# **Operating Instructions**

Translation of the Original Operating Instructions



Bioreactor prepared for Biobrain®



2882500-000-01



# SVILOTEVS

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# 1 About This Document

# 1.1 Scope

These instructions are part of the device. These instructions apply to the device in the following versions:

Device	Туре
Biostat® RM 20   50	DHR050LBRM
Connected to the control tower or basic design	
Optionally with	
Culture bag holder 20	DZ020L-R2BH
Culture bag holder 50	DZ050L-R2BH
Load cell module RM 20   50	DZ050L-R2LC
Integrated Biostat® RM 20   50 aeration module	DZ050L-R2CO2

#### **Firmware Version**

These instructions apply to devices with firmware version 2.00 or higher (devices with serial numbers from 0400.1014).

## 1.2 Accompanying Documents

- ▶ In addition to these operating instructions, please refer to the following:
  - When used with a control unit: Operating instructions for the Biostat<sup>®</sup> RM control unit
  - When used with decentralized control systems, such as BioPAT<sup>®</sup> MFCS: Instructions for the control system
  - Instructions for the single-use culture bag

## 1.3 Target Groups

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

Target Group	Knowledge   Responsibilities
User	The user is familiar with the operation of the device and the associated work processes. They understand the hazards which may arise when working with the device and know how to prevent them. The user is trained in the operation of the device.

Target Group	Knowledge   Responsibilities
Administrator	The administrator is responsible for integrating the device into the production process. The administrator ensures the reliable functioning of the system and device software. The administrator is trained in the operation of the device.
Operator	The device operator is responsible for ensuring compliance with workplace health and safety regulations. The operator must ensure that anyone working with the device has access to the relevant informa- tion and is trained to work with the device.

# 1.4 Symbols Used

1.4.1 Warnings

#### A WARNING

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

#### 

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

#### NOTICE

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

#### 1.4.2 Other Symbols

- Required action: Describes actions which must be carried out.
- ▷ Result: Describes the result of the actions carried out.
- [] Text inside brackets refers to control and display items.
- [] Text inside brackets indicates status, warning, and error messages.

#### Figures on the Operating Display

The figures on the operating display of the device may deviate from those in these instructions.

# 2 Safety Instructions

## 2.1 Intended Use

The device is used to cultivate cells and microorganisms in single-use systems. The device must be operated with a single-use culture bag. Only use approved culture bag (see Chapter "13.5 Approved Culture Bags," page 78).

Do **not** carry out any processes using biological materials in Safety Classes 3 or 4. Do **not** cultivate non-aqueous solutions.

Make sure that **no** unauthorized objects are attached to or placed on the rocker and the hood.

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

Only use the device with the equipment and under the operating conditions described in the Technical Data. Do **not** modify the device or make any technical changes.

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

Any further use beyond this is considered **improper**. If the device is **not** used properly: the protective systems of the device may be impaired. This can lead to personal injury and property damage.

# 2.2 Personnel Qualification

All persons working on the device must possess the necessary knowledge (see Chapter "1.3 Target Groups," page 7).

The actions described are addressed to the user. If individual actions must be carried out by other target groups or by Sartorius Service personnel, the required qualification will be indicated.

# 2.3 General Safety Instructions

- 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 local Sartorius Service.
- In addition to the operating instructions, follow all general and local regulations for accident prevention and environmental protection.
- Observe the applicable safety regulations for the operating and auxiliary materials used.

# 2.4 Significance of these Instructions

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

- Before working with the device: read the instructions carefully and completely.
- ▶ If the instructions are lost: request a replacement.
- The information contained in these instructions must be available to all individuals working on the device.

# 2.5 Proper Working Order of the Device

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

- Operate the device only when it is in proper working order.
- Observe the maintenance intervals (see Chapter "7.3 Maintenance," page 64).
- Have any malfunctions or damage repaired immediately by Sartorius Service.
- Check all screw connections at regular intervals and tighten if necessary.

# 2.6 Safety Equipment

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

Do not remove or modify the safety equipment (For safety equipment, see Chapter "3.11 Safety Equipment," page 23).

# 2.7 Danger due to Electrical Power

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

- Make sure that the power connection is equipped with a ground lead.
- Never open the control cabinet. The device may only be opened by Sartorius Service personnel. Work on the electrical equipment of the device may only be carried out by Sartorius Service.
- 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 Service.
- During maintenance, cleaning, and repair work, turn the power supply off and secure it against reactivation.
- Keep moisture away from parts under voltage, as it can lead to short circuits.

- Have the following tested by a qualified electrician according to the national regulations: electrical components, connection cables with plugs and extension, and device connector cables with their sockets, if used.
- Observe the protection class of the device (For information on the protection class, see Chapter "13.8.1 Mains Connection," page 78).

#### 2.7.1 Unsuitable Power Supply Cables

You could sustain life-threatening injuries as a result of using unsuitable power supply cables.

- Please use only the original power cable supplied to connect the device to the power supply socket.
- ▶ If the power supply cable is damaged, please contact Sartorius Service.

## 2.8 Danger due to Gasses

#### 2.8.1 Danger of Fire due to Pure Oxygen $(O_2)$

Pure oxygen can give raise to chemical reactions that could cause substances to self-combust. Areas where pure oxygen can escape must be ventilated so that the air cannot be saturated with pure oxygen.

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

- Use only grease and oil-free gasses in the cultivation process.
- When working on the oxygen line: make sure your work equipment and hands are free from grease and oil.
- ▶ Keep pure oxygen away from combustible materials and ignition sources.
- Avoid sparks in the vicinity of pure oxygen.
- Ensure that pure oxygen does not come into contact with oil or grease.
- ▶ Use only materials and substances suitable for use with pure oxygen.

#### 2.8.2 Danger due to Carbon Dioxide

Escaping carbon dioxide poses a risk of poisoning.

- Check the gas lines and culture vessels for leaks when delivered and during each service interval.
- Ensure good ventilation of the installation site.

# 2.9 Accessories, Consumables, and Spare Parts

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

- Risk of injury to persons
- Damage to the device
- Malfunctions of the device
- Device failure
- Only use accessories, consumables, and spare parts supplied by Sartorius.
- Only use accessories, consumables, and spare parts that are in proper working condition.

## 2.10 Emergency Instructions

If there is an immediate danger of personal injury or equipment damage, e.g., due to malfunctions or dangerous situations, take the device out of operation immediately.

- First press the emergency stop switch in the laboratory and shut off the laboratory's energy supply lines.
- Switch off the unit at the main switch (1). The main switch is located at the back of the device.

# 2.11 Personal Protective Equipment

Personal protective equipment protects against risks arising from the equipment and the material being processed.

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



- ▶ Wear suitable personal protective equipment.
- Also follow any instructions posted in the work area pertaining to personal protective equipment.

## 2.12 Danger due to Leaked Substances

#### 2.12.1 Danger of Scalding due to Defective Components

Defective components can cause hot media or substances to leak. Hot media can burn and cause personal injury.

- Inspect the device before starting the process.
- Check the vessel connections and the connections to the control unit.
- Regularly check tubes for leaks and replace any leaking tubes.

# 2.12.2 Danger of Chemical Burns from Contact with Feed and Culture Media

Contact with feed and culture media can cause injury and lead to scalding and chemical burns.

- ▶ Use only the specified tubes.
- ▶ Use tube clamps on connecting pieces.
- Empty the feed tubes before loosening the tube connection.
- ▶ Wear personal protective clothing.
- Wear safety glasses.

# 2.12.3 Danger of Contamination from Contact with Feed and Culture Media

Contact with feed and culture media can cause injury and contaminate surfaces.

- Empty the feed tubes before loosening the tube connection.
- ▶ Wear personnel protective equipment.

## 2.13 Danger due to Components under Pressure

#### 2.13.1 Danger of Injury from Escaping Substances

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

- Turn the device off and secure it against reactivation when working on pressurized components.
- Depressurize system sections and pressure lines to be opened before starting any repair work.
- Regularly check all lines, tubes, and connections under pressure for leaks and external damage.

# 2.13.2 Risk of Death from Energy that is Unexpectedly Released

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

- Ensure that the safety equipment is present and in working condition:
  - 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 ID labels (for type plate position, see Chapter "3.1 Device Overview," page 16) and the connection values for the device (for connection values, see Chapter "13.8 Laboratory Energy Sources," page 78).

#### 2.13.3 Danger due to Bursting of the Culture Bag

There is a risk of impermissible pressurization breaking the culture bag when using aeration devices from third-party manufacturers.

- Only use the integrated aeration module (optional) or a Sartorius control unit, since these have an overpressure relief valve.
- ▶ Use the filter heaters during cultivation when the device is operated.

# 2.14 Hot Surfaces

During operation, parts of the device can heat up, thereby making their surfaces hot. There is a danger of burns to parts of the body which come into contact with these surfaces.

- Avoid contact with hot surfaces.
- Before working with the device: allow the heating mats and device equipment to cool.
- Wear personal protective equipment.
- Cordon off the danger zone.

# 2.15 Heating Mats

In an uncontrolled state the surfaces of the heating mats can reach a temperature of up to 75°C. There is a danger of burns to parts of the body which come into contact with these surfaces.

- ▶ Wear personal protective equipment.
- Use the heating mats only with the device.

# 2.16 Moving Parts

There is a risk of limbs being crushed if personnel come into contact with the rocker while the device is in operation.

- Do not remove the safety mechanisms.
- Allow only qualified and authorized personnel to work on the device.
- Disconnect the device from power when performing maintenance and cleaning tasks.
- Do not adjust the rocker during running operation.
- ▶ Wear personnel protective equipment.

# 2.17 Unexpected Startup of the Device

After a power outage, device components can unexpectedly be set into motion and cause personal injury depending on the configuration of the system behavior.

Please note that the device begins automatically operating again using the set parameters after a power outage. This function can be activated | deactivated in the system menu under [Automatically controller-start after system power-restart?] (see Chapter "6.2.10.5 Setting the Controller Behavior after a Restart," page 53).

## 2.18 Heavy Weight of the Device

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

- ▶ Get help from additional persons when lifting and transporting objects.
- Use suitable conveyance devices, e.g., trolleys, when covering long transport routes.
- ▶ Lift the device by the base plate and never by the weighing platform.

# 3 Device Description

# 3.1 Device Overview



Fig. 1: Overview of the Biostat® RM 20 | 50 (example)

No.	Designation
1	Filter heater
2	Sterile filter for exhaust air
3	Sterile filter for supply air
4	Hood
5	Culture bag
6	Culture bag holder
7	Module with rocker
8	Control unit
9	Connections, right side
10	Load cell module (weighing device)
11	Connections, left side
12	Display
13	Heating mat



#### Intended Use of the Device

The Biostat® RM 20 | 50 is a rocker bioreactor platform for single-use culture bags. The platform is also referred to as a "rocker" in these instructions. The shaft mixing process of this platform uses mechanical energy to ensure homogenous mixing of cells. The energy supply required for this is achieved via the low-shear, rocking motion of the rocker to which the culture bag is attached. This protective type of motion provides a homogeneous distribution of cells in the cultivation medium, where the surface of the medium is continuously renewed without bubbles or forming.

The Biostat<sup>®</sup> RM 20 | 50 is a medium-scale platform with replaceable culture bag holders (size 20 or 50) for culture bags with an operational or cultivation volume of max. 10 or max. 25 liters. The system can be operated standalone on a laboratory table.

An optional internal aeration module is available that can produce an air  $|CO_2$  mixture. Both compressed air and ambient air can be used for this. An IR sensor is used to measure the CO<sub>2</sub> concentration.

#### Connection to the Control Unit

The Biostat<sup>®</sup> RM 20 | 50 can also be combined with the Biostat<sup>®</sup> RM control unit, which is operated via a separate operating display and controls the process via single-use sensors. It can be also connected to the software for automatic measured value recording (BioPAT<sup>®</sup> MFCS).

If the rocker is attached to the Biostat<sup>®</sup> RM control unit, it can be controlled using this Biostat<sup>®</sup> RM unit. "Biostat<sup>®</sup> RM serial port active" appears on the rocker display. All setpoints and control functions can be displayed and controlled via the Biostat<sup>®</sup> RM.

If the rocker is attached to the Biostat<sup>®</sup> RM control unit, both these instructions and the instructions for the Biostat<sup>®</sup> RM unit must be observed.

#### Culture Bag

Cell cultivation takes place in the chamber of the culture bag. The culture bags come gamma-sterilized and ready for use.

The film that the culture bags are made of corresponds to USP Class VI requirements. The volume data for the culture bag always refers to the gross volume. The maximum operating volume is 50% of the gross volume because the remaining space acts as the headspace.

The culture bag is designed for single use. This eliminates cleaning and sterilization required for conventional bioreactor, saving considerable effort and labor. Thanks to the single-use design of the culture bag, cross-contamination can be prevented and process reliability increased.



# 3.2 Connections

## 3.2.1 Rear Connections



Fig. 2: Biostat<sup>®</sup> RM 20 | 50 connections, rear side

No.	Designation	Description
1	Manufacturer's ID label	
2	D-LINK1	Ethernet port (Connection to Biostat® RM control unit)
3	SIG 2	Potential-free alarm output
4	SIG 3	Serial interface to the load cell module, RS-232 connection
5	D-LINK 2	RS-232 serial interface for connection to BioPAT® MFCS   Modbus Master
6	D-LINK 3	Profibus DP connection
7	AIR	Connection for compressed air   air pump intake
8	CO <sub>2</sub>	Connection for gas supply
9	Mains connection	Power supply connection with 6.3 AT fuse
10	Main switch	Switches the device on and off. The main switch illuminates when switched on.

#### RS-232 24 VDC Biscall Biscal

#### 3.2.2 Load Cell Module Connections

Fig. 3: Load cell module connections, rear side

No.	Designation	Description
1	RS-232	Serial interface for the load cell module
2	Mains connection for the load cell module	Power supply connection for the load cell module
3	Manufacturer's ID label	

## 3.2.3 Connections on the Left and Right of the Device



Fig. 4:  $Biostat^{\otimes}\,RM$  20 | 50 connections, left and right sides of the device

No.	Designation	Description
1	GAS 1	Gas mixture output for the culture bag on the left
2	TEMP1	Temperature sensor installed in heating mat H1 on the left
3	H1	Heating mat for the culture bag on the left
4	FH1	Filter heater for the culture bag on the left
5	GAS 2	Gas mixture output for the culture bag on the right
6	TEMP 2	Temperature sensor installed in heating mat H2 on the right
7	H 2	Heating mat for the culture bag on the right
8	FH 2	Filter heater for the culture bag on the right
-		



# 3.3 Load Cell Module (Optional)

The RM 20 | 50 load cell module is an optional weighing platform for the Biostat<sup>®</sup> RM 20 | 50, which is used to weigh the culture medium during the process. The weighing platform is added to the Biostat<sup>®</sup> RM 20 | 50 base plate.

