

User Guide

Steritest[®] Symbio Pumps



The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the US and Canada.

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Introduction

System overview

The Steritest[®] Symbio peristaltic pumps are used for sterility testing and are available in three versions. Combined with optional accessories, the pumps provide a wide range of installation possibilities (see <u>Steritest[®]</u> <u>Symbio Pump</u> <u>Versions</u>), enabling integration in all testing environments (laminar flow hood, biosafety cabinet, clean room, and isolator), including existing isolators without table rework.

The Steritest[®] Symbio pumps have been designed to be used with Steritest[®] devices. Many types of sterile products can be tested with the Steritest[®] system, including:

- Large- and small-volume parenteral solutions in glass or plastic bottles, collapsible bags, ampoules, and vials
- Pre-filled syringes
- · Lyophilized and other soluble products in ampoules or vials
- Antibiotics in ampoules or vials
- Medical devices
- Difficult-to-dissolve powders

The easy-load automatic pump head facilitates the Steritest[®] tubing placement in an isolator configuration and protects the user from the rotor.

A timer coupled with a rotor position compensation provides repeatability of small-volume sampling.

A pressure control system constantly monitors the pressure inside both canisters. An alarm signals pressure increases above the specifications. In regulation mode, the pump decreases the pumping speed automatically until the pressure returns to normal.

The microorganisms present in the sample are captured on the microporous membrane in the Steritest[®] canisters . Appropriate medium is pumped into each canister separately to promote the growth of the captured organisms. The canisters are incubated and examined for contamination in accordance with the relevant pharmacopoeia.

About this Manual

All screen shots and drawings in this manual are examples and may vary depending on the pump version. All dimensions indicated in the illustrations are in millimeters.

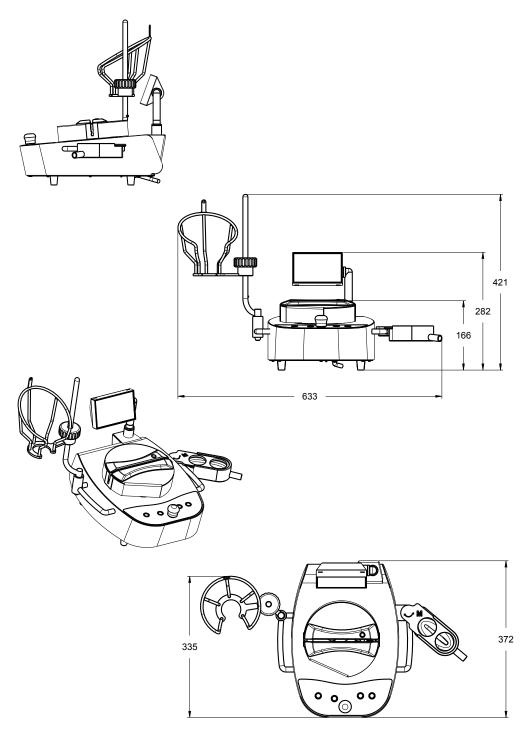
Steritest[®] Symbio Pump Versions

Steritest[®] Symbio LFH Pump

This pump is used, on feet, in a laminar flow hood, a biosafety cabinet, or in a clean room. It can also be used in an isolator, using special feet.

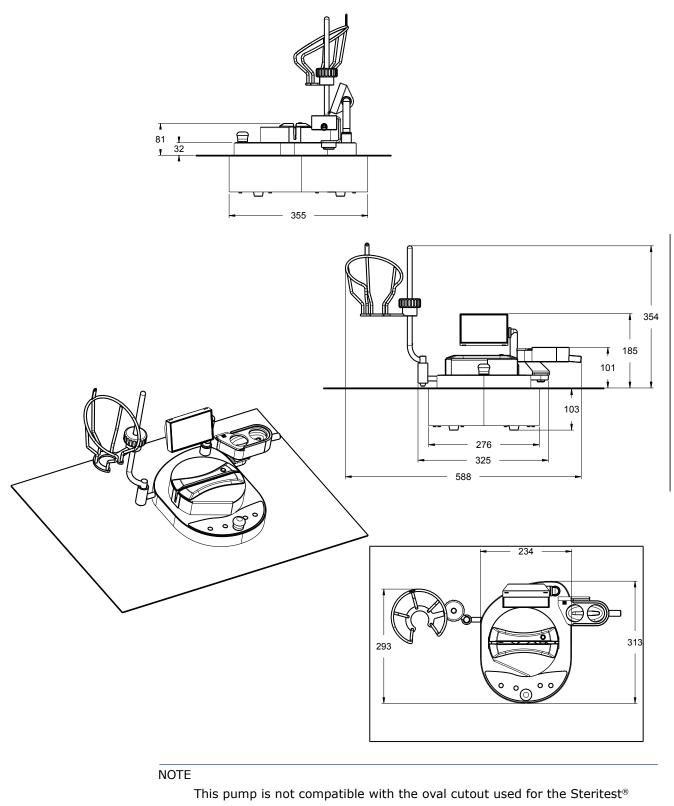
NOTE

To use this pump in an isolator, on feet, replace the standard feet with special feet for use in isolator, and use the optional connection cable extension with Tri-Clover clamp for the connection of the pump to the communication hub (see <u>Accessories and Replacement Parts</u>).



Steritest[®] Symbio ISL Pump

This pump is integrated in an isolator equipped with a standard round cutout.

