sartorius stedim biotech

Operation Manual

BioSealer®

85030-531-89

Content

1. Important Notes

Please read this manual carefully. It includes important information for the safe and successful use of the BioSealer®.

1.1 Proper Use

BioSealer® was exclusively developed, constructed and built for the industrial and commercial purpose of sealing thermoplastic tubing in pharmaceutical and biotechnological production and laboratory operations.

The BioSealer® is not to be used for human medical applications.

The unit is not intended for use in or with explosive atmospheres!

The system is exclusively designed for the purpose defined above. Any other application above or beyond this or any modifications to the unit without the written permission of the manufacturer is considered as improper use.

Sartorius Stedim Biotech GmbH cannot assume liability if BioSealer® Units integrity are subjected to improper use or improper operation. Sartorius Stedim Biotech is not liable for any damages resulting therefrom. The operator bears the sole risk.

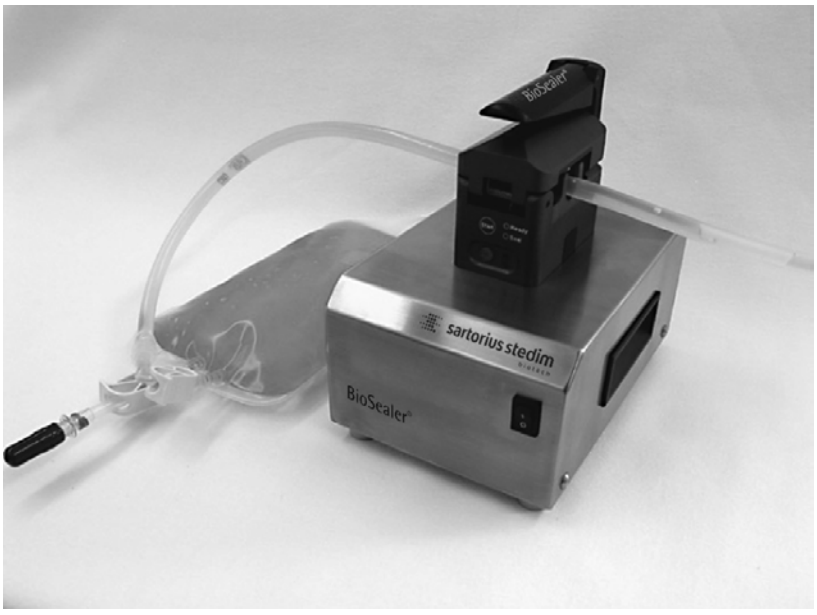
Proper use also includes compliance with operating, inspection and maintenance conditions prescribed by the manufacturer. Non-compliance with the warnings in the operating instructions and installation instructions, in particular, constitutes improper use of the equipment. Only EMC-tested control leads and accessories may be used. Units may only be returned in their original boxes or appropriate secure packaging. No liability can be accepted for transport damage.

1.3 Patents

US and European patents pending. BioSealer® is a trademark.

The manufacturer reserves the right to make any changes and improvements in the product and process described in this manual at any time without notice.

2. Introduction



2.1 Performance

The BioSealer® is a fully automated device, designed to make permanent and consistent leak-free seals using thermoplastic tubing. There is no laminar flow cabinet or similar environmental control device needed to guarantee sterility.

The machine is useful to disconnect tubing between process containers and equipment or simply sealing tubes of single use bags. The unit is able to seal up to 19 mm or 3/4 inch OD tubing, enabling the easy handling to disconnect thermoplastic tubing such as C-Flex®, SaniPure®, FluiSoft™, AdvantaFlex®, and Pharmed® with the for the specific tube quality adjusted programs. Major uses are in bioprocessing and aseptic pharmaceutical applications.

Features

- Fully automated operation
- Seals thermoplastic tubing up to 3/4 inch OD
- Uses C-FLEX® 072/082/374, Pharmed BPT®, Sanipure 60®, Raumedic® FluiSoft™, AdvantaPure AdvantaFlex® and custom specified hoses Sanipure AF/BDF®
- true thermal seal provides exceptional strength
- Sterile seals without a laminar flow hood
- Compact design, portable
- Can seal many different tubing diameters

2.2 Standard Sealing Parameter Sets

The sealing parameters such as temperature and duration are controlled according to the tubing brand and size.
Standard sealing parameter sets are programmed for correct sealing temperature and sealing duration of standard brands. The required sealing parameter set has to be defined with the order.
Only one sealing parameter can be programmed. For standard sealing parameters which have been evaluated see section “Parameter Sheet”.

