OK."

**Resetting the Filling Counter**

▶ Press the "Reset" key in the "LEVELT-# Mode" submenu.
▷ The filling counter is reset.

**Activating the Filling Counter**

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

### 8.8.11 Balance Taring

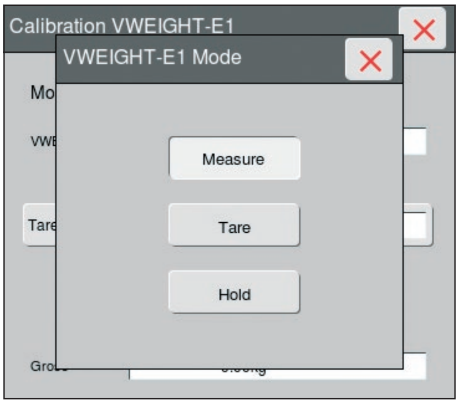
**Function**

The weight of culture vessels, feed bottles, or media and harvest containers can be measured on weighing platforms or pressure gauges.
Any tare corrections required, e.g. after re-equipping the culture vessel or refilling a holding bottle, can be made during running operations. To do so, determine the net weight and adapt the tare weight to the change in weight caused by the changed equipment.

**"Calibration VWEIGHT-#" Submenu**


| Field | Value | Function, input required |
|---|---|---|
| Mode | | Display of the active operating mode |
| – Measure | [Measure] | Indicates that the measurement in process is active |
| – Tare | [Tare] | Zero taring |
| – Hold | [Hold] | Indicates that the measurement in process has been paused |
| | | Display net weight (WEIGHT = gross tare): |
| FWEIGHT-A#/B# | g/kg | Weight of substrate or harvest container |
| VWEIGHT-# | g/kg | Weight of culture vessel |
| BWEIGHT-# | g/kg | Weight of the media or correction media bag |
| Tare | g/kg | Tare weight display or input (DCU system) |
| Gross | g/kg | Gross weight display (measured value of the balance) |

**Zero-taring in Balance/Culture Vessel Example**




- ▶ In the "VWEIGHT-# Mode" submenu, press "Tare" for zero-taring.
- ▷ The "Tare" display (measured value in the DCU system) is set to zero.
  The gross weight "Gross" (measured value of the balance) remains unchanged.

**Tare Correction during Running Operation**


- ▶ Press the "Hold" key in the "VWEIGHT-# Mode" submenu.
- ▷ The "Tare" display is frozen.
- ▶ Make changes to the equipment: for example, re-equipping the culture vessel or refilling a holding bottle.
- ▶ Stop the tare correction by pressing "OK."
- ▷ Despite a change in the gross weight, the "Tare" display remains the same.


### Changing the Tare Weight via Direct Entry

▶ Press the "Tare" key in the "VWEIGHT-#" submenu.
▶ In the "VWEIGHT-#: Tare" input window, input the new weight via the on-screen keypad.
▶ Confirm the weight change with "OK."
▷ The "Tare" display (measured value in the DCU system) is set to the entered value. The gross weight "Gross" (measured value of the balance) remains unchanged.

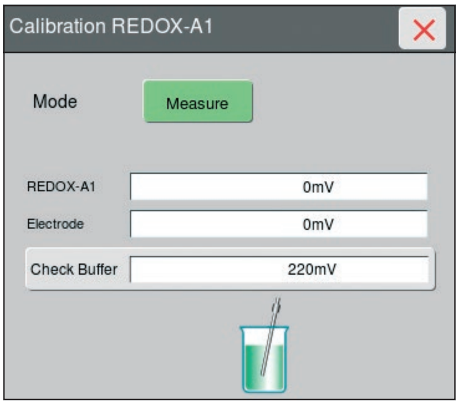
## 8.8.12 Redox Calibration

### Function

The redox calibration covers a function test of the redox electrode (measurement of the redox value of a reference buffer).

During sterilization, thermal effects and interactions with the culture medium can impair the metrological properties of the redox electrode.
You should therefore always check the electrode prior to use.

### "Calibration REDOX-#" Submenu




| Field | Value | Function, input required |
|---|---|---|
| REDOX | mV | Display the combination electrode voltage measured in the reference buffer |
| Electrode | mV | Combination electrode voltage of the last calibration |
| Check Buffer | mV | Enter: Reference current of the reference buffer for the current temperature of the reference buffer (information on the buffer bottle) |

### Calibration

The function test of the Redox electrode is carried out prior to installation in the culture vessel, i.e., before sterilization.
▶ Pour the reference buffer into a measuring beaker.
▶ Place the redox electrode in the reference buffer.
▶ Press "Check Buffer" and enter the reference value of the buffer in [mV], as indicated for the current temperature on the buffer bottle.

When there are deviations of more than 6 mV (approx. 3%), the redox electrode must be serviced. Follow the manufacturer's instructions on the documents supplied with the electrode.

### 8.8.13 Turbidity Calibration

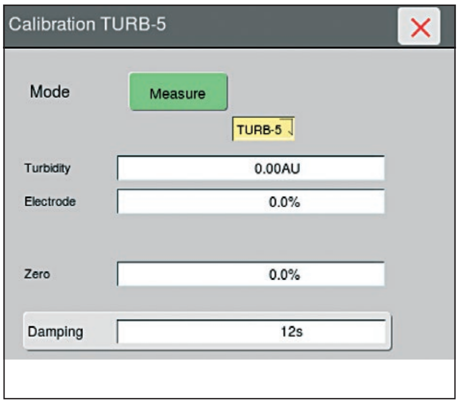
**Function**

Calibrating the turbidity measuring probe determines the electrode parameter "zero offset" by means of a one-point calibration.

Taking the zero point deviation into account, the system calculates the turbidity value as a mean over a defined measuring time in absorption units (AU) and as a function of the damping factor. To obtain stable process values, you can select DAMP in four setting ranges.

The screen for the turbidity electrode displays the absorption units (AU) and the direct electrode raw signal in [%] at the same time, along with the "zero offset" for "0 AU." This allows you to easily check the turbidity sensor's functional capacity.

**"Calibration TURB-#" Submenu**




| Field | Function, input required |
|---|---|
| Turbidity | Display of the process value in [AU] |
| Electrode | Display of the electrode raw signal in [%] |
| Zero | Display of the zero point after calibration in [%] |
| Damp | Set and display signal damping: 6 s, 12 s, 30 s, 60 s |

**Calibration**

- ▶ Place the electrode in the zero point solution.
- ▶ Select the "Calibration" function and
- ▶ Press "Measure" key.
- ▶ In the "Calibration TURB_Unit#" submenu, press the "Measure" key.
- ▶ Press "Calibrate" key.

Depending on the process requirements, you can calibrate the light absorption before inoculation and aeration as a reference parameter. This is possible in particulate and bubble-free water, deionized water, in a suitable buffer, or in the culture medium directly in the culture vessel.

### 8.8.14 Setting the Speed of the Internal Analog Pumps

The speed of the internal analog pumps can be changed. Note that changing the pump speed will affect other process parameters.

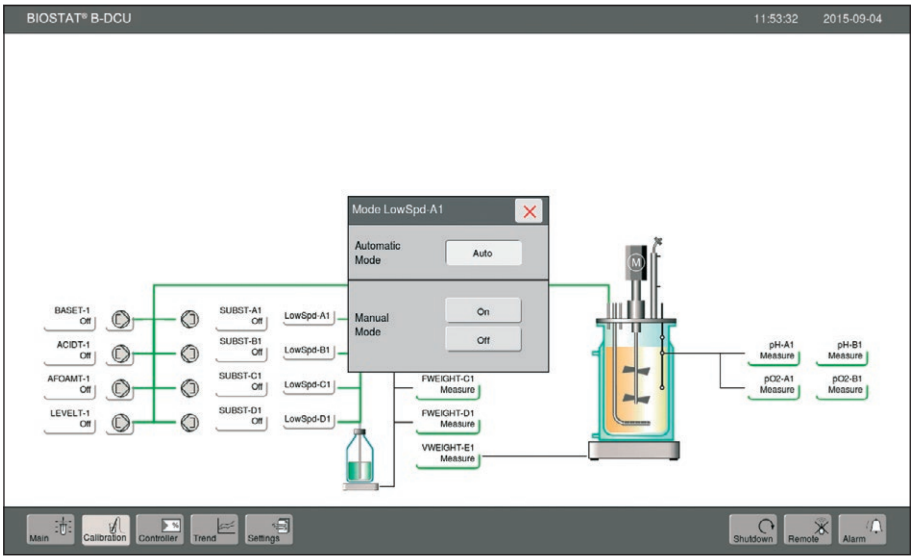



Fig. 8-7: Setting the speed range of the internal analog pumps

▶ In the "Calibration" menu, press the pump to be configured ("LowSpd-##").
▶ In the "LowSpd-##" window, select the following settings:

| Parameter | Value | Speed [n/min] |
|---|---|---|
| Automatic Mode | Auto | 5–150 |
| Manual Mode | | |
| | On | 0–5 |
| | Off | 5–150 |

▷ The pump is set to the desired speed.

The following settings must be adjusted after changing the speed:

– The flow rate of the respective pump totalizer.
  If this setting is not adjusted, the feed volume calculated by the totalizer will deviate significantly from the actual feed volume.
– If the pump is used in the gravimetric filling pump controller (FLOW):
  The WORK MIN and WORK MAX parameters for the filling pump controller.
  If these settings are not adjusted, the control quality of the gravimetric filling pump controller will deteriorate significantly.

## 8.9 "Controller" Menu

### 8.9.1 Functional Principle and Equipment

The control loops in the DCU system work as PID controllers, setpoint generators, or two-point controllers and are adapted to their control circuits. PID controllers can be parameterized to match the control task. The controller outputs control their actuators either continuously or using pulse-width modulation. Single-sided and split range control are implemented.

Which controllers are implemented in a DCU system depends on the device (e.g., bioreactor). Controllers can be customized. Available controllers in the DCU software include:

| Controller | Function |
|---|---|
| "TEMP" temperature controller | PID cascade controller with pulse-width modulated split range outputs for the control of the heater or valve on the cooling water intake with the measured value of the culture vessel temperature as controlling value |
| "JTEMP" double-walled temperature controller | Slave controller for temperature control:<br>– with TEMP controller "off," possible as setpoint generator for heating/cooling |
| Speed regulation (STIRR) | Setpoint generator for external motor controller controlling the stirrer motor |
| pH controller "pH-##" | PID controller with pulse-width modulated split-range outputs:<br>– controls the acid pump or the $CO_2$ feed and base pump |
| DO ($pO_2$) controller "pO2-##" | PID cascade controller for controlling up to 4 slave controllers:<br>– Gas filler controller air, $O_2$, or $N_2$<br>– Gas flow controller<br>– Speed controller<br>– Controller for substrate supply |
| Gas filler controller: | |
| "Additive Flow 2-Gas" module<br>UniVessel® Glass / UniVessel® SU<br>– AIROV-#<br>– AIRSP-# | Slave controller or setpoint generator for gas solenoid valves, pulsed feed:<br>– Air for headspace aeration (overlay)<br>– Air for submerged aeration (sparger) |
| "Additive Flow 6-Gas" module<br>UniVessel® Glass / UniVessel® SU<br>– AIROV-#, AIRSP-#<br>– O2OV-#, O2SP-#<br>– N2OV-#<br>– CO2OV-# | Slave controller or setpoint generator for gas solenoid valves, pulsed feed:<br>– Air for headspace aeration (overlay) and submerged aeration (sparger)<br>– $O_2$ for headspace aeration (overlay) and submerged aeration (sparger)<br>– $N_2$ for headspace aeration (overlay)<br>– $CO_2$ for headspace aeration (overlay) |
| Gas flow controller | Slave controller or setpoint generator for mass flow controller<br>– Each of the gases listed in each segment |
| "AFOAM" anti-foam controller | Pulse pause controller for introduction of "AFOAM" anti-foam agent |
| "LEVEL" controller | Pulse pause controller for "LEVEL" controller |
| "SUBS" substrate controller | Setpoint generator for filling pumps |
| "VWEIGHT" gravimetric level controller | PID controller with pulse-width modulated outlet for pump (harvest and filling operation); works with the weight of the culture vessel "VWEIGHT" as master variable |
| "FLOW" gravimetric filling controller | Setpoint generator for internal or external filling pump; works with the weight of the substrate vessels "BWEIGHT," "FWEIGHT" as master variable:<br>– Only controlled end devices with associated weight measurement |
| "PRESS" pressure controller | PID controller with constant output for pressure control valve:<br>– Only controlled end devices with pressure regulation |

### Controller Mode

You can switch between controller operating modes:

| | |
|---|---|
| Off | Controller switched off with defined output |
| Auto | Controller activated |
| Manual | Manual access to actuator |
| Profile | Selection of previously defined profile.<br>If no profile is defined, the controller automatically switches to "auto" mode |

### 8.9.2 Controller Selection

You can access the operator screens on the controllers of a configuration in various ways:

- For the controllers most frequently used, from the "Main" menu or from the "Controller" menu, both in the "All" view.
- For other frequently used controllers, from the "Main" menu in the detail views for "Unit-1" to "Unit-6."
- For all controllers, from the "Controller" menu in the detail views for "Unit-1" to "Unit-6."

### 8.9.3 General Controller Operation

For the most part, operation of the controller is uniform. It includes setting the setpoints and alarm limits and the selection of the control operating mode. If a controller can control more than one output, the controller output is assigned by means of the parameterization functions that can be accessed using a password. This also applies to controller settings not required during routine operation.

### Controller Screen

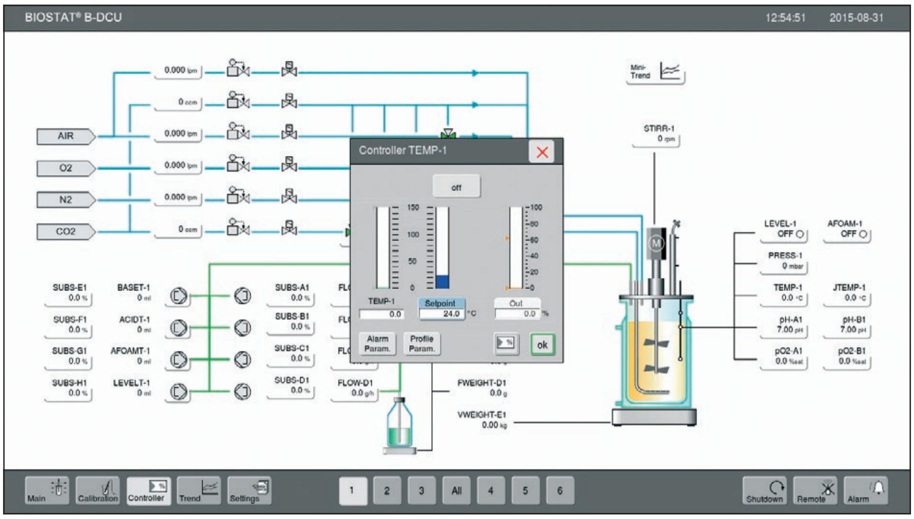



Fig. 8-1: Example, selection of the TEMP-1 temperature controller

| Field | Display | Function, input required |
|---|---|---|
| Controller mode | Selection | Input of the controller mode |

| Field | Display | Function, input required |
|---|---|---|
| Mode | Off | Controller and slave controller switched off |
| | Auto | Controller switched on, slave controller in "Cascade" operating mode |
| | Manual | Manual access to control output |
| | Profile | Selection of previously defined profile. If no profile is defined, the controller automatically switches to "auto" mode |
| Actual value | TEMP-1 | Actual value of process value in the physical unit, e.g., °C for temperature |
| Setpoint | Setpoint | Set value of process value in the physical unit, e.g. °C for temperature |
| Controller output | Out | Display of controller output in % |
| Alarm Parameter | | Input of the alarm limits (high limit, low limit) and switching the alarm on/off |
| Profile Parameter | Profile Param. | Option to input a time-dependent setpoint profile (max. 20 spikes) |
| Function key |  | Access to controller parameters (with password) for cascade controllers: Selection of the slave controller (see Chapter "8.9.5 General Controller Parameterization," page 119) |
| Function key | ok | Confirm entries with "OK" |

### 8.9.4 Setpoint Profiles

**Controller Profile**

The "Profile Parameter" function can be used to navigate to the setpoints of the individual controllers. Time-based setpoint profiles can be set up.

Most control loops can be operated with time-dependent setpoint profiles (Control Loop Profiles). The profile is input into a table using the operator terminal. Jumps and ramps are possible in the profile; however, a profile can have a maximum of 20 spikes. You can start and stop profiles at any time. The elapsed time is displayed for started profiles.

### Accessing Screens

- ▶ Call up the appropriate controller.
- ▶ Press the "Profile Param." key to open the following screen.

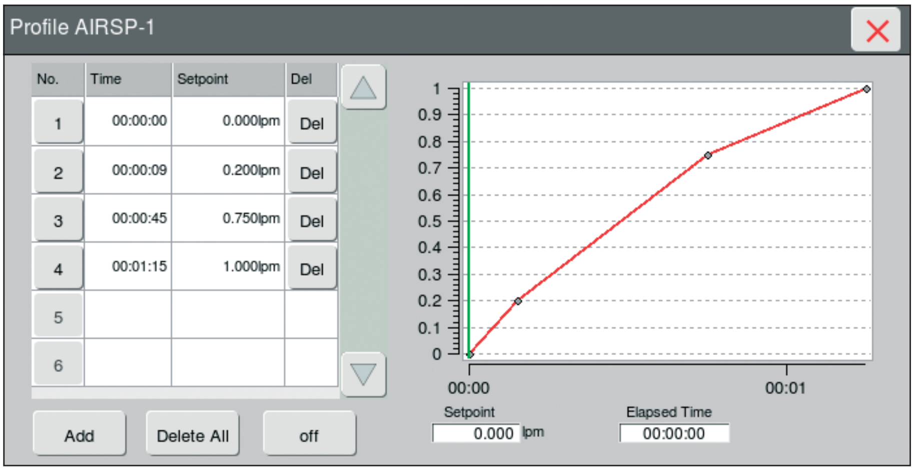



Fig. 8-2: Screen using the example of the AIRSP profile

| Field | Value | Function, input required |
|---|---|---|
| Add | | Add a profile spike |
| Mode | Off | Setpoint profile not active |
| | Profile | Setpoint profile has been started and is being processed |
| Setpoint | [PV] | Display of the current controller setpoint in the physical unit of the process value, e.g., °C for temperature |
| Elapsed Time | h:m:s | Display of elapsed time since profile start in [hours:minutes:seconds]<br>Graphical display of the elapsed time on the profile screen |
| No. | 1–20 | Number of the profile spike |
| Time | h:m:s | Input of the time for the profile spike |
| Setpoint | [PV] | Input of the setpoint for the profile spike in the physical units of the process value, e.g., °C for temperature |
| Del | | Delete a profile spike |

### Operation

We recommend that you create a sketch with spikes and associated setpoints for your profile. The time and setpoints to be programmed can be read directly from the spikes entered into the sketch.

A profile must contain at least one profile spike with a non-zero time in order to be started.

When starting the setpoint profile, the controller mode will automatically be switched to "profile" in the "Controller" menu.

If you do not input the zero time "00:00 h:m" for the first spike, the system will use the current setpoint as the starting time.

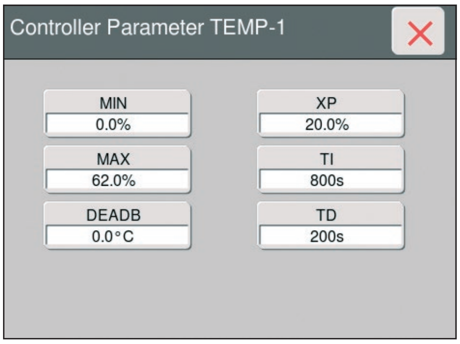
In the case of a setpoint jump, the same time is programmable for both spikes.

When starting a "DO" ($pO_2$) profile, whichever profile for "STIRR," "AIR," or "PRESS" has been started will be automatically stopped and switched to "cascade" mode.

### 8.9.5 General Controller Parameterization

For optimum adaptation of the controller to each control segment, the controller parameters can be changed using the parameterization screens:

**Controller Parameterization Using the Example of a TEMP Controller**




| Field | Display | Function, input required |
|---|---|---|
| MIN, MAX | Value in % | Minimum and maximum output limit for the controller output |
| DEADB | Value example: °C | Dead zone setting (PID controller only) |
| XP, TI, TD | Value in %, sec | PID parameters (PID controller only) |

Parameterization screens are accessible after selecting  on the controller screen and entering a password. DCU systems are configured at the factory with parameters that ensure the stable operation of the control circuits in the device. Factory-configured parameters can be found in the customer-specific configuration documentation.