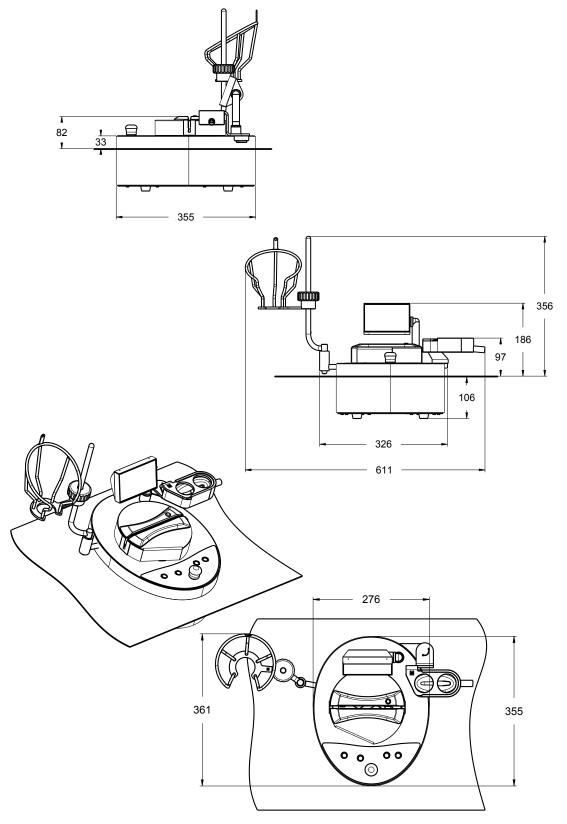


Equinox Isofit pump.

Steritest[®] Symbio FLEX Pump

This pump can be used in multiple configurations:

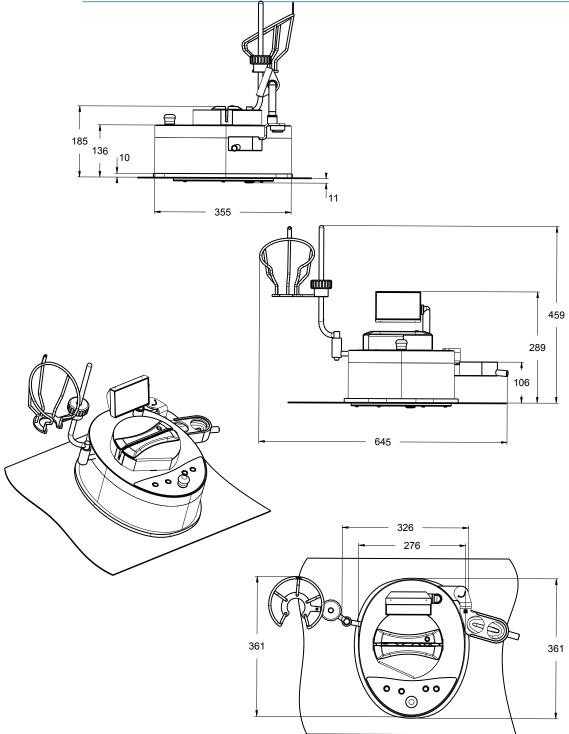
In an isolator - low integration on round or oval cutouts



In an isolator - high integration on round or oval cutouts

NOTE

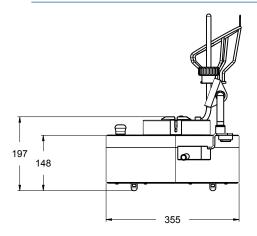
To install the pump in an isolator in high integration configuration, a special integration kit (sold separately) is required (see <u>Accessories and</u> <u>Replacement Parts</u>). There are two integration kits, one for a round cutout and one for an oval cutout. The following drawings show the dimensions of the pump when installed in an isolator equipped with the standard round cutout.

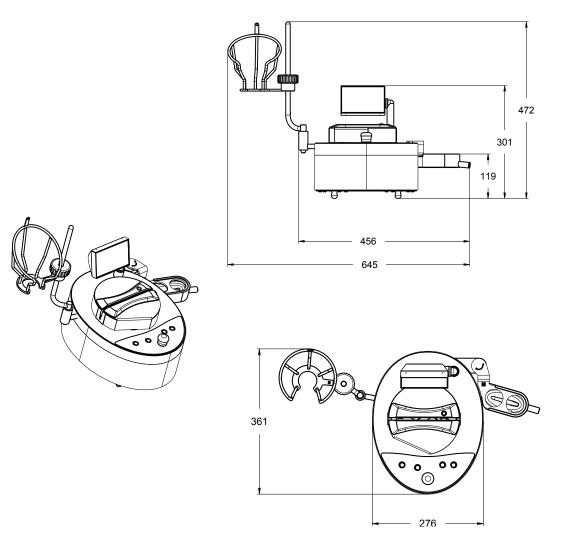


In an isolator without table cutout, using special feet

NOTE

To install the pump in an isolator, on feet, replace the standard feet with special feet for use in isolator. Use the optional connection cable extension with tri-clover clamp for the connection of the pump to the communication hub. Use the optional carrying handles to facilitate pump handling (see **Accessories and Replacement Parts**).

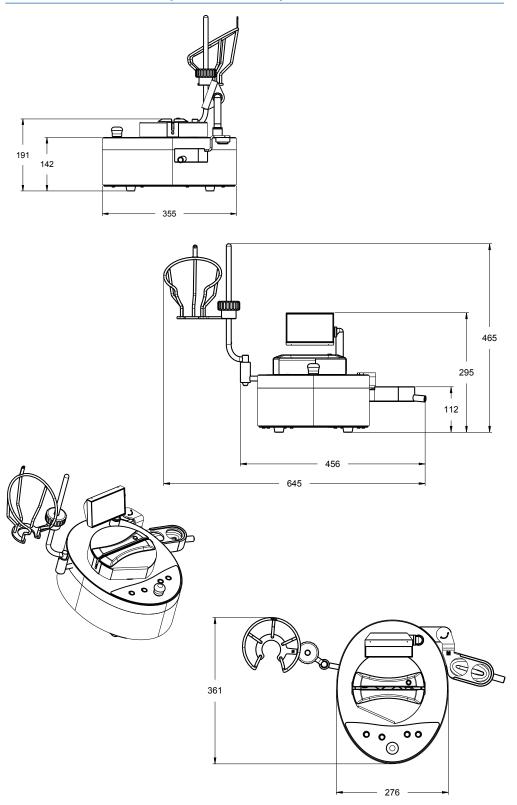




In a vertical laminar flow environment, on feet

NOTE

Use the optional carrying handles to facilitate pump handling (see **Accessories and Replacement Parts**).