The load cell module is supplied with power via a separate mains connection. Data is transferred from the load cell module to the Biostat<sup>®</sup> RM 20 | 50 via a serial interface (RS-232 data cable).

The measured values are shown on the Biostat<sup>®</sup> RM 20 | 50 display.



# 3.4 Culture Bag Holder

The culture bag holder is a platform that holds the culture bag during operation.

The culture bag holder is equipped with two heating mats.

The culture bag is fastened to both sides of the culture bag holder using clamping levers. Culture bags can be replaced at any time without the need for tools.



# 3.5 Hood for Culture Bag Holder 20 | 50

The hood is a safety cover with an opening (1) for culture bag handling, e.g., during sampling.

The hood protects the attached culture bag from mechanical influences during operation and reduces heat loss. The hood must always be used during operation.

The hood is fixed to the culture bag holder with a magnetic snap and allows for easy placement and removal of the hood.

# 3.6 Aeration Module (Optional)

#### Air and CO<sub>2</sub> Supply

Mixture control using the  $CO_2$  concentration controller (For control ranges, see Chapter "13.8.2 Aeration and Ventilation," page 79).

For the air intake, you can select either an integrated air pump that supplies the culture bag with room air or a compressed air supply on the rear side of the rocker housing for external air intake.

The overpressure in the culture bag is monitored via the device pressure sensor (see Chapter "13.7 Pressures in the Culture Bag," page 78 and Chapter "18.1.2 Overpressure Control," page 96).

You must observe the gas pressure values listed in the operating instructions. This is the only way to ensure proper functioning of the system.

- Room air supply: via a membrane pump which compresses the air at the rear "AIR IN" connection
- Compressed air: integrated pressure regulator for connection to an external compressed air source; quick coupling for direct connection of a rigid tube
- CO<sub>2</sub>: integrated pressure regulator for connection to an external CO<sub>2</sub> source; quick coupling for direct connection of a rigid tube

#### Aeration Control

The setpoint for the flow rate is freely selectable. A suitable tubing set with connectors for the culture bag are included with the culture bag itself. An integrated pressure sensor controls the overpressure in the culture bag and stops aeration when an overpressure of 30 mbar is reached.

# 3.7 Heating Mats

Heating mats H1 (1) and H2 (2) are inserted directly into the culture bag holders. The heating mats use electric resistance heating with an integrated overheating protection mechanism (bimetal release).

The device has two heating circuits that can be controlled seperately if the rocker is used in a standalone mode depending on the size and configuration of the culture bag in use.



AIR

Working Pressure 1.5 ± 0.2 bar

CO2



# 3.8 Temperature Sensor

The temperature sensor is a surface temperature sensor and measures the temperature of the culture bag.

The temperature sensor is run through the opening into the culture bag holder and connected to the device via a plug connection. The head of the temperature sensor is fixed in the opening of the culture bag holder using an O-ring.

The surface of the temperature sensor (1) must make full contact with the underside of the installed culture bag in order to ensure correct and safe system operation.



# 3.9 Filter Heaters

The heating of the culture bag produces slight condensation on the exhaust filter. The filter heaters keep the filter dry and prevent it from being blocked.

A green LED indicates when the filter heaters are in operation:

- When the LED flashes, this means it is heating up.
- If the LED lights up continuously, this indicates that the operating temperature has been reached.
- Fast flickering indicates overtemperature or faulty electronics.

The rocker PLC checks to ensure that the filter heaters are connected as soon as aeration starts. If this is not the case, an alarm message is triggered. For correct positioning of the filter heater the electrical cable needs to face downwards.

The filter heaters must be connected to the exhaust filter and to the device before aerating the culture bag. This is the only way to ensure problem-free operation of the system. The filter heaters must only be used with the device.

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# 3.10 Display

The rocker is a fully automated PLC system. Operation takes place via a display.

The display features hierarchical menu navigation and backlighting. The integrated functions include:

- Configuration of the rocking rate and angle
- Individual temperature control for culture bag depending on room temperature
- Aeration of culture bag
- Bag configuration
- Integrated air | CO<sub>2</sub> mixture (optional)
- Platform positioning for harvesting and sampling
- Alarm display
- Three different user levels
- Trend display for the display of data
- Time and date display
- Selection of control mode: local or control unit
- Service interval display

The following cultivation parameters can be set and viewed on the display:

- Rocker speed and angle
- Aeration
- Temperature

# 3.11 Safety Equipment

#### 3.11.1 Main Switch

The main switch (1) serves as a switch disconnector. The device is switched on and off via the main switch. The main switch is located at the back of the device.



The overheating protection mechanism limits the maximum permissible temperature for the temperature control system. Without overheating protection, components may be damaged.

When using a culture bag holder with heating mats: the temperature of the heating mats is limited by an integrated overheating protection mechanism (bimetal release).

# 3.12 Symbols on the Device

Symbol	Description	
<u>sss</u>	During operation, parts of the device can heat up, there- by making their surfaces hot. There is a danger of burns to parts of the body which come into contact with these surfaces.	
4	During operation, parts in the device may be electrified. Only electricians are permitted to access and work on these parts, such as to perform maintenance and repairs.	
	If parts of the body come into contact with rotating components: there is a risk of crushing. This can lead to severe injury.	



# 3.13 Temperature Control

The device comes with a dual temperature measurement and control system as standard.

If the device is connected to a Biostat<sup>®</sup> RM control unit: only the left temperature measurement can be used. The heating mats can be used to heat culture bags. Room air is used for cooling. No additional device is required.

# 4 Setup

# 4.1 Acclimatization

Condensation from humidity can form on the surfaces of a cold device when it is brought into a substantially warmer area. You should therefore allow a device that has been disconnected from its power source to acclimatize for approximately two hours before reconnecting it to the power.

# 4.2 Conditions at the Place of Installation

Procedure

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

Condition	Characteristics
Ambient conditions	<ul> <li>For ambient conditions, see Chapter 13.10, page 80.</li> </ul>
Setup surface	<ul> <li>Stable and level surface</li> <li>Sufficient footprint for the device and peripheral devices (for space requirements, see Chapter 13.1, page 75).</li> <li>Sufficient load bearing for the device and peripheral devices, even when filled (for weight, see Chapter 13.2, page 75).</li> <li>Easy to clean</li> </ul>
Space for ventilation and access to the connections on the back of the device	<ul> <li>Distance to the wall at least 100 mm</li> <li>Approx. 300 mm wall distance recommended</li> </ul>
Work area	<ul> <li>Sufficiently large work area for positioning the device, connecting components and positioning the culture bag</li> </ul>
Access to the device	<ul> <li>Access to operation-relevant parts of the device must be easy and safe</li> <li>Access to the device only possible for authorized personnel</li> </ul>
Access to safety equipment at the installation location	<ul> <li>Access to emergency shut-off equipment and shut-off devices must be easy and safe, e.g., shut-off devices for the power, water, and gas supplies</li> </ul>

# 4.3 Unpacking the Device

#### Procedure

- Unpack the device.
- If the device is stored temporarily: Observe the information on storage (see Chapter 11.1, page 73).
- ▶ Install the device at the intended installation location.

# 4.4 Laboratory Energy Sources

#### 4.4.1 Emergency Shut-Off Equipment

The following supplies are connected to the control unit:

- Power supply
- Gasses:
  - Compressed air (Air)
  - Carbon dioxide (CO<sub>2</sub>)
  - Oxygen (O<sub>2</sub>)

#### Procedure

- WARNING Risk of death from energy that is unexpectedly released!
  - Check whether emergency shut-off equipment is present and in perfect working condition, e.g., ground fault circuit interrupters (residual current protection) for mains connections and fittings for shutting off water, compressed air, and gas supplies.
  - Check whether the specifications of your power supply correspond to the information located on the manufacturer's ID labels (For type plate position, see Chapter "3.1 Device Overview," page 16).
- When corrosive gasses are used, check whether the installed fittings are suitable, e.g., stainless steel fittings. Please contact Sartorius Service in case of any questions concerning equipment.

#### 4.4.2 Power Supply

#### Procedure

- ▶ ▲ WARNING Risk of death due to electrical shock! The power supply in the laboratory must meet the device specifications. Check the power supply at the installation location:
  - Check whether the devices match your voltage supply rating (For type plate position, see Chapter "3.1 Device Overview", page 16). Do not switch on the device if the laboratory's mains voltage is incorrect.
  - The laboratory's mains connections must be grounded, free from interference, and splash-protected.
  - The laboratory's power supply (mains wall outlet) must be equipped with a protective grounding conductor.

- Do not use multiple socket outlets for connecting multiple devices to a mains wall 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.
- Ensure that the power supply cable is suitable for the device output and voltage and the mains connection at the installation location. If required: contact Sartorius Service.
- Do not repair defective mains cables or replace incorrect connectors. Please contact Sartorius Service.
- NOTICE Risk of damage to the device due to voltage dips and spikes! The laboratory supply voltage must not fluctuate by more than 10% from its nominal rating.
- ► Keep access to the emergency shut-off devices inside the laboratory and the device's power connection clear.

#### 4.4.3 Gas Supply

Gas supply comprises the following gasses:

- Suctioned ambient air or compressed air (device connection "AIR")
- $CO_2$ , possibly  $O_2$  (device connection " $CO_2$ ")

#### A WARNING

#### Danger of explosions and fire due to escaping oxygen!

There is danger of explosions and fire when high amounts of oxygen are released in an uncontrolled manner. Pure oxygen can give rise to chemical reactions that could cause substances to self-combust. Escaping gasses that contain carbon can cause chemical reactions and cause a fire.

- ▶ Keep pure oxygen away from flammable materials and ignition sources.
- Avoid sparks in the vicinity of pure oxygen.
- ▶ Keep the whole aeration line free from oil and grease.
- Check the leak-tightness of the connections.

#### **WARNING**

#### Danger of suffocation due to escaping gasses!

There is danger of suffocation due to  $CO_2$ .

- Ensure good ventilation of the installation site.
- Keep independent breathing apparatus ready for emergencies.
- Monitor the limit values at the system and in the building (sensors recommended).
- Check process gas lines and filters regularly.
- Check the leak-tightness of the connections.

#### Procedure

- ▶ NOTICE Risk of malfunctions and damage to gas-carrying components due to unsuitable gasses!
  - Ensure that all gas-carrying components are corrosion-resistant if corrosive gasses are used in the supply. Gas-carrying components made of brass may corrode when exposed, for example, to ammonia.
  - Check whether the gas supply at the installation location meets the requirements (see Chapter "13.8.2 Aeration and Ventilation", page 79).
  - ▶ If required: Install suitable filters.

# 5 Getting Started

# 5.1 Installation Kit

The scope of delivery includes the required connections and connecting pieces.

- Only use the connections and accessory parts supplied and approved by Sartorius.
- Only replace connections and accessory parts with accessories from Sartorius.

# 5.2 Installing the Culture Bag Holder

#### 5.2.1 Culture Bag Holder with Heating Mats

#### Requirements

The device is switched off.

#### Procedure

- CAUTION Risk of burns from hot surfaces! Allow the device and heating mats to cool down when the device has been in operation. Wear personnel protective equipment. Avoid direct contact with hot surfaces.
- Place the culture bag holder (1) on the rocker. Ensure that it is positioned between both holding points on the front and back of the device in the designated openings.
- Place the two heating mats (2) in the openings of the culture bag holder. The heating mats must be completely inserted in the openings of the culture bag holder.



2

Run the heating mat cables through the side openings on the culture bag holder.



Connect the cable of the left heating mat to connection H1 (1) and the cable of the right heating mat to connection H2 (2).

# 5.3 Installing the Temperature Sensors

#### 5.3.1 Temperature Sensor in Connection with Heating Mats

If the temperature sensors are positioned incorrectly, this can lead to overheating of the heating mats. In this case, the heating will stop automatically via the overheating protection mechanism (bimetal release) when the temperature reaches 70°C,  $\pm$ 5°C.

#### Procedure

- Run the temperature sensor cable through the round opening in the center of the heating mat.
- Attach the temperature sensor (1) to the culture bag holder.
- Press down on the temperature sensor from above until it is attached in the opening via the O-ring. The temperature sensor is positioned correctly when its silver side is pointing up so that it will later lie directly on the culture bag.



- ► Now connect the temperature sensor plug to connection "TEMP 1" (2) reserved for it on the left side of the device.
- ▶ Follow the procedure given above for the other temperature sensor.

#### 5.3.2 Connecting the Compressed Air and CO<sub>2</sub> Supply

#### **WARNING**

Danger of poisoning by escaping carbon dioxide!

- Check the gas lines and culture vessels for leaks.
- Ensure good ventilation of the installation site.

#### Procedure

- If you are using a compressed air supply, connect it to the "AIR" connection on the back of the device.
- Connect the CO<sub>2</sub> source to the "CO<sub>2</sub>" connection on the back of the device.

# 5.4 Connecting to the Power Supply

#### Procedure



- If the input voltage is too high: Do not connect the device to the power supply. Contact Sartorius Service.
- Insert the power supply cable plug into the "Mains Connection" (1) on the back of the device.
- Connect the power supply cable to the power supply at the installation location.



RS-232	24 VDC	Biesslat® Loadced BM 20/50 Series 027801/82/ Gene No 1027801/82/ Gene No 1027801/82/ G
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en je		C US Metrin Surfamental

- If the device is equipped with a load cell module: Connect the accompanying power supply adapter of the load cell module to the "Mains Connection for Load Cell Module" (1).
- Connect the power supply cable of the adapter to the power supply at the installation location.

# 5.5 Switching the Device On and Off

# 

#### Danger of crushed limbs by the rocker!

Making adjustments between the culture bag holder and the rocker during operation may result in hand injuries.

Allow only qualified and authorized personnel to work on the device.

Procedure

- Make sure that the device has been set up in accordance with the steps listed above and that all components have been properly installed.
- ▶ Turn the device on at the main switch (1).



- 5.6 Connecting the Device to Decentralized Control Systems (DCS)
- 5.6.1 Options for Connecting the Device to Other Devices



Fig. 5: Overview of options for connecting the device to other devices

No.	Designation	Description
1	Omron Host Link	
2	Flow modules	Connection optional
3	Profibus connection	Connection optional
4	D-LINK1	Connection socket for RJ45 plug
5	D-LINK2	Connection socket for D-SUB 9-pin plug
6	SIG 3	Connection socket for Lemo 4-pin plug
7	D-LINK 3	Connection socket for D-SUB 9-pin plug
8	Profibus DP	Communication interface for external DCS, e.g., DeltaV systems
9	Modbus RTU	Communication interface for external DCS, e.g., DeltaV systems
10	Ethernet	
11	Biostat <sup>®</sup> RM	Biostat <sup>®</sup> RM control unit
12	BioPAT <sup>®</sup> MFCS system	External SCADA system
13	Ethernet connection	
14	External power supply	Power supply for load cell module
15	Load cell module	
16	Mains connection	24 V DC connection socket
17	RS-232	Connection socket for D-SUB 9-pin plug

## 5.6.2 Options for Connecting to DeltaV Systems

The device can be connected to DeltaV systems. The following options are available:

- Connection to Ethernet and OPC server
- Profibus and a DeltaV controller with a Profibus module
- Modbus RTU and a DeltaV controller with a Modbus module

DeltaV systems are not included in the equipment supplied with your device. For more information on DeltaV systems, contact DeltaV support.



