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sartorius stedim biotech

Operating Instructions

BIOSTAT® Aplus



85037-540-79

Vers. 09 | 2013

The enclosed CD contains the operating instructions as a PDF file in varius international languages.

If the CD is missing, you can obtain a copy form us by specifying the order number:
Order number: 85037-541-69

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System Requirements:
– Windows, MacOS X
– Browser with JavaScript enabled
– PDF-Reader

Use start.html to run the application

Notes on Using these Instructions

All information and instructions in these operating instructions have been compiled in consideration of applicable standards and guidelines, the state of the art, and our many years of experience and knowledge.

These operating instructions provide you with all the information necessary to install and operate the BIOSTAT® Aplus (referred to as "device" in the following).

The operating instructions must be read, understood, and used by all personnel entrusted with the operation, service, cleaning and troubleshooting of the device. This applies particularly to the safety instructions listed.

Symbols used
As a means of instruction and direct warning against hazards, all text statements to be particularly noted in these operating instructions will be marked as follows:



This symbol denotes an immediate danger with high risk that death or (severe) injury may result if it is not avoided.



This symbol denotes a possible danger with medium risk that death or (severe) injury may result if it is not avoided.



This symbol denotes a possible danger with risk that moderate or minor injury may result if it is not avoided.



This symbol denotes a danger with low risk that could result in property damage if it is not avoided.



This symbol is an indication of useful information or a function|setting on the device, or that caution should be exercised while working.

The following presentations will also be used:

– Texts that follow this mark are lists.

1., 2., ... Texts that follow this mark describe activities that must be carried out in the specified order.

▷ Texts that follow this mark describe the result of an action.

“ ” Texts in quotes are references to other chapters or sections.

▶ Texts following this symbol make reference to other chapters or sections.

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Operating Instructions

BIOSTAT® Aplus Part A

Setting Up, Connecting and Operating Your Bioreactor



1. Introduction

This documentation describes the BIOSTAT® Aplus bioreactors from Sartorius Stedim Systems GmbH. It contains information on complete systems and any customer-specific versions of the same. It also describes how to set up the bioreactors at your work area and provides information on their equipment and operating in a process.

This description is based on known bioreactor models. The equipment supplied does not necessarily cover every available type of equipment; some may differ from the description while others may contain equipment not described here. The names, characteristics and information can differ from the ones in the technical documentation because these are each adapted to the equipment supplied. Documentation on customer-specific equipment can be delivered with the documentation provided to the customer and | or separately supplied and are available on request.



You can find detailed information on the "UniVessel®" culture vessels, the measurement and control system "Micro DCU system with touch panel" and other accessories in the [▶ "BIOSTAT® Aplus technical documentation"].

After study of the operating manual, you will be able to
- operate the device safely,
- service the device according to guidelines,
- clean the device according to guidelines,
- take appropriate measures should a fault occur.

In addition to the operating instructions, all generally valid legal and otherwise binding regulations for accident protection and environmental protection of the country of use must be observed.

▷ Please read these instructions carefully and completely before using the device.
▷ Read the safety instructions carefully.
▷ These instructions are part of the product. Keep them in a safe and easily accessible location.
▷ If the instructions should be lost or misplaced, please contact Sartorius for a replacement or download the latest version from our website: www.sartorius.com

1.1 Service Center

Repairs can be carried out on-site by authorized service personnel or by the responsible Service representative of Sartorius Stedim Systems GmbH.
The model designation can be found on the model plate or signage. The manufacturer's ID label is specified on the device.

For equipping and retrofitting as well as repairs, you may only use parts approved by Sartorius Stedim Systems GmbH for the device.
Sartorius Stedim Systems GmbH shall not be liable for repairs made by the customer or any resulting damage.

The warranty shall expire particularly in the case of:
– The use of unsuitable parts that deviate from the device's specifications.
– Modification to parts without the approval of Sartorius Stedim Systems GmbH.

BIOSTAT® Aplus bioreactors are just a small sampling of the entire product array available from Sartorius Stedim Systems GmbH. This array includes further laboratory- and pilot-scale bioreactors, production-scale fermenter systems as well as peripheral devices and automation systems for fermentation technology. For more information, please contact Sartorius Stedim Systems GmbH [▶ Contact details].

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In the event of service requests or warranty claims, please notify your representative of Sartorius Stedim Systems GmbH and|or Sartorius Stedim Biotech GmbH: [▶ Contact details].

Send defective devices or parts to Sartorius Stedim Systems GmbH.

Returned devices must be clean and in hygienically flawless condition and packed carefully. Contaminated parts must be disinfected and|or sterilized in accordance with the safety guidelines applicable to the area application.

The sender must prove compliance with the regulations. Use the Decontamination Declaration in the Appendix for this purpose [▶ Chapter "10.5 Decontamination Declaration"]. Transport damage as well as measures for subsequent cleaning and disinfection of the parts by Sartorius Stedim Systems GmbH shall be charged to sender.

2. Safety Information

This document only contains safety information on dangers when handling the devices and possible preventive measures. It does not go into detail on process-dependent risks and applicable legal or otherwise obligatory guidelines for the protection of personnel and working environment.





Failure to observe the following safety precautions can have severe consequences:
– Danger to personnel due to electrical, mechanical, or chemical influences
– Failure of important device functions

Read the safety precautions and dangers listed in this chapter thoroughly before starting the device.
In addition to the instructions in this operating manual, also observe all generally valid safety and accident protection guidelines.
The operator | user must observe all existing national workplace, operating, and safety guidelines in addition to the instructions in this operating manual.
Existing internal plant guidelines must also be observed.

2.1 General Safety Instructions

– The device may only be started and serviced after gaining familiarity with this operating manual.
– Use the device only for its intended purpose [▶ Chapter "2.4 Intended Use and Foreseeable Misuse"].
– The device is not ATEX (ATmosphère EXplosive)-certified. The device may not be operated in potentially explosive atmospheres.
– During operation of the device, do not permit any work method that hinders the safety of the device.
– Always keep the working area of the device clean and orderly in order to avoid danger from dirt or scattered parts.
– Always squat to work on low-lying components; do not bend over. Carry out work on high components in an upright, straight body position.
– Do not exceed the technical performance data (see ▶ data sheet for the device).
– Keep all safety precautions and danger descriptions at the device in legible condition, and replace them as needed.
– Operation as well as work on the device may only be carried out by trained personnel.
– Do not start the device if other people are in the danger zone.
– In case of malfunction, immediately stop the device.
Have the fault corrected by appropriately trained personnel or by your Sartorius Stedim Service office.

2.2 Informal Safety Measures

– Always keep the operating manual in the location where the device is in use.
– In addition to the operating manual, follow all general and local regulations for accident prevention and environmental protection.

2.3 Symbols Used on the Device

The following symbols are used on the device:



Especially hazardous area or hazardous use!
Follow the instructions in the accompanying documents.



Access to conductive parts.
Only specially qualified and authorized persons may access and work on this equipment, such as to perform maintenance and repairs.
Turn off the equipment power and unplug it from the power supply (mains).



Danger of crushing your hand or fingers – do not attempt to put your hand inside rotating parts, e.g. the pump head!
To thread the tubing or adjust the rollers, be sure to switch off the pump first.
– For pumps that have a manual switch:
  Adjust this switch to the "off" position (if not marked, "off" is the middle position between "man" and "auto").
– For pumps without a manual switch:
  Switch off the pump in the measurement and control system (in the "Main" menu or the respective controller operator screen).



Danger of becoming crushed by heavy parts or by the corners of the housing!
Take note of the equipment's weight and dimensions [▶ Chapter "3 Device Overview"] and | or in setup plans, where available. Get help from others before you attempt to perform this step.
Use appropriately rated auxiliary equipment for moving and setting up the system.



Burn hazard – equipment becomes too hot to touch when in operation.
– Avoid touching the equipment surfaces accidentally.
– Use protective gloves when operating the equipment.



Equipment manufacturers have placed some identifying marks, symbols or labels on the various pieces of equipment. These may not always correspond to the safety labels commonly used by Sartorius Stedim Systems.
Be sure to follow the instructions given in this manual.

– Keep all safety precautions and danger descriptions at the device in legible condition, and replace them as needed.

2.4 Intended Use and Foreseeable Misuse

The operational safety of the device is only ensured when it is used for its intended purpose and operated by trained personnel.

BIOSTAT® Aplus bioreactors are designed for cultivating microorganisms and cells in discontinuous and continuous fermentation processes.
They may be used only with the equipment and only under such operating conditions as are described in this manual or in the supplementary documents, unless Sartorius Stedim Systems confirms in writing that deviations therefrom will not lead to any hazardous situations.

The process may present certain risks when cultivating microorganisms and animal cells (biological or chemical influences of cultures and media). These can make special demands on the work area, device equipment or training of the operating personnel concerned.

Only biological materials in Safety Classes 1 and 2 may be used in the device.

The intended use also includes:
- The observation of all instructions from the operating manual.
- Observation of inspection and maintenance intervals.
- The use of oils and greases if they are suitable for use with oxygen.
- The use of operating and auxiliary materials according to applicable safety guidelines.
- Observation of operating and repair conditions.

All other applications are not considered the intended use. They may include risks that cannot be estimated and they are the sole responsibility of the operator.

Claims of any kind resulting from damages due to use other than the intended use are excluded.
Sartorius Stedim Systems GmbH bears no liability for use other than the intended use.



Danger due to use other than the intended use!
Any use beyond and | or other than the intended use of the device can lead to dangerous situations.

The following uses are considered not the intended use and are strictly forbidden:
- Processes with biological working materials of the safety classes 3 and 4
- Cultivation in non-aqueous solutions
- Overloading the device
- Work with parts under voltage
- Operation outdoors

2.5 Residual Risks

This device is a state-of-the-art machine and is built in accordance with recognized safety standards. Nevertheless, the use of the device may pose bodily or physical harm to users or third-parties as well as potentially cause impairments to the testing system itself or other material damage.

Anyone assigned to the installation, commissioning, operation, maintenance, or repair of the device must have read and understood the operating manual.

The device may only be used:
- for its intended use.
- with its safety systems in perfect working order.
- by qualified and authorized personnel.

Furthermore, the following rules must be followed:
- All moving parts must be lubricated as required.
- All screw connections must be checked at regular intervals and tightened if necessary.

2.6 Danger Due to Electrical Power



Danger to life caused by electrical voltage!
Electrical switching elements are installed in the device. Contact with parts under voltage can be life-threatening. Damage to the insulation or individual components can be fatally dangerous.

- Never open the device. The device may only be opened by personnel authorized by Sartorius Stedim Biotech.
- Work on the electrical equipment of the device may only be carried out by Sartorius Stedim Service or authorized technicians.
- Check the electrical equipment of the device regularly for defects such as loose connections or damage to the insulation.
- In case of defects, turn the power supply off immediately and have the defects corrected by Sartorius Stedim Service or authorized technicians.
- If work is required on parts under voltage, ask a second person to be ready to turn off the device's main switch if needed.
- Always make sure any electrical equipment is disconnected from AC power before performing any maintenance, cleaning or repair work.
- During maintenance, cleaning, and repair work, turn the power supply off and secure it against reactivation.
- Keep moisture away from parts under voltage, as this can lead to short circuits.
- Have the electrical components and stationary electrical equipment checked by an electrician at least every 4 years.
- Have non-stationary electric equipment, cables with plugs, and extension or connector cables and their connectors, if any, checked at least every 6 months by an electrician or, if using suitable testers, by a trained person.

Non-stationary equipment is any equipment that is designed to be continually moved while still connected to power. This includes electrical floor cleaning systems, for example.

2.7 Danger Due to Components Under Pressure



Danger of injury from leaked substances!
If individual components are damaged, gaseous and liquid materials may escape under high pressure and e.g. cause injury to eyes.

Therefore:
- Do not start the vessel without a safety valve or comparable overpressure safety (e.g. a burst disk).
- Turn the device off and secure it against reactivation when working on it.
- Release the pressure from system sections and pressure lines to be opened before starting any repair work.
- Regularly check all lines, hoses, and connections under pressure for leaks and externally detectable damage.

2.8 Danger Due to Culture Vessels Bursting



Danger of injury from shattered glass!
Damaged and bursting glass can cause cuts and eye injuries.

Therefore:
- Provide operating personnel with training regarding glass breakage due to external influences. Ensure the culture vessel remains stable at all times.
- Wear personal protective equipment.
- Ensure that the culture vessel is securely connected to the supply and control unit.
- Ensure that the culture vessel remains within the maximum permissible pressure limits.
- Ensure that cooling water flowing back is unpressurized.
- Regularly check all lines, hoses, and connections under pressure for leaks and externally detectable damage.

2.9 Danger Due to Gases

2.9.1 Dangers Due to Oxygen



Danger of explosion and fire!

- Keep pure oxygen away from flammable materials.
- Avoid sparks in the vicinity of pure oxygen.
- Keep pure oxygen away from ignition sources.
- Keep the entire aeration segment oil- and grease-free. Ensure that cooling water flowing back is unpressurized.



Reaction with other materials!

- Ensure that oxygen does not come into contact with oil or grease.
- Use only materials and substances suitable for use with pure oxygen.

2.9.2 Danger Due to Nitrogen



Danger of suffocation due to escaping nitrogen!

Escaping gas at high concentrations may force the air out of closed rooms and can cause loss of consciousness, leading to suffocation.

- Check the gas lines and culture vessels for leaks.
- Provide good ventilation where the device is installed.
- Keep a breathing device independent of ambient air ready for emergencies.
- If personnel appear affected by symptoms of suffocation, immediately provide them with a breathing device independent of ambient air, bring them into fresh air, make them comfortable, and keep them warm. Call a doctor.
- If a person stops breathing, initiate first aid measures with artificial respiration.
- Do not eat, drink, or smoke during work.
- Monitor the limit values at the system and in the building (sensors recommended).
- Check process gas lines and filters regularly for leaks.

2.9.3 Danger Due to Carbon Dioxide



Danger of poisoning by escaping carbon dioxide.

Check the gas lines and culture vessels for leaks.
- Provide good ventilation where the device is installed.

2.10 Danger Due to Leaked Substances



Danger of scalding due to defective components.

- Inspect the device before starting the process.
- Check the connections of containers and the connections to the supply unit.
- Regularly check hoses for leaky places and replace any leaking hoses.



Danger of injury from escaping feed and culture media.

- Only use prescribed hoses.
- Use hose clamps on connecting pieces.
- Empty the feed hoses before loosening the hose connection.
- Wear personal protective equipment.
- Wear safety glasses.



Danger of contamination from escaping feed and culture media.

- Empty the feed hoses before loosening the hose connection.
- Wear personal protective equipment.
- Wear safety glasses.

2.11 Danger Due to Hot Surfaces



Danger of burns upon contact with hot surfaces.

- Avoid contact with hot surfaces like the vessel and motor housing.
- Block the danger zone off.
- Wear protective gloves when working with hot culture media.

2.12 Danger Due to Rotating Parts



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

- Do not remove the safety mechanisms.
- Allow only trained technicians to work on the device.
- Disconnect the device from power when performing maintenance and cleaning tasks.
- Block the danger zone off.
- Wear personal protective equipment.

2.13 Danger Due to Use of Incorrect Consumables



Danger of injury due to incorrect consumables.

- Incorrect or erroneous consumables can lead to damage, malfunction, or the total failure of the device, as well as affecting safety.
- Use only original consumables.
- Purchase consumables through Sartorius Stedim Systems GmbH. You can find all necessary specifications for consumable materials in the overall documentation.

2.14 Personal Protective Equipment

When operating the device, personal protective equipment must be worn in order to minimize dangers to health.

– During work, always wear the protective equipment needed for that work.
– Follow any instructions posted in the work area pertaining to personal protective equipment.

Wear the following personal protective gear during all work:



Protective work clothing
Protective work clothing is tight-fitting work clothing with low tear resistance, tight sleeves, and without any projecting parts. It is primarily intended to protect you from being caught by moving machine parts.
Do not wear rings, chains, or other jewelry.



Head covering
To protect your hair from being caught and pulled into moving parts of the device, wear a head covering.



Safety gloves
Wear safety gloves to protect your hands from process materials.



Safety glasses
Wear safety glasses to protect yourself from media escaping under high pressure.

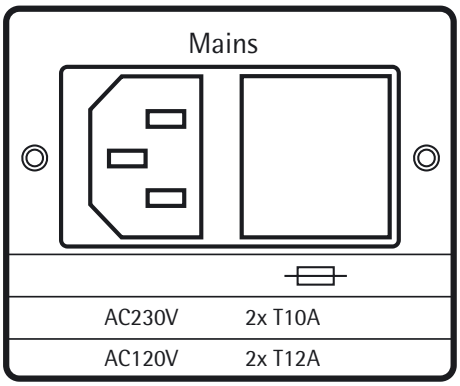


Safety boots
Wear non-slipping safety boots to protect against slipping on smooth floors.

2.15 Safety and Protective Systems

2.15.1 Switch Disconnector

The switch disconnector "Mains" is on the back of the device and is designed to be a physical on | off switch for the power supply.



▷ Unplug the power plug from the socket to disconnect the device from the power supply.

2.15.2 Safety Valve Aeration

WARNING!

Danger of injury from bursting culture vessels and lines.

- Do not operate the device without safety valves and pressure reducers or similar pressure relief devices.
- Have the safety valves and the pressure reducer checked regularly by Sartorius Stedim Service.
- Follow the information in the overall documentation.

Aeration segment overpressure valves

Overpressure valves are built into the device's aeration segment for aeration of the sparger and overlay.

Using the overpressure valves, the aeration pressure is limited to 1 bar_g (14.5 psi_g)

2.15.3 Overheating Protection

WARNING!

Danger of burns from overheated components!

If individual components are damaged, gaseous and liquid materials may escape under high pressure and e.g. cause injury to eyes.

- Do not operate the device without overheating protection.
- Have the overheating protection checked regularly by Sartorius Stedim Service.
- Follow the information in the overall documentation.

The device's overheating protection limits the maximum permissible temperature for the temperature control system. The following temperature control systems can be used:

- Water circulation cooling system (cooling finger, exhaust cooler)
- Heating blanket temperature control system

2.16 Emergency Instructions

Preventive measures
- Always be prepared for accidents or fire.
- Keep first aid equipment (bandages, blankets, etc.) and fire extinguishers handy.
- Familiarize personnel with accident reporting, first aid, fire extinguishing, and rescue facilities.
- Keep entry and rescue routes free for rescue vehicles and rescue personnel.

Measures to be taken after accidents
- Trigger an emergency stop at the switch disconnector.
- Keep personnel out of the danger zone.
- In case of stopped heart and | or breathing, initiate first aid measures immediately.
- Report personal injuries to the first aid officer and an emergency doctor and | or the rescue service.
- Keep entry and rescue routes free for rescue vehicles and rescue personnel.
- Extinguish fires in the electrical equipment with a CO_2 extinguisher.

2.17 Operator Responsibilities

The device is used in the commercial sphere. The operator of the device is therefore subject to the legal obligations for workplace safety.
In addition to the safety instructions in these operating instructions, the safety, accident prevention, and environmental protection regulations valid for the location of use of the device must also be observed.

In particular, the following apply:
- The operators must inform themselves of the applicable workplace safety regulations and carry out a hazard evaluation to determine additional dangers that may result due to the special working conditions at the location of use of the device. These must be expressed in the form of operational instructions for the operation of the device (hazard prevention plan).
- During the entire period of use of the device, the operator must check whether the operating instructions correspond to the current state of regulations and adapt them as needed.
- The operator must clearly regulate and determine responsibilities for operation, maintenance, and cleaning.
- The operator may only allow trained and authorized individuals to work with the device. Trainees, apprentices and auxiliary staff members may only work with the device under the supervision of specialist personnel [▶ Chapter “2.18 Personnel Requirements”].
- The operator must ensure that all employees involved with the device are suitable in terms of physical capacity, person, and character to operate the device responsibly.
- The operator must ensure that all employees are familiar with the basic regulations concerning workplace safety and accident prevention, trained in the handling of the device, and have read and understood the operating instructions.
- Furthermore, the operator must evaluate the safety-conscious work of personnel at regular intervals and demonstrate training of personnel and notification of danger.
- The operator must avoid stress situations during operation of the device by means of technological and organizational work preparation.

– The operator must provide adequate workplace lighting in the place of operation of the device in accordance with locally applicable workplace guidelines.
– The operator must provide personnel with personal protective equipment.
– The operator must ensure that no-one works on the device whose reaction time is impaired, for example by drugs, alcohol, medications, or the like.

Furthermore, the operator is responsible for ensuring that the device is always in technically perfect condition.

The following therefore applies:
– The operator must ensure that the maintenance intervals described in this operating manual are observed.
– The operator must regularly have the safety systems tested for functionality.

2.18 Personnel Requirements



Danger of injury if personnel qualifications are insufficient!
Improper use can lead to significant personal injury and | or property damage.

Have all activities performed only by qualified personnel.

Only those people are permitted as personnel of whom it can be expected that they will carry out their work reliably. No-one may work on the device whose reaction time is impaired, for example by drugs, alcohol, medications, or the like.

2.19 Personnel Qualification Requirements

In the operating manual, the following qualifications are cited for different areas of activity:

Trainee
A trainee such as an apprentice or an auxiliary staff member does not know all the dangers that can occur during operation of the device. They may only perform work on the device under the supervision of technicians.

Trained person
A trained person has been informed in a training session by the operator about the tasks assigned to them and the possible dangers of improper behavior.

Technician
Due to his or her technical education, knowledge, and experience, as well as knowledge of applicable regulations, a technician is capable of carrying out tasks assigned to him or her and independently detecting and avoiding possible dangers.

Electrician
Due to his or her technical education, knowledge, and experience, as well as knowledge of applicable standards and regulations, an electrician is capable of carrying out work on electrical equipment and independently detecting and avoiding possible dangers.
The electrician is trained for the special place of use where he or she works and knows the relevant standards and regulations.

2.20 Personnel Responsibilities

Before undertaking any work with the device, all personnel are obliged to:

- Pay attention to the basic occupational safety and accident prevention regulations.
- Read the safety instructions and warnings in this operating manual and confirm by signature that they are understood.
- Follow all safety and operation instructions in this operating manual.

2.21 Responsibilities

The responsibilities of personnel for operation, maintenance, and cleaning must be clearly defined.

2.22 Unauthorized Personnel



Danger to unauthorized personnel.
Unauthorized personnel who do not meet the qualification requirements for personnel do not know the dangers in the work area.

Therefore:

- Keep unauthorized personnel away from the work area.
- In case of doubt, speak to personnel and instruct them to leave the work area.
- Stop work as long as unauthorized personnel remain in the work area.

2.23 Instruction

Personnel must regularly receive instruction from the operator.
Log the performance of this training for better tracking.

Date	Name	Type of training	Training given by	Signature

3. Device Overview

The BIOSTAT® Aplus is a bioreactor that is designed for cultivating microorganisms and cells at various reactor volumes. It can be used to conduct studies on developing and optimizing fermentation procedures and to perform limited-volume production fermentation processes in a reproducible way, efficiently and cost effectively.

BIOSTAT® Aplus bioreactors can be used to study and optimize fermentation processes using different operating volumes and different framework conditions (temperature, speed, aeration, pH | pO_2, media composition, addition of active agents that speed up or slow down cells' metabolism) in parallel.

The measurement and control system "micro DCU system" enables online measurement, control, and evaluation of the process parameters (e.g. temperatures, pH and DO (pO_2)).

3.1 System Setup

BIOSTAT® Aplus bioreactors can be comprised of the following basic units:

- Supply and control unit "MO" (BIOSTAT® Aplus) to enrich air with oxygen, e.g. for microbial cultures.
- Supply and control unit "CC" (BIOSTAT® Aplus) to enrich air with oxygen, to reduce the O_2 content by feeding in N_2, to add CO_2 for pH adjustment e.g. for tissue cell cultures with animal cells in the suspension culture.
- Measurement and control system "micro DCU system".
- Optional:
  Laptop PC with pre-installed software to control the micro DCU system.
  - Network cable (version: "cross patch")
- 3 peristaltic pump modules.
- UniVessel® single-walled culture vessels:
  - Vessels with working volumes of 1 L, 2 L and 5 L.
  - Temperature control via heating blanket and cooling finger.
  - Cooling water circuit for the exhaust cooler.
  - With fittings for either microbial cultures (MO) or cell cultures (CC).
- Stirrers | drives:
  - Top-mounted drive for culture vessels:
  - Stirrer shaft in the vessel lid, direct drive with sliding ring seal, attachable motor
  - 6-blade disk impeller for microbial cultures and | or segment-shaped paddle stirrer with adjustable blades for cell cultures

3.2 Supply Unit

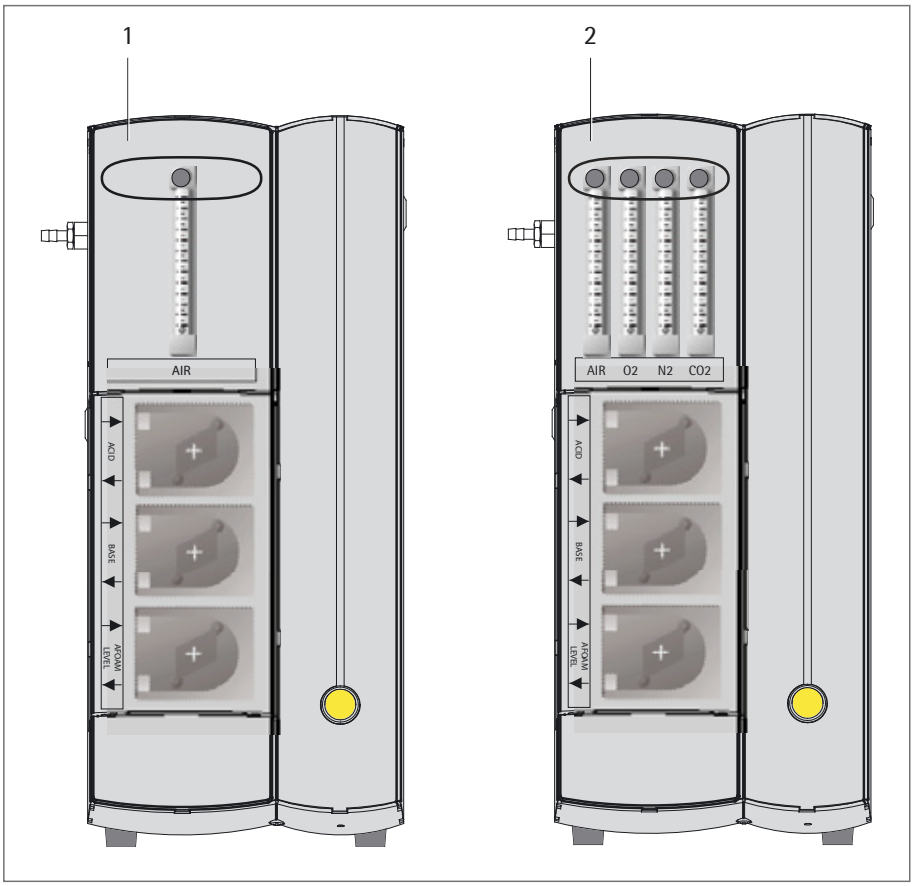


Fig. 3-1: BIOSTAT® Aplus (MO), (CC)

1 BIOSTAT® Aplus (MO) to cultivate microorganisms
2 BIOSTAT® Aplus (CC) to cultivate cell cultures

3.2.1 Connections and Controls

3.2.1.1 BIOSTAT® Aplus MO

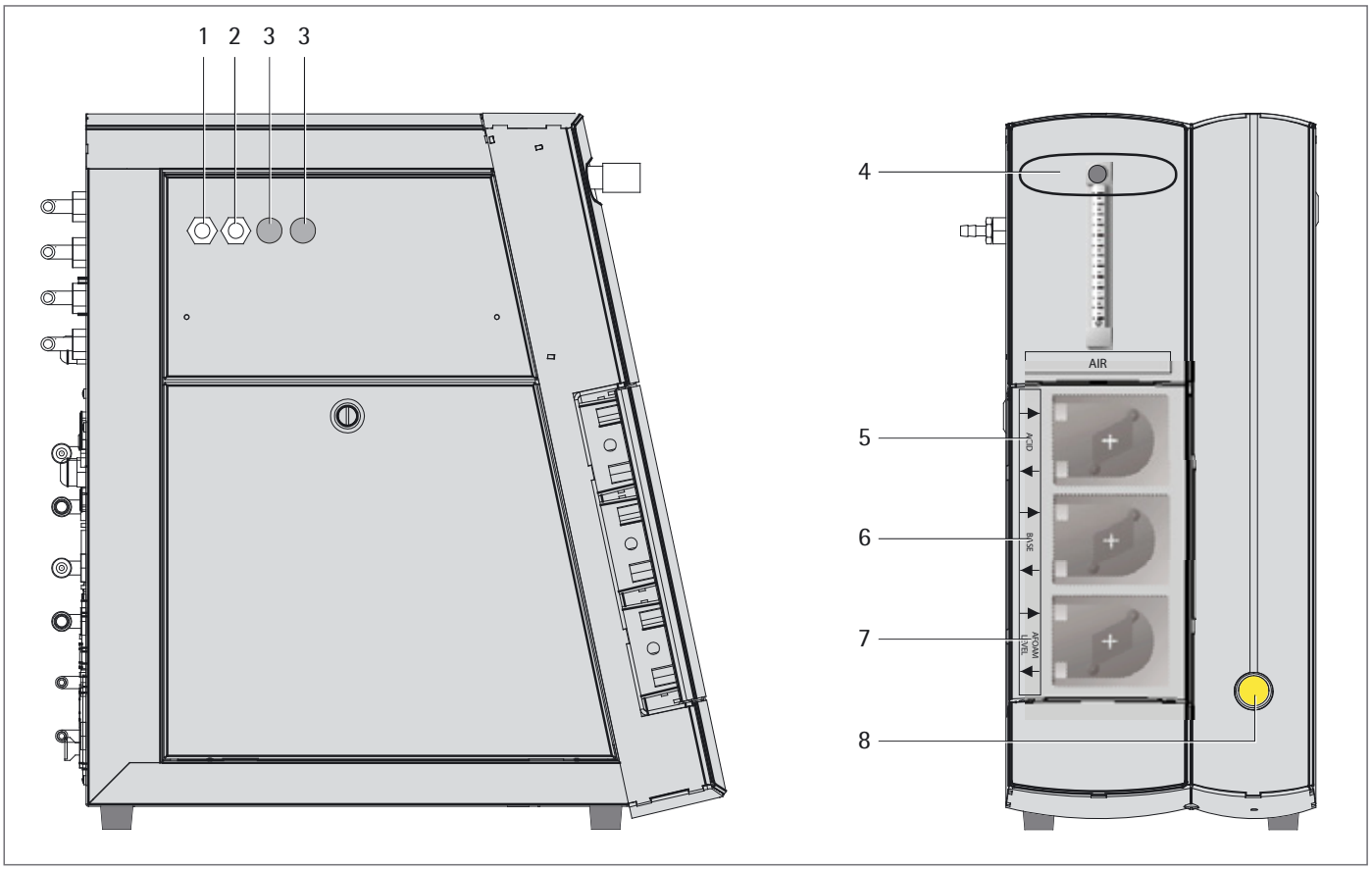


Fig. 3-2: Connections and controls: left side view, front view

1 Culture vessel aeration “AIR”
2 Culture vessel aeration “O_2”
3 Dummy plugs (N2, CO_2 aeration: not assigned for BIOSTAT® Aplus MO)
4 Flow meter “AIR”
5 Pump module “ACID”
6 Pump module “BASE”
7 Pump module “AFOAM/LEVEL”
8 Main switch

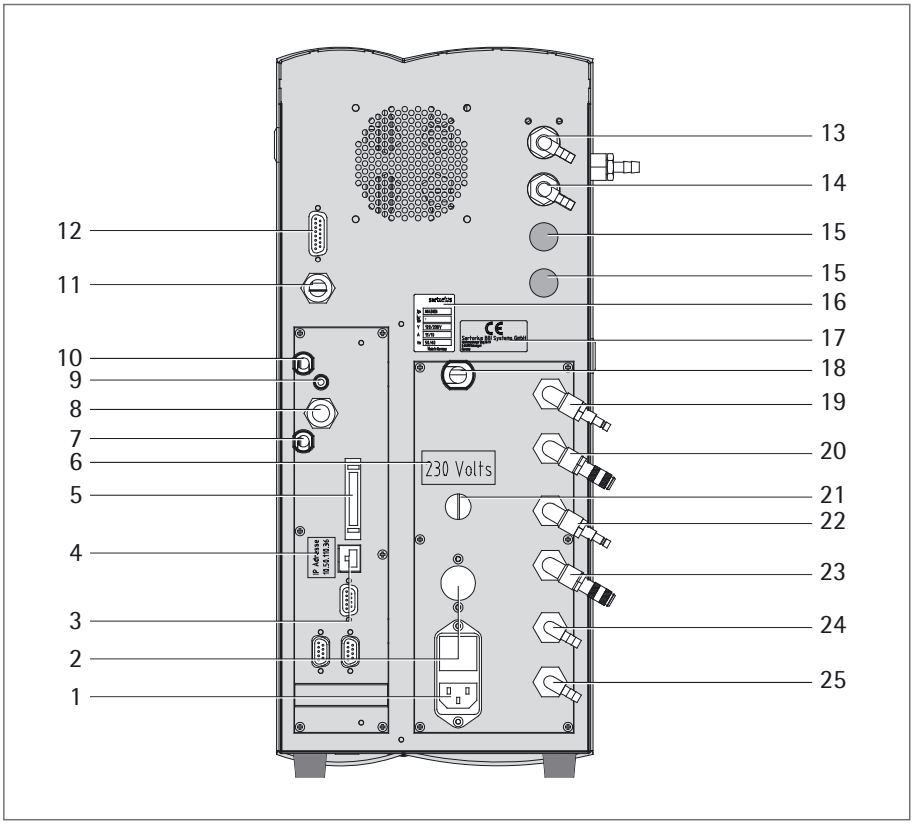


Fig. 3-3: Connections and controls: back view

1 Mains connection
2 Heating blanket Amphenol plug (year of manufacture from middle of 2013) | Heating blanket with IEC receptacle (year of manufacture until middle of 2013)
3 Network port (Laptop, PC)
4 IP address
5 MFCS control touch panel
6 Voltage
7 pH sensor
8 Temperature sensor
9 Foam and level sensor
10 DO sensor (pO_2)
11 Substrate
12 External signal connection
13 Aeration AIR (laboratory connection, max. 1.5 bar_g (21.76 psi_g))
14 Aeration O_2 (laboratory connection, max. 1.5 bar_g (21.76 psi_g))
15 Dummy plugs (aeration, laboratory connection)
16 Manufacturer's ID label
17 CE marking
18 Agitator motor connection cable
19 Cooling finger: cooling agent input
20 Cooling finger: cooling agent output
21 "Heating blanket" fuse
22 Exhaust cooler input
23 Exhaust cooler output
24 Cooling media supply line (laboratory connection, max. 2 bar_g (29 psi_g))
25 Cooling media return line (laboratory connection, pressure-free)

3.2.1.2 BIOSTAT® Aplus CC

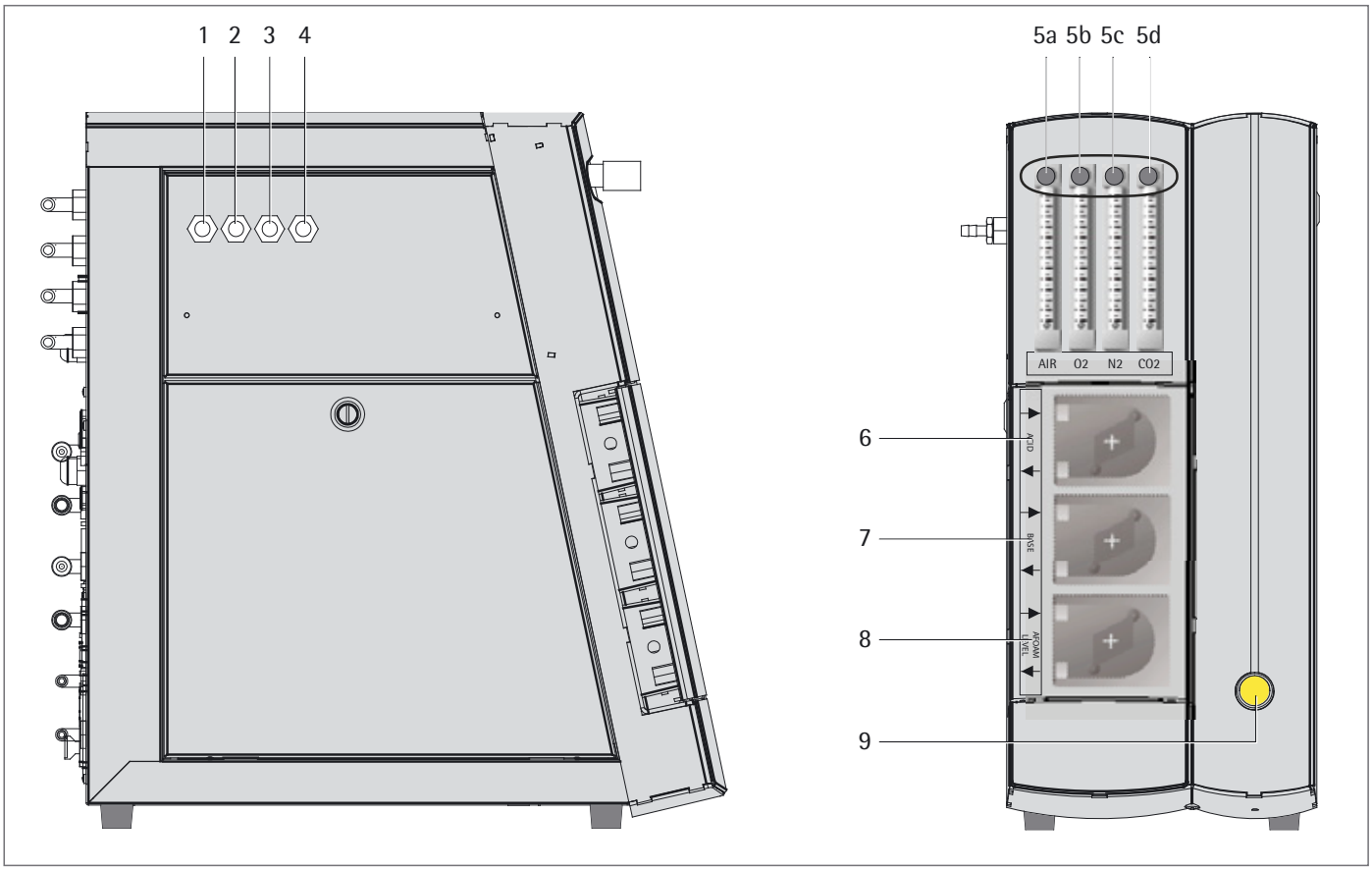


Fig. 3-4: Connections and controls: left side view, front view

1 Culture vessel aeration "AIR"
2 Culture vessel aeration "O_2"
3 Culture vessel aeration "N_2"
4 Culture vessel aeration "CO_2"
5a Flow meter "AIR"
5b Flow meter "O_2"
5c Flow meter "N_2"
5d Flow meter "CO_2"
6 Pump module "ACID"
7 Pump module "BASE"
8 Pump module "AFOAM/LEVEL"
9 Main switch

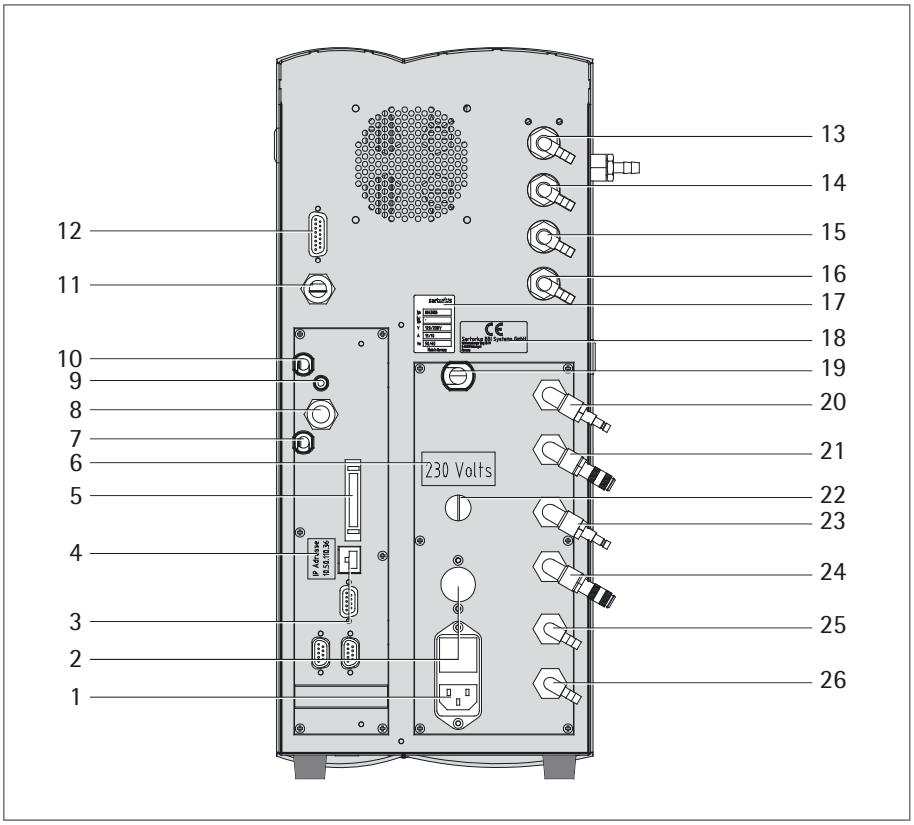


Fig. 3-5: Connections and controls: back view

1 Mains connection
2 Heating blanket Amphenol plug (year of manufacture from middle of 2013) | Heating blanket with IEC receptacle (year of manufacture until middle of 2013)
3 Network port (Laptop, PC)
4 IP address
5 MFCS control touch panel
6 Voltage
7 pH sensor
8 Temperature sensor
9 Foam and level sensor
10 DO sensor (pO_2)
11 Substrate
12 External signal connection
13 Aeration AIR (laboratory connection, max. 1.5 bar_g (21.76 psi_g))
14 Aeration O_2 (laboratory connection, max. 1.5 bar_g (21.76 psi_g))
15 Aeration N_2 (laboratory connection, max. 1.5 bar_g (21.76 psi_g))
16 Aeration CO_2 (laboratory connection, max. 1.5 bar_g (21.76 psi_g))
17 Manufacturer's ID label
18 CE marking
19 Agitator motor connection cable
20 Cooling finger: cooling agent input
21 Cooling finger: cooling agent output
22 "Heating blanket" fuse
23 Exhaust cooler input
24 Exhaust cooler output
25 Cooling media supply line (laboratory connection, max. 2 bar_g (29 psi_g))
26 Cooling media return line (laboratory connection, pressure-free)

3.3 Aeration Modules

You can equip the device with different aeration modules.
Each device can only be equipped with one of the aeration modules described below.

– For specifications on the aeration modules of the bioreactor supplied, please refer to the P&I diagram [▶ "Technical Documentation"].
– The laboratory gas supplies for each of the gases must be preset to 1.5 bar_g (21.76 psi_g).
  The pressure in the vessel supply lines is limited to max. 1 barg (14.5 psi_g) by the safety valves in the aeration modules.

3.3.1 "BIOSTAT® Aplus MO" Modules

The aeration modules are used to supply air and to enrich cultures with oxygen, e.g. microbial cultures.

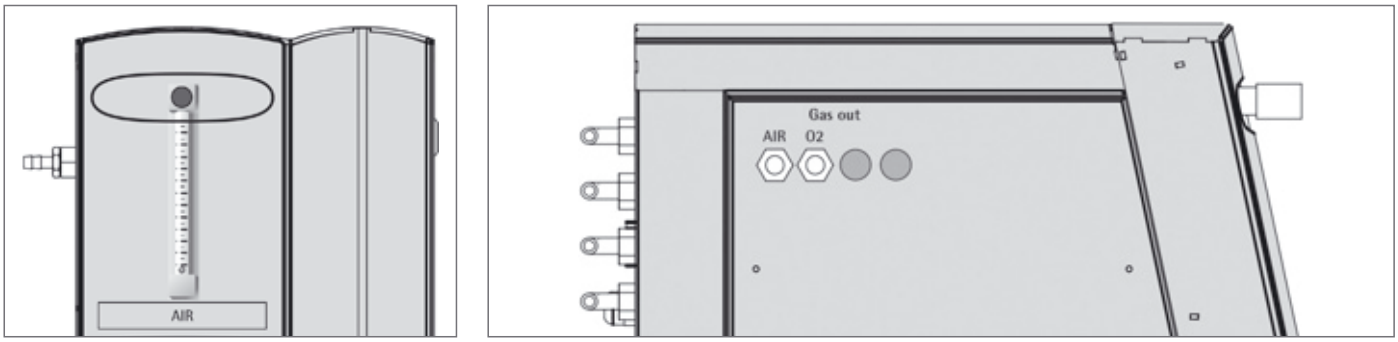


Fig. 3-6: BIOSTAT® Aplus O2 enrichment aeration module, separate gas outlets

– Air and O_2 supplied as the base gas (carrier gas)

Air and O_2 can be fed both into the medium in the culture vessel and into the headspace.

– Supplies air and O_2 through 3/2-way solenoid valves, flow regulated by the DCU DO controller (pO_2).
  – Choice of operating modes: manual ("man"), automatic ("auto") and "off" in the operating menu.
  – You can adjust the gas flow rate on the variable area flow meter.

