Operating Instructions

# BioPAT® Fundalux

Online measurement of turbidity and total biomass

85037-544-97

SARTORIUS

# Contents

# 1 About this Document

## 1.1 Use of the BioPAT® Fundalux Measuring System, Restrictions

The BioPAT® Fundalux measuring system is designed for turbidity and total biomass measurement in the culture vessels of the bioreactors type Biostat® from Sartorius Stedim Systems GmbH. The necessary version for equipment depends on the type of the bioreactor, the design of the culture vessel and the intended process.

This operating information refers to:
- Turbidity sensors for autoclavable Univessel® 1 L, 2 L, 5 L and 10 L by standard port Ø 12 mm or Ø 19 mm
- Turbidity sensors for standard ports Ø 25 mm of in-situ sterilizable culture vessels
- Integrated measuring amplifiers for DCU systems

and describe the equipment, the installation of the sensors, the operation of the DCU control and the maintenance of the sensors.

The BioPAT® Fundalux turbidity measuring system shall only be used at the bioreactors and under the provitions described in the documentation delivered with the devices. If the equipment is used, however, for other purposes and under different conditions, responsible FRT application specialists shall verify that they are suitable for such a use and can be operated safely. Necessary addititional equipment and safety devices shall be available in place.

Safe operation of the measuring system requires that the personnel is familiar with the operation of the bioreactors and their equipment. The safety information included herein only refers to potential risks at handling of equipment supplied by Sartorius Stedim Biotech GmbH, and remedial measures. It completes the safety instructions on the bioreactors and regulations on running the intended process safely, e.g. as provided by the FRT application specialist.

## 1.2 Validness, Exclusions

 Dies ist eine “Original”-Dokumentation, die im bestehenden Zustand (“as is“) geliefert wird. Sie beschreibt das Gerätedesign und den zum Zeitpunkt der Dokumentationsfreigabe bekannten Geräteumfang. Sartorius Stedim Biotech GmbH behält sich das Recht vor, jederzeit Änderungen am Gerät und an der Dokumentation vorzunehmen.

The BioPAT® Fundalux turbidity measuring system and complementary equipment are subject to an ongoing development and can be customized.

Sartorius Stedim Biotech GmbH assume no obligation for the fitness of the equipment for any particular use. Apart from restrictions by legal or elsewhere compulsory rules, any liability for malfunctions and damages to equiment arising from or in connection with the documentation is excluded.

The BioPAT® Fundalux turbidity measuring systems are examples of the vessel equipment available for the bioreactors of Sartorius Stedim Systems GmbH.

## 1.3 Symbols Used

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

**⚠ WARNING**
This instruction denotes a possible danger with medium risk that death or severe injury may result if it is not avoided.

**⚠ CAUTION**
This symbol denotes a possible danger with risk that moderate or minor injurymay result if it is not avoided.

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

**NOTE**
- is an indication of a function or setting on the device.
- that caution should be exercised while working.
- identifies useful information.

**The following presentations will also be used:**

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

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

## 1.4 Relevant Standards and Directive

Turbidity sensors and accessories for installation in vessels are submitted to a classification according to the European pressure equipment directive 97/23/EC (PED). The sensor assemblies are pressure equipment according to article 1, section 2. 2.1.4. All approvals and classifications with respect to PED have been done together with the notified body off RWTÜV Essen, Germany, identification number 0044.

The assemblies, delivered either mounted or as component parts, are suitable for use as follows:

- According to article 3, section 1, figure 1.1 a), first bar, PED, for vessels applied for: Gases, liquefied gasses, gasses dissolved under pressure, vapors and those liquids whose vapor pressure at the maximum allowable temperature is greater than 0.5 bar above normal atmospheric pressure, as long as it is a fluid of groups 1 or 2 [Annex II (B) , Chart 1].
- And acc. to article 3, section 1, figure 1.1 b), first bar, PED, for vessels applied for: Liquids, including liquids having a vapor pressure at the maximum allowable temperature of not more than 0.5 bar above normal atmospheric pressure, as long as it is a fluid in groups 1 or 2 [Annex II (B), Chart 3].
- The options for installation of the sensors also fulfill the requirements in Category I and Category II of the Conformity Assessment Procedure Module E1, part “Quality Assurance for Final Inspection and Testing”. They are suitable for gasses and liquids of fluid groups 1 and 2.

# 2 Safety Instructions

## ⚠ WARNING

**Danger of injury by escaping materials!**

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

- Adding a visual check of the o-rings before installation and replacement if degraded or damaged.
- Do not start the culture vessel without a safety valve or comparable overpressure safety (e. g. a burst disk).
- Turn the unit off and secure it against reactivation when working on the unit.
- Release the pressure from system sections and pressure lines to be opened before starting any repair work.
- Regularly check all lines, hoses, and connections under pressure for leaks and externally detectable damage.
- Only well informed and suitably trained personnel must install, operate resp. service the turbidity measuring devices.

## NOTE

For mounting into a side entry port Ø 25 mm, the vessel must be emptied below the port level.

Therefore follow this overview on tasks to be performed:

| Task to be performed | first start-up | after power-down |
|---|---|---|
| Read these instructions carefully | × | × |
| Check completeness of delivery | × | |
| Visually check the parts for damages | × | |
| Visually check the sapphire window for dirt | × | × |
| Check O-rings and their proper seat in the ports | × | × (*) |
| Connect sensor to amplifier | × | × (*) |
| Check mains (external amplifier only) | × | |
| Switch-on the units | × | × |
| Wait for 15 minutes “warm-up“ | × | × |
| Check zero of sensor | × | × (*) |
| (*) If dismounted during power-down | | |

| Task to be performed | first start-up | after power-down |
|---|---|---|
| Adjust amplifier, calibrate sensor (see documentation on control unit) | × | × (*) |
| Make a record of all settings | × | × (*) |
| Check measured values on plausibiliy | × | × |
| Approve measuring | × | × |
| (*) If dismounted during power-down | | |

## IMPORTANT

**Possible damage to equipment!**

The medium must not cause corrosion of the sensors or change the optical properties of the sapphire window. Otherwise the reliability and lifetime of the sensors will be affected!

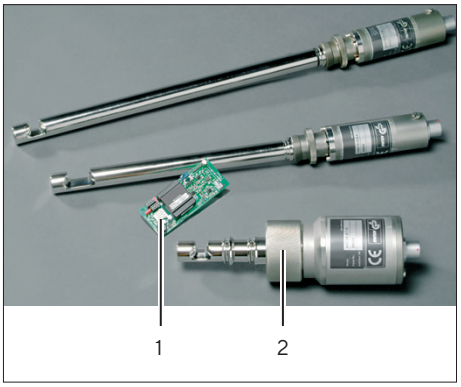
- The BioPAT® Fundalux sensors are not allowed to connect to amplifiers of third party vendors.
- Sensors from other vendors are not allowed to connect to BioPAT® Fundalux amplifiers!