This parameter sheet precises also which distance place to use in the BioSealer® Head. There are 3 distance plates available: black plate, green plate and yellow plate. The distance plate is selected according to the tubing brand and size to allow the required tubing compression during sealing process.

2.3 Sealing Process

The sealing process consists of five sealing phases:

- Heat up to pre-heating temperature
- Pre-heat phase, electrical heating at pre-heating temperature pre-heating time
- Heat up to sealing temperature
- Heating phase, electrical heating at heating temperature
- Cooling down with fan to release heat.

3. Installation

3.1 Unpacking

Remove the BioSealer® from the shipping container. You should have the following items:

- BioSealer® main unit
- Power cable
- 2 Ceramic heating elements
- Screw driver for Ceramic heating element to exchange the ceramic elements
- Manual (CD)
- Certificate of Conformity

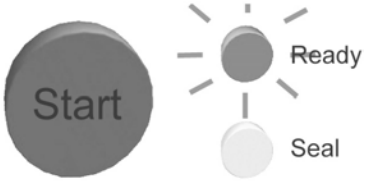
You may have ordered additional ceramic heating elements as spare parts.
Remove any tape and packaging material from the sealer. Please keep this packing for storage or for shipment. Please use only original packing for any shipment.

3.2 Setting Up

Step 1: Installation
The BioSealer® is designed to be portable. The instrument is designed for normal laboratory environments and must be protected from splashes or dusty operations.

Please place the BioSealer® directly on a table or on a stable surface.

Caution!
Observe the permissible voltage mentioned in the "Technical Data" section before you connect the BioSealer® to your power supply.



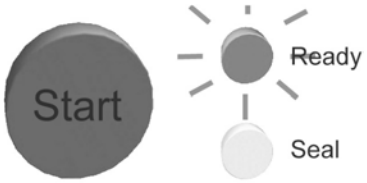
Step 2:
Connect at power supply
Plug the power cable into the BioSealer® and the power supply.
Switch on the main switch at the frontside to power the BioSealer®.
The green LED "Ready" is flashing.

4. Operation

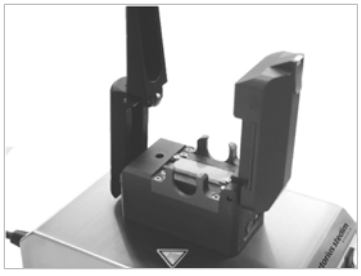
4.1 Controls

Normal operations are performed by closing the lever and pushing the “Start” button. The green LED “Ready” and the red LED “Seal” provide process information.

4.2 Operation Procedure



Step 1: Switch on
Switch on the main switch at the frontside to power the BioSealer®.
The green LED “Ready” is flashing.



Step 2: Open black latch
Open the black latch, this will release the blue head of the rotary latch.
The green LED “Ready” is lit.

Step 3: Insert correct tube
Insert the tubing in between the two red forks so that the tubing is crossing the ceramic heating element.

Make sure that the tubing size and tube material (brand) is corresponding with dimension and material quality mentioned on the BioSealer® housing.

Wrong tubing size or tube material (brand) will result in improper sealings.

Use only tubes which are dry on the outside.
Tubes which are wet on the outside can be damaged.

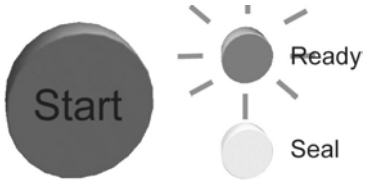
Observe permissible operating temperature range and pressure range mentioned at section “Technical Data”.

Exceeding permissible operating temperature range and pressure range may result in improper sealings.

Observe tube regarding scratches, cuts, tear etc.
Damaged tubes may result in leaks.

Make sure that no valves such as pinch valves are closer than 20 cm to the blue sealing head.
Valves to close to the sealing head may increase pressure in the tube improperly.

If you do two or more sealings on the same tubing, make sure that the first sealing is cool before starting with the second sealing.



