

User Manual

Dialysis probe



1000056315



SARTORIUS

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1 About this document

These instructions provide all the information necessary for operation of the dialysis probe. The instructions must be read, understood and used by all personnel using the dialysis probe.

- These instructions are part of the dialysis probe.
- Before working with the dialysis probe, read the instructions carefully and completely.
- Keep them in safe and easily accessible place near the dialysis probe site of installation.
- If the instructions are lost, request a replacement or download the latest instructions from our website.

Masculine or feminine forms are used to facilitate legibility in these instructions and always simultaneously denote the other gender as well.

1.1 Validity

These instructions apply to the dialysis probe out of stainless steel.

1.2 Target groups

The instructions are designed for the target group „User“, who is familiar with the operation of the dialysis probe and the associated working processes.

The training takes place within the scope of start-up and is performed by Sartorius Stedim Biotech or an authorized distributor.

1.3 Symbols used

The symbols used in the user manual are specifically intended to draw attention to the safety precautions! The symbol may not replace the text of the respective safety precaution. Therefore, the text must always be read completely!

NOTICE

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

1.4 Intended use

The dialysis probe provide the perfect solution for sterile online sampling in connection with an online analyser (e.g. BioPAT® Trace and BioPAT® Multi Trace) in bioreactors used in industrial and laboratory facilities.

The user must ensure that

- the dialysis probe is used for its intended purpose only, see chapter “2 Product description”, page 6),
- the dialysis probe is used only when functional and in proper working order.
- the user manual is always kept legible and complete at the place of use.

1.5 Disposal

1.5.1 Packaging

The packaging is made of environmentally friendly materials that can be used as secondary raw materials. If the packaging is no longer needed, it can be disposed of by local waste disposal authorities.

1.5.2 Dialysis probe

The dialysis probe including accessories does not belong in your regular household waste as this equipment is manufactured from high-grade materials which can be recycled and reused.

1.6 Hazardous materials

The dialysis probes and accessories do not contain any hazardous materials that would necessitate special disposal measures.

Dialysis probes contaminated with hazardous materials (NBC-contamination) will not be accepted for repair or disposal.

2 Product description

The **dialysis probe** provides the perfect solution for sterile online sampling in connection with an online analyser (e.g. BioPAT® Trace and BioPAT® Multi Trace) in bioreactors used in industrial and laboratory facilities.



Fig. 1: Dialysis probe out of stainless steel

The dialysis probe in its entirety is made of stainless steel and ensures a high level of sterility by the use of an extremely robust membrane.

The dialysis probe is installed in the bioreactor and sterilized in situ.

It is suitable for all types of cultivation and can be installed in the bioreactor as well as in the PG 13.5 and 19 mm top plate and in a 25 mm side port.

Optimal results can only be achieved if the membrane is completely immersed. Therefore, a minimum immersion depth of 5 cm is required.

The application options for the dialysis probe depend on the reactor dimensions and the process conditions. In general, the dialysis probe is recommended for use on smaller bioreactors, where any loss of volume during sampling is unacceptable.

The use of the dialysis probe as a sampling system ensures analysis at constant volumes.

In addition to the standard membrane, there are special membranes available:

- Cellulase resistant membrane for cultures, in which cellulases are released during the process (primarily microbial cultures).
- Gas diffusion membrane for samples with volatile components (e.g. methanol and ethanol).

The different membranes are ready-to-use, can easily be installed in the dialysis probe and replaced after every cultivation.

3 Function

If the dialysis probe is used to feed the sample from the bioreactor into an online analyser, then the analyte is transferred through a diffusion membrane into an internal pump-driven buffer stream and transported to the measuring cell.

The following figure shows the principle function of the dialysis probe.