3.3.2 "BIOSTAT® Aplus CC" Modules

The aeration modules are used to supply up to four gases. In the standard version, these are as follows:

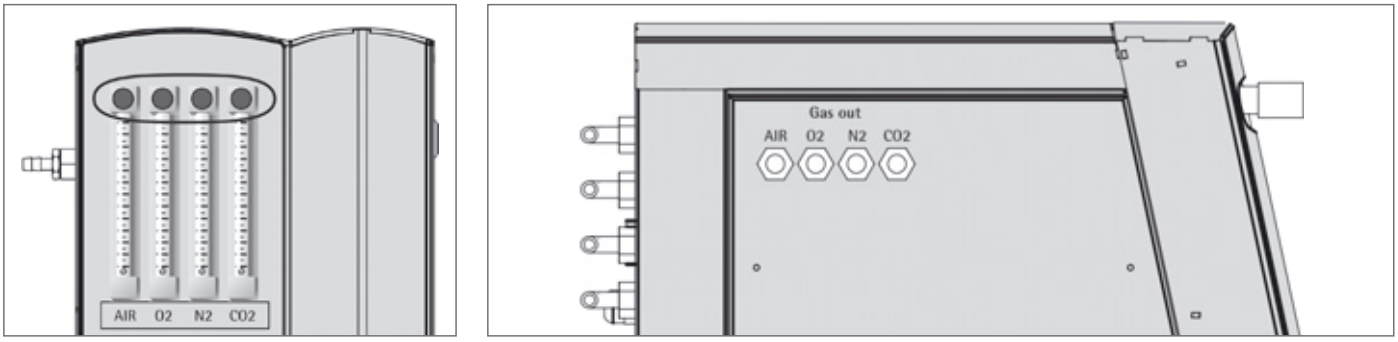


Fig. 3-7: BIOSTAT® Aplus Additive Flow aeration module, separate gas outlets

- Air, supplied as the base gas (carrier gas)
- N_2 for decreasing the O_2 content, or O_2 for increasing the oxygen content;
- CO_2 for adjusting the pH or use as a carbon (C) source;

Air and CO_2 can be fed both into the medium in the culture vessel and into the headspace, while the other gases are fed into the supply line for the culture medium by default.

The modules are suitable for use with cultures with special aeration requirements (if CO_2 needs to be used as the carbon source, e.g. in anaerobic bacteria or algae cultures). They are designed for tissue cell cultures, e.g. suspension cultures that contain animal cells.

- Regulates N_2 and O_2 flow by means of 3/2-way solenoid valves, controlled by the DCU DO controller (pO_2). Regulates CO_2 flow by means of a 3/2-way solenoid valve, controlled by the DCU pH controller (acidity controller).
  - Operating modes available for selection in the controller operating menu: man, auto, off;
  - You can adjust the gas flow rate on the variable area flow meters;



All of the aeration modules are fitted with a flow meter. The ranges of the measurement and control equipment supplied with the aeration modules will match the culture vessel they are intended for or will be as agreed in the order confirmation.

3.3.3 Features of the Aeration Modules

Flow meter version "MO" (for all gases)

Range	Culture vessel	Reading display
0.16 – 1.6 l/min	1 l	Scale on tube
0.42 – 4.2 l/min	2 l	Scale on tube
1.3 – 13 l/min	5 l	Scale on tube

Flow meter version "CC" (for "Air", "N_2")

Range	Culture vessel	Reading display
16 – 166 ml/min	1 l	Scale on tube
33 – 333 ml/min	2 l	Scale on tube
50 – 500 ml/min	5 l	Scale on tube

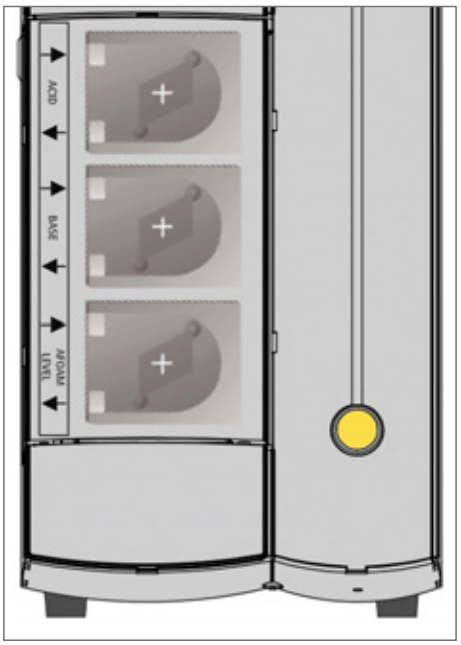
Flow meter version "CC" (for "O_2", "CO_2")

Range	Culture vessel	Reading display
3.3 – 33 ml/min	1 l	Scale on tube
16 – 166 ml/min	2 l	Scale on tube
33 – 333 ml/min	5 l	Scale on tube

Selection of possible equipment; actual equipment as per device or customer specifications.

3.4 Pump Modules

The device contains 3 peristaltic pumps for supplying correction media (e.g. acid, base, antifoam agent or nutrient solutions). If the micro DCU system's configuration options include a level control, the pump "AFOAM/LEVEL" can also be configured and used to remove media in 'harvest' mode.



Features:

- Watson Marlow pump head, 2 or 20 rpm, on | off operation; operating modes available:
  - manual "man" via button or micro DCU4 operating menu
  - "auto", "off" in the micro DCU4 operating menu

3.4.1 Performance Parameters and Features

		Feed rate | revolutions for tubing		Feed rate | revolutions for tubing	
Pump head	**Speed**	**Dia. 1.6 mm**	**Dia. 3.2 mm**	**Dia. 1.6 mm**	**Dia. 3.2 mm**
102 FS/R	2 rpm, fixed	0.22	0.81	4.4	16
102 FS/R	20 rpm, fixed	0.22	0.81	4.4	16
102 FD/R*	10 rpm, variable	[▶ Manufacturer]			
	50 rpm, variable				
	120 rpm, variable				

* Optionally available: snap-in pump head; the feed rate depends on the pump controller and the gear ratio

3.5 Temperature Control Modules

The temperature control modules contain the power supply for the electrical heating blankets 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 temperature control finger.

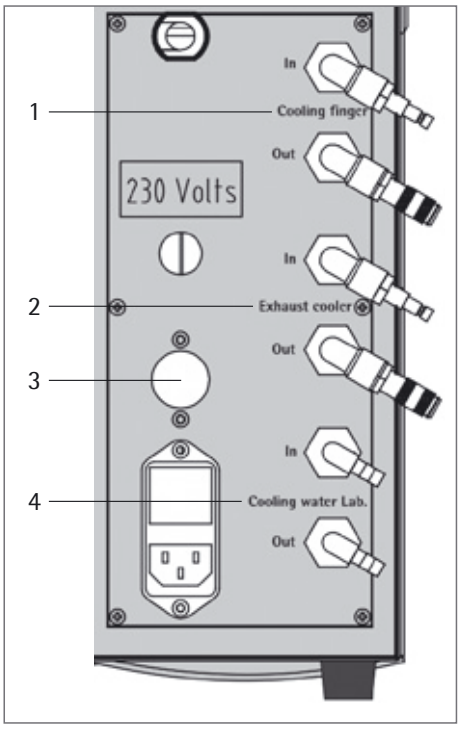
Only single-walled culture vessels can be operated with the device.

Structure and Components

The temperature control modules contain the power supplies for the heating blankets of the culture vessels. The temperature controls for single wall culture vessels comprise:

- 230 VAC, 50 Hz | 120 VAC, 60 Hz electrical connection
- Heating blanket, see below
- Temperature control finger for cooling water supply (controlled flow)
- Exhaust cooler cooling water inlet and outlet

Heating blanket	Heating output	Culture vessels
230 V | 50 Hz	170 W	1.0 l
	170 W	2.0 l
	400 W	5.0 l
120 V | 60 Hz	170 W	1.0 l
	170 W	2.0 l
	400 W	5.0 l



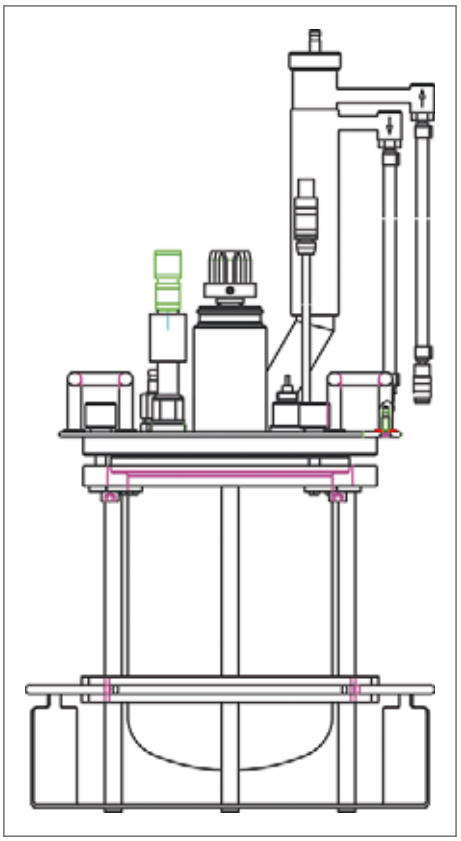
Operating Principle

- The temperature controller of the device activates the power supply for the heating blanket on the culture vessel.
  - The heating blanket must be connected to the female connector (3) on the back of the device. The heating blanket must not be connected to any other power supply.
- The cooling water supply "In" from the laboratory and the return pipe "Out" are connected with the adapters (4) on the back of the device.
- The cooling finger is connected with the adapters (1) on the back of the device. The cooling finger will be supplied with cooling water as regulated by the temperature controller.
  - Connection "Out": to the cooling finger
  - Connection "In": return from the cooling finger
- The exhaust cooler is connected with the adapters (2) on the back of the device. 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.
  - Connection "Out": to the exhaust cooler
  - Connection "In": from the exhaust cooler

3.6 Culture Vessels

Materials (all glass culture vessels)
- AISI 316 L (German std. 1.4435) for all parts that come in contact with media
- Glass parts made of borosilicate glass
- O-rings and other seals made of EPDM (FDA-approved)

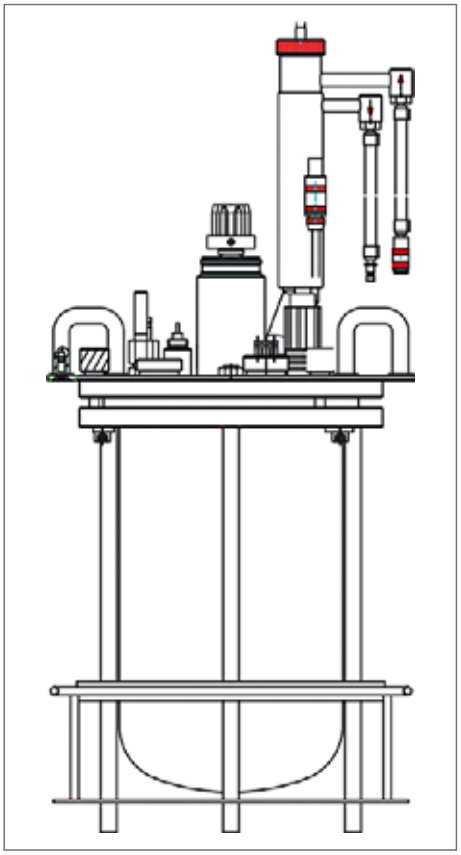
Only single-walled culture vessels can be operated with the device.



3.6.1 UniVessel® 1 L
- Total volume 1.6 l, working volume 0.4 ... 1 l
- Stainless steel cover with hand grips, polished
- Stainless steel stand with holder for correction media bottles
- Features of vessels and agitation systems:
  - Single wall vessels with a round bottom, temperature controlled through a heating blanket and cooling finger
  - All vessels feature an integrated stirrer shaft, standard coupling or an optional magnetic coupling
- Vessels are equipped as ordered, with kits for MO versions (for microbial cultures) or CC versions (for cell cultures). Amongst others, typical equipment includes culture vessel versions with:
  "MO" equipment:
  - 2-3 disk impellers with 6 blades
  - Aeration pipe with injection ring

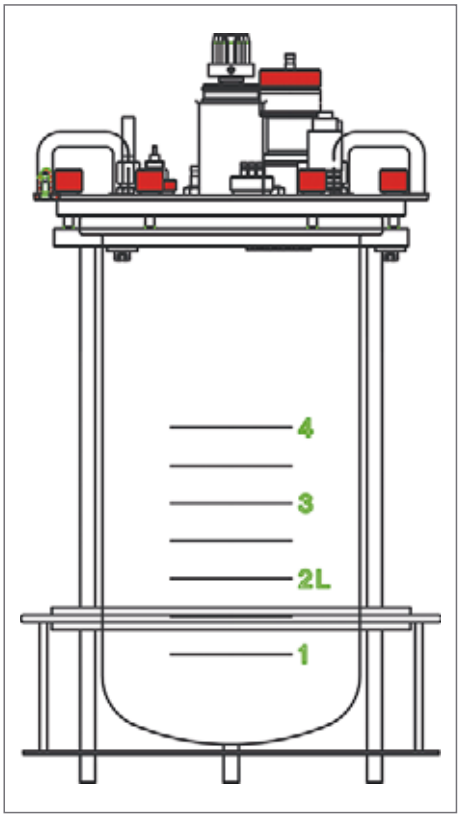
  "CC" equipment:
  - 1 ... 2 disk impellers with adjustable blades
  - Aeration pipe with micro-sparger, 20 µm frit
  - Aeration rig: Vessel insert with silicone membrane (hose with a specific permeability rating for the gases).

The vessels can also be fitted with spin filters for perfusion operation.



3.6.2 UniVessel® 2 L

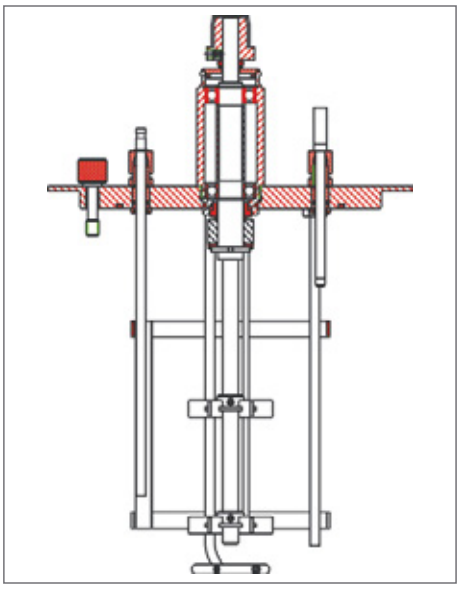
– Total volume 3 l, working volume 0.6 ... 2 l
– Vessel versions, other features and equipment options are identical to those of UniVessel® 1 L [▶ Documentation, e.g. UniVessel® Operating Manual].



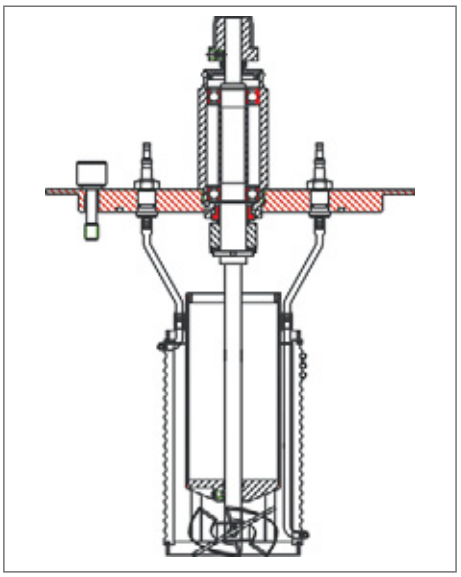
3.6.3 UniVessel® 5 L

– Total volume 6.6 l, working volume 0.4 ... 5 l
– Vessel versions, other features and equipment options are identical to those of UniVessel® 1 L [▶ Documentation, e.g. UniVessel® Operating Manual].

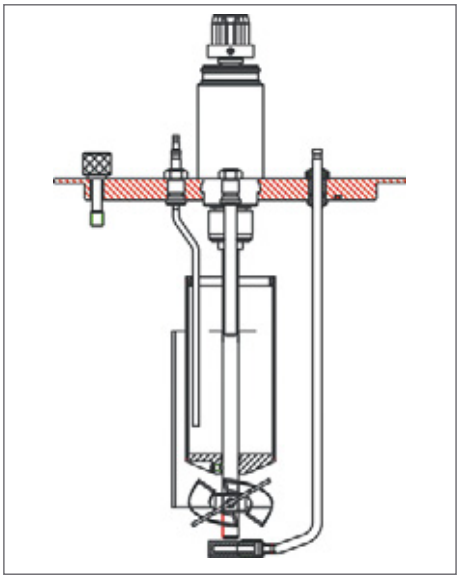
3.6.4 Examples of Internal Vessel Equipment



“MO” equipment
6-blade disk impeller, aeration ring and baffle insert

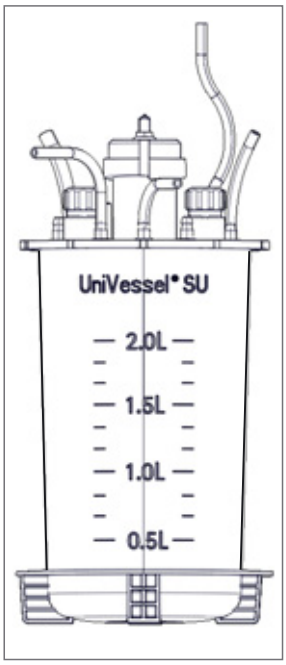


“CC” equipment
Segment-shaped paddle stirrer and aeration hose



“Perfusion” equipment
Segment-shaped paddle stirrer, spin filter and guide sleeve

3.6.5 UniVessel® SU (Single Use) 2 L



Materials
- pre-sterilized polycarbonate

Properties
- Stirrer shaft with connecting piece for motor adapters of different control units
- Cover plate with ports (holders for sensors, added media)
- Sampling, aeration, exhaust
- Temperature control via heating blanket or heating|cooling blanket
- Culture vessel stand

3.7 Drive System

CAUTION!

Danger of burns on hot motor housing!
The motor housing can reach operational temperatures of max. 60 °C and cause serious burns when touched.
Follow the instructions on the motor housing sticker. The sticker changes color automatically as the temperature increases.

IMPORTANT!

Operating the stirrer at impermissible high speeds can affect the culture vessel's stability and cause damage to their fittings.
Depending on the size and equipment of the culture vessels, the permissible speed may be limited, e.g. to max. 300 min^{-1} in vessels with gas supply rigs for bubble-free gas supply.



The drive includes a direct drive for the stirrer shaft [▶ "UniVessel®" Operating Manual].

Available drive motor:

- Motor 140 W, 3-phase, DC:
  - UniVessel® 1 l: rpm range 20 ... 1,200 ^{1}/min
  - UniVessel® 2 l: rpm range 20 ... 1,200 ^{1}/min
  - UniVessel® 5 l: rpm range 20 ... 800 ^{1}/min

The standard stirrer shaft is sealed with a rotating mechanical seal.

4. Transportation and Storage

The device will be delivered by the customer service of
Sartorius Stedim Systems GmbH or by a transport company engaged by
Sartorius Stedim Systems GmbH.

4.1 Inspection Upon Acceptance by the Recipient

Transport Damage
Upon acceptance of the device by the customer, the device must be inspected for visible transport damage.

▶ Report transport damage immediately to the delivering office.

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

▶ Check that the delivery is complete by comparing it against your order.

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



Components that do not correspond to the specifications of Sartorius Stedim Systems GmbH may not be used.

4.1.1 Packaging

The packaging used for transport and protection of the device consists primarily of the following materials suitable for recycling:
- Corrugated cardboard
- Styrofoam
- Polyethylene film
- Pressed particle board
- Wood



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

4.2 Instructions for Transport Within the Company

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



Danger of severe personal injury and property damage due to improper transport!

- These devices require two or more people to transport and set up.
- Wear protective work clothing and safety boots during these tasks.
- Lift the device only at suitable points.
- Always lift the device slowly and carefully to ensure stability and safety.
- Secure the device from falling during internal transport.



Protect the device during transport against:
– moisture,
– shocks,
– falling,
– damage.

Loading | Unloading



When loading and unloading, pay attention to the following aspects:
– Do not unload the device outdoors during rain or snow.
– If necessary, cover the device with plastic sheeting.
– Do not leave the device outdoors.

4.2.1 Intermediate Storage

If the device is not set up immediately after delivery, or will temporarily not be used, the following conditions of storage must be observed:



Only store the device in dry buildings and do not leave the device outdoors.



In case of improper storage, no liability will be assumed for resulting damage.

4.2.2 Loads

Supply unit, laptop PC (optional), culture vessels
The exact weight of an individual supply unit depends on its internal equipment. The exact weight of a UniVessel® culture vessel depends on the vessel equipment and size (see following table).

Component	Weight [kg]
Supply unit	Approx. 20
Laptop PC (optional)	Approx. 3.5
UniVessel® 1 L SW	10
UniVessel® 2 L SW	14
UniVessel® 5 L SW	20
UniVessel® 2 L SU without vessel holder	1.5
UniVessel® 2 L SU with vessel holder	15

5. Installation

5.1 Installation Location

The guide for setup of the device is the setup drawing.
The setup of the device is to take place according to contractual conditions,
- by Sartorius Stedim Service,
- by Sartorius authorized specialist personnel,
- by the customer's authorized specialist personnel.



Danger of severe personal injury or property damage due to improper setup of the device!
- The proper setup of the device is critical for its safe operation.
- Observe the guidelines for building and laboratory equipment.
- Observe the laboratory and process-related safety rules and guidelines on setting up your workplace and securing it from access by non-authorized persons.
- This equipment requires two or more people to transport and set up, or the use of appropriately rated lifting equipment.
- Ensure that only authorized persons have access to the device.
- Follow the instructions in the following sections.

5.2 Ambient Conditions

The device may only be operated under the following ambient conditions:

Criterion	Ambient Conditions
Installation Location	Conventional laboratory rooms, max. 2,000 m above sea level
Ambient temperatures in the operating temperature range	0 – 40 °C
Relative humidity	<80 % for temperatures up to 31 °C, decreasing linearly to 50 % at 40 °C
Contamination	Pollution degree 2 (normally only non-conductive pollution occurs. Occasionally, however, temporary conductivity caused by condensation must be expected.)
Acoustic Emission	Max. sound pressure level < 70 dB(A)

5.3 Work Surfaces and Loads

5.3.1 Culture Vessels

You can setup the culture vessel on a stable laboratory table next to the device. The work surface must be big enough for the equipment required for the process. It must be easy to clean and, where relevant, to disinfect.



Danger of injury due to insufficient stability of the culture vessels!

- Follow any other manufacturer's operating manuals for individual system parts and additional components.
- Follow the construction guidelines required to ensure that the device stands stably.
- Ensure that the laboratory table is dimensioned sufficiently for the weight of the device, the culture vessels and the process media in use.

The laboratory table must be constructed to withstand the following weights (at maximum filling of the culture vessel):

Component	Weight [kg]
Supply Unit	Approx. 20
Laptop PC (Optional)	Approx. 3.5
UniVessel® 1 L, single-walled	10
UniVessel® 2 L, single-walled	14
UniVessel® 5 L, single-walled	20
UniVessel® 2 L SU without vessel holder	1.5
UniVessel® 2 L SU with vessel holder	15

- 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.

5.3.2 Supply Unit

The supply unit weighs approx. 20 kg. The exact weight depends on the internal equipment.

The supply unit and the culture vessel can require an area of around 600 × 750 mm (in some cases, more space still if all of the equipment is to be conveniently accessed).



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 100 mm from any walls to ensure adequate ventilation and access to the connections at the rear. The recommended wall distance is about 300 mm.

5.3.3 Laptop (optional), PC

You can set up the device (Laptop | PC) required to control the process on a separate workbench next to the bioreactor. Using the network cable supplied, connect the bioreactor to the laptop | PC.

5.3.4 Setup Example

The following set up example only gives an approximation of the space required, as the actual space required depends on the additional equipment used for the fermentation process.

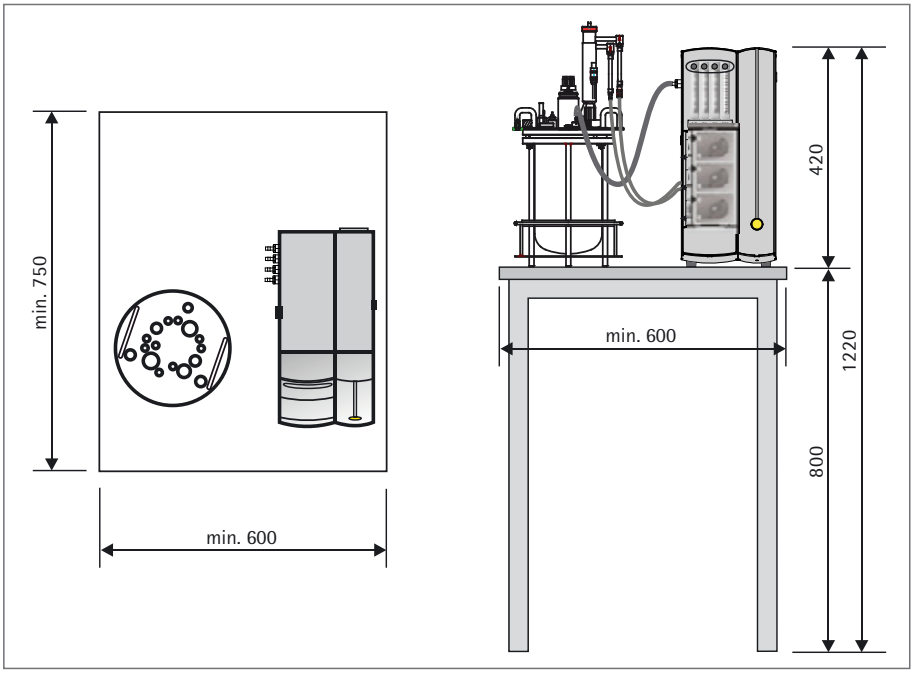


Fig. 3-1: Setup example of BIOSTAT® Aplus with UniVessel® 2 L.

5.4 Laboratory Energy Sources

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

The connections for the supply media are located at the back of the supply units.



Risk of injury from energy that is unexpectedly released, such as electric shocks!
Energy supply lines may have the wrong dimensions and might not be protected against inadmissible fluctuations and malfunctioning or failure.
Safety equipment must be available and fully functional:
– Ground fault circuit interrupters (residual current protection) for mains connections
- Fittings for shutting off water, compressed air and gas supplies.
Observe the energy specifications on the [▶ Manufacturer's type plates] and on the [▶ P&I diagram].

Connecting Cables and Tubing | Piping
The equipment supplied includes the matching cables, tubing, fittings, fasteners and tools for connecting the bioreactor to the utilities in the lab and for connecting the bioreactor modules, culture vessels and equipment to one another.

You will find information on the equipment in the [▶ Major component list] on the P&I diagram and in the [▶ Spare parts lists] of the [▶ Technical documentation]. Only use these parts.

5.4.1 Power



Danger: risk of injury by electrical shock!
The power supply (mains) in your laboratory must meet the equipment specifications.
- Check whether the equipment ratings match your voltage supply rating [▶ Manufacturer's type plates].
- Do not switch on any devices if the laboratory's mains voltage is incorrect.
- Your laboratory must have grounded, interference-free power outlets that are protected from splashes of water.
- The safety equipment for emergency shutoff (residual current circuit breaker, emergency shutoff switch) must be fully functional.
- The laboratory power supply [▶ C power outlet] must be equipped with a protective grounding conductor.
- Do not use multiple socket outlets for connecting the bioreactor modules to an AC power outlet (mains outlet).
- The power cables must have the correct plugs that match your laboratory AC outlet. Do not use any damaged power cables, e.g., those on which the insulation is not intact, especially if the wires are exposed.
- Do not attempt to repair any defective power cables or replace incorrect plugs. For this purpose, please be sure to contact a qualified service provider or technical customer service at Sartorius Stedim Systems GmbH.

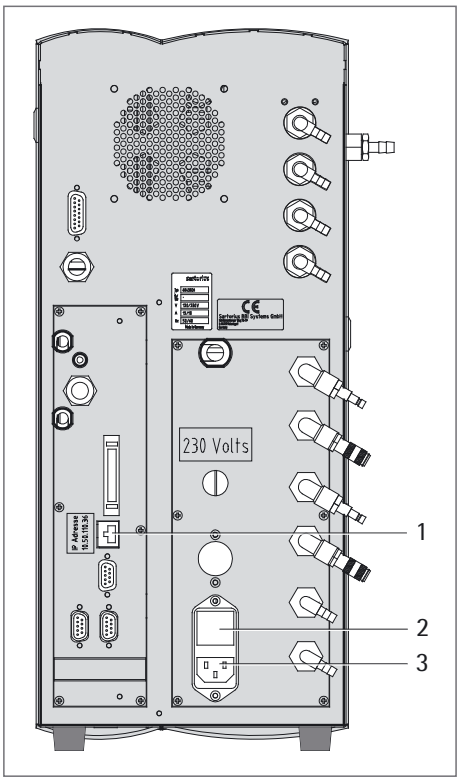


Risk of damage due to voltage dips and spikes.
The laboratory supply voltage may not fluctuate by more than 10% from its nominal rating.



Keep access to the emergency shut-off devices inside the laboratory and the equipment's power connections clear.
If you need to switch off the device in an emergency, first press the emergency off switch in the lab and shut off the laboratory energy supply lines, then disconnect the power cables from the equipment.
Always switch off equipment and disconnect the mains cable before cleaning and maintaining the devices.

All information on the correct supply voltage can be found on the manufacturer's ID label.
The manufacturer's ID label is located on the back of the device.



Device Ports
The "mains in" On | Off switch and interface to the Laptop | PC are located at the back of the supply unit.

Mains Connection
- Supply units can be supplied in the voltage versions below:
  - 230 V (± 10 %), 50 Hz at a maximum current consumption of 10 A or
  - 120 V (± 10 %), 60 Hz at a maximum current consumption of 12 A
  - Voltage 230 V~:
    2 × device fuse (2) 6,3 × 32 mm, time lag, 250 V, 10 A/T (IEC)
  - Voltage 120 V~:
    2 × device fuse (2) 6,3 × 32 mm, time lag, 125 V, 12 A/T (UL)
  - IP 20 protection class

- Use the power cables supplied with the device in accordance with the power specifications of your country.

- Only use the supplied or equivalent and matching hoses, fittings and fastening equipment for connecting the equipment inside the laboratory.

- The supply unit must only be switched on by pressing the main switch on the front panel when all of the following connections have been made:
  - Cooling water,
  - Gas supplies (AIR, O_2, N_2, CO_2,)
  - Signal cable from the supply unit (1) to the Laptop | PC,
  - Signal cable to the culture vessel.

- First, plug the mains cable "Mains" (3) into the mains socket and then into a mains wall outlet with a protective grounding conductor in the laboratory.

- If you wish to stop operating the device, especially if you need to clean the supply units or perform user maintenance on them, switch off this equipment using the LED-illuminated "Mains" switch first, then disconnect the power cable from the laboratory AC power outlet (mains outlet).

5.4.2 Manufacturer's ID Label
The information on the correct supply voltage can be found on the manufacturer's ID label of the supply unit. The manufacturer's ID label is located near the power connection of the devices.

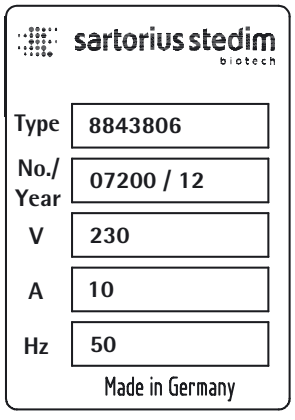


Fig. 3-2: Manufacturer's ID label on the supply unit

5.4.3 Tempering Media

Water is the device's tempering medium and is used for following functions:

- Coolant for the cooling finger
- Coolant for the exhaust cooler

IMPORTANT!

Inadequate water quality can affect the functioning of the heat circulation pump and fittings in the thermostat system.

In particular, the following can result:

- Formation of lime scale if the water is hard
- Corrosion caused by distilled or demineralized water
- Malfunctions caused by contaminants or corrosive residues

Use tap water with max. 12 dH, not distilled or demineralized water.

Check whether the water is clean before connecting it to the bioreactor. Flush the laboratory water feed supply.

If necessary, install a suitable prefilter in the laboratory or feed line routed to the supply units.

Using water with a maximum hardness of 12 dH minimizes scale buildup in the thermostat loop and in the double wall of the culture vessels.

Growth of a green layer inside the UniVessel® double wall is a sign of algae formation caused by organic contaminants in the water. Do not use water contaminated in this way.

Inlets and Outlets Required Inside the Laboratory

- Laboratory cooling water supply:
  - Tap water, 2 bar_g (29 psi_g), preset, max. 5 l/min
  - Clean water, free of particles, max. hardness 12° dH
  - Laboratory cooling or chilled water circuit or cooling thermostat, e.g. FRIGOMIX®, operated at ambient pressure

- Drain pipe into the laboratory drain; every discharge line without an end connector at ambient pressure or:
  - Laboratory cooling or chilled water loop, operated at ambient pressure
  - Cooling thermostat, e.g. FRIGOMIX®, operated at ambient pressure

IMPORTANT!

The cooling media of chilled water supply systems or cooling thermostats must not contain any anti-freeze or anti-corrosion agent. If they do, you must ensure that these cannot damage the fittings of the thermostat system.

We do not accept any responsibility for operating faults and breakdowns and defects caused by contaminated cooling water, nor any downtimes or secondary damage arising from this.

The conversion table below contains water hardness specifications that can be provided by your local water supplier.

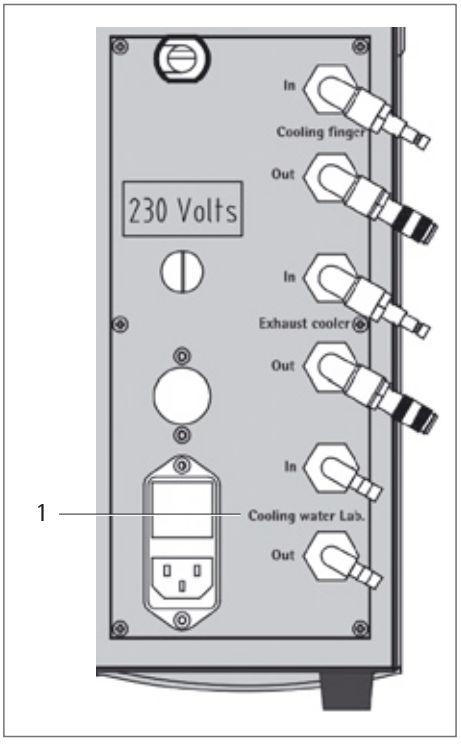
Water Hardness Conversion Table

	Alkaline earth ions [mmol/l]	Alkaline earth ions [mval/l]	German hardness [°d]	$CaCO_3$ [ppm]	English hardness [°e]	French hardness [°f]
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° hardness [°d], Germany	0.18	0.357	1.00	17.80	1.25	1.78
1 ppm $CaCO_3$	0.01	0.020	0.056	1.00	0.0702	0.10
1° hardness [°e], UK	0.14	0.285	0.798	14.30	1.00	1.43
1° hardness [°f], France	0.10	0.200	0.560	10.00	0.702	1.00

5.4.3.1 Connecting the Water Supply

WARNING!

Danger of damage to the power supply unit and the culture vessel!
- Make sure that you have correctly connected the cooling water feed and the cooling water drain.
- Avoid kinking the tubing; the cooling water must be able to flow freely into the drain outlet.
- If you are connecting cooling devices or connecting the equipment to a sealed cooling circuit inside the laboratory, the water must not be allowed to dam up or be able to flow into the return connection when under pressure.



The connections for the laboratory cooling water feed and the cooling water drain are located at the back of the supply unit (1).

Cooling Water Supply
- Connect the equipment to the "Cooling water" inlet using the tube connectors and tubing supplied with the equipment (or using those that have identical specifications [▶ "Major Component List" or Spare Parts List]).
- Carefully fasten the connections and secure them from accidentally working loose.
- Adjust the cooling water supply to the correct pressure before opening the feed inlet to the supply unit.

Cooling Water Drain
- Use the tube connectors and tubing supplied with the equipment (or those that have identical specifications [▶ Spare parts list] in the [▶ Technical documentation]).
- Carefully fasten the connections and secure them from accidentally working loose.
- Install the tubing to avoid kinks and so that no water pockets can form. Regularly check that any excess water can freely drain off.

5.4.3.2 External Cooling Equipment

It's possible to connect a laboratory cooling water circuit or cooling device to the cooling water inlet and outlet.

The following signal specifications apply to any external cooling equipment:

- Water pressure max. 1.5 bar_g (21.76 psi_g)
- Flow volume max. 5 l/min
- Temperature min = 4 °C
- Drain, pressureless
- Connection hose barb | ∅ outer = 10 mm



The minimum operating temperature in the culture vessels is around 8°C above the cooling water temperature. To operate the system at lower temperatures, connect the bioreactor to a closed cooling water supply loop or to a cooling device.

- Make sure that the inlet and outlet are connected in the right order:
  - Connect the outlet of the external loop or the cooling device to the inlet of the supply unit.
  - Connect the outlet of the supply unit to the laboratory return line or the inlet of the cooling device.

- Operate the cooling device or the external cooling loop at ambient pressure.

- Prevent the cooling medium from flowing back into the supply unit's outlet.

5.4.4 Gas Supply

The gas supply for the BIOSTAT® Aplus MO and BIOSTAT® Aplus CC device category covers the following gases:

BIOSTAT® Aplus MO	**BIOSTAT® Aplus CC**
Air	Air
Oxygen (O_2)	Oxygen (O_2)
	Nitrogen (N_2)
	Carbon dioxide (CO_2)



Risk from large amounts of accidentally escaping gases!
The following hazards may arise:
- Pure oxygen can cause chemical reactions leading to an explosion;
- Volatile hydrocarbons or alcohols can result in a fire;
- Danger of suffocation if CO_2 or N_2 is released

The fittings inside the bioreactor are designed for use with pure oxygen.
- Use fittings for the external connections (gas supplies, exhaust air) that are free from oil and grease.
- Check the leaktightness of the connections.
- If gases supplied or discharged contain pure oxygen, CO_2, flammable or combustible media, ensure that your work area is well ventilated. Check whether it is necessary to feed exhaust air into laboratory disposal systems.



Danger of suffocation due to escaping gases!
If CO_2 is released, this can cause suffocation.
- Provide good ventilation where the device is installed.
- Keep a breathing device independent of ambient air ready for emergencies.
- If personnel appear affected by symptoms of suffocation, immediately provide them with a breathing device independent of ambient air, bring them into fresh air, make the them comfortable, and keep them warm. Call a doctor.
- If a person stops breathing, initiate first aid measures with artificial respiration.
- Do not eat, drink, or smoke during work.
- Monitor the limit values on the system and in the building (sensors: recommended).
- Check process gas lines and filters regularly.
- Check the leaktightness of the connections.



Danger of damage and malfunction to gas supply components!
Contaminants, e.g., oil and dust, can adversely affect the functioning of gas supply components and lines.
- The gas supply components must be corrosion-resistant whenever corrosive gases are used in the gas supply or required for processes (e.g., ammonia corrodes gas supply components made of brass).
- Make sure that the supply gases are dry and free of oil, dust and ammonia.
- If necessary, install suitable filters.
- Malfunctions and damages arising from contaminated gas media are excluded from the warranty granted by Sartorius Stedim Biotech.

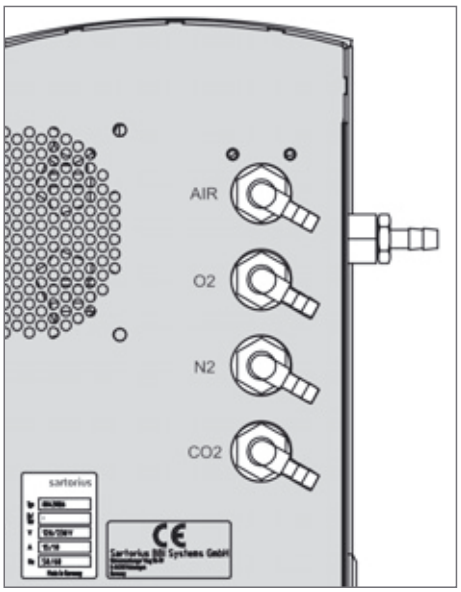


We do not accept any responsibility for operating faults and breakdowns and defects caused by contaminated gases nor any downtimes or secondary damage arising from this.

5.4.4.1 Connecting the Gas Supply

The gases supplied inside the laboratory must correspond to the supply unit's specifications. The connections for the gas supply are located at the back of the supply media unit.

Please observe the following information and the P&I diagram:



Specifications of the Supply Units

- Compressed air, preset to 1.5 bar_g (21.76 psi_g)
- Gas required, e.g., O2, N2 or CO2, preset to 1.5 bar_g (21.76 psi_g)
- Gases must be dry and clean, i.e., free of condensate and contaminants from the tubing | piping.
- The unused inlets on the "O2 Enrichment" aeration modules are sealed with dummy plugs.

In-process Aeration

- After autoclaving, connect the culture vessel to the aeration module outlets (hose nozzle, ∅ = 6 mm).
- Configure the laboratory gas supply points for supplying gas to the equipment during the fermentation process.
  To calibrate the DO sensor (pO_2) and control the pO_2 (and the pH value if necessary), activate the in-process gas supply.
- Set the CO_2 feed to pH control (on the BIOSTAT® Aplus CC model).

5.4.4.2 Supplemental Information

Dimensions of Variable Area Flow Meters

The variable area flow meters must be sized to accommodate the types of gas to be used. The measurement tubes of these meters are calibrated to standard conditions. You will find all specifications labeled on the glass tube or holder, for example:

- Gas type: Air
- Temperature: 20° C = 293 K
- Pressure: max. 1.5 bar_g (21.76 psi_g)

If used with other gases with a different pressure or temperature, the variable area flow meters may deliver flow rates that are too high or too low. To determine the actual gas flow volumes, you will need to convert the flow rates measured.

Variable area flow meter manufacturers provide tables and monograms for calculating the correction factors for flow rates under defined operating conditions [▶ Manufacturer's Information], e.g., the "Technical Documentation" folder.

Specific Data for Gases

Gas	Density [kg/m3]
Carbon dioxide (CO_2)	1.977
Air	1.293
Oxygen (O_2)	1.429
Nitrogen (N_2)	1.251

6. Startup and Operation

Read the operating instructions carefully before carrying out processes on the device. This particularly applies to the safety instructions [▶ Chapter 2 “Safety Information”].

6.1 Overview

Starting up and operating the bioreactor during the relevant fermentation process involves the following main steps:

- Set up the device as well all of the other devices and equipment, in addition to the measures described in [▶ Chapter 5 “Installation”].
- Install the control program “PC-Panel µDCU” on a laptop | PC to control the device.

The device can also be optionally ordered with a laptop.
In this case, the control program “PC-Panel µDCU” to control the device is already installed on the laptop.

- Connect the laptop | PC to the device (network cable).
- Switch on the device.
- Equip and change the equipment of the culture vessels [▶ UniVessel® Operating Manual]:
  - UniVessel®
  - UniVessel® SU
- Autoclave of the culture vessel and the accessories to be connected [▶ UniVessel® Operating Manual]
- Connect the culture vessels and set up the bioreactor at the site designated for the fermentation process
- Clean and maintain the system (to be performed by the user)

6.2 Control Program “PC-Panel µDCU”

If the device was ordered without a laptop, the control program “PC-Panel µDCU” must be installed on the customer’s laptop | PC.
The installation CD is included with the device.