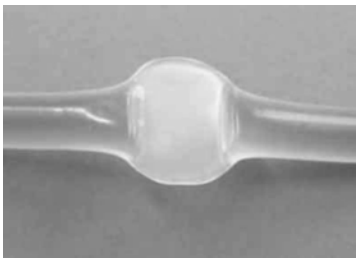
Step 4: Close black latch
Turn the blue head of rotary latch downwards and close black hand lever by pressing the lever gently back until it is kept by the black hand lever.
Close the black latch.
The tubing will be compressed between the ceramic heating and cooling elements.
The fastener should be slowly closed by hand with downward force.
Do not compress with body weight.
The green LED “Ready” is flashing.

Step 5: Start Sealing process
Push the red “Start” button at the front of the aluminium housing.
The automated heating process will start until the tubing is sealed and cooled down. The red LED “Seal” will stay lit until the sealing process has finished.
Afterwards an beep is given for 3 sec.

Do not open the latch during the sealing process. This will interrupt the sealing process and the tubing will not be sealed.

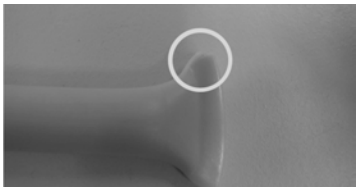
Step 6: Open black latch
Open the black latch. This will release the blue head of rotary latch.
The tubing will be decompressed.

Remove the tube and visually check the sealing.
See section “Quality Control”.
The green LED “Ready” is lighting.

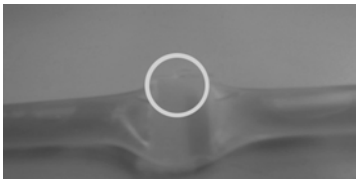


Step 7: Inspect seal quality visually after each sealing

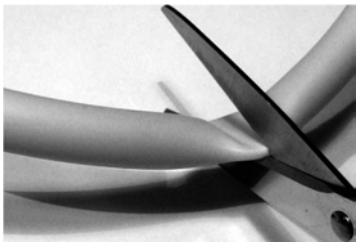
Check the sealing visually for:
- No inclusions such as bubbles filled with liquid or air
- Straight sealing edges (line)



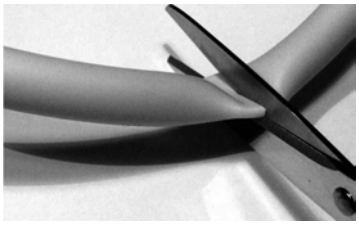
Small broken edges off sealing area can be accepted.

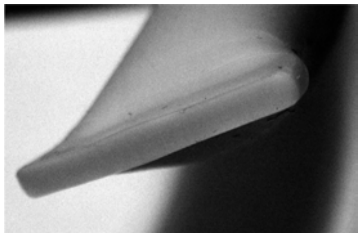


Little deformation at flat sealing surface can be accepted.



Step 8: Cut sealing if required
Cut the sealing with scissors into two parts to separate the tubes. The sealing is designed to seal both ends.
Cut exactly in the middle of the sealing surface to ensure leak-proof sealing halves.
Use sharp scissors.





Step 9: Inspect seal quality
Check sealing cut visually for:
- No inclusions such as bubbles filled with liquid or air
- No sealing seam visible in the middle of the sealing
Sealings with visible seam may result in leaky sealings.

4.3 BioSealer® Handheld

The BioSealer® Handheld device operates like the BioSealer® desktop device but offers addtional flexibility.
Additional sliding connectors mounted on the top of the stainless steel housing allows you to remove the sealing head of the housing.

The sealing head can be operated as follows:

- On the stainless steel housing
- On a desk if space is limited
- Kept in operators hand
- Hang on a wall for tubes located on high elevation

4.3.1 Disposition on desk

Step 1: Remove sealing head from stainless steel housing
Slowly slide the sealing head to the front or the back to remove sealing head.

Do not apply to much pressure. Do not pull at grey extension cable.
Do not use any tools.

Step 2: Place BioSealer® head on desk
BioSealer® sealing head is now ready to seal.
For operation of BioSealer® hand held see section “Operation Procedure”.

4.3.2 Disposition on a wall

Step 1: Fix black support hook
Insert black support hook at sealing head and secure with both hexagonal socket head screws (2.5 mm).

Step 2: Place BioSealer® head on desk
BioSealer® sealing head is now ready to seal on a desk. For operation of BioSealer® hand held. Please see the procedure in section 4.2.

Once the hook is mounted, it is not possible to fix the sealing head on the stainless steel housing anymore.