Fig. 6: Overview of options for connecting to DeltaV systems

No.	Designation	Description	
1	Laboratory	Device installation location	
2	Profibus	Connection optional	
3	Process	Process area	
4	Driver	Provided on site (not included with the equipment supplied)	
5	Office	Data collection and analysis	

Operating Instructions Biostat® RM 20 | 50 35

#### 5.6.3 Changing the Communication Settings

Basic functions of the device can be adjusted in the communication settings.

#### Requirements

You have "supervisor" user authorization (For authorizations, see Chapter "6.2.8 User Management | "User level" Menu," page 46).

#### Procedure

- Press the home button in the footer.
- ▷ The "Main Screen" menu appears.
- Press the [Settings] button in the "Main Screen" menu.

Main-screen ser-level: Loo	ked	DD.MM. Bag-com	20YY/HH:m nfig:
SPEED	r/m	ANGLE	odeg · · ·
TEMP 1	••• • •	TEMP 2	
GASFLOW1	ml/m	GASFLOW	2 ml/m
POSITION		Next	>
Overview	Alarm	Userlevel	Settings
			T

Control mode User-level: Locked	DD.MM.20YY/HH:mm Bag-config:		
Bioreactor is controll	ed by:		
Local	Display		
Seriel port prepared for: DCU MFCS MODBUS			
Please reboot the rocker.			
Back Com Setup IP Setup 📥			

- Press the [Control mode] button in the "Settings" menu.
- $\triangleright$  The "Control mode" display appears.
- Press the [Com Setup] button.
- ▷ The following settings can be changed on the display:
  - IP address
  - Modbus slave address
  - MFCS node number
- Change the desired communication settings, such as the IP address.
- ▶ To apply the changes: Press the [SET CONFIGS] button.
- ▶ When the message "Please reboot the rocker" appears on the display:
  - Switch the device off at the main switch.
  - ▶ Wait 10 seconds.
  - Switch the device back on at the main switch.
- $\triangleright$  The new settings are now saved and applied.


#### 5.6.4 Connecting the Device to Ethernet

#### Procedure

- NOTICE Damage to the device or malfunctions due to incorrect connection! Observe the information on the communication interfaces (see Chapter "13.12.1 D-LINK 1: Ethernet," page 81).
- Connect the Ethernet cable to the [D-LINK 1] (Ethernet) port.
- ▶ We recommend using an OPC server including Omron FINS Ethernet protocol. These servers are provided by various manufacturers. For further information, see www.opcfoundation.org and www.omron.com.

#### 5.6.5 Connecting the Device to the Biostat® RM Control Unit

#### Procedure

Connect to the Biostat<sup>®</sup> RM control unit via the "D-LINK 1" connection. Use the supplied connection cable for the control unit for this and follow the instructions in the Biostat<sup>®</sup> RM control unit manual.

## 5.6.6 Connecting the Device to Decentralized Control Systems

#### Procedure

- NOTICE Damage to the device or malfunctions due to incorrect connection! Observe the information on the communication interfaces (see Chapter "13.12.2 D-LINK 2: RS-232 Serial Interface," page 82).
- Connect a suitable connection cable to the [D-LINK 2] port.
- ► NOTICE Damage to the device due to incorrect connection! The PIN assignment of the [D-LINK 2] port is different from the standard PIN assignment of RS-232 interfaces for D-SUB 9-pin connectors. PIN no. 1 and the sheath are connected to the ground connection (GR) of the supply unit inside the serial communication board. For this reason the cable screen can be grounded by grounding the control unit ground connection (GR).

#### 5.6.7 Connecting the Device to Profibus Networks

- NOTICE Damage to the device or malfunctions due to incorrect connection! Observe the information on the communication interfaces (see Chapter "13.12.3 D-LINK 3: Profibus DP," page 84).
- To integrate the device in a Profibus network, you must download the GSD file for Omron Profibus slave module CJ1W-PRT21: http://www. myomron.com//downloads/4.Products/Network/Profibus/GSD/PLC/ CJ1W-PRT21%20GSD.zip.
- ▶ Load the GSD file in your Profibus configurator.
- Enter the required values for the device in the Profibus configurator (For values, see Chapter "13.12.3 D-LINK 3: Profibus DP," page 84).

## 6 Operation

## 6.1 Process Sequence Overview

The process sequence and the operation of the device involves the following steps:

Process Sequence Steps	Chapter, Page	
Installing the culture bag on the culture bag holder	6.3.1, 54	
Installing the filter heater	6.3.2, 54	
Connecting the air supply	6.3.3, 55	
Inflating the culture bag	6.3.4, 56	
Filling the culture bag with the culture medium	6.3.5, 56	
Setting the cultivation parameters and starting cultivation	6.3.6, 57	
Sampling and Inoculation	6.4.3, 60	
Completing the process, cell harvesting, and shutting down the device	6.5, 60	

## 6.2 Operating the Control Elements

The rocker display is only used in conjunction with the Biostat<sup>®</sup> RM 20 | 50 for data entry. If the rocker is connected to the Biostat<sup>®</sup> RM control unit, it is operated via this device's operating display. The control mode of the bioreactor must be set to "DCU Tower" (control unit) in the menu (see Chapter "6.2.10.4 Selecting the Control Mode," page 51).

#### Welcome Screen

The welcome screen is displayed for approx. five seconds when the device is turned on. The firmware version of the CPU, the configuration version of the display, and the culture bag configuration are displayed.

The bag configuration includes information about which culture bags can be used with the current bioreactor settings (control parameters).



SPEED	1	ANGLE	1
	r/m ••••		●°deg
TEMP 1	°C ·	TEMP 2	°C .
GASFLOW1	ml/m	GASFLOW:	2 ml/m
POSITION		Next	>
Overview	Alarm	Userlevel	Settings

DD.MM. 20YY /HH:mm Bag-config: C02 Messuresystem warm-up phase

TT.MM.20JJ/HH:mm

Bag-config:

Main-screen User-level: Locked

LOADCELL

Overview

Main-Screen User-Level: Locked

### 6.2.1 "Main Screen" Menu

The "Main Screen" menu is the central user interface from which the submenus and footer menus can be selected.

The "Main Screen" menu may take up several pages depending on the equipment.

Procedure

 Press the [Next] button to access the next page of the "Main Screen" menu.

Menu Page 1	Menu Page 2	Footer Menu
SPEED	LOADCELL	Overview
ANGLE	CO2	Alarm
TEMP1		User level
TEMP 2		Settings
GASFLOW1		
GASFLOW 2		
POSITION		

#### Header

The header displays the following status information:

- Menu area
- Date, time
- "User Level" status
- Bag configuration ("Bag-config:")

SPEED	25 r/m	ANGLE	08.0 °des
TEMP 1	37.0 °C	TEMP 2	37.0 °C
AIRFLOW1	0.200 slpm	AIRFLOW2	0.201 slpm
POSITION		C02	0.50

Userlevel

Alarm

Overview

#### Working range

In addition to the submenu buttons, the actual values for the different parameters are always displayed.

- Grayed out buttons indicate
- that a function is deactivated
- that the user lacks the authorization to access the settings in question

## Footer

Additional settings can be defined, user rights managed, and alarm messages viewed in the function area of the menu in the footer.



Settings

The <u>button</u> can be used to access the "Main Screen" menu from every submenu and footer menu.



### 6.2.2 "Overview" Menu

The "Overview" menu displays the most important parameters as actual values. A green dot next to the nominal values indicates whether or not the respective controller has been started.

The asterisk (\*) in the figures shown here acts as a placeholder for the actual value.

#### 6.2.3 Aeration

6.2.3.1 Aeration with Air ("GASFLOW 1," "GASFLOW 2" Menu) There are two flow circuits that can be controlled independently.

#### Procedure

- Press the [SET] button to enter the setpoint. Maximum aeration rate (see Chapter "13.8.2 Aeration and Ventilation," page 79).
- Activate controller "Gasflow# control:"
- Press the [Supply over:] button to configure the setting for the air supply.
- Press the [Process air] button to switch to the internal air pump if necessary "Process air" means that the reactor is supplied by extern
- necessary. "Process air" means that the reactor is supplied by external process air (1.0 1.5 bar).
- If this pump is activated, make sure that no external compressed air source is connected because this input is used as the intake line for the pump.

The "Bag-inflation OFF" function can be used to automatically inflate a completely empty culture bag. To do this, the correct bag configuration must be specified in the "Settings" menu. A timer function is then used to pump the proper amount of air into the culture bag. The aeration will also stop when the pressure in the culture bag reaches 30 mbar.

The red bar shows the current activity of the valve.

#### "Gasflow1-2 trend" Submenu

The trend for Gas1 and Gas2 is set up with a time window of 30 minutes.





6.2.3.2 Aeration with CO<sub>2</sub> ("CO<sub>2</sub>" Menu)

Procedure

- CO2-menu User-level: Locked Bag-config: Setpoint (%): \*\*\*\* SET Pres.value (%): \*\*\*\* CO2 control: OFF Trend PID parameter
- Press the [SET] button to enter the setpoint. (For setpoint, see Chapter "13.8.2 Aeration and Ventilation," page 79).
- $\triangleright$  The % display of CO<sub>2</sub> is the amount in the entire gas flow.

#### "CO<sub>2</sub> Trend" Submenu

The trend for  $CO_2$  is set up with a time window of 30 minutes.



# 

#### CO<sub>2</sub> Aeration in Optional TWIN Operation

 $CO_2$  aeration of culture bag II (2) is subordinate to aeration of culture bag I (1).

If the rocker is running in optional TWIN operation with two culture bags aerated with  $CO_2$ , the supply to culture bag II is only permitted when culture bag I has already been aerated.

If the aeration in culture bag I is interrupted, the  $\rm CO_2$  supply in culture bag II also fails.



### 6.2.4 Rocker Speed, Rocker Angle | "SPEED" and "ANGLE" Menus

The "rocking process" can be started and stopped in both menus. The controller regulates the rocking rate as well as the angle for the desired setpoints.

One rock (rocker movement) corresponds to one movement from the center to the front position – then to the back position – and then back to the center.

#### Procedure

Press the [SET] button to enter the setpoint in the keypad. (For control range, see Chapter "13.9.1 Rocker Function," page 79).

Angle-menu User-level: Locked	TT.MM.20JJ/HH:mm Bag-config:
Setpoint: 07.0°deg SET	12.0*
Pres.value: 07.0 ° deg	
Rockingprocess:	20" SP PV
Trend	

The "Sample Position" function automatically moves to the sampling position. When this button is pressed, the platform moves to a suitable 10° forward position. At the same time, the heating is turned off to avoid inhomogeneous temperature distribution. When the button is pressed again, the process continues. The "Sample" function is also equipped with an automatic safety timer. Once the time is set in the Sampling Time menu (see Chapter "6.2.3.1 Aeration with Air ("GASFLOW 1," "GASFLOW 2" Menu)," page 40) expires, the rocker turns back on automatically.



#### "Speed-Angle Trend" Submenu

The trend for speed and angle is displayed together. A max. of 30 minutes is displayed on the screen. This scaling is fixed and cannot be changed by the user.





TT.MM.20JJ/HH:mm

Bag-config:

Temp1-Temp2 trend

Locked

Temp2

User-level:

50.0°C

25.0°C

Temp1

## 6.2.5 Temperature | "TEMP 1" and "TEMP 2" Menus

There are two heating circuits on the reactor that can be controlled independently depending on the bag configuration (see Chapter "6.2.10.3 Setting the Culture Bag Size," page 50).

Procedure

- Press the [SET] button to enter the setpoint. (For control range, see Chapter "13.9.3 Temperature Control," page 80).
- Activate controller "Temp1 control:"
- ▷ If the temperature sensor is **not** connected, this will trigger an alarm.



The trend for Temperature1 and Temperature2 is set up with a time window of 30 minutes.



## 6.2.6 Tray Position | "POSITION" Menu

The settings in the "POSITION" menu can be used to set the tray at a specific angle and hold it in position.

The rocking process must be deactivated in order to start positioning.

If the positioning operation must be stopped, [Start pos process] must be deactivated. This moves the tray to the center position.

## 

#### Danger of injury from rocker!

Making adjustments between the culture bag holder and the rocker during operation may result in injury.

Do not insert your hand between the culture bag holder and the rocker during operation. Procedure

- ▶ Press the [Start pos process] button to activate the function.
- ▶ Press the [SET] button to configure the setpoint.
- Select the direction in which the tray should be moved.

## 6.2.7 Weighing Function | "LOADCELL" Menu

#### Procedure

Press the [LOADCELL] button in the "Main Screen" menu to access the "Loadcell" submenu.



Load cell User-level:	Locked	DD.MM.20YY/HH:mm Bag-config:
-	*	- * * * Kg
OFF	> 0 < Zero	> T < Tare Function
		·

► Configure the desired settings:

Function	Meaning				
OFF ON	<ul> <li>Switch the weighing function off   on</li> </ul>				
Zero	<ul> <li>Show the "Loadcell Zero" submenu</li> <li>Delete the measured values (including "History" data) and create a new zero point</li> </ul>				
Tare	<ul> <li>Show the "Loadcell Tare" submenu</li> <li>Calculate the weight on the weighing platform</li> </ul>				
FN Function	<ul> <li>Switch between the gross or net weight</li> </ul>				
History	<ul> <li>Show the "Loadcell History" submenu</li> <li>Display:         <ul> <li>The last 10 tare measurements</li> <li>The sum of all tare values</li> <li>The current zero point value</li> </ul> </li> </ul>				

#### 6.2.7.1 "Loadcell Zero" Submenu

Procedure

DD.MM. 20YY /HH:mm

Zero

DD.MM. 20YY /HH:mm

Tare

-

Bag-config:

Bag-config:

Run the zero point function only at the beginning of the process. Note that overwritten zero point values cannot be restored.

Loadcell Zero User-level: Locked Bag-config: Manual Zero Input - \* \* \* \* \* Kg Cancel Set Zero

ATTENTION!

Press Tare for 3 seconds to proceed

The first Tare will delete all tare values

ATTENTION! Zero will delete all weights and tare values. Press Zero for 3 seconds to proceed

Loadcell Zero User-level: Locked

or press Cancel to abort.