Additional Features

Tests can be run in either the Standard Mode, in which filtration parameters are chosen manually, or in the Test Method Mode, in which every step of the method appears on the screen with preloaded parameters for speed and time to ensure there is no deviation from the approved test protocol. The test methods are created with the Steritest[®] Symbio Software and transferred to the Steritest[®] Symbio Pump through a network cable or with USB flash drive.

The software (from version 1.1.0.0) can be used in ten languages (German, English, Spanish, French, Italian, Portuguese, Japanese, Simplified Chinese, Turkish, and Russian).

The drain tray and bottle holder are ergonomically positioned around the pump head for easy access in limited-space environments.

A wide range of optional accessories are available to improve the sterility testing workflow:

- A footswitch with two operation modes
- A glass ampoule breaker
- A support rod extension for hanging sterile bags or the Steridilutor vent chamber
- A syringe support that facilites the handling of pre-filled syringes (with or without needles), and provides an automatic rinsing function
- A liquid waste overfill sensor that signals an alarm on the pump screen
- A communication hub holder to fix the communication hub to one of the four legs of the laminar flow hood
- A communication hub holder to fix the communication hub below the isolator
- A tray that carries up to 5 Steritest[®] canisters and an optional rack to hold up to 4 carrying trays.

NOTE

Go to <u>www.millipore.com/steritest-symbio</u> to check the latest version of this document and get information about Steritest[®] Symbio Pump optional accessories.

Operator and Equipment Safety

All employees who will operate and/or be near the Steritest[®] Symbio Pump must comply with the following:

• Read and understand this user guide before using the pump. Failure to follow operating instructions could result in user injury or damage to the instrument.

- Read and understand all maintenance instructions in this user guide before performing maintenance on the pump. Failure to follow instructions could result in user injury or damage to the instrument.
- Any alteration of the pump from factory specification may cause unsafe conditions, and will void the product warranty.
- Any attempt to use the pump in a manner not specified in this user guide may result in damage to the instrument, operator injury, and will void the product warranty.
- Do not attempt to open and repair the pump. Service should be performed by trained and authorized personnel only.
- Place the pump on a clean, flat, stable, horizontal surface, away from any source of excessive heat and close to an easily accessible, properly grounded power supply outlet.
- Do not expose the pump or the communication hub to liquid. If this happens, immediately switch off and disconnect the pump from the power outlet, and then decontaminate the pump and communication hub surfaces using a wipe moistened with one of the recommended cleaning agents listed in <u>Cleaning</u> <u>the Pump</u>.
- Never expose the equipment to extreme temperatures. Operating temperature must be between 15 °C and 40 °C (59 and 104 °F).
- Use only accessories and replacement parts designed for the pump. See
 <u>Accessories and Replacement Parts</u>. Using accessories not designed for the
 pump could result in user injury or damage to the instrument.
- The Steritest[®] Symbio Pump has been designed to be used with the Steritest[®] devices and accessories.
- When filtrating hazardous liquids, wear and use proper protective clothing and equipment for the handling and the disposal of the liquid to be filtrated.
- In case of skin contact with the filtrated liquid, refer to the safety datasheet of the filtrated liquid for first aid measures.
- Dispose the filtrated liquids according to local regulations.
- Do not use the Steritest[®] Symbio Pump to filtrate flammable products.
- Never touch the display or control panel with a sharp object.
- Before cleaning, shut down the the Steritest[®] Symbio Pump and switch off and disconnect the communication hub from power source.
- The power supply must be protected by a fuse below the main connection.
- The electrical installation must comply with local standards.
- Use an electrical surge protector to prevent damage to the system.
- The communication hub is a specific component of the Steritest[®] Symbio Pump and should not be used for any other purpose.

Specifications and Operating Requirements

Parameter	Value/Range		
	Width		633 mm (24.9 in.)
	Depth		372 mm (14.6 in.)
Dimensions and weight:	Height		410 mm (16.1 in.)
LFH version, equipped pump	Weight		15.8 kg (34.8 lb)
equipped pump			14.2 kg (31.3 lb) (without accessories)
	Pump head height		158 mm (6.2 in.)
	Width		588 mm (23.1 in.)
Dimensions and	Depth		313 mm (12.3 in.)
Dimensions and weight:	Height		354 mm (13.9 in.)
ISL version, equipped pump	Weight		17.6 kg (38.8 lb)
equipped pump			16.0 kg (35.3 lb) (without accessories)
	Pump head height		81 mm (3.2 in.)
		Width	645 mm (25.4 in.)
	On feet in a	Depth	355 mm (14.0 in.)
	laminar flow	Height	464 mm (18.3 in.)
	hood	Pump head	189 mm (7.4 in.)
		height	
		Width	645 mm (25.4 in.)
	On feet in an	Depth	355 mm (14.0 in.)
	isolator	Height	472 mm (18.6 in.)
		Pump head	197 mm (7.8 in.)
Dimensions and		height	
weight:	Low integration in an isolator	Width	611 mm (24.1 in.)
FLEX version, equipped pump		Depth	361 mm (14.2 in.)
		Height	356 mm (14.0 in.)
		Pump head height	82 mm (3.2 in.)
		Width	645 mm (25.4 in.)
		Depth	361 mm (14.2 in.)
	High Integration in an isolator	Height	459 mm (18.1 in.)
		Pump head height	185 mm (7.3 in.)
		1	19.6 kg (43.2 lb)
	Weight		17.9 kg (39.5 lb)
Performance	erformance Rotation speed		up to 240 rpm
specifications	Timer		from 0.5 to 999