Step 3: Hang BioSealer® head on wall
For tubes located at high elevation hang BioSealer® sealing head on at wall by using screws. BioSealer® sealing head is now ready to seal on a wall. For operation of BioSealer® hand held see section “Operation”.

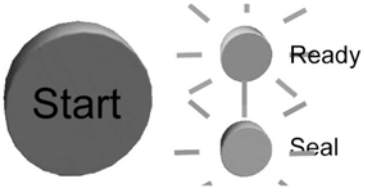
Do not pull at grey extension cable or at tube to be sealed.

5. Trouble Shooting

5.1 Accident

In case of liquid flowing on the BioSealer®:
Disconnect power supply of BioSealer® immediately and clean BioSealer® as per section “Calibration and Maintenance” (Section 6).

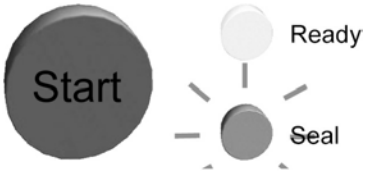
In case of liquid entering into the housing, please get in contact with Sartorius Stedim Biotech GmbH or its representative.



5.2 Interrupted Sealing Process

If the black latch is opened during a sealing process the sealing process will be interrupted.
The green LED “Ready” and the red LED “Seal” are flashing alternately, a beeping tone will be heard.
The BioSealer® will return to the start of program, automatically.

Repeat the sealing process as per section “Operation Procedure”.



5.3 Broken Ceramic Heating Element

The ceramic heating elements are dedicated parts. Improper insertion, to hard tubes may break the elements. If the lower or upper ceramic heating element breaks during a sealing process, the sealing process will be interrupted.
The red LED “Seal” will be flashing.

Exchange the broken ceramic heating element with a new one as per section “Exchange Ceramic Heating Element” (Section 6.3).

5.4 Inaccurate of Temperature Measurement

The resistance thermometer Pt100 built in the ceramic heating element measures the temperature of the ceramic heating element. In case of a defective resistance thermometer or dirty contacts, the temperature measurement will be too high.
The internal fan will cool continuously and will not stop.

The green LED “Seal” is lit (not showing an alarm).
Remove both ceramic heating elements, clean both sides with ethanol.
Install the clean ceramic heating elements as per section “Exchange Ceramic Heating Element” (Section 6.3).

If the problem persists, replace both ceramic heating elements with new ones as per section “Exchange Ceramic Heating Element” (Section 6.3).

6. Calibration and Maintenance

6.1 Fundamental

The BioSealer® is a maintenance-free device. No recalibration is required. The two identical ceramic heating elements are manufactured from a long-life ceramic with integrated resistance thermometer Pt100 that controls the temperature of each ceramic heating element.

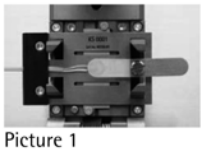
The BioSealer® is pre-calibrated and does not need to be recalibrated before use (see enclosed Certificate of Conformity).

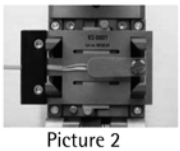
To achieve the required sealing quality it is required to clean the BioSealer® and check the sealings frequently:

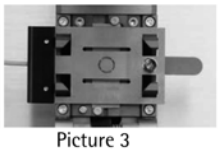
Calibration	Not required.
Maintenance	Not required.
Replacement Ceramic Heating Plate	Only if damaged.
Cleaning	Depending on tube brand, if residue is observed.
Pressure Test	Each 1,000 sealings or once per year.

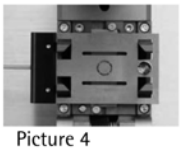
6.2 Calibration

Calibration could be performed only on the BioSealer® with the 2.1 version.
For the BioSealer® with the 2.0 version, please contact your Sartorius Stedim Biotech Service representative.
Make sure the unit is switched off.
Clean both ceramic elements with alcohol.
For the BioSealer® with black plate, calibrate the bottom heating element by inserting the holder as shown in Picture 1.
For the BioSealer® with green plate and yellow plate, calibrate the bottom heating element by inserting the holder as shown in Picture 2.
For the BioSealer® with black plate, calibrate the top heating element by inserting the holder as shown in Picture 3.
For the BioSealer® with green plate and yellow plate, calibrate the top heating element by inserting the holder as shown in Picture 4.

