**Operating Instructions** 

Original Operating Instructions

# Sartocheck<sup>®</sup> mini

Integrity Test Device







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# 1 About these Instructions

## 1.1 Validity

These instructions are part of the device; they must be read in full and stored. These instructions apply to the following version of the device:

Device	Туре
Sartocheck <sup>®</sup> mini	2629203

### 1.2 Target Groups

These instructions are addressed to the following target groups. The target groups must possess the knowledge specified below.

Target group	Knowledge and Qualifications	
Operator	The operator is familiar with the device and the associated work processes. The operator understands the hazards which may arise when working with the device, and knows how to prevent them.*	
Operating en- gineer labora- tory manager	The operating engineer   laboratory manager makes decisions about the use and configuration of the device.*	
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.*	
* If a person in the target group operates the software interface of the		

\* If a person in the target group operates the software interface of th device, they are also the "user".

### 1.3 Symbols Used

### 1.3.1 Warnings in Operation Descriptions

### **WARNING**

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

### **A**CAUTION

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

### NOTICE

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

- 1.3.2 Other Symbols Used
- Required action: Describes activities that must be carried out. The activities in the sequence must be carried out in succession.
- ▷ Result: Describes the result of the activities carried out.
- [] Refers to operating and display elements. Indicates status, warning, and error messages.

#### **Figures in These Instructions**

Depending on the device configuration, the figures depicting the device and operating display may differ slightly from the supplied device. The variants shown in these instructions are examples.

# 2 Safety Instructions

### 2.1 Intended Use

The device is a small, lightweight and portable filter test device for automatic testing of membrane filters for integrity.

The device is used to perform pressure drop tests on membrane filters. In the process, the device does set the test pressure automatically. The device must be vented after each integrity test.

The device is intended for use with external charger adapter with Separated Extra Low Voltage (SELV) output (18.0  $V_{DC}$ , 800 mA).

The device is intended exclusively for use in accordance with these instructions. Any other use is considered improper and can interfere with the device's protective functions.

#### **Operating Conditions for the Device**

Do not use the device in potentially explosive environments. Only use the device indoors.

The device may only be used with the equipment and under the operating conditions described in the Technical Data section of these instructions.

### 2.1.1 Modifications to the Device

If the device is modified, persons may be put at risk. Device-specific documents and product approvals may lose their validity.

Contact Sartorius if you have any questions concerning modifications.

### 2.1.2 Maintenance and Repairs on the Device

Device maintenance and repairs may only be carried out by persons with specialized knowledge of the device. If the device is not serviced or repaired by a specialist, persons may be put at risk. Device-specific documents and product approvals may lose their validity.

Only the maintenance tasks described in these instructions may be carried out. For maintenance tasks that need to be carried out by Sartorius Service, contact Sartorius Service.

Sartorius recommends that any repair work, even that carried out after the end of the warranty period, is carried out by Sartorius Service or after consulting with Sartorius Service.

### 2.2 Qualifications of Personnel

Persons who do not possess adequate knowledge about how to use the device may injure themselves and other persons

If a particular qualification is required for an activity, the target group will be specified. If **no** qualification is specified, the activity may be carried out by the "operator" target group.

### 2.3 Functionality of the Device Parts

**Non-**functioning device parts, e.g., as a result of damage or wear, can cause malfunctions. There is a risk of injury to persons.

- ▶ If device parts are not functional, do not use the device.
- Comply with the maintenance intervals (for intervals and maintenance tasks, see chapter "9 Cleaning and Maintenance", page 30).

### 2.4 Protective Equipment

The protective equipment on the device protects persons who work with the device against the hazards associated with it, e.g., electrical current. If the device's protective equipment is dismantled or modified, people may be seriously injured.

Do not open the device and the power supply unit.

### 2.5 Electrical Equipment

### 2.5.1 Damage to the Device's Electrical Equipment

Damage to the device's electrical equipment, e.g., damaged insulation, can be life-threatening. Contact with parts under voltage represents a danger to life.

- If the electrical equipment of the device is defective, cut off the power supply and contact Sartorius Service.
- ▶ Keep live parts away from moisture. Moisture can cause short circuits.
- Keep the covers of the connections at the back of the device closed when not in use.

### 2.5.2 Power Supply Unit and Power Supply Cable

The use of an unauthorized power supply unit or power supply cable may cause life-threatening injuries as a result of electric shocks, for example.

- ▶ Only use the original power supply unit and power supply cable.
- If the power supply unit or power supply cable needs to be replaced, contact Sartorius Service. Do not repair or modify the power supply unit or power supply cable.

### 2.6 Overpressure

Overpressure can make unsuitable tubes, vessels, filters, etc. burst and can cause injuries.

- Adhere to the maximum permitted inlet pressure (see chapter "15.7 Pressure Range and Accuracy", page 45) and use a regulated compressed air source.
- Use a maintenance unit with pressure regulator.

### 2.7 Accessories and Consumables

The use of unsuitable accessories and consumables such as unsuitable compressed air tubes or unsuitable compressed air tanks can affect the functionality and operating reliability of the device and have the following consequences:

- Risk of injury to persons
- Damage, malfunctions, or failure of the device
- Only use accessories and consumables that have been approved by Sartorius for this device.

# 3 Device Description

# 3.1 Device Overview



Fig. 1: Device Overview

Pos.	Name	Description
1	Display	Graphical display that has 4 lines of text and and icon line underneath
2	Status LEDs	<ul> <li>Show a visual identification of the test</li> <li>result or prompts to the next step:</li> <li>Green: Positive   pass test result</li> <li>Yellow: Device busy, wait</li> <li>Red: Negative   failed test result</li> </ul>
3	Keyboard	
4	Power LED	
5	"On   off" switch	
6	Printer	Has a protective cover (IP54) to pro- tect the printer from liquids.
7	Housing	Splash-proof, protects the device from moisture and damages.

## 3.2 Special Buttons on the Keyboard

Icon   buttons	Description	
*	Special functions. They are shown in the display, if required.	
#	Used to delete entries.	

## 3.3 Connections

### 3.3.1 Compressed Air Connections

The connection is made using suitable pressure-resistant and flexible pressure tubes with the prescribed connection couplings and nipples.