Cancel

Loadcell Tare

in the history

Cancel

User-level:

Locked

or press Cancel to abort.

 Holding down the [Zero] button for longer than three seconds allows the user to enter the zero point manually.

If the zero point is entered manually, the "History" data is not deleted.

▶ Confirm the input with [Set Zero].

#### 6.2.7.2 "Loadcell Tare" Submenu

The first weight measurement after setting the zero point deletes all values in the "History." Overwritten values ("T1" to "T10," "Tsum") cannot be restored.

- ► Holding down the "Tare" button for longer than three seconds allows the user to enter the weight value manually. If the weight value is entered manually, the "History" data is not deleted.
- ▶ Confirm the input with [Set Tare].



#### Switching between the Gross or Net Weight Display

#### Procedure

Press the [Fn Function] button in the "Loadcell" submenu to switch between the gross and net weight displays.



DD.MM. 20YY /HH:mm

#### User Management | "User level" Menu 6.2.8

The user status ("User-level:") is displayed in the header. If the user status is "locked," no changes can be made to the system.

#### Changing the User Status

#### Procedure

Press the [Enter password] button to change the user status.



1	2	3	4	5	6	7	8
A	B	C	D	E	F	9	0
G	H	Ι	J	K	L	ESC	CLR
M	N	0	P	Q	R	Y	BS
S	T	U	V	W	X	Z	ENT
			****	скжж			A

- $\triangleright$  The keypad appears.
- Enter the password and confirm the entry with [OK].
- You can enter up to eight characters.
- The default passwords in the factory settings are:
   User: SART02
  - Supervisor: SART01
- ▷ The system automatically switches to the respective user status depending on the password.

User Level	Meaning			
Locked	<ul> <li>Changes to the system cannot be carried out.</li> <li>Most menus are locked.</li> </ul>			
User	<ul> <li>All parameters can be changed.</li> <li>All menus can be accessed (except PID parameter settings).</li> </ul>			
Supervisor	<ul> <li>All functions are permitted including the PID parameter settings.</li> <li>The supervisor can also create new passwords for users and supervisors.</li> <li>Calibration functions can only be accessed by service technicians.</li> </ul>			

#### Creating a New Password

User
****
****

The [Lock User] button is used to re-lock the system for the user. Pressing the [User] button switches the user status "User" to user status "Supervisor."

If you are logged in as a supervisor on the system, a new password can be assigned for the user level.

- Press the [Create new passwords] button.
- $\triangleright$  The window for changing the password appears.
- Press the [Enter new password] button.
- $\triangleright$  The keypad appears.
- Enter the password and confirm the entry with [Enter].
- Press the [Re-enter new password] button to enter the password again.
- $Descript{S}$  The keypad appears.
- Enter the password again and confirm the entry with [Enter].
- Press the [Save new password] button to save the password.

dd/MM	24:00	Trig	Battery Low
dd/MM	24:00	Trig	Motor Controller Err
dd/MM	24:00	Trig	Loadcell Overload
dd/MM	24:00	Trig	Error Pt100_1
dd/MM	24:00	Trig	Error Pt100_2
dd/MM	24:00	Trig	Error Heater1
dd/MM	24:00	Trig	Error Heater2
dd/MM	24:00	Trig	Drive System Err

## 6.2.9 Alarms | "Alarm" Menu

The window with alarm messages can be accessed from the "Main Screen" menu. This screen is displayed automatically by the system when an alarm or message occurs. You can view the alarm list even if no alarms have been triggered by the system.

#### Procedure

- Press the [Alarm] button.
- $Descript{S}$  The alarms are listed in chronological order in the alarm list.
- ▶ Press the  $[\blacktriangle]$  or  $[\blacktriangledown]$  button to browse through the list.
- ▶ To acknowledge an alarm or message, press the [ 📥 ] button.

#### Example

If an unfavorable status is detected for the reactor, i.e., overpressure in the culture bag, the flow regulator is shut down, the alarm page is displayed with the current alarm along with its entry.

After leaving the alarm page, the reason for the overpressure must be found and the flow regulator restarted after correcting the problem.

### 6.2.10 Settings | "Settings" Menu

#### The settings window can be accessed from the "Main Screen" menu.

The following settings can be configured here:

- Setting the date and time
- Viewing and resetting the operating hours
- Setting the culture bag size
- Selecting the control mode (Biostat<sup>®</sup> RM 20 | 50 or control unit)
- Activating the automatic controller start after a restart
- Setting the start time for the rocker function ("Sampling Function")
- Viewing and resetting the process sequence time

ettings-menu er-level: Locked	TT.MM.20JJ/HH:n Bag-config:
Date and time	Service
Bag configuration	Technician level
Control mode	System
Batch-timer	

#### 6.2.10.1 Setting the Time and Date

- Press the [Date and time] button in the "Settings" menu to open the entry window.
- ▶ Press the entry fields to set the time and date.
- $\triangleright$  The keypad appears.
- Once all entries have been made, press the [Set date and time] button to confirm.
- $\triangleright$  The data is transferred to the CPU.

Date and time User-level: Locked	T1 Ba	F.MM.20JJ ag-config:	/HH:mm
hh: mm: ss: ** : ** : ** Set dat	∭ <b>***</b> * e and time	mm:   <b>**</b>	dd: **
Automatically Summe	er-Wintertim sabled	e change:	5
Back			

#### Automatic Adjustment for Daylight Saving Time

You can set whether the clock is automatically adjusted by one hour for daylight saving time on the last Sunday in March and the last Sunday in October in the "Automatically Summer-/Wintertime change:" field.

The device must be in operation at the time of the adjustment, because the clock will not adjust retrospectively.

#### 6.2.10.2 Displaying Service Information

If a service is not carried out on time, the message "Service required" appears on the screen every three minutes. No functions are disabled. However, the service should be carried out promptly.

- Press the [Service] button in the "Settings" menu to get the following information:
  - Operating hours
  - Number of rocker movements
  - Time at which the next service must be carried out

Operating Hours	Meaning
::::::	These values remain saved regardless of whether or not a service takes place.
:::::	These displays are reset by the service technician once the service is complete. (The reset takes place at a password-protected technician level).



#### 6.2.10.3 Setting the Culture Bag Size

#### Requirements

Both Pt100 temperature sensors are installed.

#### Procedure

Press the [Bag configuration] button in the "Settings" menu to set the bag configuration. The following configurations are available:

Configuration	Description
1 x 1 L, 1 x 2 L, 1 x 10 L	<ul> <li>Only Heater 1 (left heating mat) in operation</li> <li>Pt100_1 and Temp_1 controller in operation</li> <li>Display Temp 1</li> <li>Display Temp 2: inactive (99.9°C)</li> </ul>
1x 20 L, 1x 50 L	<ul> <li>Heater 1 and 2 (left and right heating mat) in operation</li> <li>Pt100_1 and Temp_1 controller in operation</li> <li>Pt100_2 and Temp_2 controller in operation</li> <li>Display Temp 1</li> <li>Display Temp 2: inactive (99.9°C)</li> </ul>
2 x 1 L, 2 x 2 L, 2 x 10 L	<ul> <li>Heater 1 and 2 (left and right heating mat) in operation</li> <li>Pt100_1 and Temp_1 controller in operation</li> <li>Pt100_2 and Temp_2 controller in operation</li> <li>Display Temp 1</li> <li>Display Temp 2</li> </ul>

 $\triangleright$  The bag configuration is displayed in every window.



#### 6.2.10.4 Selecting the Control Mode

- ▶ Press the [Control mode] button in the "Settings" menu.
- ▷ The "Control mode" display appears. The following settings can be configured for the control mode:

Input	Description
Display	The device is selected as the master. All alarms and warnings are shown on the device display.
Modbus	External devices or systems are selected as the master. All alarms and warnings are displayed on the external devices and systems.
Local	All parameters are entered on the device display.
Remote	Remote control is activated for the device. The de- vice can be operated via remote control by other de- vices or systems.
DCU	Entering parameters for the serial interface, connection [D-LINK2] when connecting the device to DCU systems
MFCS	Entering parameters for the serial interface, connection [D-LINK2] when connecting the device to MFCS systems
MODBUS	Entering parameters for the serial interface, connection [D-LINK2] when connecting the device to Modbus systems
Com Setup	Changing communication settings and addresses

- Press the [Display] button to activate the Biostat<sup>®</sup> RM control unit (DCU) as the master.
- $\triangleright$  The device switches to the next display.

Control mode User-level: Locked	DD.MM.20YY/HH:mn Bag-config:
Bioreactor is control	led by:
Local	Display
Seriel port prepared DCU MFC Please reboo	for: S MODBUS
Back Com Setur	o IP Setup 📥

<b>Biostat<sup>®</sup> RM</b> DCU/MFCS or Remote Control active
Firmwareversion-CPU: * . * * * Display-configuration: * . * * * Bag-configuration: Choose controlmode



Load cell User-level

OFF

Locked

0 <

Zero

DD.MM.20YY/HH:mm

Kg

Fn

Function

Bag-config:

Te

Tare

- ▶ Press the [Local] button to activate remote control for the device.
- The device switches to the next display. The following information is displayed:
  - CPU firmware version
  - Display configuration
  - Bag configuration
  - Connection status.

The connection status is displayed with the symbol " $\checkmark$ " when a connection is successfully established. The device automatically switches to this display after a device restart. All commands, setpoints, and alarms are now managed using the selected control mode.

- If a service or calibration task is to be carried out on the device, these tasks must be performed on the device display. Due to the high amount of data, these tasks are not possible via the control unit. Press the [Choose controlmode] button to change the control mode to service or calibration tasks.
- $\triangleright$  The control mode selection display appears.



- Press the button [DCU], [MFCS] or [MODBUS] to set the parameters for the serial interface on D-LINK2 (see Chapter "5.6 Connecting the Device to Decentralized Control Systems (DCS)," page 33).
- If the communication settings and addresses for the device may be changed, press the button [Com Setup] to set the parameters (see Chapter "5.6 Connecting the Device to Decentralized Control Systems (DCS)," page 33).

System settings User-level: Locked	DD.MM.20YY/HH:mm Bag-config:
Automatically controller-start after system power-restart?	User level after system power-restart?
Time period to hold t	he sampling position:
Back	

6.2.10.5Setting the Controller Behavior after a Restart

Access to the device and the device behavior after a restart can be configured:

Procedure

- ► To define the start-up behavior for the controller after a restart: Press the [System] key in the "Settings" menu.
- $\triangleright$  The "System settings" window appears.
- Configure the desired settings. The following settings are possible:

Setting	Query	Input	Description
Controller Automatically [ON] behavior controller-start after system power-restart?	[ON]	The controller is automatically started after the device is re- started, e.g., the controller for speed, Temperature1   2, Gas- flow1   2, and CO <sub>2</sub> .	
		[OFF]	The controller is <b>not</b> automati- cally started after the device is restarted.
User level	User level after system power- restart?	[User]	The user level "User" is set after the device is restarted.
		[Locked]	The user level "Locked" is set after the device is restarted.
Sampling time	Time period to hold the sampling position. ***.* seconds	*** <sub>.</sub> * seconds	The entered time sets the time period for the sampling function (see Chapter "6.4.1 Preparing Sampling or Inoculation," page 58). Once this time period has elapsed, the rocker is automatically restarted.

6.2.10.6 Starting the Timer for the Process Sequence

#### Procedure

▶ Press the [Batch-timer] button in the "Settings" menu to view the menu.

The device has a timer that can be started in this menu and displays the process time that has expired. The batch time is also displayed in the "Overview" menu.

Press the [Start batch-timer] button to start the timer.



## 6.3 Preparing the Culture Bag

## 6.3.1 Installing Culture Bags on the Culture Bag Holder

One culture bag can be inserted in the culture bag holder depending on its size. (Detailed information on the size of the culture bags that may be installed on the rocker can be found in Chapter "13.4 Culture Bag Positioning and Operating Volumes," page 77.]

#### Procedure

- ▶ Remove the sterile culture bag from the protective plastic film.
- NOTICE Damage due to sharp objects! Open the protective plastic film carefully. Do not use a sharp instrument as this could damage the culture bag.
- Open the guide rails (1) on the culture bag holder by releasing the levers
   (2) on both sides of the holder as shown in the figure.
- If you are only placing one culture bag on the holder, place it on the left side of the holder to ensure error-free temperature measurement.
- Place one culture bag in the culture bag holder and press the plastic bars on both sides of the culture bag into the now open guide rails of the culture bag holder.
- Press the levers down again to secure the culture bag.
- Press all open levers straight down without twisting them to secure the inserted culture bag into the culture bag holder. If the levers are not straight, they cannot be properly secured.

### 6.3.2 Installing the Filter Heaters

The filter heaters must be connected to the exhaust filter and to the device before aerating the culture bag. This is the only way to ensure problem-free operation of the system.

The device controller queries whether or not both filter heaters are connected as soon as aeration starts. Both filter heaters must be connected to the device even if the device is only being operated with one culture bag. If both filter heaters are not connected, this will trigger an alarm.

The filter heaters heat the exhaust filter to more than 40°C. This helps to ensure that the filter does not become blocked.

- Install one or both filter heaters to the exhaust filter of the culture bag. To do so, complete the following steps:
  - Position the exhaust filter (1) between both parts of the filter heater (2). Both parts are held together by magnets. The exhaust filter is equipped with an overpressure valve.
  - Two magnets close at the opening of the filter heater to ensure a secure hold.
- If only one filter heater is installed, place the second filter heater on a heat-resistant surface.







- Connect the filter heater to the corresponding socket on the left and right side of the device:
  - The filter heater for the left culture bag must be connected to connection "FH 1" (1).
  - ► The filter heater for the right culture bag must be connected to connection "FH 2" (2).
- $\triangleright$  A green LED indicates when the heaters are in operation.
  - $\triangleright$  If the LED flashes, this indicates the warm-up phase.
  - ▷ If the LED lights up continuously, this indicates that the operating temperature has been reached.

### 6.3.3 Connecting the Air Supply

### \land WARNING

#### Excessive pressure may cause the culture bag to burst!

The culture bag's integrated pressure sensor for aeration control does not receive a signal to regulate the pressure of the external gas source in the case of overpressure. Direct connection of the culture bag to a source of gas or the use of different air pump can create overpressure and burst the bag. Bursting culture bags can cause media to escape and lead to injury due to chemical burns.

- Connect the air supply only to the connections on the device.
- Only use the integrated aeration module or a Sartorius control unit, since these have an overpressure relief valve.



#### Procedure

- Connect the supplied tube to connection "GAS 1" (1).
- ▶ If two culture bags are inserted, connect the second supplied tube to connection "GAS 2" (2).



Connect the other end of each tube to the sterile intake air filter (1) of the culture bag. The intake air filter is the filter without the overpressure valve.