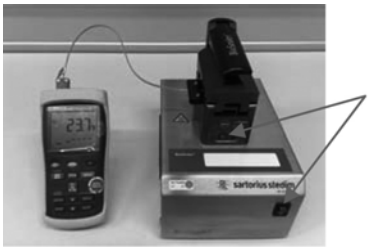

Picture 1


Picture 2


Picture 3


Picture 4

Close the lever.
Connect the Calibration Holder to the measuring instrument and prepare it to record.
Start recording. Press the red button and hold it wile you switch on the unit.
Hold the red button for 5secondes. The calibration process will start automatically.



The unit heats up to 100°C (pre heat temperature) and holds this temperature for 30 seconds. After the unit heats further up to 150°C (sealing temperature) and hold this temperature for 30 seconds. Then, the unit cools down to 60°C (reopen temperature) and a signal will acoustically indicate the end of the calibration process. The maximal temperature deviation between the calibrated measuring equipment (measuring instrument and Calibration Holder) and the indicated temperature on the display at 150°C is +/-5°C. Disconnect the measuring instrument, open the lever and remove the Calibration Holder. The unit is now ready again for a normal sealing process. If a calibration process does not finish correctly the unit will go back to the normal sealing process. Switch the unit off and repeat from the beginning. The temperature must be within +/- 5°C of the set temperature within 30 seconds including a 7 second delay period which means the first 7 seconds out of the 30 seconds can be outside tolerance. This is valid for both preheat and sealing temperature. The time is always counted backwards from the temperature were the unit heats further up after the preheat temperature or starts cooling down after the sealing temperature.

If the temperature measured is outside range, please contact your Sartorius Stedim Biotech Service representative.

6. 3 Cleaning

Disconnect BioSealer® from power supply. Clean residue immediately on the stainless steel housing, on the blue sealing head, and on the ceramic heating elements.

The BioSealer® can be cleaned with most disinfection solutions such as 70% ethyl alcohol.

Residue on the ceramic heating elements may result in improper sealings.

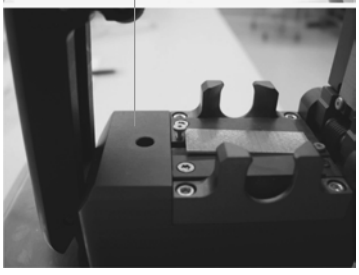
A brown tape with PTFE surface is located on the ceramic heating element.
Do not remove this tape.

Do not use acetone!

Do not wash the equipment in liquid or submerge the equipment.
Use only a wet cloth. Major damage can be caused to electronical components.

Observe the materials of construction mentioned at section “Technical Data” (Section 7).

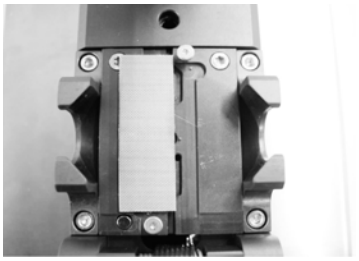
6.4 Replacement of the Ceramic Heating Element



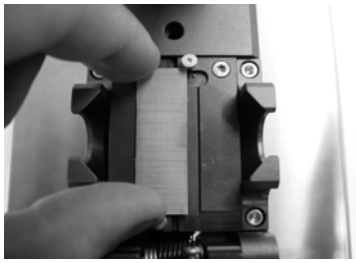
Basic remarks
The ceramic heating element does not need to be maintained and can be replaced. The ceramic heating elements will break if hard tubing has been inserted and compressed. The upper and lower ceramic heating element are identically fixed with the same screws.
The damaged ceramic could be the upper one, the lower one or both.

Step 1: Remove both fastening screws

Switch off and disconnect power supply before the exchange of the ceramic heating elements. Remove the two fastening screws on both sides of the ceramic element with the included ceramic heating element screw driver.



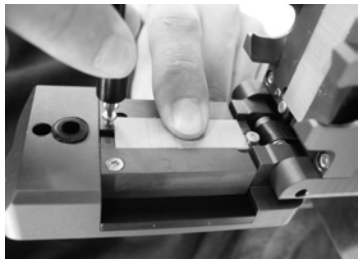
Step 2: Remove the damaged ceramic heating elements
Carefully remove the damaged ceramic heating elements with your fingers.
Do not use any tools.