Manadala	Duran have in a				
Materials of construction	Pump housing	316L Stainless steel			
	Pump housing seal (LFH version)	Silicone foam			
	Pump housing flat seal (ISL version)	Silicone foam			
	Pump housing fastening screws	A2 Stainless steel			
	Pump head protective cover	216L Chainless sheet			
	housing	316L Stainless steel			
	Pump head protective cover tubing guide	Polyphenylsulfone (PPSU)			
	Pump head	316L Stainless steel			
	Seal plate (closing system seal)	Polyoxymethylene (POM)			
	Pump handles / pump supports	316L Stainless steel			
	for drain tray and bottle holder	Taughanad alaga			
	Screen pane/window	Toughened glass 316L Stainless steel			
	Screen housing				
	Screen housing seals	Ethylene propylene diene monomer (EPDM)			
	Screen seal	Silicone			
	Pump control panel / key pad	Polyester			
	Rotary control knob	316L Stainless steel			
	Determy control knob cools	Ethylene propylene diene monomer			
	Rotary control knob seals	(EPDM)			
	Pump power inlet	Chrome-plated brass			
	Pump feet	Polyvinyl chloride (PVC)			
	Pump feet screws	A2 Stainless steel			
	Drain tray	Drain tray			
	Drain tray container	Polyphenylsulfone (PPSU)			
	Drain tray support	316L Stainless steel			
	Drain tray support seal	Ethylene propylene diene monomer (EPDM)			
	Steritest [®] canisters carrying trays	Polyphenylsulfone (PPSU)			
	Bottle holder				
	Bottle holder support rod	316L Stainless steel			
	Bottle holder basket	316L Stainless steel			
	Bottle holder fastening system	Polyphenylsulfone (PPSU)			
	screw clip				
	Communication hub	1			
	Housing	316L Stainless steel with epoxy paint			
	Feet	Nylon and ethylene vinyl acetate (EVA)			
	USB port	Nickel-plated brass and polybutylene terephthalate (PBT)			
	Fuse holder	Thermoplastic+tin-plated copper alloy			
		Nickel-plated brass and polybutylene			
	Ethernet port	terephthalate (PBT)			
	Communication ports (for	Nickel-plated brass and polybutylene			
	footswitch, etc.)	terephthalate (PBT)			
	Power inlet	Polyamide 6.6 and nickel-plated steel			
i		Polyvinyl chloride (PVC)			
	Pump connection cable	r oryvnityt chloride (r ve)			
	Pump connection cable Pump connection cable grommet	Nickel-plated brass			

	Power supply voltage	100 to 240 Volt AC, 50/60 Hz		
		24 Volt DC		
Electrical	Input to pump			
Specifications	Denner	LFH version: maximum 120 W		
	Power	ISL version: maximum 140 W		
		FLEX version: maximum 150 W		
	Ambient temperature	15 to 40 °C (59 to 104 °F)		
	Relative humidity	< 90%		
	Altitude	< 2000 meters (6561 feet)		
Operating		Compatible with all Steritest [®] ,		
Requirements	Filtration units	Sterisolutest, Steridilutor and liquid		
		transfer kits		
	Protection type (IEC 60529-2004)	IP64 for the pump		
	Sound intensity	<70 dB		
	Millipore SAS certifies that the Ster	itest [®] Symbio Pump is designed and		
	manufactured in application of:	manufactured in application of:		
	The following European Council	The following European Council directives:		
	- Electromagnetic compatibility 2014/30/EU			
	- Low voltage directive 2014/35/EU			
	- Restriction of the use of certain Hazardous Substances in electrical			
	equipment (RoHS) 2011/65/I			
	The following standards: IEC 61010 1/Ed 2) Safety requirements for electrical equipment			
		 IEC 61010-1(Ed. 3) Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General 		
	requirements			
	- IEC 61326-1 (Ed. 2) Electrical equipment for measurement, control			
	and laboratory use -EMC requirements – Part 1: General requirements.			
D	These standards include the national deviations as appropriate for the			
Regulatory Information	relevant countries: USA, Canada, Australia, Argentina, Brazil, China, India,			
	Japan, Mexico, Russia, Saudi Arabia, South Africa, South Korea, Singapore			
	The Federal Communications Commission (FCC) standard and test method: Chandend:			
	- Standard:			
	FCC part 15: 2014 Code of federal regulations			
	Title 47 – Telecommunication chapter 1- Federal Communication			
	Commission.			
	Part 15 - Radio frequency devices Subpart B - Unintentional Radiators			
	Limits and Methods of measurement of radio disturbance.			
	- Test method:			
	Section 15 .107 - Information to the user			
	Section 15 .109 - Conducted	limits		
	The European Union Directive 2	The European Union Directive 2012/19/EU on Waste Electrical and		
	Electronic Equipment (WEEE)			

Overview of the Pump Assembly

The Steritest[®] Symbio Pump assembly consists of the following components:

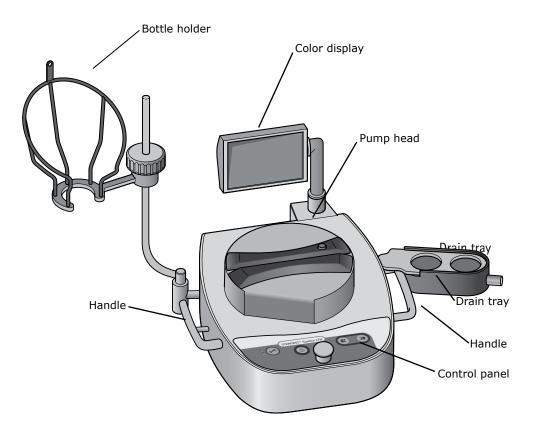
- The pump, including:
 - A control panel on the front
 - An adjustable color display at the back
 - A pump head located below a protective cover on the top
 - · Carrying handles (standard on LFH version; optional on FLEX version)
- A bottle holder (mounted on the left side of the pump)
- A drain tray (mounted on the right side of the pump)
- A communication hub equipped with the cable dedicated to connect it to the pump
- A power cord