### 6.3.4 Inflating the Culture Bag

The culture bag should be inflated before it is filled with the culture medium. This reduces the foaming of the medium.

Regulate the air intake so that the culture bag remains inflated during filling and does not collapse. The rocker function should be turned off during filling.

#### Requirements

The culture bag is inserted in the culture bag holder and secured with the clamps.

#### Procedure

- Make sure that the tube clamps on the intake air filter and exhaust filter are open and close all additional tube clamps on the culture bag.
- Turn the device on via the main switch on the back.
- The start menu appears on the display for a few seconds showing the respective program version of the device before switching to the main menu.
- Start aeration.
- NOTICE Damage to internal pump! If the internal pump is activated and compressed air is connected to the device, this can cause damage to the pump. The internal pump must **not** be selected if another compressed air source is connected to the device.
- Wait until the culture bag has inflated completely and make sure that it is secured to the culture bag holder via the levers. The culture bag should be fully inflated, i.e., it should have no folds or kinks.
- Make sure that the exhaust filter is functioning by pressing down gently on the culture bag chamber and making sure that air escapes.
- Once the culture bag is inflated, the air intake can be shut down when the desired process values have been reached.

#### 6.3.5 Filling the Culture Bag with the Culture Medium

- Make sure that there is an aseptic connection between the chamber of the culture bag and the medium container. Use a Biowelder<sup>®</sup>, Luer connections, or MPC connections to connect the tubes of the culture bag and medium container.
  - If Luer or MPC connections are used, the culture bag must be filled on a sterile workbench.
- Open the tube clamps of the intake and exhaust air filters.
- Pump the desired quantity of culture medium into the culture bag. In addition, follow the instructions concerning the permissible volumes (Please refer to the information on the approved volumes in Chapter "13.4 Culture Bag Positioning and Operating Volumes," page 77).
- Disconnect the medium container from the culture bag under aseptic conditions.
- Place the hood on the culture bag holder.

## 6.3.6 Setting the Cultivation Parameters and Starting Cultivation

If the foam build-up is too high, the rocking speed must be reduced. The culture bag must be fully inflated, since the formation of foam increases due to folds or unevenness.

#### Recommendations for Rocker Speed, Rocker Angle, and Aeration Rate

#### Air intake (aeration rate) and CO<sub>2</sub> concentration

Excessive air intake has only minimal effect on the oxygen intake. The aeration rate should be kept to a minimum to reduce the evaporation of the medium. The recommended aeration rate is 0.1 liters/minute. We recommend a  $CO_2$  concentration of 5% as it is used for most mammalian cells. However, this must be adjusted for each cell line and medium.

#### Rocker speed

The rocker speed must be set to the minimum speed that ensures thorough mixing and oxygen intake without leading to excessive foam buildup and the associated shearing forces. At the start, the rocker speed is normally 15–20 rocker movements/minute. The rocker speed required for the oxygen intake is designed for the respective cell population and its metabolism. Normally, 15–25 rocker movements/minute are enough to ensure the oxygen requirement of cell densities up to  $5 \times 10^6$  cells/ml.

#### Rocker angle

A smaller rocker angle can minimize foaming of the medium. The rocker angle can be reduced  $2-3^{\circ}$  for high foaming media. The rocker angle can be increased up to 8° for cells with a high oxygen requirement, e.g., insect cells. The maximum recommended rocker angle is 10°.

#### Cultivation parameters

Each cell line requires optimization of the cultivation conditions. The following table contains recommendations for the aeration rate and the rocker angle to start the cultivation process (room air with an oxygen content of 20%):

Liquid Volume in Culture Bag; Max. Operating Volume   Total Volume [L]	Rocker Speed [r/min]	Rocker Angle [°]	Aeration Rate [L/min]
0.5 1	10-15	6-8	0.1
1 2	15-20	6-8	0.1
5 10	15-20	6-8	0.1-0.2
10 20	15-20	6-8	0.2
25 50	15-20	6-8	0.3-0.5

#### Setting the Cultivation Parameters and Starting Cultivation

#### Requirements

The device is switched on.

#### NOTICE

## Risk of overheating due to no contact between the temperature sensor and the culture bag!

There is a risk of overheating if the temperature sensor is not correctly installed. Uniform heating of the culture medium is ensured when the rocker movements are started before activating the heating mat.

Check whether the temperature sensor is positioned correctly under the culture bag. The surface of the temperature sensor (1) must make full contact with the underside of the installed culture bag in order to ensure correct and safe system operation.

#### Procedure

- Select the size of the culture bag you are using in the bag menu.
- Adjust the rocker speed to generate a visible wave movement.
- ▶ Set the cultivation temperature in the "Temperature (T)" menu.
- Start the heating process by pressing the "ON" button to activate controller "TEMP 1" or "TEMP 2."

## 6.4 Sampling and Inoculation

This procedure requires a standard laboratory syringe with a Luer septum without a needle. This procedure must not be carried out on a sterile workbench.

#### 6.4.1 Preparing Sampling or Inoculation

- Stop the rocker movement. The rocker provides a convenient sampling function for this purpose (see Chapter "6.2.4 Rocker Speed, Rocker Angle | "SPEED" and "ANGLE" Menus," page 42).
- Do not interrupt the surface aeration.
- Remove the protective cover from the Luer septum of the sampling tubing.





 Disinfect the Luer septum. Wipe or spray the upper part of the Luer septum with 70% alcohol (or similar medium).



Connect a sterile, single-use syringe without a needle to the Luer connection under aseptic conditions.



• Open the tube clamp of the Luer septum.

#### 6.4.2 Inoculation

- Fill the culture bag with the syringe contents via the Luer septum.
- Remove the syringe from the Luer septum.
- Disinfect the Luer septum again and re-close it using the protective cover.
- Let the remaining liquid in the tubing flow back into the culture bag. To do this, press the tubing together a few times to ensure that any remaining liquid runs back into the culture bag.
- Close the tube clamp.
- ▶ Now restart the rocker movement. Set the speed so that a wave motion is visible on the surface of the liquid. Decrease the speed if too much foam builds up.

#### 6.4.3 Sampling

Sampling is carried out in exactly the same way as inoculation; a syringe without a needle is also used here.

However, you must make sure that the cells which are inside the tubing are removed before taking your representative sample.

The Luer septum is designed for 50 sterile sampling and | or inoculation procedures. It contains a silicon septum that seals the tubing automatically when the connection is severed. The sample is also protected completely because no aerosols can get in from the outside. At lower rocker speeds (<15 rocker movements/min), the cells may settle so that the sampling may not be representative. Therefore, the rocker speed should be increased to 15 rocker movements/minute approx. 5–10 minutes before sampling takes place. Then it can be reduced again.

#### Procedure

- ▶ Take two samples as described in this chapter.
  - ▶ Discard the first sample.
  - Retain the second sample. This is the representative sample.
- If you are working with large micro carriers or large cell aggregates, you should not use the sampling equipment because it has a relatively small opening. You should use the tubing with the MPC connection (external diameter 11.1 mm).

## 6.5 Completing the Process, Cell Harvesting, and Shutting Down the Device

#### 6.5.1 Stopping the Rocker Movement

- Stop the rocker movement.
- The culture bag holder stops automatically at a slightly forward angle so that the dip tube remains in the medium. For culture bags with the dip tube at the back, the rocker can be moved to another stop position (see Chapter "6.2.6 Tray Position | "POSITION" Menu," page 43).
- Switch off the temperature control.
- Switch off aeration.

## 6.5.2 Emptying the Culture Bag and Cell Harvesting

We recommend emptying the culture bag completely before removal.

#### Procedure

- Remove the hood from the culture bag holder.
- Clamp off the intake air and exhaust filters.
- Remove the air intake tubing from the sterile intake air filter.
- There are several options available for emptying the culture bag, depending on the process conditions:
  - To remove the entire contents via the harvest tubing (with a dip tube), use a suitable peristaltic pump. Hold the culture bag in an upright position until it is completely empty.
  - To get rid of the excess, remove the holder with the attached culture bag from the rocker platform and wait 10–15 minutes until the cells have settled. Pump out the excess and add fresh medium or transfer the cell culture to a larger Biostat<sup>®</sup> RM bioreactor.
- ▶ Unplug the connection cables for the filter heaters from the device.
- ▶ Remove the filter heater from the culture bag exhaust filter.
- Open the guide rails (1) on the culture bag holder by releasing the levers
   (2) on both sides of the holder as shown in the figure.
- Remove the culture bag from the culture bag holder.
- Store the culture bag under the prescribed process conditions before you begin with downstream processing.
- ▶ ▲ WARNING Contamination due to operating media or additives! The culture bags are single-use items that must be disposed after each cultivation. Sterilization may be required before you can dispose the culture bag. Used culture bags must be handled in a way that corresponds to the respective national regulations for the disposal of biological harmful single-use devices.

#### 6.5.3 Switching Off the Device

- ▶ Turn off the aeration with the compressed air (if connected).
- ▶ Turn the device off at the main switch.



## 7 Cleaning and Maintenance

Incorrect cleaning and maintenance can lead to erroneous process results, causing high production costs. Regular cleaning and maintenance is therefore essential. Among other factors, the operational safety and effective performance of fermentation also depend on proper cleaning and maintenance.

## \land WARNING

#### Danger to life caused by electrical voltage!

Electrical switching elements are installed in the device. Contact with parts under voltage represents a direct danger to life.

- Never open the control cabinet. The device may only be opened by Sartorius Service personnel.
- Work on the electrical equipment of the device may only be carried out by Sartorius Service.
- During maintenance and cleaning work, turn the power supply off from the main switch, and unplug the power plug from the device.
- Keep moisture away from parts under voltage, as it 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 Service.
- Have the electrical components and stationary electrical equipment checked by an electrician at least every four years.

### A WARNING

#### Danger of crushed limbs by the rocker!

- Allow only qualified and authorized personnel to work on the device.
- Disconnect the device from power when performing maintenance and cleaning tasks.
- ▶ Wear personnel protective equipment.

#### **WARNING**

#### Contamination due to operating media or additives!

The culture bags are single-use items that must be disposed after each cultivation. Sterilization may be required before you can dispose the culture bag.

Used culture bags must be handled in a way that corresponds to the respective national regulations for the disposal of biological harmful single-use devices.

## 7.1 Preliminary Steps

Make sure to always perform the following preliminary steps during cleaning and maintenance.

#### Procedure

- ▶ Turn the device off at the main switch.
- Remove the power supply from the laboratory connection.
- ▶ Turn off all supply media in the lab (water and gas supply).
- Ensure that the connections and hoses have been depressurized.
- ▶ If necessary, remove the supply media lines from the device.

## 7.2 Cleaning

The Biostat<sup>®</sup> RM 20 | 50 is a single-use bioreactor system that does not require cleaning or sterilization contrary to conventional, reusable bioreactors. However, the device should be cleaned on a regular basis because soiling from daily operation, e.g., splashes or spilled liquids are unavoidable.

#### Procedure

- NOTICE Corrosion or damage of the device due to unsuitable cleaning agents! Do not use solvents | liquids that can corrode or damage the device or its components.
- Ensure that the cleaning agents used are suitable for the material they are used on.
  - Rocker housing: stainless steel (frame) and ABS (housing)
  - Culture bag holder and hood: ABS
- Observe the safety instructions for the cleaning agents. The use and disposal of cleaning agents, and water containing such agents, may be subject to legal or environmental protection regulations in your country.

#### **Cleaning the Rocker Housing**

- Ensure that the device has been disconnected from the power supply.
- NOTICE Damage to electrical components due to contact with water! Make sure that water does not get into the housing because this can cause serious damage to the electrical components.
- For cleaning, you can use either water or a common disinfecting agent such as 70% ethanol.
- Wipe down the rocker housing using a moist cloth.

#### Cleaning the Culture Bag Holder

#### Procedure

- ▶ Unplug the cable of the temperature sensor from the device.
- Keep the temperature sensor installed in the culture bag holder.
- Clean the culture bag holder with alcohol or other common cleaning agents.
- If there is heavy soiling, the culture bag holder can be carefully rinsed out with water.

#### **Cleaning the Hood**

#### Procedure

▶ Wipe down the hood of the culture bag holder using a soft, moist cloth.

## 7.3 Maintenance

#### 7.3.1 Device Servicing by Operating Personnel

The maintenance activities to be carried out by operating personnel are limited to:

 Replacing the aeration tubing between the "GAS 1" | "GAS 2" connection and the sterile air intake filter of the culture bag.

Defective components must be replaced immediately. These are:

- Filter heater for rocker 20|50
- Culture bag holder 20 and 50
- Hood for culture bag holder 20 and 50
- Temperature sensor
- Heating mat 20 | 50

Regular lubrication is not required.

#### 7.3.2 Servicing the Device by Authorized Personnel

Service and calibration of the Biostat<sup>®</sup> RM 20 | 50 are reserved for qualified, trained, and authorized service personnel.

#### Maintenance Intervals

Several components, such as bearings, require regular maintenance. It is recommended to carry out maintenance work every 8000 working hours. This work also includes the necessary calibration of all parameters.

The battery for operating the PLC integrated into the Biostat<sup>®</sup> RM 20|50 has a lifespan of more than five years. However, we recommend that it be replaced within this five-year period. This service is included within the scope of maintenance, if necessary.

For more information on maintenance work, contact Sartorius Service.

## 8 Faults

## 8.1 Troubleshooting

### **WARNING**

Danger to life caused by electrical voltage!

Contact with parts under voltage represents a direct danger to life.

- Work on the electrical equipment of the device may only be carried out by Sartorius Service.
- 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.

#### **WARNING**

Danger of limbs being crushed if caught or in the event of direct contact!

- Do not remove the safety mechanisms.
- Allow only qualified and authorized personnel to work on the device.
- ▶ Wear personnel protective equipment.

### **A**CAUTION

#### Danger of burns upon contact with hot surfaces!

- Avoid contact with hot surfaces like the heating mat.
- ▶ Let the heating mat cool before troubleshooting.

- Always proceed according to the following steps when faults occur on the device.
  - Switch off the device and unplug it from the power supply (pull power plug) if the fault (e.g., smoke or odors, abnormally high surface temperatures) 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.
- ▶ If the fault cannot be remedied, please consult Sartorius Service.

## 8.2 Hardware-Related Faults

## \land WARNING

#### Danger of injury if qualifications are insufficient!

Improper use can lead to significant personal injury and property damage.

▶ It is important that all troubleshooting activities be carried out by qualified personnel.

### 8.2.1 Contamination Troubleshooting Table

We recommend carrying out a sterility test before each process for a duration of 24-48 h. Conditions for a sterility test:

- All planned components, peripheral devices, medium feed lines, and sampling systems to be tested, must be connected to the culture bag.
- The system must be set to the planned operating conditions (e.g., temperature, rocker speed, rocker angle, and aeration).