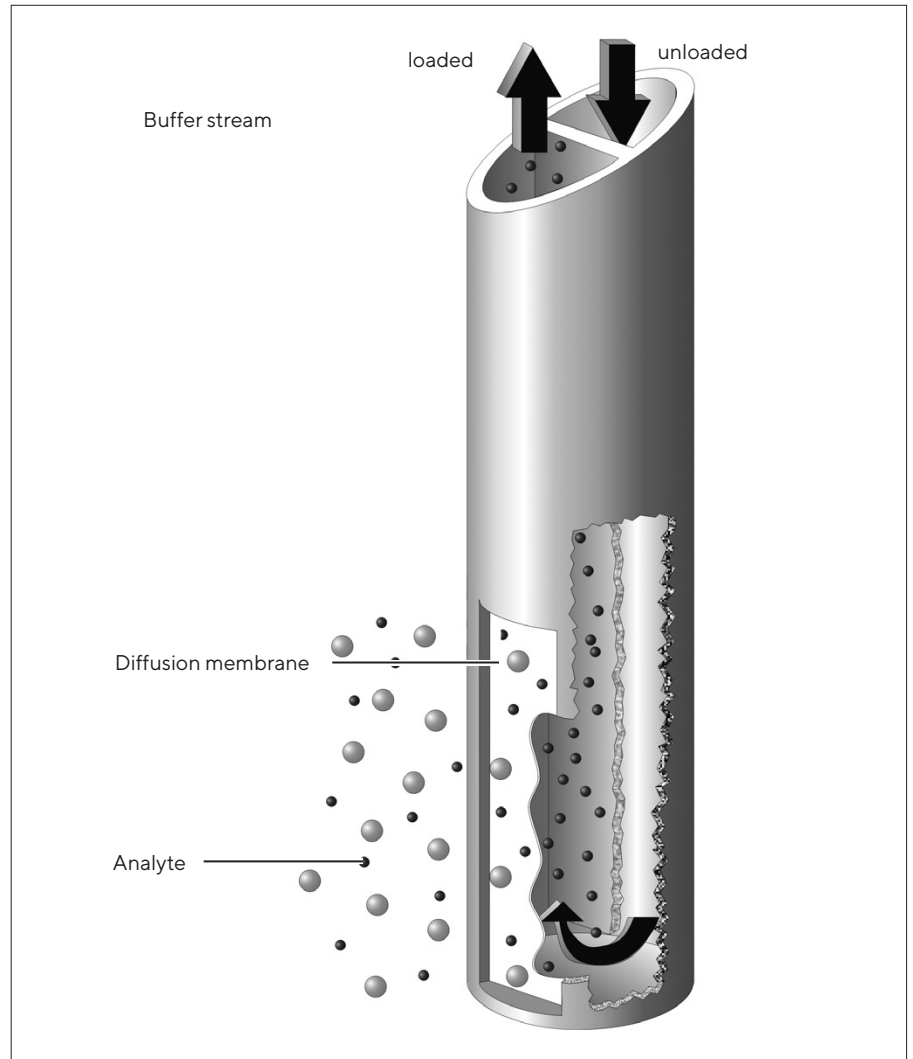


Fig.2: Principal function of the dialysis probe

4 Scope of delivery, consumables and spare parts

The dialysis probe including accessories is delivered in protective packaging.

- ▶ Please save this packaging; proper (return) shipping is only possible in the original packaging.
- ▶ Upon receipt, check the delivery for completeness and any possible damage that may have occurred in transit.
- ▶ Any transport damage must be reported within a week of delivery. Complaints made after this date will not be accepted.

4.1 Scope of delivery

The scope of delivery of the dialysis probe (1) for installation includes dialysis probe lunette (2), 2 TORX screws (3), 4 autoclavation caps (4), user manual and one installation kit.

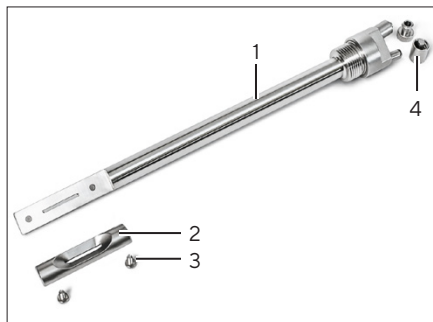


Fig. 3: Dialysis probe



Fig. 4: Content of the installation kit

The installation kit contains the following parts:

- Single-use syringe 5 ml
- O-ring
- Sliding ring
- TORX screwdriver

4.2 Consumables

Coloured membranes are available for each application (see chapter “8 Order information”, page <?>).

Application	Colour of the membrane lunette
Glucose / Lactate	green / white
Glucose / Lactate / Low	blue / white
Glucose / Lactate / cellulase stable	silver / white
Ethanol / Methanol	red / white

4.3 Optional spare parts

Two adapter 19/12 mm (M26 x1) with fine thread and (RD28 x 1/8”) with coarse thread are available for the installation of the dialysis probe into the 19 mm top plate.