The ventilation takes place via the [Venting] connection. As long as sufficient pressure equalization is ensured, it is not absolutely necessary to drain the exhaust air via a connected tube.



Fig. 2: Compressed air connections

Pos.	Name	Description
1	[Venting]	Connector for ventilation
2	[ln]	Compressed air input connector
3	[Out]	Filter connector. Connects the tube to the filter system.

### 3.3.2 Other Connections



Fig. 3: Connections at the back of the device

Pos.	Name	Description
1	[Valve]	For directing any harmful or sticky aerosols that may arise during ventila- tion to the outside.
2	[USB]	For connecting a Mini-USB.
3	[Power]	Charging socket, protected by a IP65 proof cover

# 3.4 Holding Eyelets



Fig. 4: Holding eyelets for transport on both sides

Pos.	Name	Description
1	Holding eyelet	For use with the shoulder strap. The holding eyelets can also be used for alternative attachment with cara- biners or similar.

### 3.5 Measuring Principle

During the integrity test, the device performs a very accurate pressure measurement. The device then determines the pressure drop, and calculates the diffusion rate from the pressure drop and the housing volume.



Fig. 5: Measuring principle (example)

Abbreviation	Description
P1	Pressure source
P2	Pressure
PO	Ambient pressure (air pressure)
V1	Input-side volume
V2	Escaped air quantity

The calculation is based on the following measuring principle:

- In the stabilization phase, the filter housing is connected to the pressure source P1. The filter housing with the upstream volume V1 is subject to pressure P1.
- At the beginning of the measurement, the device stops regulating the pressure. The air escaping through diffusion on the outlet side of the filter then causes a pressure drop in the filter housing.
- At the end of the test, the filter housing is only subject to pressure P2. The escaped air quantity V2 is subject to the ambient pressure (air pressure) P0.

The escaped gas volume V2 (by diffusional flow) is calculated as follows:

Description	Formula
Total gas quantity initially in the filter:	C = P1 x V1
Corresponds to the gas quantity after the test plus the escaped gas quantity:	C = (P2 x V1) + (P0 x V2)
Consequently:	P1 x V1 = (P2 x V1) + (P0 x V2)
P1 and P2 are measured, V1 and P0 are known.	
Consequently:	V2 = ((P1 - P2) x V1) / PO
The diffusion rate is the escaped gas volume in milliliters per minute.	Diff = V2 / measurement du- ration [mL/min]

# 4 Operating Design



Fig. 6: Display (example)

Pos.	Name	Description
1	Button indicator	Shows possible buttons that can be pressed next, e.g. [Start] or [↑].
2	Icon line	Displays the relevant icons.
3	Actions to be performed	

# 4.1 Icon Overview

lcon	Description
	Shows the battery status.
⊅-	Charger is plugged in.
5	Battery is charging.
X	Calibration required.
×	Access to service menu. Can only be accessed through a password, which is known to the service personnel.
₩	External vent valve is connected (optional).
	Test log storage warning. Appears when memory is > 90 % occcupied.
SD-Card	SD card inserted.

## 4.2 General Functional Diagram and Overview

The diagram shows the relationship between the individual functions of the device. The main functions block contains all the functions that are necessary for the filter test and the management of the test results:



Fig. 7: Selection of the main functions

Function	Description
TEST FILTER ? PROCEED > ↑↓	Performs a filter test defined earlier in test programs. The test log is automatically stored.
TEST RESULTS ? PROCEED > ↑↓	Selects 1 test from up to 150 test logs, and- shows its data.
PRINT DATA ? PROCEED > ↑ ↓	Prints a test log using a Bluetooth printer.
TEST PROGRAMS ? PROCEED > ↑↓	Defines up to 19 different filter tests. This function can be switched off when configurating the device.
SET CLOCK ? PROCEED > ↑↓	The clock time, data, summer or winter time can be set. This function can be switched off when configurating the device.
PRESSURE RELEASE ? PROCEED > ↑ ↓	Vents a pressurized volume.

Function		Description
CLEAN ? PROCEED	>↑↓	Removes dust or moisture from the pneumat- ic system. All valve combinations are sequen- tially opened and closed. Thus, all valves and tubing inside can be flushed by compressed air or water if applied at the pressure input.
SERVICE ? PROCEED	> ↑ ↓	Leaves the main functions and goes to the service options. For routine use of the device, these functions are not required.

## 4.3 Validating Entries and Deleting Text

The entry arrow appears bright if an entry is not in the valid range. As soon as the entry is in the valid range, the arrow appears black  $(\blacktriangleright)$ .

Entries can be deleted with the [#] key: A short press deletes 1 character; a long press deletes everything.

Entry as a pure numerical value via the device keyboard is possible by pressing the [O]-[9] buttons for longer than 1 second or as any text using the SartoControl mini software.

You can stop a test anytime by pressing the [Stop] button or the "on | off" switch which takes you back to the main menu.

## 4.4 Service Functions

The [SERVICE] menu contains all the functions that are necessary for special settings of the device. The default access code is "7".

The service functions should be utilized only by users who have been given instruction. They are accessible with a password (security code). You can change this code (up to 5 digits) in the corresponding Service Menu.

Function	Description
	Description
SET CLOCK? PROCEED > ↑↓	Changes the time   date of the device.
CALIBRATION ? PROCEED > ↑↓	For calibration of the device use this func- tion. For more information see chapter "9.4 Calibrating the Device", page 31.
LANGUAGE ? PROCEED > ↑↓	For setting the language: – German – English – French – Italian – Spanish – Portuguese
INFORMATION ? PROCEED > ↑↓	<ul> <li>Shows information on operational data:</li> <li>Firmware version</li> <li>Hardware version</li> <li>Charge status and measured data</li> <li>Hours of operation</li> <li>Memory occupancy</li> </ul>
ACCESS CODE ? PROCEED > ↑↓	For entering a number of 1-5 digits, with which to unlock access to the [SERVICE] menu. When entering a 0, access is open without a code request.
ERASE DATA ? PROCEED > ↑↓	For deleting either the entire device memo- ry or specific areas of the memory: - Calibration data - Test log data - Test programs - All data If the calibration values are deleted, a recali- bration of the device is necessary, see chap- ter "9.5 Deleting Data from the Device Memory", page 36.
CONFIGURATION ? PROCEED > ↑↓	Sets, activates or deactivates the device functions, see chapter "6.7 Configurating the Device", page 24.
MANUAL OPERATION ? PROCEED > ↑↓	For selecting and activating any valve and observing the pressure value.
SERVICE PRINT ? PROCEED > ↑↓	Generates and prints a detailed device re- port.