Contamination	Potential Causes	Corrective Measures
Generalized and widespread, even without having inoculated the culture (during the sterility test phase)	Intake air line or filter defective	<ul><li>Replace the tubing.</li><li>Check the filter and replace if necessary.</li></ul>
Generalized and gradual (even without inoculating the culture)	Intake air line or filter defective	<ul><li>Replace the tubing.</li><li>Check the filter and replace if necessary.</li></ul>
After inoculation (widespread)	Contaminated inoculum culture Non-sterile inoculation equipment	<ul> <li>Take control samples of the inoculation culture and test inoculated culture me- dium from the vessels (e.g., on test nu- trient solutions).</li> </ul>
	Incorrect inoculation	<ul><li>Check the inoculation procedure.</li><li>Carefully practice the inoculation process.</li></ul>
	Intake air filter or connection has become non-sterile or defective	<ul> <li>Check the filter and replace if necessary.</li> <li>Replace the connection line.</li> </ul>
During the process (rapid)	Intake air filter or connection has become non-sterile or defective	<ul> <li>Check the filter and replace if necessary.</li> <li>Replace the connection line.</li> </ul>
	Accidental or unauthorized tampering with equipment	<ul> <li>Take organizational measures at the work site to prevent the equipment from unauthorized tampering.</li> </ul>
During the process (gradual)	Exhaust air filter(s) or connection has become unsterile or is defective (contamination from the exhaust air line)	<ul> <li>Check the filter (if possible, perform a validity test) and replace if necessary.</li> <li>Replace the connection line.</li> </ul>

Fault	Potential Causes	Corrective Measures
The bioreactor heats up too slowly.	The culture medium does not heat up at all or only very slowly.	<ul> <li>Check that the temperature sensor is positioned correctly.</li> <li>Make sure that the desired temperature is set correctly (see Chapter "6.2.5 Temperature   "TEMP 1" and "TEMP 2" Menus," page 43).</li> <li>Make sure that the correct bag configuration is selected. (see Chapter "6.2.10.3 Setting the Culture Bag Size," page 50). The LEDs must light up continuously or flash.</li> <li>Make sure that the culture bag is in motion. The heating process for the medium takes place slowly and continually. The device requires over one hour to heat up a 25-liter culture medium from room temperature to 37°C.</li> </ul>
The temperature controller is not functioning properly.	The temperature of the culture medium is not being controlled correctly.	<ul> <li>Make sure that the temperature sensor is positioned correctly under the culture bag.</li> <li>Make sure that the culture bag is in motion. If the temperature controller is still not working properly, recalibration of the temperature measurement may be necessary. Contact Sartorius Service about this problem.</li> </ul>
The temperature seems to be incorrect.	The temperature displayed in the main menu does not match that of the room temperature or an independent measurement.	<ul> <li>Make sure the temperature sensor is positioned correctly.</li> <li>Make sure that the culture bag is in motion.</li> <li>If the temperature control is still not working properly, recalibration of the temperature measurement may be necessary. Contact Sartorius Service about this problem.</li> </ul>

## 8.2.2 "Temperature Control" Troubleshooting Table

Fault	Potential Causes	Corrective Measures
The culture bag seems to be over- inflated.	The culture bag should be inflated so that there are no folds. It should also not be so tight that overpres- sure occurs and kinks form at the hold points.	<ul> <li>If the culture bag inflates too tightly, check that the sterile exhaust filter is not blocked. Do this by connecting a tube to the filter and placing the other end in a container with water. The filter is blocked if no bubbles appear. Replace the filter on a sterile workbench.</li> <li>In some cases, the return valve to the sterile exhaust filter may be blocked. Unscrew it and replace it with a new one.</li> </ul>
The culture bag seems to be under- inflated.	If the culture bag is under-inflated, it cre- ates excessive foam- ing and poor mixing. "No airflow" may ap- pear on the display.	<ul> <li>Check the "AIR OUT" output on the rocker to ensure that aeration is functioning.</li> <li>The sterile intake air filter could be blocked, the closing clamp could be shut, or the aer- ation tubing not properly secured. Replace the intake air filter on a sterile workbench or fill a new culture bag with the culture medi- um.</li> </ul>
Extreme foam buildup in the culture bag	A certain amount of foam is normal for the Biostat® RM 20   50. However, the surface of the medium should not be covered with more than 50% foam.	<ul> <li>If there is too much foam buildup, make sure that culture bag aeration is functioning properly. Under-inflation can lead to strong foam buildup. Normally, the foam will recede after a few hours.</li> <li>If the foam remains unchanged after this time, reduce the rocker speed. However, make sure that it is fast enough to ensure sufficient oxygen supply for the medium.</li> <li>If there is still too much foam after this, reduce the rocker angle. A smaller rocker angle produces less foam and the rocker speed can again be increased slightly.</li> <li>For more information, please contact Sartorius Service.</li> </ul>
The culture bag is released from the guide rails.	The pressure in the culture bag is too high.	<ul> <li>Reduce the aeration rate.</li> </ul>
	The exhaust air filter is blocked.	<ul> <li>Check whether the filter heating is fully functional. If necessary: Replace the filter heating.</li> <li>For bags with a second exhaust air filter: <ul> <li>Close the tube clamp of the blocked exhaust air filter.</li> <li>Install the filter heater on the second exhaust air filter and open its tube clamp.</li> </ul> </li> </ul>

## 8.2.3 "Aeration and Ventilation" Troubleshooting Table

Please contact Sartorius Service if you have any further questions.

## 8.3 Alarm Messages

The Biostat<sup>®</sup> RM 20 | 50 displays alarm messages on the screen to inform the user of various malfunctions. Contact Sartorius Service in case of doubt.

Alarm Message	Potential Causes	Measures
Battery low	This is displayed when the PLC backup battery is too weak.	<ul> <li>The battery must be replaced within two weeks to prevent a program loss.</li> <li>Have the battery replaced by a service technician.</li> <li>Acknowledge this alarm by turning the system off and on.</li> </ul>
Error Pt100_1	This is displayed when an error occurs in the Pt100 sensor during heating operation or when the sensor is disconnected from the system during heating operation. Temp controller 1 is deactivated for safety reasons in case of malfunction	<ul> <li>Connect the temperature sensor.</li> <li>If required, you should also test the other Pt100 sensor.</li> <li>Press the Home button to acknowledge this alarm. The controller must be restarted manually</li> </ul>
	reasons in case of manufiction.	after acknowledging the alarm.
Error Pt100_2	This is displayed when an error occurs in the Pt100 sensor during heating operation or when the sensor is disconnected from the system during heating operation. Temp controller 2 is deactivated for safety	<ul> <li>Connect the temperature sensor.</li> <li>If required, you should also test the other Pt100 sensor.</li> <li>Press the Home button to acknowledge this alarm.</li> </ul>
	reasons in case of malfunction.	after acknowledging the alarm.
Error Heater1	This is displayed when no power consumption for heating mat 1 is being measured during heating operation. Either the overheating protection (bimetal trip) integrated in the heating mat was triggered due to overheating or the heater was disconnected from the system during heating operation.	<ul> <li>Ensure there is contact between the temperature sensor and the culture bag.</li> <li>Wait until the heating surface has cooled before repeating the test.</li> <li>Press the Home button to acknowledge this alarm. The controller must be restarted manually after acknowledging the alarm.</li> </ul>
	Temp controller 1 is deactivated for safety reasons in case of malfunction. Upon request, Temp controller 1 can be activated by the service technician.	
Error Heater2	This is displayed when no power consumption for heating mat 2 is being measured during heating operation. Either the overheating protection (bimetal trip) integrated in the heating mat was triggered due to overheating or the heater was disconnected from the system during heating operation. Temp controller 2 is deactivated for safety reasons in case of malfunction. Upon request, Temp controller 2 can be activated by the service technician.	<ul> <li>Ensure there is contact between the temperature sensor and the culture bag.</li> <li>Wait until the heating surface has cooled before repeating the test.</li> <li>Press the Home button to acknowledge this alarm. The controller must be restarted manually after acknowledging the alarm.</li> </ul>

Alarm Message	Potential Causes	Measures
No CO <sub>2</sub>	If the $CO_2$ controller is active (requires that the Gasflow1 controller is also active), this alarm message is displayed after five minutes when the $CO_2$ actual value is less than 0.6% (setpoint min. 0.8%). This does not deactivate the $CO_2$ controller.	<ul> <li>Please check whether or not the connection tubing to the device has been crushed or kinked.</li> <li>Press the Home button to acknowledge this alarm.</li> </ul>
	$CO_2$ aeration in TWIN operation if the rocker is used in a standalone mode: culture bag II is not supplied with $CO_2$ , since culture bag I is not aerated. If the aeration in culture bag I is interrupted, the $CO_2$ supply in culture bag II also fails.	<ul> <li>Ensure that culture bag I is aerated.</li> </ul>
Drive System Err	If no movement is detected in the motor within a period of 15 s or an error is detected in the motor amplifier (e.g., overload), this alarm is triggered. This message is also displayed on the screen as a ticker when there is an error.	<ul> <li>This alarm is acknowledged by turning the device off and on (min. 5 s off).</li> <li>If the error continues to be displayed even after a device restart, you should contact a service technician.</li> </ul>
Error Filter-H1	The filter heater is always in operation when connected to the system. However, it is only monitored during active gas aeration. In this case, it is important that the filter heater functions. It's function is measured via the power consumption. If filter heater 1 is disconnected from the system (or defective) while the Gasflow1 controller is active, this alarm is triggered after a few seconds. This does not deactivate the controller. This alarm message is only used one time per gas flow controller start.	<ul> <li>Make sure that the filter heater is connected to the correct output. If this error should continue to occur, test the function using another filter heater.</li> <li>Press the Home button to acknowledge this alarm.</li> </ul>
Error Filter-H2	The filter heater is always in operation when connected to the system. However, it is only monitored during active gas aeration. In this case, it is important that the filter heater functions. It's function is measured via the power consumption. If filter heater 2 is disconnected from the system (or defective) while the Gasflow2 controller is active, this alarm is triggered after a few seconds. This does not deactivate the controller. This alarm message is only used one time per gas flow controller start.	<ul> <li>Make sure that the filter heater is connected to the correct output. If this error should continue to occur, test the function using another filter heater.</li> <li>Press the Home button to acknowledge this alarm.</li> </ul>

Alarm Message	Potential Causes	Measures
Overpr Flow1	If the pressure for culture bag I should exceed the upper limit set in the Technician menu (normally 30 mbar), the Gasflow1 valve will close and the alarm message is triggered. This does not deactivate the Gasflow1 controller. If the pressure decreases below the lower limit set in the Technician menu (normally 20 mbar), the Gasflow1 valve is reopened and the control process continues.	<ul> <li>Please check whether or not the connection tubing between the device and culture bag has been crushed or kinked.</li> <li>Ensure that the filter heater of the respective culture bag is functional and in operation. This can be checked by touching the filter heater - it should feel warm.</li> <li>Correct any excessive gas flow rate by adjusting the culture bag size.</li> <li>Press the Home button to acknowledge this alarm.</li> </ul>
Overpr Flow2	If the pressure for culture bag II should exceed the upper limit set in the Technician menu (normally 30 mbar), the Gasflow2 valve will close and the alarm message is triggered. This does not deactivate the Gasflow2 controller. If the pressure decreases below the lower limit set in the Technician menu (normally 20 mbar), the Gasflow2 valve is reopened and the control process continues.	<ul> <li>Please check whether or not the connection tubing between the device and culture bag has been crushed or kinked.</li> <li>Ensure that the filter heater of the respective culture bag is functional and in operation. This can be checked by touching the filter heater - it should feel warm.</li> <li>Correct any excessive gas flow rate by adjusting the culture bag size.</li> <li>Press the Home button to acknowledge this alarm.</li> </ul>
No Airflow1	If the Gasflow1 controller is active and no airflow higher than 40 ml/m is measured for two minutes (setpoint is at least 50 ml/m), this alarm message is displayed. This does not deactivate the controller.	<ul> <li>When operating with process air - please check the input pressure range. It must be between 1.0 and 1.5 bar.</li> <li>Please check whether or not the connection tubing to the device has been crushed or kinked.</li> <li>When operating with an internal air pump - please contact Sartorius Service.</li> <li>Press the Home button to acknowledge this alarm.</li> </ul>
No Airflow2	If the Gasflow2 controller is active and no airflow higher than 40 ml/m is measured for two minutes (setpoint is at least 50 ml/m), this alarm message is displayed. This does not deactivate the controller.	<ul> <li>When operating with process air - please check the input pressure range. It must be between 1.0 and 1.5 bar.</li> <li>Please check whether or not the connection tubing to the device has been crushed or kinked.</li> <li>When operating with an internal air pump - please contact Sartorius Service.</li> <li>Press the Home button to acknowledge this alarm.</li> </ul>
Loadcell Overload	The load cell module is overloaded.	Follow the instructions in the load cell module operating instructions.

## 9 Decommissioning

## 9.1 Decommissioning the Device

#### Requirements

The process has ended.

There is **no** culture bag inserted in the culture bag holder.

#### Procedure

- Disconnect the compressed air supply.
- Clear the culture bag, pipelines, and hoses of all culture media lines and additives.
- Clean the entire device.
- Sterilize the entire device.
- Turn the device off at the main switch and secure it from being turned back on.
- ▶ Disconnect the device from power and the supply lines.

## 10 Transport

## 10.1 Transporting the Device

- Decommission the device.
- CAUTION Risk of injury when lifting and transporting the device! The device has a high intrinsic weight.
  - Get help from additional persons when lifting and transporting objects.
  - Use suitable conveyance devices, e.g., trolleys, when covering long transport routes.
  - ▶ Lift the device by the base plate and **never** by the weighing platform.
- Bring the device to the desired installation location.
# 11 Storage and Shipping

# 11.1 Storage

#### Procedure

- If the device is in operation:
  - Decommission the device.
  - Clean the device.
- Store the device at ambient conditions (for ambient conditions, see Chapter 13.7, page 78).

## 11.2 Returning the Device and Parts

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

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

#### **WARNING**

#### Risk of injury due to contaminated devices!

Devices contaminated with hazardous materials (ABC contamination) will **not** be accepted for repair or disposal.

 Observe the information on decontamination (see Chapter 12.1, page 74].

#### Procedure

- Decommission the device.
- Contact Sartorius Service for instructions on how to return devices or parts.
- Pack the device and its parts in their original packaging for return.

# 12 Disposal

# 12.1 Information on Decontamination

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

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

If the device has come into contact with hazardous substances: steps must be taken to ensure proper decontamination and declaration. The operator is responsible for adhering to local government regulations on the proper declaration for transport and disposal and to the proper disposal of the device.

# 12.2 Disposing of Device and Parts

#### 12.2.1 Information on Disposal

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

Two batteries are installed inside the device. Batteries must be disposed properly by disposal facilities.