Fig. 5: Dialysis probe with adapter M26 x1



Fig. 6: Dialysis probe with Adapter RD28 x 1/8”

The dialysis probe with a minimum length of 165 mm can also be installed in a 25 mm side port of the bioreactor using the adapter 25/12 mm.



Fig. 7: Dialysis probe with 25 mm adapter

The dialysis probe, length 300 mm (BPT0086) can also be used in the single-use bioreactor Biostat STR® via a Kleenpak™ Adapter (BPT0079).

The adapter is available from the company Sartorius Stedim Biotech, article number BPT0079 (3 pack).

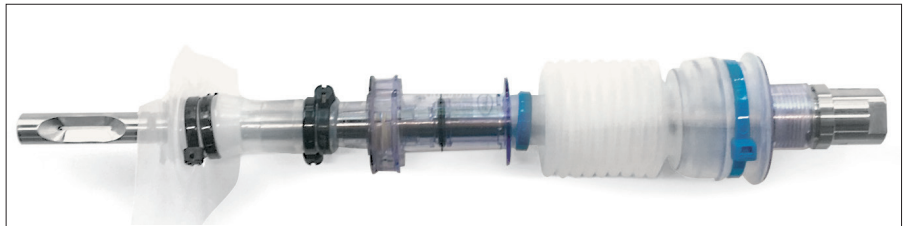


Fig. 8: Dialysis probe 300 mm with Kleenpak™ Adapter

Kleenpak™ is a registered trademark of Pall Corporation.

5 Design of the dialysis probe

The dialysis probe is available in the following nominal lengths:

- 132 mm
- 165 mm
- 212 mm
- 232 mm
- 300 mm
- 332 mm
- 432 mm

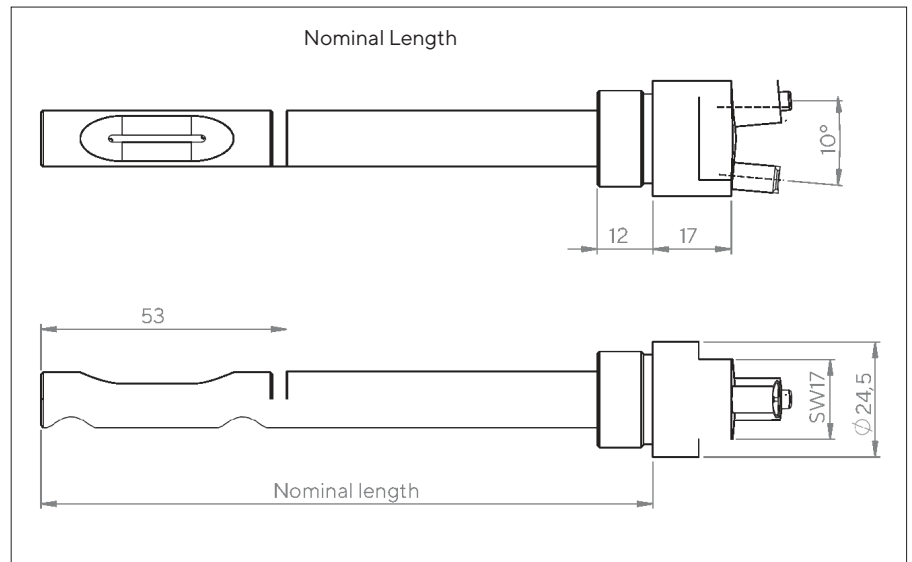


Fig.9: Drawing of the dialysis probe

6 Getting started

6.1 Connecting the dialysis probe

6.1.1 Mounting the membrane in the dialysis probe

Install a new membrane in the dialysis probe before every online measurement involving bioprocesses with sterile feeds, see figure below. If this rule is not observed, a lack of sterility may jeopardize the entire cultivation process.