After entering the password, you have access to the parameterization screen to set PID parameters, output limits, and if necessary a dead zone. In "Remote" operation, the host PC defines the setpoints 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 and DO ($pO_2$) control loops.

#### 8.9.5.1 Output Limits

You can limit the controller output for the target value generator and PID controller downwards (MIN) and upwards (MAX). In this way you can avoid unintentional, extreme actuator controls or limit the setpoint range for the slave controller during cascade control.

- The limits are entered in the MIN (minimum limit) and MAX (maximum limit) fields. The setting is made relative to the overall controller range in %.
- The following limits apply to the full modulation of the controller output:
  - One-sided controller output: MIN = 0%, MAX = 100%
  - Split-range controller output: MIN = -100%, MAX = 100%

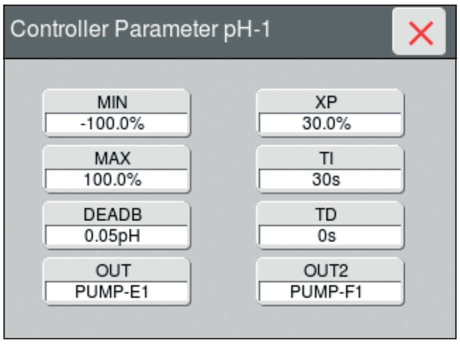
#### 8.9.5.2 Dead Zone

A dead zone can be set up for PID controllers. If the control deviation remains within this dead zone, the controller output maintains a constant value or is set to zero (pH controller). If the nominal values fluctuate stochastically, the dead zone enables more stable control operations with minimized actuator movements. For controls with split-range outputs, this prevents oscillation of the controller output (e.g., constantly changing acid/base proportioning on the pH controller).

- The dead zone is displayed in the DEADB field or configured in the associated submenu. Example for pH controller:

| | |
|---|---|
| Set dead zone | ± 0.1 pH |
| Used setpoint | 6.0 pH |

- In that case, the control loop is inactivated at nominal values between 5.9 pH and 6.1 pH.




#### 8.9.5.3 Controller Parameterization Menu Screen

| Field | Value | Function, input required |
|---|---|---|
| MIN | % | Minimum output limitation, limit value for switch to upstream slave controller |
| MAX | % | Maximum output limitation, limit value for switch to down-stream slave controller |
| DEADB | pH | Dead zone in the unit of the process value |
| XP | % | P share (proportional range); signal amplification of the control response proportional to the input signal |
| TI | sec | Integral portion; time function. With a higher I portion control will react more slowly (and vice versa) |
| TD | sec | Differential portion: Damping, greater D portion, damps the controller response (and vice versa) |
| OUT | | Controller output 1 (only in configurations in which the switching of the output is provided) |
| OUT2 | | Controller output 2 (only in configurations in which the switching of the output is provided) |

#### 8.9.5.4 PID Parameters

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. They allow structural toggles (P, PI, PD, PID) and changing the parameters during ongoing operations.

– The controller structure can be configured by setting individual PID parameters to zero:

| | |
|---|---|
| P controller: | ➡ TI = 0, TD = 0 |
| PI controller: | ➡ TD = 0 |
| PD controller: | ➡ TI = 0 |
| PID controller: | All PID parameters defined |

#### 8.9.5.5 PID Controller Optimization

Knowledge about control technology are prerequisite in order to be able to optimally tune a PID controller to a controlled loop path; otherwise empirically tested tuning methods (e.g., Ziegler Nichols) can be found in the pertinent literature.

As a general guideline:

– Only switch the D portion (TD) if the nominal values are relatively stable. For stochastically variable actual values, the D portion makes fast, large changes to the output. This causes unstable control.
– As a rule, the TI:TD ratio should be around 4:1.
– Periodic oscillations in the control circuit can be counteracted by increasing XP or TI/TD.
– If the adjustments are too slow after setpoint jumps or in the case of nominal value drift, you can lower XP or TI/TD.

### 8.9.6 Guide and Slave Controller (TEMP, JTEMP) Temperature Measurement

Temperature measurement with guide and slave controller is only possible in conjunction with double-walled vessels.

The temperature control works like a cascaded regulation. The TEMP controller uses the temperature measured in the culture vessel as a master value and acts on the mode of the JTEMP slave controller. JTEMP's output controls the assigned actuators through pulse-width modulated or constant outputs in the split-range operation.

Associated actuators can include:

- Electrical heaters in the temperature control circuit
- Electrical heating jackets or heating mats
- Valves of the cooling water supply line(s):
  - Double-walled culture vessel
  - Heating/cooling jacket

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

#### Master Controller TEMP Screen

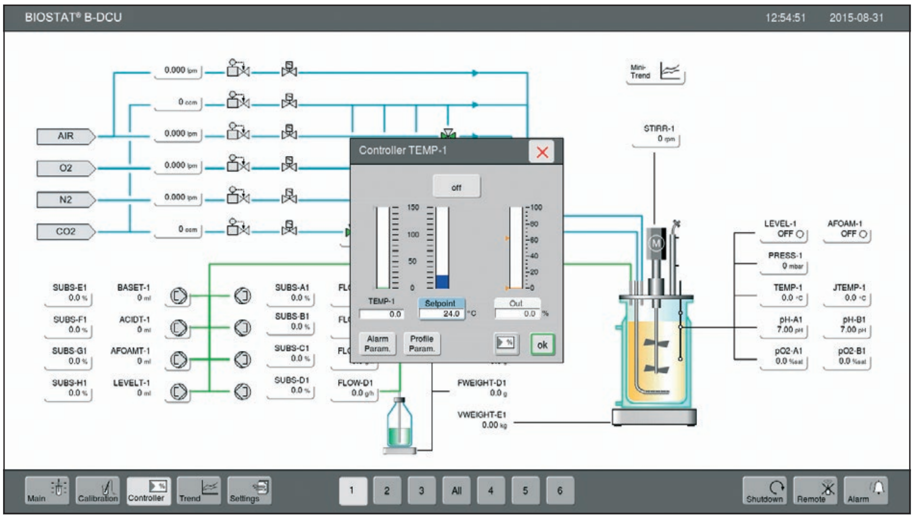



Fig. 8-3: Master controller TEMP-1 screen

#### Operation

Observe the maximum permissible temperatures of the component groups and fixtures your bioreactor is equipped with.

| Culture vessel | Maximum permissible temperatures for "TEMP" master controller |
|---|---|
| UniVessel® Glass double-walled (thermostat) | 80°C |
| UniVessel® Glass single-walled (heating jacket) | 60°C |
| UniVessel® SU heating jacket | 40°C |
| UniVessel® SU (heating/cooling jacket) | 40°C |

The temperature cascade controller is operated from the master controller. You can only change setpoints and operating modes on the "TEMP-#" master controller. All operations of the slave controller "JTEMP-#" are triggered automatically.

- For routine operation, you only need to configure the master controller "TEMP-#" (setpoint, mode, and alarm limits).
- Direct configuration for heating and cooling can be done on the slave controller "JTEMP-#" when the master controller "TEMP-#" is turned off ("manual" mode).
- For test purposes, the cascaded regulation can be disconnected and a setpoint for the actuator preset on the slave controller (JTEMP) in the "auto" operating mode.

**Special Notes**

- In "auto" mode of the "TEMP-#" master controller, the "JTEMP-#" slave controller automatically switches to "cascade" mode. In the "off" setting of the master controller, the slave controller is also automatically "off."
- On certain systems, a setpoint limit must be parameterized for the slave controller using the "MAX" output limit of the master controller.
  - Example, UniVessel® Glass double-walled:
    max. out = 62% for max. temperature = 93.5°C in double wall
- 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.

### 8.9.7 Speed regulation (STIRR)

**Function**

The speed controller works like a setpoint generator for an external 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 ($pO_2$) regulation.

**Controller Screen**

Operator entries, output of the analog setpoint signal for the motor controller and the display of the speed signal from the controller are all done on the controller screen.


| Field | Display | Function, input required |
|---|---|---|
| STIRR-1 | rpm | Display of the current stirrer speed |
| SetPoint | rpm | Configuration of the target speed in "auto" mode |
| Out | % | Display of the speed limitation (MIN / MAX) and setting configuration of the target speed in "manual" mode |
| Alarm Param. | | Input of the alarm limits (high limit, low limit) and switching the alarm on/off |
| Profile Param. | | Input of a time-dependent setpoint profile (max. 20 spikes) |
| Function key |  | Input of the speed limitation (MIN/MAX) |

**Operation**

## NOTICE

**High speeds can damage vessel attachments!**

Often only a certain maximum stirrer speed is allowed depending on the vessel type, volume, and equipment. Higher stirrer speeds can damage vessel attachments, e.g., a hosed aeration system. Vessels can become unstable and move across the surface of the floor.

Note the maximum permissible stirrer speed for your bioreactor:

**Motor 200 W**

| | **UniVessel® Glass Standard coupling** | **UniVessel® Glass Magnetic coupling** | **UniVessel® SU** |
|---|---|---|---|
| **Volumes [L]** | **Speed range [rpm]** | | |
| 1 | 20 ... 2000 | 20 ... 2000 | |
| 2 | 20 ... 2000 | 20 ... 2000 | 20 ... 400 |
| 5 | 20 ... 1500 | 20 ... 800 | |
| 10 | 20 ... 800 | 20 ... 700 | |

**Motor 400 W**

| | **UniVessel® Glass Standard coupling** | **UniVessel® Glass Magnetic coupling** | **UniVessel® SU** |
|---|---|---|---|
| **Volumes [L]** | **Speed range [rpm]** | | |
| 10 | 20 ... 1200 | 20 ... 1200 | |

| **Culture vessel** | **Maximum stirrer speeds** |
|---|---|
| UniVessel® Glass, 1 L, 2 L | 2000 rpm |
| UniVessel® Glass, 5 L | 1500 rpm |
| UniVessel® Glass, 10 L | 800 rpm |
| UniVessel® SU, 2 L | 400 rpm |

When inputting MIN/MAX output limits or making direct entries into the "Out" field, the permissible speed controller range must be considered.

▶ Set the desired stirrer speed via "Setpoint."

**Speed Limitation**

When selecting the speed control MIN/MAX 0–100% for speed range 0–2000 rpm and with 1200 rpm as a max. permissible stirrer speed, a value of OUT = MAX 60% must be configured.

If the MIN/MAX setting is changed after a system reset, you must reset them new limits to the range permissible for the bioreactor.

### 8.9.8 Anti-foam Controller (FOAM)

#### Function

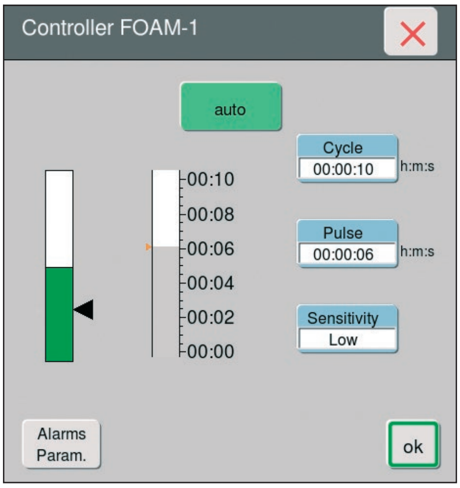
The autoclavable foam sensor is installed in the culture vessel. The sensor is adjustable in height, so that the sensor tip can be adjusted to the maximum level of the medium.

A threshold signal generated by the foam sensor and amplified by a measurement amplifier serves as the input signal of the "Controller FOAM-#" foam controller.

This is activated, as long as the sensor is in foam. The trigger sensitivity "Sensitivity" of the amplifier can be adjusted.

The output of the foam controller modulates a correction medium pump and switches it on and off (Cycle/Pulse) periodically when a sensor signal is emitted.

#### Controller Screen




| Field | Display | Function, input required |
|---|---|---|
| Mode | Off | Controller switched off |
| | Auto | Controller switched on |
| | Manual | Manual activation of the controller output; pump runs permanently as a function of Cycle/Pulse |
| Cycle | hh:mm:ss | Total cycle time in [hours: minutes: seconds] |
| Pulse | hh:mm:ss | Pump runtime (dispensing time) in [hours: minutes: seconds] |
| Sensitivity | – Low<br>– Medium Low<br>– Medium High<br>– High | Trigger sensitivity for the foam sensor |
| Alarms Param. | | Switching the alarm on/off |

#### Operation

▶ Set the cycle time "Cycle" and the pump runtime "Pulse" according to process requirements.

▶ Configure the trigger sensitivity "Sensitivity" of the sensor.

To prevent proportioning errors resulting from leakage currents and sensor growth, you should set the trigger sensitivity as low as possible.

▶ Switch to "auto" mode.

In "manual" mode, the pump periodically runs in continuous operation as a function of the "Cycle" and "Pulse" settings.

#### Special Notes

– The measurement amplifier is equipped with a response lag time mechanism (approx. 5 sec), that prevents activation after splashing liquid.

– Switching to the "auto" or "manual" mode automatically also activates the "FOAMT-#" filling counter.

### 8.9.9 Level Control with Level Sensor (LEVEL)

**Function**

The autoclavable level sensor is installed in the culture vessel. The sensor is adjustable in height, so that the sensor tip can be adjusted to the maximum level of the medium.

A threshold signal generated by the level sensor and amplified by a measurement amplifier serves as the input signal of the "Controller LEVEL-#" level controller.

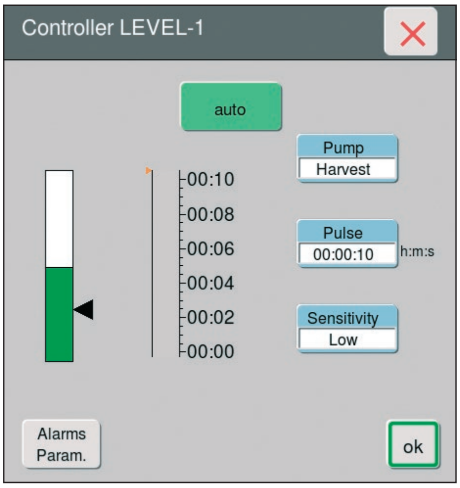
It is active when the level of the medium rises to where it is in contact with the level sensor. The trigger sensitivity "Sensitivity" of the amplifier can be adjusted.

The level controller is normally operated during the harvesting operation. By changing the direction of hoses and switching from "Pump" to "Feed," the level controller can also be used during feed operation.

**The harvesting operation is described in the following:**

The output of the level controller controls a harvesting pump. The pump speed is constant. If the medium has not been in contact with the level sensor, the pump stops pumping after a specified period. If the level is controlled via the level sensor, an additional harvesting pipe should be installed.

**Controller Screen**




| Field | Display | Function, input required |
|---|---|---|
| Mode | Off | Controller switched off |
| | Auto | Controller switched on |
| | Manual | Manual activation of the controller output; pump runs permanently |
| Pump | Harvest<br>Feed | Pump during harvest operation<br>Pump during feed operation |
| Pulse | hh:mm:ss | Pump runtime (harvest time) in [hours: minutes: seconds] |
| Sensitivity | – Low<br>– Medium Low<br>– Medium High<br>– High | Trigger sensitivity for the sensor |
| Alarms Param. | | Switching the alarm on/off |

**Operation**

▶ Select the "Harvest" pump operation.
▶ Set the harvest time "Pulse" according to the process requirements.
▶ Configure the trigger sensitivity "Sensitivity" of the sensor.

To prevent proportioning errors resulting from leakage currents and sensor growth, you should set the trigger sensitivity as low as possible.

▶ Switch to "auto" mode.

In "manual" mode, the pump runs continuously.

### 8.9.10 Adjusting the "VWEIGHT" Gravimetric Level Controller

With gravimetric leveling, it is possible to maintain a particular medium volume in the culture vessel. The pump speed is controlled automatically depending on the weight change in the culture vessel. When the medium volume is regulated, there is a difference between:

– Feed operation
– Harvest operation

The controller is set to feed operation by default.

**Feed Operation**

When the weight of the culture vessel drops below the setpoint: It activates a variable speed (analog) feed pump. The substrate is added to the culture vessel until the setpoint is reached again.

**Harvest Operation**

When the weight of the culture vessel exceeds the setpoint: It activates a variable speed harvest pump. The medium is harvested until the setpoint is reached again.


**Procedure**

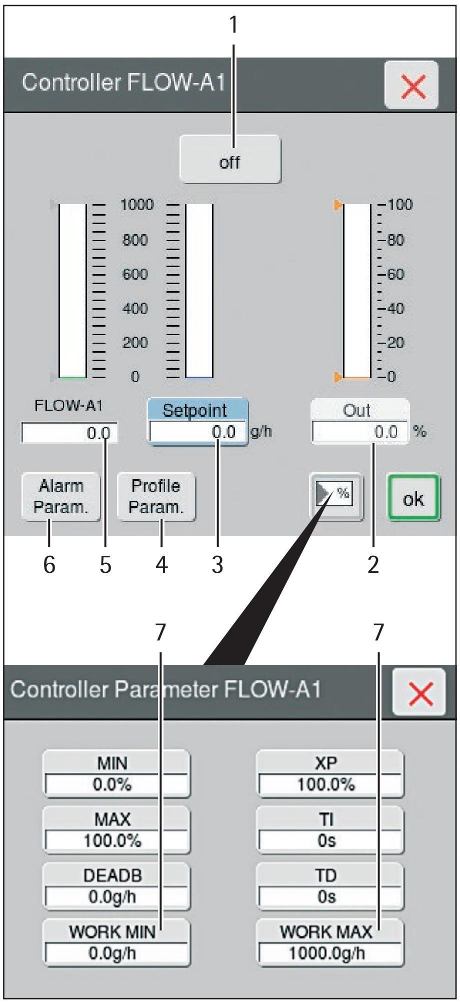
▶ Configure the controller according to requirements, for example:

| No. | Parameter | Value | Description |
|---|---|---|---|
| 1 | Operating mode | | Shows the operating mode selection window |
| | | Off | Switch off gravimetric level control |
| | | Auto | Adjust the media volume to a weight using the "Setpoint" key |
| | | Manual | Adjust the feed/harvest pump to a constant pump speed using the "Out" key (pump runs permanently) |
| | | Profile | Have the medium volume controlled by a set weight profile |
| | | Cascade | Gravimetric level control is controlled by a master controller |
| 2 | Out | % | In "manual" mode only: Adjust the controller output (feed/harvest pump) to a constant pump speed |
| 3 | SetPoint | kg | Enter weight |
| 4 | Profile Param. | | Create weight profile |
| 5 | VWEIGHT | kg | Displays the current weight: medium with culture vessel |
| 6 | Alarm Param. | | Adjust alarm parameters |
| 7 | PUMP | | Shows the "pump" selection window for choosing the pump operating mode |
| 8 | Harvest | | Activate harvest operation |
| 9 | Feed | | Activate feed operation |

### 8.9.11 Adjusting the "FLOW" Gravimetric Filling Pump Controller

The gravimetric filling pump controller works with a weighing system and a variable speed filling pump. The controller works directly with the weight measured by the balance as an input signal, facilitating precise filling over days and weeks.
The following information must be taken into account when adjusting the controller:

– The feed rate of the filling pump has an important influence on the controlled 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%. For that purpose, the feed range of the pump must be adapted to the working range of the controller. You can use hoses with a different diameter that offer the desired feed range, for example. Alternatively, the controller can also be adapted to the feed range of the pump.