The packaging is made of environmentally friendly materials that can be used as secondary raw materials.

The consumables are designed and intended for single use.

#### 12.2.2 Disposal

#### Requirements

The device has been decontaminated.

#### Procedure

- Dispose the device. Inform the disposal facility that there are two batteries installed inside the device:
  - Control unit
  - Load cell module
- Dispose packaging in accordance with local government regulations.
- ▶ Dispose consumables in accordance with local government regulations.

# 13 Technical Data

# 13.1 Dimensions

	Unit	Value
Device (width   depth   height)		
Biostat <sup>®</sup> RM 20 with bag holder 20, hood	mm	765   613   500
Biostat <sup>®</sup> RM 20 with bag holder 20, hood, Loadcell RM 20	mm	765   662   562
Biostat® RM 50 with bag holder 50, hood	mm	1085   625   500
Biostat® RM 50 with bag holder 50, hood, Loadcell RM 50	mm	1085   625   562
Culture bag holder (width   depth   height)		
Culture bag holder 20	mm	763   597   60
Culture bag holder 50	mm	1085   598   60
Hood for culture bag holder		
Hood for culture bag holder 20 (article number: DS020L-R2WL)	mm	761   597   252
Hood for culture bag holder 50 (article number: DS050L-R2WL)	mm	1083   576   252

# 13.2 Weights, Materials

	Unit	Value	
Device			
Biostat <sup>®</sup> RM 20 with bag holder 20, hood	kg	30	
Biostat® RM 20 with bag holder 20, hood, Loadcell RM 20	kg	39	
Biostat <sup>®</sup> RM 50 with bag holder 50, hood	kg	31.3	
Biostat® RM 50 with bag holder 50, hood, Loadcell RM 50	kg	40.3	
Culture bag holder			
Culture bag holder 20	kg	5.5	
Culture bag holder 50	kg	7.8	
Hood for culture bag holder			
Hood for culture bag holder 20 (article number: DS020L-R2WL)	kg	2.5	
Hood for culture bag holder 50 (article number: DS050L-R2WL)	kg	3.7	
Material of culture bag holder, hood for culture bag holder: ABS			

# 13.3 Device Components

# 13.3.1 Heating Mat

	Unit	Value
Article number		DZ020L-R2HP
Power supply	V <sub>DC</sub>	48
Power consumption	W	140
Overheating protection: bimetal trip		
Trip temperature for overheating protection	°C	+70 ± 5

## 13.3.2 Temperature Sensor

	Unit	Value
Article number		DZR2PT
Type: resistance thermometer Pt100, class A (EN 60751), three-phase		
Protection class		IP67
Material		
Surface: POM white		
Cable: PFA		
Sensor surface: chromium steel AISI 316L (1.4404)		

#### 13.3.3 Filter Heater

	Unit	Value
Article number		DZR2FH, DZR3FH
Supply voltage	V <sub>DC</sub>	24
Power consumption	W	6
Setpoint operating temperature (reference value)	°C	37
Working range	°C	+15-+45

## 13.3.4 Loadcell RM 20 | 50

	Unit	Value
Article number: DZ050L-R2LC		
Dimensions (width   depth   height adjustable)	mm	609   536   60 - 68
Weight	kg	9.0
Weighing capacity (without device weight)	kg	0-50
Accuracy with 10 kg load and ambient field strength ≤3 V/m		

	Unit	Value	
Static (with centered medium load)	g	±10	
Static (with uncentered lateral load)	g	±30	
Dynamic	g	±50	
Material			
Frame: stainless steel			
Housing: ABS (UL-compliant)			
Interfaces			
Data			
Power supply: external power supply with country-specific adapters		RS-232	
Electrical characteristics			
Input voltage	V <sub>AC</sub>	100-240	
Output voltage	V <sub>DC</sub>	24	
Power consumption	W	15	

# 13.4 Culture Bag Positioning and Operating Volumes

Culture Bag Holder	Culture Bag Size	Number and Position in Culture Bag Holder	Min. Working Volume in Culture Bag [Liters]**	Max. Working Volume in Culture Bag [Liters]
Culture bag holder 20	Flexsafe® RM 1L	1 left* 1 left and 1 right***	0.1	0.5
	Flexsafe® RM 2L	1 left* 1 left and 1 right***	0.2	1
	Flexsafe® RM 10L	1 left* 1 left and 1 right***	1	5
	Flexsafe <sup>®</sup> RM 20L	1 central	2	10
Culture bag holder 50	Flexsafe® RM 50L	1 central	5	25

\* If the device is connected to a Biostat<sup>®</sup> RM control unit. The culture bag must be placed on the left side of the culture bag holder.

\*\* "Optical" and "perfusion" culture bags require a higher min. volume due to the integrated single-use sensors.

\*\*\* If the rocker is used in a standalone mode.

# 13.5 Approved Culture Bags

Туре	Unit	Gross volume of the culture bag
Flexsafe® RM basic	L	1-50
Flexsafe® RM optical	L	2-50
Flexsafe® RM perfusion	L	2-50
Flexsafe® RM Viamass	L	2-50

# 13.6 Culture Bag Properties

Туре	Properties
Material	Film material, corresponds to the USP Class VI requirements
Use	Single use
Method of sterilization	Gamma sterilized

# 13.7 Pressures in the Culture Bag

Size of the culture bag	Unit	Minimum permissible operating pressure in the culture bag	Maximum permissible operating pressure in the culture bag
1 L, 2 L, 10 L, 20 L, 50 L	mbar	6	30

# 13.8 Laboratory Energy Sources

## 13.8.1 Mains Connection

	Unit	Value
Voltage	V <sub>AC</sub>	100-240
Frequency	Hz	50   60
Protection class (without load cell module)		IP23
Power consumption	W	600

#### 13.8.2 Aeration and Ventilation

	Unit	Value	
Room air			
A membrane pump compresses the room air at the rear "AIR" compressed air connection*			
Compressed air			
The integrated pressure regulator must be connected to an external compressed air source*	bar	1.5 ± 0.2	
Quick coupling for the direct connection of a rigid tube, external diameter	mm	4.0 ± 0.2	
CO <sub>2</sub>			
The integrated pressure regulator must be connected to an external $\rm CO_2$ source*	bar	1.5	
Quick coupling for the direct connection of a rigid tube, external diameter	mm	4.0	
* All gasses must be dry and free of dust, particle, grease, and ammonia			

# 13.9 Measurement and Control Ranges

## 13.9.1 Rocker Function

	Unit	Value
Rocker Speed (rocker movements [r/min])	r/min	8-42
Adjustable increments	r/min	1
Display accuracy	r/min	±1
Rocker angle		4°-10°
Adjustable increments		0.1°
Display accuracy		±0.3°

## 13.9.2 Aeration and Ventilation

	Unit	Value
Aeration rate (mass flow controller for flow speeds)*	ml/min	50-1,000
Reading accuracy	%	±5
Max. aeration rate per control circuit (flow circuit):		
1 flow circuit active	ml/min	1000
2 flow circuits active	ml/min	500
CO <sub>2</sub> aeration*		
$CO_2$ concentration controller with target value range (% = $CO_2$ in overall gas flow)	%	2-10
Permitted bulk flow for stable CO <sub>2</sub> control	ml/min	100-1,000
Reading accuracy	%	0.1
* when using the integrated aeration module (optional)		

## 13.9.3 Temperature Control

	Unit	Value
Displayed temperature	°C	+15 -+40
Display accuracy	°C	±0.5
Minimum temperature: depends on ambient temperature		

# 13.10 Ambient Conditions

	Unit	Value
Installation location: conventional laboratory rooms, max. altitude above sea level	m	2000
Temperature	°C	+5-+40
Relative humidity		
< 80% for temperatures up to 31°C		
< 50% decreasing linearly at temperatures from 40°C		
Impurities		
Pollution degree in accordance with EN 61010		2

# 13.11 Acoustic Emissions

	Unit	Value
Device switched on, idle, aeration off	dB (A)	39
Device switched on, 42 RPM, aeration off	dB (A)	62
Device switched on, idle, aeration on	dB (A)	54
Device switched on, 42 RPM, aeration on	dB (A)	63

# 13.12 Communication Interfaces

#### 13.12.1 D-LINK 1: Ethernet

#### **Interface Specification**

	Unit	Value
Type: 100Base-TX (100 Mbit/s)		
Transmission medium: shielded twisted pair cable (STP), Cat 5/5e		
Medium access: CSMA/CD		
Default IP address: 192.168.250.49		
	Unit	Value
Protocol: Omron FINS Ethernet/UDP	Onit	Value
Port: 9600		
Destination network address: 00		
Destination node number: 01		
Destination unit address: 00		

Omron Ethernet module: CJ2M-CPU32

## 13.12.2 D-LINK 2: RS-232 Serial Interface



#### **D-SUB** Connector

PIN no.	Abbreviation	Signal Name	I/O
1	FG	Shield	
2	SD	Send data	Output
3	RD	Receive data	Input
4	RTS (RS)	Request to send	Output
5	CTS (CS)	Clear to send	Input
6	5V	Power supply	
7	DSR (DR)	Data set ready	Input
8	DTR (ER)	Data terminal ready (see note 4)	Output
9	SG	Signal ground	
Housing	FG	Shield	

 $\operatorname{\textbf{NOTE}}$  The PIN assignment differs from the standard PIN assignment of an RS-232 plug.

#### Modbus RTU

	11	Value
	Unit	value
Type: RS-232		
Transmission rate	Baud	57600
Data bits		8
Parity control: Even		
Stop bits		2
Connector: D-SUB		
Protocol: Modbus RTU slave mode		
Slave address: 10		
Supported commands		
0x03 Read Holding Registers: Reads multiple registers from the DM or EM area of the I/O memory at the same time.		
0x06 Write Single Register: Writes one register in the DM or EM area of the I/O memory.		
0x08 Diagnostic: Runs an echo back test.		
0x0F Write Multiple Coils: Writes multiple bits in the I/O memory.		
0x10 Write Multiple Registers: Writes multiple registers in the DM or EM area of the I/O memory.		
Register		
As per Chapter "13.12.4 Data Table," page 84; all registers are "holding" registers with addresses that are the same as the PLC data address (+40001 offset).		

#### MFCS (Omron Host Link)

	Unit	Value
Туре: RS-232		
Transmission rate	Baud	9600
Data bits		7
Parity control: Even		
Stop bits		2
Connector: D-SUB		
Protocol: Omron Host Link		

## 13.12.3 D-LINK 3: Profibus DP

#### Interface Specification

	Unit	Value
Address: 2 (factory setting; cannot be changed)		
Connector: D-SUB		

#### 13.12.4 Data Table

Name   Description	PLC Address	Туре	Scaling Factor	Range
UNIT: 16 bits   2 bytes				
System data (read-only)				
Serial number	D7000	DWORD	1	0-999.999.999
Machine type	D7002	WORD	1	0000-9999
CPU firmware version	D7003	WORD		0000-9999
Display version	D7004	WORD		0000-9999
Number of rocker movements (rocks)	D7005	DWORD	1	0–99,999,999 rocks
Drive system operating hours since last service	D7007	DWORD	1	0-32,000 h
Hours until next drive system service	D7009	UINT	1	0-32,000 h
Air flow system operating hours since last service	D7010	DWORD	1	0-32,000 h
Hours until next air flow system service	D7012	UINT	1	0-32,000 h
Active use				
(0 = Locked, 1 = User, 2 = Supervisor)	D7013	UINT	1	0-2
Free	D7014 D7019			

Name   Description	PLC Address	Туре	Scaling Factor	Range
Process values (read-only)				
Setpoint for rocker speed	D7020	UINT	1	8-42 rocks/min
Current rocker speed	D7021	UINT	1	8-42 rocks/min
Setpoint for rocker angle	D7022	UINT	10	4.0-10.0°
Current rocker angle	D7023	UINT	10	4.0-10.0°
Setpoint for heating mat 1	D7024	UINT	10	15.0-40.0°C
Current value for heating mat 1	D7025	UINT	10	5.0-99.9°C
Setpoint for heating mat 2	D7026	UINT	10	15.0-40.0°C
Current value for heating mat 2	D7027	UINT	10	5.0-99.9°C
Setpoint for air flow 1	D7028	UINT	1	0–1000 ml/min
Current value for air flow 1	D7029	UINT	1	50–1000 ml/min
Setpoint for air flow 2	D7030	UINT	1	0–1000 ml/min
Current value for air flow 2	D7031	UINT	1	50–1000 ml/min
Setpoint for CO <sub>2</sub>	D7032	UINT	10	0.0-17.0%
Current value for CO <sub>2</sub>	D7033	UINT	10	0.8-15.0%
Current value for pressure 1	D7034	UINT	1	0-350 mbar
Current value for pressure 2	D7035	UINT	1	0-350 mbar
Raw weight	D7036	UINT	100	0–99.99 kg
Gross weight	D7037	UINT	100	0–99.99 kg
Netweight	D7038	UINT	100	0–99.99 kg
Free	D7039 D7049			
Process status (read-only)				
Rocker "alive" bit	D7050.00	BOOL		1s pulse signal
Remote control ON	D7050.01	BOOL		
Rocker function active	D7050.02	BOOL		
Heating mat 1 active	D7050.03	BOOL		
Heating mat 2 active	D7050.04	BOOL		1 = Active
Air flow 1 active	D7050.05	BOOL		O = Off
Air flow 2 active	D7050.06	BOOL		_
CO <sub>2</sub> active	D7050.07	BOOL		
Load cell module activated	D7050.08	BOOL		
Free	D7050.09 D7050.15			

Name   Description	PLC Type Address		Scaling Factor	Range	
Error status (read-only)					
Battery weak	D7052.00	BOOL			
Reserve	D7052.01	BOOL			
Load cell module overload	D7052.02	BOOL			
Pt100_1 error	D7052.03	BOOL			
Pt100_2 error	D7052.04	BOOL			
Heater 1 error	D7052.05	BOOL			
Heater 2 error	D7052.06	BOOL			
Drive system error	D7052.07	BOOL			
Filter H1 error	D7052.08	BOOL		I = Error has occurred	
Filter H2 error	D7052.09	BOOL			
Air flow 1 overpressure	D7052.10	BOOL			
Air flow 2 overpressure	D7052.11	BOOL			
No air flow 1	D7052.12	BOOL			
No air flow 2	D7052.13	BOOL			
No CO <sub>2</sub>	D7052.14	BOOL			
Remote control error	D7052.15	BOOL			
Free	D7053.00 D7053.15				
Setpoints (write-only)					
Setpoint for rocker speed	D7060	UINT	1	8-42 rocks/min	
Setpoint for rocker angle	D7061	UINT	10	4.0-10.0°	
Setpoint for heating mat 1	D7062	UINT	10	15.0-40.0°C	
Setpoint for heating mat 2	D7063	UINT	10	15.0-40.0°C	
Setpoint for air flow 1	D7064	UINT	1	50–1000 ml/min	
Setpoint for air flow 2	D7065	UINT	1	50–1000 ml/min	
Setpoint for CO <sub>2</sub>	D7066	UINT	10	0.8-15.0%	
Free	D7067 D7069				