Documentation and some accessories are also delivered with the pump:

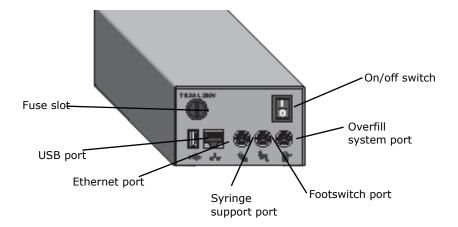
- A network cable (for connection of the pump to a network or directly to a computer) for the transfer of test methods from a computer to the pump
- A USB flash drive for the transfer of test methods from a computer to the pump
- Silicone drain tubing for the liquid disposal
- 2 threaded stems (ISL and FLEX versions only)
- A flat seal (FLEX version only)
- Quick guides (in German, English, Spanish, French, Italian, Portuguese, Japanese, Simplified Chinese, Turkish, and Russian):
 - Steritest[®] Symbio Pump Startup Quick Guide
 - Steritest[®] Symbio Pump User Interface Quick Guide
 - Steritest[®] Symbio Software Quick Guide
- Safety instructions (in German, English, Spanish, French, Italian, Portuguese, Japanese, Simplified Chinese, Turkish, and Russian)
- Steritest[®] Symbio 2 media pumps EAC request
- 2 Steritest[®] canisters carrying trays with user quick guide

WARNING

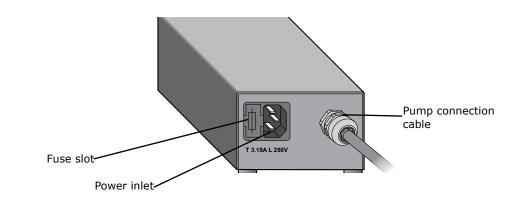
Do not discard the Steritest[®] canisters carrying trays. Deliver them to the final user of the pump.



Communication hub – front view:



Communication hub – rear view:



NOTE

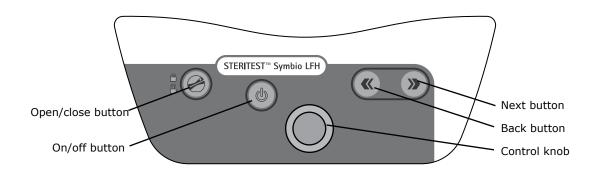
To use the pump in Test Method Mode, it is necessary to previously create test methods and transfer them from the computer to the pump using the Steritest[®] Symbio Software.

To access this software and the software user guide, go to **www.millipore.com/steritest-software**.

Overview of the Pump Control Panel

Use the control panel to start, operate, and stop the pump. The control panel consists of the following components:

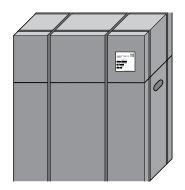
- An on/off button (\mathbf{b}) that is used to switch the pump on and off.
- A control knob that can be rotated and pressed to perform various operations.
- An open/close 🥔 button that is used to open and close the pump head.
- A next button ()) that is used to perform various operations.
- A back button (\mathbf{K}) that is used to perform various operations.



Installing the Pump

Unpacking the Equipment

The Steritest[®] Symbio Pump is delivered in two boxes that are strapped together.



The larger box contains:

- The Steritest[®] Symbio Pump
- The communication hub
- 2 Steritest[®] canisters carrying trays
- The pump Certificate of Quality
- The safety instructions
- Steritest[®] Symbio 2 media pumps EAC request
- Steritest[®] cannisters carrying tray and rack user quick guide

WARNING

Do not discard the Steritest[®] canisters carrying trays. Deliver them to the final user of the pump.

The smaller box contains the pump accessories and the quick guides.

To unpack the boxes:

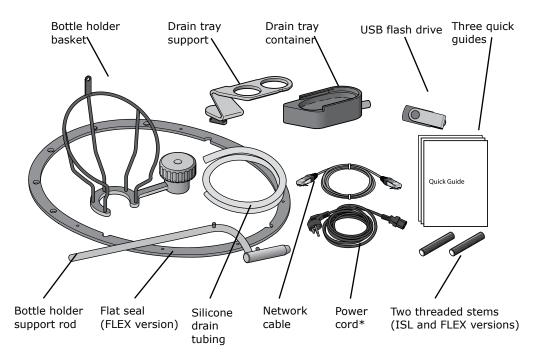
- 1. Using the carrying handles on the larger box, place the package on a flat, stable, and horizontal surface.
- 2. Cut the plastic straps to separate the two boxes.
- 3. Put the smaller box aside.
- 4. Open the larger box.
- Retrieve the pump documentation (an envelope containing the Certificate of Quality and a plastic file folder containing the safety instructions, the EAC request, and the Steritest[®] canisters carrying tray and rack user quick guide).

- 6. Remove the communication hub from the top wedging system.
- 7. Remove the top wedging system.
- Using the pump carrying handles (for LFH version) or placing the hands below the pump (ISL and FLEX versions), take the pump out of the box and place it on a flat and stable surface.

NOTE

Store all packaging materials in a dry area for future use. The pump and the communication hub must be packaged in this certified packaging if shipment back to a service center is required. The pump and the communication hub can also be packaged in the Steritest[®] Symbio pumps shipment case (see **Accessories and Replacement Parts**).

- Remove the 2 Steritest[®] canisters carrying trays and deliver them to the user of the pump.
- 10. Open the smaller box that contains the accessories.
- 11. Remove the accessories.



*The power cord is not included in the Steritest[®] Symbio FLEX BQ Pump kit, 2 media (see <u>Accessories and Replacement Parts</u>).

NOTE

The Steritest® Symbio Pumps User Guide, the Steritest® Symbio ISL Pump Installation Guide, the Steritest® Symbio FLEX Pump Installation Guide, and the Steritest® Symbio Software User Guide are available at www.millipore.com/steritest-symbio.