The following programs are on the CD:

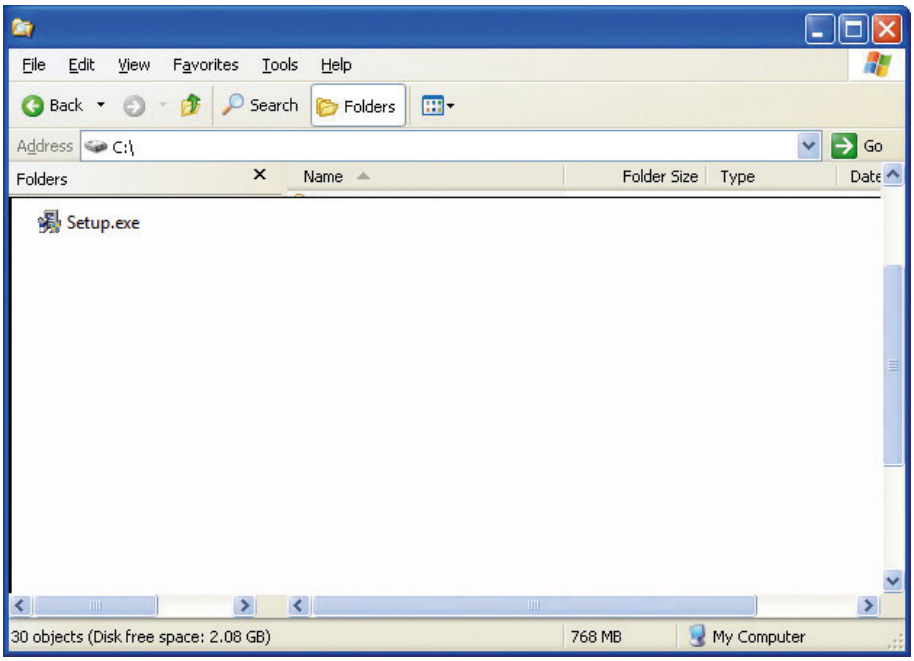
- BIOSTAT® Aplus control program “DFC Remote”
- BIOSTAT® Aplus data logging program “MFCS | DA” Version 2.1 SCADA (can be installed optionally [▶ Operating Instructions “MFCS | DA”])

System Requirements for Customer’s Laptop | PC

Operating system: Windows® XP or Windows® 7
Internet connection: Optional registration for Service Support via Internet

6.2.1 Installing the Program “PC-Panel µDCU”

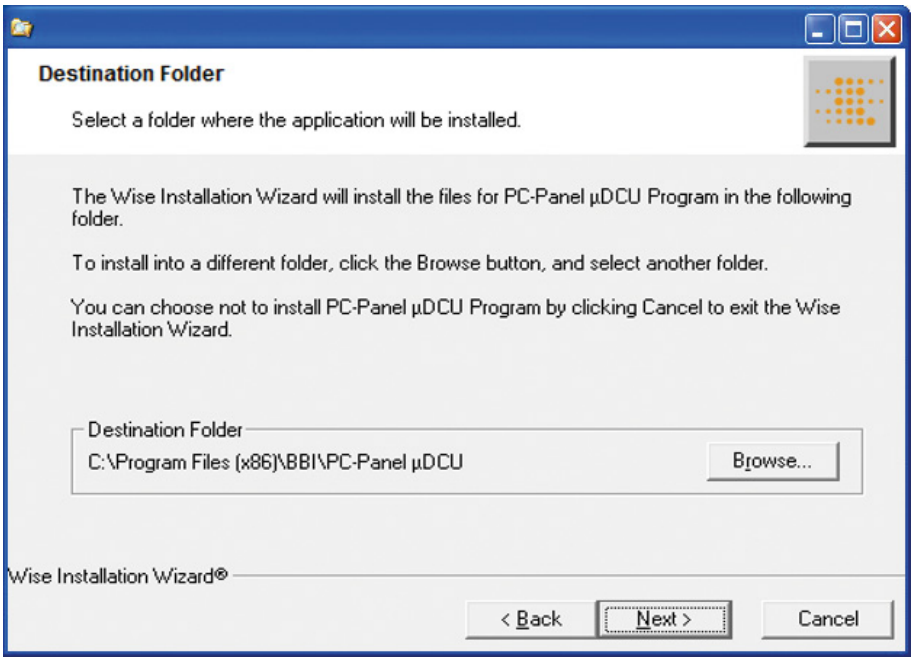
– Insert the CD into the DVD | CD drive.
– In Windows Explorer, double click on the drive icon.
▷ The installation file “setup.exe” is on the CD directory



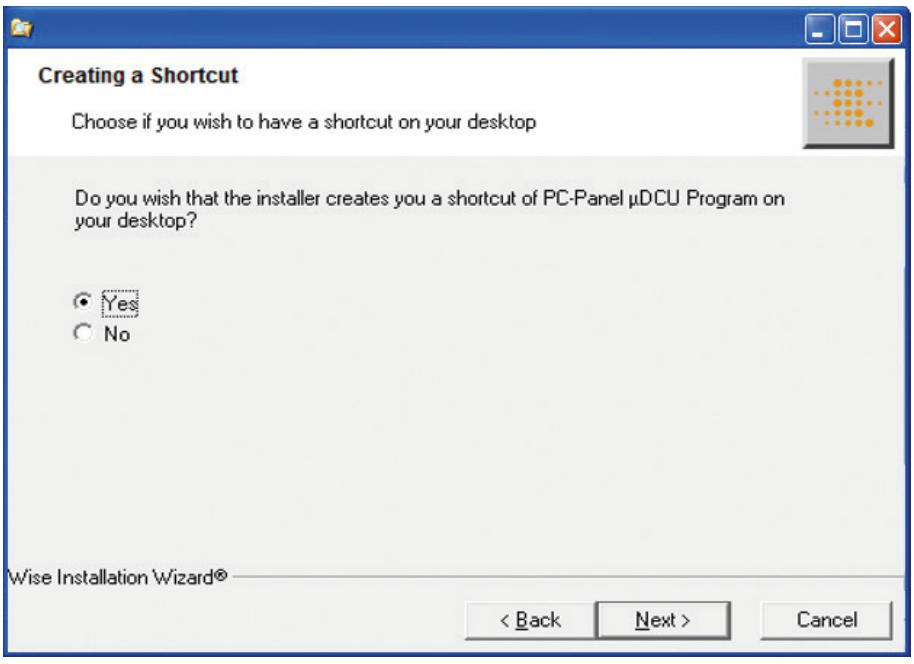
– Double-click on the file “setup.exe” to start the installation.



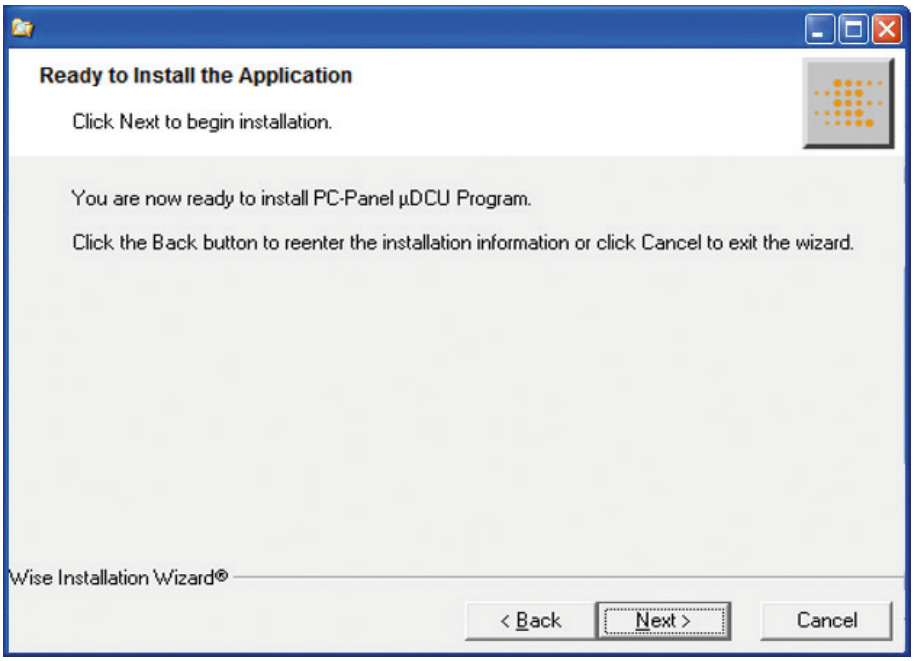
– Click on the button [Next] to continue with the installation.



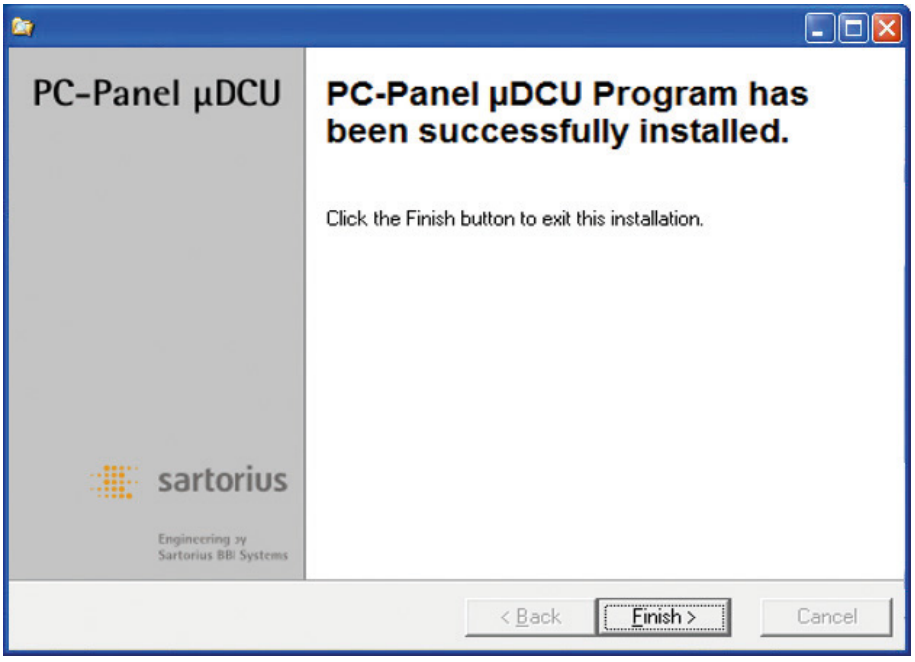
– Choose a directory where the program should be installed and click on the button [Next] to continue with the installation.



– Choose the setting "Yes" if you want to place a program shortcut symbol on the desktop.
– Click on the button [Next] to continue with the installation.



– Click on the button [Next] to continue with the installation.
– The program is being installed.



– Confirm the installation of the program and click on the button [Finish].
– The program "PC-Panel µDC" is installed.

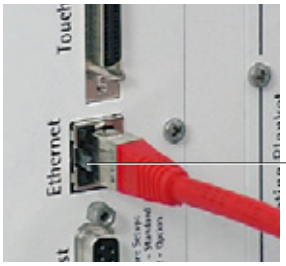
6.2.2 Connecting a Laptop | PC to the Device

Before you start the program, ensure that the device is set up for the process.

Setup includes:

- Setting up the bioreactor and other devices and equipment necessary for the process
- Equipping and changing the equipment of the culture vessels [▶ UniVessel® Operating Manual]:
- Connecting the culture vessels and setting up the bioreactor at the site designated for the fermentation process.
- Connecting the laptop | PC to the bioreactor

Ensure that the device and the laptop | PC are switched off.



The connection "Ethernet" (1) is on the back of the device.

- Establish the connection between laptop | PC and bioreactor using the "cross patch" network cable delivered with the device.

6.3 Control Unit

6.3.1 Turning the Control Unit On and Off

Requirements

The system must be properly installed and connected in accordance with the specifications. You must also have gained familiarity with the safety instructions in the ▶ Chapter 2 "Safety Information".

Ensure that all required supply energies are connected to the device.
Ensure that the device is connected with the laptop | PC via the network cable.



Switching on

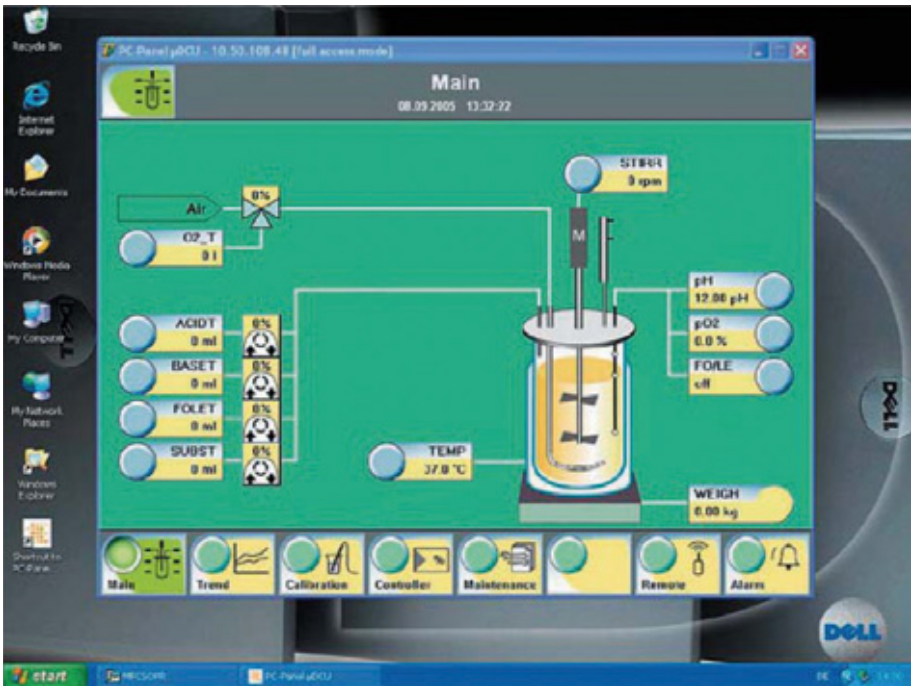
- Turn the device on at the main switch (1).
- Wait one minute.
- Turn on the laptop | PC.



– Click on the program symbol (1).
– All devices connected to the laptop | PC are shown in a list.



– Select the device and click on the button [Master Panel].
– The window for the "Main" menu is displayed (▶ following figure).
  – Settings that control the device can be changed.
  – Control functions can be carried out.



Switching off
– Turn the device off at the main switch after the process ends.

6.4 Installation Equipment

The bioreactor is supplied with a full set of all of the required connection lines and fittings:
– Only use lines and fittings approved for use with the bioreactor or whose suitability has been confirmed in writing by Sartorius Stedim Biotech.
– Only replace damaged components and wear parts with Sartorius Stedim Biotech-approved parts.

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

6.5 Culture Vessel Features



Risk of injury when handling heavy culture vessels!
Fully equipped and filled culture vessels are heavy, e.g. a UniVessel® with an operating volume of 5 liters weighs > 18 kg.
– The culture vessels must be handled with care.
– Always use suitable transport and lifting equipment.
– Only lift the vessels using the handles provided for this purpose.

These operating instructions contain information on the installation and connection of the culture vessels to the device.

6.5.1 Preparing the Culture Vessels

Equip the culture vessels with the components you need for the process [▶ UniVessel® Operating Manual].

General measures
Make sure that the culture vessel equipment is in perfect condition and clean before installing it in a culture vessel:
– Remove all residues, contaminations or microbes from the previous fermentation process from the culture vessel and its fittings.
– Carefully check all equipment, particularly the glassware, seals and silicone tubing, for any damage. Replace all damaged and worn out parts.

Measures required before installing and connecting certain parts:
pH sensor (see operating instructions of the manufacturer):
– If the pH sensor has turned dry after a long period of storage, regenerate it
– Calibrate the zero point and slope of the sensors using the buffers in accordance with the scheduled measuring range [▶ Operating Instructions Part B Control].

DO sensor (pO_2):
– 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 (pO_2) must be calibrated after the culture vessels have been sterilized in readiness for the fermentation process.

Correction media bottles:
– Prepare the bottles for acid, base, antifoaming agent and nutrient solutions.

6.5.1.1 Preparing the Corrective Solution Bottles

When using culture vessels with an operating volume of 1 L and 2 L, the bottles provided for supplying acid, base and antifoaming agent have a filling volume of 250 ml; for culture vessels with an operating volume of 5 L, a filling volume of 500 ml. You can also use these bottles for feeding substrate or for automated sampling using a bypass sampler.

Correction medium bottle retainer

- The glass culture vessels of UniVessel® are available with a retainer for the correction medium bottles.
- The UniVessel® SU culture vessel is not equipped with a retainer for the correction medium bottles. The corrective solution bottles have to be set up separately.

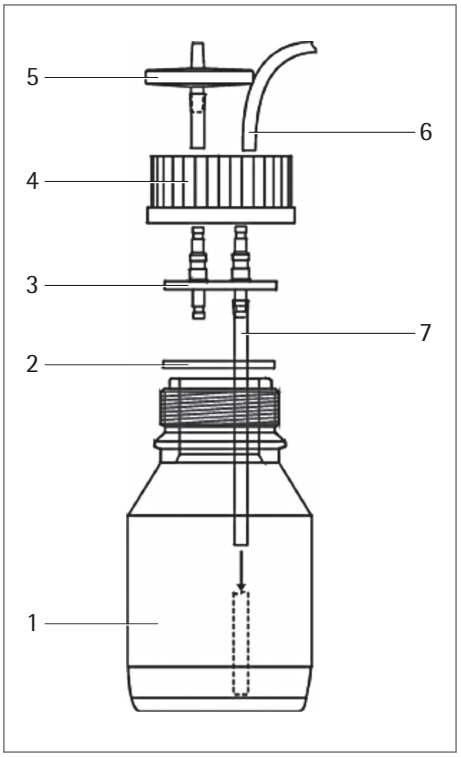
To ensure that there will be a sufficient amount of sterile solution available in continuous or fermentation processes that run over long periods of time, prepare several bottles at once.

CAUTION!

Risk of chemical burns from acids and bases!

When working with acidic or alkaline supply media there is a risk of chemically burning the skin or eyes.

Wear personal protective equipment (protective clothing, safety boots, safety goggles).



Structure of the Correction Media Bottles

- Stainless steel cap (3) with hose couplings and seal (2) on top of the storage bottle (1), held in place by a screw cap (4).
- PTFE riser pipe (7), for use as barrel sampler, acid and base resistant, including at high temperatures.
- Sterilizing-grade filter (5) for ventilation and equalizing the pressure when correction media are removed.
- Silicone hose (6) for transferring the medium.

Assembly

- Place the PTFE riser pipe (7) onto a hose nozzle on the bottom. Shorten the PTFE riser pipe to such to extent that it rests 1 – 2 mm above the bottle's bottom.
- Fill the reservoir bottle (1) with the medium needed and close by tightening the screw cap (4).
- Empty bottles for sampling:
- Fill the bottle with a small amount of water to create a moist atmosphere when autoclaved and ensure that the bottle will be properly sterilized.
- Using a short piece of silicone hose, fit the sterile filter (5) to the tube connection on the storage bottle that is not connected to the riser pipe.
- Attach the connecting pipe (6) leading to the culture vessel to the tube connection to which the PTFE riser pipe (7) is connected.

6.5.1.2 Fitting the Transfer Lines

Connect the transfer lines between culture vessel and corrective solution bottle as follows:

– Fit a piece of silicone hose onto the tube connection on the correction media bottle to which the riser pipe 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.



Risk of chemical burns from acids and bases!

If the hoses are not securely fastened, there is risk that they will slide off, in which case the correction media will leak out.

– Use the hoses included with the equipment supplied.
– Make sure that the hoses are securely fastened.

– Before autoclaving, clamp off the tubing using tube 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.
– Place the corrective solution bottles and culture vessels in the holder or basket to be autoclaved.
– Autoclave the culture vessels and bottles.

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.



Please refer to the UniVessel® operating manual for detailed information on connecting the STT quick release couplings.

6.5.2 Sterilizing the Culture Vessels

– Sterilize the culture vessels in the autoclave.
– Depending on whether the culture medium can be sterilized with heat, fill the culture vessels either with medium, parts of the medium that can be autoclaved, or water.



Risk of breaking the culture vessels!

Excess pressure inside the glass vessel, in particular in the double wall, that is created when the vessel is being heated up in the autoclave, can destroy the vessel. The sterile filter of the exhaust air segment makes sure that the pressure between the inside of the vessel and the surrounding atmosphere is equalized in a sterile manner.

– Do not disconnect the exhaust air segment.
– In double wall vessels, pressure is equalized through the outlet (connection piece at the top, piece of hose with the male end of the coupling).
– This piece of hose must not be kinked, disconnected or sealed.

IMPORTANT!

Foam will block intake and exhaust air filters!
At the end of sterilization, vacuum may cause heavy foaming in the medium. Foam flowing into the air inlet or outlet filters can block the filters, making them unusable.
– Do not use vacuum autoclaves

– To autoclave, only fill the culture vessels with heat-sterilizable media. In culture media that cannot be sterilized using heat, fill the culture vessels with a small amount of water to ensure that the moist atmosphere required for sterilization can develop.

Part of the media will evaporate during autoclaving.
– Establish whether the inoculum culture will make up for this lost volume. If necessary, prepare more medium and autoclave it separately.



In double wall vessels, the double wall must be fully filled. If necessary, add more cooling media.

– Clamp off the air | aeration lines with a hose clamp to prevent medium from being pushed back into the supply line from the culture vessel.
– Autoclave the culture vessels at 121° C. You will need to empirically determine the dwell time required inside the autoclave to ensure reliable sterilization.



To ensure reliable sterilization (e.g., to kill off thermophilic spores), the temperature in the culture vessels must be maintained at 121°C for at least 30 minutes.
To check whether all items have been reliably sterilized, autoclave test spores inside the culture vessels (e.g. commercially available sets containing Bacillus stearothermophilus).

The culture vessels are ready to use after autoclaving, but you will need to wait approx. 24-48 h before inoculating them. This is the period of time required for any contaminants that may be left inside them because of insufficient sterilization to appear.

6.5.3 Preparing the Fermentation Process



Danger of burns due to hot surfaces!
The premature removal of culture vessels from the autoclave can cause burns.
- Leave the culture vessels to cool down inside the autoclave.
- Wear protective gloves to transfer them.



Risk of injury when handling heavy culture vessels!
Fully equipped and filled culture vessels are heavy, e.g. a UniVessel® with an operating volume of 5 liters weighs > 18 kg.
The culture vessels must be handled with care. Always use suitable transport and lifting equipment. Only lift the culture vessels using the handles provided for this purpose.

– Carefully transport the culture vessels to the work site.

Place the culture vessels in front of the device in such a way that all of the lines and peripheral devices can be easily connected.
– Attach the motors to the couplings of the stirrer shafts.

Temperature control system – UniVessel® Glass | UniVessel® SU (Single Use):
– Install the heating blanket on the culture vessel and close the mains supply on the device.

Exhaust cooling – UniVessel® Glass | UniVessel® SU (Single Use):
– Connect the supply and return lines of the exhaust cooling to the ports of the exhaust cooler at the culture vessel.

Exhaust heater – UniVessel® Glass | UniVessel® SU (Single Use):
– Install the exhaust filter heater on one of the exhaust filters and connect the plug into the outlet.
– Connect the culture vessel sensor cables to the associated female connectors. Calibrate the DO sensor (pO_2).
– Place the connection hoses of the correction medium bottles into the associated peristaltic pumps of the device.
– Configure the measurement and control parameters for the process in the µDCU system.



The preparatory work is described in the following sections.

6.5.4 Installing the Stirrer Shaft Motor

CAUTION!

Risk of injury when motor is running!
The motor can be started up for testing purposes before being fitted by switching on the DCU system.
Reaching into the running drive can cause injuries to the fingers.
- Do not reach into the protective sleeve with your fingers.
- Leave the motor control off (except during function tests), until you have attached the motor to the stirrer shaft on the culture vessel.

IMPORTANT!

Danger of motor damage due to short circuiting!
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 illustrations show possible sleeve and stirrer shaft coupling models. The actual model supplied may differ from the illustration.



- Connect the motor plug (1) into the female connector and tighten the knurled screw (2) by hand.

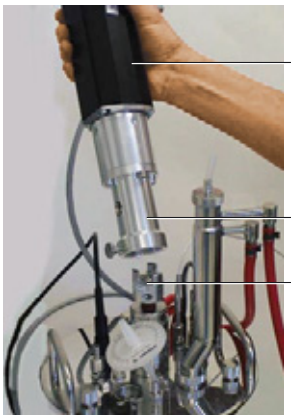


The connection cable (3) of the stirrer motor has been securely preinstalled on the device.



The coupling (4) of the motor is equipped with a rubber compensation element (5). The compensation element establishes a positive connection to the coupling of the stirrer shaft, ensuring a silent force transmission of the drive.

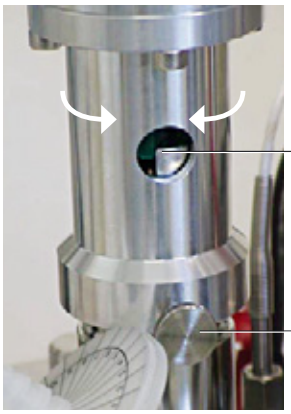
The stirrer drive motor can be fitted to the following stirrer shafts:
- UniVessel® Glass
- UniVessel® SU (with corresponding adapter)



Assembly of UniVessel® Glass Culture Vessels

The motors are wired ready for fitting. The power supply cable of the motor has been securely preinstalled on the device.

– Take the motor (1) from the tray and stick the coupling with the sleeve (2) on the agitator shaft.
– Gently twist the motor housing to the left or right until the motor's coupling and the coupling (3) on the stirrer shaft engage.



Using the bore hole (4) in the sleeve, you can check whether the sleeve is engaged.

– Tighten the knurled thumbscrew (5) on the sleeve to securely fasten the motor to the stirrer shaft.



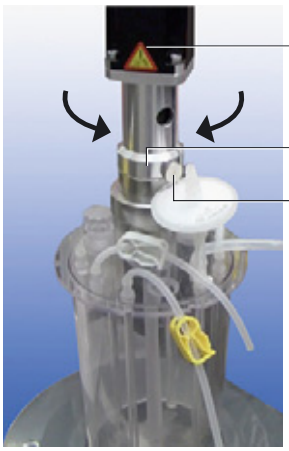
The motor is installed on the stirrer shaft.

Installation in UniVessel® SU culture vessels

In UniVessel® SU culture vessels, the motor for the stirrer shaft cannot be directly installed on the coupling.
You need an adapter to install the motor.
The adapter is not part of the of the device's standard equipment. You can order the adapter from Sartorius Stedim Biotech.



The motors are wired ready for fitting. The power supply cable of the motor has been securely preinstalled on the device.
- Install the adapter (1) on the coupling of the stirrer shaft.
- To do this, hold the two lock rings tight at the top, so that they are lying over one another.
- Gently twist the motor housing to the left or right until the motor's coupling and the coupling (3) on the stirrer shaft engage. This is easiest if you twist above the motor coupling (4).
- Release both lock rings and firmly tighten the lower one. The lock ring can only be tightened when the adapter is properly fitted.



- Prior to placing the supply unit, take the motor (1) and connect the coupling with the sleeve (2) to 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 (3) of the sleeve.

6.5.5 Sensors

6.5.5.1 Installing the Temperature Sensor



The installation position of the temperature sensor is dependent on the culture vessel (header plate) used. Information on the culture vessels and on the assignment of the header plates can be found in the UniVessel® Operating Manual on the accompanying CD.
- Guide the temperature sensor into the appropriate opening of the header plate and tighten the knurled screw (1) by hand.

After autoclaving and setting up the culture vessel at the workplace, close the temperature sensor on the back of the device [▶ Chapter 3 "Device Overview"].



6.5.5.2 Installing the pH Sensor

The installation position of the pH sensor is dependent on the culture vessel (header plate) used. Information on the culture vessels and on the assignment of the header plates can be found in the UniVessel® Operating Manual on the accompanying CD.

– Guide the pH sensor into the appropriate opening of the header plate and tighten the knurled screw (2) by hand.

After autoclaving and setting up the culture vessel at the workplace, close the pH sensor on the back of the device [▶ Chapter 3 "Device Overview"].



6.5.5.3 Installing the DO Sensor (pO_2)

The installation position of the DO sensor (pO_2) is dependent on the culture vessel (header plate) used. Information on the culture vessels and on the assignment of the header plates can be found in the UniVessel® Operating Manual on the accompanying CD.

– Guide the DO sensor (pO_2) in the appropriate opening in the header plate and tighten the knurled screw (2) by hand.

After autoclaving and setting up the culture vessel at the workplace, close the DO sensor (pO_2) on the back of the device [▶ Chapter 3 "Device Overview"].

6.5.6 Temperature Control

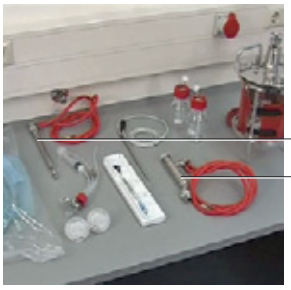
CAUTION!

Danger of injury from glass splinters!

Excessive pressure can make the culture vessels burst.

Bursting glass culture vessels can cause lacerations and damage the eyes.

– Make sure that the hose on the return connection leading to the basic device is not kinked or disconnected.



Hose Kits

The device is delivered with:

– Cooling finger (1) and matching hose kit.
– Exhaust cooler (2) and matching hose kit.



6.5.6.1 Installing the Cooling Finger

The installation position of the cooling finger is dependent on the culture vessel (header plate) used. Information on the culture vessels and on the assignment of the header plates can be found in the UniVessel® Operating Manual on the accompanying CD.

– Guide the cooling finger in the appropriate opening in the header plate and tighten the knurled screw (3) by hand.



6.5.6.2 Installing the Exhaust Cooler

The installation position of the exhaust cooler is dependent on the culture vessel (header plate) used. Information on the culture vessels and on the assignment of the header plates can be found in the UniVessel® Operating Manual on the accompanying CD.

– Guide the exhaust cooler in the appropriate opening in the header plate and tighten the knurled screw (3) by hand.

6.5.6.3 Connecting the Cooling Finger and the Exhaust Cooler to the Device

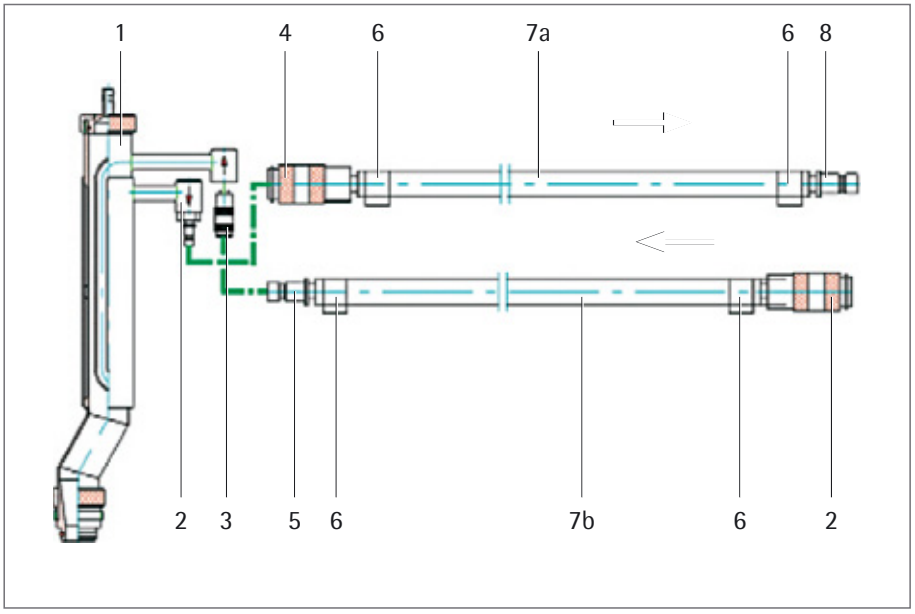
Once the culture vessel has been autoclaved and set up at the work site, connect the cooling finger and the exhaust cooler to the device.
Note the markings for the inlet and return to the tubing adapters [▶ UniVessel® Operating Manual].



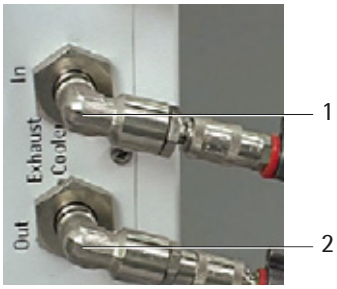
Cooling Fingers

– Connect the hoses of the exhaust cooling finger to the hose supply line (2) and return line (1) of the device.
– During the fermentation process, the cooling water is only fed into the temperature control circuit if the vessel needs to be cooled.

Exhaust Cooling



1 Exhaust cooler
2 Plug-in nipple with outer diameter
3 Coupling
4 Coupling with tubing connection
5 Sealing clip with hose connection
6 1-ear clamp
7a Hose return line (5 × 1.5 length 1000 mm)
7b Hose supply line (5 × 1.5 – length 1000 mm)
8 Plug-in sleeve with tubing connection



– Connect the hoses of the exhaust cooler to the hose supply line (2) and return line (1) of the device.

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.

6.5.7 Exhaust and Supply Air Filter, Exhaust Filter Heater



Filters

The exhaust filter is installed on the following component:

– Exhaust cooler
– Exhaust pipe (when using without exhaust cooling)

Air inlet filter are installed on the following components:

– Media aeration (port sparger)
– Headspace aeration (port overlay on version BIOSTAT® Aplus CC)

The installation position of the ports is dependent on the culture vessel (header plate) used.

– Cut the connecting hoses for the filter to a length of approx. 5 cm.

6.5.7.1 Installing the Exhaust Air Filter on the Exhaust Cooler



– Place the hose over the exhaust filter nozzle.

6.5.7.2 Installing the Filter on the Cover Port



– Place the hose over the nozzle of the corresponding port
  – Sparger
  – Overlay
  – Exhaust nozzle

Exhaust Filter Heating



When using UniVessel® SU culture vessels, the exhaust air is dried by the exhaust filter heater. The exhaust filter heater ensures that the filter cannot become clogged from moist exhaust. For further information, please refer to the UniVessel® SU installation instructions.

6.5.8 Heating Blanket

The heating blanket is used for heating single-walled culture vessels.

– UniVessel® Glass
– UniVessel® SU

WARNING!

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

The heating blankets have to be in perfect condition. Observe the accompanying safety instructions.

WARNING!

Danger to life when using heating blankets with too high power consumption!

The power consumption of the heating blanket may not exceed 780 watts.

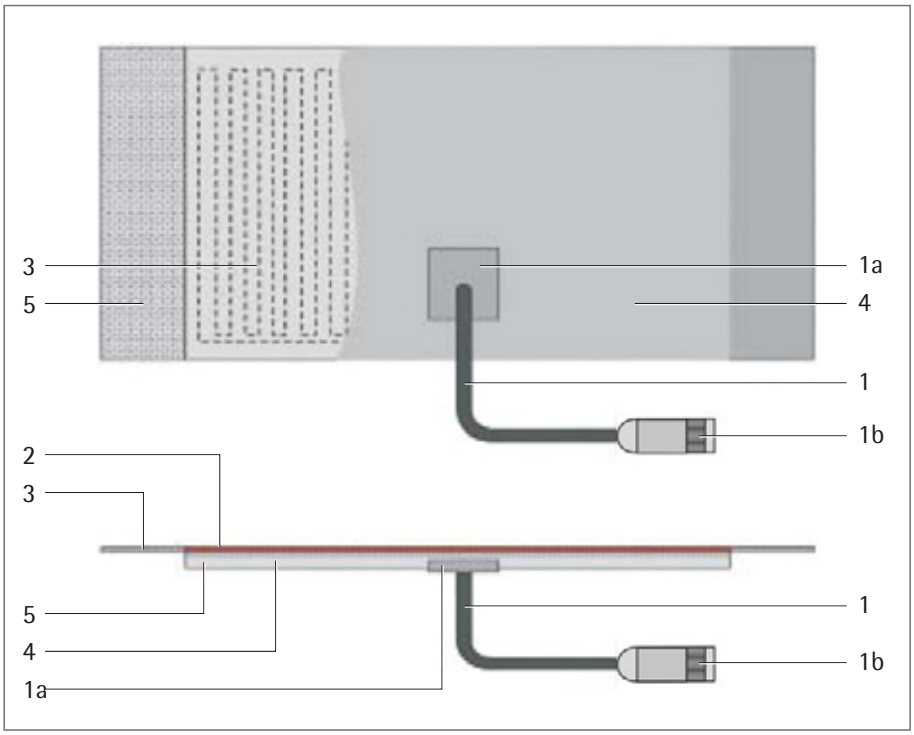
– Only use the parts specified by Sartorius Stedim Systems.
  Special versions and especially models from other suppliers require the prior written agreement of Sartorius Stedim Systems.

IMPORTANT!

Supplying the heating blanket with the wrong kind of voltage will damage the heating blanket.

– The heating blankets must only ever be connected to the socket 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 device's temperature controller.

Construction of Heating Blanket



1 Power cord
1a Cable connection with overheating protection
1b 6-pin Amphenol power plug
2 Protective film of the heating coil (vessel side)
3 Heating coil
4 Silicone foam shell
5 Velcro fastener

6.5.8.1 Installing the Heating Blanket

After unpacking the heating blanket, roll it out flatly on the benchtop for the fitting.

IMPORTANT!

Sharp-edged or heavy objects can damage the heating coil and cause a short circuit.

– Never put any objects on the heating blanket.

– After autoclaving, set up the culture vessel at the work place.
  Take note of the length of the heating blanket's power cord.
– Carefully lift and hold the blanket at the edge opposite to the cable connection.
  During this procedure, the power cord should be hanging downwards.

IMPORTANT!

Damage to the cable attachment!

Do not lift the heating blanket by the power cord. This can damage the cable attachment.

Do not roll the blanket together more tightly than the shape of the culture vessel allows.

Do not bend or fold the heating blanket.

The silicone foam-isolated side serves as grip protection.



– Wrap the heating blanket around the culture vessel with foil-shielded side touching the vessel.
  The side insulated with silicone foam should face outwards.
– Carefully insert the heating blanket between the stand rods and place them around the glass vessel so that you can close the Velcro fasteners.
– The power cord should be hanging downwards.
– Secure the Velcro fasteners so that the blanket is lying flat on the culture vessel without folds, warping or dents.

6.5.8.2 Connecting and Monitoring the Heating Blanket

WARNING!

Danger of burns on the heating blanket!
Depending on the operating temperature in the culture vessel, the heating blanket can heat up to approx. 75 °C.
- Danger of burns! When in operation over 40 °C, never touch the heating blanket with your bare hands.
- Wear protective gloves when handling the culture vessel.

IMPORTANT!

When connecting to another power supply in the lab, there is a danger of short circuit or overheating.
Only connection to the device is controlled through the temperature control on the bioreactor.



- Only connect the power cord of the heating blanket to the device's power supply (figured here: Amphenol socket) (1).
- Lay the power cord so that it cannot be pulled unintentionally. Do not place any devices or objects on the cable.
- Turn the device on.
- Configure the temperature control (▶ Operating Instructions Part B) and activate it if necessary for the process.

The measurement and control system activates the power supply of the heating blanket when the culture vessel needs to be heated and the cooling water supply to the cooling finger when cooling is necessary [▶ Chapter "6.5.6.1 Installing the Cooling Finger", ▶ UniVessel® Service Manual].

- Regularly check the heating blanket during the process.

Black discolorations occurring on the power cord connection or on the silicone foam along the heating coil indicate that the heating coil and | or cable are defective.
- Immediately interrupt operation and replace the heating blanket.

- Whenever there is contact with splashing water or media, interrupt heating operations, remove the heating blanket from the culture vessel and clean and dry it thoroughly.

6.5.8.3 External Cooling Equipment

The minimum culture vessel temperature is around 8 °C above the ambient temperature. To operate the bioreactor at lower temperatures, it needs to be connected to an external cooling system.

If you are connecting the equipment to an external cooling circuit in the laboratory or a cooling thermostat, the temperature control circuit must be operated at zero pressure (at ambient pressure).

6.6 Aeration Modules



Risk to health from gases!
The gases used or formed during the fermentation process can be hazardous to health.
- Make sure that there is adequate ventilation at the work site.
- If you are using large amounts of CO2, e.g. for regulating pH, or if CO2 is created as a result of the cell's metabolism, connect the exhaust air connection of the culture vessel to a laboratory exhaust air treatment system.
- Establish the potential amounts of hazardous gases that might occur and could escape.
- If necessary, fit suitable equipment for monitoring the air in the room.

The supply unit is fitted with aeration systems that have independently controllable spargers, depending on the specifications of the device:
- The "CC" aeration modules for cell cultures have an adjustable "Sparger" outlet for medium aeration and an "Overlay" outlet for headspace aeration for every culture vessel [▶ Chapter 3 "Device Overview"].
- The aeration module "MO" only has one output "Sparger" for the media aeration [▶ Chapter 3 "Device Overview"].

6.6.1 Preliminary Steps

The culture vessels must be equipped for media aeration [▶ Chapter "6.5.7 Exhaust and Supply Air Filter, Exhaust Filter Heater", ▶ UniVessel® Operating Manual]:
- Aeration pipe with ring sparger or microsparger or aeration basket with a silicone tube membrane,
- Air inlet filter,
- Exhaust cooler with exhaust filter ("UniVessel®" Glass),
- Exhaust filter with filter heater ("UniVessel® SU"),
- Supply air filter for headspace aeration when using the aeration unit "Additive Flow".

The culture vessels must be autoclaved together with the supply air and exhaust air filters and then set up next to the supply unit.
- Connect all sensors and switch on the device [▶ Chapter "6.5.5 Sensors"].
- Configure the calibration parameters for the DO sensor and select the aeration mode using the DCU system [▶ Operating Instructions Part B].

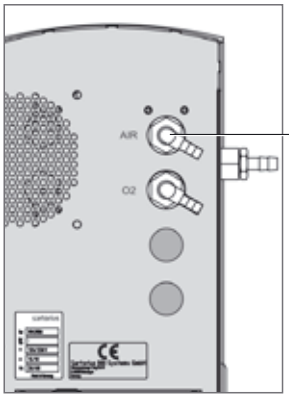
The DO sensor's zero point can be calibrated after autoclaving with nitrogen, and before the culture medium is supplied with air or oxygen.



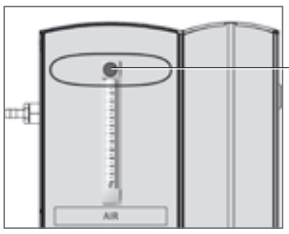
If the supply unit can no longer supply nitrogen ("O_2 enrichment"), conduct medium aeration directly by connecting an external nitrogen source at the supply air filter of the culture vessel.

– Aerate the culture medium using nitrogen up until no more oxygen is left.
– Calibrate the zero point [▶ Operating Instructions Part B].
– Connect the gas outlet of the device with the air inlet filter to aerate with air or gas mixture.
– Connect the gas outlet of the device with the air inlet filter to carry out the headspace aeration ("Additive Flow").

6.6.2 Connecting the "MO" Aeration System







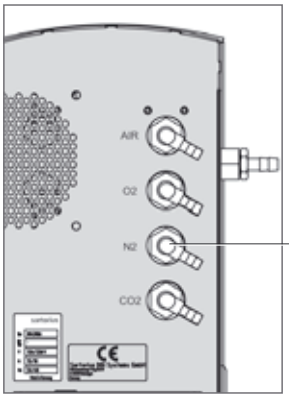
Zero Point Calibration
To calibrate the DO sensor's zero point by feeding nitrogen into the vessel through the aeration system "MO", proceed as follows:
– Connect the laboratory nitrogen supply line to the "AIR" (1) inlet on the device.
– Connect the hose from the culture vessel's supply air filter to the variable area flow meter at the "AIR" (2) outlet.
– Switch the "Air" flow path in the "DO controller" to the "man" operating mode [▶ Operating Instructions Part B]. Leave or switch "O_2" to "off".
– Open the laboratory nitrogen supply and the variable area flow meter at the "AIR" (3) outlet. Aerate the culture medium with nitrogen and calibrate the zero point.

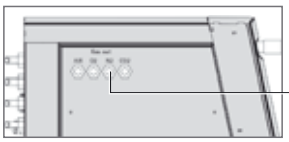
Slope Calibration and Process Aeration
To aerate the medium to calibrate the slope during process, proceed as follows:
– Connect the laboratory air supply line to the "AIR" (1) inlet on the supply unit.
– Depending on whether you wish to calibrate the slope to the air or oxygen feed, switch the "AIR" or "O_2" flowpath in the DO controller menu to "man". Set the line that is not required to "off".
– Set the variable area flow meter "AIR" (3) to the gas flow rate to which the slope calibration relates.
– Calibrate the slope of the DO sensor (pO_2) [▶ Operating Instructions Part B].
– Set the variable area flow meter "AIR" to the gas flow rate that you want to use at the start of the fermentation process.

Manual Control:
– To control the gas feed manually, switch the "AIR" and "O_2" flow paths in the DO controller menu of the DCU system to "man" or to "off", as needed.

Automatic DO Control:
– For automatic air feed to control the dissolved oxygen (DO), set the desired parameters and switch the air flow paths "AIR" and "O_2" to "auto".

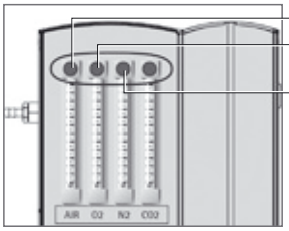
6.6.3 Connecting the "CC" Aeration System





Zero Point Calibration
To calibrate the DO sensor's zero point by feeding nitrogen into the vessel through the aeration system "CC", proceed as follows:
- Connect the laboratory nitrogen supply line to the "N_2" (1) inlet on the supply unit.
- Connect the hose from the culture vessel's supply air filter to the outlet of the variable area flow meter "N_2" (2).
- Open the laboratory nitrogen supply and the variable area flow meter at the outlet "N_2" (3). Aerate the culture medium with nitrogen and calibrate the zero point.

Slope Calibration and Process Aeration
To aerate the medium to calibrate the slope during process, proceed as follows:
- Depending on whether you wish to calibrate the slope to the max. air or oxygen feed, switch the "Air" or "O_2" flow path in the DO controller menu to "man". Set the lines that are not required to "off".
- Set the gas flow rate for "AIR" and "O_2" on the variable area flow meter "AIR", "O_2" (4, 5), to which the slope calibration should refer.
- Calibrate the slope of the DO sensor (pO_2) [▶ Operating Instructions Part B].
- Set the gas flow rate for headspace aeration on the variable area flow meter "AIR" (4).



Manual Control:
To regulate the gas supply systems manually, switch the gas lines in the DCU system's controller menu to "man".

Automatic DO Control:
- For automatic air feed to control the dissolved oxygen (DO), set the desired parameters in the DO controller menu of the DCU system and switch the air flow paths "Air" and "O_2" to "auto".
- To control the pH using CO_2, set the control parameters in the pH controller and switch the "CO_2" flow path to "auto".

The addition of "N_2" takes place using the manual setting on the variable area flow meter (flow meter).

6.7 Corrective Solution Supply Systems
The supply unit is fitted with 3 WM102 peristaltic pumps for supplying correction media (acid, base, antifoaming agent or nutrient solution | substrate).