# 5 Installation

## 5.1 Scope of Delivery

Item	Quantity
Sartocheck® mini integrity test unit	1
Printer paper rolls	4
Pressure inlet tubing (18104)	1
Pressure outlet tubing	1
Carrier bag (soft case)	1
Hard case	1

### 5.2 Selecting an Installation Site

#### Procedure

 Ensure that the setup conditions have been met (see chapter "15 Technical Data", page 43).

### 5.3 Unpacking

#### Procedure

- Unpack the device.
- Sartorius recommends keeping the original packaging to return the device appropriately, e.g., for repairs.

### 5.4 Acclimatization

When a cold device is brought into a warmer area: The temperature difference can lead to condensation from humidity in the device (moisture formation). Moisture in the device can lead to malfunctions.

Procedure

Allow the device to acclimatize to the installation site. The device must be disconnected from the power supply beforehand.

### 5.5 Charging the Batteries for the First Time

The charging procedure is temperature-controlled. This procedure will not operate at too high or low temperatures as this could damage the battery. The temperature is measured inside the filter tester near the battery pack.

Requirements

For a full recharge, the device must be switched off.

- Connect the charger to the mains voltage.
- Wait until the control lamp in the charger turns yellow. This may take a few seconds.
- Remove the protection cover on the back side of the device and insert the DC-connector of the charger into the charging socket.
- After a maximum of 4 hours, the rechargeable batteries are fully charged.

# 6 Getting Started

## 6.1 Turning the Device On

### Procedure

- ▶ NOTICE Equipment damage due to unsuitable surroundings! Operate the device in dry conditions (see chapter "15.3 Ambient Conditions", page 43 ). Do not operate or store the device in damp surroundings for a long period of time.
- ▶ To turn the device on, press the "on | off" switch (1).



## 6.2 Turning the Device On

### Procedure

- ▷ If the device does not receive any input for several minutes, it will automatically switch off. This can be set in the device configuration.
- ▶ To turn the device off, press the "on | off" switch (1).



- When switching off the device, check whether a connected container is still under pressure.
- ▷ If this is the case, the container is first vented.
- After venting, switch off the device again using the "on | off" switch.

### 6.3 Setting the Clock

The time and date data will be used and stored with the test logs. The device configuration allows for the definition of whether a user has access to this function.

Procedure

- ▶ Open the [SERVICE] menu.
- Open the [SET CLOCK] function and confirm with the [Start] button.
- $\triangleright$  The actual daylight-saving time (DST) and time is displayed.
- Select daylight saving time with the [\*] button.

WINTERTIME 11:32:01

SELECT WITH \* ↑↓

- Before entering the current time, delete the displayed time with the [#] button.
- Enter a 4-digit time value as follows: 1135 = 11:35 or 0729 = 7:29 (hh:mm)
- ▶ Confirm with the [\*] button to store the new settings.
- Enter the current date in the same way.

### 6.4 Calculating the Diffusion Rate

When entering the test program, it is assumed that only uniform filters or uniform 10 inch cartridge filters are in the filter housing. The maximum diffusion rate of a cartridge or a cartridge filter element must be determined and entered in the test program.

Diffusion rate = maximum permissible diffusion per unit [x] number of units

#### Procedure

- Note whether the diffusion rate of the filters is indicated for a 10 inch filter element or for the entire filter.
- If the filter housing contains different cartridges, calculate the overall diffusion rate.
- For this purpose, calculate (for example) the overall diffusion rate, and enter this as a single value.

### 6.5 Calculating the Filter Input Volume

The filter input volume includes the complete input-side volume of the unfiltered material side (from the shut-off valve of the filter input through the connection pipe up to the filter). It can be approximately calculated with the following formula:

Filter input volume = content of housing + vol. of connection pipe - vol. of all filters

- Calculate the filter input volume.
- Note that an approximate volume of 1 L per 10" cartridge filter can be assumed.

# 6.6 Programming

Programming may be performed manually on the device, or with the assistance of the SartoControl mini software. Programming using SartoControl mini makes entry of model numbers and series numbers much easier, and is therefore recommended.

The device checks the entered test parameters for the lowest possible limit. If the resulting pressure drop deltaP falls below a reasonable limit, a warning will be displayed. This can have one of the following reasons:

- Test time too short
- Diffusion rate too small
- Upstream volume too large

The following screens are examples and may differ from your processes and filter types. Not all possible screens and click paths are shown.

#### Procedure

- ▶ Choose the [TEST PROGRAMS] function.
- Click on [Start].
- ► Enter the desired program number between 1 and 19 using the [↓ ↑] buttons. If a type designation was entered for this test program, it will be displayed here.
- > At this point the input of the filter parameters starts.
- You can print out the test program at any point in this menu by pressing the [\*] button.
- ▷ Information about the type of test method is displayed. This method cannot be edited.
- Enter the pore size of the filter.
- Enter the maximum diffusion rate according to the data sheet of the filter used.
- If different filter sizes are present, indicate the total diffusion rate and enter only 1 filter at the next stage.
- Enter the number of identical filters used in this filter housing.
- Enter the upstream volume. Note that tubes and other external components as well as the filters have to be considered.



Input FILTER PARAMETERS PRINT: \* >↑↓

TEST-METHOD: PRESSURE DROP TEST > ↑↓

> PORE SIZE 0.33 µm

DIFFUSION RATE PER CARTRIDGE MAX► 20.0ml/min > ↑↓

NO. OF CARTRIDGES ► 5 > ↑ ↓

UPSTREAM VOLUME ► 5,000 ml

>↑↓

TEST PRESSURE					
►120mbar	>				
	> ↑ ↓				
STABILIZATION	NTIME				
►180sec	>				
	> ↑ ↓				
TESTTIMI	E				
►180sec	>				
	> ↑ ↓				
INPUT					
FILTER DATA	> ↑ ↓				

- Enter the test pressure according to the specifications of the filter used. Use the displayed unit of pressure. The test pressure will also be used for the stabilization phase.
- Enter the stabilization period.