Installing the Pump in the Work Environment

LFH version

- 1. Clean the pump and accessories. See <u>Cleaning the Pump</u>.
- 2. Place the pump and accessories in a laminar flow hood on a flat, stable, and horizontal surface.

NOTE

To optimize working comfort, place the pump 160 mm (6.3 in.) from the front edge of the hood bench.

The communication hub is not intended to be placed in the laminar flow hood. To fix the communication hub to one of the laminar flow hood feet, use the optional communication hub holder for hoods (see <u>Accessories</u> and <u>Replacement Parts</u>.)

The Steritest[®] Symbio LFH pump can also be used inside an isolator, using the Steritest[®] Symbio connection cable extension with Tri-Clover clamp and the Steritest[®] Symbio feet for use in isolator (see <u>Accessories and</u> <u>Replacement Parts</u>.)

ISL version

Refer to the **Steritest® Symbio ISL Pump Installation Guide** (PF16599). To access this document, go to <u>www.millipore.com/steritest-symbio</u>.

FLEX version

Refer to the **Steritest® Symbio FLEX Pump Installation Guide** (PF17222). To access this document, go to <u>www.millipore.com/steritest-symbio</u>.

Installing the Communication Hub

NOTE

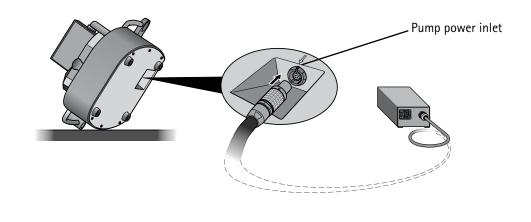
The communication hub is equipped with specific fuses to protect the pump components in case of overload:

- One T 6.3A L 250V fuse at the front
- Two T 3.15A L 250V fuses at the rear

To order spare fuses for the Steritest[®] Symbio communication hub, see <u>Accessories and Replacement Parts</u>.



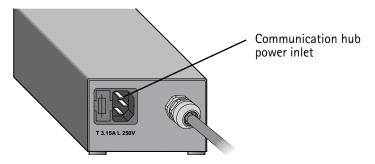
1. Connect the end of the pump connection cord to the pump power inlet.



NOTE

For the LFH pump, place the pump on the side to connect the pump connection cord to the pump power inlet.

2. Connect one end of the power cord to the communication hub power inlet.



- 3. Connect the other end of the power cord to a properly grounded power outlet.
- To transfer test methods to the pump using the company network or using direct connection between pump and computer (see <u>Configuring the</u> <u>Pump, Method Transfer, Transfer Using a Network Cable</u>), connect the network cable to the dedicated port of the communication hub.



 To transfer test methods to the pump using a USB flash drive (see <u>Configuring the Pump, Method Transfer, Transfer Using a USB</u> <u>Flash Drive</u>), connect a USB flash drive to the dedicated USB port of the communication hub



6. If using the optional footswitch, connect the footswitch to the dedicated port of the communication hub (see **Overview of Optional Accessories**).



 If using the optional syringe support, connect the syringe support to the dedicated port of communication hub (see <u>Overview of Optional</u> <u>Accessories</u>).



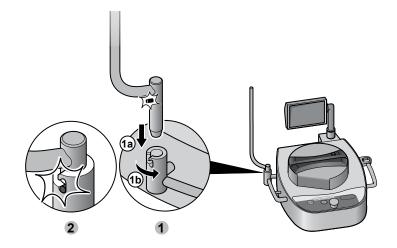
 If using the optional waste overfill sensor for solid containers, connect the waste overfill sensor to the dedicated port of the communication hub (see Overview of Optional Accessories).



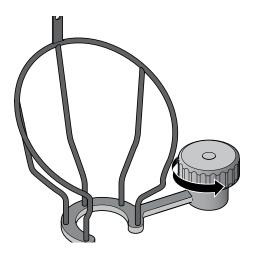
9. Switch on the communication hub by pressing the on/off switch (position I).

Installing the Bottle Holder

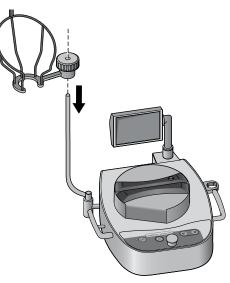
- 1. Insert the bottle holder support rod into its dedicated support on the left side of the pump.
- 2. Secure the support rod by placing the lug into the dedicated slot located on the support.



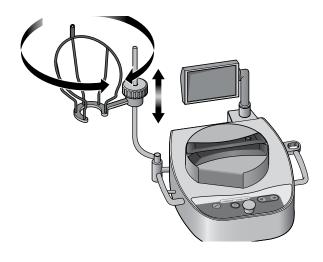
3. Loosen the fastening screw on the bottle holder basket, but do not unscrew it all the way.



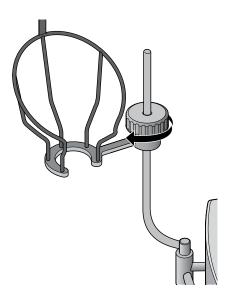
4. Insert the bottle holder basket on the bottle holder support rod.



5. Adjust the height and orientation of the basket.

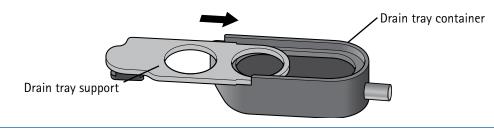


6. Secure the position of the bottle holder basket by tightening the screw.



Installing the Drain Tray

1. Assemble the two parts of the drain tray as shown:

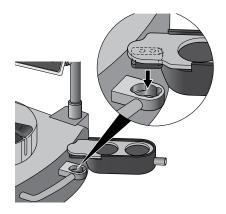


NOTE

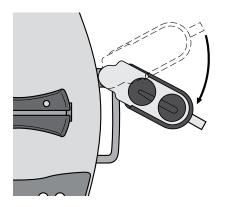
The drain tray supports are not the same for all pump versions.