**Procedure**

▶ Configure the controller according to requirements, for example:

| No. | Parameter | Value | Description |
|---|---|---|---|
| 1 | Operating mode | | Shows the operating mode selection window |
| | | Off | Switch off gravimetric filling pump control |
| | | Auto | Adjust the filling pump to a filling value using the "Setpoint" key |
| | | Manual | Adjust the filling pump to a constant pump speed using the "Out" key (pump runs permanently) |
| | | Profile | Have the filling pump controlled by a set filling profile |
| | | Cascade | Filling pump controller is controlled by a master controller |
| 2 | Out | % | In "manual" mode only: Adjust the controller output to a constant pump speed |
| 3 | SetPoint | g/h<br>kg/h | Enter filling value |
| 4 | Profile Param. | | Create filling profile |
| 5 | FLOW | g/h<br>kg/h | Displays the filling amount |
| 6 | Alarm Param. | | Adjust alarm parameters |
| 7 | WORK MIN / WORK MAX | | Optimize the controller for the pump/hose combination:<br>– Set the required amount at the minimum "WORK MIN" pump speed in combination with a specific hose size<br>– Set the required amount at the maximum "WORK MAX" pump speed in combination with a specific hose size |

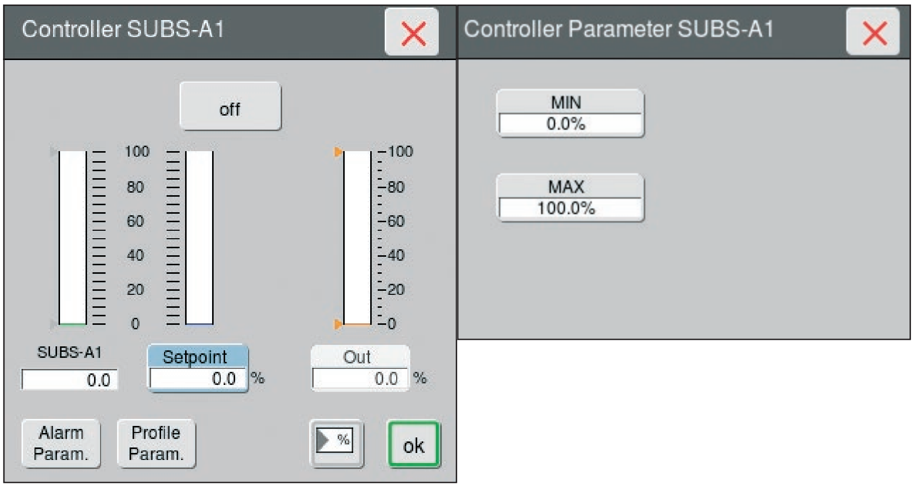
▶ Tare the balance to zero.
▶ Place the vessel on the balance.
▶ Enter the desired filling value using the "Setpoint" key.
▶ Set the operating mode to "auto."
▷ A negative weight readout on the balance or on the DCU indicates the feed volume which has already been added.

### 8.9.12 Filling Pump Controller (SUBS)

**Function**

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

**Controller Screens**




**Operation**

▶ Set the desired quantity to add via "Setpoint."
▶ Switch the mode of the filling pump controller to "auto."

**Special Notes**

– Matching connecting cables are available for certain pumps, like WM 120, WM 323. Ordering information is available on request.
– Pumps from other manufacturers can be connected if they have an external setpoint input from 0 to 10 V.

### 8.9.13 Adjusting 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" or "Sparger" aeration segments.

The gas controllers are controlled by the master controller in DO ($pO_2$) or pH regulation. If the gas controllers are controlled by the master controllers, the slave controllers automatically switch to "cascade" mode.

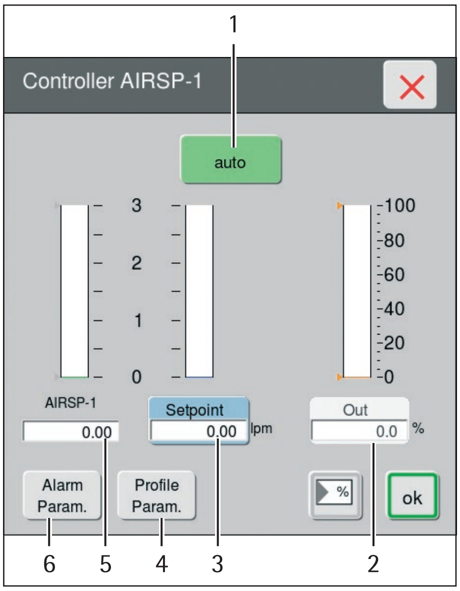
The gas controllers can be used as setpoint generators, if:

– The master controllers are switched off ("off" mode).
– The gas controllers are deactivated in the master controller.

The following information must be taken into account when adjusting the controller:

– MIN/MAX output limits are entered in % of the control range of the gas feed.
– If the gas controllers is controlled by a master controller: The MIN/MAX values must be entered in the configuration window for the controller parameters of the DO ($pO_2$) controller. The settings will then act as a switching criterion for the actuators.
– If the gas controller is switched off ("off" mode), 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**

▶ Configure the controller according to requirements, for example:

| No. | Parameter | Value | Description |
|---|---|---|---|
| 1 | Operating mode | | Shows the operating mode selection window |
| | | Off | Switch off aeration |
| | | Auto | Adjust the aeration rate to a setpoint using the "Setpoint" key |
| | | Manual | Adjust aeration to a constant gas flow using the "Out" key |
| | | Profile | Have aeration controlled by a set aeration profile |
| | | Cascade | Gas controller is controlled as a slave controller by the master controller for DO ($pO_2$) or pH regulation |
| 2 | Out | % | In "manual" mode only: Adjust the gas controller to a constant gas flow |
| 3 | SetPoint | lpm / cm / % | Adjust the aeration rate |
| 4 | Profile Param. | | Create aeration profile |
| 5 | AIRSP-1 | lpm / cm / % | Displays the current total gas flow in the AIRSP gas segment |
| 6 | Alarm Param. | | Adjust alarm parameters |

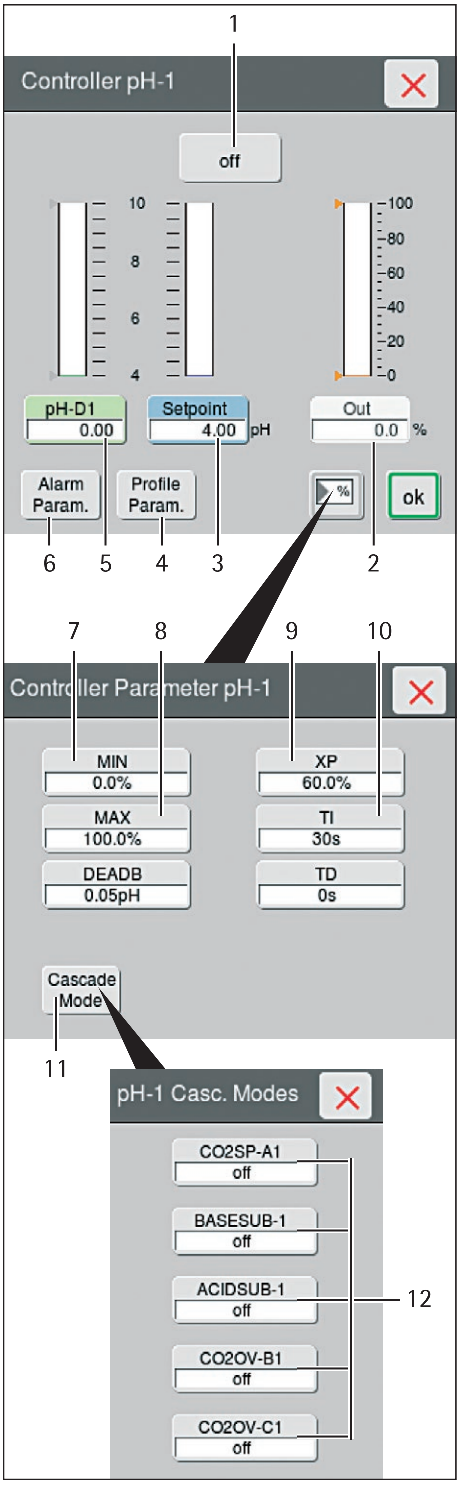
### 8.9.14 Adjusting the pH Controller

The following slave controllers are controlled to facilitate pH regulation:

– "SUBS" filling pump controllers for adding acid and base.
– Gas controllers or solenoid valves for adding $CO_2$.

The controller output (OUT: 50%–0%) influences the acid pump or $CO_2$ feed. The controller output (OUT: 50%–100%) influences the base pump. The pH controller does not activate the slave controllers until the control deviation falls outside of the set "DEADB" dead zone.

When the "auto" or "manual" operating modes are activated, the filling counters (e.g., "ACIDT-1") automatically switch to the "Totalize" operating mode.




**Procedure**

▶ Configure the controller according to requirements, for example:

| No. | Parameter | Value | Description |
|---|---|---|---|
| 1 | Operating mode | | Shows the operating mode selection window |
| | | Off | The pH controller is switched off. Slave controllers can be individually adjusted |
| | | Auto | Adjust and regulate the pH value using the "Setpoint" key |
| | | Manual | Adjust the controller outputs to a constant value using the "Out" key |
| | | Profile | Have the pH value controlled by a set pH profile |
| 2 | Out | % | In "manual" mode only: Adjust the controller output to a constant value (split range) |
| 3 | Setpoint | pH | Adjust pH value |
| 4 | Profile Param. | | Create pH profile |
| 5 | pH-## | pH | Change the process value source Displays the pH value |
| 6 | Alarm Param. | | Adjust alarm parameters |

### Adjusting the PID Parameters

The TI parameter must be greater than 0. From firmware V 7.8, the pH controller does not work in split range operation; instead it starts with OUT = 50%.

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

| No. | Parameter | Calculation of base parameters in split range operation |
|---|---|---|
| 7 | MIN | $= (100\% - \text{absolute value of } MIN_{\text{split range}}) / 2$ |
| 8 | MAX | $= (100\% + \text{absolute value of } MAX_{\text{split range}}) / 2$ |
| 9 | XP | $= XP_{\text{split range}} \times 2$ |
| 10 | TI > 0 | TI > 0 |

### Selecting Slave Controllers for pH Regulation

▶ Press the "Cascade Mode" key (11) in the "Controller Parameter" configuration window.

▶ Use the keys (12) to activate or deactivate the desired slave controllers for pH regulation.

The "off" or "auto" text displayed on the keys of the slave controllers describes the current working status of the controller if the slave controllers are activated. If the slave controllers are deactivated, "disabled" appears on the keys.

If the master controller is deactivated, the slave controllers can be used in other ways:

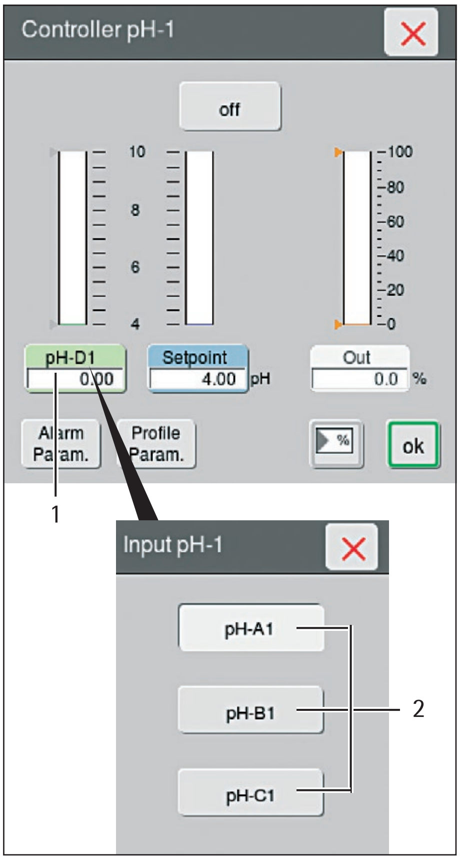
– The $CO_2$ gas controllers can be used as independent setpoint controllers.
– The acid or base pumps (ACID/BASE) can be used as substrate controllers.

### Applicable Value Range of PID Parameters

| Parameter | Unit | Value |
|---|---|---|
| MIN | % | 0 … 100 |
| MAX | % | 0 … 100 |
| XP | % | 0.1 … 1000 |
| TI | s | 1 … 10,000 |
| TD | s | 0 … 1000 |

### Change the process value source

Multiple, different pH sensors (conventional, optical) can be installed on the device. One of these sensors can be selected as the process value source for pH regulation.




Procedure

▶ Press the "pH-A1" key (1) in the advanced configuration window.
▷ The "Input pH-1" selection window appears.

▶ Press the "pH-##" key (2) to select the desired process value source:

| Description/process value source | pH sensor type |
|---|---|
| pH-A1 | conventional or digital pH sensor |
| pH-B1 | conventional or digital pH sensor (dual measurement) |
| pH-C1 | optical pH sensor |

▶ Confirm the input in the advanced configuration window with the "OK" key.

### 8.9.15 DO ($pO_2$) Regulation Methods

The DCU system features various methods of DO ($pO_2$) regulation. The configuration and process being used determine which method is possible, required or sensible for the controlled end device.

- When aerating, either the oxygen portion can be reduced by adding nitrogen or the air can be enriched with oxygen.
- The mixture can be influenced, e.g., by controlling the stirrer speed.
- Cell growth can be influenced by adding or reducing substrate.

DO ($pO_2$) regulation works like 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 ($pO_2$) regulation only affects one of the available setting variables.
- Up to four-stage simultaneous control cascade, during which the DO ($pO_2$) regulation affects 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 setpoint for each slave controller. In multi-stage cascaded regulation, the output of the DO ($pO_2$) controller modulates the slave controllers after sequential switch-on as follows:

- The DO ($pO_2$) controller acts on the slave controller with priority 1 (Cascade 1) and defines its setpoint. 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 are reset to the reverse order.

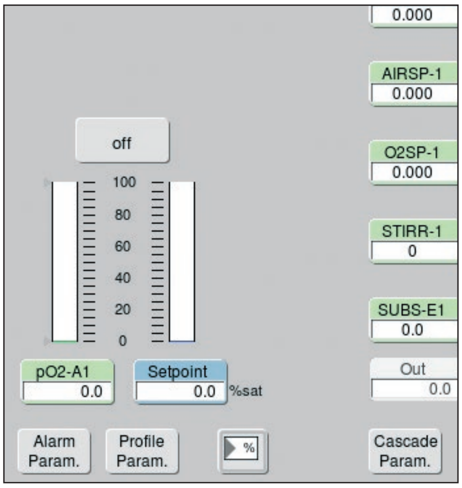
This regulation method can control the in-process DO ($pO_2$) value, even if there are considerable fluctuations in the need for oxygen in the culture. In order to still be able to additionally optimally adapt the control to the behavior of the controlled loop path, the PID parameters of the slave controller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

### 8.9.15.1 Adjusting the DO ($pO_2$) Sensor Process Value Source

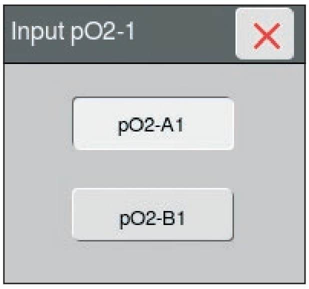
The DO ($pO_2$) controller must be set to the process value to be used for control with reference to the DO ($pO_2$) sensor used.

**Types of DO ($pO_2$) Sensors**

| Description | Type |
|---|---|
| $pO_2$-A "Unit #" | conventional DO ($pO_2$) sensor (amperometric or optical, e.g., Visiferm, manufactured by Hamilton) |
| $pO_2$-B "Unit #" | conventional DO ($pO_2$) sensor (dual measurement, amperometric or optic, e.g., Visiferm, manufactured by Hamilton) |
| $pO_2$-C "Unit #" | optical DO ($pO_2$) sensor UniVessel® SU |




▶ On the "Controller pO2-##" controller screen, press the "pO2-##" key.
▷ The "Input pO2-##" selection window appears.




▶ Select the process value source by pressing the corresponding "pO2-##" key.
▶ Confirm the input on the controller screen by pressing "ok."

#### 8.9.15.2 DO ($pO_2$) Controller CASCADE (Cascade Controller)

**Screen**

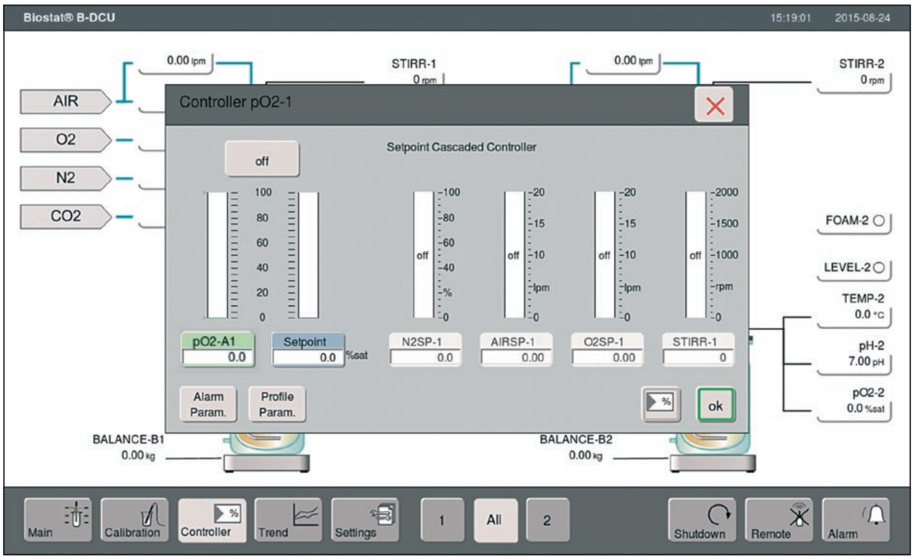



Fig. 8-4: DO ($pO_2$) cascade controller menu on the "Controller – All" screen

Refer to Chapter "8.9.3 General Controller Operation," page 116 for notes on the fields, entered values, and entries.

The screen also include the following input fields:

| Field | Value | Function, display, input required |
|---|---|---|
| Setpoint | % sat | Preset setpoint in the master controller |
| Setpoint Cascaded Controller | | Preset setpoint for the slave controller in the cascaded regulation, in the sequence of the priority predefined in the parameterization screen: |
| Mode | Off | Selected slave controllers will automatically be switched to "off" |
| | Auto | Selected slave controllers will automatically be switched to "cascade" mode |
| | Profile | With the profile, selected slave controllers will automatically be switched to "cascade" mode |
| Alarm Param. | | – Input of the limit values "High," "Low"<br>– Input of the time delay<br>– Enable/disable alarm |
| Profile Param. | | Input of the profile parameter |
|  | | Sub-menu – parameterization screens |

### DO ($pO_2$) Cascade Controller Parameterization Screen

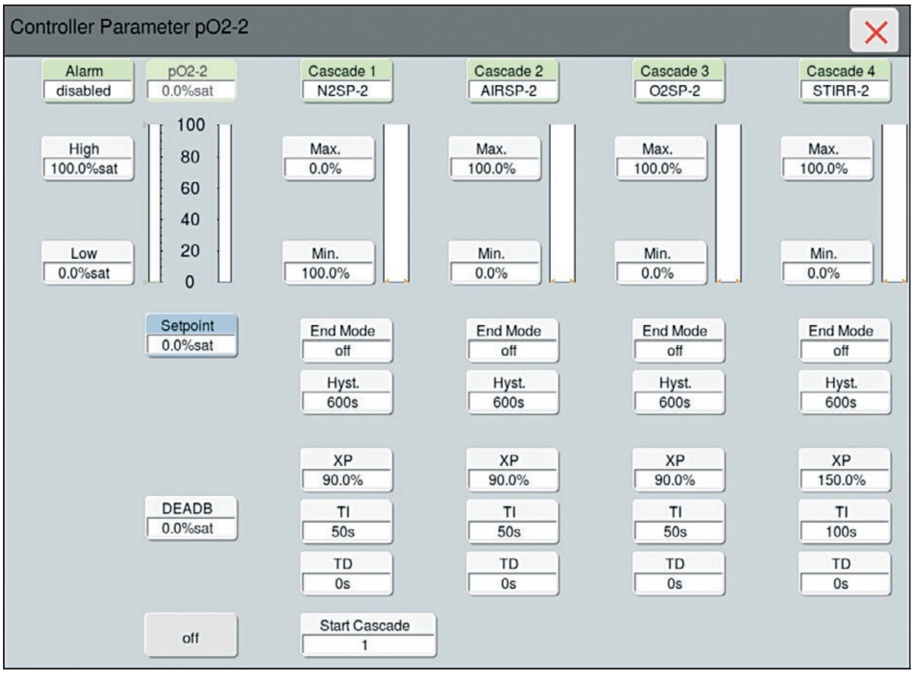



Fig. 8-5: Example: configuration of the screen

| Field | Value | Function, display, input required |
|---|---|---|
| DEADB | % | Input of the deadband |
| Cascade # | [Controllers] | Slave controller with the relevant parameters |
| MIN | % | Minimum output limit, corresponding to the minimum setpoint for the slave controller |
| MAX | % | Maximum output limit, corresponding to the maximum setpoint for the slave controller |
| XP | % | P share (proportional range); signal amplification of the control response proportional to the input signal |
| TI | sec | Integral portion; time function. With a higher I portion control will react more slowly (and vice versa) |
| TD | sec | Differential portion; damping, greater D portion, damps the controller response (and vice versa) |
| End Mode | Off, Auto | Mode for slave controller when the master controller is "off" or "disabled" |
| Hyst. | m:s | Delay time for switching between the slave controllers |
| Mode | Off | Selected slave controllers will automatically be switched to "off" |
| | Auto | Selected slave controllers will automatically be switched to "cascade" mode |
| | Profile | With the profile, selected slave controllers will automatically be switched to "cascade" mode |

**Operation of the Multi-stage Cascade Controller**

- ▶ Select the slave controller according to the desired priority in the "Cascade Parameter pO2-#" submenu.
- ▶ Set each minimum and maximum controller setpoint limit for the selected slave controller using the output limits MIN or MAX in the parameterization screen of the DO ($pO_2$) controller.
- ▶ When switching on the DO ($pO_2$) controller, the slave controller modulated by the DO ($pO_2$) controller is displayed as "active."