## NOTE

Prior to a first use in the process it is recommended to test, in which placement and orientation in the culture vessel (in which port) the sensor delivers stable and reproducible results.

# 3 Device Overview

## 3.1 Setup and Function Principle



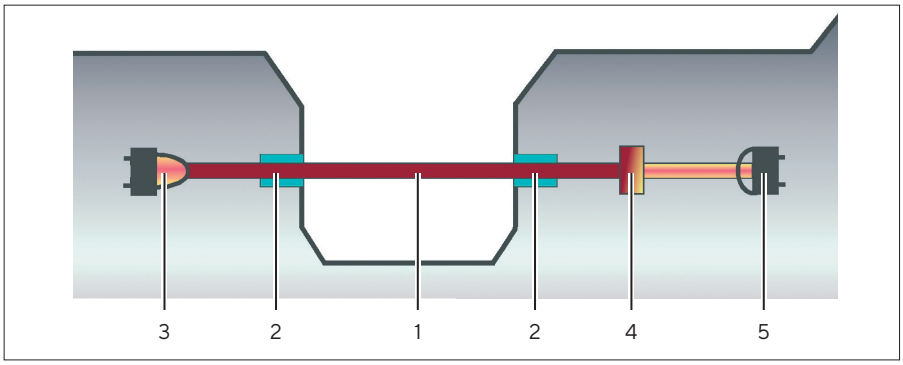

The turbidity measuring system BioPAT® Fundalux is based upon measuring the attenuation of the intensity of light brought about by the process medium by use of a high precision single channel absorption photometer. The measurement range is 0 – 6 AU (Absorbance units). The BioPAT® Fundalux system applies approved turbimetry sensor technology of optek-Danulat GmbH and includes the measuring sensor (2) and a signal converter | amplifier module (1).

The amplifier module is integrated in control systems DCU of bioreactors of the Sartorius Stedim Systems GmbH. The functions for sensor calibration and monitoring the measured signal are implemented in the software. Other, existing bioreactors can be retrofitted with an external amplifier

The turbidity sensors were adapted for use with the culture vessels of bioreactors type Biostat®:

- BioPAT® Fundalux sensor for lid ports Ø 12 mm with thread PG13.5 of autoclavable Univessel®.
- BioPAT® Fundalux sensor for lid ports Ø 19 mm with thread M26×1 of autoclavable Univessel®.
- BioPAT® Fundalux sensor for standard side-entriy ports Ø 25 mm (“Safety ports”).
- Optical path length (OPL) 1, 5 and 10 mm.
- Sensors Ø 12 mm and Ø 19 mm are autoclavable (without cable).
- Sensor Ø 25 mm is sterilized in-situ with the culture vessel.

### 3.1.1 Basic setup of the measuring system




| Pos. | Description | Pos. | Description |
|---|---|---|---|
| 1 | Optical path length (OPL) | 4 | Daylight filter |
| 2 | Sapphire windows | 5 | Detector |
| 3 | LED-light source | | |

The sensors use light in the near infrared (NIR), ranging from 840 to 910 nm, which is optimal for measuring the absorption of biomass and is independent of color changes.

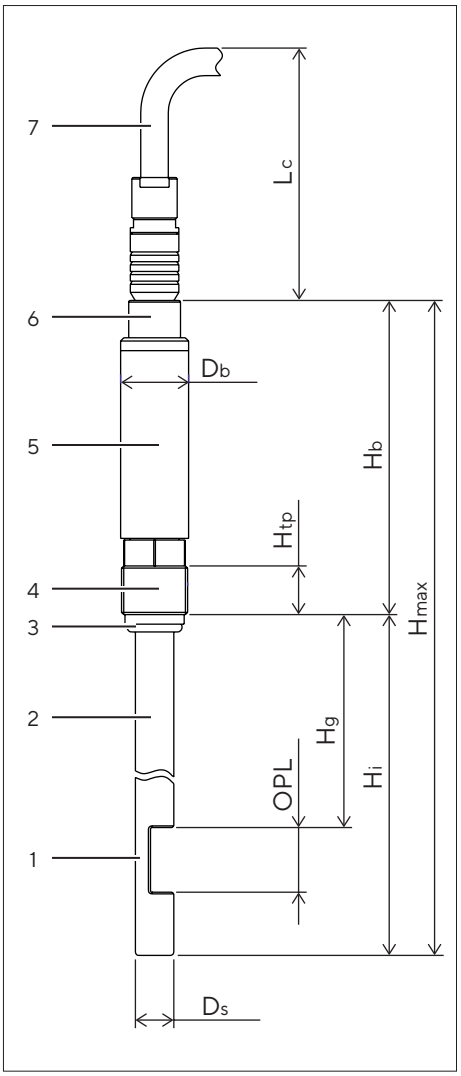
A precisely focused, constant light beam penetrates the process medium. An encapsulated photoelectric silicon cell measures the drop of light due to absorption and scattering by ingredients in the culture medium and transmits the resulting photo-current to the amplifier.

According to Beer-Lambert's law the logarithm of the loss in transmission is proportional to the concentration of substances (either dissolved or undissolved).

By continuously measuring the drop of light due to increasing light absorption and scattering during cell growth, the BioPAT® Fundalux delivers reliable information on the formation of biomass. Thus it reduces the necessity of sampling and time-consuming laboratory operations for evaluation of the cell number or the dry mass.

The measuring gap design is optimized with respect to gas and liquid flow characteristics and safe sterilization. The different optical path lengths and various insertion depths, allows complete scalability across a wide range of processing and culture (medium) conditions.