If the DCU is configured to allow it, acid or base pumps that are not being used can be assigned to other controllers. For configurations with level controllers, the pumps can also be used to remove media in "Harvest" mode [▶ Operating Instructions Part B].

Preliminary Steps:
The culture vessels must be fitted with the following equipment needed for supplying correction media or media removal [▶ Operating Instructions Part B]:
– pH sensor, feed pipe for acid and base
– Antifoam sensor, feed pipe for antifoaming agent
– Harvest pipe for removal of media

The bottles have to be ready for use [▶ Chapter "6.5.1.1 Preparing the Corrective Solution Bottles"]. The bottles are autoclaved together with the culture vessel.

6.7.1 Preparing the Peristaltic Pumps



Danger of crushing limbs by being pulled into the rotation pump!
Allow only qualified technical personnel to work on the device.
Keep the associated DCU controller function switched off or switch this controller function off, e.g. antifoam, pH or level controller [▶ Operating Instructions Part B].
Only turn the pump head by hand when installing the hose.

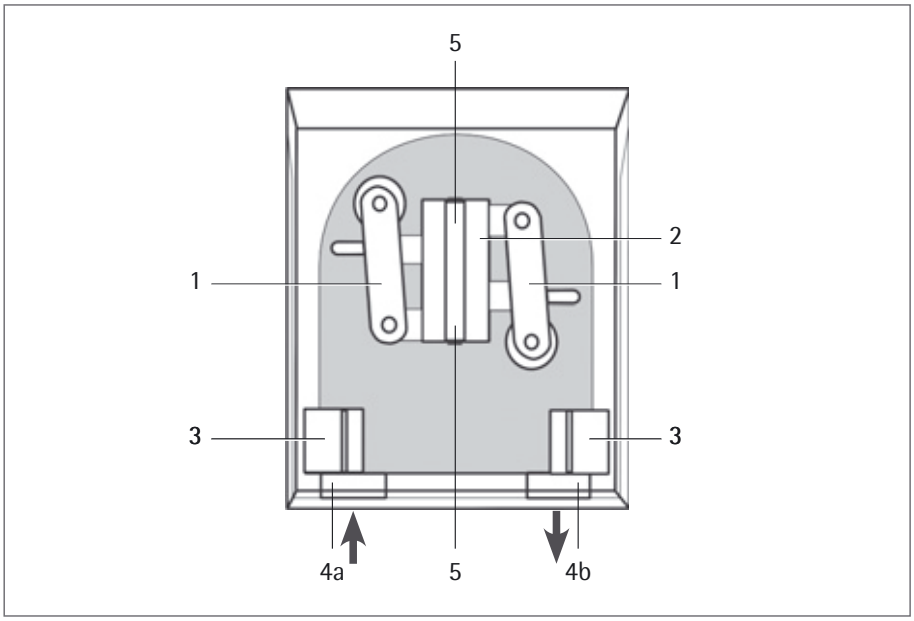


Fig. 6-1: Peristaltic pump, contact pressure setting

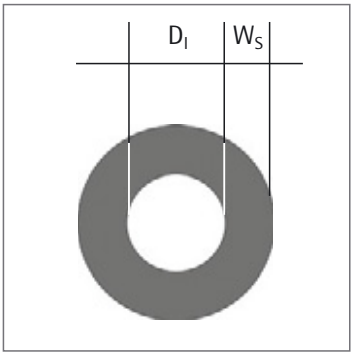
1 Pressure rollers, tube guide
2 Rotor pump head
3 Hose clamps
4a Input clamp
4b Output clamp
5 Contact pressure adjusting screws

In the peristaltic pumps, the silicone hoses can be installed with different wall thicknesses.



The contact pressure is pre-configured for silicone hoses with a wall thickness of 1.6 mm.

Silicone hose example:
Version 3.2 × 1.6

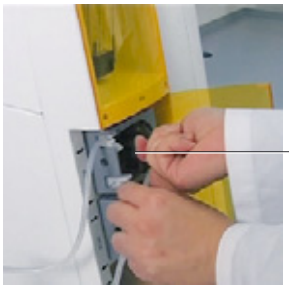


D_I Inner hose diameter 3.2 mm
W_S Wall thickness 1.6 mm

To install silicone hoses in the peristaltic pump, perform the following steps:



– Open the cover on the pump head.
– Press the input (4a) hose clamp to open it and then insert the hose.



– Thread the hose into the 1st rotor guide. Turn the rotor (2) clockwise and insert the hose into the 2nd rotor guide.



– Continue turning the rotor until you are able to insert the hose into the output clamp (4b). The tubing must be uniformly threaded inside the pump head.
– Test the contact pressure of the rollers. These must clamp off the hose to prevent medium from flowing back.

The silicone hose must not be pressed too tightly, as this may damage the hose.



Correcting the Contact Pressure

– To correct the contact pressure, turn the rotor (2) until you can see the setting screws (5) [▶ "Fig. 6-1: Peristaltic pump, contact pressure setting"]
– To increase the contact pressure, turn the setting screws clockwise, to decrease it, anticlockwise. Adjust the same contact pressure for both rollers.
– Close the cover over the pump head.

Configuration

Before starting automatic control of the correction media feed, you will need to prime the tubing with correction media. To fill them, start up the hose pumps manually:

If you do not compensate for the priming volume inside the tubing, the correct feed volumes will not be calculated.

– Activate the pump via the touch display "man".
– Let the pump run until the tubing is filled (primed) with correction medium up to the end section on the culture vessel.
– Use the touch display to re-set the pump to "auto" status.
  The DCU system controller assigned to this pump, e.g. the pH or antifoam controller, will now switch on the pump as and when required.

When using other, optionally available pumps, to which these operating instructions do not apply, please refer to the manufacturer's documentation, e.g. Watson Marlow.

6.8 Performing a Process

6.8.1 Safety Information



Danger of injury from glass splinters!
After aerating at impermissible pressure levels, the culture vessel can burst and glass splinters can cause cuts and eye injuries.
Only operate the temperature control circuit of doubled wall vessels at ambient pressure. Do not exceed a max. pressure of 1.3 bar_g (18.85 psi_g) when aerating the culture vessels (▶ UniVessel® Service Manual).
- Make sure that the culture vessel is positioned stably.
- Wear personal protective equipment.
- Make sure that the culture vessel is properly connected to the supply and control units.
- Make sure that the cooling water flows back without pressure.
- Regularly check all lines, hoses, and connections under pressure for leaks and externally detectable damage.



Danger of contamination from escaping feed and culture media!
Accidentally released hazardous substances, infectious cultures and corrosive media can result in health hazards.
- Follow the companies' safety instructions (e.g. for processes which pose special requirements to your workplace, the use of components or on handling of media and contaminated components).
- Empty the feed hoses before loosening the hose connection.
- Wear personal protective equipment.
- Wear safety glasses.



Danger of contamination from media and cultures used and products generated in the process!
The media and cultures used for the fermentation process and the products generated during it can be hazardous to health.
- Where necessary, always disinfect or sterilize contaminated equipment. This can be done by filling the UniVessel® and the accessories that have come into contact with the culture with water before dismantling and cleaning it, and autoclaving it again.
- In some cases, it is sufficient to heat the UniVessel® to >65°C for around 1 hour. This will kill off any viable cells, but not spores or thermophilic microorganisms. When using non-hazardous cultures and media, the UniVessel® only needs to be carefully rinsed with water.



Danger of chemical burns from acids and bases!
Excess acids and alkalines in correction media bottles can cause chemical burns in the event of uncontrolled leakage!
- In order to neutralize the acids and alkalines, empty the lines into appropriate containers.
- All other equipment that has come into contact with acids, bases or (potentially) hazardous media must be treated with appropriate cleaning solutions or safely disposed of.



Danger of burns upon contact with hot surfaces of culture vessels!
In double wall vessels, the outlets on the temperature control module, the temperature control system hoses and the culture vessel can become very hot and cause burns.
- In single wall culture vessels, the heating blankets become hot.
- Wear protective gloves when working with hot culture media.

CAUTION!

Danger of burns upon contact with hot surfaces of the stirrer drive motor!
The stirrer motors can become hot if operated over long periods, run at high rpm speeds and when stirring viscous media.
- Take note of the motor's safety label. This label will become discolored at high temperatures.
- Avoid accidental contact with the motor and only touch drive motors during the fermentation process wearing gloves.

IMPORTANT!

Operating the stirrer at impermissible high speeds can affect the culture vessel's stability and cause damage to their fittings.
Depending on the size and equipment of the culture vessels, the permissible speed may be limited, e.g. to max. 300 min^{-1} in vessels with gas supply rigs for bubble-free gas supply.

6.8.2 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 operator display [▶ Operating Instructions Part B].
- Select the measurement and control functions and set the parameters required for your process:
  - Operating temperature of the culture vessel (in the temperature controller)
  - Stirring speeds (in the speed controller)
  - pH values, top | bottom limit (in the pH controller)
  - Target values, limit values and operating mode of the DO control (in the DO controller).

- If available in the DCU system configuration menu:
  - Response thresholds for antifoam (in the "Antifoam" controller)
  - Operating modes and parameters for level control (in the level controller "level")

6.8.3 Guaranteeing 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.
- Enter all of the process parameters as specified (temperature, speed, aeration, pH regulation, etc.).
- Leave the bioreactor running for 24 hours and monitor it for signs of error, e.g.:
  - Change in the 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 seals.

Corrective Measures:
– Sterilize with new medium for longer sterilization times.



Do not raise the sterilization temperature!

– Dismantle all of the vessel equipment and connections and check all of the seals and lines for damage.

6.8.4 Performing a Cultivation Process

Transfer the inoculation culture to the culture vessel [t UniVessel® Operating Manual].
– Perform the scheduled process steps.
– Take samples as necessary for monitoring the progress of the process [▶ UniVessel® Operating Manual].
– On completion of the process, harvest the culture and transfer it to the next point of use (scale-up, processing, etc.).

7. 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.

The cleaning and maintenance 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.

7.1 Safety Information



Danger to life caused by electrical voltage!
Electrical switching elements are installed in the device. Contact with parts under voltage represents a direct danger of death.
- Never open the device. The device may only be opened by specialist personnel authorized by Sartorius Stedim Biotech.
- Work on the electrical equipment of the device may only be carried out by Sartorius Stedim Service or authorized technicians.
- During maintenance, cleaning, and repair work, turn the power supply off and secure it against reactivation.
- Keep moisture away from parts under voltage, as this can lead to short circuits.
- Check the electrical equipment of the device regularly for defects such as loose connections or damage to the insulation.
- In case of defects, turn the power supply off immediately and have the defects corrected by Sartorius Stedim Service or authorized technicians.
- Have the electrical components and stationary electrical equipment checked by an electrician at least every 4 years.



Danger of crushing limbs by being pulled into the rotation pump!
- Do not remove the safety mechanisms.
- Allow only trained technicians to work on the device.
- Disconnect the device from power when performing maintenance and cleaning tasks.
- Block the danger zone off.
- Wear personal protective equipment.



Danger of burns upon contact with hot surfaces!
- Avoid contact with hot surfaces like vessels, motor housings, and pipelines carrying steam.
- Block the danger zone off.
- Wear protective gloves when working with hot culture media.



Danger from projecting components!
Ensure that danger points such as corners, edges, and projecting components are covered.

Preliminary Steps
Make sure to always perform the following preliminary steps during cleaning and maintenance:
– Turn the device off at the main switch.
– Unplug the power plug from the laboratory connection.
– Turn off all supply media in the lab (water and gas supply).
– Ensure that the connection and hoses have been depressurized.
– If necessary, detach the media supply lines from the device.

7.2 Cleaning



Danger of corrosion and damage to the device and the culture vessel by unsuitable cleaning agents.
– Avoid strongly caustic or alkaline and | or chloride-containing detergents.
– Avoid 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 the same, may be subject to legal or environmental protection regulations.

7.2.1 Cleaning the Device
– Clean the device housing with a slightly dampened, cleaning cloth; for greater contamination use a mild soap.
– Clean the control operating screen with a slightly dampened, lint-free cleaning cloth; for greater contamination use a mild soap.



Be sure not to scratch the device or operating display. Future contamination is otherwise more difficult to remove.

7.2.2 Cleaning the Culture Vessels

In some cases, it may be sufficient to carefully rinse the culture vessels (UniVessel®) with water. If the bioreactor is not used for a while, always fill the culture vessels with water, as this will protect the integrated sensors from drying out.

Thorough cleaning is required if components of the culture or media adhere to the inside surfaces of the culture vessels and components installed:

- Culture vessels and glass containers can be cleaned in a dishwasher. Before cleaning culture vessels inside a dishwasher, always remove the support frame, the cover plate and the vessel fittings.
- Glass surfaces that are contaminated with organic substances can be cleaned with conventional laboratory glass cleaners. To remove stubborn organic contaminants, you may use mechanical means to remove them.
- Dissolve inorganic deposits using diluted hydrochloric acid. Once these contaminants have been removed, carefully rinse the culture vessel with water.
- The metallic parts (cover plate, etc.) can be cleaned mechanically, with a mild cleaning agent or alcohol.
- Mechanically clean seals and other O-rings. If deposits on the seals and O-rings prove to be persistent, replace the seals and O-rings.



Detailed information on cleaning culture vessel, vessel equipment and sensors can be found in the [UniVessel® Operating Manual].

7.2.3 Cleaning and Maintaining the Heating Blankets



Danger of damage from unsuitable cleaning agents and cleaning procedures.

- Do not use cleaning agents or solvents that can attack the power cord, the silicone foil or the silicone foam.
- Do not use any hard and | or sharp objects to remove stubborn soiling.



The heating blankets are insensitive to water and the media used in conventional culture procedures. Test the resistance to the laboratory acids, alkaline agents and solvents used.

- Clean soiled heating blankets carefully using only a wet cloth and warm water or mild soapy water.
- Before every use, check especially the following components to make sure they are in perfect condition:
  - the power cord, especially where it connects to the heating blanket
  - the silicone foil on the heating side,
  - the silicone foam isolation
  - the Velcro fasteners

Possible Damage

Risk of electric shock if heating blanket is damaged!
No parts should be porous or have cracks, kinks, folds or chipped areas.
The silicone foil should not be discolored. This indicates a short circuit due to a broken heating coil or defective power cord. In this case, discontinue use of the heating blanket and replace it.

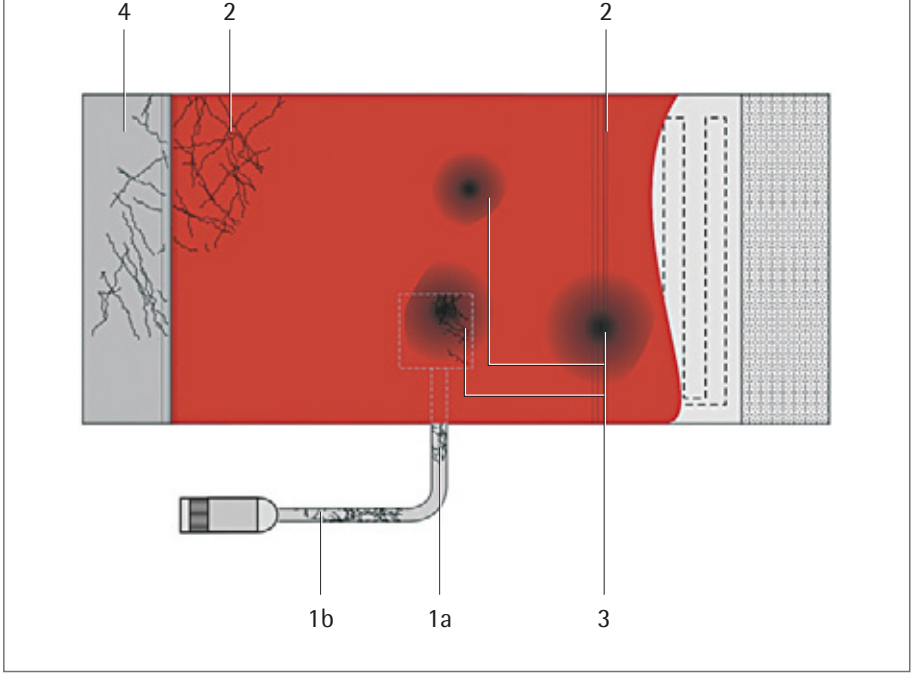


Fig. 7-1: Damage

1a Cracks, porosity of the cable connection
1b Cracks, porosity of the power cord
2 Cracks, porosity of the silicone foil over the heating coils
3 Short circuiting of the heating coil, indicated by discoloration of the silicone foil
4 Cracks, porosity of the Velcro fasteners

After using the heating blanket, only store it in a clean, dry location.
Do not expose it to sunlight for extended periods.
In flawless condition, the heating blankets allow safe heating of the culture vessels.
Malfunctions and dangerous operating states may occur if damage is overseen during the pre-use inspection.

Spare and Wearing Parts

Heating blankets do not contain spare and wearing parts. If worn or defective, they must be replaced.

7.3 Maintenance

7.3.1 Maintaining the Device

The maintenance work carried out by the user is limited to the following tasks:

- Maintaining the pH, pO_2 or Redox sensors as per the manufacturer's | supplier's specifications.
- Checking and replacing parts subject to wear as well as disposables, e.g., glass vessels, filters, tubing and seals with identical components with the same specifications [Spare parts list].
- Replacing O-rings, other seals, filters, tubing and single-use items, e.g., inoculation membranes.



Detailed information on maintaining culture vessels, vessel equipment and sensors can be found in the [UniVessel® Operating Manual].
The internal modules of the device, and the safety equipment, pump modules , drive motors and stirrer shaft couplings, must only be serviced by qualified and correspondingly authorized service personnel.
Any servicing instructions for internal equipment, electrical modules and safety equipment contained in this manual and the technical documentation must be forwarded to the servicing personnel.
Please return the device to Sartorius Stedim Systems GmbH if it is defective.
Observe the Decontamination Declaration [▶ Chapter 10 "Appendix"].

7.3.2 Maintenance Intervals

Cyclical maintenance of the device depends on its service life.
The maintenance intervals are listed in the following table according to the respective components:

Component	Activity	Before every process	After 10–20 autoclave cycles	If unsterile	1 × yearly
Culture vessel					
Leak test	Pressure-hold test Tightness test	•		•	
Connections between control unit and culture vessel, air, water					
Leak test	Visual inspection	•			
Temperature control system					
Leak test and | or heating blanket inspection	Visual inspection	•			
Tapping septa					
→	Replace	•			
O-rings					
→	Visual inspection, replace if needed	•			
→	Replace	•		•	•
Intake and exhaust air filters					
Filter cartridges	Integrity testing	•			
→	Replace		•	•	
→	Replace		•	•	•
Holding bottles, sampling bottles					
→	Visual inspection, replace if needed	•			
Gaskets | ventilation filters	Replace			•	•
Rotating mechanical seal					
Check for contamination and damage	Visual inspection	•			
Peristaltic pumps					
Pump hoses	Visual inspection, replace if needed	•			
Sensors	Visual inspection, replace if needed				
pH sensor	Calibration, visual inspection for damage	•			
DO sensor (pO_2)	Calibration, visual inspection for damage	•			
Membrane body | electrolyte (Clark probes)	Visual inspection, replace if needed	•			
Sensor cap (optical O_2 probe)	Visual inspection, replace if needed	•			
Foam sensor	Calibration, visual inspection for damage	•			
Level sensor		•			

Component	Activity	Before every process	After 10–20 autoclave cycles	If unsterile	1 × yearly
Plugs | contacts | lines					
→	Visual inspection	•			
Maintenance according to maintenance schedule					
Maintenance and functional test according to maintenance report	May only be performed by Sartorius Stedim GmbH specialists. Please contact the Sartorius Stedim Service.				•

8. Malfunctions

8.1 Safety Information



Danger to life caused by electrical voltage!
Electrical switching elements are installed in the device. Contact with parts under voltage represents a direct danger of death.
- Work on the electrical equipment of the device may only be carried out by a competent electrician.
- Before any work, turn the device off and disconnect it from power.
- Always make sure any electrical equipment is disconnected from AC power before performing any maintenance, cleaning or repair work.



Danger of crushing limbs by being pulled into the rotation pump!
- Do not remove the safety mechanisms.
- Allow only trained and authorized technicians to work on the device.
- Disconnect the device from power when performing maintenance and cleaning tasks.
- Block the danger zone off.
- Wear personal protective equipment.



Danger of burns upon contact with hot surfaces!
Avoid contact with hot surfaces like temperature-controlled culture vessels, motor housings, and pipelines carrying steam.
- Let the culture vessels cool before troubleshooting.
- Block the danger zone off.

8.2 Troubleshooting

Always proceed according to the following steps when faults occur on the device.
- Turn the device off if the fault represents a direct danger to personnel or property.
- Inform management on site about the fault.
- Determine the cause of the fault and remedy it before switching the device back on. [▶ Chapter “6.3.1 Turning the Control Unit On and Off”].

Faults, possible causes and corrective measures are listed in the following fault tables.

8.2.1 Fault Table "Contamination"

Contamination	Possible 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. – Increase the autoclaving time. – Perform sterility tests using test spores.
	– Air inlet line or air inlet filter defective.	– Replace the tubing. – Check filter(s) and replace, if necessary.
Generalized and gradual (even without inoculating the culture)	– Seals on the culture vessel or the integrated components are damaged (e.g., hairline cracks).	– Carefully check the integrated parts. – If suspected to be damaged (rough, porous surfaces or dents), replace seals.
After inoculation, widespread	– Contaminated inoculation culture – Unsterile inoculation equipment	– Take control samples of the inoculum culture and test inoculated culture medium from the vessels (e.g. on test nutrient solutions).
	– Errors made during inoculation	– Check the inoculation procedure – Carefully practice correct inoculation procedure beforehand.
	– Air inlet filter or connection not sterile or defective	– Check the filter(s) and replace, if necessary. – Replace the connection line.
During the process, rapid	– Air inlet filter or connection not sterile and | or defective	– Check filter(s) and replace, if necessary. – Replace the connection line.
	– Accidental or unauthorized manipulation of components	– Take organizational measures at your work area to prevent tampering with the equipment.
During the process, gradually	– Seals on the culture vessel or the integrated components are damaged (e.g. hairline cracks or porous)	– If possible, continue process up to the end point. At the end of the process, dismantle the vessel and carefully check the integrated components. – If suspected to be damaged (rough, porous surfaces or dents), replace seals.
	– Exhaust air filter(s) or connection has become unsterile or is defective (contaminated from the exhaust air line).	– Check the filter(s) by performing a sterility test, if possible, and replace, if necessary. – Replace the connection line.

We recommend that you perform a sterility test before each process.
Duration 24 – 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 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 prescribed operating conditions (e.g., temperature, stirrer speed, aeration).

8.2.2 Fault Table "Counter Cooling System"

The counter-cooling system does not work or does not provide sufficient cooling power.

Problem	Possible causes	Corrective measures
The cooling water is not fed into the system	– The laboratory supply line is blocked or the valves of the cooling water feed are defective.	– If you can exclude all other possible sources of error (see the following), please inform our Technical Customer Service.
	– The cooling water feed valve does not work because of particulate contaminants in the cooling water or scale deposits.	– Check the water hardness (no more than 12 dH). – Feed clean cooling water into the system (install a prefilter, if necessary).
Insufficient cooling power	– Flow rate too weak – Cooling water temperature too high – During strong exothermal processes	– The minimum operating temperature is approx. 8°C (46°F) above the cooling water temperature. – If necessary, connect a separate cooling device upstream. – Activate and use separate cooling device.

8.2.3 Fault Table "Aeration and Ventilation"

Aeration or ventilation does not work or is insufficient.

Problem	Possible causes	Corrective measures
Air inlet line blocked	– Air inlet filter blocked	– Check the supply air (dry, free from oil and dust). – Install an air prefilter, if necessary.
The gas or air supply is blocked or decreases suddenly	– The tubing is kinked or disconnected – The exhaust air filter is blocked (e.g. as a result of moist air, condensation or foam back flow)	– Check the tubing and filters and, if necessary, install new sterilizing-grade filters.

9. Disassembly and Disposal



9.1 General Notes

The WEEE guidelines on waste electrical and electronic equipment do not apply to the bioreactor. Observe all relevant national regulations governing the disposal of particular components (e.g. electronic waste, metals, plastics).

- If necessary, the devices and components should be disposed of separately by material group:
  - Metals and non-ferrous metals must be brought to metal recycling facilities
  - Plastics and composites of plastics must be brought to plastics recycling and disposal facilities
  - Glass must be placed in glass recycling bins
- If necessary, you will need to unregister the bioreactor or may have to return some of its components to the manufacturer.

9.2 Hazardous Materials

The BIOSTAT® Aplus devices equipped with "O_2 Enrichment" and "Additive Flow" do not contain hazardous materials that require special disposal measures.

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

Note in accordance with European directive on hazardous substances!



According to the EU directives, 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.

Corrosion



When using corrosive gases, the fittings must be chosen accordingly, (e.g. made of stainless steel instead of brass). To change such fittings, please contact Sartorius Stedim Service.
We do not accept any responsibility for operating faults and defects resulting from the use of unsuitable gases.

9.3 Decontamination Declaration

Sartorius Stedim Systems GmbH has a duty to protect its staff from hazardous substances. When returning devices and device components, you as 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 Stedim 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 "10 Appendix". To create additional copies, simply copy the attached form or request additional forms from Sartorius Stedim Systems GmbH.

10. Appendix

10.1 Technical Documentation

The operating manuals describe how to operate the devices along with the standard equipment intended for this purpose.

The operating manuals may contain additional documentation such as a P&I diagram, lists with fittings, floor plans, technical drawings, etc. All of these documents will either be provided in the technical documentation folder or separately.

The equipment supplied will not necessarily contain all equipment described. Customer-specific equipment may contain modified or additional components. Please refer to the order or delivery documents for detailed information on the device specifications and the scope of the delivery as contractually agreed or as supplied with the device.

If the documents supplied do not match the equipment delivered to you or if any documents are missing, please contact the person responsible for your area at Sartorius Stedim Biotech GmbH.

10.2 BIOSTAT® Aplus Technical Specifications

	BIOSTAT® Aplus (MO)	BIOSTAT® Aplus (CC)
Model designation	BIOSTAT® Aplus (MO)	BIOSTAT® Aplus (CC)
Item No.	8843814 (MO 1 L) 8843816 (MO 2 L) 8843818 (MO 5 L)	8843822 (CC 1 L) 8843824 (CC 2 L) 8843826 (CC 5 L)

Laboratory Energy Sources

Power connection Supply unit	230 V (± 10 %), 50 Hz, power consumption 10 A 120 V (± 10 %), 60 Hz, power consumption 12 A Protection class: IP 20
Fuses	Voltage 230 V~: 2 × device fuse 6,3 × 32 mm, time lag, 250 V, 10 A/T (IEC) Voltage 120 V~: 2 × device fuse 6,3 × 32 mm, time lag, 125 V, 12 A/T (UL)
Cooling water supply	Supply rate: max. 5 l/min
	Supply pressure: max. 2.0 bar_g (29 psi_g)
	Water hardness: max. hardness 12° dH
	Water quality: clean water, free from particles
Process gas supply	Supply pressure [bar_g/psi_g]: – Compressed air [AIR]: preset to 1.5 bar_g (21.76 psi_g) – O2: max. 1.5 bar_g (21.76 psi_g) – N2: max. 1.5 bar_g (21.76 psi_g) – CO2: max. 1.5 bar_g (21.76 psi_g)
	Aeration rate [l/min] – Compressed air [AIR]: 15 l/min – O2: 5 l/min – N2: 5 l/min – CO2: 5 l/min
	Gas quality: Gases must be dry and clean

Culture vessels

	Operating volume | total volume [l] | [l]: – UniVessel® 1 l: 1 | 1.5 – UniVessel® 2 l: 2 | 3 – UniVessel® 5 l: 5 | 6.6 Material: Steel | glass
	– UniVessel® SU 2 l: 2 | 2.6 Material: pre-sterilized polycarbonate

Size [mm]

Supply unit (Width | Height | Depth)	530 | 420 | 750	200 | 420 | 475

Weights [kg]

Supply unit	20
Culture vessels	– UniVessel® 1 L DW: 10 – UniVessel® 2 L DW: 14 – UniVessel® 5 L DW: 20
	– UniVessel® 2 L SU without vessel holder: 1.5
	– UniVessel® 2 L SU with vessel holder: 15

	BIOSTAT® Aplus (MO)	BIOSTAT® Aplus (CC)
Temperatures		
Maximum operating temperatures:	+ 75 °C	
Minimum operating temperatures (cooling water):	+ 8 °C	
Agitator drive		
Motor	Motor 140 W, 3-phase, DC	
Rpm range for culture vessels	– UniVessel® 1 l: 20 ... 1,200 – UniVessel® 2 l: 20 ... 1,200 – UniVessel® 5 l: 20 ... 800	
Ambient conditions		
Installation Location	Conventional laboratory rooms, max. 2,000 m (6.5 ft.) above sea level.	
Ambient temperatures in the operating temperature range	0 – 40 °C	
Relative humidity [%]	<80 % for temperatures up to 31 °C (87.8 °F), decreasing linearly < 50 % at 40 °C (104 °F).	
Impurities	Pollution degree 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	

10.3 Replacing Electrical Fuses

The BIOSTAT® Aplus has two fuses.
These are located in a fuse drawer at the bottom of the back of the device, directly above the power connection (see Section "5.4.1 Power" on pages 48 and 49)



Only trained and qualified personnel may replace defective fuses.



Always remove the plug from the electrical outlet prior to replacing defective fuses.



Remove the old fuses from their sockets and ensure that they are always replaced with fuses of the same type and rating.

- Gently press the locking device of the fuse drawer upwards and pull out the fuse drawer.
- Replace the defective fuses.
  - Voltage 230 V~: 2 × device fuse 6,3 × 32 mm, time lag, 250 V, 10 A/T (IEC)
  - Voltage 120 V~: 2 × device fuse 6,3 × 32 mm, time lag, 125 V, 12 A/T (UL)
- Push the fuse drawer back into the housing until it clicks into place.

10.4 Additional Documentation

In addition to this operating manual, you can find all necessary technical documentation on the devices in the folder "Overall documentation".

The spare parts list is in the folder "Overall documentation".

If customer-specific modifications were implemented, the appropriate documents can either be integrated into the "Overall documentation" folder or they can be delivered together with the bioreactor as separate documents.

10.5 EC Declaration of Conformity

With the attached declaration of conformity, Sartorius Stedim Systems GmbH confirms the compliance of the device BIOSTAT® Aplus ("MO", "CC") with the directives cited. The signatures on the English edition are representative for the Declarations of Conformity executed in the other languages.

10.6 Decontamination Declaration

Observe the form in the "Overall documentation" folder for the "Declaration concerning the Decontamination and Cleaning of Equipment and Components (for Returning Parts)".

When returning equipment, copy and carefully complete this pre-printed form as required, and enclose it with the delivery documents.



The recipient must be able to inspect the completed declaration before removing the device from the packaging.

Decontamination Declaration

sartorius stedim biotech

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 local service representative or directly to Sartorius Stedim Biotech GmbH.

Sartorius Stedim Systems GmbH
Service Department
Robert-Bosch-Str. 5–7
34302 Guxhagen
Germany

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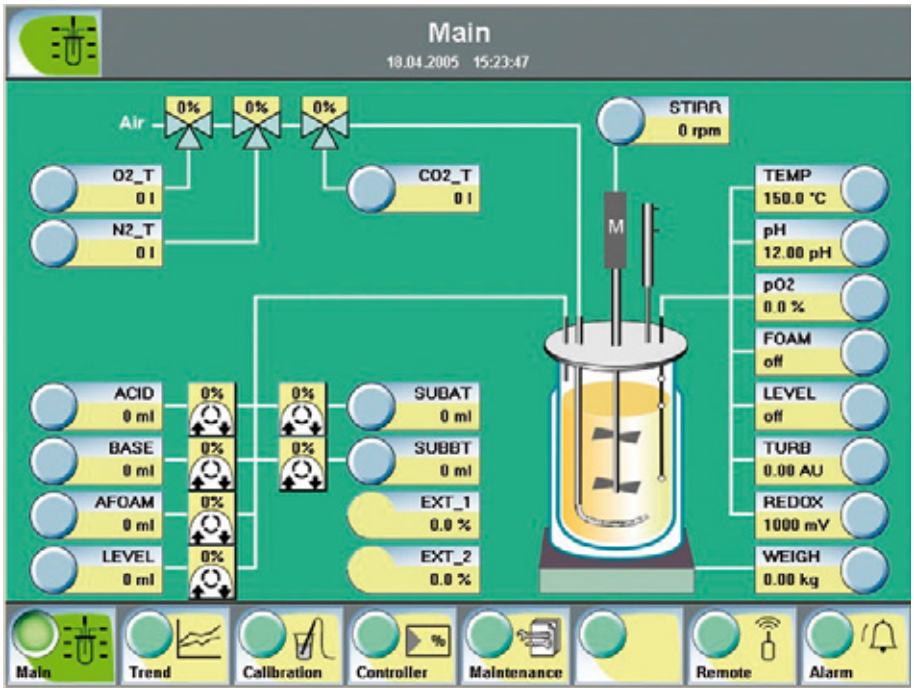
CE EG-Konformitätserklärung

Firma	**Sartorius Stedim Systems GmbH**
Adresse	Robert-Bosch-Straße 5-7 34302 Guxhagen, Deutschland Telefon +49.551.308.0, Fax +49.551.308.3289 www.sartorius-stedim.com
	Hiermit erklären wir, dass das nachfolgend bezeichnete Gerät aufgrund seiner Konzeption und Bauart sowie in der von uns in Verkehr gebrachten Ausführung den einschlägigen grundlegenden Sicherheits- und Gesundheitsschutzanforderungen der EG-Richtlinie entspricht. Diese Erklärung verliert ihre Gültigkeit, wenn an dem Gerät Modifizierungen durchgeführt werden, die durch Sartorius Stedim Systems nicht bescheinigt worden sind.
Dokumentationsbevollmächtigter	Sartorius Stedim Biotech GmbH z. Hd. Marc Hogreve August-Spindler-Straße 11 37079 Göttingen, Deutschland Telefon +49.551.308.3752, Fax +49.551.308.2062
Bezeichnung des Gerätes	BIOSTAT® Aplus
Gerätetyp	Bioreaktor | Fermenter
Artikelnummer	BB-8843812
Einschlägige EU-Richtlinien	2006/42/EG Maschinenrichtlinie 2004/108/EG Elektromagnetische Verträglichkeit 2006/95/EG Elektrische Betriebsmittel zur Verwendung innerhalb bestimmter Spannungsgrenzen 97/23/EG Druckgeräte
Harmonisierte Normen	EN ISO 12100 EN 61000-6, EN 55011 EN 61010-1
Angewandte nationale Normen und technische Spezifikationen, insbesondere	nicht angewendet
Datum und Unterschrift 07.03.2013	i.V. i.V.
Funktion des Unterzeichners	**Lars Böttcher** Director of R&D for Automation, Sensors and Instruments **Dr. Susanne Gerighausen** Director of Quality Engineered Systems and Instruments

Operating Instructions

"PC-Panel µDCU" Control Part B

Digital Measurement and Control System for BIOSTAT® Aplus



11. User Information

The control system delivered in the bioreactor BIOSTAT® Aplus basic unit on PC hardware, e.g. notebooks, is based on the digital measurement and control system DFC for measured value logging and bioreactor control.

This documentation describes standard functions of the micro DCU system. All data are based on technical characteristics valid at the time the documentation was created.

Other bioreactor modules (culture vessels, equipment, peripheral devices) and, where relevant, the micro DCU system's connection to higher-ranked host PCs are described in separate documents. Technical information on the delivered micro DCU system hardware and software ("as-built") contain the electronic and configuration documentation. You can find information on equipment from suppliers in the manufacturer's documentation.

The documentation delivered with the devices does not go into details on the legal or otherwise obligatory guidelines applicable to the work area process. If applications, e.g. in reference to biological security, represent particular requirements for the work area, device equipment, component handling or protection of personnel and work environment, please contact your safety representative to clarify potential implementation restrictions.

The micro DCU systems for measured value logging and bioreactor control are examples of the product portfolio of Sartorius Stedim Systems GmbH.
More information about our product portfolio is available from:

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This operating manual shows 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.



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

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12. Product Information

12.1 Design and Function

The micro DCU system with touch panel is an upgrade to the tried and tested digital measurement and control system micro DCU. All measurement and control functions are localized in the system's software.
Conventional notebooks serve as the control unit for the BIOSTAT® Aplus.
All functions can be accessed using its mouse and | or mouse stick or mouse pad.

The standard functions include measured value logging, monitoring of process sequences, probe calibration, filling counters and regulators. The scope of the functions actually contained within a system depends on the respective bioreactor and the customer's desired configuration. An overview of the available systems can be found below.

The micro DCU system can be integrated into hierarchical automation systems. For example, the MFCS system can take on host PC functions like process visualization, data storage, process logging etc.

12.2 Micro DCU Systems and Configurations

Bioreactor	**Configuration**	
	O_2 Enrichment (MO)	**Additive Flow (CC)**
BIOSTAT® Aplus	•	•

Range of functions of the configurations		
Measurement | Recording		
Temperature	•	•
Speed	•	•
pH value	•	•
pO_2	•	•
Foam	•	•
Filling volume (Level)	•	•
Antifoam filling volume	•	•
Harvesting filling volume (Level)[1]	•	•
Supply filling volume (Level)[1]	•	•
Gas supply - air	(DV + SK)[2]	–
Gas supply - O_2	(DV + SK)[2]	–
Gas supply - N_2	–	(SK)[2]
Gas supply - CO_2	–	(DV + SK)[2]
Turbidity (TURB)	•	•
Reactor weight	•	•

[1] For product harvesting or adding media, depending on the operating mode of the associated pump
[2] 3/2 diverter valves (DV) and variable area flowmeters are standard equipment

Bioreactor	Configuration O_2 enrichment (MO)	Additive flow (CC)
BIOSTAT® Aplus	•	•

Range of functions of the configurations		
Regulators		
Reactor temperature	•	•
Speed	•	•
pH value	•	•
pO_2	•	•
Adding anti-foaming agent	•	•
Reactor filling level (Level)[1]	•	•
Substrate A filling level	•	•
Gas supply	(DV + SK)[2]	(DV + SK)[2]

[1] For product harvesting or adding media, depending on the operating mode of the associated pump

[2] 3/2 diverter valves (DV) and variable area flowmeters are standard equipment

13. Operating Behavior

13.1 Switching the System On and Off

After powering on the control unit (of the PC system for the BIOSTAT® Aplus) or restoration of voltage after a power outage, the measurement and control system starts in a defined basic state:

- User-defined parameters (target values, parameters from calibrations, profiles, etc.) of previous processes are saved and re-loadable.
- All regulators are turned off, all actuators (pumps, valves) are in the rest position.
- Profiles and timer sequences are stopped.

13.2 Handling Operating Interruptions

For interruptions in operation, the startup behavior of outputs and system functions that have a direct effect on the bioreactor (regulators, timers, etc.) depend on the type and duration of the interruption. There are three different types of interruptions:

- Powering down and restarting the computer or switching the system on and off with the main switch "Mains" on the basic unit.
- Interruptions when the power supplied from the connection in the laboratory is cut off.

In the "System Parameter" submenu of the main function "Maintenance", a maximum duration for power interruptions can be set as the "Failtime".

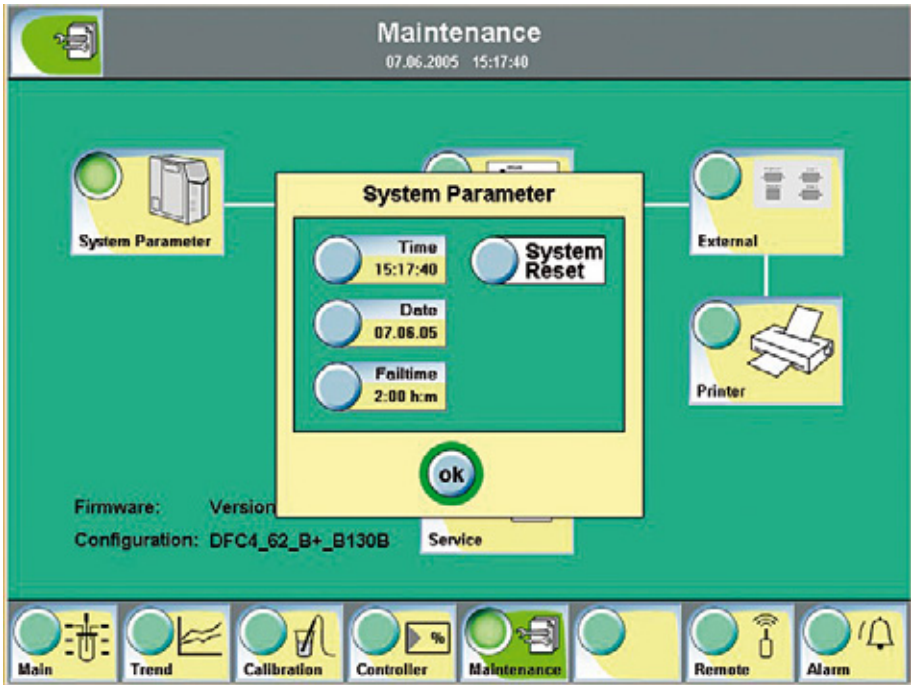


Fig. 13-1: Main function "Maintenance" with submenu "System Parameter"

If voltage is restored after a power outage shorter than this “Failtime”, the system continues all activities as follows:
– Controllers continue to work with the set target value
– Timer and target value profiles continue to be processed

If the power failure lasts longer than the “Failtime”, the system reacts as if the user had turned it off normally, i. e. the system goes into the defined default mode.

The system indicates a power failure by displaying the message “Power Failure” and stating the time and duration of the interruption. After the maximum duration for power interruptions (“Failtime”) has passed, the message “System Power Failure” is displayed, stating the time of the interruption.



Information on configuring the system parameters and system alarm messages are contained in the Section “Maintenance”.

14. Principles of Operation

After powering on the bioreactor supply unit (a notebook or PC for the BIOSTAT® Aplus), the micro DCU System will start up and display the menu "Main". This menu is the starting point for operations [▶ Section "6.3.1 Turning the Control Unit On and Off"].

14.1 Functional Groups and Submenus

All system operating functions are organized into functional groups, the "main functions":

– "Main" ("Overview"):
  Overview of the bioreactor, display of its functional elements with measured values and calculated variables, direct access to important sub-functions and sub-menus.

– "Trend":
  Display of important measured values and calculated variables over time.

– "Calibration":
  Menus for operation of calibration functions for sensors and filling counters.

– "Controllers":
  Menus for configuration and parameterization of the implemented controllers.

– "Maintenance":
  System configuration, system reset, settings for the recorder, printer or communication for remote operation, manual specification of measurement and set values.

– "Remote":
  Switching between operation via the micro DCU system or host computer.

– "Alarms":
  Displays any alarms that have occurred.

The micro DCU system is operated directly on the display by selecting a main function and the associated sub-menus. The functional elements in the work area and the menu buttons in the footer contain touch keys you can activate as follows.

▷ Move the mouse pointer over the "Touch key" and click on it.

14.2 Structure of the Operating Displays

14.2.1 Header

The header of the screen only shows status information, e.g. "Main":

– Displays the active main function in the work area



14.2.2 Work Area

The work area of the screen shows the functional elements and associated variables with their abbreviated designations ("tags"): Depending on the system configuration, these are e.g.:

- Totalizer or pumps with process parameters, e.g. aeration rates or filling amounts
- Actuators, e.g. speed controller, massflow controllers, etc., with working values
- Probes and electrodes, e.g. pH, pO_2, foam, etc. with measured values
- Peripheral devices, e.g. scales / balances, with measured values or working values

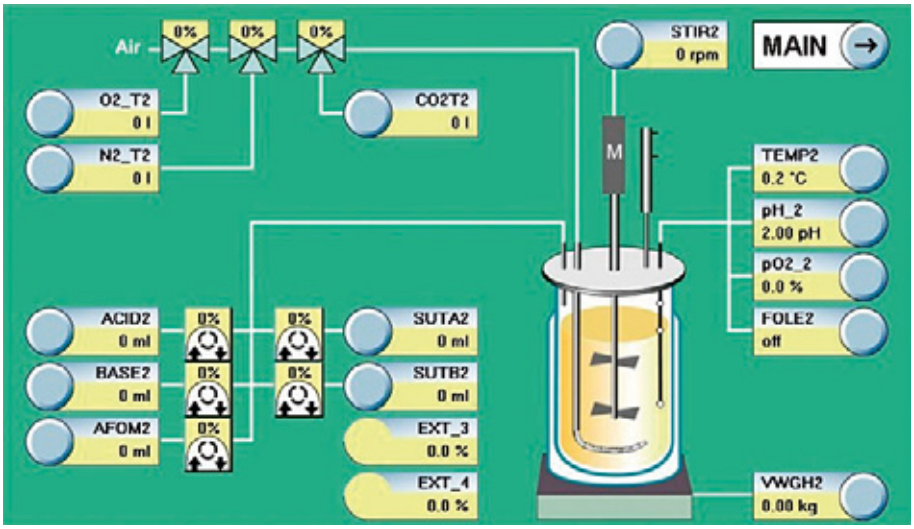
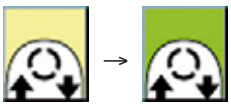
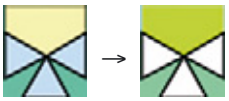


Fig. 14-1: Work area

Icon	Display	Meaning, use
	Function element: ← Blue background ← Yellow background	– Field for short name ("tag") for the function element, e.g. TEMP, STIRR, pH, pO_2, ACID, SUBAT, WEIGH – Field for measured or set values in their physical units – Display [----]: Process parameter or actuator is not allocated and | or is in an "invalid state"
	Round field "[blue]"	Sub-menu or function selectable by touching on the button (except for tables for controller parameterization)
	Round field "[green]"	Display when selecting a sub-menu or function
	← Green background	Measured value collection or output of functional element is active, with measured value or set value as shown
	Round field "[empty]"	
	Round field with arrow "→", "←", "↓", "↑"	Move forward or back in specified menu or to the function
	Pump off → on	Direct access to pump to switch modes

Icon	Display	Meaning, use
	Valve off → on	Direct access to valve to switch modes for the 2-way valve
	Valve off → on	Direct access to valve to switch modes for the 3/2-way valve

The Section [▶ "Main" Display] contains examples for functional elements and sub-menus as well as measured values and working values, which are accessible using the "touch keys".