Step 3: Insert the new ceramic heating elements
Clean the blue heating block with a wet cloth, if neccessary.
Do not use solvents or too much liquid.

Carefully insert the new ceramic heating element with your fingers.
Do not use any tools.

The ceramic heating element is fragile to any kind of tension.
Do not bend the element.



Step 4: Tighten fastening screw
Fix the ceramic heating element with your finger in the right position and fix then the screws only with the included ceramic heating element screw driver.

Step 5: Make test sealing for verification
The contacts of the heating circuit and the circuit of resistance thermometer Pt100 are spring loaded. To verify the contacts it is required to make three sealings.

- For operating see section 4 “Operation”.
- For pressure test of sealing see section 6.4 “Pressure Test”.

In case of improper sealing quality, reinstall the ceramic heating elements again.

Required Spare Parts:
Art. no. 16366.
Art. name: Ceramic heating element type 1.
Number of ceramic elements required: 1 or 2.

6.5 Pressure Test

Prepare three tubing samples (length 300 mm). Use only tubing material and dimension which the BioSealer® has been programmed for. See section 7 “Technical Data” and Certificate of Conformity.

- Seal all 3 samples one after the other, see section 4 “Operation”.
- Take 3 tubing samples and cut the seals through the middle, see section 4 “Operation”.
- Connect the separated 6 samples to a pressure gauge as shown below and pressurize them slowly to max. 1.0 bar, but not higher than the specifications of tube manufacturer. Before pressurizing the sealed samples they must be cooled down to room temperature.
- There should be no leakage on all samples in order to complete a successful test.
- Hold the pressurised sealing into a water bath and check visually on bubbles rising.
- Leaky spots can immediately be observed by rising air bubbles.

Attention!

Only do pressure testing with an over pressure protection device.
Repeat the validation after each exchange of ceramic elements.

7. Technical Data

7.1 Technical Data BioSealer®

Sealing time	One sealing cycle takes between 60 and 240 seconds.
Temperature measurement	Resistance temperature sensor 1x Pt100 B EN 60751 built-in ceramic heating elements.
Permissible pressure range liquid in tube	– During sealing process: -1...+0.5 bar. – After sealing process: -1...+1.0 bar, but not higher than specification of tube manufacturer. Tube has to be cooled off to room temperature.
Permissible temperature range liquid in tube	After sealing process +10...+50°C
Sealing counter	Mechanical counter at bottom of housing showing number of sealings.
Serial interface	Infra red (IR) port to upload sealing parameters. Access by separately available IR-Interface cable.
Material housing	Stainless steel 1.4301 (304), handle anodised aluminium.
Ingress protection rating	IP 20.
Dimensions	W x D x H 220 x 150 x 210 mm.
Weight	3.0 kg.
Power Supply	1 x 100...240 V / 47...63 Hz, 1.5 A
Ambient temperature range	+20...+30°C.
Ambient humidity range	35...65 %.

7.2 Technical Data

Ceramic Heating Element

BioSealer® Type 1

Execution

Ceramic heating elements type 1 are used for all BioSealer® heads.

Temperature sensor

Resistance temperature sensor 1x Pt100 B EN 60751.

Material

Ceramic with PTFE liner in contact with outer surface of tube.

Tool for replacement of heating element

The tool required to exchange the ceramic heating element is included in the scope of delivery.

Also included in scope of delivery

Two ceramic heating elements type 1 (spare parts).

8. Regulations|Applied Standards

89/392/EEC,	CE marked, a declaration of conformity is included in the documentation „ECMachinery
Appendix IIA	Directive 89/392/EEC (Amended 98/37/EEC), Appendix II A“. Applied harmonised directives and standards:
73/23/EEC	Directive relating to electrical equipment designed for use within certain voltage limits.
	Council Directive relating to Electromagnetic Compatibility.
89/336 /EEC DIN EN 292-1	Safety of machinery; Basic concepts, general principles for design; Part 1: Basic terminology, methodology.
DIN EN 294	Safety of machinery; safety distances to prevent danger zones from being reached by the upper limbs. Human body measurements - Part 1: Principles for determining the dimensions
DIN EN 547-1	required for openings for whole body access into machinery. Applied technical specifications:
DIN 45635-1	Measurement of noise emitted by machines; airborne noise emission; enveloping surface method; basic method, divided into 3 grades of accuracy.
DIN EN 60204-1	Safety of machinery - Electrical equipment of machines - Part 1: General requirements.