To optimize working comfort when using the Steritest[®] Symbio FLEX Pump on feet or in an isolator in high integration configuration, use the Steritest[®] Symbio drain tray support for 2 canisters, FLEX pump, high integration. This drain tray support is not delivered with the FLEX pump (see <u>Accessories</u> <u>and Replacement Parts</u>.)

2. Insert the drain tray into its dedicated housing on the right side of the pump.

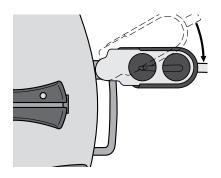


3. Secure the drain tray in its housing by turning it to the front of the pump.

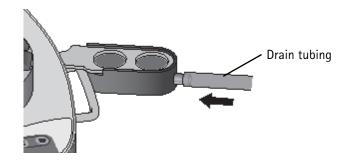


NOTE

On the LFH version, a intermediate position exists for use when the pump must be carried without removing the drain tray.



4. Connect the silicone drain tubing to the drain tray.



 Place the other end of the drain tubing directly into a waste container (for LFH version) or connect it to the isolator table drain (for ISL and FLEX versions).

NOTE

To prevent back flow of fluid and reverse pressure into the drain tray, ensure that the tubing does not touch the liquid in the waste container and that the waste container is open or correctly vented. Also ensure that the drain tray is higher than the waste container, and that the tubing between them is straight, without any bends or loops.

A waste overfill sensor can be used to automatically check the liquid level in the waste container (see **Overview of Optional Accessories**).

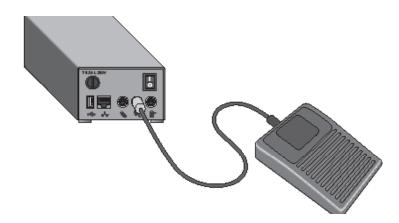
Follow safety procedures for the handling of the filtrated liquid.

Dispose of the liquid in accordance with local regulations.

Overview of Optional Accessories

These accessories are not delivered with the pump but can be ordered separately (see **Accessories and Replacement Parts**).

Steritest[®] Pump Footswitch



Operating the pump with the footswitch frees hands for easier handling of samples and the Steritest[®] filtration device.

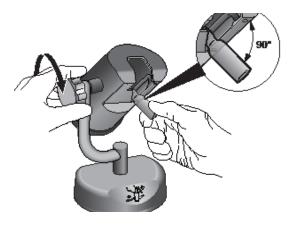
The footswitch is compatible with Steritest[®] Symbio Pumps and with Steritest[®] Equinox pumps.

The footswitch is connected to the pump through a dedicated port on the communication hub. The footswitch operates in two modes: **Start/Stop** and **Continuous**. Set the mode in the **Configuration** menu, which is accessed from the **main screen**, or directly from the **Standard Mode** by pressing the **b**utton on the control panel when the pump head is closed but the pump is not running.

NOTE

See **<u>Configuring the Steritest</u>® <u>Symbio Pump/Footswitch</u> for details on the operating modes of the footswitch and how to configure the footswitch.**

Steritest[®] Glass Ampoule Breaker



Use the Steritest[®] glass ampoule breaker to file and break glass ampoule necks. The glass parts are collected inside the container.

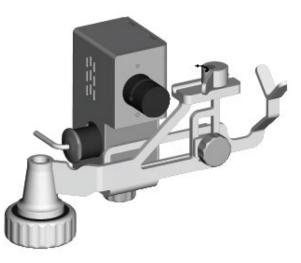
The glass ampoule breaker is independent from the Steritest[®] Symbio pump. Choose a location in the testing environment to accommodate either right- or lefthanded technicians.

An optional cutting file is available for use with ampoules without a prescored neck.

The glass ampoule breaker is autoclavable and is resistant to vaporized hydrogen peroxide (VHP)) and peracetic acid decontamination cycles in isolators.

For more information, see the **Steritest**[®] **Glass Ampoule Breaker User Guide** (see <u>Accessories and Replacement Parts</u>).

Steritest[®] Pumps Syringe Support



Use the Steritest[®] Pumps syringe support together with the Steritest[®] device for prefilled syringes to test most prefilled syringes (with or without needle) produced by the pharmaceutical industry.

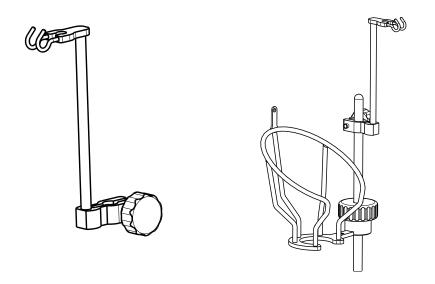
The syringe support holds the syringe. The distribution of sterile fluid to dilute the content of the syringe is controlled by an electrovalve, eliminating the necessity to turn the dilution bottle between each syringe testing.

The syringe support valve is connected to the pump through a dedicated port on the communication hub.

This accessory is autoclavable (except for the removable automatic valve) and is fully resistant to vaporized hydrogen peroxide (VHP) and peracetic acid decontamination cycles in isolators.

For more information, see the **Steritest**[®] **Pumps Syringe Support User Guide** (see <u>Accessories and Replacement Parts</u>).

Steritest® Holder for Sterile Bags and Steridilutor Vent Chamber



Use this accessory to hang:

- Bags on the Steritest[®] Symbio bottle holder during liquid sampling
- The vent of the Steridilutor expansion chamber (an accessory used to dissolve and/or dilute powder samples in small vials before filtration on a Steritest[®] device)

This accessory is autoclavable and resistant to vaporized hydrogen peroxide (VHP) and peracetic acid decontamination cycles in isolators.