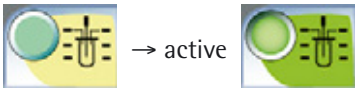
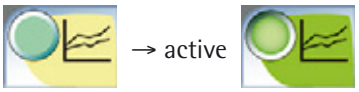
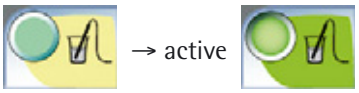
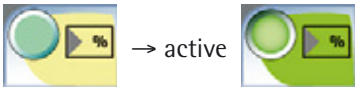
14.2.3 Footer

The screen footer contains the "main function keys". All "main functions" can be selected at any time using the main function keys.
The main function key of the active main function has a green background.

Example: Selecting the main function "Controller" using the main function key:



Overview of Main Functions

Button, symbol	Meaning, use
	Graphic overview of the bioreactor: – Display of components of the current configuration – Overview of measured values and process parameters – Direct access to menus for operating input
	Display of process flow overviews – Process value trends (only display)
	Calibration menus for: – Sensors for pH, pO_2, Redox or turbidity – Totalizer for pumps and | or aeration rates for valves – Scales / balances
	Operating and configuration menus for controllers, for example: – Temperature regulation TEMP – Speed regulation STIRR – pH control and DO control (pO_2) – Pump control AFOAM, LEVEL or SUBS1 … 2 – Aeration rate regulation

The symbol of the main function shown in the work area is also displayed (without a "touch key") in the header.

14.2.4 Direct Access to Submenus from the Main Menu

You can access important functions and settings directly from the "Main" main menus:

- for the numerical input of setpoints, conveying and flow rates etc.
- for the selection of controller modes
- for configuring and | or performing calibration functions

Which functions can be reached from the main menu depends on the configuration. You can view the available functions by pressing the "touch keys".

In the Section "Main" Display, you can find overviews of the sub-menus, which you can reach via direct function keys. Detailed instructions for the associated functions and inputs can be found in the sections "Calibration" and "Controller".

Example for the entry of numerical values: target speed value

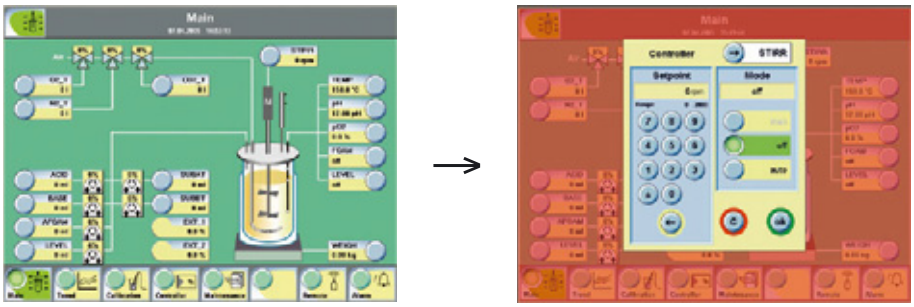
- In the work area of the main menu, press the touch key for "STIRR".
  The sub-menu "Controller" contains a keypad for data input on the left.
- Enter the target value in accordance with the permitted range.
- Confirm the input with "Ok". If you don't want to save the new value, leave the sub-menu by pressing the "C" key.

Example for selecting the controller mode "mode"

- Press the touch key for "STIRR" in the work area of the main menu.
  The sub-menu has keys for selection of the controller mode on the right side.
- By pressing the touch key "Mode: auto" and confirming with "Ok", the function (the controller) is activated. If you do not wish to activate the function (the controller), select "C".

The functional element displays the current working value, i.e. the actual speed value for the speed controller.

Example:
Direct access to target value entry and selection of the controller mode via the functional element "Stirr" in the main menu "Main"

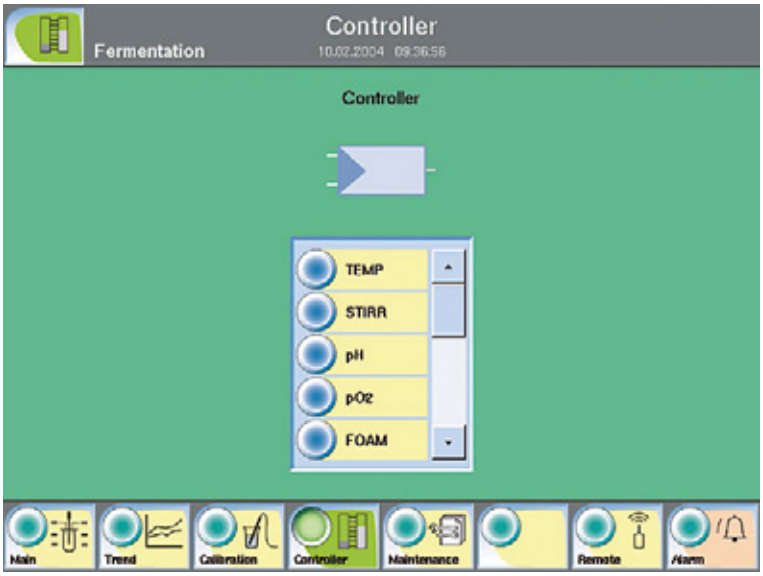


Via the key STIRR in the sub-menu, you can switch to the speed controller operator screen. This corresponds to selection of the main function key "Controller" and switching to the speed controller operator screen, cf. Section "Speed Controller".

14.2.5 Selection Lists

If sub-menus contain lists of elements that cannot be displayed in a window, a scrollbar with a position marker is displayed.

Example:
Access to controller menus after selection of the main function "Controller"



To browse through the list, carry out the following operating steps:
– Press down arrows (↓) and | or up arrows (↑).
– Press and move position marker (blue field within the scrollbar).
– Press the gray surface at the relative position of the element in the list.

15. “Main” Display

15.1 Start Screen “Main”

The start screen “Main” shows a graphic overview of the configuration of the bioreactor with the culture vessel, symbols for components of the aeration segment (e.g. valves), the agitation drive (Motor M), pumps, totalizers, scale(s) / balance(s) and probes with their measurement locations.

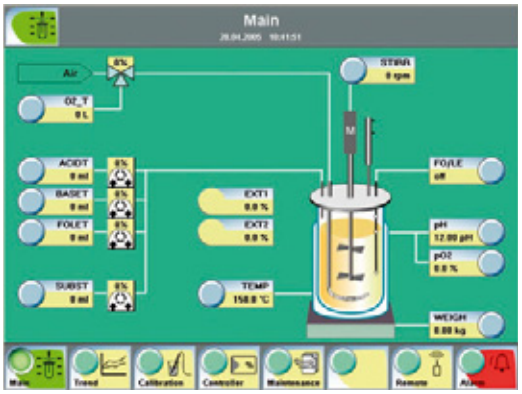
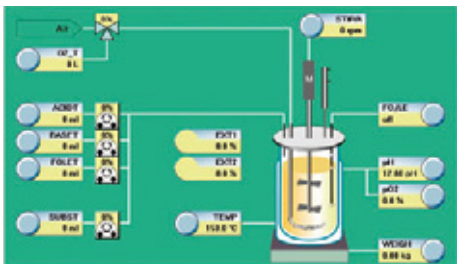


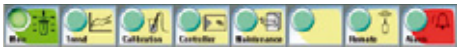
Fig. 15-1: Start screen “Main”, example of “O_2 enrichment” configuration:



Header with status display



Work area
Display of the function elements:
- Gas supply air + O_2_T
- With 3/2-way valve
- Corrective solution supply ACIDT, BASET, FOLET
- Filling pump SUBST
- Speed regulation STIRR
- Measurement locations (electrodes) for TEMP, FOLE, pH, pO_2 and WEIGH



Footer with function keys

* Displayed functional elements, TAGs and parameters depend on the configuration delivered

15.2 Functional Elements – Operator Screen "Main"

Functional element	Displayed value(s)	Touch key function
STIRR 	Stirrer speed in [rpm]	Direct access to sub-menu for: – Entry of the target speed value – Selection of the operating mode for the speed controller Option to switch to the controller menu
TEMP 	Temperature measurement value Culture vessel [TEMP]	Direct access to sub-menu for: – Entry of the target temperature value – Selection of the operating mode for the TEMP controller Option to switch to the controller menu
pH 	Measured values in [pH]	Direct access to sub-menu for: – Entry of the target pH value – Selection of the operating mode for the pH controller Option to switch to the controller menu
pO_2 	Measured values in [% pO_2]	Direct access to sub-menu for: – Entry of the target pO_2 – Selection of the operating mode for the DO controller (pO_2) Option to switch to the controller menu
FO/LE 	Switching state of the controller [on | off]	Access to sub-menu to select the mode Option to switch to the controller menu
WEIGH 	Weight in [kg]	Access to sub-menu to enter the target controller value and select the mode Option to switch to the controller menu
TURB	Turbidity in [AU]	Access to submenu to calibrate the probe
Valve 	Outlet for valve in [%]	Selecting the mode of the valve: – off: symbol has a yellow background; on: has a green background
Air_1, O2_T, N2_T, CO2_T2	Supply of air, O_2, N_2 and CO_2 in [l/min]	Access to totalizer calibration function and reset function for process values
ACIDT 	Pump filling level in [ml]	Access to totalizer calibration function and reset function for the process value
BASET 	Pump filling level in [ml]	Access to totalizer calibration function and reset function for the process value
FOLET 	Pump filling level in [ml]	Access to totalizer calibration function and reset function for the process value
SUBST 	Pump filling level in [ml]	Access to totalizer calibration function and reset function for the process value
Pump 	Outlet for pump in [%]	Selecting the mode of the pump: – off: symbol has a yellow background; on: has a green background

15.3 Direct Function Keys with Accessible Submenus

In the following figures, the background is red in order to particularly highlight the "pop-up" windows.
The display background remains green on the screen.



Fig. 15-2: "O2 enrichment" configuration

16. Main Function "Trend" Display

16.1 Intended Use

The trend display serves to graphically display a time curve of important process parameters. This overview enables you, for example, to get a quick impression as to whether the process is running as expected or whether irregularities or disruptions are present.
The trend display works retroactively from the point in time when recording was activated.

Trend readouts are not saved. Use a host system (e.g. MFCS) to log these data and permanently document the process value time profiles.



Fig. 16-1: Variation of process values over time

- Up to 6 out of 24 process values can be selected
- Variation over time over 1, 12 or 72 h
- Display range 0 ... 100 % or 20 %,
- At a display range of 20 %, the base value is variable in increments of 10 %

16.2 Configuration

Making changes to a configured process value



- Select the main function key "Trend".
- Press | click the touch key of the process value to be modified in the header area. The sub-menu "Channel Parameters" will appear.
- Press the touch key "PV" to assign another process value to a channel.



- In the sub-menu "Select Process Value", select the process value from the list of those available in the configuration.
- If the desired process value is not in the visible area of the list, browse through the list by pressing the arrow keys or the position marker.
- Pressing the touch key in the list will select the process value.

Changing the process value display area



- Select the touch key "Range" in the sub-menu "Channel Parameters".
- Select the desired display range from the list of display ranges "Range" for the process values in the sub-menu "Select Range".
- Confirm selection for "PV" and "Range" with "ok" in the menu "Channel Parameters".
- If the new process value and | or display range should be ignored, exit the menu "Channel Parameters" with "C".

Defining a new time range



- Selecting a new time range deletes the current recorded data.
- Activate the main function "Trend".
- Press the touch key "Settings" in the header at the top right.
- Select time range.
- Confirm with "ok" or press "C" to ignore the change.

17. Main Function "Calibration"

17.1 Overview Menu

The main function "Calibration" combines the calibration functions for electrodes, filling counters for pumps and valves, as well as for scale(s) / balance(s) which are included in a system configuration. When the main function key "Calibration" is activated, an overview menu initially appears where you can access individual calibration functions. This menu indicates or contains:

- "Sensors": Calibration of the probes
  - "pH": pH electrode
  - "DO": DO sensor (pO_2)
  - "TURB": Turbidity electrode*)
  - "REDOX": Redox electrode*)

- "Totalizer": Determination of the feed volume of the correction medium pumps or valves for
  - "ACID": Acid pump
  - "BASE": Alkaline pump
  - "AFOAM": Antifoaming agent pump
  - "LEVEL": Level-control pump
  - "SUBAT/BT": Substrate pump SUBSA or SUBSB, etc.
  - "O2_T", "N2_T" *), "CO2_T" *): Valves for the corresponding gas feeds

- "Balance": Setting functions for scales / balances, such as zero taring and tare correction
  - "WEIGH" (or "VWGHT"): Scale / balance for weighing the culture vessel

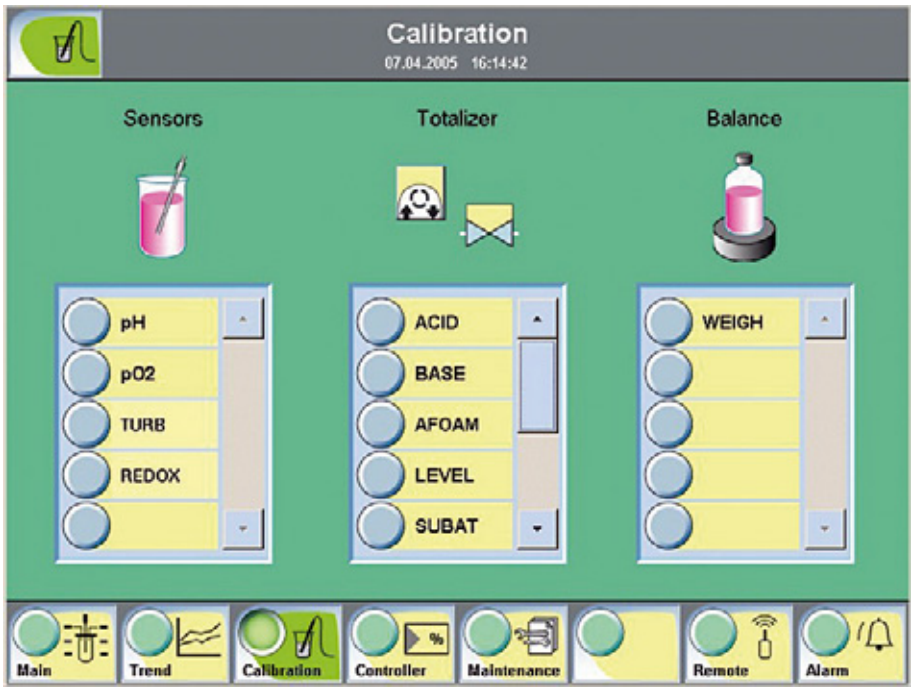


Fig. 17-1: Overview menu "Calibration"

17.2 General Operation

Some of the calibration functions are accessible from the "Main" menu [▶ Section "'Main" Function", via sub-menus selectable with direct function keys.]

To access the "Calibration" overview menu, use the main function button "Calibration". That is where you select the calibration function to be performed. You can select the main function at any time during the process to make entries, e.g. for re-calibration of the pH electrode or to change parameters for totalizers.

All inputs for a calibration function should be entered in logical sequence via sub-menus, which are either displayed automatically or are activated via the operating mode selection "Mode".

After activation of the first calibration step, the display of the function key "Mode" switches from "meas" to "calib", and back to "meas" after the last calibration step:

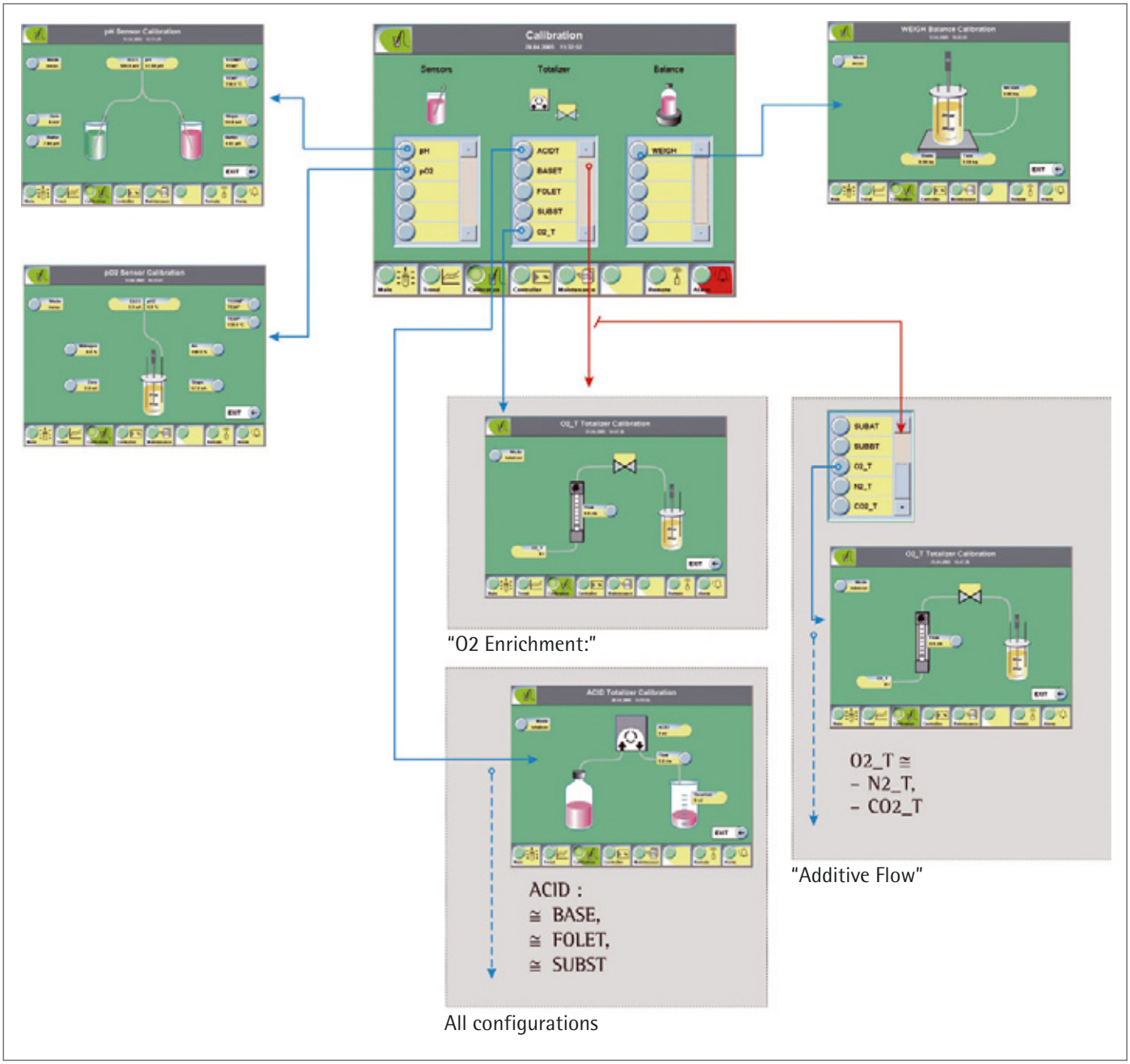


Individual calibration functions, such as the tare detection of the weighing system or the calibration of the Redox or turbidity electrode include only the current measured values as reference parameters for further measurements. The function key "Mode" continuously displays .

All calibration parameters are retained in memory when the basic device of the bioreactor or the control unit (a laptop, in case of BIOSTAT® Aplus) is switched off.

17.3 Selecting Calibration Functions

Main Menus and Submenus



17.4 pH Calibration

Uses, Restrictions
The pH calibration is available in all system configurations.

17.4.1 General Notes

The calibration of the pH electrode is a "2-point calibration". You calibrate the pH electrode before installation in the culture vessel by measuring the pH value for the "zero point" ("zero") and the ("slope") in the corresponding buffer solutions.



Danger of chemical burns due to the calibration buffers!
Adopt appropriate precautions for the handling of the buffers.
Wear safety gloves



Use only buffer solutions of the electrode manufacturers for calibration, as are supplied along with the pH electrodes [▶ Ordering information].
Detailed information on preparation of the pH electrodes and on handling procedures for calibration can be found in the documentation from the electrode manufacturer.
Instructions on how to install the electrode in the culture vessel are available in the documentation for the bioreactor and | or the culture vessels, for example, in the " UniVessel® Operating Manual".

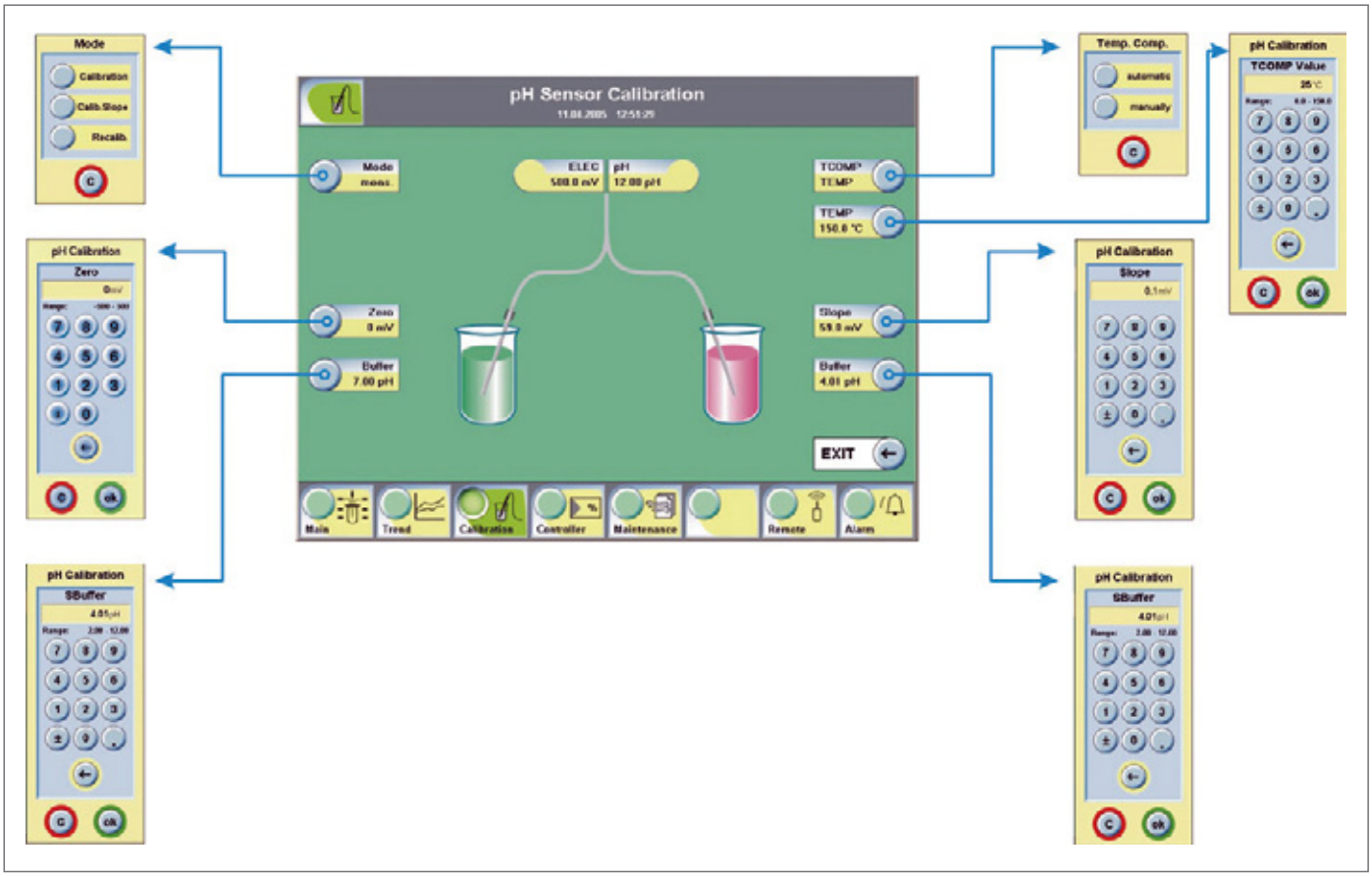
During the pH measurement process the system calculates the current pH value according to the "Nernst" equation [▶ Specialist literature for pH measurement] from the electrode potential, while taking zero point, slope and temperature of the medium into consideration:

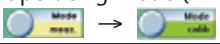
- Enter the reference temperature (current temperature of the buffer during the measurement) to calibrate the pH electrode manually.
- During the pH measurement the temperature compensation in the cultural vessel is set automatically via the reading of the measured value of the reactor temperature.

The zero point for pH electrodes can shift as a result of sterilization (e.g. in case the culture medium reacts with the electrolyte and | or diaphragm). This is why the pH electrode can be re-calibrated. To do this, you should determine the pH value in a sample from the process and enter this value in the calibration menu. The calibration routine calculates the resulting zero offset from pH value measured online and the externally determined pH value and displays the corrected process value.

In addition to the calculated pH value, the calibration menu of the pH electrode also displays the measured value of the electrode potential and the parameter "Zero point (deviation)" and the "slope". The functionality of the pH electrode can be easily monitored by regular monitoring of these parameters and checking them for plausibility

17.4.2 Operating Display and Input Window for "pH Sensor Calibration"



Field	Value	Function, display, entry required
Mode	meas | calib	Operating mode ("Mode") for pH measurement 
ELEC	mV	Current measurement chain voltage (raw signal)
pH	pH	Current pH measured value
TCOMP	degC	Type of temperature compensation; switch between - Automatic compensation for pH measurement in process – manual compensation for calibrating the pH electrode
TEMP	°C	Reference temperature, access to sub-menu "TCOMP value" for input of the temperature for manual temperature compensation
Zero	mV	Zero point offset, measurement chain voltage of the zero point buffer
Slope	Mv	Slope, measurement chain value of the slope buffer
Buffer	pH	Input of the pH values for - Zero point buffer "Zero" (pH 7.0) and | or – Slope buffer "Slope" (pH 4.0 or pH 9.0, depending upon the measurement range) The exact pH values of the buffer are temperature-dependent. Please observe the information on the buffer bottles.

17.4.3 Calibration Sequence



- Press TCOMP and select manual temperature compensation.
- Fill the zero point buffer pH 7.0 in a measuring beaker.
- Fill the buffer solution with pH 4.0 or pH 9.0 (depending on the measuring range in the process) in another beaker.
- Measure the temperature of the buffer.



- Press "TEMP".
- Enter the measured temperature as a reference value for the calibration and confirm with "ok".
- Place the pH electrode in the measuring beaker with the zero point buffer.

If you wish to calibrate the slope, place the electrode in the measuring beaker with the slope point buffer.



- Press "Mode" to select the calibration step:
  - Calibration: complete routine
  - Calib slope: Slope calibration
  - Recalib zero: Recalibration

If you select "Calib. slope", you can start with the slope calibration directly.

- Use "Calibration" to start the zero point calibration. The status display "Mode" switches to "calib".



- In the "ZBuffer" window, enter the pH value of the buffer for the reference temperature [▶ information on the buffer bottle].
- The calibration step starts when "ok" is entered. A clock icon appears and displays the progress of the measurement [▶ next image].



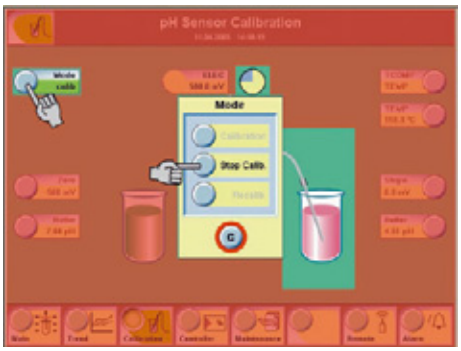
– The calibration step terminates automatically if the electrode potential ELEC is stable (after a maximum of approx. 1 min.). To terminate the step prematurely, press “Mode” and “Stop Calibration”. The window “SBuffer” appears: see below.
– Remove pH electrode from the zero point buffer, rinse it with distilled water and place it in the slope buffer pH 4.0 or pH 9.0.



– Enter the pH value of the slope buffer corresponding to the measurement range (pH 4.0x oder pH 9.0x) in the window “SBuffer”.

For information as to the precise pH value of the buffer at the reference temperature, refer to the buffer bottle.

– Confirm with “ok”. The clock icon shows the progress of the measurement.
– The calibration step terminates automatically if the electrode potential ELEC is stable for a defined time period or after about 1 minute.



– To terminate the step prematurely, press “Mode” and “Stop Calibration”.
– After the calibration has run its course fully, the menu “Calibration - pH Sensor” is displayed once again.
– Switch TCOMP back to “Automatic”.
– Close the menu with “Exit”.

After the calibration, you can mount the pH electrode in the culture vessel and prepare it for sterilization and the process.

The measured value displayed during the calibration is not valid. The field for the measured value display shows the correct value only after the calibration process.

The field “Zero” displays the measurement chain voltage for the zero buffer, and the field “Slope” the electrode potential for the slope buffer.

The pH electrode must be maintained and replaced if necessary, if the calibration or the comparison of the externally measured pH value with the current measured value indicates a possible malfunction, for example, if during calibration:
– The zero point offset falls outside of the range - 30 ... +30 mV or
– The slope is less than 56 mV/pH.

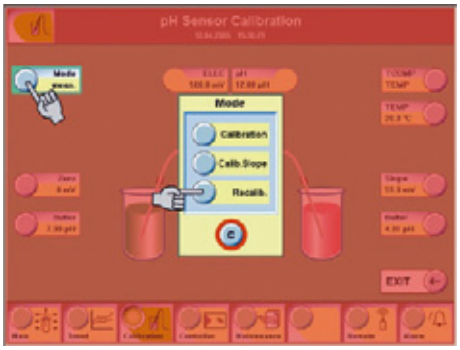
User Maintenance Instructions:
Follow the documentation of the electrode manufacturer.

17.4.4 Recalibration

After the sterilization, you can adjust the calibration to the modified measurement properties of the pH electrode. For the external pH measurement for re-calibration of the pH electrode please note the following:

– Use a fresh sample. Make sure that the pH value of the sample cannot be modified due to the removal of the sample, the container or during storage.
– Use a precise and carefully calibrated external pH measurement device.

If the current pH measured value deviates significantly from the pH value of the sample, check the external measurement process before you modify the calibration parameters. Entering incorrect values for re-calibration influences the pH adjustment. Correction media could be incorrectly dosed and thus interfere with the process.





– Measure the pH value of the sample with a laboratory pH measurement device.
– Select the step "Recalib" in the calibration menu.
– Enter the externally measured pH value in the window "pH-Re-Calibration".

The system determines the zero point offset and corrects the pH value.

17.4.5 Special Notes

Reference parameters and limits of the calibration routine
The calibration of the pH electrode takes into account the following reference parameters and limits:

– Stable measured value of the electrode within 0.2% of the measurement range for 60 seconds

If the limits are not observed, the system returns the error message "**ALARM**, Calibr. out of range". The system continues to use the zero point determined and the slope for the pH measurement, however the readings should be checked.

Handling of the pH electrodes
If you place the pH electrode from the zero point buffer in the slope buffer, drying of the diaphragm with paper towels is not permitted, as this can affect the slope calibration. Rinse the electrode with distilled water only.

The service life of the pH electrode depends on the sterilization cycles and operating conditions in the process. Follow the manufacturer's instructions for the pH electrode.

The effects of heat and reactions with constituents of the medium impair the metrological properties of the pH electrode.

17.5 DO Calibration (pO_2)

Uses, Restrictions
The DO calibration (pO_2) is available in all system configurations.

17.5.1 General Notes

The calibration of the DO sensor (pO_2) is based on a 2-point calibration of the parameter "Zero Current" and "Slope". The reference parameter for the zero current is the oxygen-free culture medium. The reference parameter for the slope is the medium saturated with oxygen from the feed of air gas mixture.

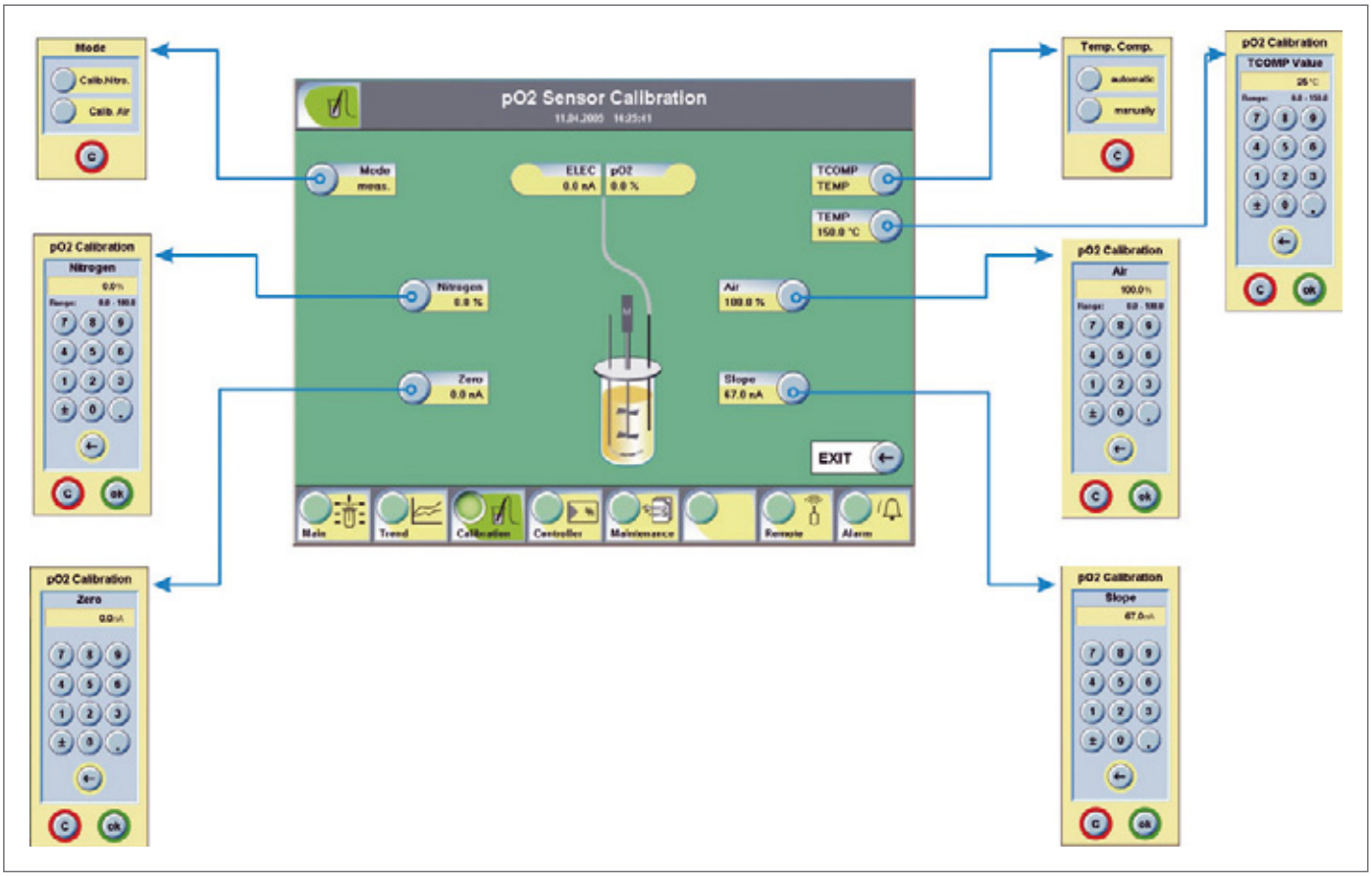
When the bioreactor has an autoclaved culture vessel (BIOSTAT® Aplus), the DO sensor (pO_2) is calibrated after sterilization, prior to the start of the process.

Calibration after the sterilization compensates for changes of the measuring characteristics of the electrode due to the effects of heat on the membrane or reactions of the electrolyte with constituents of the medium.

Basic Aspects:
- Please calibrate the zero point before you feed air or gases containing oxygen into the culture vessel. Heating during sterilization will degas the culture medium to such an extent that the any residual oxygen will still be within the accuracy range.
  Alternatively, prior to the inoculation, you can feed nitrogen (purity >99.8%) into the medium, so that the dissolved oxygen is displaced. The zero point may then be calibrated.
- Measure the slope of the electrode ("Air") in the saturated condition, after aeration of the medium with air (and | or a technical gas mixture) under the process's operating conditions.
- The system calculates the pO_2 taking into consideration the zero point current, the slope and the temperature [▶ Specialist literature "Principles of DO (pO_2) Measurement"].
- To calibrate the DO sensor (pO_2) you can enter the reference temperature (temperature during the measurement) manually or work with automatic temperature compensation. In the latter case, the system uses the current temperature reading in the culture vessel.
- Always use the automatic temperature compensation via the measured value of the reactor temperature for pO_2 measurements.

In addition to the "pO_2 saturation" the operator screen for DO calibration (pO_2) displays the current electrode current, the "Zero Current" and the "Slope". This allows easy regulation of the electrode's functions.

17.5.2 Operating Display and Input Window for "DO Sensor Calibration (pO_2)"



Field	Value	Function, display, entry required
Mode	meas | calib	Switch the operating mode ("Mode") during the DO calibration (pO_2)
ELEC	nA	Display of the electrode current (raw signal)
pO_2	%	pO_2
TCOMP	degC	Temperature compensation, access the window to switch between automatic and manual compensation
TEMP	°C	Reference temperature, access to sub-menu "TCOMP value" for input of the temperature for manual temperature compensation
Nitrogen	%	Zero point pO_2
Zero	nA	Zero point current
Air	%	pO_2 at oxygen saturation (calibration point for slope)
Slope	Mv	Electrode current in case of oxygen saturation
Buffer	pH	Input of the pH values for - Zero point buffer "Zero" (pH 7.0) and | or – Slope buffer "Slope" (pH 4.0 or pH 9.0, depending upon the measurement range) The exact pH values of the buffer are temperature-dependent. Please observe the information on the buffer bottles.

17.5.3 Calibration Sequence

Before the calibration, and if the DO sensor (pO_2) was not connected to the amplifier for more than 10 minutes, it must be polarized. Polarization can take up to 2 hours (rule of thumb: Double the time of the interval during which the electrode was not connected to the active amplifier). Connect the DO sensor (pO_2) to the basic unit or use a polarization module from the electrode manufacturer.

Zero Point Calibration



- Measure the zero current before aerating the medium with air (gas containing oxygen) and confirm it as the zero point.
- Or flush with nitrogen to displace the dissolved oxygen.



- Should the calibration be performed using the temperature measured in the vessel, leave the setting TCOMP on "TEMP".
- For manual temperature compensation, select TCOMP and enable "manually" in the window "Temp. Comp".
- For TEMP, enter the temperature to which the calibration refers.



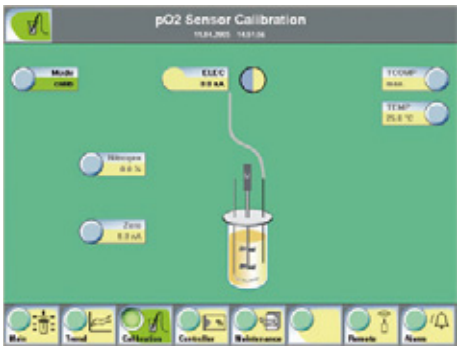
- Start the calibration with "Mode" and the selection of the calibration step.
  - Calib nitro: complete routine
  - Calib air: only slope calibration

Start the zero point calibration with "Calib. Nitro".

The display "Mode" switches over to "Calib". All functional elements other than "Nitrogen" are hidden [▶ figure below].



– Confirm the value "0.0 %" for nitrogen. The system uses the current measured by the DO sensor (pO_2) as a reference parameter for the zero point.
– Pressing "ok" starts the calibration step.



▷ The clock icon next to "ELEC" shows the progress of the measurement. The calibration step terminates automatically if the electrode potential ELEC is stable for a defined time period or after about 1 minute.



– To terminate the step prematurely (in case of a stable measured value display in the range of 0.0 nA) you can press "Mode" → "Stop Calib.".
▷ The window for calibration of the slope "Air" pops up.



– If you want to cancel the calibration and perform the slope calibration later, if the process conditions required for the purpose are available in the reactor, close the window "Air" with "C" and exit the calibration menu with "Exit".

Slope Calibration

In case of separate zero point and slope calibration, restart the DO calibration (pO_2). If you calibrate the slope directly after previous zero point calibration [⚠ previous section] the window "DO Calibration Air" continues to remain visible.

– Set the rotation speed for the process in case of culture vessels with an agitator drive.
– Flush the medium with air or the gas mixture provided for the oxygen supply up to point of saturation with oxygen. You can recognize the saturation point by the fact that pO_2 does not increase any longer, but varies slightly around a constant value.

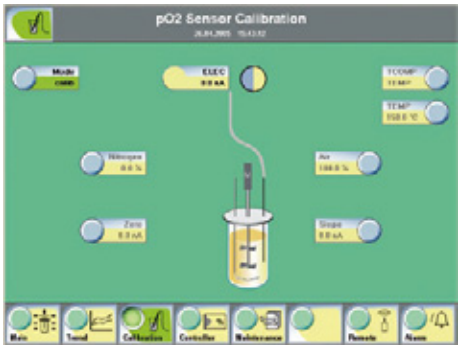


You can set the maximum flushing or a flushing rate relevant to your process.
In case of processing in a medium, the measured pO_2 can even rise to above 100%.
– For the purpose of separate calibration of the slope select "Mode: Calib. Air", in order to begin directly with the slope calibration.



– To use the pO_2 measured by the electrode as a reference value, enter "100.0 %" for "air".

In order to use a different reference parameter, enter under "AIR" the value which the calibration refers to.
– Confirming with "ok" starts the calibration step.



The clock icon next to "Elec" shows the progress of the measurement.
▷ The calibration step terminates if the electrode current ELEC is stable for a defined time period, or after about 1 minute.



– In order to stop the step prematurely (in case of a stable measured value display) press "Mode: Stop Calib.".
▷ The menu "Calibration DO Sensor pO_2" is once again displayed in the operating mode "Meas".

– In case of manual temperature compensation switch this back to "Automatic".
– You can exit the calibration menu via "Exit".

17.5.4 Special Notes



The measured value displayed during the calibration is not valid. The field for the measured value display shows the correct value only after the calibration.

Monitoring of the DO sensor (pO_2) after confirming the values for "Nitrogen" and "AIR" with "ok" takes into account the following reference parameters and limits:
- Stable measured value of the electrode within 0.2% of the measurement range for 60 seconds
- Electrode current for the zero point within the limits: 0 … +10 nA
- Electrode slope within the limits 25 … 200 nA

If these limits are not observed, the system returns the error message "**ALARM**, Calibr. out of range". The system still uses the zero point and slope determined for the measurement. Clarify whether you can continue the process. After later removal of the DO sensor (pO_2), you must perform maintenance.

As a result of chemical and thermal stress the DO sensor (pO_2) has only a limited service life. Check the electrode regularly and perform maintenance, in particular:
- If the membrane is visibly damaged or contaminated,
- The calibration described above fails,
- In case of an expected 0% pO_2, a zero current outside of the limits mentioned above is observed.
- The response time of the electrode is slow.

The maintenance of the DO sensor (pO_2) is limited to the cleaning of the anode, replacement of the membrane module and replacement of the electrolyte after approx. 5 sterilization cycles or use of over 6 weeks approx. Media with ingredients which penetrate the membrane can contaminate the electrolyte to such an extent that more frequent replacement becomes necessary.



For maintenance instructions, information on recommended maintenance cycles and the service life please refer to the manufacturer's documentation supplied along with the electrode.

17.6 Totalizer for Pumps and Proportioning Valves

Uses, Restrictions
The system provides calibration functions for filling counters of the following pumps and valves:
- Acid pump "ACID"
- Alkaline pump "BASE"
- Antifoaming agent pump ("AFOAM")
- Pump level control "LEVEL", in operating modes "Feed" or "Harvest"
- Substrate pump 1 "SUBAT"

On the bioreactor BIOSTAT® Aplus, the antifoaming control "AFOM" and the level control "LEVL" work on the same pump. The feed rates are therefore always calibrated for their totalizer function "AFOAM", regardless of the function for which you actually use the pumps.

The calibration functions correspond to each other for all pumps and valves.
The following information for calibration of the pumps "ACID" and | or "AFOAM" therefore apply to all pumps, and the information for valves of the oxygen feed "O2_T" for all other proportioning valves.

17.6.1 General Notes

During the process, the totalizers determine the dispensing volumes for the media and the total flow of the gases from the specific feed rates of the pumps and valves, and the total of the filling times.