Enter the test period.

- Enter the common data for the filter used and the filter test.
- You can enter data in different ways:
- [#] for deleting data
- [1]-[9] to enter numeric data
- [\*] to create a shortcut for this filter data: E.g. 05x30 inch 1.00 = 5 filters x 30 inch and diffusion rate = 1.0 mL/min. In this mode you can change the length value of the cartridge by pressing the referring button in a range of:
  - $-5 \rightarrow 05$  inch
  - $-1 \rightarrow 10$  inch
  - $-2 \rightarrow 20$  inch
  - $-3 \rightarrow 30$  inch
  - $-4 \rightarrow 40$  inch
- Enter the filter lot number.
- Add the filter serial number or a designation.

FLUID TYPE				-
WATER	>	↑	$\downarrow$	

PROGRAM TEST SAVED PRINT \*>↑↓

- Use the [\*] button to select from the pre-programmed fluid types or use the SartoControl mini software for any text input.
- $\triangleright$  The test program is saved now.
- ▶ Optional: Print the test program with the [\*] button.
- ▷ The following screens show the calculated test parameters:
  - The overall diffusion rate of all filters
  - The maximum possible pressure drop per minute of the entire filter

**CONFIGURATION?** 

PROCEED

> 1 ↓

# 6.7 Configurating the Device

The configuration function is used for individual adaptation of the device. Device functions can be set, activated, or deactivated here. This is a service function and password-protected.

Procedure

- Start the [Configuration] function.
- Activate or deactivate these functions as required:
  - Pressure unit in mbar or psi
  - Setting the [USER CODE] prompt for filter integrity testing
  - Assigning an ID-Code for each filter integrity test (manually, automatically, off)
  - Filter test parameter menu in the main menu
  - Setting the clock in the main menu (full, partly: only DST, off)
  - [CLEAN] function in the main menu (on | off)
  - Automatic pressure release after the test is over
  - Automatic printing after the test is over
  - Automatic printing on error conditions
  - Print errors (on | off)
  - System test at the beginning of an integrity test (on | off)
  - External Valve (on | off) (optional)
- Proceed to the next section using the [Start] button.
- Activate or deactivate these functions as required:
  - Beeper (off | reduced | full)
  - Appearance of the display (black | white background)
- ▶ Proceed to the next section using the [↑] button.
- Optional: Set the [AUTO OFF TIMER] to switch off the device after the specified time when no user activity has been detected.
- ▷ This function is not active during a filter test and in the service menus.
- Optional: Set the max. deviation (tolerance of the test pressure).
- The test pressure is regulated to a target value that lies within the deviation.
- Enter the positive and negative deviation value separately.

AUTO-OFFTIMER 15min ok:\*del.# >↑↓

MAX DEVIATION+ ► 30mbar ok:\* del.# > ↑ ↓

# 7 Process Preparation

The device is connected with means of a flexible compressed air tube to the filter housing. Only purified and filtered compressed air to keep the valves clean must be used.

### \land WARNING

Risk of injury and equipment damage due to unsuitable connection pressure!

- ▶ Use only suitable pressure proof tubes.
- Use regulated compressed air and do not exceed the maximum connection pressure of 4500 mbar (see chapter "15 Technical Data", page 43). A higher inlet pressure than 4500 mbar will prevent from starting the test.
- Connect to the filter system only with standard compressed air couplings, matching the nipple, depending on the design of the device.



Fig. 8: Connection to the filter housing

Pos.	Name	Description
1	Filter housing outlet	Must be open
2	Pressure regulator	Not in the scope of delivery
3	[In] tube	Pressure inlet
4	[Venting] tube	For depressurization
5	[Out] tube	Test port

- Connect the device as shown in the image above.
- Rinse the membrane filters prior to using the integrity test in accordance with the manufacturer's instructions.
- Before inserting the tester on the connecting piece of the filter housing, have the flushing medium (test fluid) at least partly drained.
- $\triangleright$  This will prevent the test fluid from being pressed into the device.
- ▷ The test will drive the remaining fluid out of the filter.

# 8 Operation

A constant ambient temperature should be maintained during diffusion tests as pressure measurement and diffusion rate are affected. Tests should not be conducted directly after the sterilization of the filter with superheated steam; instead, they should only be performed after the filter housing has cooled down to prevent distorted values.

Extreme temperatures for such tests should be avoided. A stable and sufficiently large input-side pressure from the compressed air supply must be ensured to prevent unnecessarily long adjustment periods and error messages.

When calculating diffusion rates from pressure drops, it is assumed that the temperature remains a constant 20 °C, and the air pressure parameter is taken from the value stored in the device.

## 8.1 Performing a Filter Test

The following screens are examples and may differ from your processes and filter types. Not all possible screens and click paths are shown.

### NOTICE

#### Erroneous measurement results or error messages!

Operating outside the defined temperature range leads to erroneous measurement results or error messages.

 Operate the device within the defined temperature range (see chapter 15.3, page 43).

#### Requirements

The device is connected to the pressure system.

- Switch on the device.
- ▷ The device is automatically in the [FILTER TEST] function.

TEST PROGRAM Nb 5 quick > ↑↓	When repeating the last test, use the [*] button to skip the next steps.
	<ul> <li>Otherwise select a different test program number.</li> <li>If you have selected a program number which is not defined yet, this will be indicated.</li> </ul>
	<ul> <li>Enter a program number between 1 and 19.</li> <li>If you have selected a defined program, the details out of this program will be indicated.</li> </ul>
	The test method is indicated. After a short time, the menu moves for- ward to the next item.
INPUT TEST-ID 12	If you have activated a manual input of a test-ID in the device's configu- ration, enter the identification number for the subsequent filter test.