**Special Notes**

- In 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 controller, 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 more than 2% of the specific measurement range.

### 8.9.15.3 DO ($pO_2$) Controller ADVANCED (Polygon Controller)

The advanced DO ($pO_2$) controller monitors and regulates the DO ($pO_2$) in the bioreactor or the controlled end device for which the DCU system was designed.

The controller acts as the master controller during DO ($pO_2$) regulation. It acts on a configurable selection of slave controllers for the intake of media or to control actuators that influence the DO ($pO_2$) in the process. Examples of such media include gases like $N_2$, air, $O_2$, or nutrient solutions. The DO ($pO_2$) value measured in the process depends on the media introduced, the oxygen consumed during cell growth and cell metabolism, and material distribution from mixing.

The master controller works as a PID controller with configurable control behavior. It uses the DO ($pO_2$) measured at a measurement point (up to two measurement points can be selected) as the actual value. In case of deviation from the setpoint, the master controller sends an output signal to the slave controllers. Due to the variety of possible slave controllers, the output signal is relative to the control range 0 to 100%.

One configuration can include up to six slave controllers, of which five can be selected simultaneously for the polygon controller. They control their actuators using analog or digital output signals. Each slave controller can be assigned up to five setpoints in the physical units of the set value, dependent on the output "Out" of the master controller. The controller screen shows this graphically as a polygonal curve above the output "Out."

In comparison with conventional DO ($pO_2$) cascade controllers, the advanced DO ($pO_2$) polygon controller supports the parallel operation of the slave controllers, that is, all actuators are controlled simultaneously. In combination with the determination of multiple setpoints dependent on the "Out" of the master controller, this results in an easy-to-understand and convenient-to-operate DO ($pO_2$) regulation.

### Screen

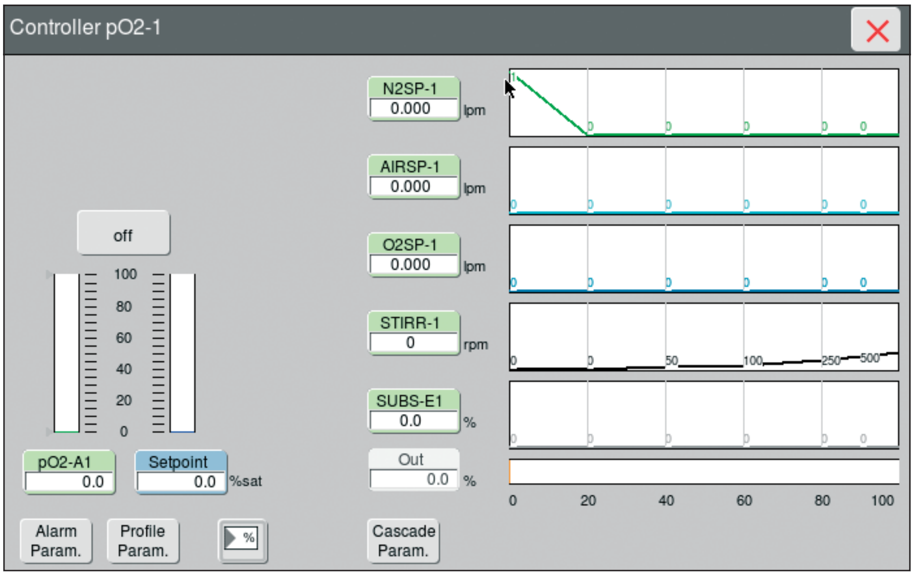



Fig. 8-6: DO ($pO_2$) controller menu on the "Controller – All" screen

### Settings for the Advanced DO ($pO_2$) Controller

#### Operating Display for the Master Controller

| Field | Value | Function, display, input required |
|---|---|---|
| Mode | Off | Controller switched off, output on stand-by |
| | Auto | Controller active, controls the actuator if necessary |
| | Manual | Manual access to controller output |
| DO ($pO_2$) | | Display of the DO ($pO_2$) |
| Setpoint | % | Setpoint; in % relative to the control range 0 to 100% |
| Out | % | Current controller output; in % relative to the control range 0 to 100% |
|  | | Access to the parameterization menu with standard password |
| "Cascade Param." | | Access to the selection menu for the slave controllers, via standard password |
| Alarm Param. | Alarm Parameter | Input of the alarm limits (high limit, low limit) and Switch the alarm on/off |

#### Operating Menus for Configuring Slave Controllers

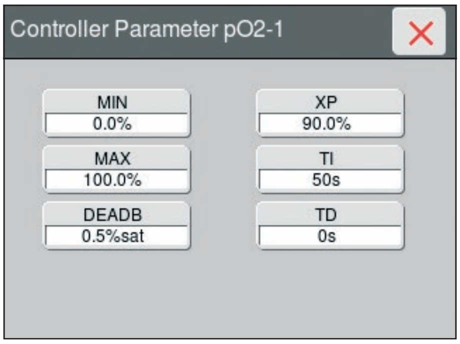
| Field | Value | Function, display, input required |
|---|---|---|
| N2-SP1 | Tag | Slave controller assigned to this channel |
| N2, O2, AIR, etc. | Tag | Media feed (gas, substrate) or function (e.g., speed controller) |
| SP etc. | Tag | Feed to the culture vessel, e.g., sparger or overlay |
| 1, 2, etc. | # | The unit assigned to the controller output, e.g., culture vessel 1, 2 |
| End mode | "Off" "Auto" | Mode for slave controllers when the master controller is "off" or "disabled"; mode restored after emergency shut off or power-on |
| Mode | "Disable" "Enable" | Activate or deactivate the slave controller for DO ($pO_2$) regulation (only available when the master controller is in operating state "off" or "disabled") |

### Example: Input (modification) of the DO ($pO_2$) setpoint

Since the selection of slave controller can be changed according to process requirements, the setpoint of the DO ($pO_2$) controller output is set in % relative to the control range. The slave controllers control their actuators with setpoints in their physical units.

▶ Press "$pO_2$" in the "Controller" menu.
▶ Press "Setpoint."
▶ Use the numeric keypad to enter the set value. Confirm with "OK."
▶ Press the function key of the slave controller to be configured, e.g., "N2-SP1." Enter up to five setpoints that depend on the "Out" output of the master controller. The settings are graphically displayed with a polygonal curve.
▶ Activate the DO ($pO_2$) controller by switching to the "auto" mode and confirming with "OK."

### Parameterization of the DO ($pO_2$) Master Controller




| Parameters | Unit | Value | Function, display, input required |
|---|---|---|---|
| MIN | % | 0 … 100 | Minimum output, within 0 ... 100% of the control range |
| MAX | % | 0 … 100 | Maximum output, within 0 ... 100% of the control range |
| DEADB | % | 0.5 | Dead zone; controller output remains unchanged as long as DO ($pO_2$) deviates from the setpoint by less than DEADB |
| XP | % | 0.1 ... 1000 | P share (proportional range); signal amplification of the control response proportional to the input signal; in % of the measurement range |
| TI | s | 1 … 10,000 | Integral portion; time function of the control response. With a higher I portion, the controller will react more slowly (and vice versa). |
| TD | s | 0 … 1000 | Differential portion; damping of the controller. With a greater D portion, the controller response is reduced (and vice versa) |

Normally you only change the parameters "MIN," "MAX," and "DEADB."

▶ In the "Controller" menu, select "$pO_2$" of the corresponding assembly to be configured and open the controller screen.
▶ Press the  key.
▶ Select the parameter to be set ("MIN," "MAX," or "DEADB"), enter the value and confirm with "OK."

**Setting the "P," "I," or "D" Controller Parameters:**

The adaptation of PID controllers requires knowledge of control theory. The setting options listed here are rough guidelines. Only qualified personnel should carry out controller optimization.

Depending on the process (e.g., stability of gas intake or actuator), it may be necessary to change the parameters "P," "I," or "D" to adapt control behavior. You can test the following changes:

- If the measured DO ($pO_2$) value (process value) fluctuates around the setpoint and does not stabilize, you can reduce the "P" portion.
- If the actual value only approaches the setpoint very slowly or does not reach it, you can increase the "P" portion.
- 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 create a tendency for the controller 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.

**Selecting and Configuring Cascade Parameters**

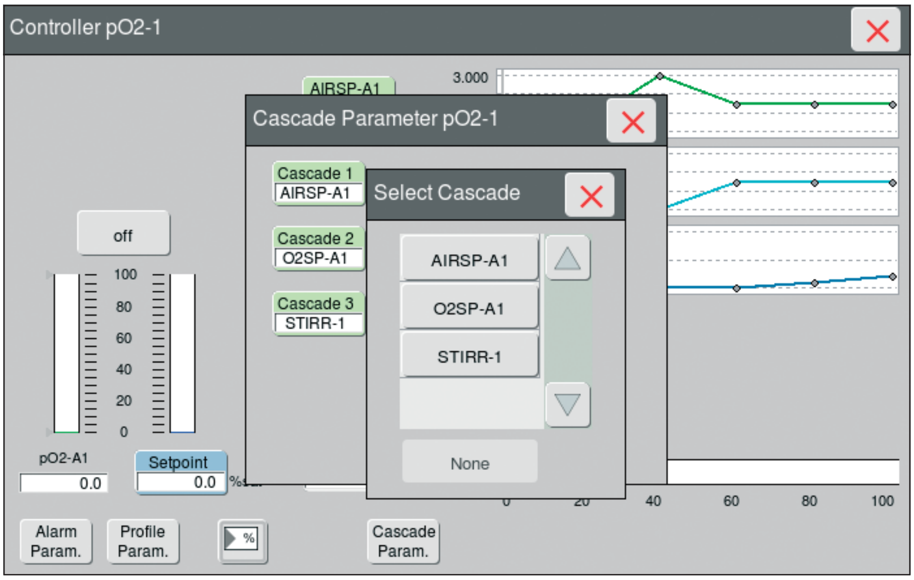



Fig. 8-7: Selecting cascade parameters

| Field | Value | Function, display, input required |
|---|---|---|
| Cascade # | | Slave controller to be assigned to the position "Cascade #":<br>– Up to six slave controllers are possible<br>– Up to five slave controllers can form a polygon controller |
| N2, O2, AIR etc. | Tag | Feed of media (gases, substrate) or actuators (e.g., drives) |
| SP, OV | Tag | Introduction to control segment (e.g., sparger "SP", headspace aeration "OV" in the culture vessel or container, mass flow controller "FL") |
| 1, 2 | # | The unit assigned to the controller output, e.g., number 1, 2 |
| Out | % | Output signal "Out" from master controller in control range 0 to 100% to which the setpoints of the slave controllers should be assigned |

| Field | Value | Function, display, input required |
|---|---|---|
| Setpoint | PV | Input of the setpoint for the master controller |
| Mode | Disable<br>Enable | Manually switchable mode of the slave controllers (only available when the master controller is in operating state "off" or "disabled") |

### Selecting Slave Controllers

▶ Activate "Cascade Param." to open the submenu for selection of slave controllers and change the previous selection.

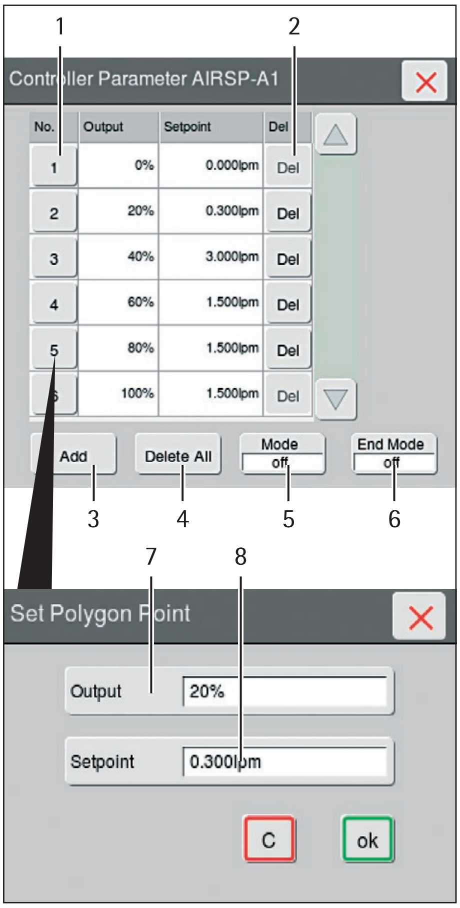
▶ Enter the password.

▶ Press the key for position "Cascade #" for which another slave controller should be selected or the existing one deselected.

Changes to a controller "Cascade #" deletes the subsequent selection. You must reassign all downstream controllers. Since the slave controllers control their actuators simultaneously, the order of the controllers has no effect on the control.

### Adjusting the Polygonal Curve of a Slave Controller

The following description uses the "AIRSP" slave controller as an example.




▶ Activate the function key of the slave controller you want to configure, e.g., "AIRSP-#."

▶ Adjust the polygonal curve of the slave controller to the requirements, for example:

| No. | Parameter | Description |
|---|---|---|
| 1 | No. | Pressing shows the "Set Profile Set Point" window for configuring the values of the polygon point |
| 2 | Del | Pressing deletes the polygon point |
| 3 | ADD | Pressing shows the "Set Polygon Set Point" window for entering another polygon point |
| 4 | Delete All | Pressing deletes all polygon points |
| 5 | Mode | Pressing shows a window for activating/deactivating the slave controller |
| 6 | End Mode | Selection of the slave controller mode when the master controller is "off" or "disabled" |
| 7 | Output | Pressing shows a window for entering the output value; output is 0–100% related to the DO ($pO_2$) controller output |
| 8 | Setpoint | Pressing shows a window for entering the setpoint value |

▷ After closing the submenu with "OK," the setpoints for the slave controller are graphically displayed as a polygonal curve above the "Out" of the master controller.

▶ Set the polygonal curves of the other slave controllers.

**Special Notes**

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 (in state “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 controller and slaves:

– The setpoint
– The settings for alarm monitoring
– The PID 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” menu) restores the factory settings. You must therefore store process or user-specific settings before the reset if you want to use them again later.

After loading a new system configuration, the DCU system initially starts up with the factory settings. Here, too, you must reenter any process or user-specific settings.

**Application Instructions and Examples of Applied Control Strategies**

Other control strategies, such as Exclusive Flow, can be implemented by selecting and configuring the polygon controller:

**Example for “Advanced Additive Flow” Aeration Strategy**

▶ Give “N2SP-#” a setpoint in the range “Out” = 0 to 20%, with the maximum at 0%.
▶ Give “AIRSP-#” a setpoint in the range “Out” = 0 to 20%, with the maximum at 20%. Leave “Out” constant for 20 to 100%.
▶ Set “O2SP-#” between “Out” = 20 to 40%, with the maximum at 40%. Leave “Out” constant for 40 to 100%.
▶ Set “STIRR-#” between “Out” = 0 to 40% and increase to a maximum at 60%. Leave “Out” constant for 60 to 100%.
▶ Leave “SUBS-A” constant in the range “Out” = 0 to 60% and increase to a maximum at 80%.
▷ This activates the slave controller in the sequence shown, based on the deviation between the actual and setpoints and the output signal of the master controller. If the actual value approaches the setpoint, the slave controllers switch back in the reverse order.

**Example for "$O_2$ Enrichment" Aeration Strategy (Air, $O_2$)**

In the "$O_2$ Enrichment" 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 in the medium.

▶ Select "AIRSP-1" and "O2SP-1" as slave controllers.
▶ For "AIRSP-1," set a minimum setpoint for "Out" = 0% and a maximum setpoint in the control range "Out" = 20 to 100%.
▶ For "O2SP-1," set
– a minimum setpoint for "Out" = 0 to 20% and
– a setpoint climbing to 100% in the control range "Out" = 20 to 100%.

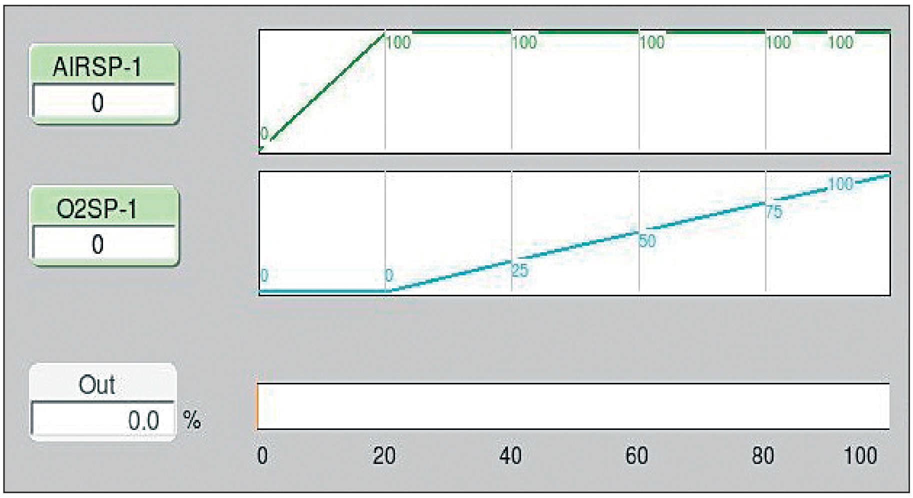



Fig. 8-8: Configuration of the aeration strategy "$O_2$ Enrichment"

▷ This cascade control initially leads to oxygen enrichment in the control range "Out" = 0 to 20%.
Then, the oxygenation capacity in the control range "Out" = 20 to 100% is continuously increased via the addition of $O_2$.

### Example for "Gasflow Ratio" Aeration Strategy (Air, $O_2$)

In the "Gasflow Ratio" aeration strategy, a constant amount of gases is supplied to the culture vessel.

▶ Select "AIRSP-1" and "O2SP" as slave controllers.
▶ For "AIRSP-1," set
  – a maximum setpoint for "Out" = 0%
  – a minimum sinking setpoint in the control range "Out" = 100%.
▶ For "O2SP-1," set
  – a minimum setpoint for "Out" = 0%
  – a maximum climbing setpoint in the control range "Out" = 100%.

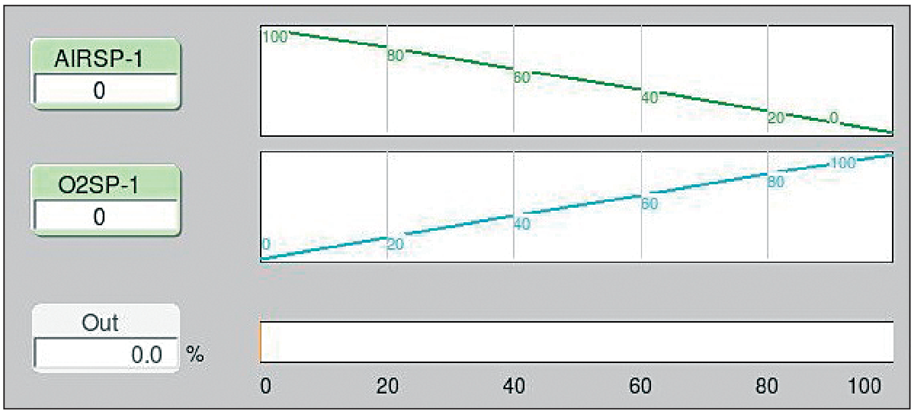



Fig. 8-9: Configuration of the aeration strategy "Gasflow Ratio"

▷ In this cascade control, only air is supplied within the control range "Out" = 0%. The supply of air is continuously reduced. To the same extent, the supply of $O_2$ is increased until solely oxygen is supplied within the control range "Out" = 100%.

## 8.9.16 Using Pumps from pH, Foam, and Level Control for Substrate Addition

This function is optionally available for standard configurations.

The pumps from foam and level control can be deselected from your controllers and used for substrate addition. However, only one controller at the time can be connected to the corresponding pump.

If the existing foam or level control is not used, you can switch the substrate controller to the corresponding digital pump.

### Operation

Changing the assignment of a controller output is described here with the example of changing AFOAM to SUBS-G:

▶ Open the "AFOAM-#" controller screen.
▶ Open the controller parameters.