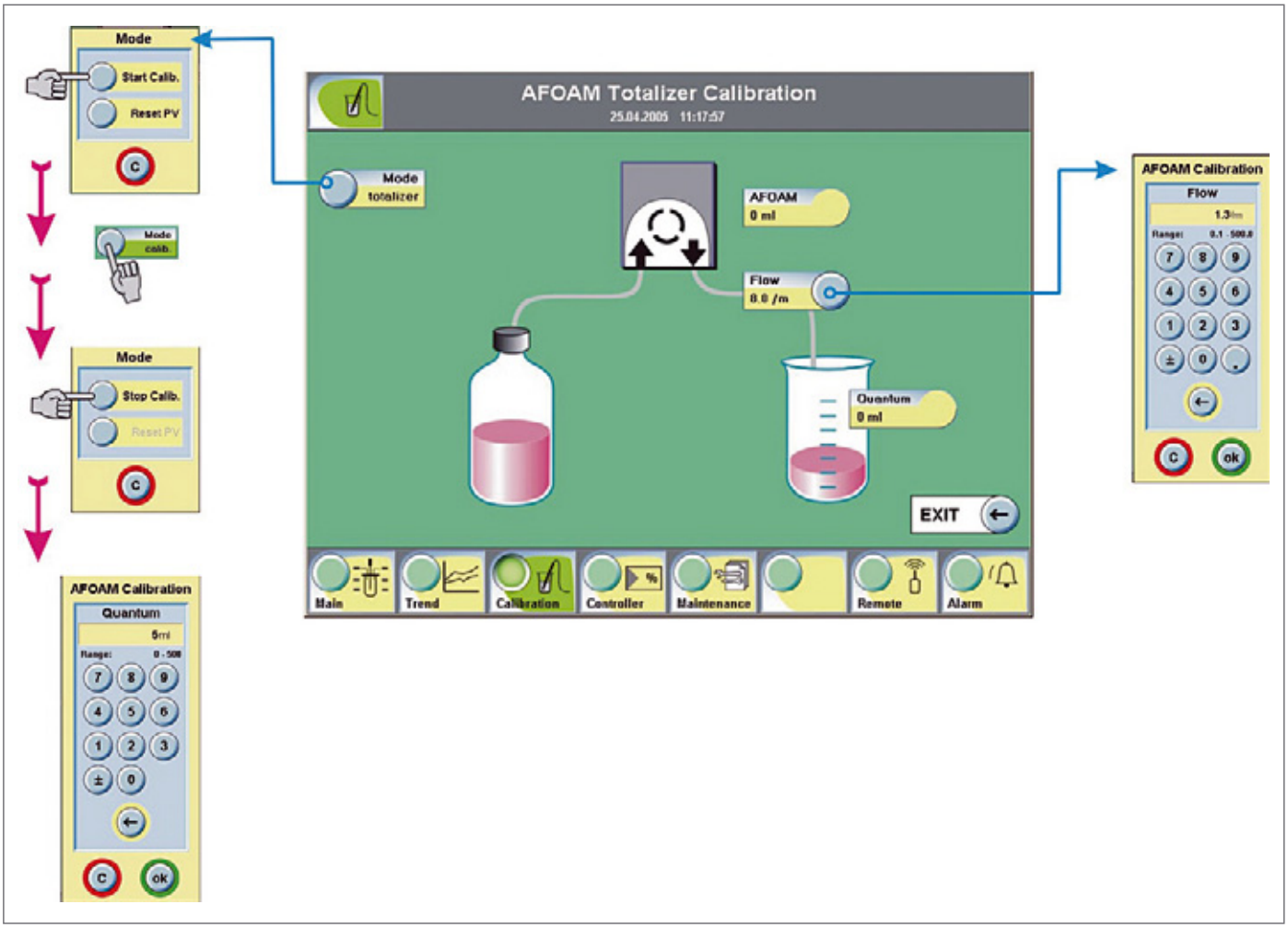
If you do not know the specific feed rates of the pumps, you can calibrate these. To do this, feed any medium into a measuring beaker via the calibration function, and determine the required volume. Enter this value in the calibration menu and the system will calculate the specific flow rate from the run time and the required volume.

You can enter specific feed rates directly into the calibration menu, if these are known.

The totalizers of the valves use the gas flow "Flow" set on the floating flow meter and entered in the calibration menu, and the total of the opening times of the valves.

You can at any time reset all the filling counters to zero via the calibration menu.

17.6.2 Operating Display, Sub-functions and Input Window

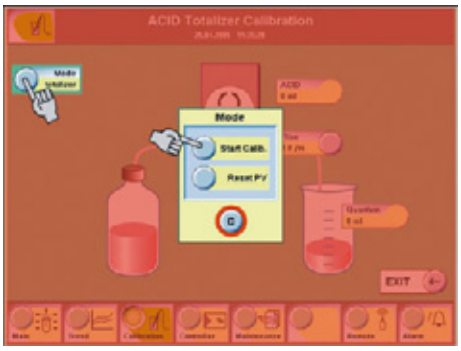


Field	Value	Function, display, entry required
Mode	Totalizer | calib	Operating mode of the totalizer
Start calib.		Start of calibration
Quantum	ml	Input window for the quantity required for calibration
Reset PV		Reset the filling counter to zero
AFOAM	ml	Required amount of liquid in the process – Corresponding display for Acid, Base, Level, Subat, etc.
Flow	/m	Calculated flow rate and | or specific pump feed rate (flow rate of the metering valve), if known

17.6.3 Calibrating the Totalizer Function for a Pump

Always use the identical hoses for calibration and for feeding of the media.

– In order to measure the feed volume, place the hose in the pump head, one end of the hose into a container of water and the other into a measuring beaker.
– In order to compensate for the dead volume of the hose, activate the pump manually. Keep filling in water until the hose is completely filled. The following is an example of "ACID":
– Select the calibration menu via the main function "Calibration " - "Totalizer" - ACID, etc.
– Select "Mode: Totalizer" and in the "Mode" window, switch over to "Start Calib.".





▷ The display "Mode" changes to "calib". The pump feeds water into the beaker.



Stop the feed by selecting "Mode" and "Stop Calib.".



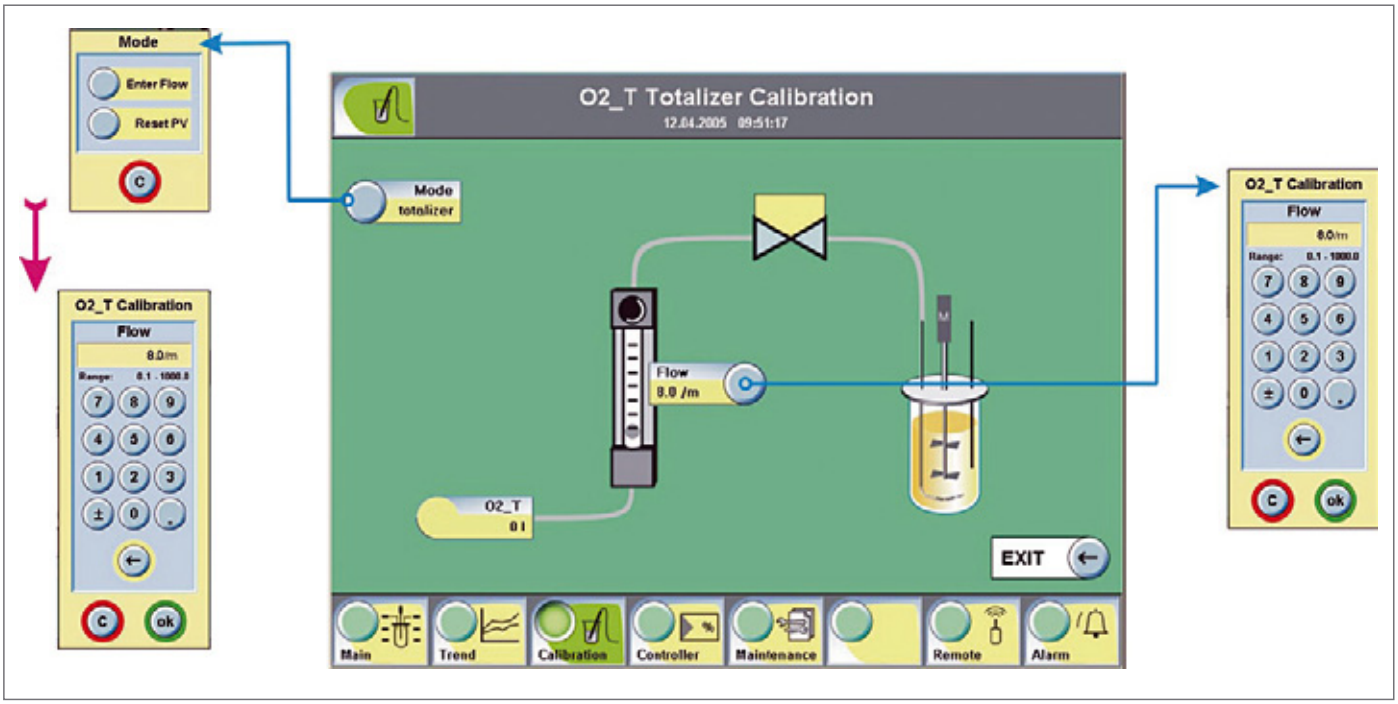
– Determine the required volume and enter the value in the window "Quantum".
▷ The system calculates the flow rate from the pump run time and the measured volume, and displays it in the field "Flow".

– If the flow rate is known, you can enter it directly in the field "Flow".

If you want to reset the current process value only, select the sub-menu "ACID Calibration" there, select "Reset PV".

The filling counter is automatically activated after the calibration routine is completed and | or switching on the associated controller. It calculates the feed volume from the feed rates determined by means of calibrating or the feed rates directly entered, and the (totaled) filling times.

17.6.4 Operating Display and Input Window "O2_T Totalizer Calibration"



Field	Value	Function, display, entry required
Mode	Totalizer | calib	Operating mode of the totalizer
Enter Flow	/m	Entry of the flow rate for the floating flow meter which should be the reference parameter for the calculation of the gas feed.
Reset PV		Reset the filling counter to zero
O2_T	l	Calculated gas flow – Corresponding display for N2_T, CO2_T
Flow	/m	Direct input of the current flow rate, as set on the floating flow meter – After confirming with "ok" the filling counter calculates the flow of gas with the new reference parameter

Calibrating the Totalizer Function for a Valve
Select "Mode - Enter Flow" or "Flow" and enter the flow rate which you have set on the floating flow rate meter into the appropriate window.

Special Notes
In case of changes to the flow rate at each floating flow meter, you must recalibrate the totalizer. Otherwise, the system cannot calculate the correct volumes of gas from the opening times of the metering valve.

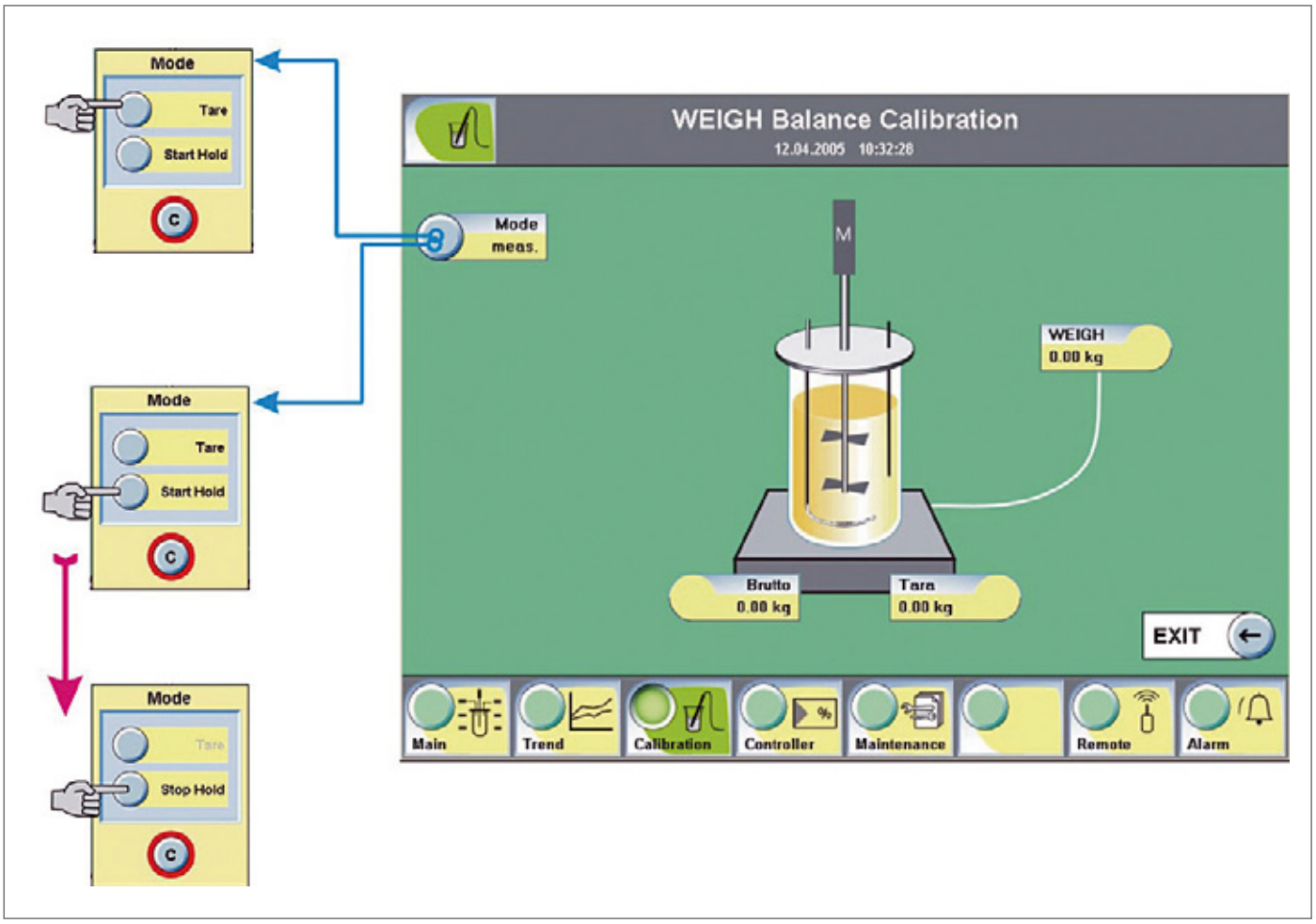
For continuous measurement and recording of the feeds of air and | or of the gases in case of variable through-flow rates, you require the equipment of the air | gas supply lines with with flow controllers [▶ optional equipment, on request].

17.7 Calibrating Scales / Balances

Uses, Restrictions
The calibration function is available in the configuration of the BIOSTAT® Aplus.

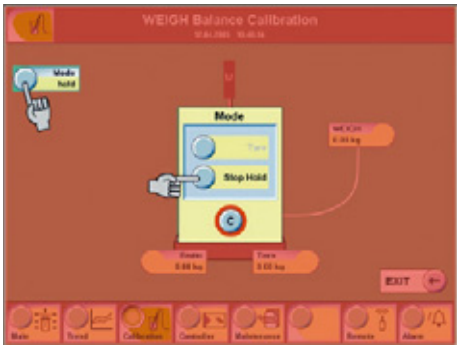
The function implemented in the micro DCU system is limited to the recording of the tare weight and fresh taring in case of modifications to the culture vessels after retrofitting. The basic calibration is performed on the scale / balance with the implemented calibration function. Please follow the manufacturer's documentation supplied along with the scale / balance.

17.7.1 Operating Display and Input Window "WEIGH Balance Calibration"



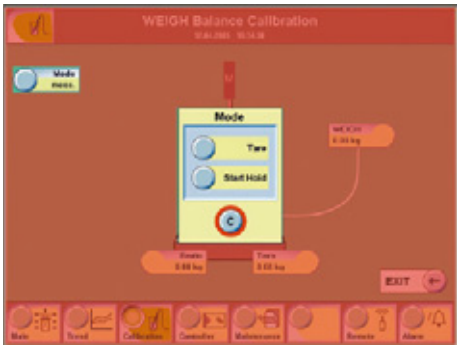
Field	Value	Function, display, entry required
Mode	meas | hold	Weight Measurement Operating Mode
Tare		Start the taring process
Start Hold		Start the "Hold" function: – e.g. for retrofitting and refilling of vessels, which are located on the scale / balance with the culture vessel
Stop Hold		Exit the "Hold" function
WEIGH	kg	Net weight (WEIGH = Gross - Tare)
Gross	kg	Gross weight
Tare	kg	Tare weight: – Empty weight with all equipment (if the total volume of the medium in the reactor is displayed in case of "WEIGH" and should be the basis of weight control) – Weight of the media volume in the reactor, if modifications to the media volume should be the basis of weight control

17.7.2 Taring the Weighing System



– For the "Zero" taring of the vessel, first press the "Mode" key, and then press "Tare".

▷ The system saves the current measured weight as a reference value.



– In case of retrofitting onto the culture vessel or in case of correction media vessels which are located on the weighing equipment, activate the "Hold" function with "Start Hold".

▷ The display "Mode" switches to "hold".

– After retrofitting you must deactivate the "Hold" operating mode in order to activate weight measurement and control. To do this, press "Mode: Stop hold".

▷ The display "Mode" switches back to "meas".

Special Notes

For scales / balances featuring an integrated calibration function that also includes a taring function, you must either turn this function off, or use this function only. Read the documentation on the weighing equipment.

18. Main Function “Control Loops”

18.1 Functional Principle and Equipment

18.1.1 Overview of Controllers

The controllers implemented in the system depend on the bioreactor and the customer’s desired configuration [▶ Chapter “12 Product Information”]. A selection of the following controllers is possible:

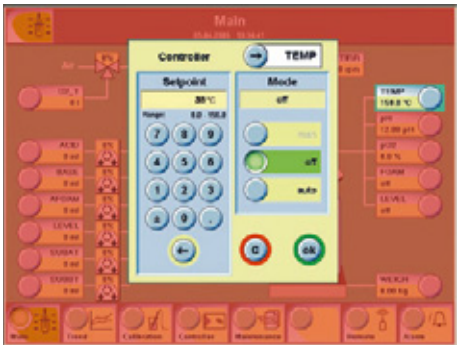
Controllers (control loops)	Controller type, actuators, functionality
TEMP temperature controller	PID cascade controller with pulse-width modulated outputs – runs with the reactor temperature as a reference value – with structural toggle of P in the starting condition to PID – TEMP controls the heating and cooling valve during “split range” operation – runs with the heating circuit temperature as a reference value, when the guide controller is turned off (separate control cascade)
Speed controllers	Setpoint generators for motor control
pH controller	– PID controllers with pulse-width modulated outputs – Controls acid pump (or CO_2 valve in configuration “Additive Flow”) and alkaline pump during “split range” operation
DO controller (pO_2)	PID cascade controller for controlling 1-2 slave controllers: – Speed controller – DO – O_2 enrichment controller and | or pO_2 additive flow controller – Controller for substrate feed SUBS1
Antifoam controller	Impulse-pause controller for antifoam
Level controller	Two-point controller for harvest or filling pump (“Harvest”, “Feed”)
Substrate controller	PID controllers, setpoint generators for an external filling pump
Weight controller	PID controller with pulse-width modulated output for harvesting pump



A system configuration takes into consideration the adequate operational parameters and necessary limits of the controller for the respective bioreactor [▶ Configuration Documentation]. Every controller is parameterized to provide stable control. If required for the process, but also for the control task, the controller structure (PID) and | or individual control parameters can be adjusted.

18.1.2 Accessing the Controller Operator Screens

For all controllers that require quick access, operating menus for setpoint entry "Setpoint" and selection of the controller operating mode "Mode" can be accessed directly from the main menu:



Example

Direct access from the "MAIN" menu to the sub-menu of the temperature controller:

- After pressing "TEMP" in the "MAIN" menu, a window appears where you can configure the setpoint and select the operating mode
- Pressing TEMP opens the operator screen of the temperature controller [▶ Section "18.4 Temperature Controller "TEMP""]

An overview of controller operator screens and sub-functions that can be accessed in this way can be found in the figures in Chapter 15 ""Main"-Display".



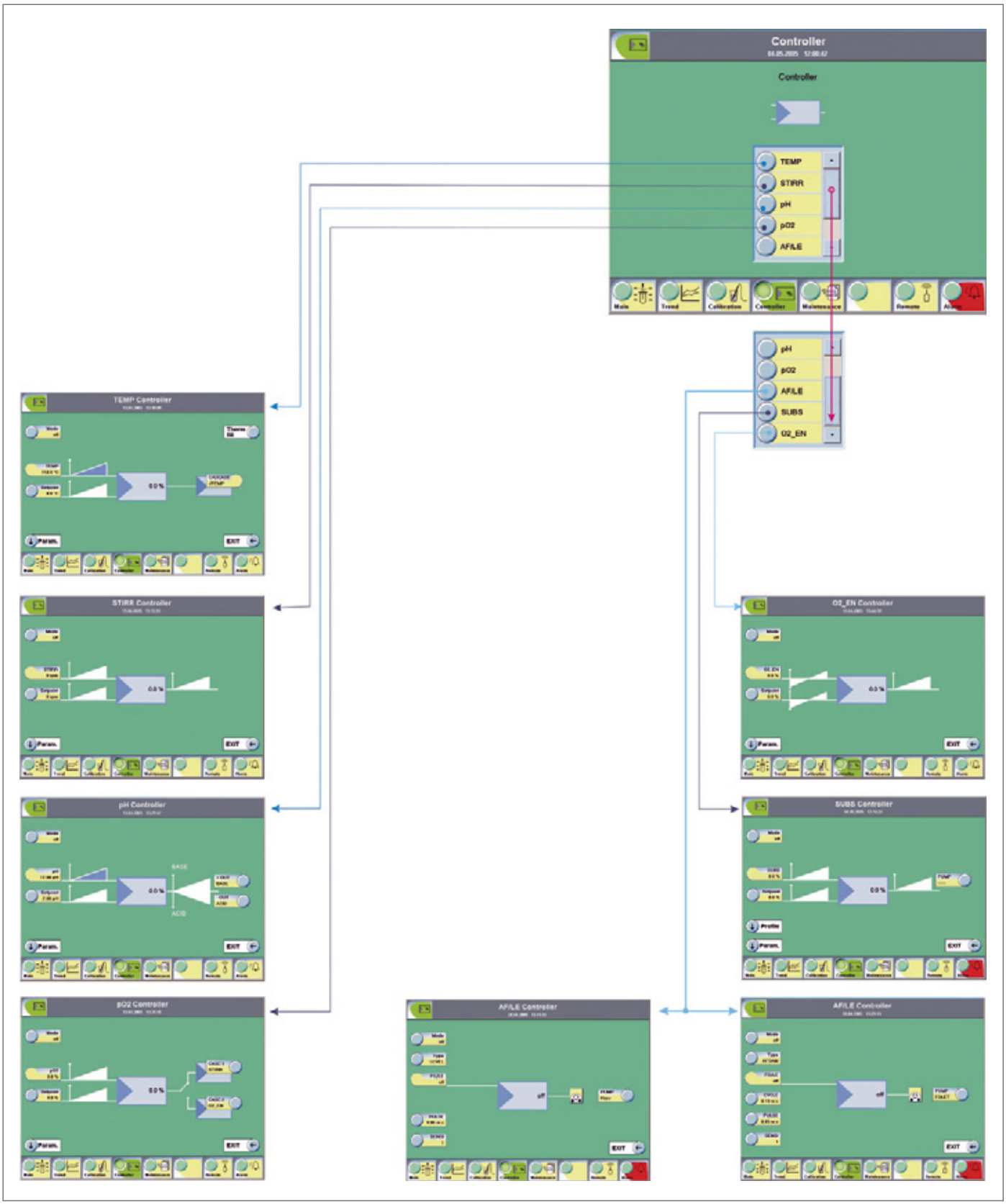
You can access all controllers of a configuration via the main function key "Controller" in the footer. After pressing the key, an overview menu appears. The individual controller operator screens then open by pressing the touch key in the list of controllers.

Field	Value	Function, display, entry required
TEMP, STIRR, etc.		Controller to be configured **Example** Pressing the TEMP touch key opens the associated operator screen of the temperature controller.

The overview screen of the controller menu on the following page shows the available controllers for different system configurations.

18.1.3 Overview of the Controller Menus

Example
BIOSTAT® Aplus, configuration "MO"



18.2 General Controller Operation

Operating functions necessary during routine operation and accessible for normal users include the selection of the controller operating mode "Mode", the configuration and modification of the setpoints ("Setpoint") and of the controller outputs ("Out") in the controller operator screen.



Setpoint entries ("Setpoint") must be within the measuring range limits of the control variables. Invalid (larger or smaller) values will not be saved.

- In "Remote" operation, the host PC defines the setpoints and operating modes.
- Settings that are not necessary for routine operation take place via parameterization functions. These include settings for PID parameters, controller output limits "Min" | "Max" and a dead band DEADB [▶ Section "18.3 General Controller Parameterization"].
- The controllers switching their actuators between operating modes is mostly shock-proof.
- Fields and value entries of the operator screens (overview)



Not all fields and functions are available for all controllers.

Field	Value	Function, display, entry required
Mode		Controller operating modes:
	Off	– Controller switched off and slave controller switched off; the output assumes a defined position (rest position of the actuator)
	auto	– Controller is switched on and works on the configured setpoint (on externally defined setpoint during "Remote" operation) – Setpoints are configured via "Setpoint" – Slave controllers are switched to "cascade"
	casc	– Controller works as slave controller in cascade, the guide controller defines the setpoint – Setpoints for the controllers cannot be entered directly – The operating mode "cascade" is not available for all controllers
	profile	– Controller works with time profile for the setpoint – Operating mode "profile" is not available for all controllers
	Manual	– Manual access to control output
process value	[PV]	Nominal value of the process value in its physical unit, e.g. [°C] for temperature, [rpm] for revolutions per minute, [pH] for pH value, etc.
Setpoint	[PV]	Setpoint of the process value in its physical unit, e.g. [°C] for temperature, [rpm] for revolutions per minute, [pH] for pH value
OUT	%	Controller output; entries are only possible in operating mode "manual"
Cascade	[Controllers]	Slave controller that the controller output works on Example JTEMP: Output acts on controllers for temperature control loop
Param		Access to controller parameter with standard password [▶ Section "20.6 Password Protection"]; when entered, the password is not visible on the display.
ALARM		Activate the alarm display
PROFILE		Input menu for setpoint profile

18.3 General Controller Parameterization

The controllers are configured with suitable control parameters that match the bioreactor and can guarantee stable operation of the controls under normal operating conditions. Information on the factory-set parameters can be found in the reactor- or customer-specific configuration documentation.



Control parameters are not normally changed. Exceptions: Controlled loop paths, whose behavior is heavily influenced by the process, e.g. pH and DO control.

In order to better adapt a controller to the behavior of its controlled loop path, the following parameters can be changed in the parameterization screen of the controller:

- MINimum, MAXimum: Minimum and maximum controller output limits
- DEADB: Dead zone setting (PID controller only)
- XP, TI, TD: PID parameters (PID controller only)



Parameterization screens are only accessible with the touch key "Param" by entering a password in the controller operator screen [standard password ▶ Section "20.6 Password Protection"].

IMPORTANT!

Danger of unstable controls and unexpected malfunctions of the system when uncontrolled, unauthorized changes to control parameters are made.
Only authorized users may change control parameters. Only give passwords to individuals who are qualified to make such changes.

18.3.1 Fields and Entered Values of the Parameterization Screens (Overview)

Field	Value	Function, display, entry required
MIN (Minimum)	%	Minimum output limit; minimum setpoint for the slave controller
MAX (Maximum)	%	Maximum output limit; maximum setpoint for the slave controller
DEADB	[PV]	Dead zone, unit dependent on process value – As long as the deviation of an actual value from the setpoint is less than the value of DEADB, the corresponding control will remain inactivated
Xp	[Tag]* in "%"	P share (proportional range); signal amplification of the control response proportional to the input signal; in "%" of the measuring range.
TI	[Tag]* in "s"	Integral portion; time function of the control response. With a higher I portion, the controller will react more slowly (and vice versa).
TD	s	Differential portion; damping of the controller. With a greater D portion, the controller response is reduced (and vice versa).
Hyst. time	m:s	Switch-over or start delay for controllers
Cascade	[Tag]*	Controllers assigned in cascade, order according to priority
Process value		Selection of the process value the control should act on (for control during dual measurements)

* [Tag] = Short name for controllers or actuator

18.3.2 Output Limits

The controller output limits for setpoint generators and PID controllers prevent unintentionally extreme actuator controls and | or limit the setpoint range for the slave controller during cascaded regulation.

Entry of the limits takes place in [%] of the maximum possible controller output.

For full modulation of a controller output, the following limits must be set:
- Unilateral controller output: MIN = 0 %, MAX = 100 %
- Split range controller output: MIN = -100 %, MAX = 100 %



For safe operation of the bioreactor, the output must be limited for certain controllers. Information on this can be found in the description of the controller.

18.3.3 Dead Zone

A dead zone is configurable for PID controllers. Then, the controller output holds a constant value (and | or is at zero for the pH controller), as long as the control deviation is within the dead zone. Dead zones allow stable control with minimized actuator movement for controlled loop paths with stochastically variable actual values. For controls with split range outputs, this prevents oscillation of the controller output (e.g. constantly changing acid | alkaline proportioning on the pH controller).

The dead zone is input into the field DEADB in [%] of the actual value's measuring range spread and is symmetrical to the set setpoint. Example for pH controllers:
- Measuring range pH = 2 – 12 pH, measuring range spread 10 pH;
- Configured dead zone 1% = ± 0.1 pH, configured setpoint 6.0 pH

In that case, the control is inactivated at a nominal value between 5.9 pH and 6.1 pH. The pumps are activated when the actual value falls short of or exceeds these limits.

18.3.4 PID Parameter and PID Controller Optimization

PID controllers can be optimized via the following PID parameters:

Xp	Proportional range in [%] of the measuring range (P portion)
TI	Reset time in seconds (I portion)
TD	Hold time in seconds (D portion)

The control structure can be set by zeroing individual PID parameters:

Function as	Configuration of
P controller	TI = 0, TD = 0
PI controller	TD = 0
PD controller	TI = 0
PID controller	all PID parameters defined.

The optimal adaptation of PID controllers to the controlled loop path requires knowledge of control theory. Empirically tested tuning methods (e.g. Ziegler Nichols) can be found in the pertinent literature. General guideline:

- Only switch on the D portion (TD) if the actual values are relatively stable. If the actual values fluctuate, the controller output changes fast and dramatically through the D portion, which can lead to unstable control.
- As a rule, the TI : TD ratio should be around 4 : 1.
- Periodic oscillations in the control loop can be counteracted by increasing XP and TI | TD.
- If the adjustments are too slow after setpoint jumps and | or in the case of nominal value drift, you can lower Xp and TI | TD.

18.4 Temperature Controller "TEMP"

The temperature in the culture vessel serves as the reference value for the temperature controller TEMP. Its output regulates the heating blanket and the cooling valve for the cooling finger during "split range" operation via pulse-width modulated or continuous outputs.

18.4.1 Controller Operating Display and Input Window

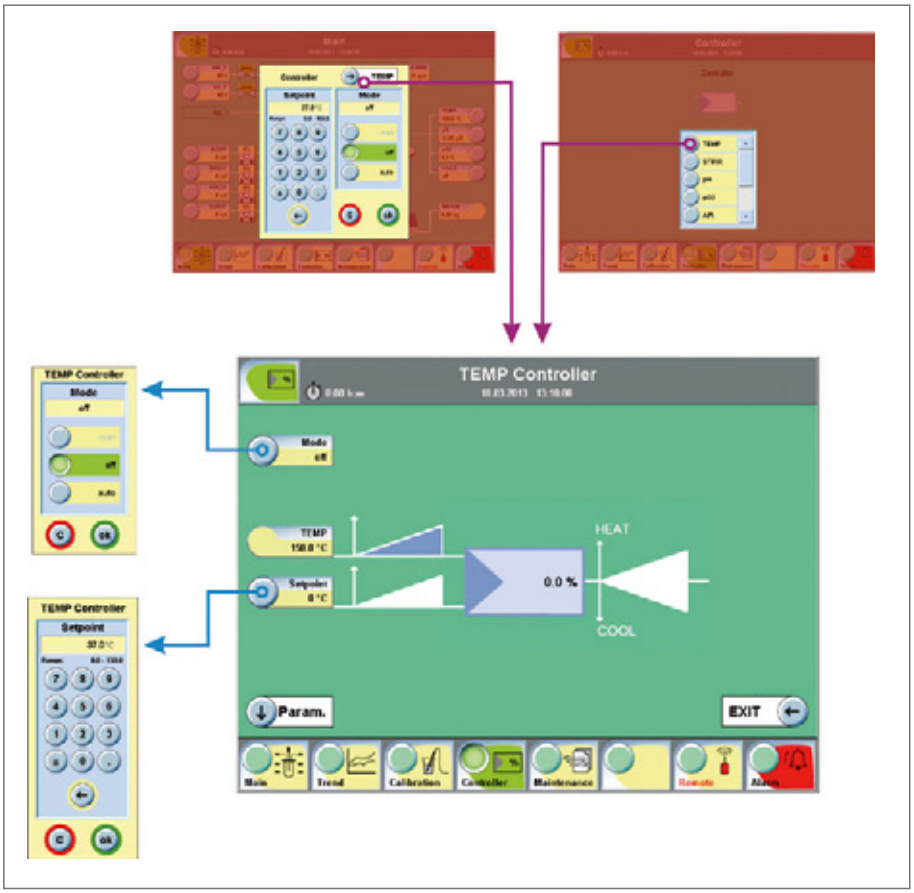


Fig. 18-1: Selection of operator screen and input window of the TEMP guide controller

Field	Value	Function, display, entry required
Mode		Controller operating modes:
	Off	– Controller switched off
	auto	– Controllers on
	man	– Manual access to control output
TEMP	°C	Actual value (numerical value and graphical display relative to the measuring range)
Setpoint	°C	Setpoint (numerical value and graphical display relative to the control range)
[Controller]	%	Controller output (proportional to the max. controller output [▶ Configuration]
Param.		Access to controller parameters with standard password [▶ Section "Password"].

CAUTION!

Danger of burns and | or scalding at process temperatures >45 °C!
Culture vessels and connection lines can become very hot.
– Wear safety gloves to operate hot device parts.

The temperature control works like a simple temperature controller. You normally only configure the setpoint "Setpoint" and the operating mode "Mode" in the operator screen of the guide controller TEMP.

– Select the touch key "TEMP" in the "MAIN" menu and the touch key "Controller TEMP" in the sub-menu, or select the main function key "Controller" and the controller "Temp" from the list. [▶ Fig. 18-1]
– Enter the setpoint for the temperature in the sub-menu "Setpoint"
– Switch to "auto" in the sub-menu "Mode" to activate temperature control.

Special Notes

The temperature controller cannot be operated with a time profile.

In its starting condition, the temperature controller works with the controller structure "PD" [▶ Section "PID Parameters"]. When the setpoint is approached, a structural toggle switches this structure to "PID". This toggling can suppress most control overshoot.

If the temperature controller TEMP is switched off, a digital output also switches off the agitation pump of the bioreactor.

The temperature controller works with the temperature in the culture vessel as a reference value. However, this is not available as a measured value if the culture vessel is empty at the start of the process or the vessel temperature is not determined and | or should not be the reference value of the temperature control (e.g. for testing purposes).

18.4.3 Controller Parameterization

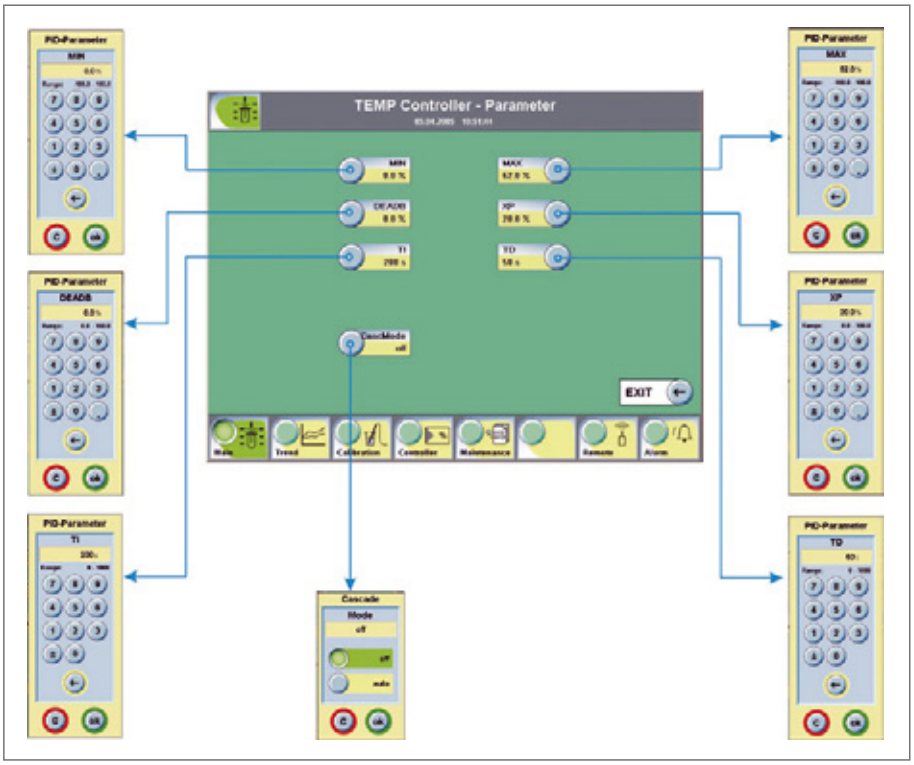


Fig. 18-2: Parameterization screen and input window for the TEMP controller

Field	Value	Function, display, entry required
MIN (Minimum)	%	Minimum output limit; minimum setpoint for the slave controller
MAX (Maximum)	%	Maximum output limit; maximum setpoint for the slave controller
DEADB	[PV]	Dead zone, unit dependent on process value
XP	%	Proportional range in [%] of the measuring range (P portion)
TI	sec	Enter reset time
TD	sec	Enter hold time

IMPORTANT!

Danger of overheating of the temperature control circulation after system reset!
The controller output "0 ... 100%" is designed for a max. temperature range "0 ... 75 °C" and must be limited to the acceptable value for the bioreactor.
This output limit is preset at the factory [▶ Configuration Documentation].
– After a system reset, determine whether the output of the temperature controller is still limited to the acceptable range and reconfigure where necessary.

The bioreactor BIOSTAT® Aplus is designed for process temperatures up to 75 °C.

18.5 Speed Controller

The speed controller runs on the separate motor control as a setpoint generator, which controls the speed of the stirrer motor. It also emits an analog setpoint signal. User entries and the display of the speed signal transmitted by the motor control take place on the touch display.

18.5.1 Controller Operating Display and Input Window

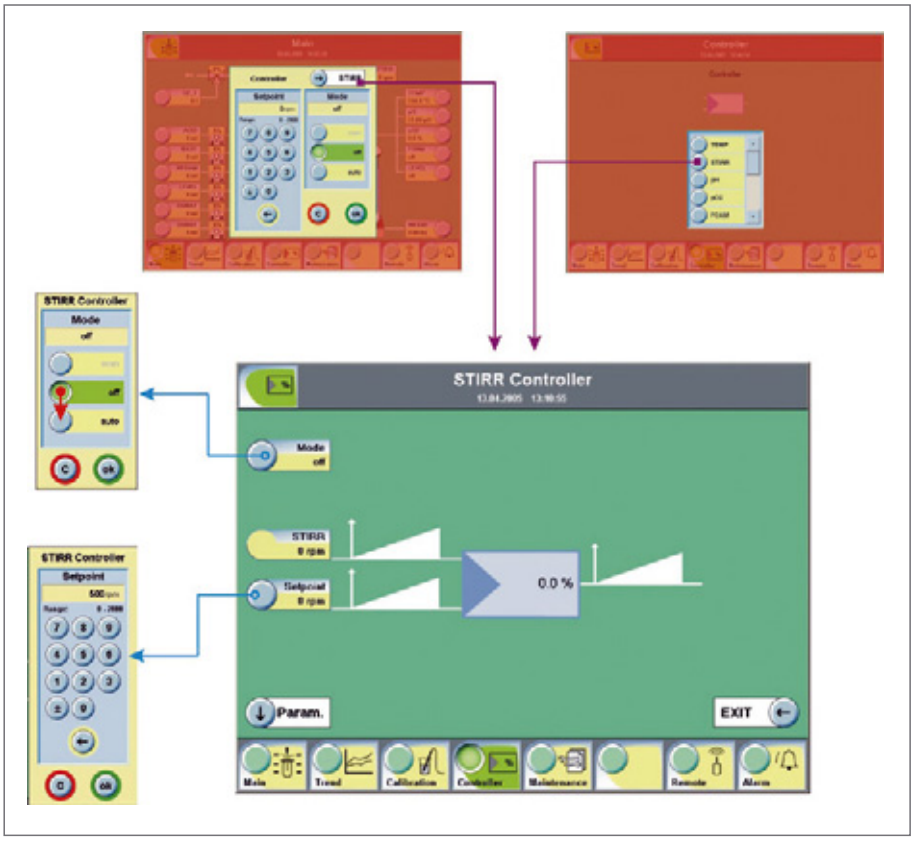


Fig. 18-3: Selection of operator screen and input window of the speed controller

Field	Value	Function, display, entry required
Mode		Controller operating modes:
	Off	– Controller switched off and slave controller switched off; the output assumes a defined position (rest position of the actuator)
	auto	– Controller on and slave controller switched to "cascade"
	man	– Manual access to control output
STIR	rpm	Actual value
Setpoint	rpm	Setpoint
[Controller]		Controller output
Param		Access to controller parameters with standard password [▶ Section "Password"].

18.5.2 Operating Notes

Example
Entering | Changing the Speed:
– Press the touch key "STIRR" in the "MAIN" menu or select the main function "Controller" and the touch key "STIRR" from the list.
– Enter the setpoint "Setpoint".

Observe the acceptable settings for different culture vessels and equipment, [▶ Table in Section "18.5.4 Special Notes"].

– Activate speed control by switching to "Mode: auto".
– Confirm with "OK".

18.5.3 Controller Parameterization

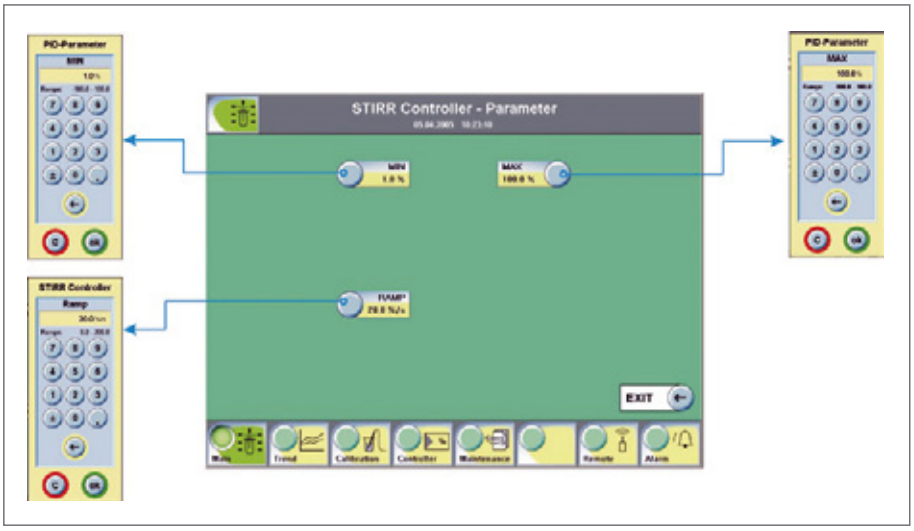


Fig. 18-4: Parameterization screen and assigned sub-menus of the speed controller

Configuration example BIOSTAT® Aplus 2 L
Control range 0 … 60 % = 20 … 1200 rpm:
– Enter the lower speed limit for "MIN" (1 % = 20 rpm).
– Enter the upper speed limit for "MAX" (60 % = 1200 rpm, 40 % = 800 rpm, etc.)

Observe the limits for the culture vessels and installed equipment [▶ Table in Section "18.5.4 Special Notes"; ▶ Configuration Documentation].

– "RAMP" is used to enter how quickly the controller should reach the setpoint [▶ "Setpoint" in the operator screen of the controller]. Smaller values cause the setpoint to be reached more slowly.

IMPORTANT!

Danger of damage to vessel attachments and the culture vessels.

UniVessel:
Excessively high speeds can cause the culture vessel to vibrate and reduce the stability of the laboratory table. The culture vessel could fall off of the setup surface.

Tubing Aeration Systems:
In tubing aeration systems, the hose may come loose from the holder.

BIOSTAT® Aplus 1 L, 2 L:
The controller output "0 … 60 %" is designed for a max. rpm range of "20 … 1200 rpm" and must be limited to the acceptable value for the bioreactor.

BIOSTAT® Aplus 5 L:
The controller output "0 … 40 %" is designed for a max. rpm range of "20 … 800 rpm". and must be limited to the value permissible for the bioreactor.

This output limit is preset at the factory [▶ Configuration Documentation].

Some typical reference variables, i.e. settings to be checked in individual cases are:

Version	MIN … MAX [%]	Speed range [rpm]
BIOSTAT® Aplus 1 L, 2 L	1 … 60	20 … 1200
BIOSTAT® Aplus 5 L	1 … 40	20 … 800

After a system reset, determine whether the controller output limit is still limited to the acceptable range and reconfigure where necessary [▶ Configuration Documentation].

The speed controller can be configured as a slave controller in the DO cascade control loop. To operate it as slave controller, enter the base speed and | or max. permissible rpms in the MIN | MAX output limits.

When the speed controller function is switched off, an additional digital output also switches off the drive protection.