# INPUT USER CODE 123 FILTER-LOT. 123 > ↑↓

STARTTEST >↑↓

- If the user code function is activated during device configuration, enter your [USER CODE] (your personal user ID).
- ▶ Update the batch number if needed.
- ▷ Confirming initiates the documentation of the integrity test. From this point on the test program runs automatically.
- Documentation data and memory space is being initialized. This can take a few seconds.
- For the next steps, connect the device to compressed air and the filter system.
- ▷ At this point the pressure system is tested if you have activated the system test in the device configuration. This test includes:
- Pressure value of the compressed air supply
- Function of the input and filter valve
- Leak proofness of the tester
- ▷ In case of an error, this function indicates how to fix the problem. It is recommended that this function is activated.
- The next screens show the current process progress which runs automatically. The ongoing time needed for this process is shown on the display.
- Optional: Use the arrow buttons for additional measured values from, e.g., the pressure drop test.
- ▷ At some point, the display indicates that the test is complete. The result is shown and after a short time the display continues to the next item.
- ▶ The test result is displayed with status LEDs below.
- ▷ After the test result, the display shows the pressure curve measured in the device, not the filter. Peaks indicate airflow into the filter during pressure increase.
- ▷ The device vents automatically after 30 sec. The external vent valve (optional), if connected, is used for this.
- ► ▲ CAUTION Risk of injury due to pressure in the filter housing! The automatic venting function is activated by default.
  - Make sure that the filter housing is properly depressurized after every filter test and is not kept under pressure.
  - When the function is deactivated, manually vent the pressurized filter housing before opening it.
- After the test is complete, choose from these options:
  - ▶ Use the [↑] button to view specific test results.
  - Use [  $\downarrow$  ] button to print the results.
  - ▶ Use the [\*] button to repeat the test in Quick mode.
  - ▶ Use the [#] button to depressurize the system.

END OF TEST	

				RE	SUL	T				
	PASS									
		4								
		A								
-	7									

TEST DATA: 08.01.2024 13:30 TEST-ID 123 SELECT WITH ↑↓

# 8.2 Viewing Documentation Data

### Procedure

- Start the [TEST RESULTS] function to select any test protocol stored in the device memory and to display the related data.
- Confirm with the [Start] button.
- Choose a test protocol using the  $[\uparrow][\downarrow]$  buttons.
- Search forward or backward for a particular test or select the most recent test with the [#] button.
- $\triangleright$  Date, time and the relevant test-ID are displayed.
- ▶ Confirm the selected filter test with the [Start] button.
- ▷ Recorded comments for this test program are displayed here.
- ▶ Optional: Select the pressure graph with the [\*] button.
- ► Continue to display the details of this test protocol.
- > Among other items, the following information can be displayed:
  - Date and time of the selected test
  - User code (if configured)
  - Test method
  - Test result
  - Pressure values | calculated diffusion rate
  - Detailed test information including pressure decay/min, pressure drop, diffusion rate, stabilization pressure, stabilization time, test pressure, test time, etc.

## 8.3 Printing Documentation Data

The integrated printer prints out test data.

#### Procedure

- Make sure there is the proper thermal printer paper in the printer.
- Start the [PRINT DATA] function.
- Select the documentation to print using the  $[\uparrow][\downarrow]$  buttons.
- Alternatively, select the most recent test using the [#] button.

▶ Confirm the selected filter test with the [Start] button.

- If you want to print multiple test results, select the last test result you want to print using the [↑][↓] buttons.
- Continue to print 1 data set only.
- $\triangleright$  The number of data sets to be printed is shown.
- $\triangleright$  The test details are printed.

FIRST DATA SET 02.01.2024 7:14

LAST FILTERTEST: #

### 8.4 Changing the Paper Roll on the Printer

To ensure functional safety during printing (well preserved printouts and a perfectly functioning printer), always use original thermal printer paper.

#### Procedure

Open the protective cover on the printer.



- Open the black shield by pressing the 2 holding points on the left and right together lightly and then lifting the shield.
- Remove the empty paper roll.
- Place a new paper roll in the paper recess.
- Make sure to place the roll pointing in the correct direction and to roll up the beginning of the paper strip a bit so that it extends out of the paper recess.
- $\triangleright$  After closing the cover, the printer is ready for use again.
- You can scroll the paper roll to feed it forward and tear off the beginning of the roll by pressing the blue button above the printer.

### 8.5 Saving Documentation on a PC

The measuring logs stored in the device can be transferred to a PC through the USB connection using the SartoControl mini data backup program to further process or print them.

Once a data backup is performed, all data in the device are preserved and marked as backed up. They can be overwritten with new data without requiring the appearance of a warning message, and the memory is thus once again made freely available.

- Connect the device to a PC via a USB mini-cable and switch it on.
- NOTICE Risk of data loss! If the memory is full, the device starts to overwrite the oldest data with new measurements. Thus, the oldest data is gradually lost. Carry out the backup when you receive a warning message from the device that only 10 or fewer free memory locations are available.
- The backup is carried out through the SartoControl mini data backup program.

# 9 Cleaning and Maintenance

## 9.1 Cleaning

#### Requirements

The process has been completed.

#### Procedure

- Switch off the device.
- Only use suitable cleaning agents and observe the product information for the cleaning agents used (for compatability see chapter "15.8 Housing", page 45).
- Wipe the housing with a slightly damp cloth. Use a mild soapy solution or a suitable cleaning agent for more severe contaminations.

### 9.2 Maintenance Schedule

Interval Component		Action	Chapter, page	Target group	
At least prior to every use	General	<ul> <li>Carry out a visual inspection.</li> <li>If dirty, clean with a damp cloth.</li> </ul>		Operator	
Every 30 days	Battery	Charge the battery.	9.3, 31	Operator	
Only if the battery is weak due to very low charge	_	<ul> <li>Charge the battery for 10 min.</li> <li>Disconnect the charger for another 10 min.</li> <li>Repeat this 5-10 times.</li> <li>Then charge the battery completely and watch the charging level.</li> </ul>		Operator	
Every 12 months	Pressure sensor	Calibrate the pressure sensor.	9.4, 31	Operator with password to service functions	

### 9.3 Charging the Battey

The charging procedure is temperature-controlled. This procedure will not operate at too high or low temperatures as this could damage the battery. The temperature is measured inside the filter tester near the battery pack.

The older the batteries are, the more the period of operation is reduced. If you notice that the period of operating of the charged battery pack is very short, replace it with a new battery pack from Sartorius.

#### Requirements

For a full recharge, the device must be switched off.

#### Procedure

- Connect the charger to the mains voltage.
- Wait until the control lamp in the charger turns yellow. This may take a few seconds.
- Remove the protection cover on the back side of the device and insert the DC-connector of the charger into the charging socket.
- ▷ The charger and active charging is indicated in the icon bar.
- ► For a full recharge, switch off the device.
- After a maximum of 4 hours, the rechargeable batteries are fully charged.