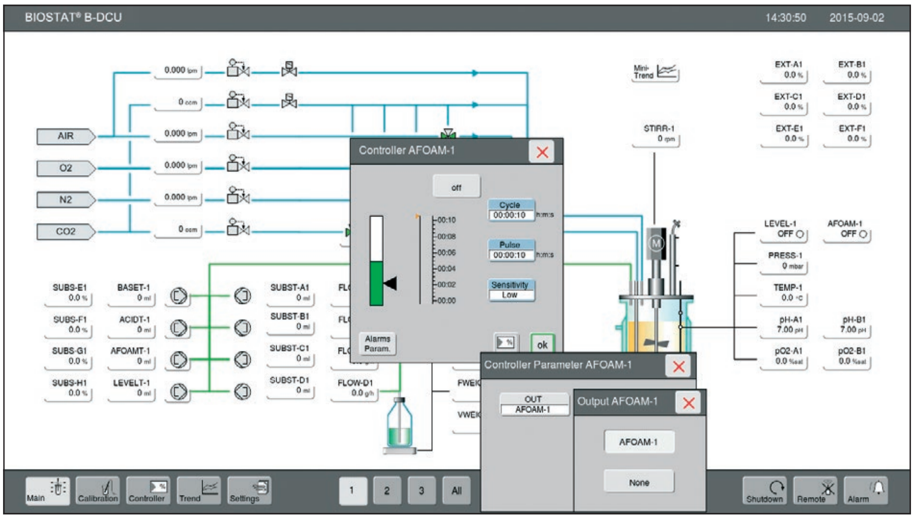



Fig. 8-10: Deactivating the anti-foam controller output

▶ Change the "AFOAM-#" controller output on the "Output AFOAM-#" controller screen to "NONE."

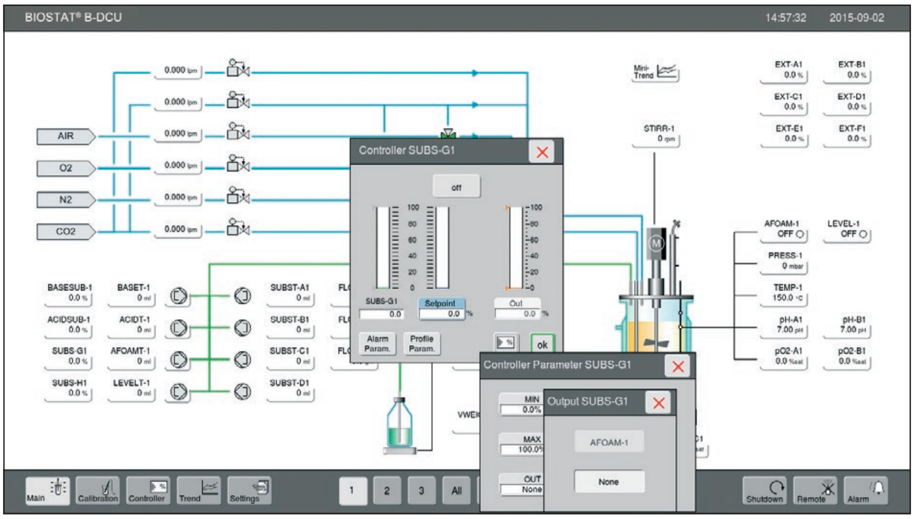



Fig. 8-11: Activating the output of the SUBS-G# substrate controller

▶ Open the "SUBS-G#" controller screen.
▶ Open the controller parameters.
▶ Change the "SUBS-G#" controller output on the "Output SUBS-G#" controller screen to "AFOAM-#."

**Special Notes:**

The configuration of the DCU system must permit the desired assignment and switch the pumps to the controller outputs. If not,

– Either no "OUT" switch is visible or selectable
– Or the pump disappears and is not selectable, e.g., when a pump is already being used for another control function
– The configuration does not permit switching

### 8.9.17 Glucose Controller (GLUCO)

**Function**

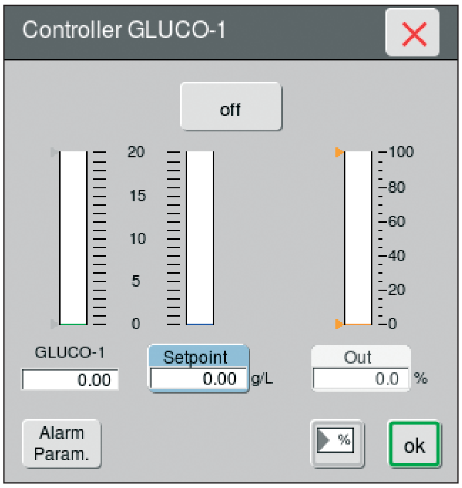
The glucose controller controls the addition of glucose in the culture vessel, so that the glucose concentration in the culture is maintained at a constant level.

The measured value calculated by the BioPAT® Trace is used as the input signal of the "GLUCO-#" glucose controller.

As soon as the glucose concentration falls below the setpoint in the culture, the speed of the addition pump is increased by the DCU system. More substrate containing glucose is added to the culture vessel until the setpoint for the glucose concentration is reached again.

If the glucose concentration exceeds the setpoint in the culture, the speed of the addition pump is decreased by the DCU system. Less substrate containing glucose is added to the culture vessel until the glucose in the culture vessel breaks down biologically and the setpoint is reached again.

**Controller Screen**




| Field | Display | Function, input required |
|---|---|---|
| Mode | Off | Controller switched off |
| | Auto | Controller switched on |
| | Manual | Manual activation of the controller output; pump runs permanently |
| SetPoint | g/l | When the set value is not reached or is exceeded, the pump output changes accordingly |
| Alarm Param. | | Input of the alarm limits (high limit, low limit) and switching the alarm on/off |
| Profile Param. | | Input of a time-dependent setpoint profile (max. 20 spikes) |
| Function key |  | Input of the weight limit (MIN/MAX) and other control parameters |

**Operation**

▶ Set the desired weight via "Setpoint."

### 8.9.18 Customer-Specific Changes to Controllers

Any pre-installed DCU system can be additionally 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.

## 8.10 "Settings" Menu

### NOTICE

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

The "Settings" main function permits changes to the system configuration. Malfunctions that have unforeseeable impacts on safe operation can result from settings that are not permissible or are unsuited for a certain end device.
Settings that impact safe operation are password-protected.
Only trained and experienced persons may change these settings.
The standard password may only be disclosed to authorized users and the service password (separate notice) only to authorized service technicians.

### 8.10.1 General Information

In the "Settings" menu, the DCU system provides various functions for system maintenance and troubleshooting:

– General settings like date, time, fail time, 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

**"Settings" Screen**

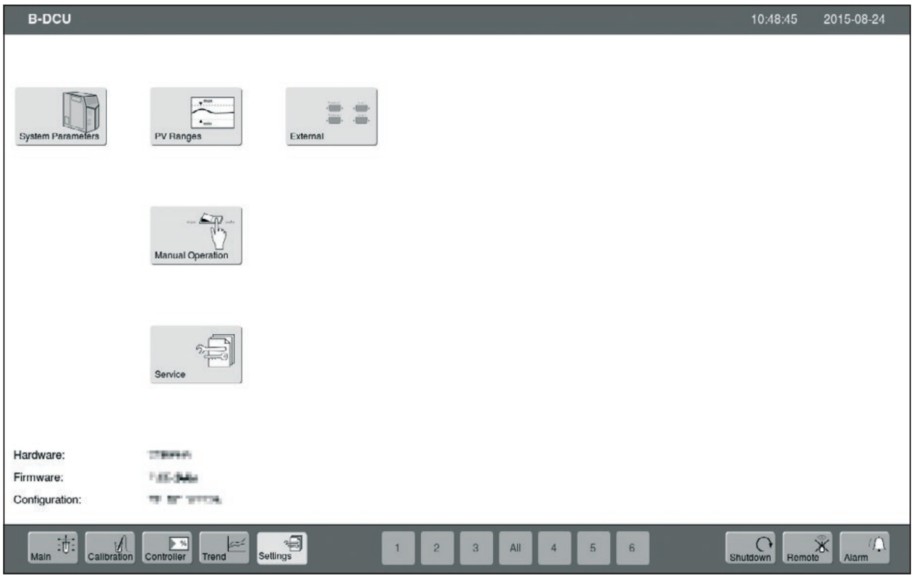



Fig. 8-1: "Settings" menu (system settings)

**Functions Available for Selection**

| Key | Function |
|---|---|
| System parameters | Change system settings |
| PV ranges | Configure measuring ranges for process values |
| Manual operation | Manual operation: Switch process inputs and outputs manually |
| External | View status of externally connected devices, e.g., balances |
| Service | Service and diagnostic access (for Sartorius Service only) |

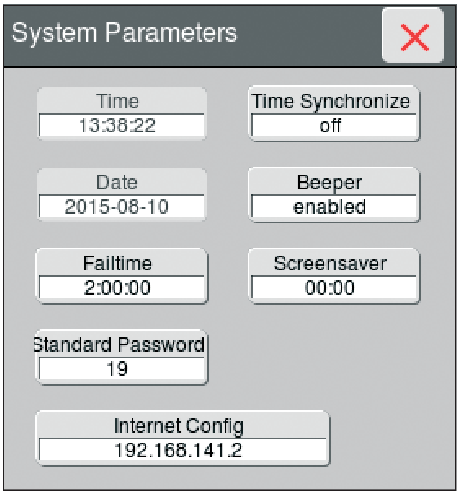
**Displayed System Information**

| Field | Value | Function, display, entry required |
|---|---|---|
| Hardware | Microbox | Version of the DCU hardware |
| Firmware | X.YY | Version of the system's firmware |
| Configuration | XX YY_ZZ | Version of the configuration |

For inquiries about the system or for contacting the service department in the event of a malfunction, please always state the serial number of the device and the firmware indicated here and configuration of your system.

### 8.10.2 Changing System Settings

▶ To change system settings, e.g., set the real time clock: Press the "System Parameters" button.




**Screen**

| Field Button | Value | Function, input required |
|---|---|---|
| Time | hh:mm:ss | Input the current time |
| Time Synchronize | Synchronize: enabled/ disabled | Enable and disable time synchronization |
| | IP Address | Entry of the IP-address |
| | Time Zone | Select the time zone |
| Date | yyyy-mm-dd | Input the current date |
| Beeper | Enabled/ disabled | Turns acoustic signals on/off, e.g., alarm tones |
| Failtime | hh:mm:ss | Enter power outage time to tell system how to behave after a power failure |
| | | Power outage time < FAILTIME: The system continues to run on the previous settings after the power failure |
| | | Power outage time > FAILTIME: System switches to default mode. All controllers and sequences remain deactivated. |
| Screensaver | hh:mm | Enter the time of inactivity after which the screen saver will be turned on (00:00 = switched off) |
| Standard password | xx | The standard password is set to 19 by default. To change the password: Press the "Standard Password" button. |
| Internet Config | 12-digit binary number | The DCU system's address in the IP network |

Changes to the date and time will only take effect in the first 5 minutes after the control unit is turned on.

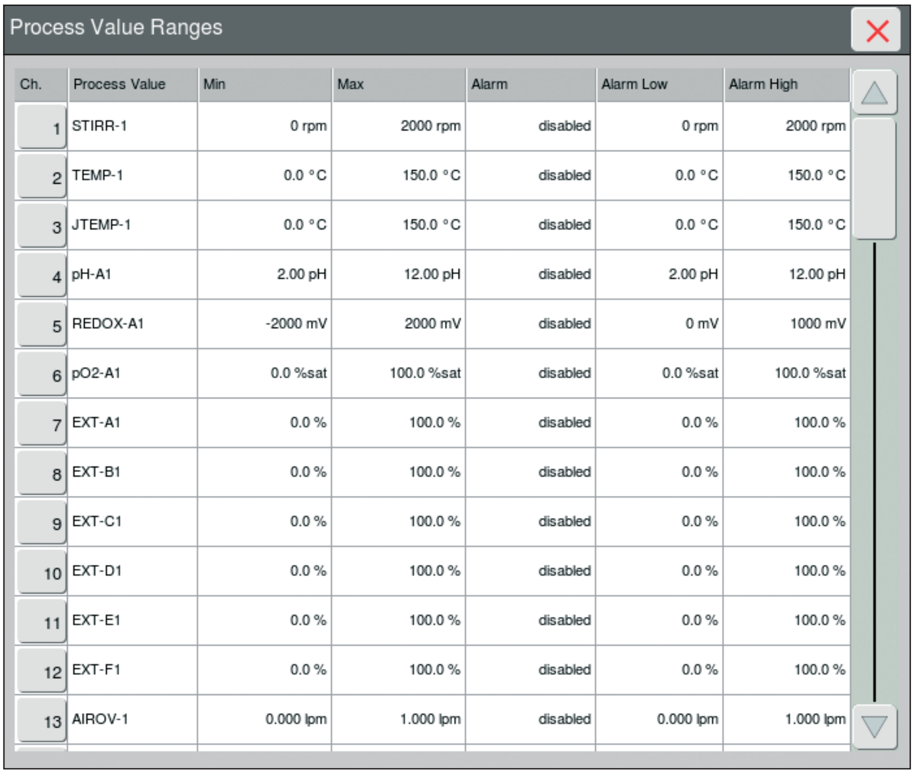
### 8.10.3 Measuring Range Settings

**Required Qualification:** Operating engineer | laboratory manager

The beginning and end of the measuring range ("Process Value Ranges") for all process values can be changed in the "Settings" menu. Measuring ranges configured specifically to devices or customer specifications are factory-set in the bioreactor.

**Screens**

– After pressing "PV ranges" and entering the standard password, the "Process Value Ranges" submenu opens:

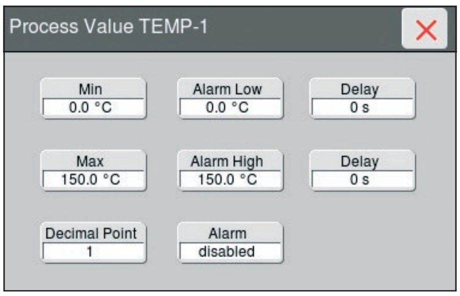



| Ch. | Process Value | Min | Max | Alarm | Alarm Low | Alarm High |
|---|---|---|---|---|---|---|
| 1 | STIRR-1 | 0 rpm | 2000 rpm | disabled | 0 rpm | 2000 rpm |
| 2 | TEMP-1 | 0.0 °C | 150.0 °C | disabled | 0.0 °C | 150.0 °C |
| 3 | JTEMP-1 | 0.0 °C | 150.0 °C | disabled | 0.0 °C | 150.0 °C |
| 4 | pH-A1 | 2.00 pH | 12.00 pH | disabled | 2.00 pH | 12.00 pH |
| 5 | REDOX-A1 | -2000 mV | 2000 mV | disabled | 0 mV | 1000 mV |
| 6 | pO2-A1 | 0.0 %sat | 100.0 %sat | disabled | 0.0 %sat | 100.0 %sat |
| 7 | EXT-A1 | 0.0 % | 100.0 % | disabled | 0.0 % | 100.0 % |
| 8 | EXT-B1 | 0.0 % | 100.0 % | disabled | 0.0 % | 100.0 % |
| 9 | EXT-C1 | 0.0 % | 100.0 % | disabled | 0.0 % | 100.0 % |
| 10 | EXT-D1 | 0.0 % | 100.0 % | disabled | 0.0 % | 100.0 % |
| 11 | EXT-E1 | 0.0 % | 100.0 % | disabled | 0.0 % | 100.0 % |
| 12 | EXT-F1 | 0.0 % | 100.0 % | disabled | 0.0 % | 100.0 % |
| 13 | AIROV-1 | 0.000 lpm | 1.000 lpm | disabled | 0.000 lpm | 1.000 lpm |

Fig. 8-2: Table of process values (or ranges) configured

By pressing the "Ch." (Channel) key, the process values (ranges) can be configured:

**Manual Configuration of Process Values Using Example "TEMP-1" (Channel 1)**




| Field | Value | Function, input required |
|---|---|---|
| Ch. | | Channel |
| Min | | Minimum value |
| Max | | Maximum value |
| Decimal Point | | Decimal point display |
| Alarm Low | e.g., °C | Lower alarm limit in the physical unit |
| Alarm High | e.g., °C | Upper alarm limit in the physical unit |
| Alarm | Disabled | Alarm monitoring deactivated |
| | Enabled | Alarm monitoring alarms active |
| Delay | s | Alarm lag time |

### 8.10.4 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").

- To switch to manual operation, the system password needs to be entered.
- You can disconnect inputs from the external signal generators and preset input values to simulate measuring signals.
- You can separate outputs from internal DCU functions and directly influence them in the operator screen, for example to test the effect of certain settings.

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 Inputs/Outputs**

- If an input or output is in "Auto" operation, the display in the "Value" column has a green background.
- If a controller is in cascade control mode, the display in the "Setpt" column has a light green background (controllers only).
- If a phase is acting on an output, the display in the "Value" column has a turquoise background.
- If an input or output is in "Manual" operation, the display in the "Value" column has a yellow background.
- If an input/output is locked, the display in the "Value" column has a violet background.
- If an emergency off is triggered during process, the displays of all outputs in the "Value" column have a red background.
- If no function is accessing an input/output, the display in the "Value" column has a gray background.
- If the process control system is accessing an output, the display in the "Value" column has a white background.

#### 8.10.4.1 Manual Operation for Digital Inputs

▶ For manual operation, disconnect the digital input from the external sensor, e.g., limit value sensors, and simulate the input signal by entering "ON" or "OFF."

### Screen

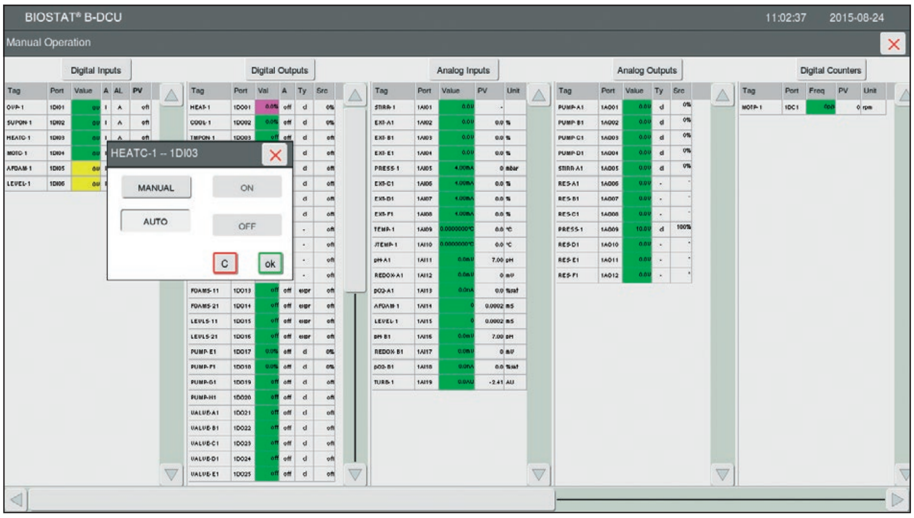



Fig. 8-3: Manual configuration of digital inputs, example "HEATC" (simulation for signal of the power-on status of the heating)

| Field | Value | Function, display, entry required |
|---|---|---|
| Day | Description | Display of the digital input, entry for "AUTO" or "MANUAL ON/OFF" operating mode |
| Port | | Hardware address |
| VALUE | | Switch status of digital output<br>Off<br>On |
| AL | | Alarm state<br>A = activated<br>- = not activated<br>expr = logical function |
| PV | | Process value |
| MODE | Auto<br>Manual | Process value |

### Special Notes

– The following signal levels apply to the switch status (status):

| | | |
|---|---|---|
| OFF | : | 0 V |
| ON | : | 5 V for DCU int. inputs (DIM); 24 V for process inputs (DIP) |

– When the selected digital input is in the "Auto MODE" status, the display in the "VALUE" column is backlit green.
– When the selected digital input is in the "Manual MODE" status, the display in the "VALUE" column is backlit yellow.

After working on the manual level, you have to switch all inputs back to the "AUTO" operating mode. Otherwise, the function of the DCU system will be limited.

### 8.10.4.2 Manual Operation for Digital Outputs

▶ During manual operation, disconnect the digital output from the internal DCU function and manipulate it directly. For static digital outputs, e.g., controlling valves, switch the output on or off. For pulse-width modulated outputs, manually enter the switch-on ratio in [%].