18.6 pH Controller

The pH control works with PID control characteristics. The pH controller controls the acid pump "Acid" (and | or the CO_2 valve of the configuration "Exclusive Flow) and the alkaline pump "Base" during "split range" operation via two pulse-width modulated outputs. This enables bilateral pH control.

The signals for dosing of acid (and | or CO_2) and base remain switched off as long as the control deviation is within a parameterizable dead zone. This prevents unnecessary supply of acid (and | or CO_2) or base.

18.6.1 Controller Operating Display and Input Window

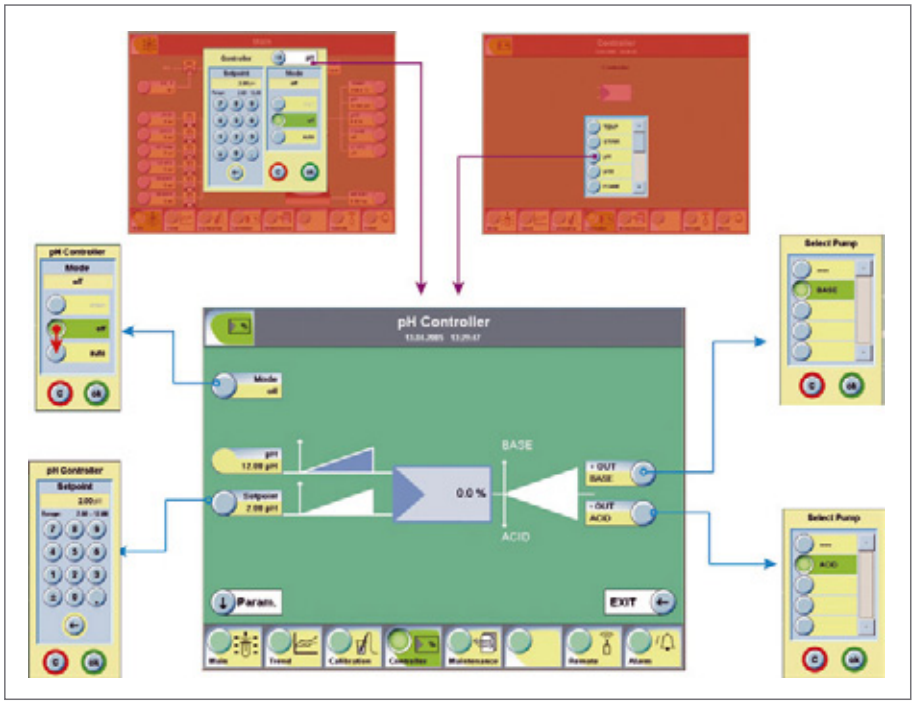


Fig. 18-5: Selection of operator screen and input window on pH controller

Field	Value	Function, display, entry required
Mode		Controller operating mode
	auto	– Automatic operation in response to the defined setpoint
	Off	– Controller is switched off, outputs are in operating modes
pH	pH	Actual pH value
Setpoint	pH	Controller setpoint
+OUT | –OUT		Allocation of the actuators (e.g. pumps) to the controller output:
	BASE | ACID	– Output controls the acid | base dosing
	BASE | -----	– Output controls the base dosing
	----- | ACID	– Output controls the acid dosing Non-assigned pumps can serve as substrate pumps
Param		Access to controller parameters using standard password [▶ Section "20.6 Password Protection"]

18.6.2 Operating Notes

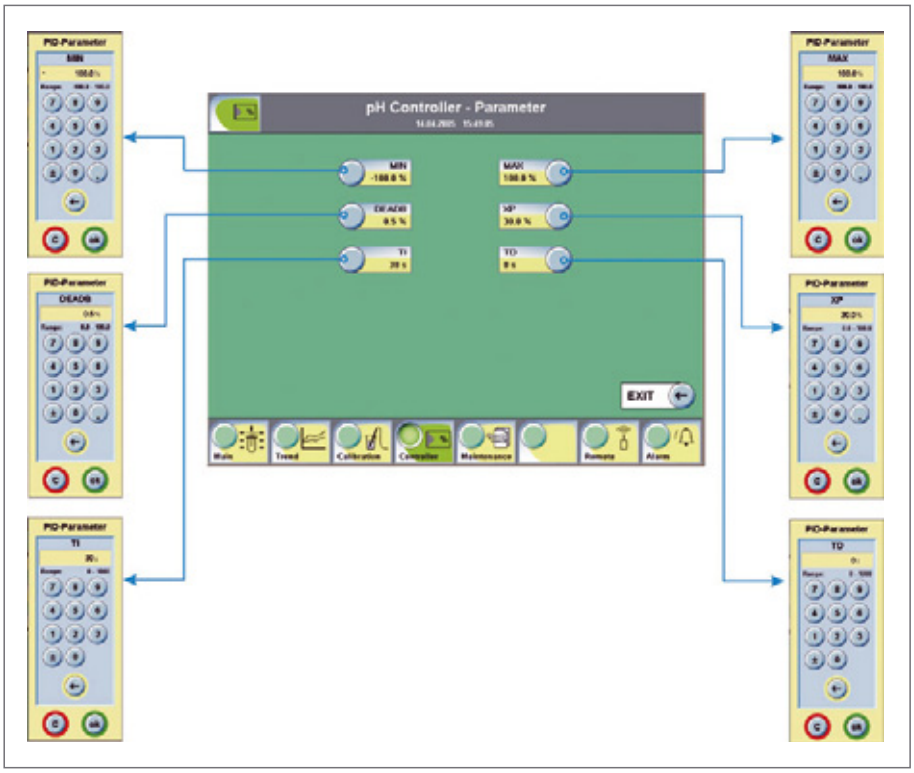
Entering | Changing the Target pH Value

– Press the touch key "pH" in the "MAIN" menu or select the main function "Controller" and the touch key "pH" from the list of controllers.
– Use the sub-menu "Setpoint" to enter the setpoint. Confirm with "ok".

If no output for acid | base dosing is assigned to the controller (this can be seen in the display [----] in the field "+OUT" and | or "–OUT"), select a pump in the sub-menu "Select Pump", [▶ Fig. 18-5].

– Activate pH control by switching to "Mode: Auto".

18.6.3 Controller Parameterization



Field	Value	Function, display, entry required
MIN	%	Minimal controller output limit (limits the addition of acid)
MAX	%	Maximum controller output limit (limits the addition of base) – "min" and "max" values refer to the specific measuring range. For modified measuring ranges, this yields new basic values of the controller output limit that may not be exceeded or fallen short of
XP		Proportional range in [%] of the measuring range (P portion)
TI	s	Integral portion ("Reset time")
TD	s	Differential portion ("Delay time")
DEAB	pH	Dead zone ("Dead band")

18.6.4 Parameterization Example:
– Select the parameterization menu by inputting the standard password [▶ Section "20.6 Password Protection"].
– Input the dead zone proportionate to the measuring range; it is symmetrical to the set setpoint.

An example for the configuration of the dead zone:
– Measuring range: 2 – 12 pH, measuring range spread: 10 pH
– DEADB: 0.1 pH, SETP: 7.0 pH

In this case, the controller output is inactivated between 6.9 pH and 7.1 pH.

Special Notes
In the configuration "Additive Flow", the controller output "– OUT" regulates the valve of the CO_2 segment with a negative output signal (0 … –100 %) and doses CO_2 into the aeration segment "Sparger".

If there is an externally connected gas mix system, the controller output "-OUT" regulates its CO_2 valve with the negative output signal (0 … –100 %).

If you select the operating mode "auto", "profile" or "manual", the filling counters ACID and BASE are automatically switched to the operating mode "Totalize".

18.7 DO Control

Different configurations are available for DO control (pO_2). They must be defined when specifying and ordering the bioreactor and implemented at the factory:

– Configuration "MO" (O_2 enrichment):
  Air supply with oxygen enrichment via clocked controller valve. Major application area: microbial cultures.

– Configuration "CC" (Additive Flow):
  Gas supplies parallel for media aeration ("Sparger") and headspace aeration ("Overlay" of the culture vessels). Major application area: cell cultures.
  The four gases Air, O_2, N_2 and CO_2 can be freely equipped at the vessel inputs "Overlay" and "Sparger".
  – Media aeration with air supply as well as decreasing O_2 is conducted via clocked controller valve.
  – Manual supply of nitrogen (N_2) is conducted via flow meter.
  – Supply of CO_2 to the pH control is conducted via clocked controller valve.

Available for all bioreactors with micro DCU system.

The DO control (pO_2) works like a cascaded regulation. The output of the DO controller (pO_2) (guide controller) directly affects the setpoint input of the slave controller. The following control strategies are possible:

- 1-stage control cascade, i.e. the DO control (pO_2) affects one of the process parameters, e.g.:
  - Impeller speed
  - Gas supply via clocked valves (configuration "MO" and | or "CC")
  - Substrate supply SUBS (DO-dependent dosing of substrate)

- 2-stage control cascade, i.e. the DO control (pO_2) affects 2 process parameters. Available slave controllers:
  - Speed controller,
  - O_2-EN controller

A range (MIN | MAX) can be defined in the DO controller (pO_2) for every slave controller within which the DO controller (pO_2) defines the setpoint for the slave controller. In 2-stage cascaded regulation, the output of the DO controller (pO_2) modulates both slave controllers after sequential switching as follows:

- The DO controller (pO_2) acts on the slave controller with priority 1 (CASC1) and defines its setpoint. The slave controller 2 receives the setpoint defined in the DO controller (pO_2) with "MIN".

- When the setpoint entry for the 1st Slave controller reaches its maximum, the output of the DO controller (pO_2) switches to an adjustable delay (enter: 5 minutes) to the setpoint input of the 2nd slave controller (CASC2). Afterwards, the following setpoints are specified:
  - Slave controller 1: with defined maximum
  - Slave controller 2: controlled output of the DO controller (pO_2)

- If the need for oxygen drops, the controllers are reset to in the reverse order.

This control can keep the pO_2 constant across broad ranges of the process flow without manual intervention. In order to be able to optimally adapt the control to the behavior of the controlled loop path, the PID parameters of the slave controller are parameterizable independently of one another.

18.7.1 Controller Operating Display and Input Window

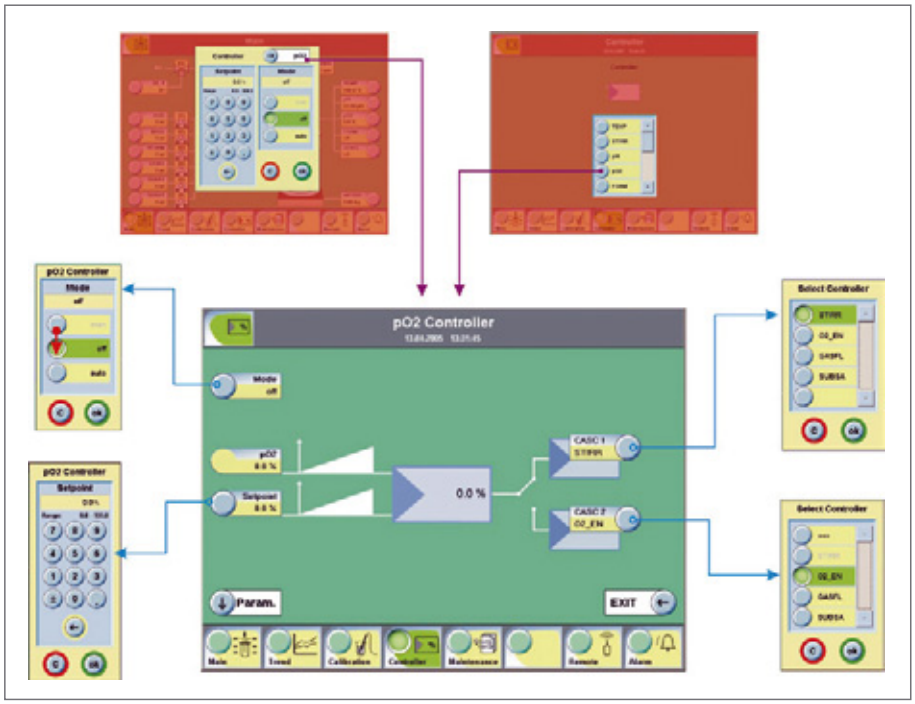


Fig. 18-6: Selection of operator screen and input window on the DO controller (pO_2)

Field	Value	Function, display, entry required*
CASC1/2		Slave controller with priority 1 and | or 2 for the sequential cascade control
	STIR	– Speed controller
	O2_EN	– Filling controller for O_2 supply to the supply air stream (if present)
	GF_SP	– Aeration rate controller for gas supply "Sparger" (if present)
	GF_OV	– Aeration rate controller for gas supply "Overlay" (if present)
	SUBSA	– Substrate controller (assigned pump A)
OUT	% – [controller]	current value of the controller output

* Available slave controllers depend on the system configuration of the bioreactor.

Operating Notes

- Define the slave controller in the operator screen of the DO controller (pO_2). To do this, press the touch key "CASC1/2" according to the priority "1 | 2" that the controller should receive.
- In the sub-menu "Select Controller", select the desired slave controller from the list the configured controllers. Confirm the selection with "OK".
- Open the parameterization screen of the DO controller (pO_2) via "Param" [▶ Example: next page]. Set the minimum and maximum controller output limit and the further control parameters for the slave controller, as required.
- Configure the setpoint for DO control (pO_2) in the operator screen of the DO controller (pO_2).
- Activate the DO controller (pO_2) by switching to "Mode: auto".

▷ In the working area of the controller operator screen, a connecting line graphically displays which slave controller the DO controller (pO_2) output is currently controlling.

Special Notes

In the operating mode "auto" of the DO controller (pO_2), the selected slave controllers are automatically switched to "cascade" mode. In the operating mode "off", the slave controllers are automatically switched to "auto".

The DO guide controller (pO_2) always uses the "Minimum | Maximum" limits of the respective slave controller as the working range.

The window for parameter entry can be opened by pressing (clicking on) the value field, not by pressing the touch key in the column "Cascade".

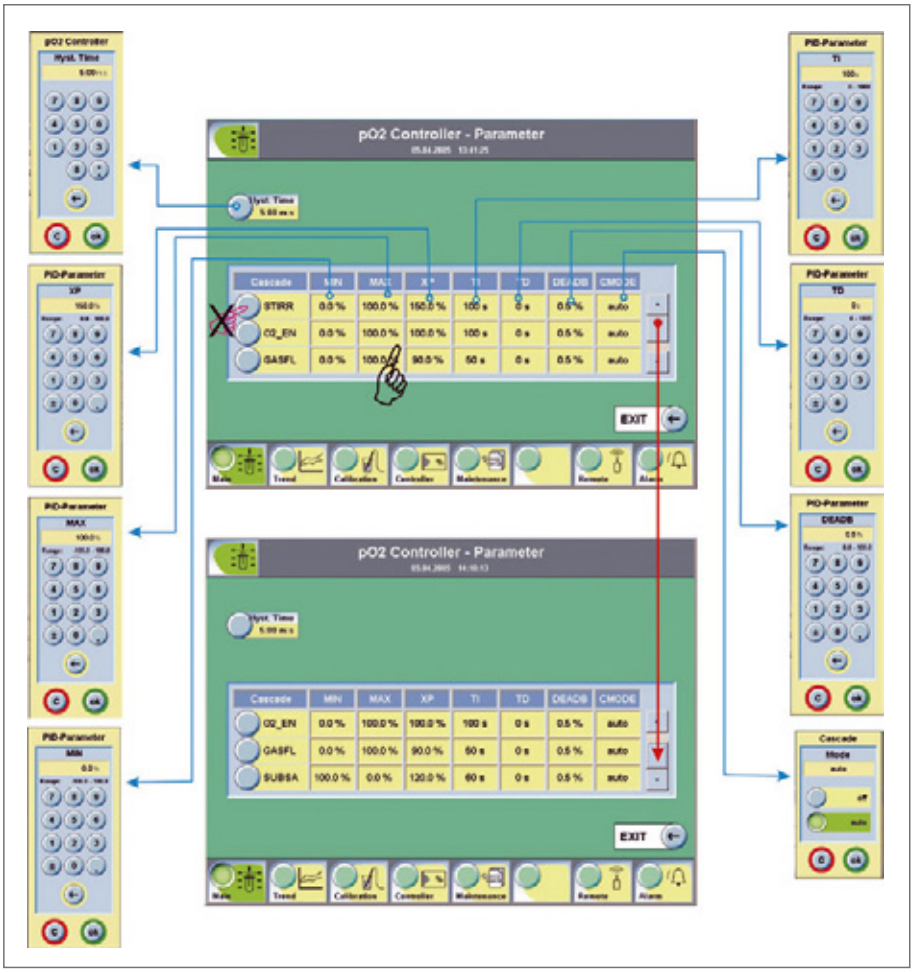


Fig. 18-7: Parameterization screen DO cascade controller (pO_2), version "MO"

Field	Value	Function, display, entry required
Hyst. Time	m:s	Time delay to switch the cascade
Cascade	[Controllers]	Display of the slave controller with the associated parameters
Minimum	%	Minimum output limit (minimum setpoint for the slave controller): Process value measuring range 0 ... 100 %
Maximum	%	Maximum output limit (maximum setpoint for the slave controller): Process value measuring range 0 ... 100 %
XP	%	Proportional range for the slave controller in relation to the measuring range
TI	sec	Entry of the reset time for the slave controller in [sec]
TD	sec	Pre-holding time for slave controller
DEADB	%	Dead zone in terms of measuring range 0 ... 100% saturation
Mode	off | auto	Mode of slave controller after DO controller (pO_2) turned off

Special Notes
Number and type of the available cascade controllers depend on the system configuration. To view the available cascade controller:
– Select the touch key CASC1/2 in the operator screen of the DO controller (pO_2) or
– Open the parameterization screen and view the list of controllers under "Cascade". If more than 3 slave controllers are available in the configuration, you can page down using the scrollbar on the side.

Switching from slave controller 1 to slave controller 2 does not occur until the respective output limit for the time span defined in the field "Hys. Time" has been fallen short of or exceeded. After this time has elapsed, check the switch conditions once again and only switch back to the slave controller if they have been met.
– To change the switch time, select the touch key "Hys. Time" in the parameterization screen of the DO controller (pO_2).

The switch direction for slave controllers, e.g. when controlling substrate pumps, can be inverted by reversing the setpoint limits (minimum > maximum).

The difference between MIN and MAX must always be >2% of the measuring range.

18.8 DO Control (pO_2) via O_2 Enrichment ("O2-EN" Controller)

DO control (pO_2) via O_2 enrichment in "MO" configurations regulates pO_2 in the culture vessel by adding oxygen to the supply air stream. The "O2-EN" controller controls the valve in the O_2 supply and adds O_2 in pulses to the supply air stream.

The gas flow rate to the culture vessel is configured manually on the variable area flow meter in the gas output [▶ P+I diagram of the bioreactor].

The "O2-EN" controller works in cascade to the DO controller (pO_2).

18.8.1 Controller Operating Display and Input Window

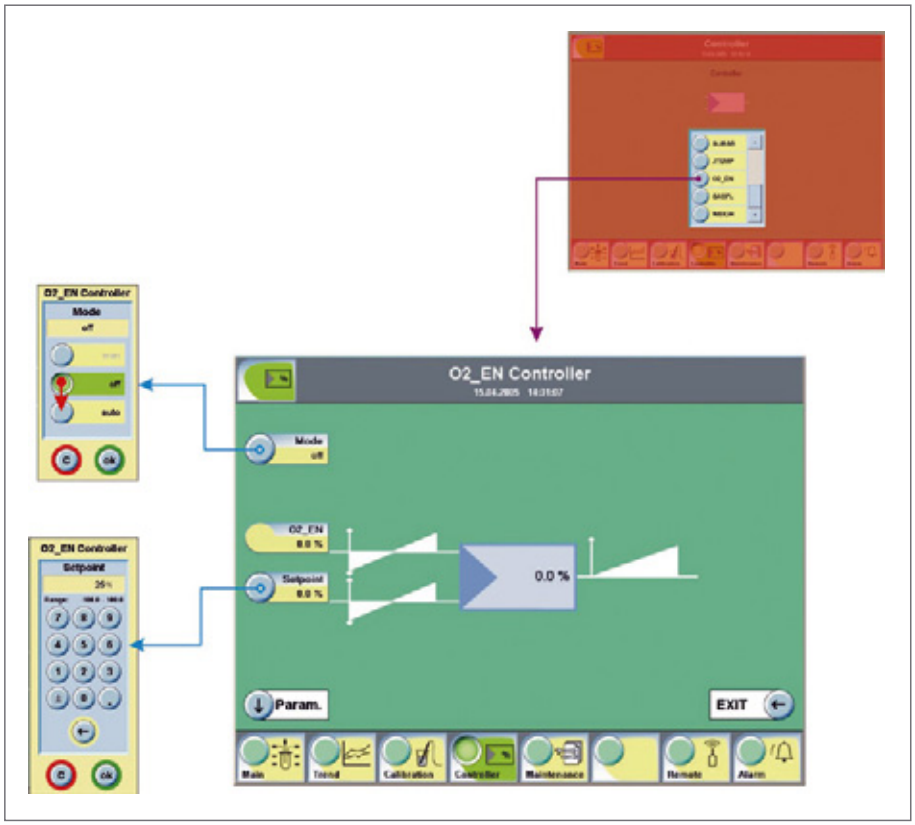


Fig. 18-8: Selection of operator screen and input window for the slave controller "O2-EN"

Field	Value	Function, display, entry required
Mode	off | auto	Active operating mode of the "O2-EN" controller
O2-EN	%	Actual value of the controller output
[Controller]	%	Display +OUT: Controllers controls valve of the O_2 supply
Setpoint	%	Specification of setpoint for the "O2-EN" controller – Current setpoint during operation not in cascade to DO controller (pO_2) – Setpoint limit of the "O2-EN" controller during operation as a cascade controller

18.9 DO Control (pO_2) via Additive Flow Controller

The configurations "CC" (Additive Flow) allow DO control (pO_2) by mixing air, N_2 and O_2. The BIOSTAT® Aplus is equipped with individual gas outlets to the culture vessel that allow flexible assignment of the individual gases to the "overlay" headspace or to the submerged aeration "Sparger".

The DO controllers (pO_2) automatically control the gases AIR and O_2 in a two-level cascade via pulsed valves and variable area flow meters.
N_2 can be batched manually via the variable area flow meter.

In the controller operator screen, the two-level cascade can be selected in random order from the following elements: Air, O_2 and STIRR (stirrer speed)

If SUBS (substrate addition) is selected in the first cascade, the selection of a second cascade is not possible because any control of the pO_2 by substrate addition works in the opposite direction.

18.9.1 Controller Operating Display and Input Window

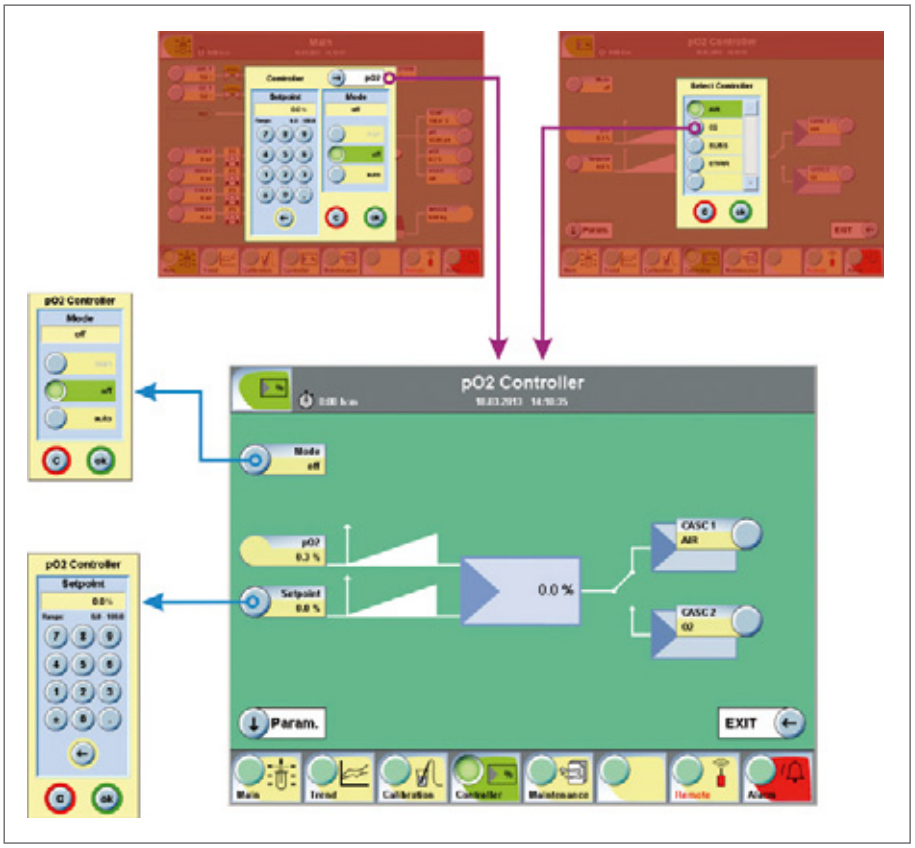


Fig. 18-9: Selection of operator screen and input window for the slave controller "O2-EN"

Field	Value	Function, display, entry required
Mode	off | auto	Active operating mode of the "O2-EN" controller
O2-EN	%	Actual value of the controller output
Setpoint	%	Specification of setpoint for the "O2-EN" controller – Current setpoint during operation not in cascade to DO controller (pO_2) – Setpoint limit of the "O2-EN" controller during operation as a cascade controller

18.10 Antifoam Controller

If foam has collected at the antifoam probe, its measurement amplifier generates a limit signal as input signal for the antifoam controller. The controller output controls the "Antifoam" pump. As long as the probe has contact with the foam for longer than the defined waiting period, the controller periodically switches the pump on and off for the set pump run and cycle times.

The output of the antifoam controller controls a pump to the antifoaming agent supply and switches this off and on cyclically. Filling and pausing times are entered on the controller operator screen. The filling volume for antifoaming agent depends on the ratio of pump run- to cycle time as well as on the tubing diameter. After you calibrate the pump [▶ Section "17.6 Totalizer for Pumps and Proportioning Valves"], a filling counter displays the fed volume.

18.10.1 Controller Operating Display and Input Window

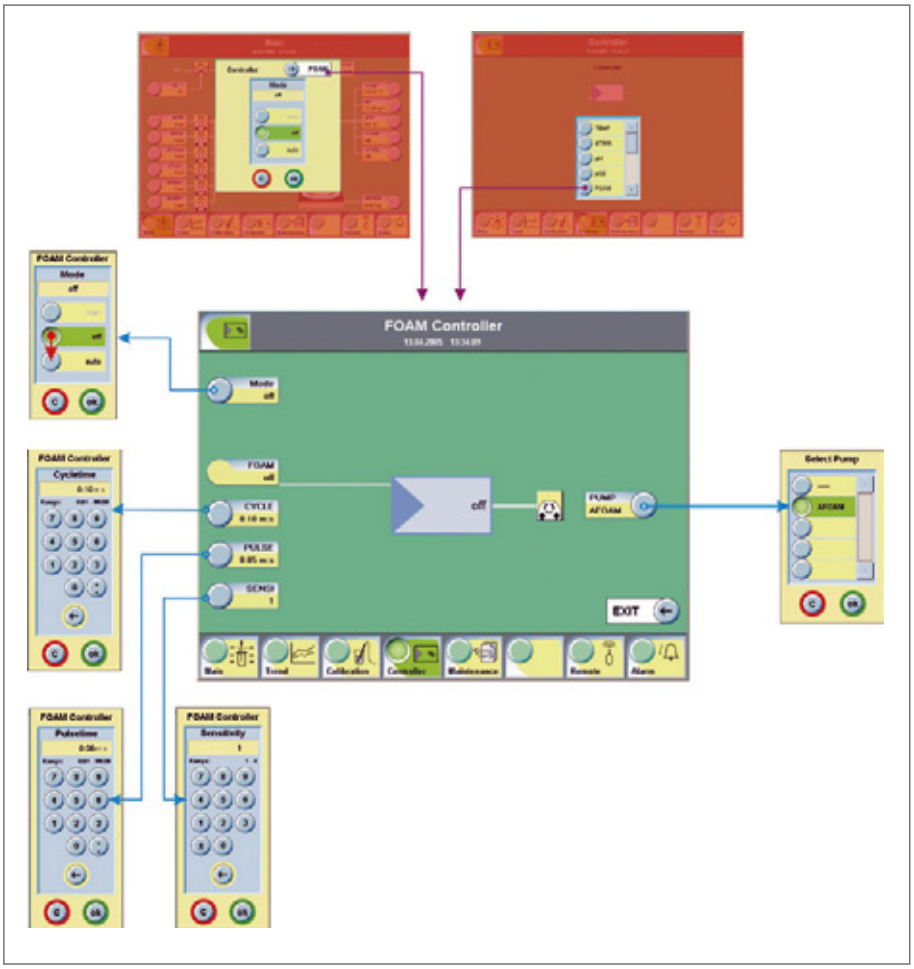
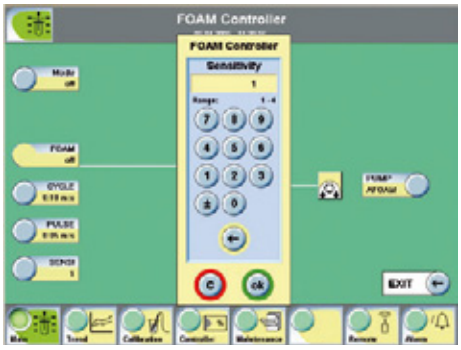


Fig. 18-10: Selection of operator screen and input windows of the antifoam controller

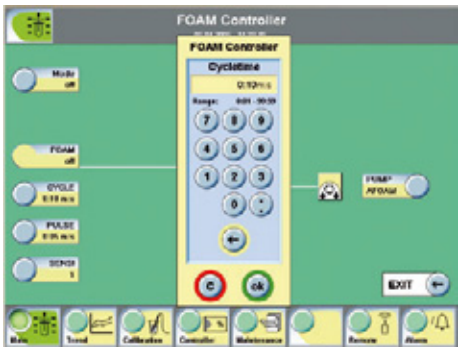
Field	Value	Function, display, entry required
MODE	off	Controller operating mode: – controller switched off, OUT = off
	auto	– controller switched on, OUT = on
	man	– Manual access to control output
FOAM	on | off	Foam signal ("on" = foam has collected on the probe)
CYCLE	m:s	Cycle time (pulse + pause time) for the control in [minutes:seconds]
PULSE	m:s	Dispensing time "Pulsetime" of the pump in [minutes:seconds]
SENSI	1 ... 4	Trigger sensitivity for foam measurement amplifier
[Controller]	on | off	Controller output (on = output active)
PUMP	AFOAM [----]	Assignment of the antifoam pump to the controller – no pump assigned, antifoam pump free for other controller

18.10.2 Operating Notes

The trigger sensitivity can be adjusted depending on the different conductivities of the medium. To prevent proportioning errors resulting from leakage currents and probe growth, you should set the response sensitivity of the foam probe as low as possible.



– Based on setting 4, you can continue reducing the trigger sensitivity "Sensitivity" until foam is just barely detectable.



– Set cycle time (CYCLE) and filling time (PULSE) to match the process requirements.
– Activate the foam control by switching "Mode: auto".
▷ In "manual" operating mode, the pump can be switched on ("on") or off ("off") for continuous operation. Selecting the "auto" or "manual" operating mode also activates automatically the filling counters "AFOAM".

– If you do not need the foam regulation function, you can release the pump "Antifoam" and use it as a substrate pump (select "----" in the window "Select Pump").

Special Notes

A response lag time of the control prevents false filling of antifoaming agent in the event of splashing liquid at the probe or brief foam contact.
It only activates control if foam stays on the probe for longer than approx. 5 s.

The reference potential for the antifoam probe is generated by the Pt-100.
The foam control is only functional if the antifoam probe and Pt-100 have been installed.

18.11 Level Controller "Level"

When the level is controlled with conductive level probes, the insertion height of the probe in the culture vessel determines the intended filling volume. When liquid has collected on the probe, the measurement amplifier sends a limit value signal as input signal to the level controller. The pump controlled by the controller can harvest medium (operating mode "Harvest") or feed substrate (operating mode "Feed"):

- In the operating mode "Harv", the controller activates the pump when the "LEVEL" signal is "on".
- In the operating mode "Feed", the controller activates the pump when the "LEVEL" signal is "off". The probe looses contact when the fill level drops below the level set with the insertion height of the probe. The controllers controls the pump that feeds the medium into the vessel.

18.11.1 Controller Operating Display and Input Window

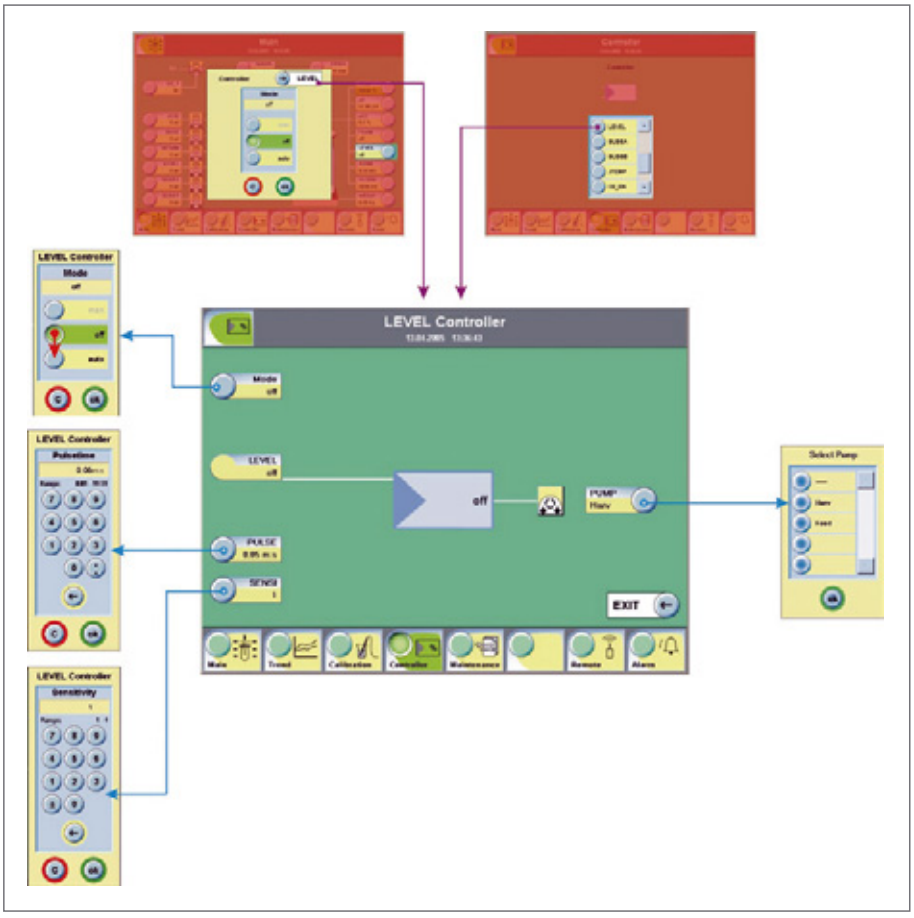


Fig. 18-11: Selection of operator screen and input windows on the level controller

Field	Value	Function, display, entry required
Mode		Controller operating mode:
	off	Controller switched off, harvest and feed pump off
	auto	Controller switched on
	man	– Manual access to controller outputs
LEVEL	on | off	Signal of the level probe (on: Medium higher than insertion height of probe)
PULSE	m:s	Run-time | cycle "Pulse time" for pump in [minutes:seconds]
SENSI	1 … 4	Trigger sensitivity, "Sensitivity" for the level measurement amplifier
[Controller]	on | off	Pump output (on: pump is controlled)
PUMP		Selection of pump that the controller controls:
	Harv	– Pump removes medium from the vessel when probe signal is "on"
	Feed	– Pump supplies medium to the vessel when probe signal is "off"
	[----]	– No pump assigned, pump free for other controller

18.11.2 Operating Notes

– Set the trigger sensitivity SENSI of the level probe as low as possible to avoid inadvertent activation of the control function, e.g. by foam coming into contact with level probe.

Settings for filling or harvesting times "PULSE" depend on the process conditions. They must be determined empirically.



Note the minimum and maximum filling volume in the reactor, which may not be undershot by removing media or overshoot by excess supply.

Special Notes

– The controller regulates the output to the pump with a response lag time of 5 s. This prevents undesired controller interventions when liquid splashes on the level probe.
– Harvest and | or dosing volumes depend on the pump run time and hose dimensions. After calibrating the pump [▶ Section "17.6 Totalizer for Pumps and Proportioning Valves"], a filling counter displays the pumped volume.
– The controller always regulates the pump output in the same way.
The operational mode of the pump ("Harvest" or "Feed" operation) can be defined by assigning the output in the menu "Select Pump".
– The filling counters "Harv" and "Feed" are activated automatically by toggling between operating modes "auto" or "manual".

18.12 Combined Controller for Antifoam and Level (FOLE)

The anti-foam and level controls are combined into one control function. For your process, you must select the type of control you want.

18.12.1 Controller Operating Display and Input Window, Controller Selection AFOAM

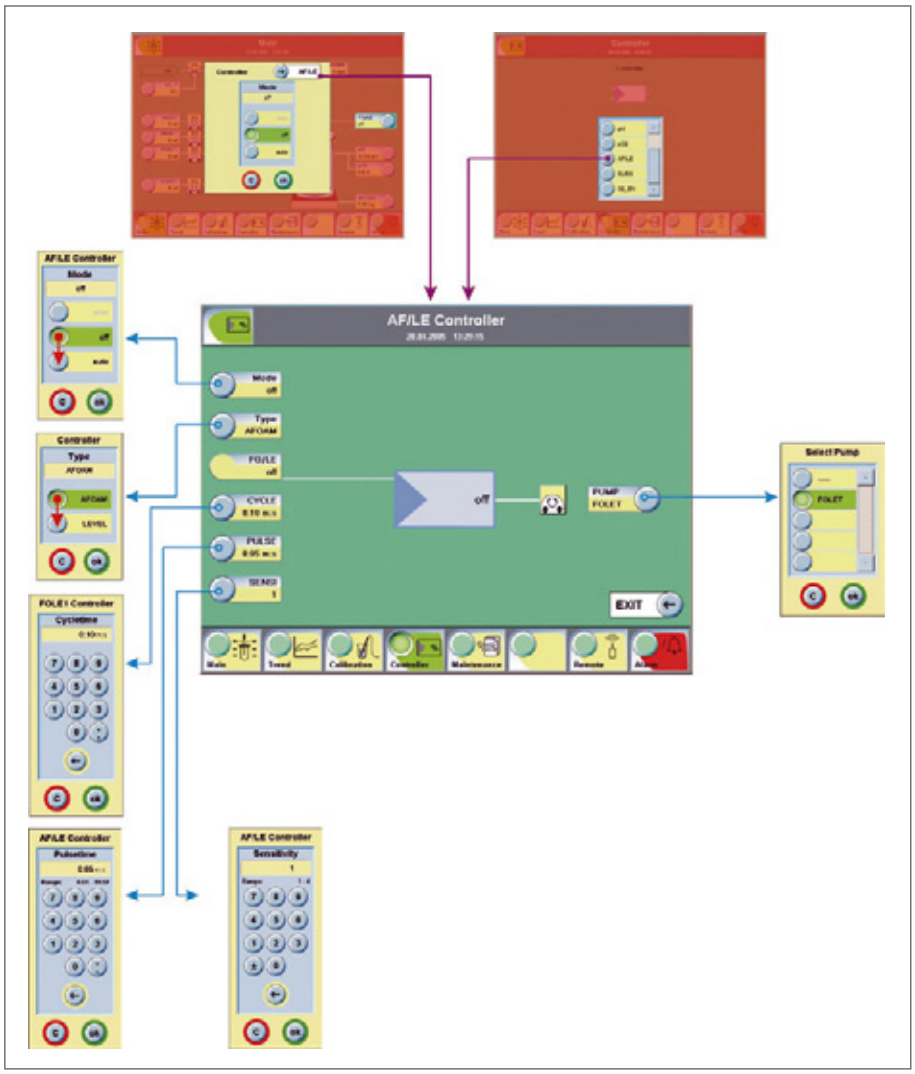


Fig. 18-12: Operator screen and input window for the AF | LE controller

Field	Value	Function, display, entry required
Mode		Controller operating mode:
	off	– Controller switched off, harvest and feed pump off
	auto	– Controller switched on
	man	– Manual access to controller outputs
Type	AFOAM | LEVEL	Selecting the controller
[Controller]	on | off	Pump output (on: pump is controlled)
CYCLE	m:s	Cycle time (pulse + pause time) of the controller
PULSE	m:s	Run-time | cycle "Pulse time" for the pump in [minutes:seconds]

Field	Value	Function, display, entry required
SENSI	1 ... 4	Trigger sensitivity of level measurement amplifier
PUMP		Selection of pump that the controller controls:
	Folet	– Pump supplies correction media when probe signal "on"
	[----]	– No pump assigned, pump free for other controllers

18.12.2 Controller Operating Display, Input Window, Controller Selection LEVEL

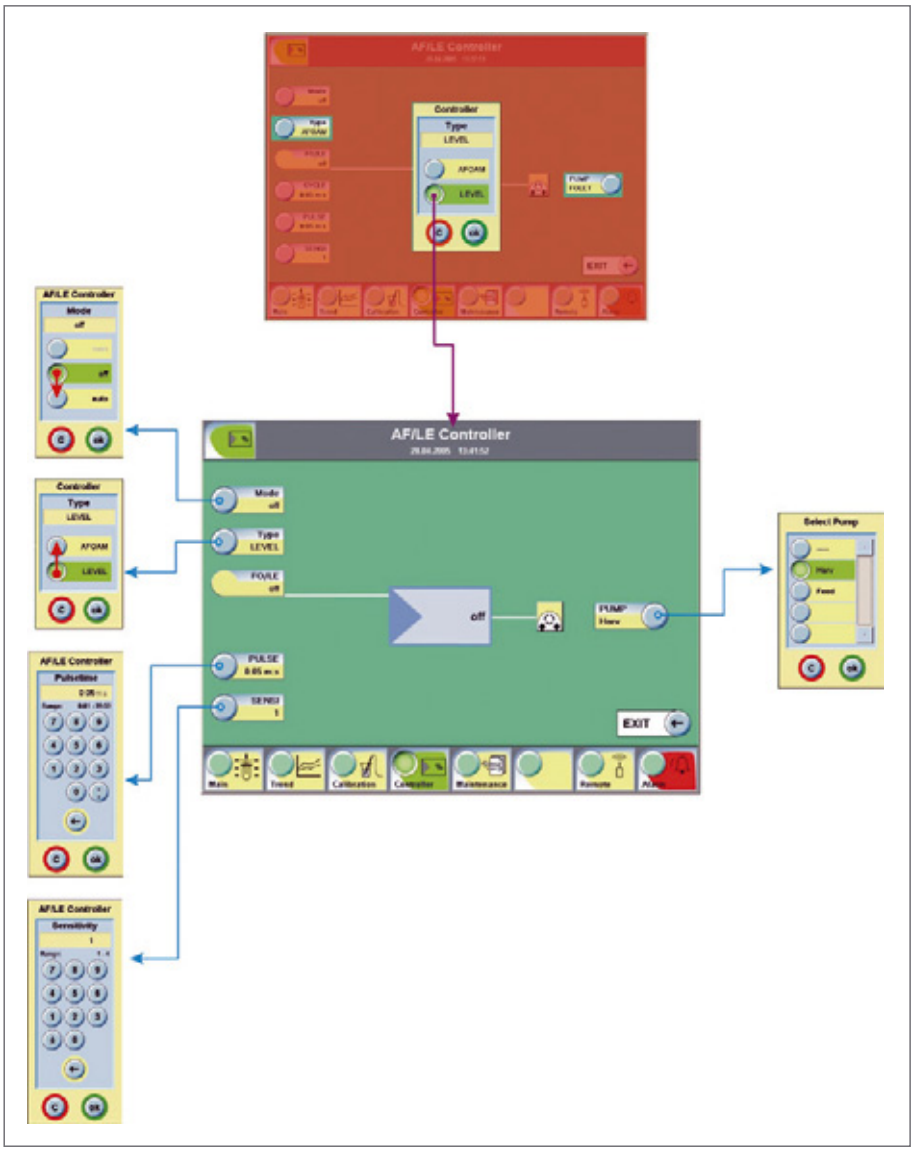


Fig. 18-13: Selection of operator screen and input window of the AF | LE controller

Field	Value	Function, display, entry required
Mode		Controller operating mode:
	off	– Controller switched off, harvest and feed pump off
	auto	– Controller switched on
	man	– Manual access to controller outputs
Type	LEVEL | AFOAM	Selecting the controller
[Controller]	on | off	Pump output (on: pump is controlled)
PULSE	m:s	Run-time | cycle "Pulse time" for the pump in [minutes:seconds]
SENSI	1 ... 4	Trigger sensitivity of level measurement amplifier
PUMP		Selection of pump that the controller controls
	Harv	– Pump removes medium from the vessel when probe signal is "on"
	Feed	– Pump supplies medium to the vessel when probe signal is "off"
	[----]	– No pump assigned, pump free for other controller

Special Notes
Follow the instructions in the sections on antifoam and level controllers.

18.13 Filling Pump Controller

Filling pump controllers can continuously or discontinuously control running pumps for the addition of substrate via a setpoint signal. For continuously running pumps, the process value display shows the actual value; for discontinuously running pumps this corresponds to the setpoint.