### 9.4 Calibrating the Device

The device has to be recalibrated regularly after a defined calibration interval. A recalibration interval of 12 months is recommended. A reminder will be displayed on the device 30 days before the configured calibration interval expires.

During the calibration procedure, the pressure sensor of the device is tuned using an external reference device. The device saves these values. The device is calibrated at 5 different reference values:

- 0 mbar
- 1000 mbar ± variance value
- 2000 mbar ± variance value
- 3000 mbar ± variance value
- 4000 mbar ± variance value

The optimal result is achieved at calibration directly on the setpoints, but it is not mandatory. The setpoint variance value can be adjusted to a maximum of 400 mbar.

The device supports setup modes for 3 different setups for the calibration (see chapter "9.4.1 Preparing the Calibration", page 32).

### 9.4.1 Preparing the Calibration

**Required equipment:** Reference gauge, accuracy ±1 mbar

Requirements

- The operating temperature is between 20 30°C.
- Reference device has reached the operating temperature before the calibration can be performed (by switching it on 15 min beforehand).

Procedure

### Setup 1

- Connect the reference gauge (4) to the regulated compressed air source (3).
- ▷ Pressure can be adjusted with the external regulator.
- Connect the reference gauge to the [In] connection (1) of the device.



Fig. 9: Setup 1 for calibrating the device

Pos.	Name	Description
1	[ln]	Connection of the device
2	Pressure regulating valve	
3	Air source	For supplying compressed air
4	Reference gauge (ma- nometer)	For compressed air measurement

### Setup 2

- Connect the pressure regulating valve (4) to the regulated compressed air source (5).
- $\triangleright$  Pressure can be adjusted with the external regulator.
- Connect the reference gauge (1) to the filter connection [Out] (2) of the device.



Fig.10: Setup 2 for calibrating the device

Pos.	Name	Description
1	Reference gauge (ma- nometer)	For compressed air measurement
2	[Out]	Filter connection of the device
3	[ln]	Connection of the device
4	Pressure regulating valve	
5	Air source	For supplying compressed air

#### Setup 3

- Connect the [In] connection (4) of the device to the air source (5).
- Connect the reference gauge (1) to the filter connection [Out] (3) of the device and a pressure vessel (2).
- ▷ Pressure can be adjusted with the interval valves of the device by pressing the arrow buttons.
- $\triangleright$  No external pressure regulator is needed.



Fig. 11: Setup 3 for calibrating the device

Pos.	Name	Description
1	Reference gauge (ma- nometer)	For compressed air measurement
2	Pressure vessel	
3	[Out]	Filter connection of the device
4	[ln]	Connection of the device
5	Air source	For supplying compressed air

### 9.4.2 Carrying out the Calibration

Calibration can only be executed in the specified temperature range of the device. Best calibration results will be obtained at the temperature value at which the device is commonly used.

The maximum deviation between the value measured by the device and the indicated reference value (measurement error) is 100 mbar. Otherwise, an error message appears.

Procedure

- Start the [CALIBRATION] function.
- Confirm with the [Start] button.

CALIBRATION ? PROCEED >↑↓

NEXT CALIBRATION 05.01.2025 >↑↓	The last and the next calibration date is shown. This information is in the last calibration data log and remains constant despite changes to the calibration interval configuration.
INPUT ATMOSPHERIC PRESSURE 1,013mbar	<ul> <li>A few current values such as pressure and temperature are displayed.</li> <li>Enter the atmospheric pressure. You can also enter the value during the device configuration.</li> </ul>
ok: * del. # > 1 ↓	<ul> <li>Confirm with the [*] button.</li> <li>Choose the setup mode number (1, 2 or 3).</li> <li>Press the [*] button to get more info about the chosen mode.</li> <li>To start the calibration steps, use the [↓ ↑] buttons.</li> </ul>
1/5 REAL: Ombar INTERNAL: 0.2mbar CALIBRATION: *	<ul> <li>The respective step number is shown in the first row, e.g., 1/5.</li> <li>Press the [*] button to calibrate the zero point.</li> </ul>
2/5 REAL: >1000mbar INTERNAL: 0.2mbar CALIBRATION:*	<ul> <li>Vary the calibration point by a range of ± 100 mbar.</li> <li>It is suggested that the next calibration point should be 1000 mbar.</li> <li>Apply a calibration pressure of round 1000 mbar.</li> <li>For setup 1   2: Adjust pressure with the external control valve.</li> <li>For setup 3: Adjust pressure with the [↓ ↑] buttons on the device.</li> <li>Check the real pressure value from your reference gauge after stabilization.</li> <li>Enter the real value with the keyboard buttons.</li> <li>Wait an additional 1 min before calibration.</li> <li>Confirm only when pressure is stable. "Wait" on the display signals instability.</li> <li>Confirm with the [*] button.</li> <li>Continue until the last step is finished.</li> <li>After the final calibration step, the protocol is printed, displaying the measured pressure with the new calibration.</li> </ul>
END >↑↓	The calibration is now complete.

# 9.5 Deleting Data from the Device Memory

For service purposes, it might be useful to clear the device memory.

### NOTICE

These functions can delete the device's entire memory, including calibration values, or only documentation and test programs. Deleting calibration values requires device recalibration.

- ▶ Do not delete the recording memory when it is full.
- ▶ If the memory is full, overwrite the oldest entries with the newest.

### Procedure

- Start the [ERASE DATA] function.
- Select a set of data to erase from the device's memory using the [↓ ↑] buttons, e.g.:
  - Calibration Data
  - Log and archive
  - Test programs
  - All data
- Confirm with the [Start] button.
- Confirm a second time using the [#] button.
- ▷ After a few seconds this message confirms that the selected data sets are erased.

ERASE DATA ? PROCEED > ↑↓

DATA ARE ERASED > ↑↓

# 10 Faults

The device performs constant monitoring of the most important operating data. If an error arises, it is reported immediately.

Important error messages, like filter leaks, are displayed until confirmation by the user pressing any button. Non-critical error messages are automatically hidden upon resolving the underlying issue.