## 3.1.2 BioPAT® Fundalux sensors for lid ports Ø 12 mm




| Pos. | Description |
|---|---|
| 1 | Measuring gap with optical path length<br>– OPL: 1, 5 and 10 mm |
| 2 | Sensor shaft \| Insertion depth Hi<br>– Ds = 12 mm, Hi = OPL + 110 mm (1 L)<br>– Ds = 12 mm, Hi = OPL + 215 mm (2 L)<br>– Ds = 12 mm, Hi = OPL + 315 mm (5 L and 10 L) |
| 3 | O-ring for sealing the bioreactor port (FDA-approved) |
| 4 | PG13.5 for screwing into port<br>– Htp = 15 mm |
| 5 | Sensor head |
| 6 | Connector (push and pull) |
| 7 | Sensor cable 2.0 m |
| Hmax | maximum total length:<br>– OPL + 207 mm (1 L)<br>– OPL + 312 mm (2 L)<br>– OPL + 412 mm (5 L and 10 L) |
| Hg | shaft length at measuring gap:<br>– sensor short: OPL + 85.5 mm (1 L)<br>– sensor short: OPL + 190.5 mm (2 L)<br>– sensor long: OPL + 290.5 mm (5 L and 10 L) |
| Hb | Length of sensor head: 97 mm |
| Db | Diameter of sensor head: Ø 21 mm |

**BioPAT® Fundalux for Univessel® 1 L**

| OPL | Cat.-no. |
|---|---|
| 1 mm | BPF1L01 |
| 5 mm | BPF1L05 |
| 10 mm | BPF1L10 |

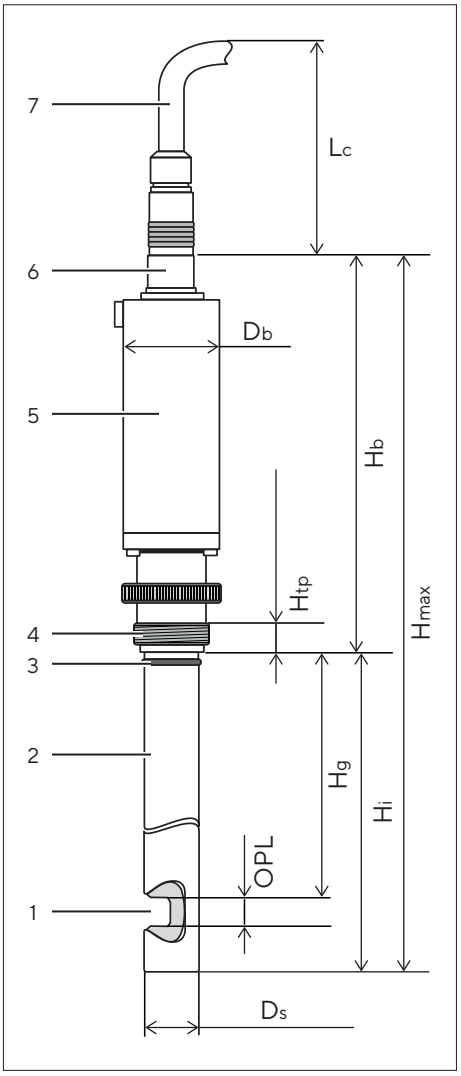
**BioPAT® Fundalux for Univessel® 2 L**

| OPL | Cat.-no. |
|---|---|
| 1 mm | BPF2L01 |
| 5 mm | BPF2L05 |
| 10 mm | BPF2L10 |

**BioPAT® Fundalux for Univessel® 5 L and 10 L**

| OPL | Cat.-no. |
|---|---|
| 1 mm | BPF5L01 |
| 5 mm | BPF5L05 |
| 10 mm | BPF5L10 |

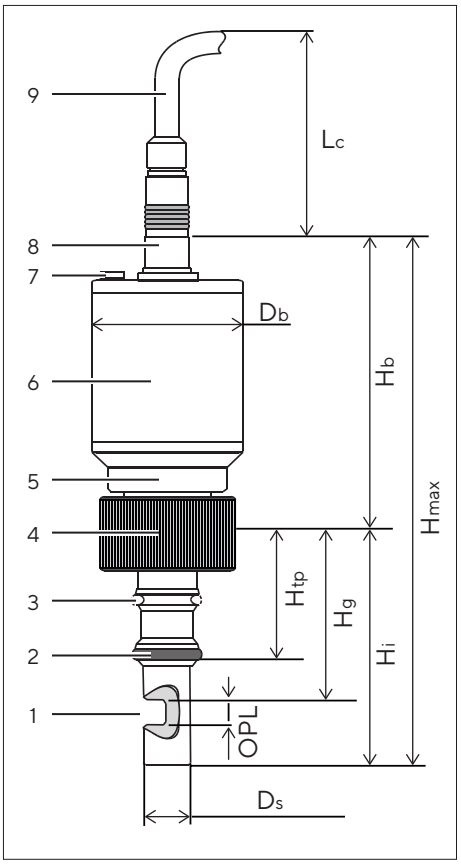
## 3.1.3 BioPAT® Fundalux sensors for lid ports Ø 19 mm




| Pos. | Description |
|---|---|
| 1 | Measuring gap with optical path length<br>– OPL: 10 mm |
| 2 | Sensor shaft \| Insertion depth Hi<br>– Ds = 19 mm, Hi = OPL + 210 mm (1 L and 2 L)<br>– Ds = 19 mm, Hi = OPL + 310 mm (5 L and 10 L) |
| 3 | O-ring for sealing the bioreactor port (FDA-approved)<br>– 15.60 × 1.78 mm for lid port Ø 19 mm |
| 4 | Fine thread M26 × 1 for screwing into port<br>– Htp = 10 mm |
| 5 | Sensor head |
| 6 | Connector (push and pull) |
| 7 | Sensor cable 2.0 m |
| Hmax | maximum total length:<br>– sensor Ø 19 mm short: OPL + 360 mm (1 L and 2 L)<br>– sensor Ø 19 mm long: OPL + 460 mm (5 L and 10 L) |
| Hg | shaft length at measuring gap:<br>– sensor short: 185 mm (1 L and 2 L)<br>– sensor long: 285 mm (5 L and 10 L) |
| Hb | Length of sensor head: 150 mm |
| Db | diameter of sensor head: Ø 34 mm |

| OPL | Cat.-no. |
|---|---|
| 10 | 8846600 |

### 3.1.4 BioPAT® Fundalux sensor for side entry ports Ø 25 mm




| Pos. | Description |
|---|---|
| 1 | Measuring gap with optical path length:<br>– OPL: 1.5 and 10 mm |
| 2 | Upper ring groove for O-ring 18.64 × 3.53 (FDA-approved)<br>– at side entry ports of port length 52 mm |
| 3 | Upper ring groove for O-ring 18.64 × 3.53 mm (FDA-approved)<br>– at side entry ports of port length 30 mm |
| 4 | Nut G1¼" ISO 228/1, about 31 mm |
| 5 | Orientation mark for measuring gap |
| 6 | Sensor head |
| 7 | AirPurge® connection |
| 8 | Connector (push and pull) |
| 9 | Sensor cable 3.0 m |
| Hmax | Maximum total length: OPL + 210 mm |
| Hg | Shaft length at measuring gap: 74 mm |
| Hb | Length of sensor head: 115 mm |
| Hi | OPL + 95 mm |
| Db | Diameter of sensor head: 60 mm |
| Insertion Depth | OPL + 35 mm (port length 60 mm) |

| OPL | Cat.-no. |
|---|---|
| 1 | BPFSS01 |
| 5 | BPFSS05 |
| 10 | 8846604 |

# 4 Installation

## 4.1 BioPAT® Fundalux sensors for lid ports Ø 12 mm and Ø 19 mm

### 4.1.1 Mounting of the Sensors

**General notes on mounting**

**NOTE**

The internal vessel equipment (i.e. stirrers, gas inlet device, or other vessel inserts) can effect both optimal placement and optimal orientation of the sensor.

