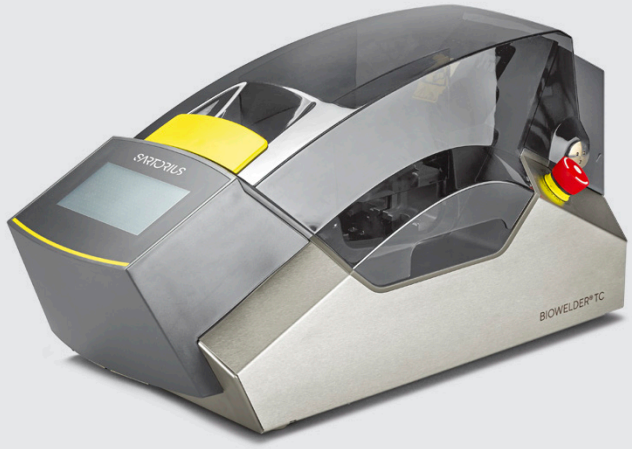
SARTORIUS

Product Datasheet

Biowelder® Total Containment

Fully Automated Device for Welding Dry And Liquid Filled Tubing



Applications

The Biowelder® TC is used to connect thermoplastic tubing such as Tuflux® TPE, C-Flex® 374*, AdvantaFlex®, SaniPure™* BDF™ and PharMed®* BPT used on disposable bags or bag assemblies within all biopharmaceutical manufacturing processes. Biowelder® TC can weld either dry or liquid-filled tubing in non classified and classified environment while maintaining product sterility.

Tuflux® TPE welding parameters only allow for the cowelding of this tubing material to C-Flex® 374 and to AdvantaFlex®. This unique feature allows one to weld together these 2 different tubing materials to Tuflux® TPE and is supported by a complete validation study."

Product Information

The Biowelder® TC is a fully automated device for connecting thermoplastic tubing in a sterile welding operation. This innovative technology allows for the sterile connection of tubing from ¼" up to 1" outer diameter.

* C-Flex®, SaniPure™ and PharMed® are registered trademarks of Saint-Gobain Performance Plastics Corporation.

Feature	Benefit
Dry or liquid filled tubing from ¼" to 1" OD	Process flexibility & multiple additions via the same tubing line
Fully automated device	Repeatable and easy to use
Standard programs	Ready to use for Tuflux® TPE, C-Flex® 374*, AdvantaFlex®, SaniPure™* (except ⅝" × ⅞" and ¾" × 1" sizes) and PharMed®* (except ⅛" × ¼" size) tubing
New design (device & color coded tube holders)	Ergonomic Operator friendly Easy to use
Extensively qualified	Safe and robust connections
Welding time	Fast connections

* C-Flex®, SaniPure™ and PharMed® are registered trademarks of Saint-Gobain Performance Plastics Corporation.

Simple Operating Principle

The holders, the blade and the tubes are inserted into the Biowelder® TC. The welding process is fully automated and is started via the LCD touch screen. The blade is first heated up for depyrogenation then cooled down to the welding temperature. An infrared sensor monitors and controls the blade temperature throughout the welding process. When the blade reaches the welding temperature, the blade cuts the tubes and the new fluid path is welded together.

Flexibility

The interchangeable and color coded tube holders are available in a variety of sizes between ⅛" ID × ¼" OD and ¾" ID × 1" OD, which allow a quick and easy adaptation to the process needs. The Biowelder® TC identifies each holder size when installed, which minimizes operator error. The standard Biowelder® TC unit is programmed with parameter sets for Tuflux® TPE, C-Flex® 374*, AdvantaFlex®, PharMed®* BPT and SaniPure™* BDF™.

Ease of Use

A LCD touch screen guides the user through the operator menu. Each process step can easily be followed and monitored by the information provided on the display. The Biowelder® TC is equipped with an SD Card slot to allow loading and printing of the welding cycle data via a computer.

Fast Process Times

The average welding cycle times are between 1 min 30 and 2 min 30 which provides time savings along the process chain.

Summary table of validated TPE tubing materials and sizes which can be welded on Biowelder® TC

TPE tubing material	Welding parameter name installed on Biowelder® TC	Validated welding capabilities	Sterilization methods of tubing covered by the parameters	Tubing sizes qualified per welding parameter						
				⅛" × ¼" (yellow)	¼" × ⅜" (orange)	¼" × 7⁄16" (red)	⅜" × ⅝" (white)	½" × ¾" (grey)	⅝" × ⅞" (green)	¾" × 1" (blue)
Tuflux® TPE	Tuflux® TPE	Tuflux® TPE to Tuflux® TPE	G-G; A-A, G-A	■	■	■	■	■		■
Tuflux® TPE	Tuflux® TPE	Tuflux® TPE to C-Flex® 374	G-G; A-A, G-A	■	■	■	■	■		■
Tuflux® TPE	Tuflux® TPE	Tuflux® TPE to AdvantaFlex®	G-G; A-A, G-A	■	■	■	■	■		■
C-Flex® 374	C-Flex® 374	C-Flex® 374 to C-Flex® 374	G-G; A-A, G-A	■	■	■	■	■	■	■
AdvantaFlex®	AdvantaFlex®	AdvantaFlex® to AdvantaFlex®	G-G; A-A, G-A	■	■	■	■	■	■	■
Pharmed® BPT	Pharmed®	Pharmed® BPT to Pharmed® BPT	G-G; A-A, G-A		■	■	■	■	■	■
SaniPure™ BDF™	SaniPure™	Sanipure® BDF to Sanipure® BDF	G-G; A-A, G-A	■	■	■	■	■		

Note: G = gamma irradiated, A = autoclaved

Ultra Safe Connection

The thermal weld produced by the Biowelder® TC have an extraordinary level of stability and guarantee a sterile connection. The thermal weld has been qualified by applying the most stringent and innovative test regimes. Biological, physical and extractable tests were combined to provide users with data representing a variety of process conditions. Methodologies and equipment are detailed in the validation guide.