Internally, several functions can have an effect on a digital output; the respectively active function is displayed in "Mode." If several functions are activated (e.g., on controller outputs that interact with sterilization), the following priority applies:

| | |
|---|---|
| Highest priority | Shut down |
| | Manual operation (manual level) |
| | Locking |
| | Sterilization (only reactors capable of in-situ sterilization) |
| | Pump calibration |
| | Controllers, timers, sensors, balances |
| Lowest priority | Operating state (OPS) |

**Screen**

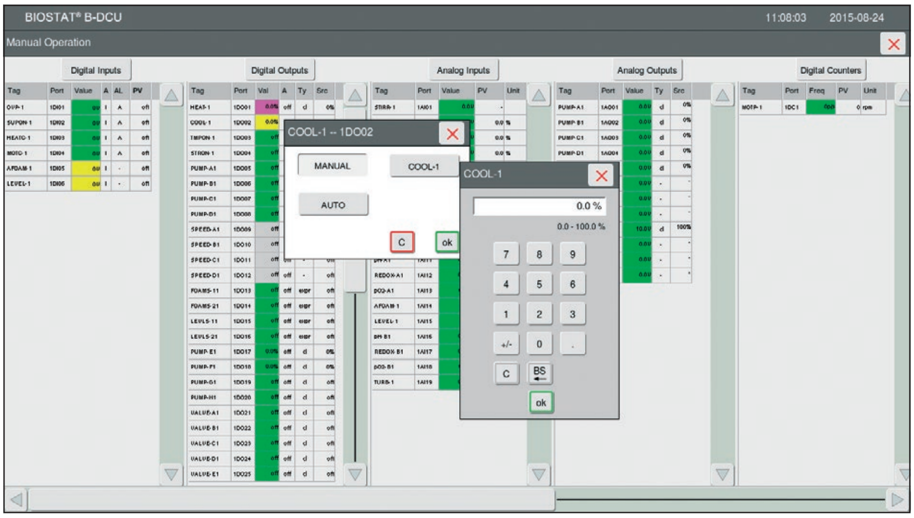



Fig. 8-4: Manual configuration of digital outputs, example "COOL-1" (simulation for signal controlling the cooling water valve)

| Field | Value | Function, display, entry required |
|---|---|---|
| Day | Description | Display of the digital output, entry for "AUTO" or "MANUAL ON/OFF" operating mode |
| Port | | Hardware address |
| VALUE | | Switch status of digital output<br>Off<br>On |
| Ty | | Upstream function<br>CL = controller<br>– = none |
| SRC | | Upstream controller output |
| MODE | Auto<br>Manual | Normal operation, external output affects DCU<br>Manual operation, manual presetting digital output |

| Field | Value | Function, display, entry required |
|---|---|---|
| VALUE | Off<br>On<br>nn% | Digital output switched off<br>Digital output switched on<br>Switch-on ratio (0 ... 100%) for pulse-width modulated digital outputs |

**Special Notes:**
– The following signal levels apply to the switch status (status):

| | | |
|---|---|---|
| OFF | : | 0 V |
| ON | : | 24 V for process outputs (DOP, DO) |

– On pulse-width modulated digital outputs, the relative power-on time is displayed or preset. The cycle time is defined in the specific configuration.

Example:
– Cycle time 10 sec, pulse-width modulated output 40%:
– Digital output 4 sec on and 6 sec off.

After working on the manual level, you have to switch all outputs back to the "AUTO" operating mode. Otherwise, the function of the DCU system will be limited.

### 8.10.4.3 Manual Operation for Analog Inputs

You can disconnect all analog inputs from the external circuitry during manual operation, e.g., a measurement amplifier, and simulate them by entering a process value.

**Screen**

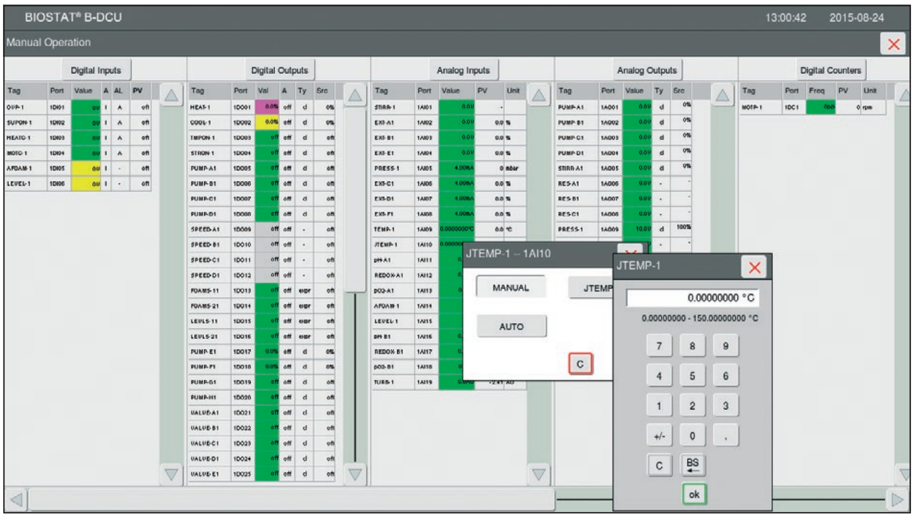



Fig. 8-5: Manual configuration of analog inputs, example "JTEMP-1" (simulation for input signal for temperature measurement in temperature control circuit)

| Field | Value | Function, display, entry required |
|---|---|---|
| Day | | Display the analog input; entry to switch to the "AUTO" or "MANUAL ON/OFF" operating mode |
| Port | | Hardware address |
| VALUE | | Input of a simulated process value |
| PV | | Process value |

| Field | Value | Function, display, entry required |
|---|---|---|
| Unit | | Physical variable |

**Special Notes:**

- 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%)

After working on the manual level, you have to switch all inputs back to the "AUTO" operating mode. Otherwise, the function of the DCU system will be limited.

### 8.10.4.4 Manual Operation of Analog Outputs

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, etc. |

**Screen**

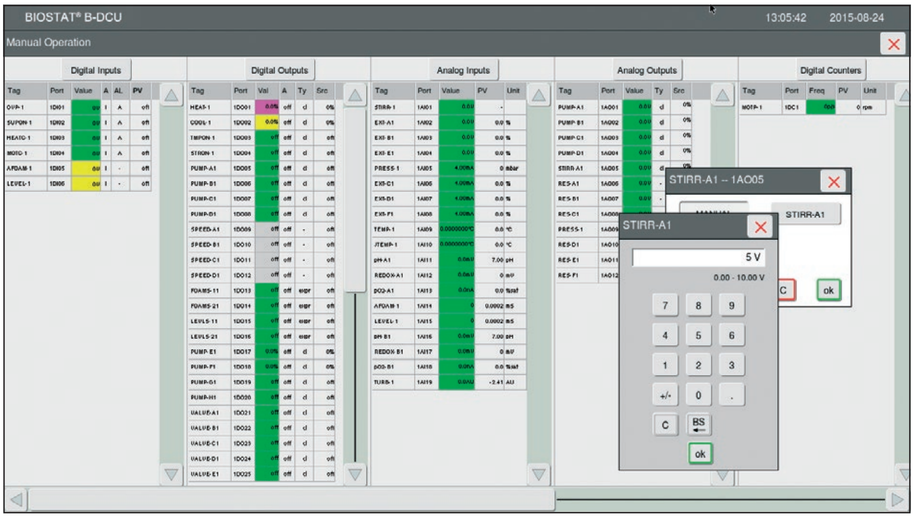



Fig. 8-6: Manual configuration of analog outputs, example "STIRR-1" (simulation of control signal for the speed regulation of the motor drive)

| Field | Value | Function, display, entry required |
|---|---|---|
| Day | | Display of analog output, selection of the "AUTO" or "MANUAL" operating mode |
| Port | | Hardware address |
| VALUE | PV | Output signal 0 ... 10 V or 0/4 ... 20 mA |

| Field | Value | Function, display, entry required |
|---|---|---|
| Ty | | Upstream function<br>CL = controller<br>expr = logical function<br>– = without |
| SRC | nn % \| off | Upstream controller output<br>Display of output value:<br>off<br>-100% ... +100% |

**Special Notes:**

- The physical 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%)

After working on the manual level, you have to switch all outputs back to the "AUTO" operating mode. Otherwise, the function of the DCU system will be limited.

### 8.10.4.5 Manual Operation for Controllers ("Control Loops")

You can simulate controllers in manual operation by entering a setpoint.

**Screen**

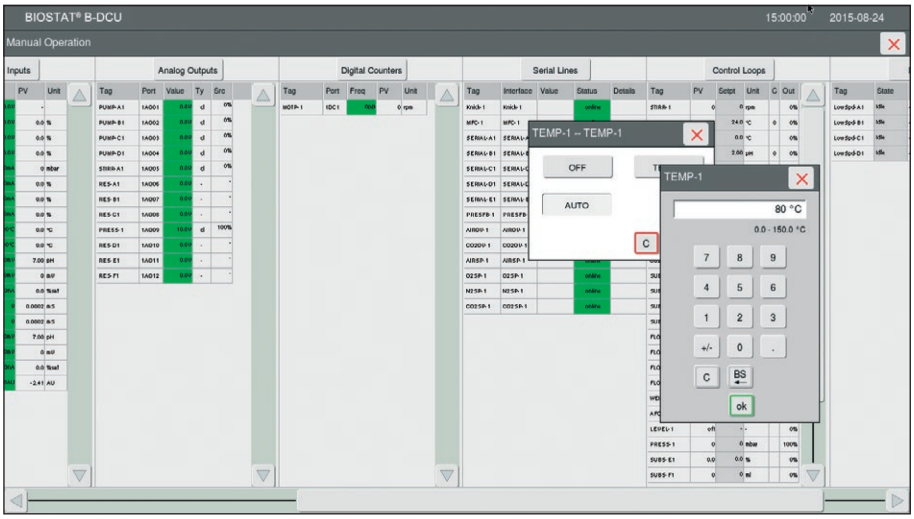



Fig. 8-7: Manual configuration of controller, example "TEMP-1" (simulation of control signal for temperature controller)

| Field | Value | Function, input required |
|---|---|---|
| Tag | Description | Display of controller, e.g., TEMP-1 |
| PV | | Process value |
| Setpt | | Display of setpoint |
| | | Input for "OFF" or "AUTO" operating mode<br>Operating modes:<br>"OFF": Controller is turned off<br>"AUTO": Normal operation, setpoint for controller can be configured |
| Unit | | Physical variable |

| | |
|---|---|
| C | Display of active cascade<br>0 = no cascade<br>1 ... n = specific cascade for cascade controller |
| Out | Calculated output value |

**Special Notes**

After working on the manual level, you have to switch all outlets back to the "AUTO" operating mode. Otherwise, the function of the DCU system will be limited.

### 8.10.5 Manual Operation of Sequence Control ("Phases")

You can simulate sequences in manual operation (e.g., during startup or in case of problems in the sequence execution during sterilization) by starting a sequence.

**Screen**

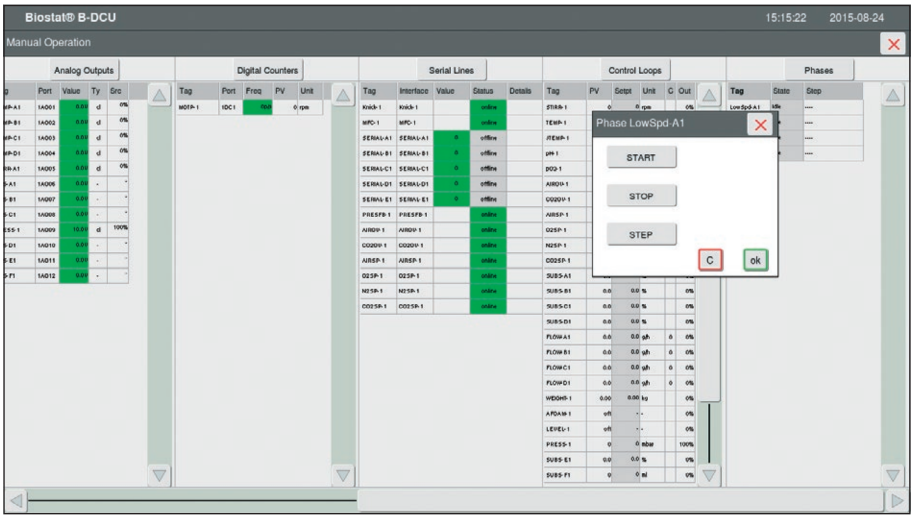



Fig. 8-8: Manually starting a sequence, example "LowSpd-A1"

| Field | Value | Function, input required |
|---|---|---|
| Tag | Description | Display of sequence, e.g., FILL-1 |
| State | | Display of sequence status \| step |
| | | Start/stop of a sequence ("START" \| "STOP")<br>Continuation to next sequence step ("STEP") |
| Step | | Display of current sequence step |

**Special Notes**

Type and number of sequence steps of individual sequences depends on the configuration of your system.
After working on the manual level, you must stop all sequences. Otherwise, the function of the DCU system will be limited.

### 8.10.6 Externally Connected Devices

The “External” main function can be used to view and set the status of externally connected devices (e.g., balances).

Only personnel authorized to do so may change the menu settings. To define settings in the menu, the standard password needs to be entered.

**Screen**

After pressing “External” and entering the standard password, the “External System” submenu opens:

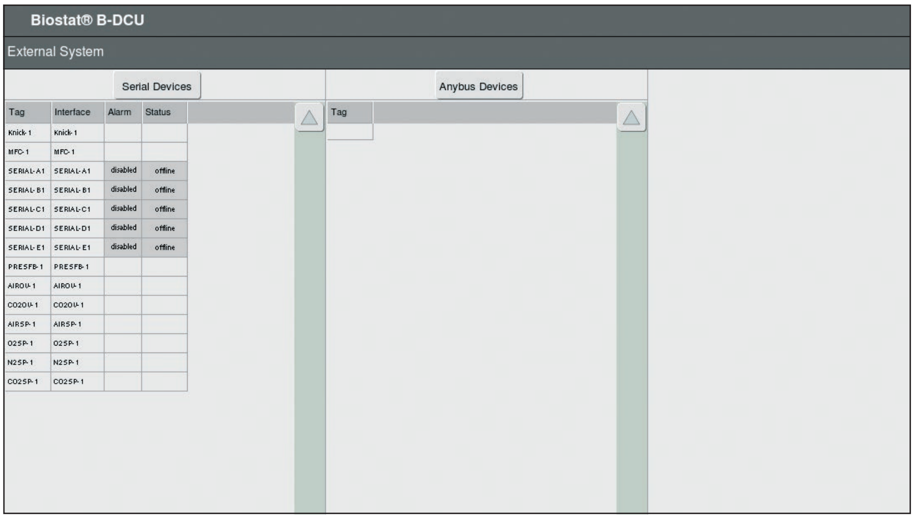



Fig. 8-9: Display of externally connected devices in the “External System” submenu (configuration example)

| Field | Value | Function, input required |
|---|---|---|
| Tag | Description | Display of the connection, e.g., SERIAL-A1 |
| Interface | Description | Display of interface |
| Alarm | | Display and configuration of alarm status:<br>enabled = activate alarm<br>disabled = deactivate alarm |
| Status | | Status display of connected device<br>(offline \| online) |

# 9 Cleaning and Maintenance

Incorrect cleaning and maintenance can lead to erroneous process results, causing high production costs. Regular cleaning and maintenance is thus essential. Among other factors, the operational safety and effective performance of fermentation also depend on proper cleaning and maintenance.

Cleaning intervals largely depend on the stress placed on the culture vessels and equipment by aggressive components contained in the media (e.g., acids and bases used to regulate pH) and the level of contamination from culture and metabolic product residues attached to this equipment.

**Preliminary Steps**

⚠ **CAUTION**

**Danger from escaping compressed air, $O_2$, $N_2$, $CO_2$!**

- Only qualified and authorized personnel are permitted to work on the aeration segments.
- When working on gas-carrying components: Wear personal protective equipment.

▶ Close all connected aeration segments.
▶ Carefully disconnect the power cables from the device. Keep the hose ends away from the body when doing this.
▶ Connect the supply lines to the device after servicing
▶ (Chapter 7.3.5, page 55, Chapter 8.4.3, page 71).
▶ When working on the oxygen line: Ensure your tools and hands are clean (grease and oil-free).

Make sure to always perform the following preliminary steps during cleaning and maintenance:

▶ Switch off the device.
▶ Disconnect the power supply from the laboratory connection.
▶ Turn off all supply media in the lab (water and gas supply).
▶ Ensure that the connections and hoses have been depressurized.
▶ If necessary: Remove the supply media lines from the device.

## 9.1 Cleaning

**ATTENTION**

**Inappropriate cleaning agents pose the danger of corrosion and damage to the device and the culture vessel!**

- Avoid strongly caustic or chloride-containing detergents.
- Avoid using solvent-based cleaning agents.
- Ensure that the cleaning agents used are compliant materials.

Observe the safety instructions for the cleaning agents.
The use and disposal of cleaning agents, and water containing such agents, may be subject to legal or environmental protection regulations in your country.

### 9.1.1 Cleaning the Device

**Control Unit and Supply Unit**

▶ Clean the housing of the device with a slightly dampened cleaning cloth. For greater contamination, use a mild soap.
▶ Clean the operating display with a slightly dampened, lint-free cleaning cloth. For greater contamination, use a mild soap.

Be sure not to scratch the device. This causes later contamination to be more difficult to remove.

### 9.1.2 Cleaning the Culture Vessels

Detailed information on cleaning culture vessels, vessel equipment, and probes can be found in the operating instructions for the culture vessels.

## 9.2 Maintenance

Maintenance performed by the user is restricted to the following tasks:
- Maintaining the pH or DO probes as per the manufacturer's | supplier's specifications.
- Checking and replacing parts subject to wear as well as disposables, e.g., glass vessels, filters, hoses, and sealing gaskets with identical components with the same specifications (see spare parts list).
- Replacing O-rings, other sealing gaskets, filters, hoses, and single-use items, e.g., inoculation membranes.

Detailed instructions on the maintenance of culture vessels, vessel equipment, and sensors can be found in the UniVessel® operating manual.

The internal modules of the device, especially the safety devices, peristaltic pumps, drive motors, and stirrer shaft couplings, must only be serviced by Sartorius Service.

Please return the device to Sartorius Stedim Biotech if it is defective. Observe the instructions for decontamination.

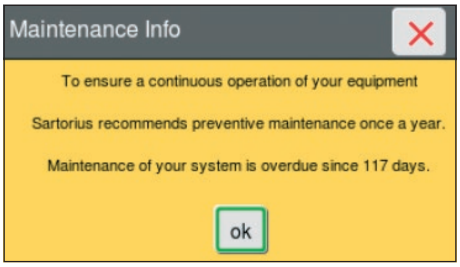
### 9.2.1 Maintenance Info

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.

### 9.2.2 Maintenance Schedule

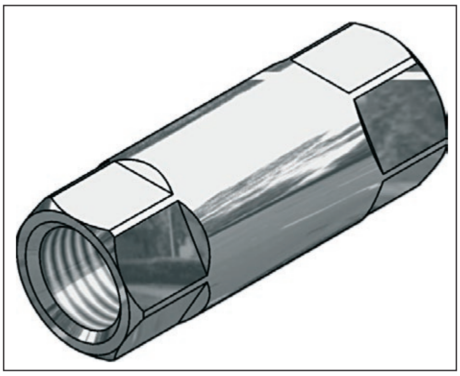
The cyclical maintenance of the device depends on its service life.

The following table lists the maintenance intervals as they are assigned to the components:

| Component | Activity | Before every process | After 10-20 autoclave cycles | If unsterile | 1 × yearly |
|---|---|---|---|---|---|
| **Glass culture vessel** | | | | | |
| Leak test | Pressure hold test<br>Leaktightness test | x | | x | |
| **Device<br>Connections to the culture vessel, air and water** | | | | | |
| Gas leak test | Visual inspection | x | | | |
| Leak test temperature control circuit | Visual inspection | x | | | |
| Tapping septa | | | | | |
| -> | Replace | x | | | |
| **O-rings** | | | | | |
| -> | Visual inspection, replace if needed | x | | | |
| -> | Replace | | | x | x |
| **Air inlet and exhaust filters** | | | | | |
| Filter elements | Integrity testing | x | | | |
| -> | Replace | | x | x | x |
| **Holding bottles, sampling bottles** | | | | | |
| -> | Visual inspection, replace if needed | x | | | |
| Gaskets, ventilation filters | Replace | | | x | x |
| **Direct coupling/ magnetic coupling** | | | | | |
| Check for contamination and damage | Visual inspection | x | | | |
| **Peristaltic pumps** | | | | | |
| Pump hoses | Visual inspection, replace if needed | x | | | |
| **Probes** | | | | | |
| pH probe | Calibration, visual inspection for damage | x | | | |
| DO probe | Calibration, visual inspection for damage | x | | | |

| Component | Activity | Before every process | After 10–20 autoclave cycles | If unsterile | 1 × yearly |
|---|---|---|---|---|---|
| Membrane body, electrolyte (Clark probes) | Visual inspection, replace if needed | x | | | |
| Sensor cap (optical $O_2$ probe) | | x | | | |
| Foam \| level probe | Calibration, visual inspection for damage | x | | | |
| Temperature probes | Calibration, visual inspection for damage | x | | | |
| Plugs, contacts, lines | | x | | | |
| -> | Visual inspection | x | | | |
| **Maintenance according to maintenance schedule** | | | | | |
| Maintenance and functional test according to maintenance report | Only to be carried out by Sartorius experts. Please contact Sartorius Service. | | | | x |
| Mass flow controller | MFC recalibration by Sartorius Service | | | | x |

### 9.2.3 Carrying Out Maintenance Work on Safety Components



**Return Valve**

The wastewater outlet in the temperature control module consists of a return valve (see P&I diagram in "Technical Documentation" folder). This valve protects the system from excessive pressure buildup if the water feed is accidentally connected to the outlet of the temperature control circuit, if water dams up, or if water flows back into the supply unit from the outlet.