- Ensure that the stirrer(s) cannot hit against the sensor shaft.
- Arrange the sensor with the measuring gap so that gas bubbles, i. e. introduced via the ring sparger or micro sparger, are not directed to the measuring gap or cannot be trapped there

▶ Note the operating information of the culture vessels for optimum placement and handling of the culture vessel equipment.

**⚠ CAUTION**

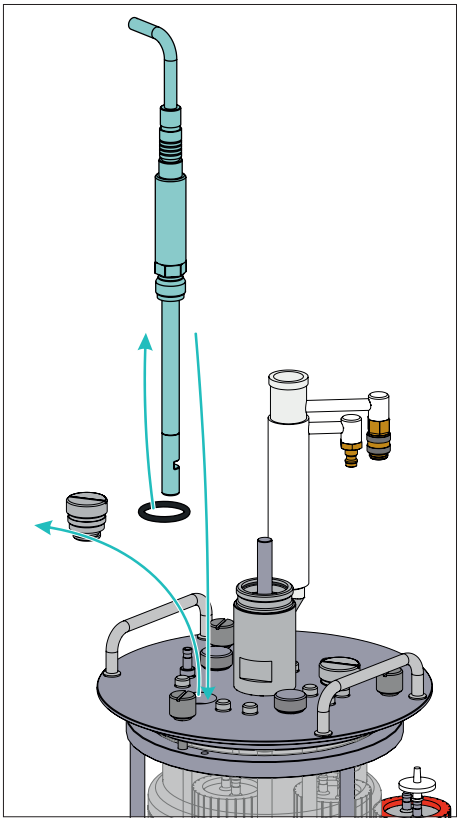
**Medium can be released unintentionally upon handling of pressurized culture vessels.**

- For mounting of a turbidity sensor the vessel must be at ambient pressure and temperature.
- For mounting into a side entry port Ø 25 mm the vessel must be emptied below the port level.

**NOTE**

BioPAT® Fundalux turbidity measuring sensors are to be installed in the culture vessel, so that the culture medium will homogeneously submerge the entire measuring gap. Insoluble; cells, cell debris, contaminates and gas bubbles must be prevented from being trapped in the measuring gap or at the LED source.

- The orientation and placement is optimal, when the measurement delivers a stable signal without large deviations (step changes) at changing either the stirrer speed or gassing.
- Best practice to mark the probe orientation in which gives the best performance for future batches.



- For mounting of additional equipment in the top-plate of the culture vessel consider the space requirements of the sensor head, see the data for “Hb” and “Db”.
- For placement of culture vessels with sensors Ø 19 mm in the autoclave consider the length of the sensor head, “Hb”. Ensure that the autoclave offers enough space (internal height).

▶ Use a free lid port Ø 12 mm | Ø 19 mm or remove the component part installed in the port.
▶ If a culture vessel has lid ports Ø 12 mm | Ø 19 mm in the middle or upper medium compartment, you should test, which port offers the best placement.

### 4.1.2 Connection of the Sensor Cables

▶ Unplug the cable from the sensor prior to moving (placing) the vessel (in)to the autoclave.
▶ Connect the cable to the sensor when placing the culture vessel at the working place, prior to enabling the control system for measurement and control. Note the location of the socket (“Turbidity” or similar) for the signal cable at the side or rear panel of the control unit

## 4.2 BioPAT® Fundalux sensor for side entry ports Ø 25 mm

### 4.2.1 Mounting of the Sensors

**General notes on mounting**

**NOTE**

The internal vessel equipment (i.e. stirrers, gas inlet device, or other vessel inserts) can effect both optimal placement and optimal orientation of the sensor.

- Ensure that the stirrer(s) cannot hit against the sensor shaft.
- Arrange the sensor with the measuring gap so that gas bubbles, i. e. introduced via the ring sparger or micro sparger, are not directed to the measuring gap or cannot be trapped there.

▶ Note the operating information of the culture vessels for optimum placement and handling of the culture vessel equipment.

**⚠ CAUTION**

**Medium can be released unintentionally upon handling of pressurized culture vessels.**

- For mounting of a turbidity sensor the vessel must be at ambient pressure and temperature.
- For mounting into a side entry port Ø 25 mm the vessel must be emptied below the port level.

**NOTE**

BioPAT® Fundalux turbidity measuring sensors are to be installed in the culture vessel, so that the culture medium will homogeneously submerge the entire measuring gap. Insoluble; cells, cell debris, contaminates and gas bubbles must be prevented from being trapped in the measuring gap or at the LED source.

- The orientation and placement is optimal, when the measurement delivers a stable signal without large deviations (step changes) at changing either the stirrer speed or gassing.
- Best practice to mark the probe orientation in which gives the best performance for future batches.

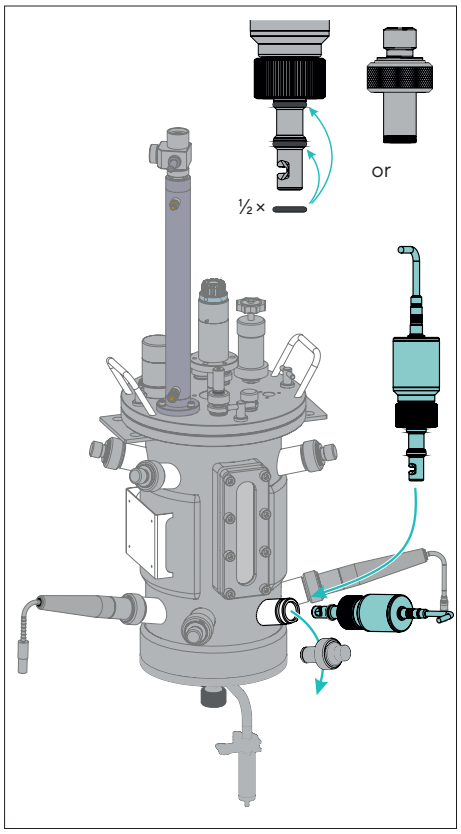
Verify that the O-ring is inserted in the correct ring groove in the sensor shaft. Sensors Ø 25 mm have 2 grooves for O-rings 18.64 × 3.53.