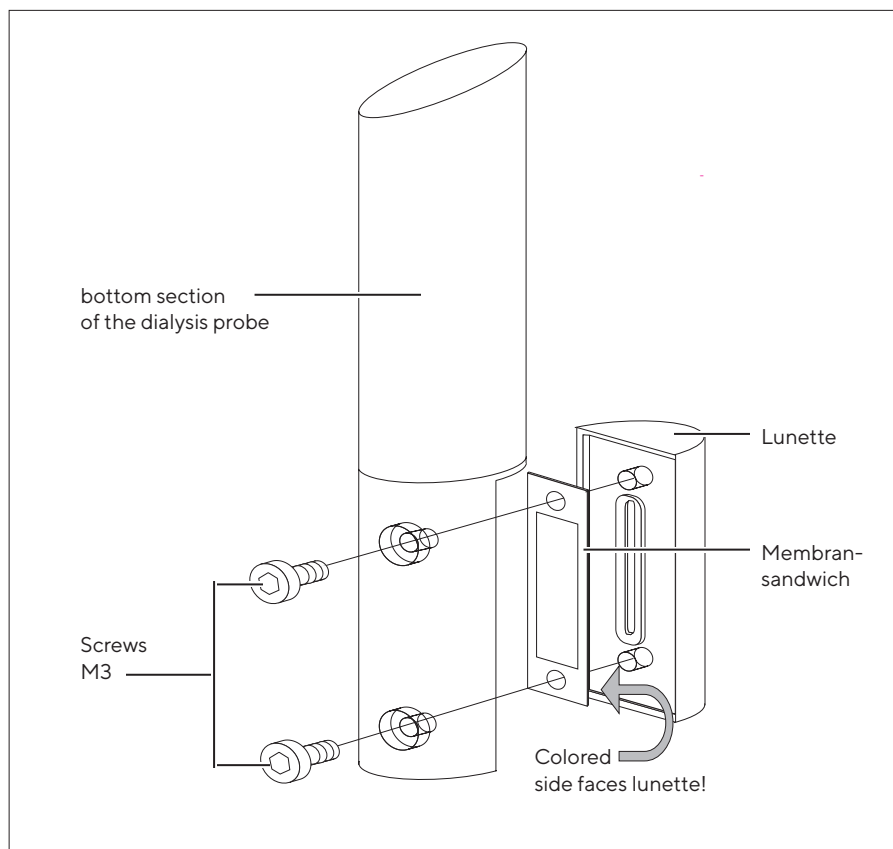


Fig.10: Replacing the membrane in the dialysis probe for the application Glucose /Lactate

The new dialysis membrane must be placed correctly (**colored side faces the lunette!**) and the probe lunette must be tightened firmly with the two screws, see fig. 11 - 13.



Fig. 11: Inserting a new membrane



Fig. 12: Installation of the lunette



Fig. 13: Tightening the 2 screws

NOTICE

Incorrect insertion of the membrane may result in leaks in the dialysis probe head and jeopardize the sterility of the entire cultivation process.

Pay particular attention to ensure that the membrane is seated correctly in the dialysis probe.

The white side of the membrane must be inserted facing the dialysis probe (buffer-touching).

The colored side of the membrane faces the probe lunette (media-touching).

NOTICE

For the measurement of methanol and ethanol a special membrane is required.

For this purpose a special lunette is to be used with marking „-0,2“.

Obstructions at the membrane lunette can occur if this special lunette is not used resulting in erroneous readings or leakage in the tubeset.

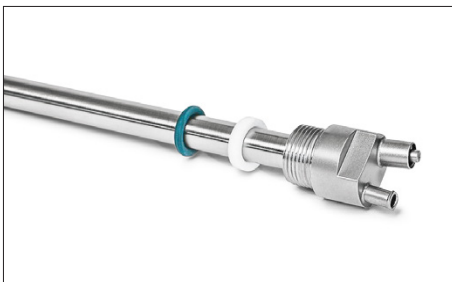


Fig. 14: Positioning the sliding ring and o-ring

6.1.2 Installing the dialysis probe into the bioreactor

Insert the sliding ring and the o-ring prior to the installation in the fermenter, see fig. 14.

Notice

Attention has to be paid to the minimum immersion depth of the dialysis probe in the bioreactor of 5 cm in order to avoid incorrect measurements.

6.1.3 Sterilization of the dialysis probe prior connecting to the device

Before connecting the dialysis probe to the analyser (e.g. BioPAT® Trace and BioPAT® Multi Trace) the probe must be sterilized along with the bioreactor.