The filling level depends on the tubing diameter. For all pumps that report a run-time signal to the system and have been calibrated [▶ Totalizer SUBAT, SUBBT, etc.], the system can calculate and display the current filling volume from the specific filling rate.

The filing pump controllers can work as a slave controllers in the DO control loop (pO_2).
A setpoint time profile can be specified for the pump. The controller can be switched to any unused internal pump.

18.13.1 Controller Operating Display and Input Window

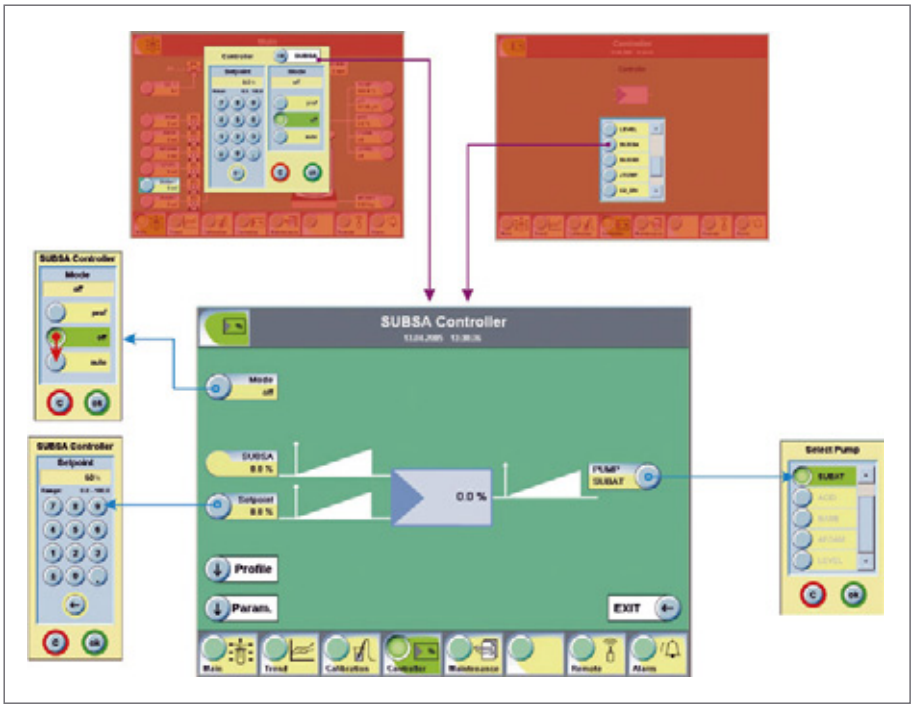


Fig. 18-14: Selection of operator screen and input window of the SUBSA controller

Field	Value	Function, display, entry required
Mode		Controller operating mode:
	off	– Controller switched off, substrate pump off
	auto	– Controller switched on
	casc	– The substrate controller is switched in cascade to the DO controller; the DO control (pO_2) controls the substrate controller
	profile	– Automatic operation with defined setpoint profile, see below
SUBSA, etc.	% (ml)	Actual value controller output (or filling volume after calibration)
Setpoint	%	Setpoint controller output
Profile		Access to sub-menu for control profile
Param		Access to the parameterization menu with standard password [▶ Section "20.6 Password Protection"]
[Controller]	%	Output of pump activated with "actual %"
PUMP		Select pump which the substrate controller should operate:
	SUBAT	– Pump output SUBAT assigned to the substrate controller
	ACID	– ACID pump assigned (not used by pH control)
	BASE	– BASE pump assigned (not used by pH control)
	AFOAM	– AFOAM pump assigned (not used by foam control)
	LEVEL	– LEVEL pump assigned (not used by level control)

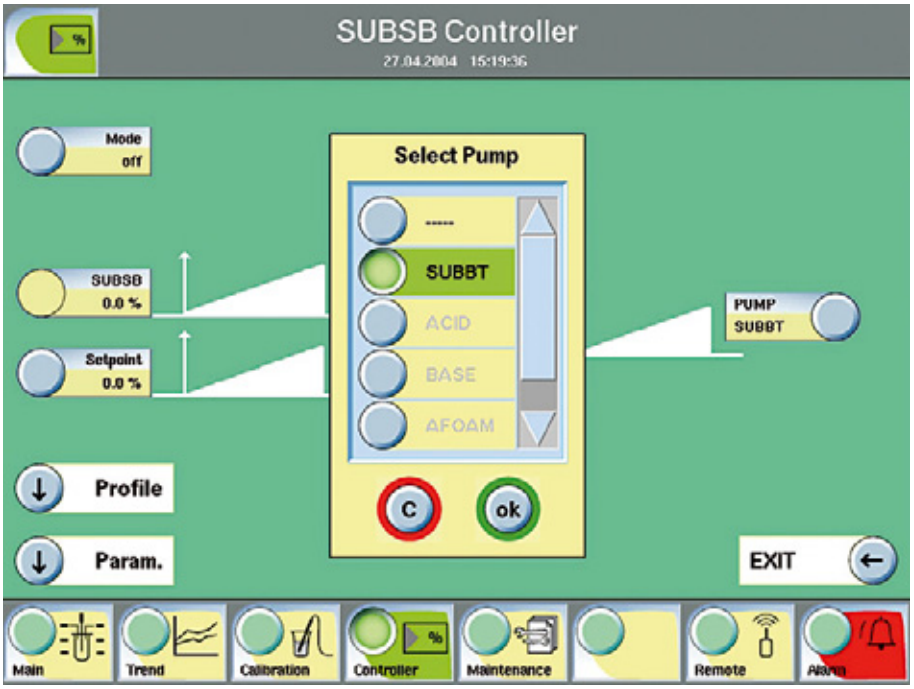
18.13.2 Operating Notes

Entering the "Setpoint"

– Set down a suitable pulse-pause ratio for the process at which the substrate should be added. Examples:
  – Setpoint 20%: Pump run-time of 2 s (PULSE), wait time of 8 s (PAUSE).
  – Setpoint 100%: Pump in long-term operation
– Enter the setpoint via the sub-menu of the touch key "Setpoint".

Switching the Substrate Controller to Another Internal Pump

To switch the substrate controller to an unused pump, you have to release the pump in the controller assigned to it. Then you can allocate the substrate controller to the free pump.



Example for "BASE" Pump:

– In the menu of the pH controller, set the "BASE" pump in the selection window "Select Pump" to [----] [▶ Section "18.6 pH Controller"].
– Select the touch key "Select Pump" in the menu for SUBSA, SUBSB, etc.
– Select the "BASE" pump from the list of the pumps and confirm with "ok".

18.13.3 Use of Setpoint Profiles

The substrate controller can be operated using time-dependent setpoint profiles which you can start and stop at any time. One profile can comprise 10 steps.

The sub-menu for entering the profile is password-protected to protect the configured profiles against unauthorized change [▶ Section "20.6 Password Protection"]. The window used for inputting profile data is opened by pressing the value fields "Time" and "Setpoint", not by pressing the touch key in the "Step" column.

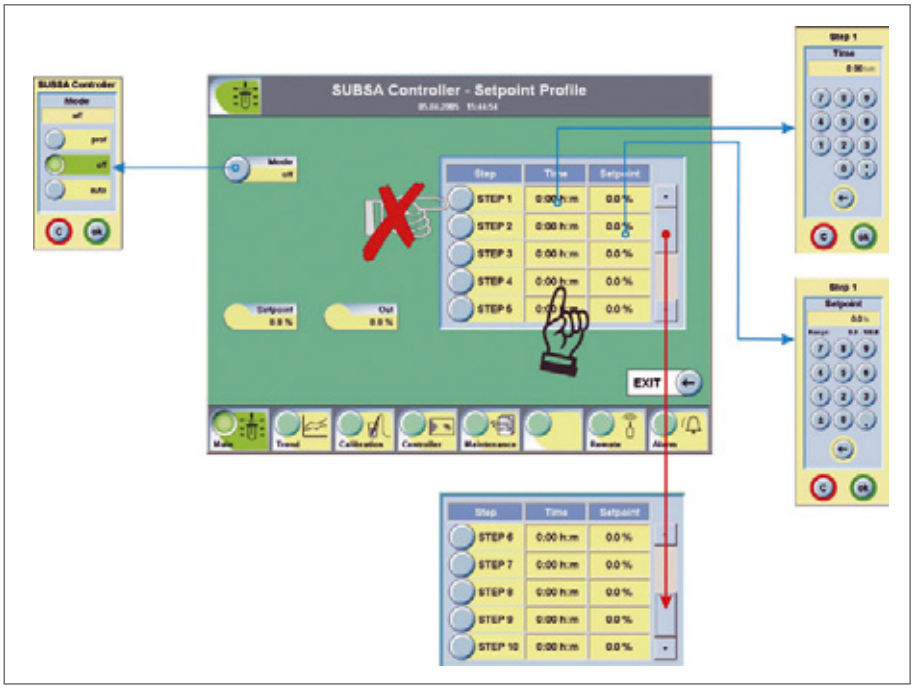


Fig. 18-15: Menu screens for inputting a setpoint profile

Input Steps

- Select "Profile" in the controller menu of the substrate controller
- Enter the standard password [▶ Section "20.6 Password Protection"].
- For each step "Step", press the touch key in the value field under "Time" and enter the length of time.
- Press the touch key in the value field under "Setpoint" and enter the setpoint.

Fed-batch operation:

- For pauses until the next filling, set "Setpoint: 0.0%"
- After inputting the profile data, activate "Mode: prof" to apply the profile.
- Switch back to "Mode: auto" or "off" to exit the profile and use the normal controls.

18.13.4 Substrate Control Parameterization



Field	Value	Function, display, entry required
Minimum	%	Minimum output limit (minimum setpoint for the slave controller): – Measuring range process value –100 … +100 %
Maximum	%	Maximum output limit (maximum setpoint for the slave controller): – Measuring range process value –100 … +100 %

18.13.5 Special Notes

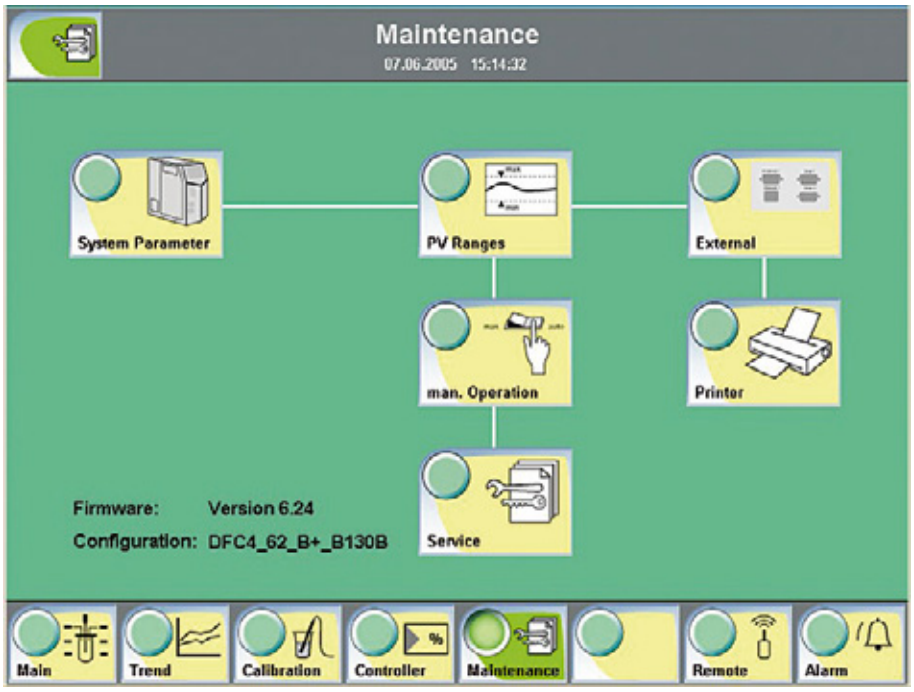
– During "solo" operation of the "SUBSA | SUBSB" controllers (if they were not selected as slave controllers in the DO control cascade (pO_2)), use the MIN | MAX output limits in the above-mentioned parameterization screen to define the setpoint limits of the substrate control.
– During operation of the "SUBSA | SUBSB" controllers as slave controllers in the DO control cascade, the output limits MIN | MAX must be input in the parameterization screen of the guide controller, i.e. of the DO controller (pO_2) [▶ parameterization screen "DO Controller (pO_2)"].

19. Main Function “Maintenance” (System Settings)

19.1 General Information

Via the main function “Maintenance” (System Settings), the micro DCU system provides the user with a number of functions for system maintenance and troubleshooting: The following functions can be called up via a selection menu:

19.1.1 “Maintenance” Selection Icon



IMPORTANT!

Malfunctions and damage to the device due to unauthorized or unsuitable settings.
The main function “Maintenance” allows interventions in 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 bioreactor.

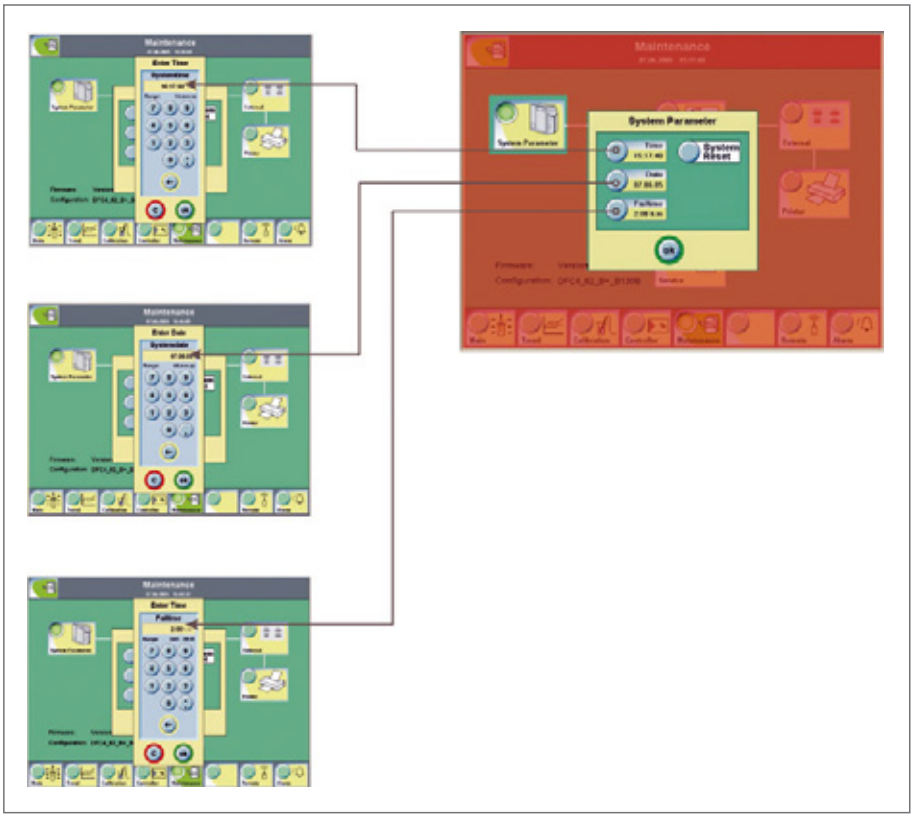
Settings that influence the intended, safe operation of the device, are protected from accidental changes by a password [▶ Section “Password”].
Only system administrators or authorized personnel trained by Sartorius Stedim Systems GmbH and experienced user may make changes to these settings.

19.2 System Settings

19.2.1 General System Settings

In "System Parameters" (System Settings), you can change general system settings, like setting the real-time clock on the micro DCU system.

Operator Screen



Field	Value	Function, display, entry required
Time	hh:mm:ss	Enter the current time in "hour:minute:second"
Date	dd.mm.yyyy	Enter current date in the format "Day.Month.Year"
Fail time	h:m	Enter power outage time to tell system how to behave when switched back on – Power outage time <Failtime: The system continues to run on the previous settings – Power outage time <Failtime: System switches to default mode
System Reset		Resets the entire measurement and control system

"System Reset" resets all parameters that can be changed by the user back to the basic configuration and is only accessible with a password [▶ Section "20.6 Password Protection"].

19.2.2 Special Notes

The system reset deletes all settings changed by the user.
For this reason, you should write down your most important user settings before a system reset:

- measurement range,
- controller parameters,
- process value and digital input alarms,
- communication parameters



After a system reset, you must check the device-specific settings and, where necessary, reconfigure them (e.g. the output limits of controllers) [▶ separate "Configuration Documentation"].



Danger of overheating due to incorrect output limit of TEMP controller.
Observe the guidelines for the culture vessels. [▶ Chapter "18.4 Temperature Controller "TEMP""; ▶ separate "Configuration Documentation"].



Danger of damage to the culture vessel if the output limit of the speed controller allows speeds that are too high.
Observe the upper limits for the culture vessels and vessel equipment [▶ Chapter "18.5 Speed Controller"].

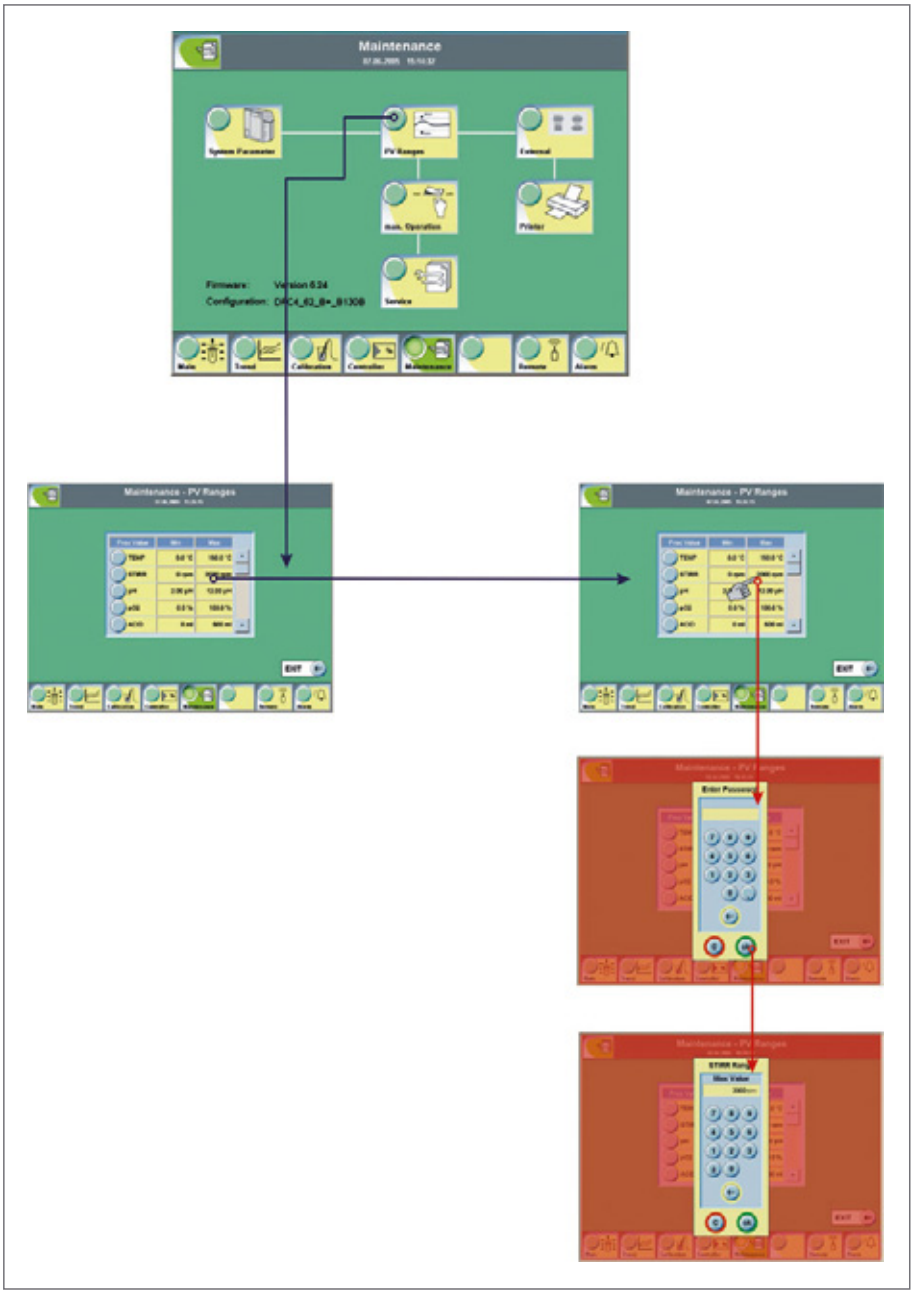
19.3 Measuring Range Settings

The measuring ranges ("PV ranges") configured specifically to devices or customer specifications are factory-set in the bioreactor [▶ cf. information in the Technical Documentation]. The beginning and end of the measuring range can be changed for all process values.



Only personnel authorized to do so may change the menu settings. The settings influence, among others, the target value for controllers (target value limits) or process value alarm monitoring.

Example of changing the settings for "Stirrer speed max."



19.4 Manual Operation

When starting up operations and troubleshooting, all analog and digital process inputs and outputs can be switched to manual operation ("Manual Operation"). You can also disconnect the outputs from the internal DCU functions and influence them directly using their operator screen.

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

Operating screen selection (overview)

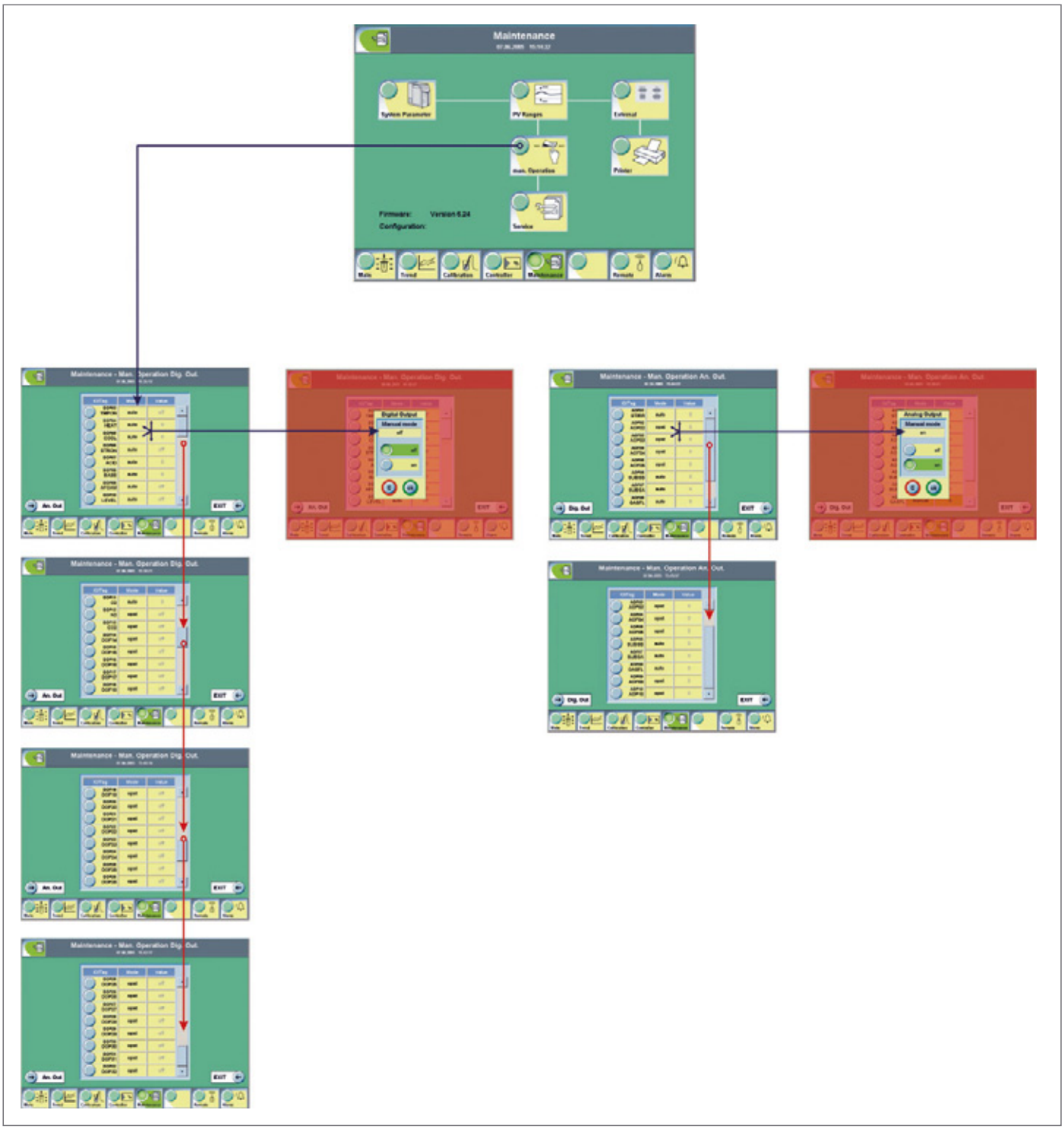


Fig. 19-1: "Manual Operation" operating screens (configuration "MO")

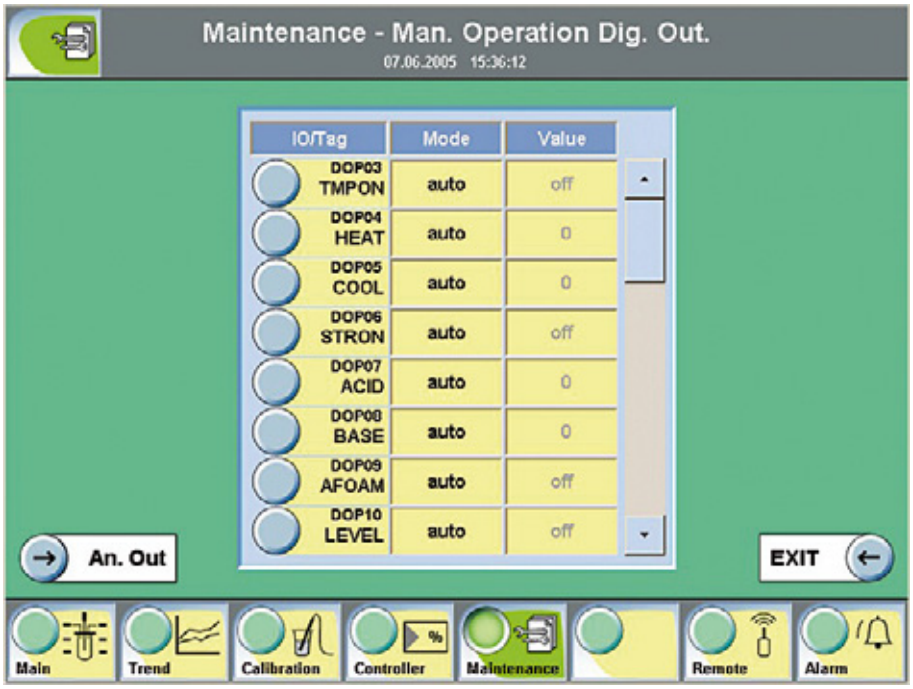
19.4.1 Manual Operation for Process Outputs

During manual operation, disconnect the digital output from the internal function and manipulate it directly. For static digital outputs, e.g. controlling valves, switch the output on or off. For pulse-duration modulated outputs, set the switch-on ratio in [%] by hand.

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 – Pump calibration – Controllers, timers, sensors, scales/balances
Lowest priority	– Operating state (opst)

Operating screen "Maintenance – Man. Operation Dig. Out."



– Page to other operating screen using the slider
– Open the input window by tapping on the table entries under the column "Mode"

Field	Value	Function, display, entry required
I/O, Tag	DOP01 TMPON, etc.	Short name for the output, operating mode "Mode" and status
MODE	Auto	–Normal operation, DFC is acting on output
	lock (display only)	– Output is locked, e.g. switch off the alarm
	shut (display only)	– Output via emergency stop (shut down) in safe condition
	Manual	– Manual operation, manual specification of output
	Pump	– Pumpen calibration routine controls output
	Host	– HOST system controls output
	opst	– Output in operating state
VALUE	Off	– Digital output turned off
	On	– Digital output turned on
	nn%	– power-on ratio (0 ... 100 %) pulse-width modulated output

Short descriptions (TAGs) for digital process outputs

Designations of the digital output TAGs	
DOM	DFC-internal digital outputs for measurement amplifier ("Digital Output Measurements")
DOP	("Digital Output Process")
DO	("Digital Outputs")

For unassigned reserve inputs, the physical channel designation serves as the TAG

Special Notes

The following signal levels apply to the switch status (status):	
Off	0 V
On	5 V for DFC-internal digital outputs (DOM), 24 V for process outputs (DOP, DO)

On pulse-duration modulated digital outputs, the relative power-on time is displayed and/or preset. The cycle time is defined in the bioreactor-specific configuration.

Example:
Cycle time 10 sec, pulse-duration modulated output 40%:
– Digital output 4 sec on and 6 sec off.



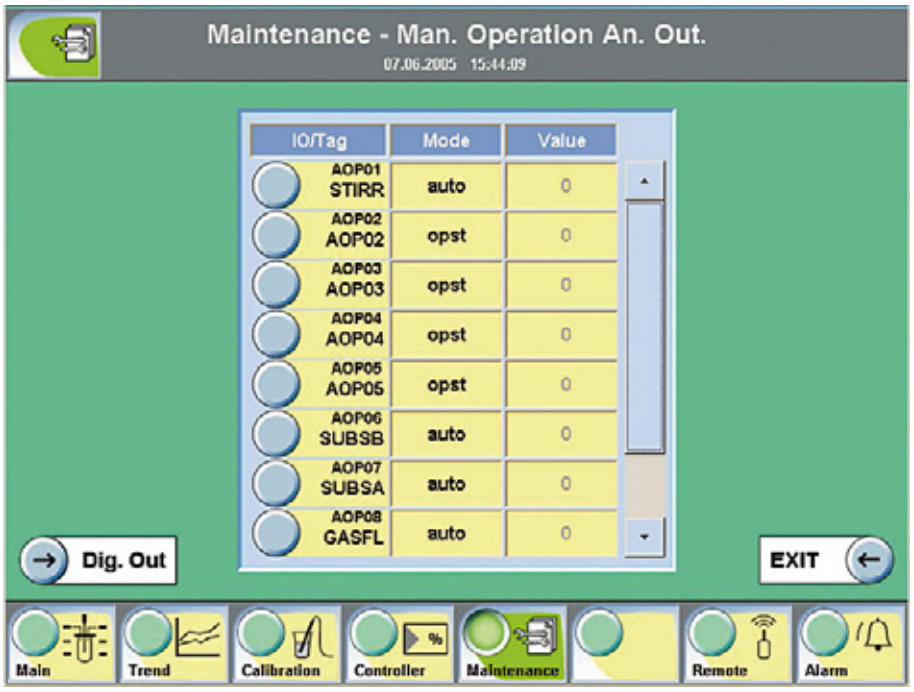
After working on the manual level, you have to switch all outputs back to the "AUTO" operating mode. Otherwise the function of the measurement and control system remains limited.

19.4.2 Manual Operation of Analog Outputs

You can disconnect all 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	– Controllers, etc.

Operating screen "Maintenance – Man. Operation An. Out."



– Using the slider, page to the second Operator Screen
– Open the input window by tapping on the table entries under the column "Mode"

Field	Value	Function, display, entry required
I/O, Tag	AOP01 STIRR, etc.	Display short name of analog output, entry for operating mode and output signal
MODE	Auto	DFC is acting on output
	lock (display only)	– Analog output put into secure status via locking function
	shut (display only)	– Analog output put into secure status via emergency stop (shut down)
	Manual	– Manual operation, manual specification of output signal
VALUE	0 ... 100 %	corresponding to 0 ... 10 V or 0/4 ... 20 mA

Special Notes
For unassigned reserve inputs, the physical channel designation serves as the "TAG":
– AOP (Analog Output Process): External analog process outputs

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 measurement and control system remains limited.

19.5 External Systems

For communication with external devices and systems, the micro DCU System comes standard with 4 interfaces, Ethernet, host (via RS232 or 422), serial (SER) and printer (PRN).

Overview

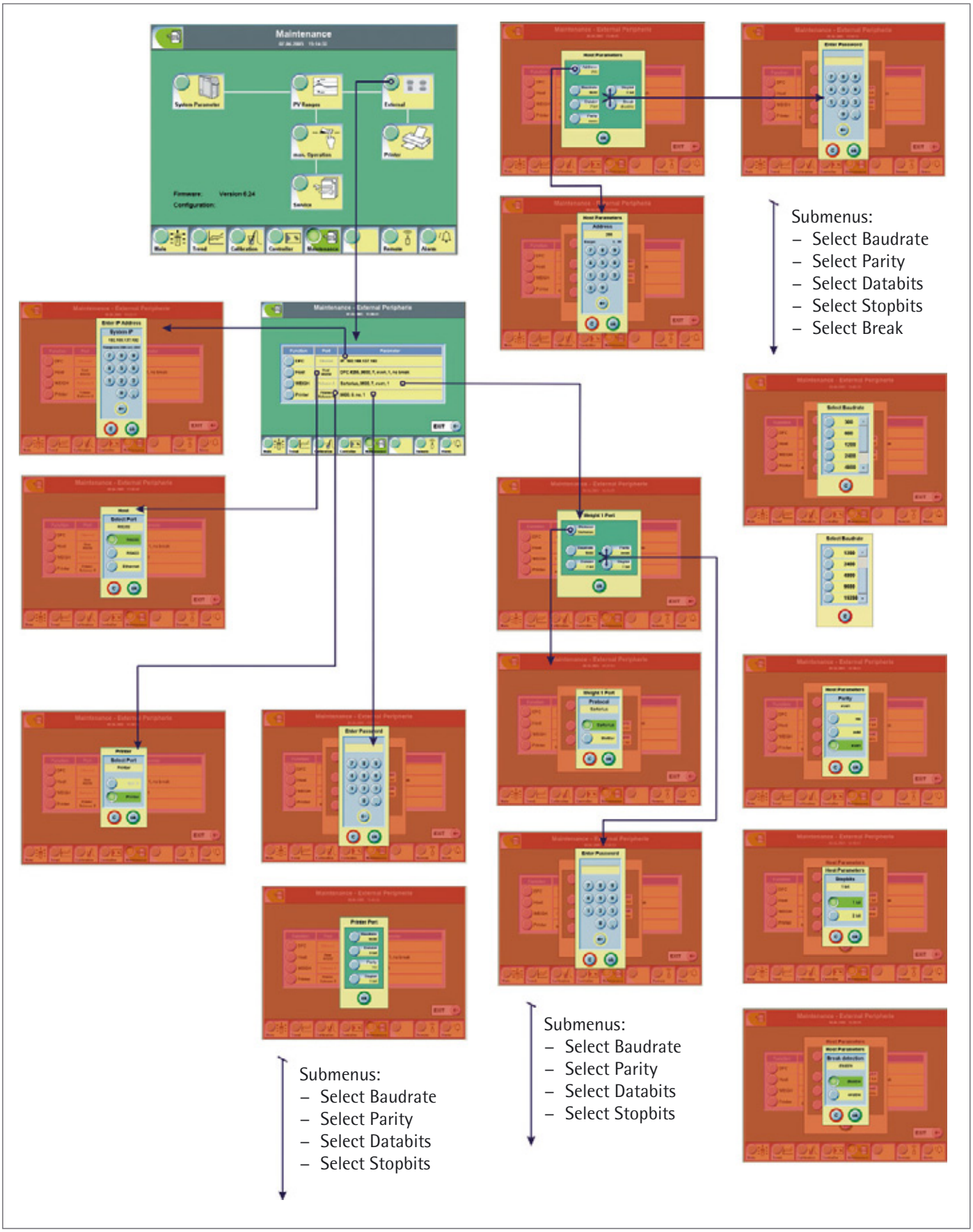


Fig. 19-2: Overview of the submenu for configuration of the interfaces to external systems

19.6 Connecting Printers

When connecting a log printer, enter the parameters for the printer log via the function "Documentation | Protocol". You will find instructions on connecting external devices, a connection diagram and information on the allocation of the interfaces and/or plugs in the "Technical Documentation on the Measurement and Control System".

Overview

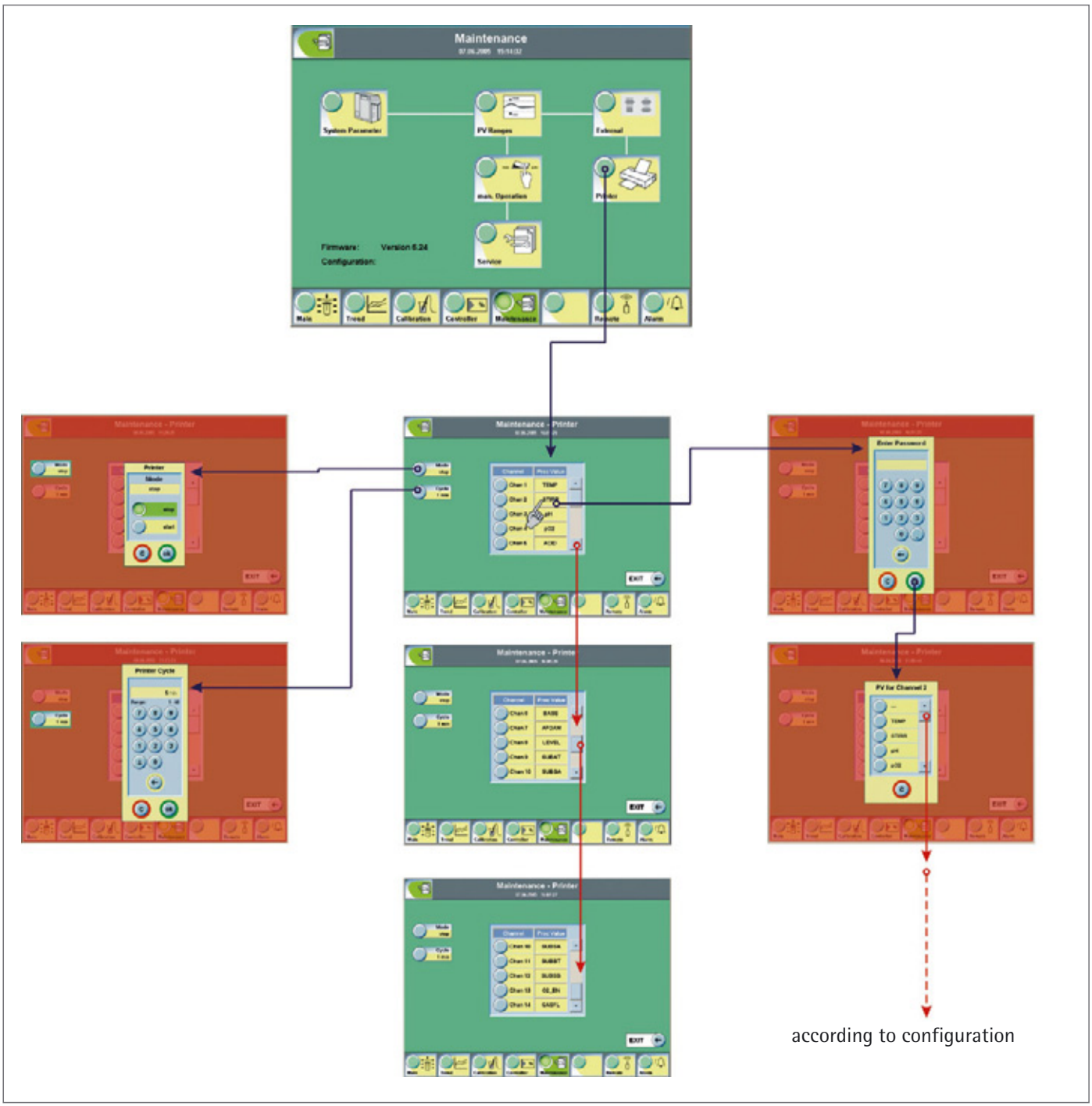


Fig. 19-3: Selecting submenus for the printer configuration

20. Appendix

20.1 Alarms, Meanings and Remedial Measures

20.1.1 Process Alarms

The user can the alarms listed in the following table switch on and off individually

Text in the alarm line	Meaning	Remedy
"Name State alarm ..."	Digital input alarm (names)	Confirm alarm with 'ACK'
"Name low alarm ..."	The process value with the (name) has undershot its lower alarm limit	Confirm alarm with 'ACK'
"Name high alarm ..."	The process value with the (name) has overshot its upper alarm limit	Confirm alarm with 'ACK'
"Heater failure ..."	Overheating protection from the temperature circulation responded	The tempering system must be refilled
"Power failure..."	A power failure has occurred	Display only; system automatically restarts when power is restored
"Motor failure ..."	Overheating protection of the motor responded	Allow the motor to cool down
"TURB Sens. failure ..."	Pt-100 not inserted in the culture vessels or defective	Check Pt-100 and connection, change sensor if defective

20.1.2 Process Messages

Message text	Meaning	Remedy
"Shut down fermentor..."	"Emergency stop" was pressed on the bioreactor	Switch the bioreactor back on
"Name <3mA alarm ..." "(Name of analog input) <3 mA alarm"	"(Name of analog input) <3 mA alarm"	Check connection and connected unit

20.2 Error Handling and Troubleshooting

Whenever technical problems occur with micro DCU systems, Sartorius Stedim Systems GmbH needs qualified feedback from the user and/or from a service technician.

The user and | or their service department can describe the problem on the form "Function bug handling" (available upon request). With the information on this form, Sartorius Stedim Systems GmbH can usually provide the user with prompt feedback on how to troubleshoot the problem.

The user should report problems to Sartorius Stedim Systems GmbH through the responsible service staff. If the user cannot contact a service partner, the form can be sent to:

Sartorius Stedim Systems GmbH
Dept. FA (Product Engineering, Automation Projects)
Robert Bosch Strasse 5 – 7
D-34302 Guxhagen

Phone +49.5665.407.0 Fax +49.5665.407.2200

20.3 Locking Functions

Locking functions are permanently configured; the user cannot change them. The system displays all outputs that are influenced by a locking function on the manual level with the "Lock" status.

The extent of the locking functionalities is specific to the bioreactor and is predefined during configuration. This is documented in the configuration lists enclosed with every system.

20.4 Abbreviations

The functional elements and displays implemented in a system depend on the respective configuration. Standard configurations utilize the following designations.

20.4.1 Process Values

Abbreviation	Meaning
TEMP	Culture vessel temperature
STIR	Speed (rpms)
MOTCR	Motor current
pH	pH value
DO (pO_2)	Partial oxygen pressure
ACID	Acid pump filling counter (feed volume)
BASE	Alkaline pump filling counter
AFOAM	Antifoam pump filling counter
SUBS	Nutrient solution pump process value
AIRFL	Supply air feed volume process value
HARV	Harvesting pump filling counter
FEEDP	Substrate pump filling counter
GAS1	Feed volume process value 1 Gas
GAS2	Feed volume process value 2 Gas
VWEIG	Weight values

20.4.2 Digital Inputs

Abbreviation	Meaning
FOAM	Status message from foam electrode
LEVEL	Status message from level electrode, upper limit reached
TEMPC	Warning message, inspection of the Pt 100 in the culture vessel necessary
HEATC	Alarm signal - heating short circuit
MOTCR	Alarm signal - motor short circuit
FUSEC	Alarm signal - safety fuse tripped | replace fuse
DFCON	Status signal from the DFC main switch: DFC switched on
SUPON	Status signal from basic unit: Basic unit switched on

20.4.3 Digital Outputs

Abbreviation	Meaning
ACID	Acid pump filling times
BASE	Alkaline pump filling times
OXYGN	Oxygen valve filling times (gas mixture system)
NITRO	Nitrogen valve filling times (gas mixture system).
AFOAM	Antifoaming agent pump filling times.
FEEDP	Substrate pump run times
HARV	Harvesting pump run times
TIMR1..2	Timer 1 ... 2 active
TMPON	Heater switched on
STRON	Drive system switched on (Motor | stirrer shaft is rotating)
AIRIN	Supply air valve active

20.5 Interface Specifications

Observe the "Technical Documentation" on the micro DCU system (contained in the documentation binder and | or delivered separately with the measurement and control system).

If the documents do not apply to your specific micro DCU system, are incomplete or flawed, please let us know. You can notify your representative of Sartorius Stedim Systems GmbH and|or Sartorius Stedim Biotech GmbH or directly contact:

Sartorius Stedim Systems GmbH
Dept. FA (Product Engineering, Automation Projects)
Robert Bosch Strasse 5 – 7
D-34302 Guxhagen

Phone +49.5665.407.0
Fax +49.5665.407.2200

20.6 Password Protection



Only disclose this information to users or service staff to whom you would like to give access to password-protected functions and menu settings.

Certain system functions and settings that should only be accessible for authorized personnel are protected by the standard password system. These include e.g.:
- controller parameter settings in the controller menus (e.g. PID),
- in the main function "Maintenance" (System Settings),
- the process value setting "PV",
- on the manual operation level ("Manual Operation"), the interface parameter setting for digital and analog process in- and outputs or for simulation controllers.

The "Service" sub-menu of the "Maintenance" main function is only accessible with a special service password. This is only provided to authorized service technicians.

When selecting password-protected functions, a key field is displayed automatically with a prompt to enter the password. The following passwords can be defined:

Standard password, factory-set:	[19]
Standard password if changed by the customer	[_____] *)
Service password	[_____] *)

Information on "[_____]*)" is delivered separately by mail or can be found in the [▶ "Technical Documentation"]. You can enter the passwords in this form.
If required, remove this page from the manual and keep it in a special place.

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