- Use the groove which seals the sensor shaft versus the port nearest the medium compartment of the culture vessel.

## IMPORTANT

With the O-ring in ring groove (2) at a short side entry port, the sensor shaft is not sealed at all and culture medium will be released from the vessel.

With the O-ring in ring groove (3) at a long side entry port, there is a large gap between sensor shaft and port, which may not become sterile during the in-situ sterilization. Hence the culture medium has the risk of being contaminated.




- Therefore, for mounting the O-ring to its ring groove consider the length of the side entry port. Use the groove (either 2 or 3) which seals the sensor shaft in the port nearest the medium compartment!

▶ Use a available side-entry port Ø 25 mm or remove the component part installed in the port.

▶ If a culture vessel has side-entry ports Ø 25 mm in the middle or upper medium compartment, you should test, which port offers the best placement.

### 4.2.2 Connection of the Sensor Cables

▶ Connect the cable to the turbidity sensor and the control unit or measurement amplifier when preparing the bioreactor for the process.

- Note the location of the socket (“Turbidity” or similar) for the signal cable at the side or rear panel of the control unit.

### 4.2.3 AirPurge® (only for side entry ports Ø 25 mm)

At cooling down after autoclaving or in-situ sterilization or if the process medium has low temperature, the dew point of the air inside the optical housing may fall to a level where condensate settles on the sapphire windows. This can be eliminated by supplying pressurized air via the AirPurge® connector.

**NOTE**

AirPurge® must be utilized whenever the product temperature falls below the ambient temperature of the sensor by more than 10 °C (18 °F)!

**For flushing the internal sensor with pressurized air via AirPurge®:**

- Use dry instrument air (free of dust or oil)
- Unscrew the sensor head a little.
- Connect air supply to the AirPurge® connector.
- Supply air to the sensor head at max. 1 barg for about 10 min.
- Reduce the air pressure to about 0.1 barg and screw tight again the sensor head.
- If necessary, leave the pressurized air supply connected to AirPurge® to maintain a slight overpressure during the measuring.

At a minimum air consumption the positive pressure of the dry air inside the ensor head prevents that moisture can enter the sensor and cause settlement of condensate.

# 5 Operation

- The information below summarizes the operation of the control system “DCU4” for the turbidity calibration. Detailed information on the handling of the control systems is provided with the corresponding operating manual.
- For the external amplifier please note the documentation delivered with the device.

## 5.1 Zero Adjustment

The base line zero of BioPAT® Fundalux should always be verified during initial start-up of the system and is recommended as part of preventive maintenance.
In general, the procedures are the same for all sensors. For setting the zero correctly, consider these aspects:

- The sapphire windows of the sensor must be clean.
- The culture vessel or container, which should be used for zero calibration, should be filled with clean, particle- and bubble-free medium (deionized water or the intended medium).
- Although the sensors include a daylight filter, incident light, such as direct sunlight or light reflected from the floor, can effect the measurement! Incident light from surroundings must not enter the detector.
  - If the culture vessel is exposed to direct sunlight you may cover the vessel or container if necessary.
- No gas bubbles adhere to the sapphire windows.
- The system has run for a warm up time of about 15 min.

## 5.2 Calibration and Setting of Parameters

The calibration of the turbidity measuring sensor is a one point calibration which measures the zero shift. You may use the light absorption of the particle-free culture medium prior to gassing and inoculation as reference for the zero or you can calibrate in deionized water.

▶ Start the routine with “CALIB.“ (DCU-Touch) resp. “Start Calibration” (DCU4).
▶ Follow the instructions given in the calibration menu.

## 5.3 Turbidity Measurement

The system measures the change of the light absorption due to culture growth relative to the calibrated zero. It detects the turbidity as the mean value of the absorption in absorption units (AU) over a defined measuring time. It considers an attenuation factor DAMP which determines how frequently the medium is measured.

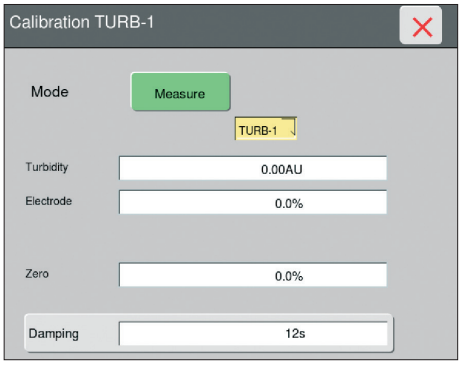
**NOTE**

To get stable process values damping can be preselected in 4 timeframes.

- You should select the lowest possible signal attenuation value which provides that the sensor delivers a stable turbidity signal.

## 5.4 Special Notes

- As far as implemented in the configuration the percentage zero deviation can directly be entered in the ZERO-entry.
- At the DCU system the calibration display shows the electrode raw signal in [%] as well as the zero shift for 0 AU, in addition to the absorption units (AU). By this you can easily check the proper functioning of the turbidity sensor.




**Zero calibration at DCU4 touch screen**

| TAG | Value | Function, input |
|---|---|---|
| Mode | Measure | Open submenu Mode |
| | Calibration | Start of the calibration routine |
| Turbidity | 0.00AU | Display of process value in 0...6 AU (Absorbing Units) |
| Electrode | % | Display of electrode signal |
| Zero | % | Display \| input of the zero deviation after calibration |
| Damping | | Display \| input of attenuation factor.<br>– The input signal is processed as the mean value of a floating reference window.<br>– Factors base upon 4 reference windows:<br>– 6 s<br>– 12 s<br>– 30 s<br>– 60 s |

## 5.5 Application Notes

### 5.5.1 Tips on Mounting into the Culture Vessel

Prior to any cultivation process you may want to test both the optimal placement of the sensor in the respective port and the best orientation of the measuring gap.

- Verify how the medium and gas circulates in the vessel:
  - Culture vessels with segment (turbine or pitched blade) stirrers, gas supply and baffles tend to have circulation in vertical loops emanating from the agitator.
- Arrange the BioPAT® Fundalux measuring gap so that the fermenter flow is directed into the gap.

**Univessel® and glass sighted vessels with sensors Ø 12 mm; Ø 19 mm:**

- Observe the distribution of the gas bubbles during gassing and stirring of the culture medium.
- Use an appropriate sized lid port and insert the BioPAT® Fundalux into the culture medium. View the flow of gas and liquid passing through the measuring gap without any holdup or dead volume.
- Or rotate the sensor in such a way, that bubbles cannot be trapped in the measuring gap at all or can be released again from the gap.
- You can modifiy the height adjustment of the stirrers and check the flow against the gap.