Name   Description	PLC Address	Туре	Scaling Factor	Range	
Commands (write-only)					
Rocker remote control "alive" bit	D7070.00	BOOL		1 s pulse signal	
Start rocker function	D7070.01	BOOL			
Start heating mat 1	D7070.02	BOOL			
Start heating mat 2	D7070.03	BOOL		1 = Starts 0 = Stops	
Start air flow 1	D7070.04	BOOL		0 0.0000	
Start air flow 2	D7070.05	BOOL			
Activate load cell module	D7070.06	BOOL		1 = Activates 0 = Deactivates	
Free	D7070.07 D7070.15				
Error acknowledgment (write-only)					
Battery weak	D7072.00	BOOL			
Reserve	D7072.01	BOOL			
Load cell module overload	D7072.02	BOOL			
Pt100_1 error	D7072.03	BOOL			
Pt100_2 error	D7072.04	BOOL			
Heater 1 error	D7072.05	BOOL			
Heater 2 error	D7072.06	BOOL			
Drive system error	D7072.07	BOOL		1 A - Lus	
Filter H1 error	D7072.08	BOOL		I = Acknowledge error	
Filter H2 error	D7072.09	BOOL			
Air flow 1 overpressure	D7072.10	BOOL			
Air flow 2 overpressure	D7072.11	BOOL			
No air flow 1	D7072.12	BOOL			
No air flow 2	D7072.13	BOOL			
No CO <sub>2</sub>	D7072.14	BOOL			
Remote control error	D7072.15	BOOL			
Free	D7073.00 D7073.15				

# 14 Accessories and Consumables

# 14.1 Accessories

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

Item	Quantity	Order Number
Filter heater for standard HEPA filter	1	DZR2FH
Sartopore® Air Midisart® filter heater (only in conjunction with Flexsafe® RM TX 2L culture bag)	1	DZR3FH

# 14.2 Consumables

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

Item	Quantity	Order Number
Flexsafe® RM basic culture bags		
Flexsafe® RM 1L basic	5	DFB001L
Flexsafe® RM 2L basic	5	DFB002L
Flexsafe® RM 2L basic SC	5	DFB002L01SC
Flexsafe® RM 10L basic	5	DFB010L
Flexsafe® RM 10L basic SC	5	DFB010L01SC
Flexsafe® RM 20L basic	5	DFB020L
Flexsafe® RM 20L basic SC	5	DFB020L01SC
Flexsafe® RM 50L basic	5	DFB050L
Flexsafe® RM 50L basic SC	5	DFB050L01SC
Flexsafe® RM 50L basic GE rocker	5	DFB050L01US
Flexsafe® RM optical culture bags		
Flexsafe® RM 2L optical	5	DFO002L
Flexsafe® RM 2L optical SC	5	DF0002L01SC
Flexsafe <sup>®</sup> RM 10L optical	5	DFO010L
Flexsafe® RM 10L optical SC	5	DF0010L01SC
Flexsafe® RM 20L optical	5	DFO020L
Flexsafe® RM 20L optical SC	5	DFO020L01SC
Flexsafe® RM 50L optical	5	DFO050L
Flexsafe® RM 50L optical SC	5	DF0050L01SC

ltem	Quantity	Order Number
Flexsafe® RM perfusion culture bags		
Flexsafe <sup>®</sup> RM 2L perfusion	3	DFP002LSM
Flexsafe <sup>®</sup> RM 10L perfusion	3	DFP010LSM
Flexsafe <sup>®</sup> RM 20L perfusion	3	DFP020LSM
Flexsafe <sup>®</sup> RM 50L perfusion	3	DFP050LSM
Flexsafe <sup>®</sup> RM 2L perfusion ATF	3	DFP002LAT
Flexsafe <sup>®</sup> RM 10L perfusion ATF	3	DFP010LAT
Flexsafe <sup>®</sup> RM 20L perfusion ATF	3	DFP020LAT
Flexsafe <sup>®</sup> RM 50L perfusion ATF	3	DFP050LAT
Flexsafe® RM Viamass culture bags		
Flexsafe <sup>®</sup> RM 10L basic Viamass	5	DFB010LVM
Flexsafe® RM 20L basic Viamass	5	DFB020LVM
Flexsafe® RM 50L basic Viamass	5	DFB050LVM
Flexsafe <sup>®</sup> RM 2L optical Viamass	5	DFO002LVM
Flexsafe® RM 10L optical Viamass	5	DFO010LVM
Flexsafe® RM 20L optical Viamass	5	DFO020LVM
Flexsafe <sup>®</sup> RM 50L optical Viamass	5	DFO050LVM
Flexsafe® RM 2L perfusion Viamass	3	DFP002LSMVM
Flexsafe® RM 10L perfusion Viamass	3	DFP010LSMVM
Flexsafe® RM 20L perfusion Viamass	3	DFP020LSMVM
Flexsafe <sup>®</sup> RM 50L perfusion Viamass	3	DFP050LSMVM
Flexsafe <sup>®</sup> RM 10L ATF Viamass	3	DFP010LATVM
Flexsafe® RM 20L ATF Viamass	3	DFP020LATVM
Flexsafe® RM 50L ATF Viamass	3	DFP050LATVM
Flexsafe® RM TX 2L perfusion Viamass culture bag		
Flexsafe® RM TX 2L perfusion Viamass TPE	3	DFT002LSMVM1
Flexsafe® RM TX 2L perfusion Viamass PVC	3	DFT002LSMVM2

# 15 Sartorius Service

Sartorius Service is at your disposal for queries regarding the device. For information about the service addresses, services provided, or to contact a local representative, please visit the Sartorius website (www.sartorius.com).

When contacting Sartorius Service with questions about the system or in the event of malfunctions, be sure to have the device information, e.g. serial number, close at hand. This information can be found on the manufacturer's type plate.

# 16 Conformity Documents

The attached documents confirm compliance of the device with the directives or standards cited.

# 17 Licensing Information

# 17.1 GNU Licensing

The software code of the DCU systems is partly subject to the license terms of the "GNU General Public License (GPL)" or "GNU LESSER General Public License (LGPL)."

If applicable, the licensing terms and conditions of the GPL and LGPL as well as information about the options for access to GPL code and LGPL code used in this product are available upon request.

The GPL code and LGPL code contained in this product are published without any guarantee and subject to the copyright of one or more authors. You can find detailed information in the documentation about the enclosed LGPL code and in the GPL and LGPL licensing terms and conditions.

	Original	SVIPCTRAS
CE	EG-/EU-Konformitätser EC / EU Declaration of Con	klärung formity
Hersteller Manufacturer	Sartorius Stedim Switzerland AG Ringstr. 24a, 8317 Tagelswangen, Schwe	iz
	erklärt in alleiniger Verantwortung, dass declares under sole responsibility that th	das Betriebsmittel he equipment
Geräteart Device type	Bioreactor	
Baureihe Type series	BIOSTAT <sup>®</sup> RM20/50 Basic	
Modell Model	DHR050LBRM	
	in der von uns in Verkehr gebrachten Au der folgenden Europäischen Richtlinien Anforderungen folgender harmonisierte zum Zeitpunkt der Erklärung geltenden	isführung allen einschlägigen Bestimmungen entspricht und die anwendbaren ir Europäischer Normen einschließlich deren Änderungen erfüllt:
	in the form as delivered fulfils all the rele Directives and meets the applicable req Standards including any amendments va listed below:	evant provisions of the following European uirements of the harmonized European alid at the time this declaration was signed
2014/30/EU	Elektromagnetische Verträglichkeit / Ele EN 61326-1:2013	ectromagnetic compatibility
2011/65/EU	Beschränkung der Verwendung bestimm Elektronikgeräten (RoHS) / Restriction of electrical and electronic equipment (Ro EN 50581:2012	nter gefährlicher Stoffe in Elektro- und of the use of certain hazardous substances in HS)
2006/42/EG 2006/42/EC	Maschinen Machines	
	EN ISO 12100:2010, EN 61010-1:2010"), E	EN 61010-2-010:2014 <sup>°)</sup> , EN 61010-2-081:2015
	Die Person, die bevollmächtigt ist, die te The person authorised to compile the te	chnischen Unterlagen zusammenzustellen: <i>chnical file:</i> Sartorius Stedim Switzerland AG Ringstr. 24a, 8317 Tagelswangen, Schweiz
	Sartorius Stedim Switzerland AG Tagelswangen, 2021-03-03	14
	A. tottostanos	AL
	Christine Lettenbauer	Chrysanthi Karageorgaki
	Geschäftsführerin CE *: angewandte, jedoch für Maschinen nicht applied standard, which however is not ha	Quality System Manager harmonisierte Norm / armonized for machines
	Doc: 2053705-01 SSTIACE002-02 do on 1	/1 PME-2053704 OP-113 fot 2020 07 03

# SVIECTEN3

Original

# **CE** EG-/EU-Konformitätserklärung EC / EU Declaration of Conformity

Hersteller Sartorius Stedim Switzerland AG Manufacturer Ringstr. 24a, 8317 Tagelswangen, Schweiz

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

Geräteart Loadcell Module / Bioreactor BIOSTAT® RM 20/50 Device type

Baureihe LOADCELL RM20/50

Modell DZ050L-R2LC

Model

Type series

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

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

2014/30/EU Elektromagnetische Verträglichkeit / Electromagnetic compatibility EN 61326-1:2013

2011/65/EU Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHS) / Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) EN 50581:2012

> Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen: The person authorised to compile the technical file:

> > Sartorius Stedim Switzerland AG Ringstr. 24a, 8317 Tagelswangen, Schweiz

Sartorius Stedim Switzerland AG Tagelswangen, 2021-07-26

Christine Lettenbauer Geschäftsführerin CE

Chrysanthi Karageorgaki Quality System Manager

angewandte, jedoch f
ür Maschinen nicht harmonisierte Norm / applied standard, which however is not harmonized for machines

Doc: 2053705-01 SST16CE002-02.de.en 1/1 PMF: 2053704

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America

10.10

UC8 /

# **CERTIFICATE** No. U8 17 07 77876 013

Holder of Certificate:

## Sartorius Stedim Switzerland AG

Ringstr. 24a 8317 Tagelswangen SWITZERLAND

77876

Production Facility(ies):

Product:

Model(s):

Tested

Parameters:

according to:

**Certification Mark:** 



#### Laboratory equipment

Protection class:

#### BIOSTAT® RM20/50 basic

Rated voltage: Rated frequency: Rated power: 100-240V 50-60 Hz 600 W

UL 61010-1:2012/R:2016-04 UL 61010-2-010:2015-01 UL 61010-2-081:2015-08 CAN/CSA-C22.2 No. 61010-1:2012/U2:2016-04 CAN/CSA-C22.2 No. 61010-2-010:2015-01 CAN/CSA-C22.2 No. 61010-2-081:2015-11

The product was voluntarily tested according to the relevant safety requirements noted above. It can be marked with the certification mark above. The mark must not be altered in any way. This product certification system operated by TÜV SÜD America Inc. most closely resembles system 3 as defined in ISO/IEC 17067. Certification is based on the TÜV SÜD "Testing and Certification Regulations". TÜV SÜD America Inc. is an OSHA recognized NRTL and a Standards Council of Canada accredited certification body.

Test report no.:

028-713097807-000

Date, 2017-07-17

Page 1 of 1



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TUV®

	SUD
CERTIFIC No. U8 17 01 77876 0	ATE America
Holder of Certificate:	Sartorius Stedim Switzerland AG Ringstr. 24a 8317 Tagelswangen SWITZERLAND
Production Facility(ies):	77876
Certification Mark:	C US
Product:	Electronic measuring equipment
Model(s):	LOADCELL RM 20/50
Parameters:	Rated voltage:24VDCRated power:15 WProtection class:IIIDegree of protection:IP20Power supply unit:PSA 15R-240P(Ratings: 100-240 V, 50-60 Hz, 0.5 A, LPS)Alternate PSU:PSA15R-240P6 (Ratings: 100-240 V, 50-60 Hz, 0.5 A, LPS)
Tested according to:	UL 61010-1:2012/R:2015-07 CAN/CSA-C22.2 No. 61010-1:2012 + UPD No. 1:2015-07 + UPD No. 2:2016-04
The product was voluntarily teste can be marked with the certificat product certification system oper 3 as defined in ISO/IEC 17067. C Regulations". TÜV SÜD America Canada accredited certification b	ed according to the relevant safety requirements noted above. It ion mark above. The mark must not be altered in any way. This ated by TÜV SÜD America Inc. most closely resembles system Certification is based on the TÜV SÜD "Testing and Certification Inc. is an OSHA recognized NRTL and a Standards Council of body.
Test report no.:	028-713099782-000
	CS-S-S-C-FUEV
Date, 2017-01-25	580590

UCB / 10.10

# 18 Appendix

# 18.1 Aerating the Cell Culture

#### 18.1.1 Schematic Representation of Aeration

The Biostat<sup>®</sup> RM 20 | 50 can be used to aerate the cell culture with either external compressed air or compressed room air. A pressure sensor monitors the pressure and is equipped with an alarm signal (see Chapter "18.1.2 Over-pressure Control," page 96).



Fig.7: Schematic representation of aeration

No.	Designation
1	Non-return valve
2	Pressure throttle valve
3	Flow throttle valve
4	Mixing chamber
5	CO <sub>2</sub> sensor
6	Mass flow
7	Pressure sensor
8	Culture bag I "BAG 1"
9	Culture bag II "BAG 2"
I	Compressed air source, 1.5 barg
11	Ambient air, O barg
	CO <sub>2</sub> source, 1.5 barg
IV	At 30 mbar: control valve is closed

#### 18.1.2 Overpressure Control

A pressure sensor records the pressure of the culture bag. If the pressure rises to more than +30 mbar, the control valve closes automatically until the pressure decreases to +20 mbar. This protects the cell culture from overpressure and protects the culture bag from damage.



Fig. 8: Overpressure control

No.	Designation
1	Overpressure [mbar]
2	Start of overpressure
3	Overpressure +20 mbar
4	Overpressure +30 mbar
5	Overpressure corrected
6	Normal operating pressure
7	Time

Sartorius Stedim Switzerland AG Ringstrasse 24a 8317 Tagelswangen, Switzerland

Phone: +41 52 354 3636 www.sartorius.com

The information and figures contained in these instructions correspond to the version date specified below.

Sartorius reserves the right to make changes to the technology, features, specifications and design of the equipment without notice. Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote all genders.

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Last updated:

03 | 2023

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