Service

All units are individually tested before released to ensure maximum reliability. The Installation Qualification and Operational Qualification is recommended and should only be performed by Sartorius Stedim Biotech Service upon customer request. Calibration and maintenance contrat services are available for Biowelder® TC.

Instrument Services

The Installation Qualification and Operational Qualification is recommended and should only be performed by Sartorius Service.

Other services are available for Biowelder® TC upon request such as device installation, temperature calibration, preventive maintenance and several levels of maintenance contracts.

Please contact us:
www.sartorius.com/en/services/instrument-service

Confidence® Validation Services

An individualized and process specific validation of your welding processes is available by our Validation Services Team. The service includes a thorough integrity check through:

- Mechanical testing
- Microbial testing
- Physico-chemical testing

Please contact us for consultancy and our tailored approach:
www.sartorius.com/en/services/validation-service

Technical Data

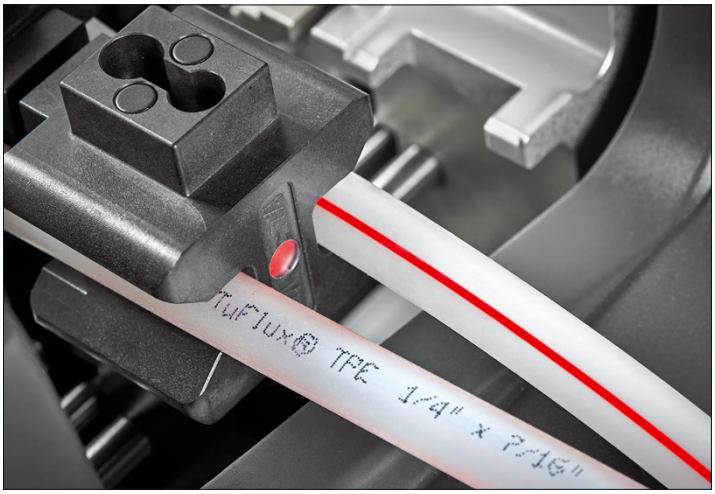
Type designation	**Biowelder® TC, BWTC**
Power connection	100 VAC – 240 VAC
Input frequency	50 | 60 Hz
Power input	300 VA
In and out connections	Device plug C14 max. 250VAC Ethernet jack type RJ45
Power connection of fuse	2 × 3.15 A T (Type FST)
Battery	CR2032
Operating temperature	+5 °C – +40 °C **
Place of use	Indoor (Laboratory)
Transient overvoltage	Overvoltage category II
Pollution degree	2
Altitude	up to 2000 m
Humidity	80% up to 31 °C, linearly diminishing to 50%; relative humidity at 40 °C, not condensing
Degree of protection	IP20
Weight	16.4 kg
External size (L × W × H)	555 mm × 261 mm × 269 mm
Power cord	According to local regulations Min. 3 × AWG18 or 3 × 0.75 mm² Min. local mains supply voltage
Tube holder size (ID × OD; color)	⅛" × ¼"; yellow ¼" × ⅜"; orange ¼" × 7⁄16"; red ⅜" × ⅝"; white ½" × ¾"; grey ⅝" × ⅞"; green ¾" × 1"; blue
Welding Cycle	1 min 30 – 2 min 30 (depending on tube diameters and material)
Standard settings for	Tuflux® TPE, C-Flex® 374*, AdvantaFlex®, PharMed®* BPT, SaniPure™* BDF™
Minimum tubing length	450 mm
Max operating pressure validated	1 bar

** The device is programmed with standard parameter sets for welding Tuflux® TPE, C-Flex® 374, AdvantaFlex®, PharMed® BPT and SaniPure™ BDF™.

These parameter sets have been validated at room temperature.

Ordering Information

Order Code	Description	Unit | Box
16389	Biowelder® Total Containment	1
16389-009	Biowelder® TC Tube Holder ⅛" ID × ¼" OD	2
16389-010	Biowelder® TC Tube Holder ¼" ID × ⅜" OD	2
16389-011	Biowelder® TC Tube Holder ¼" ID × 7⁄16" OD	2
16389-001	Biowelder® TC Tube Holder ⅜" ID × ⅝" OD	2
16389-002	Biowelder® TC Tube Holder ½" ID × ¾" OD	2
16389-003	Biowelder® TC Tube Holder ⅝" ID × ⅞" OD	2
16389-004	Biowelder® TC Tube Holder ¾" ID × 1" OD	2
16389-012	Biowelder® TC Disposable Blades in box (50)	1
16389-013	Biowelder® TC Blade Remover Tool	1
16389-006	Calibration Kit	1
16389-007	SD card	1
16389-008	Carrying case for Biowelder® TC Tube Holder (Max 6 sets)	1



Germany
Sartorius Stedim Biotech GmbH
August-Spindler-Strasse 11
37079 Goettingen
Phone +49 551 308 0

USA
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For more information, visit
www.sartorius.com

Publication No.: SG12006-e211012 | Order No.: 85032-541-48

Status: 08 | 21 | 2023