**NOTE**

Adjustable insertion depth adaptors are avalibale for the 12 mm probes article No. BB-8891281.

**At stainless steel culture vessels, where no visual observation is possible:**

- Observe the measured signal. Step signals or rapid fluctuations indicate that gas bubbles or particles are temporarily trapped or sticking in the gap.
- Vary the orientation of the sensor or the mounting height of the stirrers until the measured signal is without large fluctuations.
  - A marker at the sensor shaft outside the vessel indicates the orientation of the measuring gap.

### 5.5.2 Contamination Detection by Turbidity Measurement

Turbidity measurement is applicable for contamination control (sterile test) prior to the inoculation:

- After autoclaving or the in-situ sterilization, prior to transfer of the seed culture, enable the bioreactor for the process, i.e. let it run for approx. 24 – 36 h. Set the bioreactor's temperature, gassing, stirring speed, etc., to the process conditions.
- Measure the turbidity and monitor the plot of the measuring signal on the DCU display:
  - Constant signals show that the culture medium remains sterile and gassing or mixing have no influence on the measurement.
  - Measured signals fluctuating around a constant base value show influences of gassing and mixing of the medium on the measurement.
  - Values rising linearly and particularly exponentially (according to a growth trace) show an insufficient sterilization or microbrial contamination of the medium.

# 6 Maintenance

Keeping-up the proper function and reliable operation of the equipment is the responsibility of the user. The information herein is based on our emperical inspection and maintenance intervals in order to generate estimated lifetimes. Specific process conditions may require more frequent maintenance of the parts which come in contacts with the media that are wetted. Observe the following precautions for maintenance and repair works:

**⚠ CAUTION**

**Medium can be released unintentionally at handling of pressurized culture vessels!**
For removing of a turbidity sensor the vessel must be at ambient pressure and temperature. For removing from a side entry port Ø 25 mm, the vessel must be emptied below the port level.

**NOTE**

For maintenance and service only spare parts released for the BioPAT® Fundalux system must be used. Other parts can effect the quality and reliability of the measurement.

- Defective sensors cannot be repaired onsite and must be replaced, see Chapter “7 Commonly observed issues”, page 25.
- A functional check is performed by a Sartroius Stedim service engineer as part of our Extended preventive maintenance visits.
- After replacement of O-rings or of the entire sensor always perform a sterile check of the culture vessel (pressure hold test at in-situ sterilizable culture vessels).

## 6.1 Sensor Parts in contact with the medium

**IMPORTANT**

Damaged O-rings can cause leakage, resulting in an unintended release of medium, or contamination of the culture.

- Check the O-rings regularly, during the cleaning or checks of the fermenters connections and seals.

- A check during the usual inspection | maintenance of the culture vessel may suffice.
- The sapphire windows are without seals. Maintenance is restricted to checking whether ingredients of the culture medium stick to the windows. Such layers must be removed since they increase the baseline zero and reduce the measuring span. Change the placement of the sensor or the orientation of the measuring gap in the medium to minimize the fouling effects.

## 6.2 Detectors and Optical Filters

- Detectors are sealed and do not show any significant ageing. They need no special care.
- Optical filters may mature by exposure to high temperature or moisture entering the sensor.
- Functional checks performed annual will detect this fault.

## 6.3 Lamp Module

- The lamps in use are LED's, designed for long lifetime. Operation below their specifications further extents their life span (approx. 10 years, statistical). However, heavy vibrations, high temperatures, or frequently turning on | off of the measuring system may reduce their lifetime. Excess or variable voltage could result in a fault of the lamp electronics in the sensor.

## 6.4 Cables, Connectors

- The electric properties of the cables do no change significantly during lifetime (use). Therefore, no regular electrical testing is required.
- You may check the cables visually for damages and their terminals for isolating coatings (caused by surface corrosion). Remove such coatings. Replace damaged cables.
- Do not immerse the cables into water, solvents, etc. Dry connectors carefully if wetted.
- Extreme temperature changes and direct sunlight should be avoided to ensure signal stability and lifetime of the cables.

# 7 Commonly observed issues

## 7.1 Process-related Fluctuation

The turbidity measuring signal plot from the process gives indications for the fluctuation:

- The measurement of process turbidity (suspended cells and soluble product) requires the minimum interferance from non-homogeneous factors (gas bubbles and solids) between the measuring gap. As the processing time increases, typically the turbidity value increases.
- Rapid increases in turbidity that are atypical to your process conditions (i.e. before inoculation) can indicate microbial contamination of the culture medium:

| Problem | Cause | Remedial action |
|---|---|---|
| Signal jumps (irregularily). | Gas bubbles, cell agglomerates or particles get stuck in the measuring gap (at times). | – Change stirring speed and gas supply rate (if process permits this).<br>– Rotate sensor, change bioreactor stirrer flow against measuring gap.<br>– Install sensor in alternate lid port \| in other side entry port. |
| Signal oscillates (“bounces”), according to changes in stirring speed or gassing. | Heterogeneous gas dispersion; formation of flow whirls or dead zones at measuring gap. | |
| Signal doesn’t react to changes of stirring, gassing or optical density of medium. | Measuring gap polluted; Deposits, fouling occurs at the sapphire windows. | – Remove sensor and check carefully.<br>– Clean sapphire windows. |

Upon malfunctioning of the measuring system the following causes should be verified (and cleared, if necessary):

**Fouling of the sapphire windows**

- In typical bioprocesses conditions the sapphire windows provide significantly larger cleaning intervals, compared to other materials. However, fouling by ingredients of the media may cause an erroneous reading of the turbidity. In such a case adequately clean the windows with water or comparable solutions.

**Formation of condensate**

- Cooling down after the autoclaving resp. in-situ sterilization or low temperature of the process medium can cause condensates between the sapphire windows.
- Such condensate can be eliminated by flushing the internal sensor with dry air through the AirPurge® connector, see notes on AirPurge® further above.

**Exceeding the measurement range**

- If the signal exceeds the measuring range due to process conditions, a higher measuring range should be selected. As an alternative it is suggested to verify whether a sensor with shorter OPL can be applied.

## 7.2 Technical Defects

**Erroneous connection**

- The internal wiring of the sensor is verified in the factory. The sensor signal cable ASD-CC has plugs on both ends. If the cable is in good condition (see below) the faults is likely to be with the installation kit at the internal amplifier (due to unintended disconnection of wires, etc.).