Connect the dialysis probe to the single-use syringe, as shown in fig. 15.

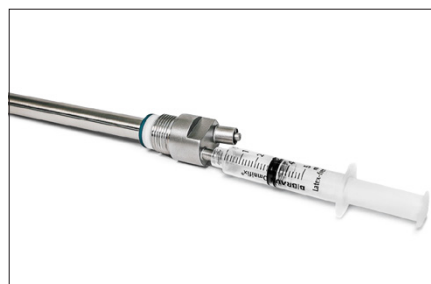


Fig. 15: Filling the probe with deionized water



Fig. 16: Sealing the probe prior to sterilization

- ▶ Prior to sterilizing, fill the dialysis probe with deionized water using the single-use syringe (see fig. 15). When doing so, the dialysis probe can also be checked for leaks.
- ▶ Seal the dialysis probe using the autoclavation caps for sterilization (fig. 16). This prevents one-sided overpressure from being produced at the membrane in the dialysis probe, which could damage the membrane.
- ▶ Now sterilize the reactor.
- ▶ After sterilization: After the cooling phase, use the single-use syringe to fill the dialysis probe with deionized water again and carefully check for free flow (see fig. 15).
- ▶ The dialysis probe can now be connected to the corresponding tubing set of the online analyser.

NOTICE

Dry sterilization is not suitable because the membrane may be damaged.

NOTICE

Steam sterilization at 1 bar and 121°C.

The membrane must be properly installed for this to work.

During sterilization, the dialysis probe must be filled with deionized water and sealed using autoclavation caps, as the membrane can become damaged.

6.1.4 Connecting the dialysis probe to the tubing set

The dialysis probe is directly connected with the dialysis tubing set of the online analyser.

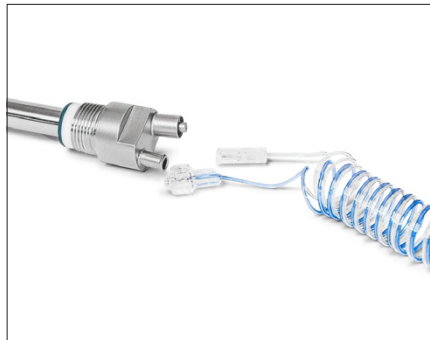


Fig.17: Connecting the dialysis probe to the dialysis tubing set

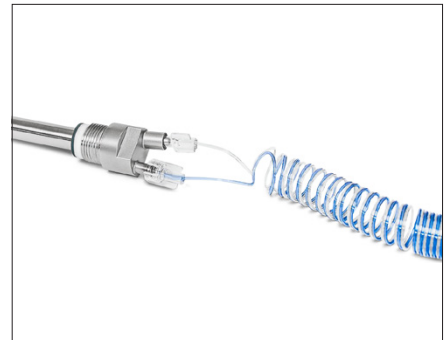


Fig.18: Connecting the dialysis probe to the dialysis tubing set

When connecting the probe to the tubing set, care must be taken to ensure that as little air as possible is introduced into the tubing set in the form of small air bubbles, since these could be trapped in the measuring cell which could lead to fluctuating measurements.

Procedure

- ▶ First, rinse the probe with deionized water.
- ▶ Then connect only the inlet line (arrow towards the probe) and leave the outlet line (arrow away from the probe) open.
- ▶ Then start the measurement. This triggers the probe purge and liquid and any remains of air escape from the output line of the probe.
- ▶ The second line of the tubing set is then connected and rinsed for a few minutes.

Basically, air bubbles in the tubing set are rinsed out over time. However, this process takes some time (e.g., during the priming process).

If air bubbles are present in the measuring cell after the connection of the dialysis probe, it would be advantageous to operate the system with a maximum measuring frequency for a duration of approx. 30 minutes.

NOTICE

If air bubbles are present in the measuring cell, under no circumstances should calibrations or referencing be carried out, as they may be faulty and consequently lead to incorrect results.