## ATTENTION

**If the pressure in the temperature control circuit is too high, the culture vessels can burst!**

In double-walled glass vessels, this can cause the wall to burst. Non-return valves are only designed for assuring the direction of flow. They must not be used as safety valves. If a sealed external cooling circuit has been connected to the system, it must be ensured that this circuit operates at zero-pressure.

The return valve's function must be checked before the device is commissioned and then once a year thereafter. The function test and replacement of the return valve, where necessary, is carried out by Sartorius Service.

# 10 Faults

## 10.1 Procedure

Always proceed according to the following steps when faults occur on the unit.

▶ Switch off the device.
▶ If the fault (e.g., smoke or odors, abnormally high surface temperatures) represents a direct danger to personnel or property: Disconnect the device from the power supply (see Chapter 2.7, page 13).
▶ Inform management on site about the fault.
▶ Determine the cause of the fault and correct it before switching on the device again.

If the fault cannot be remedied, please consult Sartorius Service.

## 10.2 Hardware-related Faults

### 10.2.1 "Contamination" Troubleshooting Table

We recommend carrying out a sterility test before each process. Duration 24 to 48 h.
Conditions for a sterility test:

- The culture vessels must be filled with the prescribed culture medium or a suitable starter medium and autoclaved in accordance with the specifications.
- All of the planned components, peripheral devices, correction medium feed lines and sampling systems to be tested must be connected to the culture vessels.
- The system must be set to the scheduled operating conditions (e.g., temperature, stirrer speed, aeration).

| Contamination | Potential causes | Corrective measures |
|---|---|---|
| Generalized and widespread, even without having inoculated the culture (during the sterility test phase) | Insufficiently autoclaved culture vessel. | Check the autoclave settings.<br>Increase the autoclaving time.<br>Perform sterility tests using test spores. |
| | Air inlet line or air inlet filter defective. | Replace the tubing.<br>Check the filter and replace if necessary. |
| Generalized and gradual (even without inoculating the culture) | Sealing gaskets on the culture vessel or the integrated components are damaged (e.g., hairline cracks). | Carefully check the integrated parts.<br>If damage is suspected (rough, porous surfaces or dents), replace sealing gaskets. |
| After inoculation (wide-spread) | Contaminated inoculum culture.<br>Non-sterile inoculation equipment. | Take control samples of the inoculation culture and test inoculated culture medium from the vessels (e.g., on test nutrient solutions). |
| | Incorrect inoculation. | Check the inoculation procedure.<br>Carefully practice the inoculation process. |
| | Supply air filter or connection has become non-sterile or defective. | Check the filter and replace if necessary.<br>Replace the connection line. |

| Contamination | Potential causes | Corrective measures |
|---|---|---|
| During the process (rapid) | Supply air filter or connection has become non-sterile or defective. | Check the filter and replace if necessary.<br>Replace the connection line. |
| | Accidental or unauthorized manipulation of equipment. | Take organizational measures at the work site to prevent the equipment from being manipulated without authorization. |
| During the process (gradual) | Sealing gaskets on the culture vessel or the integrated components are defective (e.g., hairline cracks or porosity). | If possible, continue process to the end. Once finished, dismantle the vessel and carefully check the integrated parts.<br>If damage is suspected (rough, porous surfaces or dents), replace sealing gaskets. |
| | Exhaust air filter(s) or connection has become unsterile or is defective (contaminated from the exhaust air line). | Check the filter (if possible, perform a validity test) and replace if necessary.<br>Replace the connection line. |

### 10.2.2 "Counter Cooling System" Troubleshooting Table

The counter cooling system does not work or does not provide sufficient cooling power.

| Problem | Potential causes | Corrective measures |
|---|---|---|
| The cooling water is not being fed into the system | The laboratory's supply line is blocked or the valves in the cooling water supply are defect. | If all other potential causes can be excluded (see below), contact Sartorius Service. |
| | The cooling water supply valve does not work or the non-return valve has become stuck because of contaminated cooling water or scale deposits. | Check the water hardness (no more than 12 dH).<br>Check the non-return valve.<br>Feed clean cooling water into the system (if necessary, install a pre-filter). |
| Insufficient cooling power | Flow rate too low.<br>Cooling water temperature too high. | The minimum operating temperature is around 8°C above the cooling water temperature.<br>If necessary, install an upstream cooling device. |

### 10.2.3 "Aeration and Ventilation" Troubleshooting Table

Aeration or ventilation system does not work or does not provide sufficient gas/ventilation.

| Problem | Potential causes | Corrective measures |
|---|---|---|
| Air inlet line blocked | Air inlet filter blocked. | Check the air feed (dry and free of oil and dust).<br>If necessary, install a pre-filter. |
| The gas or air supply is blocked or decreases suddenly | Hose kinked or disconnected.<br>Exhaust air filter blocked (e.g. as a result of moist air and the formation of condensate, or foam). | Check the hose and filter and, if necessary, fit new sterile filters. |

## 10.3 Process-related Faults/Alarms

Faults in the operating sequence are displayed as alarms on the operating display. To correct these process-related faults, read the following chapters.

The DCU system makes a distinction between alarms and messages. Alarms have higher priority and are displayed first ahead of the messages.

### 10.3.1 Alarm Triggering

When alarms are triggered, they are automatically displayed in a window superimposed over all other windows. The color of the alarm bell turns red.

The color of the alarm bell stays red as long as at least one unconfirmed alarm remains in memory.

**"New ALERT" Screen**

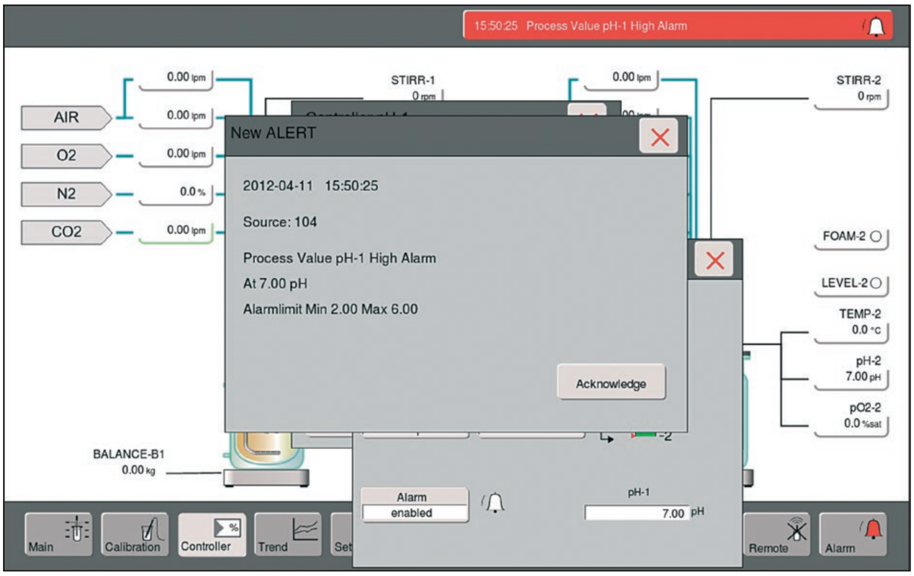
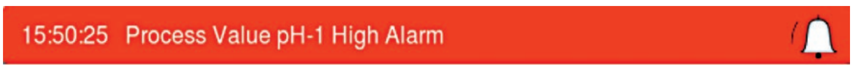



Fig. 10-1: Alarm message: "New ALERT" pop-up screen (new alarm)

– Closing the window:
  After pressing [X], the alarm is stored as an "unacknowledged alarm" (UNACK) in the alarms list and the alarm symbol remains activated.




– The alarm window closes after acknowledgment of the alarm with "Acknowledge." The alarm message disappears in the header.

### 10.3.2 "Alarm Overview" Menu

The alarm overview can be selected as follows:

▶ Press the "Alarm" main function key.


**"Alarm" Screen**

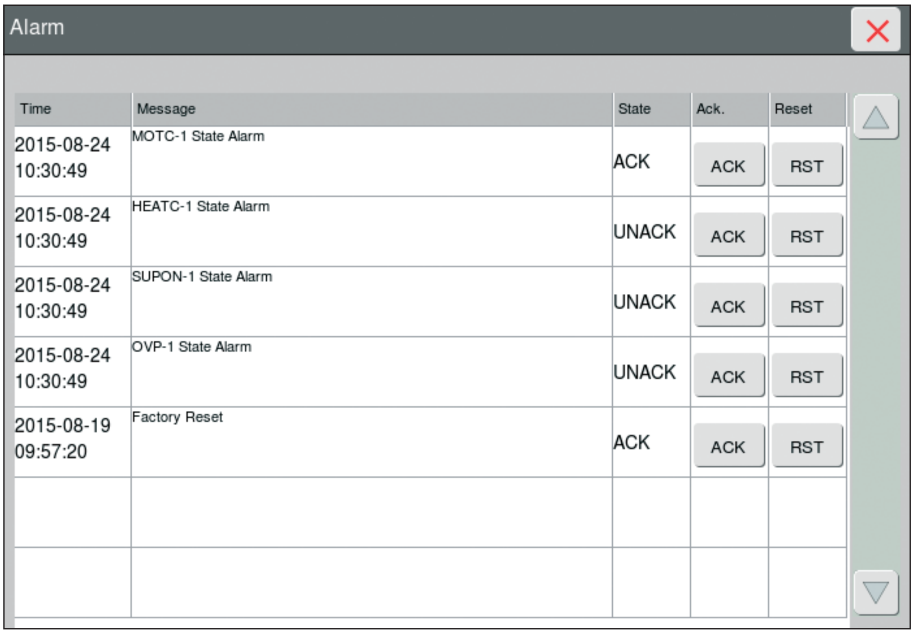



Fig. 10-2: Alarm table, accessible through the "Alarm" function key

| Key | Function, input required |
|---|---|
| ACK ALL | Acknowledges all activated alarms |
| ACK | Acknowledges the selected alarm |
| RST | Resets and deletes the selected alarm |

### 10.3.3 Process Value Alarms

The DCU system has limit value monitoring routines that monitor all process variables (measured data and calculated process values) to ensure that they are within the alarm limits (High/Low).

The alarm limits must be within the measuring range limits. After entering the alarm limits, you can release or lock the limit value monitoring individually for every process parameter.

The DCU system can lock certain process outputs after process value alarms.

### "Process Value Alarms" Screen

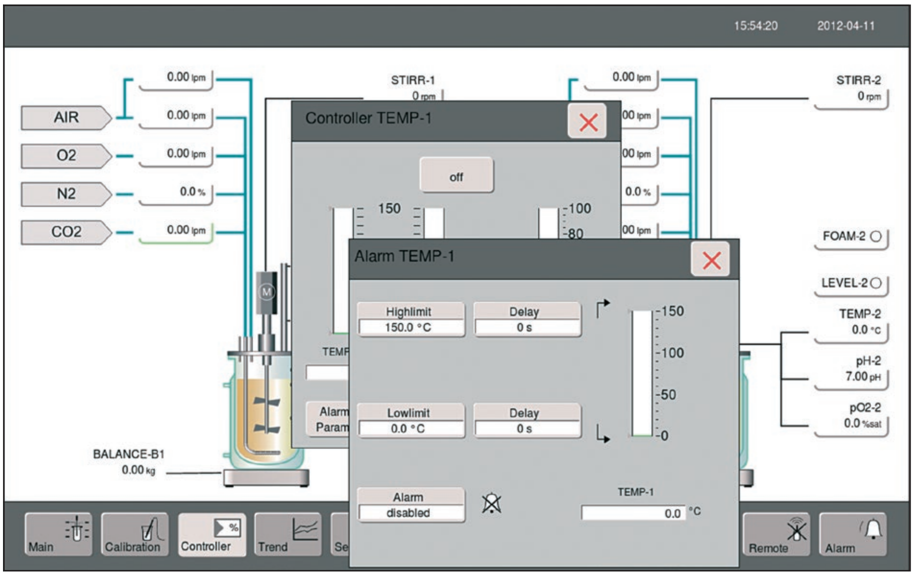



Fig. 10-3: Submenu for configuring alarm monitoring, example "TEMP-1," called from the "Controller" menu, overview "All"

| Field | Value | Function, input required |
|---|---|---|
| High limit | °C | Upper alarm limit in the physical unit of the PV |
| Low limit | °C | Lower alarm limit in the physical unit of the PV |
| Delay | s | Delay until alarm is active, after a value falls outside the alarm limits |
| Alarm | | Status for alarm monitoring |
| | Disabled | Alarm monitoring, high \| low alarms locked |
| | Enabled | Alarm monitoring, high \| low alarms activated |

### Operating Notes

Alarms are displayed on the screen and must be acknowledged:

– If the value falls outside the alarm limits, an alarm window opens above the active screen. An acoustic signal sounds. The alarm display appears in the header line of the screen.
  The process value display also shows a small alarm symbol.

**Screen Example: Exceeding the Alarm Limit**

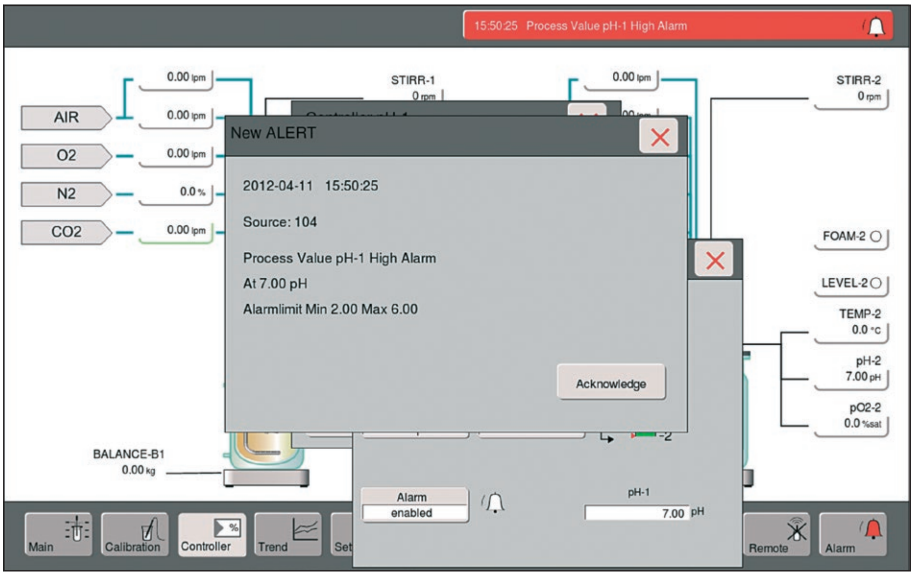



Fig. 10-4: Alarm message, exceeding the alarm limit for pH-1.

– The alarm window closes after acknowledgment of the alarm with “Acknowledge” or after pressing [X].

  – After the alarm is acknowledged with “Acknowledge,” the alarm symbol disappears.
  – After pressing [X], the alarm is stored in the alarm list as an unacknowledged alarm and the alarm symbol remains active (the alarm bell stays red).
– If several alarms have been triggered, the next, still unacknowledged alarm will be displayed after the active alarm window is closed.

The DCU system continues to display limit value alarms as long as the process value remains outside the alarm limits.

### 10.3.4 Alarms for Digital Inputs

Digital inputs can be queried in response to alarm conditions as well.
These can be used to monitor components like limit contacts (anti-foam/level sensors), motor protection switches, or circuit breakers.

When an alarm is triggered, an alarm message with the time of the alarm event and an acoustic confirmation signal is emitted.

The DCU system can lock certain process outputs after process value alarms.

### "Alarm Monitoring" Screen

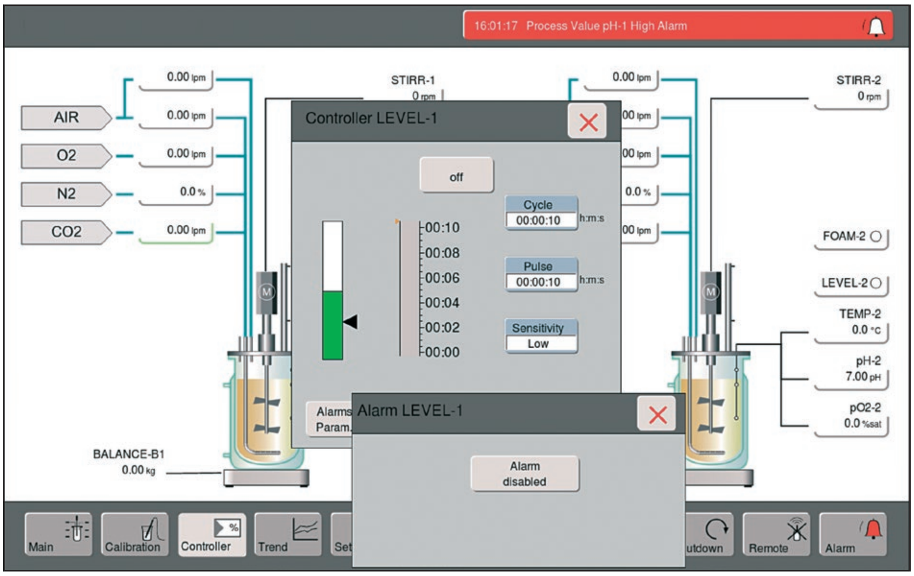



Fig. 10-5: Activating and deactivating alarm monitoring

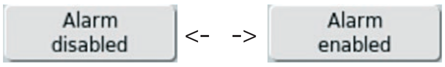



Fig. 10-6: 19-6: Alarm deactivated, alarm activated

| Field | Value | Function, input required |
|---|---|---|
| Alarms Param. | | Alarm monitoring operating mode |
| | Disabled | Alarm monitoring locked for the input |
| | Enabled | Alarm monitoring activated for the input |

### Operating Notes

A new alarm is indicated in two ways:

- When an alarm is triggered for the first time, a message is displayed in the operating display and an acoustic signal is emitted.
- The alarm symbol is displayed in the header of the operating display.

▶ Correct the cause of the alarm.
▶ Check the function of the component that is producing the input signal, the corresponding connections, and if necessary the controller settings.
▶ Acknowledge the alarm with "Acknowledge" or press [X].
▷ The alarm window closes.
  - After the alarm is confirmed with "Acknowledge," the alarm symbol disappears (the alarm bell turns white). The alarm is recorded in the alarm list as a confirmed alarm ("ACK").
  - After pressing [X], the alarm is stored in the alarm list as an unacknowledged alarm and the alarm symbol remains active (the alarm bell stays red).

For an overview of alarms that have occurred, you can open the alarm table with the "Alarm" main function key.

### 10.3.5 Alarms, Meaning, and Corrective Measures

#### 10.3.5.1 Process Alarms

The user can switch the individual alarms listed in the following table on and off:

| Text in the alarm line | Description | Remedy |
|---|---|---|
| `“Name” State Alarm` | Digital input alarm | Confirm alarm with “ACK” key |
| `“Name” Low Alarm` | The corresponding process value has fallen below its lower alarm limit | Confirm alarm with “ACK” key |
| `“Name” High Alarm` | The corresponding process value has exceeded its upper alarm limit | Confirm alarm with “ACK” key |
| `Jacket Heater Failure` | Overheating protection in the temperature circulation of the double wall has triggered | The temperature control circuit must be refilled |
| `Motor Failure` | Overheating protection of the motor has triggered | Allow the motor to cool down |
| `OVP` | Overvoltage protection | |

#### 10.3.5.2 Process Messages

| Text in the alarm line | Description | Remedy |
|---|---|---|
| `“Shut down DCU ...”` | The “SHUT DOWN” key was pressed | Confirm “SHUT DOWN” status by pressing the key once more |
| `“Shut down fermenter”` | “Emergency off” was pressed on the bioreactor | Switch the bioreactor back on with “Emergency off” |

#### 10.3.5.3 System Alarms

The alarms in the following table are system-generated messages that the user cannot switch off:

| Text in the alarm line | Description | Remedy |
|---|---|---|
| `Source: Factory Reset` | Confirmation message for a system reset triggered from the “Settings” menu | Confirm alarm with “ACK” |
| `[Name] Watchdog Timeout` | Confirmation message for a watchdog timeout, triggered by malfunctions in the DCU including reference to the source of failure | Note down the alarm and report it to Service; confirm alarm with “ACK” |
| `Power Failure`<br>`Power lost at`<br>`[yyyy-mm-dd hh:mm:ss]` | Power failure with the date and time | Confirm alarm with “ACK” |
| `Power Failure, Process Stopped`<br>`System in Standby`<br>`Power lost at`<br>`[yyyy-mm-dd hh:mm:ss]` | Power failure with the date and time; maximum power outage time exceeded | Confirm alarm with “ACK” |
| `Shut down Unit #` | “Shut down” was pressed on the bioreactor | Switch the bioreactor back on with “Shut down” |

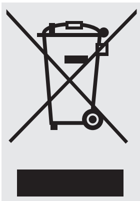
# 11 Disposal

## 11.1 General Information

**Packaging**

The packaging is made of environmentally friendly materials that can be used as secondary raw materials. If the packaging is no longer needed, it can be disposed of by local waste disposal authorities.