**Defective cables:**

- Cables and plugs can be damaged only by mishandling (bending cables, forcing the plugs into sockets that do not fit, etc.). In seldom cases isolation faults at the terminals can occur due to moisture or corrosion by chemicals. In such a case clean the terminals carefully, dry and test the connection again.
- For a continuity check of the cables note the this wiring | configuration:

| FC12 clamp | Function | Amplifier cable | Pin, contact | Sensor cable ASD-CC |
|---|---|---|---|---|
| 6 | lamp + | white \| yellow | 2 | yellow |
| 7 | lamp - | brown \| green | 3 | green |
| A1 | signal + | white | 5 | white |
| A2 | signal - | brown | 1 | brown |
| A5 | screen | black | 6 | black |

- Do not repair damaged cables or connectors. Replace with original spare parts. They alone ensure correct signal transmission and communication of data.

**Lamp failure**

- The lamp voltage of 5.00 $V_{DC}$ is the same for all BioPAT® Fundalux sensors and independent of the cable length. It is factory set. Each lamp output of a measuring amplifier can handle only one BioPAT® Fundalux sensor.
  Prior to checking the lamp voltage, the sensor should be powered for at least three minutes, as the lamp voltage at terminals 6 and 7 of the converter depends on the load!
- BioPAT® Fundalux sensors have integrated control electronics for temperature compensation and changes to light source. The current is affected by changes in the sensor temperature. Typical operational currents for BioPAT® Fundalux sensors are 80 to 100 mA DC: In case of broken lamp circuit (i.e. the lamp current falls below approx. 65 mA), the LED “LAMP FAILURE” and the lamp failure relay in the amplifier is activated.
- The light source is switched off if the temperature rises above 75°C.
- Once the temperature drops below approximately 70°C, the light source power restored.
- If either overheating or faulty wiring (broken cable, no contact in a connector) are not the reason for a lamp failure, you should contact your local Sartorius service engineer to arrange the return of the BioPAT® Fundalux probe.

**Detector failure:**

- A broken detector circuit “FAILSAFE” is displayed in the DCU error messaging service. It will be impossible to zero the system. And if the fault is not caused by defective wiring (see above), your should contact your local Sartorius service engineer for return and repair.

# 8 Technical Data

## 8.1 BioPAT® Fundalux Sensor for Ports Ø 12 mm

| Information | Unit | Value |
|---|---|---|
| Materials | | |
| – wetted parts | | stainless steel 1.4435 (SS 316 L),<br>surface electro-polished Ra < 0.4 µm,<br>dF < 1% (BN2) |
| – windows | | sapphire (encapsulated, without sealing) |
| – housing | | stainless steel 1.4571 (SS 316 Ti) |
| Port seals | mm | O-ring Ø 11.0 × 3.0<br>EPDM (FDA), other materials on request |
| Pressure rating | barg | PN10 (test pressure PT 15) |
| – permissible, PS | | pressure-free ± 0.5 bar (± 7.25 psi) |
| Permissible process temperature TS | °C (°F) | permanent: +5 (41) up to +50 (122) |
| Sterilisation conditions | | Sterilisation must be performed outside the process and the ASD must be disconnected from a power source (autoclaving possible without cable) |
| max. pressure | | 4 bar (58 psi) |
| max. temperature | | 135 °C (275 °F) (max. 60 min/day) |
| Ambient temperature | | |
| operation | °C (°F) | 0 (+32) up to +40 (+104) |
| transportation | °C (°F) | -20 (-4) up to +70 (+158) |
| Light source | nm | LED, hermetically sealed, Wave length range 840–910 |
| Detector | | silicon photodiode, hermetically sealed |
| Cable connection | m (ft) | sensor cable ASD-CC, pluggable both sides, 2.0 (7.0) |
| Weight | | |
| sensor | kg | approx. 0.5 |
| cable | kg | approx. 0.5 |
| Type of protection | | IP68 |

## 8.2 BioPAT® Fundalux Sensor for Ports Ø 19 mm

| Information | Unit | Value | | |
|---|---|---|---|---|
| Materials | | | | |
| – wetted parts | | stainless steel 1.4435 (SS 316 L),<br>surface electro-polished Ra < 0.4 µm,<br>dF < 1% (BN2) | | |
| – windows | | sapphire (encapsulated, without sealing) | | |
| – housing | | stainless steel 1.4571 (SS 316 Ti) | | |
| Port seals | mm | O-ring Ø 15.60 × 1.78<br>EPDM (FDA), other materials on request | | |
| Pressure rating | barg | PN10 (test pressure PT 15) | | |
| – permissible, PS | | 10 mbar – 10 bar with TS 0 °C | +100 °C | |
| – permissible at elevated temperature | | | | |
| TS | °C | < 100 | 125 | 150 |
| PS | barg | 10 | 8 | 6 |
| PS | psi | 145,1 | 116 | 87 |
| Permissible process temperature TS | | | | |
| permanent | °C (°F) | +5 (41) up to +65 (149) | | |
| short term (60 min/day) | °C (°F) | +5 (41) up to +135 (275) | | |
| short term (30 min/day) | °C (°F) | +5 (41) up to +145 (293) | | |
| Sterilisation conditions | | Sterilisation must be performed outside the process and the ASD must be disconnected from a power source (autoclaving possible without cable) | | |
| max. pressure | | 4 bar (58 psi) | | |
| max. temperature | | 135 °C (275 °F) (max. 60 min/day) | | |
| Ambient temperature | | | | |
| operation | °C (°F) | 0 (+32) up to +40 (+104) | | |
| transportation | °C (°F) | -20 (–4) up to +70 (+158) | | |
| Light source | nm | LED, hermetically sealed, Wave length range 840–910 | | |
| Detector | | silicon photodiode, hermetically sealed | | |
| Cable connection | m (ft) | sensor cable ASD-CC, pluggable both sides, 2.0 (7.0) | | |
| Weight | | | | |
| sensor | kg | approx. 1.0 | | |
| cable | kg | approx. 0.5 | | |
| Type of protection | | IP68 | | |