# 10.1 Warning Messages (Display)

Warning message	Cause	Solution	Chapter, page	Target group
Battery pack nearly empty	The battery is nearly depleted.	Charge the battery.	9.3, 31	Operator

## 10.2 Error Messages (Display)

Error message	Cause	Solution	Chapter, page	Target group
Charge battery	The battery is de- pleted.	Charge the battery.	9.3, 31	Operator
Pressure sensor	The calibration pa- rameters are incor- rect.	<ul> <li>Check calibration data and recalibrate the de- vice if necessary.</li> <li>If the problem has not been resolved, contact Sartorius Service.</li> </ul>	9.4, 31	Operator with password to service functions
Overpressure	The pressure is greater than the specified measure- ment range. As it in- creases further, the device may be dam- aged.	Reduce applied pressure, use a regulated pressure source.		Operator
	The calibrated pa- rameters are incor- rect or there is a measurement error.	<ul> <li>Check calibration data and recalibrate the de- vice if necessary.</li> <li>If the problem has not been resolved, contact Sartorius Service.</li> </ul>	9.4, 31	Operator with password to service functions
	The pressure sensor is defective.	Contact Sartorius Service.		

# 10.3 Troubleshooting

Fault	Cause	Solution	Chapter, page	Target group
The battery is running out quickly.	The battery is aged.	Replace the battery.	10.4, 40	Operator
The filter test does not start.	The calibration data is er- roneous.	<ul> <li>Check calibration data and recalibrate the device if necessary.</li> <li>If the problem has not been resolved, con- tact Sartorius Service.</li> </ul>	9.4, 31	Operator with password to service functions
	An empty test program has been selected.	Select a test program with valid test parame- ters.		Operator
	The test parameters are invalid.	Re-enter the test param- eters.	8.1, 26	Operator
	The pressure is outside of tolerance.	Check the test pressure.		Operator
	The test programs and documentation data are invalid.	Erase test program data in the service menu and re-enter test program data.	6.6, 22	Operator with password to service functions
	Temperature in the de- vice is too high or too low.	Bring the device to nor- mal temperature.		Operator
The pressure measure- ment is defective.	The pressure sensor is defective.	Contact Sartorius Service.		
Time   date is incorrect	Time   date is not valid, due to empty buffer bat- tery.	Buffer battery must be replaced. Contact Sarto- rius Service.		
The device does not	The battery is empty.	Charge the battery.	9.3, 31	Operator
switch on.	The battery is defective.	Replace the battery.	10.4 <i>,</i> 40	Operator
	The fuse is defective.	Contact Sartorius Service.		

Fault	Cause	Solution	Chapter, page	Target group
The charging icon does not appear when charger is inserted.	The charger is not active.	<ul> <li>Wait after the charger is connected to the power supply approx.</li> <li>15 seconds until status lamp is yellow.</li> <li>Then insert charger in the device.</li> </ul>		Operator
	The power supply unit is defective.	<ul> <li>Check control lamp in charger.</li> <li>Replace the charger and order a replacement from Sartorius Service.</li> </ul>		Operator
	The battery fuse is de- fective	Contact Sartorius Service.		
Access to the service menu is not working.	Wrong security code en- tered.	Enter correct security code.		Operator with password to service functions

# 10.4 Replacing the Battery

- ▶ ▲ WARNING Risk of injury from unsuitable batteries! Unsuitable batteries can overheat when connected to the power supply, and lead to the device catching fire.
  - Do not insert a standard, non-rechargeable battery into the device.
     Only use the batteries supplied by Sartorius.
- ▶ Unscrew the 2 screws (1) on each side of the back of the device.
- Remove the cover.
  - ▶ Remove battery pack from its compartment and the foam carrier.
  - Unplug the connector (1) of the battery from its socket by pressing the small lateral hook on the connector to detach it.
  - ▶ Insert the connector of the new battery into the battery jack.
  - ▶ Install the foam carrier.
  - ▶ Place the battery in the cover of the battery compartment.
  - Close the compartment being careful to correctly position the rubber seal.
  - Screw down the battery compartment.
  - Switch the device on to test the battery function.
  - Switch off and recharge the battery completely (see chapter "5.5 Charging the Batteries for the First Time", page 19).





# 11 Decommissioning

#### Requirements

The process has been completed.

#### Procedure

- Switch off the device.
- Depressurize the device.
- Disconnect the device from the power supply and all supply systems. To do so, remove all cables and tubing.
- ▶ Disconnect all accessories from the device.
- Clean the device (see chapter "9.1 Cleaning", page 30).

# 12 Transport

#### Requirements

The device has been decommissioned.

#### Procedure

- Transport the device in its original packaging. Use the storage and carrying case, with the foam insert.
- For short-term transportation, use the retaining eyelets for carrying the device.

# 13 Storage and Shipping

### 13.1 Storage

#### Requirements

The device has been decommissioned.

- Clean the device (see chapter "9.1 Cleaning", page 30).
- Store the device in its original packaging according to the storage conditions and use the storage and carrying case, with the foam insert (see chapter "15.4 Storage Conditions", page 44).
- NOTICE Reduced life span of the battery! If the device is stored above 30°C for a long period of time, the life of the battery will be reduced, even if the device is switched off. Avoid complete discharging of the battery and recharge the battery every 2 months.

## 13.2 Returning Device and Parts

Defective devices or parts can be sent back to Sartorius. Returned devices must be clean, decontaminated, and packed properly or in their original packaging.

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

Devices contaminated with hazardous materials, e.g., harmful biological or chemical substances, will **not** be accepted for repair or disposal.

### Procedure

- Decommission the device.
- Contact Sartorius Service for instructions on how to return devices or parts (please refer to www.sartorius.com).
- Pack the device and its parts properly or in their original packaging for return.

# 14 Disposal

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

A 10 x 1.2 V NiMH battery is inserted into the device. The battery must be disposed of properly by disposal facilities.

#### Requirements

The device has been decontaminated.

- Remove the battery from the device (see chapter "10.4 Replacing the Battery", page 40).
- ▶ Take the battery to a local collection center.
- Dispose of the device and packaging in accordance with local government regulations.

# 15 Technical Data

## 15.1 Dimensions and Weights

	Unit	Value
Weight	g	3900
Dimensions (W x H x D)	mm	315 x 150 x 280

## 15.2 Installation Conditions

The installation site meets the requirements relating to the ambient conditions.