6.2 Cleaning the dialysis probe and replacing the membrane

- ▶ Before removing the dialysis probe from the bioreactor, the tubing set is removed from the probe by removing the tube ends.
- ▶ After harvesting the bioreactor or any dead autoclaving phase, remove the dialysis probe from the bioreactor.
- ▶ The cleaning of the outer surface of the dialysis probe is carried out with a soft brush and water.
- ▶ Check to make sure that the gaskets on the dialysis probe adapter are clean and seated properly.
- ▶ Remove the two TORX screws on the end of the dialysis probe using the TORX wrench supplied; this allows the dialysis probe lunette to be removed from the lunette holder along with the dialysis membrane.
- ▶ Afterwards, clean the probe lunette and the lunette holder with a soft brush and water.

NOTICE

Removal of deposits inside the dialysis probe:

In order to avoid blocking in the dialysis probe which may result in leakages at the tubing set it is necessary to remove deposits inside the dialysis probe. Rinse the dialysis probe with deionized water using the single-use syringe. Drying afterwards by pressing air through the dialysis probe using the single-use syringe.

7 Data sheet dialysis probe

Specification	Information
Available length in mm	132, 165, 212, 232, 300, 332, 432
Material	Austenitic stainless steel
Quality of the material	1.4404/AISI 316L
Sterilization	Steam sterilization at 1 bar/121°C
Pressure range	Resistant up to 6 bar
Probe diameter	12 mm with PG 13.5 thread

8 Order information

8.1 Dialysis probe

(Equipment supplied includes installation kit, 4 autoclavation caps, and user manual)

Description	Order No.
Dialysis probe length 132 mm LUER	BPT0082
Dialysis probe length 165 mm LUER	BPT0083
Dialysis probe length 212 mm LUER	BPT0084
Dialysis probe length 232 mm LUER	BPT0085
Dialysis probe length 300 mm LUER	BPT0086
Dialysis probe length 332 mm LUER	BPT0087
Dialysis probe length 432 mm LUER	BPT0088

8.2 Membranes

Description	Order No.
Membranes (Glucose/Lactate) Content: 5 pieces	BPT0024
Membranes (Glucose/Lactate/cellulase resistant) Content: 5 pieces	BPT0040
Membranes (Glucose/Lactate/Low) Content: 5 pieces	BPT0024LR
Membranes (Ethanol/Methanol) Content: 5 pieces	BPT0047

8.3 Accessories for the dialysis probe

Description	Order No.
Installation kit, dialysis probe Gen2	BPT0080
Autoclavation caps, contents: 1 set male/female	BPT0081
Dialysis probe lunette -0.20 mm (Application Ethanol/Methanol)	BPT0070
Adapter Kleenpak™ Content: (3 pieces)	BPT0079
Fitting D19/12-M26x1	BB-8891281
Compression fitting for 12 mm probes for installation in a PG 13.5 port	UNIVESSEL-00054

9 Decontamination Declaration

Sartorius Stedim Biotech has a duty to protect its staff from hazardous substances. When returning the dialysis probe, the sender must enclose a decontamination declaration as proof of compliance with the safety regulations governing the area of application for which they were used.

- This declaration must detail the microorganisms, cells and media that the dialysis probe | components have come into contact with and the measures taken to disinfect and decontaminate it.
- The recipient must be able to read this decontamination declaration before opening the packaging.

Decontamination Declaration

Declaration Concerning the Decontamination and Cleaning of Equipment and Components

To protect our personnel, we require that all equipment or components which come into contact with our personnel at customers' facilities be free of biological, chemical, or radioactive contaminants.

We will only accept an order when:

- the equipment or components have been adequately CLEANED and DECONTAMINATED.
- this declaring document has been completed, signed and returned to us by an authorized person.

Please help us in assuring a safe, hazard-free work environment.

Description of the Equipment or Component(s)

Description | Cat. No.:

Serial no.

No. of invoice | Delivery note:

Date of delivery:

Contamination | Cleaning

Attention: Please specify exactly the biological, chemical, or radioactive contaminant

Attention: Please describe the cleaning and decontamination procedure | method.

The equipment was contaminated with:

and it has been cleaned and decontaminated by

Legally binding declaration

I (we) certify that all information given in this form is correct and complete. The equipment and components have been adequately decontaminated and cleaned according to the legal requirements. No chemical or biological or radioactive risks remain that could endanger exposed persons' safety or health.

Company | Institute:

Address | country:

Tel.:

Fax:

Name of authorized person:

Position:

Date | Signature:

Please pack the equipment properly and send it ex recipient to your Sartorius service.



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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.

Copyright notice:

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