Parametersheet

	Tube dimension			Biosealer® head plate		
	ID x OD	wall thickness		black plate	yellow plate	green plate
		inch	mm			
C-Flex® 082/374	1/8 x 1/4	1/8	1,6	P3		
	3/16 x 5/16	1/8	1,6	P3		
	1/4 x 3/8	1/8	1,6	P3		
	1/4 x 7/16	3/16	2,4	P3		
	5/16 x 1/2	3/16	2,4	P17		
	1/4 x 1/2	1/4	3,2			P8
	3/8 x 5/8	1/4	3,2			P8
	1/2 x 3/4	1/4	3,2			P8
C-Flex® 072	1/8 x 1/4	1/8	1,6	P3		
	3/16 x 5/16	1/8	1,6	P3		
	1/4 x 3/8	1/8	1,6	P3		
	1/4 x 7/16	3/16	2,4	P5		
	5/16 x 1/2	3/16	2,4	P5		
	3/8 x 5/8	1/4	3,2			P9
	1/2 x 3/4	1/4	3,2			P10
Pharmed® BPT	1/8 x 1/4	1/8	1,6	P1		
	3/16 x 5/16	1/8	1,6	P1		
	1/4 x 3/8	1/8	1,6	P1		
	5/16 x 7/16	1/8	1,6	P2		
	3/8 x 1/2	1/8	1,6	P2		
	3/8 x 5/8	1/4	3,2			P18
	1/2 x 3/4	1/4	3,2			P18
Sanipure® 60	1/8 x 1/4	1/8	1,6	P3		
	3/16 x 5/16	1/8	1,6	P3		
	1/4 x 3/8	1/8	1,6	P3		
	3/8 x 1/2	1/8	1,6	P3		
	1/4 x 7/16	3/16	2,4	P6		
	3/8 x 5/8	1/4	3,2			P11
	1/2 x 3/4	1/4	3,2			P12
Sanipure® AF & BDF	1/8 x 1/4	1/8	1,6	P13		
	3/16 x 5/16	1/8	1,6	P13		
	1/4 x 3/8	1/8	1,6	P14		
	3/8 x 1/2	1/8	1,6	P15		
	1/4 x 7/16	3/16	2,4	P14		
	3/8 x 5/8	1/4	3,2			P16
	1/2 x 3/4	1/4	3,2			P16
Raumedic® Fluisoft™	1/8 x 1/4	1/8	1,6	P19		
	3/8 x 5/8	1/4	3,2			P20
	1/2 x 3/4	1/4	3,2			P20

Advantaflex®	1/8 x 1/4	1/8	1,6	P21		
	3/16 x 5/16	1/8	1,6	P21		
	1/4 x 3/8	1/8	1,6	P21		
	5/16 x 7/16	1/8	1,6	P21		
	3/8 x 1/2	1/8	1,6	P21		
	1/4 x 7/16	3/16	2,4		P21	
	5/16 x 1/2	3/16	2,4		P21	
	3/8 x 5/8	1/4	3,2			P22
	1/2 x 3/4	1/4	3,2			P23

Parametersheet

Parameter-number	Preheat Temp. [°C]	Preheat Time [sec]	Sealing Temp. [°C]	Sealing Time [sec]	Heat-Slope [°C/sec]	Unlock-Temp. [°C]	Remarks
P1	100	30	140	10	6	55	
P2	140	35	155	20	2	55	
P3	100	15	140	5	6	65	
P4	100	10	160	10	10	65	replaced by P17
P5	130	50	150	15	10	55	
P6	130	65	140	40	2	65	
P7	140	35	155	45	2	55	replaced by P18
P8	140	40	175	15	10	65	
P9	100	20	140	20	3	55	
P10	100	30	145	40	3	55	
P11	130	30	150	5	3	65	
P12	140	30	175	10	4	65	
P13	115	60	145	10	3	65	
P14	125	60	145	10	3	65	
P15	115	60	155	10	5	65	
P16	140	60	160	10	3	65	
P17	120	30	135	1	7	55	
P18	139	35	147	55	1	55	
P19	115	30	140	10	5	65	
P20	110	30	145	10	1	65	
P21	120	60	145	30	1	65	
P22	0	0	145	60	1	65	
P23	145	60	155	20	1	65	

Parameters are only valid for ambient temperature (20-30°C)

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