**Device**



The equipment, including accessories and empty non-rechargeable and rechargeable batteries, does not belong in your regular household waste; this equipment is manufactured from high-grade materials which can be recycled and reused. European Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) requires that electrical and electronic equipment be collected and disposed of separately from other unsorted municipal waste, with the aim of recycling it.
The crossed-out waste bin symbol indicates that separate collection is required.

In Germany and several other countries, Sartorius itself assumes responsibility for the return and legally compliant disposal of its electronic and electrical products. These products may not be placed with household waste or dispensed of at collection centers run by local public disposal operations – not even by small commercial operators. Please contact Sartorius Service in this regard.

In countries that are not members of the European Economic Area (EEA) or where no Sartorius subsidiaries or dealerships are located, please contact your local authorities or a commercial disposal operator.

Prior to disposal and scrapping of the equipment, any batteries should be removed and disposed of at local collection points.

**Addresses for Disposal**

- For detailed information and service addresses for disposing of the device, visit our website (www.sartorius.com).
- For information on returning the equipment, see Chapter 12.3, page 172).

## 11.2 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 fermentation processes are potentially hazardous materials that could cause biological or chemical hazards.

According to the EU directives (European directive on hazardous substances), the owners of devices that come into contact with hazardous substances are responsible for properly disposing of these devices and to declare such devices when transporting them.

Devices contaminated with hazardous materials (NBC contamination) will **not** be accepted for repair or disposal.

**Decontamination Declaration**

Sartorius Stedim Biotech has a duty to protect its staff from hazardous substances. When returning devices and device components, the sender must enclose a decontamination declaration as proof of compliance with the safety regulations governing the area of application for which the devices were used.

This declaration must detail the microorganisms, cells and media that the device has come into contact with and the measures taken to disinfect and decontaminate it.

- The recipient (e.g., Sartorius Service) must be able to read this decontamination declaration before opening the packaging.
- This document contains an attachment with a decontamination declaration form in Chapter 15.2, page 184.
  To create additional copies, simply copy the attached form or request additional forms from Sartorius Stedim Biotech.

---

⚠ **CAUTION**

**Danger of severe injury from improperly performed work!**

The disassembly and disposal of the unit may only be carried out by technical personnel.

---

⚠ **WARNING**

**Warning of dangerous electrical voltage!**

Work on the electrical equipment may only be carried out by an electrician.

---

## 11.3 Decommissioning the Device

The cultivation process and operation of the device has been ended properly.

- ▶ Clear the culture vessel, pipelines, and hoses of all culture media and additives.
- ▶ Clean the entire device.
- ▶ Sterilize the glass vessel and hoses.
- ▶ Turn the device off via the main switch and secure it from being turned back on.
- ▶ Disconnect the device from power and the supply lines.

## 11.4 Dismantling the Device

⚠ **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 scrapping, leading to injury. There is also danger due to moving parts and falling objects.
- The unit may only be disassembled by technical personnel.
- Wear personal protective equipment.

**Required Qualification:** Operator

▶ Disassemble the device until all parts have been assigned to a material group and can be appropriately disposed of.

## 11.5 Disposal

▶ Dispose of the device in accordance with local regulations (see Chapter "11.1 General Information," page 169).

# 12 Storage and Shipping

## 12.1 Storage

**Upon Delivery (Temporary Storage)**

▶ Observe the transport conditions for the device (see Chapter “13.7 Ambient Conditions,” page 176).

**After Use**

▶ Decommission the device (see Chapter 11.3, page 170).
▶ If required: Pack the device (see Chapter 12.3, page 172).
▶ Observe the transport conditions for the device (see Chapter “13.7 Ambient Conditions,” page 176).

## 12.2 Storage Conditions

– Dry building.
– No UV radiation or direct sunlight.
– No areas where solvents, chemicals, acids, and fuels are stored.
– Observe ambient conditions (see Chapter “13.7 Ambient Conditions,” page 176).

## 12.3 Packing/Return

### 12.3.1 General Information

---

⚠ **CAUTION**

**Danger of injury due to contaminated equipment!**

Devices contaminated with hazardous materials (NBC contamination) will **not** be accepted for repair or disposal.

---

You can send defective devices or parts back to Sartorius.

Returned devices must be clean, decontaminated, and packed carefully.

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

### 12.3.2 Returning the Device

▶ Observe the information on decontamination (see Chapter 11.2, page 169).
▶ Decommission the device (see Chapter 11.3, page 170).
▶ Clean the device (see Chapter 9, page 157).
▶ Properly decontaminate the device.
▶ Complete the decontamination declaration (see Chapter 15.2, page 184).
▶ Return the device to Sartorius Service. The service addresses for returning the device can be found on our website (www.sartorius.com).

# 13 Technical Specifications

## 13.1 Control Unit

### 13.1.1 Dimensions

| | Unit | Value |
|---|---|---|
| Depth | mm | 535 |
| Width | mm | 490 |
| Height | mm | 730 |
| Weight, approx. | kg | 30 |

### 13.1.2 Mains connection

| | Unit | Value |
|---|---|---|
| Voltage | V | 120/230 V (±10%) |
| Frequency | Hz | 60/50 |
| Power consumption | A | 4 |
| Protection | | IP30 |

## 13.2 Supply Unit

### 13.2.1 Dimensions

| | Unit | Value |
|---|---|---|
| Depth | mm | 432 |
| Width | mm | 360 |
| Height | mm | 768 |
| Weight (depending on the equipment) | kg | 45 |

### 13.2.2 Mains Connection (120 V Version)

| | Unit | Value |
|---|---|---|
| Voltage | V | 120 V (±10%) |
| Frequency | Hz | 60 |
| Power consumption | A | 12 |
| Protection class as per DIN EN 60529 | | IP30 |

### 13.2.3 Mains Connection (230 V Version)

| | Unit | Value |
|---|---|---|
| Voltage | V | 230 V (±10%) |
| Frequency | Hz | 50 |
| Power consumption | A | 10 |

| | Unit | Value |
|---|---|---|
| Protection class as per DIN EN 60529 | | IP20 |

### 13.2.4 Work Surface for 6 Supply Units

| | Unit | Value |
|---|---|---|
| Depth | mm | 800 |
| Width | mm | 3300 |

## 13.3 Energy Connections Inside the Laboratory

### 13.3.1 Cooling Water Supply/Cooling Circuit

| | Unit | Value |
|---|---|---|
| Flow rate, max. | l/min | 5 |
| Water pressure, max. | barg | 2-4 |
| | psi | 29-58 |
| Temperature, min. | °C | 4 |
| Water hardness, max. | °dH | 12 |
| Water quality | | Clean water,<br>free of particles |
| Procedure | | Not pressurized |

### 13.3.2 Process Gas Supply

| | Unit | Value |
|---|---|---|
| Supply pressure | | |
| Compressed air [AIR], preset, max. | barg | 1.5/class 2 |
| $O_2$, preset, max. | barg | 1.5 |
| $N_2$, preset, max. | barg | 1.5 |
| $CO_2$, preset, max. | barg | 1.5 |
| All gases | Dry;<br>grease, oil, and particle-free | |
| Gas flow rate | | |
| Depending on the size of the culture vessel and customer-specific selection of mass flow controller | vvm | 0.0001 - 2 |
| | l/min | 0.001 - 20 |

## 13.4 Temperatures in the UniVessel®

| | Unit | Value |
|---|---|---|
| Operating temperatures, max. | °C | + 80 |
| Operating temperature, min. | °C | + 4 |

## 13.5 Stirrer Drive

**Motor 200 W**

| | **UniVessel® Glass direct coupling** | **UniVessel® Glass magnetic coupling** | **UniVessel® SU** |
|---|---|---|---|
| **Volumes [L]** | **Speed range [rpm]** | | |
| 1 | 20–2000 | 20–2000 | |
| 2 | 20–2000 | 20–2000 | 20–400 |
| 5 | 20–1500 | 20–800 | |
| 10 | 20–800 | 20–700 | |

**Motor 400 W**

| | **UniVessel® Glass direct coupling** | **UniVessel® Glass magnetic coupling** | **UniVessel® SU** |
|---|---|---|---|
| **Volumes [L]** | **Speed range [rpm]** | | |
| 10 | 20–1200 | 20–1200 | |

## 13.6 External Pumps

| | Unit | Value |
|---|---|---|
| Control range when using the control unit | | 1:100 |

## 13.7 Ambient Conditions

| | Unit | Value |
|---|---|---|
| Installation location | | Conventional laboratory rooms, max. 2,000 m above sea level |
| Ambient temperatures in the operating temperature range | °C | +5 to 40 |
| Relative humidity | % | < 80% for temperatures up to 31°C decreasing linearly < 50% at 40°C |
| Impurities | | Pollution level 2 (Normally only non-conductive pollution occurs. Occasionally, however, temporary conductivity caused by condensation must be expected) |
| Acoustic emission | dB (A) | Max. sound pressure level < 70 |

### ATEX

**WARNING**

**Ignition of explosive mixtures!**

The device is not ATEX (ATmosphère EXplosive)-certified.
The device may not be operated in potentially explosive atmospheres.

## 13.8 Calculating Water Hardness

| | Alkaline earth ions | Alkaline earth ions | German hardness | CaCO3 | UK hardness | French hardness |
|---|---|---|---|---|---|---|
| | **[mmol/l]** | **[mval/l]** | **[°dH]** | **[ppm]** | **[°e]** | **[°fH]** |
| 1 mmol/l alkaline earth ions | 1.00 | 2.00 | 5.50 | 100.00 | 7.02 | 10.00 |
| 1 mval/l alkaline earth ions | 0.50 | 1.00 | 2.80 | 50.00 | 3.51 | 5 |
| 1° German hardness [°dH] | 0.18 | 0.357 | 1.00 | 17.80 | 1.25 | 1.78 |
| 1 ppm CaCO3 | 0.01 | 0.020 | 0.056 | 1.00 | 0.0702 | 0.10 |
| 1° English hardness [°e] | 0.14 | 0.285 | 0.798 | 14.30 | 1.00 | 1.43 |
| 1° French hardness [°fH] | 0.10 | 0.200 | 0.560 | 10.00 | 0.702 | 1.00 |

## 13.9 Dimensions of the Variable Area Flow Meters

The built-in variable area flow meters and mass flow controllers are calibrated to the following standard conditions.

| Calibration parameters | |
|---|---|
| Gas type | Air |
| Temperature | 20° C = 293 K |
| Pressure | 1.21 bar (absolute) |

When gases with deviating pressures pass through, higher or lower values can be displayed. These must be recalculated to evaluate the flow rates.

Using the following conversion table, flow rates for the different processes can be recalculated.

| **Specific data for gas** | **Density [kg/m$^3$]** |
|---|---|
| Carbon dioxide ($CO_2$) | 1.977 |
| Air | 1.293 |
| Oxygen ($O_2$) | 1.429 |
| Nitrogen ($N_2$) | 1.251 |

# 14 Conformity & Licenses

## 14.1 GNU Licensing

DCU systems contain software subject to the license terms of the “GNU General Public License (GPL)” or the “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.

## 14.2 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® B-DCU: Bioreaktor | Fermenter**
***BIOSTAT® B-DCU: Bioreactor | Fermenter***

Baureihe / *Type series*
**BIOSTATBDCU2FL**

Modell / *Model*
**1000024081; 1000045251**

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:* **19**

Sartorius Stedim Systems GmbH
Guxhagen, 2019-04-04

i.V. | i.V. A. Schulze

Lars Böttcher
Head of Product Development Bioprocess Solutions

Annette Schulze
Plant Quality Manager

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: 2051019-02 SSS16CE008-02.de,en 1 / 1 PMF: 2051018 OP-113_fo1_2015.10.12

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TÜV SÜD America

# CERTIFICATE

**No. U8 18 04 73361 077**

**Holder of Certificate:** **Sartorius Stedim Systems GmbH**
Robert-Bosch-Str. 5 - 7
34302 Guxhagen
GERMANY

**Production Facility(ies):** 73361

**Certification Mark:**

TÜV SÜD Safety tested Production monitored C US

**Product:** **Laboratory Equipment**

**Model(s):** **BIOSTAT® B-DCU II**

**Parameters:**

| | | |
|---|---|---|
| Rated voltage: | 120 VAC | 230 VAC |
| Rated frequency: | 60 Hz | 50 Hz |
| Rated current: | 10 A | 10 A |
| Protection class: | I | I |

**Tested according to:**

UL 61010-1:2012/R:2016-04
UL 61010-2-010:2015
UL 61010-2-081:2015
CAN/CSA-C22.2 No. 61010-1:2012/U2:2016-04
CAN/CSA-C22.2 No. 61010-2-010:2015
CAN/CSA-C22.2 No. 61010-2-081:2015

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.:** 028-713115045-000

680677

**Date,** 2018-04-25

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TÜV SÜD America

# CERTIFICATE

**No. U8 16 03 73361 065**

**Holder of Certificate:** **Sartorius Stedim Systems GmbH**
Robert-Bosch-Str. 5 - 7
34302 Guxhagen
GERMANY

**Production Facility(ies):** 73361

**Certification Mark:** C TÜV SÜD US

**Product:** **Laboratory Equipment**

**Model(s):** **BioPAT® DCU TOWER**

**Parameters:**

| | |
|---|---|
| Rated voltage: | 120/230 VAC |
| Rated frequency: | 60/50 Hz |
| Rated current: | 4 A |
| Protection class: | I |

**Tested according to:**
UL 61010-1:2012-05
CAN/CSA-C22.2 no. 61010-1:2012-05

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 anyway. This product certification system operated by TÜV SÜD America Inc. most closely resembles system 3 as defined in ISO/IEC Guide 67. 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.:** 028-713062468-000

**Date,** 2016-03-04

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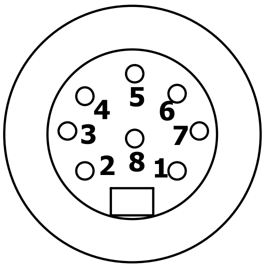
# 15 Appendix

## 15.1 Pin Assignment Female Connectors

**X202 – "Serial-A"**
**X203 – "Serial-B"**

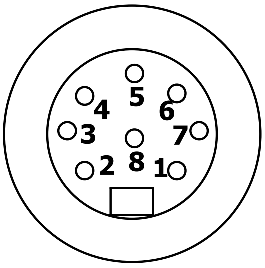



M12 | Female

| M12 | Tag |
|---|---|
| 1 | DCD (in) |
| 2 | RXD (in) |
| 3 | TXD (out) |
| 4 | DTR (out) |
| 5 | GND |
| 6 | NC |
| 7 | RTS (out) |
| 8 | CTS (in) |

Depending on the ordered configuration, a cable for connection of external components is supplied.

**X204 – "Serial-C"**
**X205 – "Serial-D"**
**X206 – "Serial-E"**

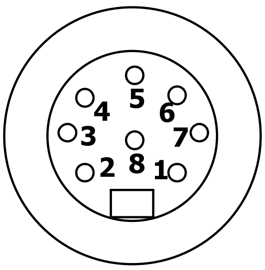



M12 | Female

| M12 | RS-232 | RS-485 |
|---|---|---|
| 1 | DCD (in) | NC |
| 2 | RXD (in) | RXD+ (in) |
| 3 | TXD (out) | TXD- (out) |
| 4 | DTR (out) | NC |
| 5 | GND | GND24V |
| 6 | NC | 24VDC |
| 7 | RTS (out) | TXD+ (out) |
| 8 | CTS (in) | RCD- (in) |

Depending on the ordered configuration, a cable for connection of external components is supplied.

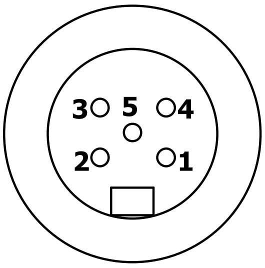
**X209 – "Ext. Drive"**




M12 | Female

| Pin | Signal |
|---|---|
| 1 | Setpoint (0–10 V) |
| 2 | Setpoint (GND) |
| 3 | Actual value (0–10 V) |
| 4 | Actual value (GND) |
| 5 | Actual value (impulse) |
| 6 | NC |
| 7 | 24VDC |
| 8 | GND24V |
| SHD | SHIELD |

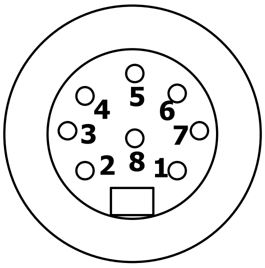
**X212 – "Power Out"**




M12 | Female

| Pin | Signal |
|---|---|
| 1 | 24VDC |
| 2 | 24VDC |
| 3 | GND24V |
| 4 | 24VDC |
| 5 | GND24V |
| SHD | SHIELD |

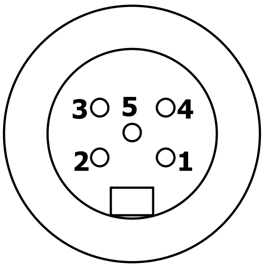
**X210 – "Ext. Signals-A/B"**
**X211 – "Ext. Signals-C/D"**
**X213 – "Ext. Signals-E/F"**




M12 | Female

| Pin | Signal | Color-coding of supplied cable | |
|---|---|---|---|
| 1 | EXT-A/C/E | WH | (white) |
| 2 | GND EXT-A/C/E | BN | (brown) |
| 3 | EXT-B/D/F | GN | (green) |
| 4 | GND EXT-B/D/F | YE | (yellow) |
| 5 | NC | GY | (gray) |
| 6 | NC | PK | (pink) |
| 7 | 24VDC/F06 | BU | (blue) |
| 8 | GND24V | RD | (red) |
| SHD | SHIELD | | |

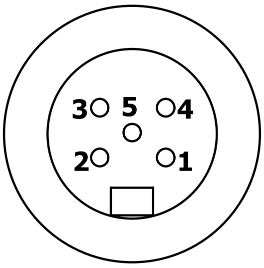
**X220 – "Pump-A"**
**X221 – "Pump-B"**
**X222 – "Pump-C"**
**X223 – "Pump-D"**




M12 | Female

| Pin | Signal |
|---|---|
| 1 | NC |
| 2 | NC |
| 3 | GND PUMP-A...D |
| 4 | PUMP-A...D |
| 5 | NC |
| SHD | SHIELD |

**X23 – "Common Alarm"**




M12 | Female

| Pin | Signal |
|---|---|
| 1 | COMAL, NO (Normally Open) |
| 2 | COMAL, COM |
| 3 | COMAL, NC (Normally Closed) |
| 4 | NC |
| 5 | NC |

## 15.2 Decontamination Declaration

- When returning equipment, use the following form:
  - Copy the form.
  - Complete the form in its entirety.
  - Enclose the form with the delivery papers. The recipient must be able to inspect the completed declaration before removing the device from the packaging.

# Decontamination Declaration

**Declaration Concerning the Decontamination and Cleaning of Equipment and Components**

To protect our personnel, we require that all equipment or components which come into contact with our personnel at customers' facilities be free of biological, chemical, or radioactive contaminants.

We will only accept an order when:
- the equipment or components have been adequately CLEANED and DECONTAMINATED.
- this declaring document has been completed, signed and returned to us by an authorized person.

Please help us in assuring a safe, hazard-free work environment.

**Description of the Equipment or Component(s)**

Description | Cat. No.:

Serial no.

No. of invoice | Delivery note:

Date of delivery:

**Contamination | Cleaning**

| **Attention: Please specify exactly the biological, chemical, or radioactive contaminant** | **Attention: Please describe the cleaning and decontamination procedure \| method.** |
|---|---|
| The equipment was contaminated with: | and it has been cleaned and decontaminated by |
| | |
| | |

**Legally binding declaration**

I (we) certify that all information given in this form is correct and complete. The equipment and components have been adequately decontaminated and cleaned according to the legal requirements. No chemical or biological or radioactive risks remain that could endanger exposed persons' safety or health.

Company | Institute:

Address | country:

Tel.: Fax:

Name of authorized person:

Position:

Date | Signature

Please pack the equipment properly and send it ex recipient to your Sartorius service.

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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