Access to operation-relevant parts is guaranteed.

Space Requirement

Suitable for the dimensions of the device and the associated components.

#### Setup Surface

Suitable for the weight of the device and the associated components.

### 15.3 Ambient Conditions

	Unit	Value
Temperature range, in operation   when charging	°C	0 - +40
Max. humidity, relative, non-condensing	%	95
Max. altitude above sealevel	m	2000
Pollution degree		2
Protection class		
Without printer cover		IP53
With printer cover		IP54
Dry environment		

# 15.4 Storage Conditions

	Unit	Value
Temperature range	°C	0 - +40
Store it in its original packaging or the case.		
Drv environment		

## 15.5 Electrical Data

	Unit	Value
Battery		
10 x 1.2 V NiMH battery pack   12 V, 3000 mAh accumulator pack with connection plug		
Charging time of the battery pack, typically	h	4
Normal operation time with battery, typically	h	8
Data retention: Independent of the battery		
Power supply		
Input	V <sub>AC</sub>	100 - 240
	Hz	50   60
Output	V <sub>DC</sub>	18.0
	mA	800
SELV output, primary adapters for various countries available		
Charging socket: Quicklock, 4-pin charging socket		
Data connector: Conec, Mini-USB		
External Valve: Quicklock, 5-pin socket		

# 15.6 Programming

	Unit	Value
Max. number of test programs		19
Max. number of stored test logs		200

# 15.7 Pressure Range and Accuracy

	Unit	Value
Overpressure protection	mbar	8000
Measurement range of pressure measurement	mbar	0 - 4500
Repeat accuracy of pressure measurement at 20 °C	mbar	±4
Relative error of the pressure measurement at 20 °C	%	> 0.2
Accuracy of diffusion measurement over pressure drop (reference device DPI150)	%	> 5
Compressed air connection: Rectus type 21.3 coupling or Festo 4 mm, stain- less		

# 15.8 Housing

	Unit	Value
Material: ABS plastic (UL 94 HB)		
Compatibility of housing: Diesel oil, sea water, weak bases, weak acids, alcohol		
Incompatibility of housing: Benzene, acetone		

# 15.9 Parameter Limits

The device can memorize 19 different test programs for the testing of 19 different filter | housing combinations. Not all combinations of parameters result in viable test programs. Therefore, the device checks the parameters while a test program is entered and gives a warning if the parameters would result in a non-feasible test program.

	Unit	Value
Program number (no. of test programs)		1 – 19
Pore size	μm²	0.1 - 2.00
Maximum diffusion rate per cartridge	mL/min	0.1 - 99.0
Number of cartridges		1 - 99
Test pressure	mbar	50 - 4000
Stabilization period	sec	60 - 1800
Test period	sec	60 - 1800
Input-side volume of the filter	mL	10 - 999999
Filter type		Text (max. 20 characters)
Filter batch		Text (max. 20 characters)
Filter series		Text (max. 20 characters)
Housing		Text (max. 20 characters)
Fluid type		Text (max. 20 characters)
Comment		Text (max. 40 characters)

### 15.10 Spare Parts

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

Item	Quantity	Order number
Charger	1	Available upon request

# 16 Sartorius Service

Sartorius Service is available should there be any queries regarding the device. Please visit the Sartorius website (www.sartorius.com) for information about the service addresses, services provided, or to contact a local representative.

# 17 Conformity Documents

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

# SVILECIENS

#### Original EU-Konformitätserklärung **EU Declaration of Conformity** Hersteller Sartorius Stedim Biotech GmbH 37070 Goettingen, Germany Manufacturer erklärt in alleiniger Verantwortung, dass das Betriebsmittel declares under sole responsibility that the equipment Filter Integritäts-Testgerät Geräteart Filter Integrity Tester Device type Sartocheck<sup>®</sup> mini Modell Model 26292---03 Artikel Article in der von uns in Verkehr gebrachten Ausführung allen einschlägigen Bestimmungen der folgenden Europäischen Richtlinien - einschließlich deren zum Zeitpunkt der Erklärung geltenden Änderungen entspricht und die anwendbaren Anforderungen folgender harmonisierter Europäischer Normen erfüllt: in the form as delivered fulfils all the relevant provisions of the following European Directives – including any amendments valid at the time this declaration was signed - and meets the applicable requirements of the harmonized European Standards listed below: 2014/30/EU Elektromagnetische Verträglichkeit / Electromagnetic compatibility EN 61326-1:2013, EN IEC 61326-1:2021 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 IEC 63000:2018 2006/42/EG Maschinen 2006/42/EC Machines EN ISO 12100:2010, EN 61010-1:2010 +A1:2019+A1:2019/AC:2019 Die Person, die bevollmächtigt ist, die technischen Unterlagen zusammenzustellen: The person authorised to compile the technical file: Sartorius Lab Instruments GmbH & Co. KG International Certification Management 37070 Goettingen, Germany Sartorius Stedim Biotech GmbH Goettingen, 2024-07-15 Magnus Signature numérique de Mag. Dr. Sigrid Digital unterschrieben von Mag. Dr. Sigrid Magnus STERING **Ouendler-**Quendler-Parkinson **STERING** Date : 2024.07.15 Datum: 2024.07.15 Parkinson 12:36:40 +02'00' 19:26:59 +02'00' Sigrid Quendler-Parkinson Magnus Stering **Regulatory Affairs Manager**

Prodduct Manager Integrity Testing Solutions

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OP-113 fo1 2015.10.12

# SVIFCTF/3

Original

# **CE** EU-Konformitätserklärung EU Declaration of Conformity

Diese Erklärung bescheinigt die Übereinstimmung mit den genannten EU-Richtlinien, ist jedoch keine Zusicherung von Eigenschaften. Bei einer mit uns nicht abgestimmten Änderung des Produktes verliert diese Erklärung ihre Gültigkeit. Die Sicherheitshinweise der zugehörigen Produktdokumentation sind zu beachten.

This declaration certifies conformity with the above mentioned EU Directives, but does not guarantee product attributes. Unauthorised product modifications make this declaration invalid. The safety information in the associated product documentation must be observed.

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Sartorius Stedim Biotech GmbH August-Spindler-Strasse 11 37079 Goettingen, Germany

Phone: +49 551 308 0 www.sartorius.com

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

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

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