## 8.3 BioPAT® Fundalux Sensor for Standard Ports Ø 25 mm

| Information | Unit | Value | | |
|---|---|---|---|---|
| Materials | | | | |
| – wetted parts | | stainless steel 1.4435 (SS 316 L),<br>surface electro-polished Ra < 0.4 µm,<br>dF < 1% (BN2) | | |
| – windows | | sapphire (encapsulated, without sealing) | | |
| – housing | | stainless steel 1.4435 (SS 316 Ti) | | |
| Port seals | mm | O-Ring Ø 18.64 × 3.53<br>EPDM (FDA), other materials on request | | |
| Pressure rating | barg | PN10 (test pressure PT 15) | | |
| – permissible, PS | | 10 mbar – 10 bar with TS 0 °C \| +100°C | | |
| – permissible at elevated temperature | | | | |
| TS | °C | < 100 | 125 | 150 |
| PS | barg | 10 | 8 | 6 |
| PS | psi | 145.1 | 116 | 87 |
| Permissible process temperature TS | | | | |
| permanent | °C (°F) | +5 (41) up to +65 (149) | | |
| short term (60 min/day) | °C (°F) | +5 (41) up to +135 (275) | | |
| short term (30 min/day) | °C (°F) | + 5 (41) up to +145 (293) | | |
| Sterilisation conditions | | not autoclavable | | |
| Ambient temperature | | | | |
| operation | °C (°F) | 0 (+32) up to +40 (+104) | | |
| transportation | °C (°F) | -20 (–4) up to +70 (+158) | | |
| AirPurge® | | connection M5 available by default | | |
| Light source | nm | LED, hermetically sealed, Wave length range 840–910 | | |
| Detector | | silicon photodiode, hermetically sealed | | |
| Cable connection | m (ft) | sensor cable ASD-CC, pluggable both sides, 3 (10) | | |
| Weight | | | | |
| sensor | kg | approx. 1.5 | | |
| cable | kg | approx. 0.5 | | |
| Type of protection | | IP68 | | |

## 8.4 BioPAT® Fundalux Measuring Amplifier DCU

- for integrating into the Biostat® DCU
- connection of one of these sensors
  - BioPAT® Fundalux for lid ports Ø 12 mm for Univessel®
  - BioPAT® Fundalux for lid ports Ø 19 mm for Univessel®
  - BioPAT® Fundalux for standard ports Ø 25 mm (“Safety Port”, by Sartorius Stedim Systems GmbH)

| Item | Description |
|---|---|
| Modules | 1 – 2 modules per motherboard |
| Electrical connections | existing connectors M30, with pin assignment acc.ording to manufacturing standard of Sartorius Stedim Systems GmbH |
| Power supply | ±15 V ± 0.75 V for the measuring amplifier; current consumption 100 mA max., not fuse protected |
| | + 5.00 $V_{DC}$ ± 0.25 V for lamp supply; current consumption 200 mA max.; fuse TR5 T0,315A |
| Grounding and EMI | grounding according to manufacturing standard of Sartorius Stedim Systems GmbH |
| RoHS | This device has been manufactured RoHS-conforming in compliance with the requirements of the european parliament. |
| Emission | no switching circuits |
| Input amplifier | logarithmic converter, optimized for photo currents |
| Dynamic range | 1 nA to 1 mA, leakage fault < 0.03 nA at 65°C |
| Range | 0 – 6 AU |
| Calibration | 0.5 $V_{DC}$ at 500 µA, 1,667 $V_{DC}$ \| decade current change |
| Accuracy | < 0.5% |
| Response time | attenuation with RC-combination to 1 – 2 seconds |
| Stability | internal temperature- and leak current compensation |
| Temperature range | – operation: + 5°C (41°F) up to + 65°C (149°F)<br>– storage: – 20 °C (– 4°F) up to +85°C (185°F) |
| Output signal | 0 – 10 $V_{DC}$, for direct connection to DCU<br>– minimum impedance 10 kOhm<br>– no galvanic insulation<br>– output signal limited to –0.4 $V_{DC}$ to +10.4 $V_{DC}$ |
| Lamp output | +4.75 - 5.25 $V_{DC}$ with 200 mA max.; no galvanic insulation<br>– short circuit protection with fuse TR5 T0.315 A<br>– over voltage protection with Transil-Diode 6V8 at TER X1<br>– current monitoring for LOW \| HIGH levels with lamp alarm (sensor switches off lamp circuit in case of overheating) |
| Sensor connection | 5 wires directly connected to Molex terminals on module; scope of delivery:<br>– MV-installation kit DCU with sensor cable ASD-CC |

## 8.5 Spare Parts and Consumables

| Cat.-no. | Item, description |
|---|---|
| SB-18-00-0117 | Maintenace kit (3 × O-ring; 1+ disc) for autoclavable culture vessels, lid port Ø 12 mm |
| SB-39120830 | O-ring BioPAT® Fundalux for autoclavable culture vessels, lid port Ø 19 mm |
| BB-39123324 | O-ring BioPAT® Fundalux for autoclavable culture vessels, lid port Ø 25 mm |
| BB-34090355 | BioPAT® Fundalux, assembly kit DCU \| DFC |
| BB-34090356 | BioPAT® Fundalux AirPurge® spare Kit |
| SB-34148808 | BioPAT® Fundalux sensor cable 2 m (7 ft) |
| SB-34148809 | BioPAT® Fundalux sensor cable 3 m (10 ft) |

**NOTE**

Signal cable and measuring amplifier (integrated in the control unit or as an standalone amplifier) are only suitable for BioPAT® Fundalux sensors.

- You cannot connect the BioPAT® Fundalux sensor to bioreactors equipped with BioPAT® Fundalux turbidity measuring devices (sensors by Monitek) and vice versa.
- (Re-)Alignment of the measuring amplifier is only permitted by qualified service engineers.

When replacing a signal cable the lamp voltage normally does not require realignment and the BioPAT® Fundalux sensor can be used again.

# 9 Conformity & Licenses

## 9.1 EU Declaration of Conformity

The attached declaration of conformity hereby confirms compliance of the device with the directives cited.

Original

# EU-Konformitätserklärung
# EU Declaration of Conformity

| | |
|---|---|
| Hersteller<br>*Manufacturer* | Sartorius Stedim Systems GmbH<br>Robert-Bosch-Str. 5-7, 34302 Guxhagen, Germany |

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

| | |
|---|---|
| Geräteart<br>*Device type* | Trübungssensor<br>*Turbidity sensor* |
| Baureihe<br>*Type series* | **BioPAT® Fundalux** |
| Modell<br>*Model* | **BPFxLy \| BPFSSy \| BB-8846604**<br>x = 1, 2 oder/or 5; y = 01, 05 oder/or 10 |

in der von uns in Verkehr gebrachten Ausführung allen einschlägigen Bestimmungen der folgenden Europäischen Richtlinien entspricht und die anwendbaren Anforderungen folgender harmonisierter Europäischer Normen einschließlich deren zum Zeitpunkt der Erklärung geltenden Änderungen erfüllt:
*in the form as delivered fulfils all the relevant provisions of the following European Directives and meets the applicable requirements of the harmonized European Standards including any amendments valid at the time this declaration was signed listed below:*

| | **EMV \| EMC** | **RoHS** |
|---|---|---|
| Richtlinie<br>*Directive* | 2014/30/EU | 2011/65/EU |
| Norm(en)<br>*Standard(s)* | EN 61326-1:2013 | EN IEC 63000:2018 |

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

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Sartorius Stedim Systems GmbH
Guxhagen, 2022-08-24

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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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