Steritest® Symbio Waste Overfill Sensor for Solid Containers

This accessory prevents the liquid waste container from overflowing, and is especially helpful when the waste container is placed out of the operator's view.

When the liquid reaches the maximum filling level, an alert appears on the Steritest[®] Symbio Pump display (see <u>Using the Waste Overfill Sensor in Standard</u> <u>Mode</u> or <u>Using the Waste Overfill Sensor in Test Method Mode</u>).

NOTE

The test in progress can be finished before the waste container is emptied or replaced.

To use the overfill sensor:

1. Place the sensor around the waste container. Use the belt to secure the position.

NOTE

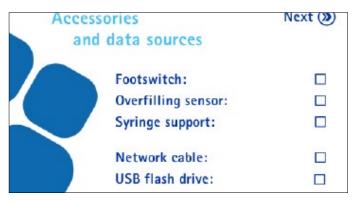
Keep enough space at the top of the container so that the filtration in progress can be completed before overflowing occurs.

2. Connect the waste overfill sensor connector to the dedicated port of the communication hub.

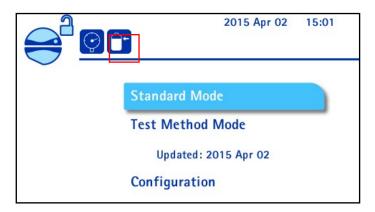
NOTE

The waste overfill sensor can be connected at any time, regardless of pump status.

3. If the pump is off, switch on the communication hub by pressing the on/ off switch (position I). The Welcome screen displays. After the autotest sequence, the Accessories and data sources screen displays. The check in the check box next to Overfilling sensor indicates that the waste overfill sensor is activated.

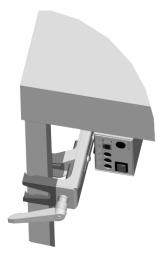


4. Press the *button*. The main screen appears. The blue waste overfill sensor icon is displayed.



5. If the icon is red, empty or replace the waste liquid container.

Communication Hub Holder for Hoods



This optional accessory is used to attach the communication hub to one of the four legs of the laminar flow hood or isolator in order to free space on the floor. Its unique design is compatible with many types of support rods.

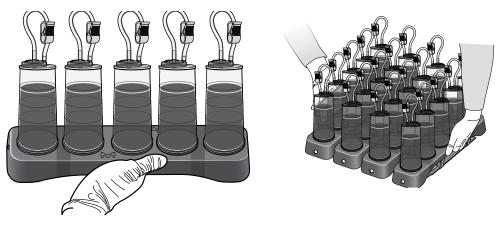
Communication Hub Holder for Isolators

This optional accessory is used to attach the communication hub to the bottom plate of the Steritest[®] Symbio ISL or FLEX pump after it is installed inside the isolator table cutout. The multiple fastening options make this optional accessory compatible with many isolators configurations; the depth adjustment frees space for the operator's legs while keeping all connection ports accessible. There are many different installation possibilities.

NOTE

For more information about this accessory, refer to the **Steritest® Symbio ISL Pump Installation Guide**, Document PF16599 or **Steritest® Symbio FLEX Pump Installation Guide**, Document PF17222. Or contact Technical Support at <u>www.millipore.com/techservice</u>

Steritest[®] Carrying Tray and Steritest[®] Rack



The Steritest[®] carrying tray provides added security and ease of use throughout the sterility testing workflow:

- The tray secures up to 5 canisters in an upright position at the end of the sterility test.
- The tray enables safe transport of the canisters from the test environment to the incubator.
- The Steritest[®] rack tightly holds up to 4 Steritest[®] carrying trays. Up to 20 media-filled canisters can be safely transported at one time.
- The Steritest[®] carrying tray and Steritest[®] rack can remain in the incubator, firmly holding the canisters.
- During intermediate and final readings of the sterility test, all 5 canisters can be visually inspected at by gently swirling the Steritest[®] carrying tray.

The tray and rack are autoclavable and resistant to vaporized hydrogen peroxide (VHP) and peracetic acid decontamination cycles within an isolator. The hole in the Steritest[®] carrying tray can be used to hang the tray in the isolator during the decontamination process.

For more information, see the **Steritest® Canisters Carrying Tray and their Rack User Quick Guide** (see <u>Accessories and Replacement Parts</u>).

Using the Steritest[®] Symbio Pump

Making Selections Using the Control Knob

Turn the control knob to highlight selections. Push the control knob in to confirm the selection.

NOTE

A \checkmark symbol indicates a currently activated value.

The value and representation of the list continues below or above. Turn the knob to scroll through the list.

Starting the Pump for the First Time and Activating the Pump Certificate

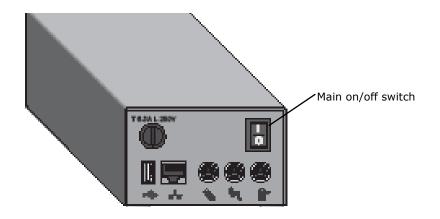
The pump has been calibrated at the factory. Once the pump is installed in its working environment and is ready to be qualified, activate the pump certificate. This resets the countdown to the next calibration to 12 months.

It is possible to activate the pump certificate within one year after the date of factory calibration. After this period, the countdown can be reset only during a standard maintenance performed by a certified technician.

Until the pump certificate is activated, the countdown before the next calibration remains based on the date of the factory calibration.

By default, the calibration countdown is 12 months. It can be changed to between 6 and 12 months. See <u>Configuring the Steritest® Symbio Pump</u>, <u>Pump</u>. <u>Information</u>. It is recommended that preventive maintenance, including the calibration of the pressure sensors, be performed on a yearly basis. Contact our local representative or Technical Service for more information.

1. Switch on the communication hub by pressing the on/off switch (position I).



 Press the pump on/off button (b). The screen displays the range of Steritest[®] devices. This is followed by the welcome screen:



The first time the pump is started, and until the pump certificate is activated, the following screen also displays:



 To activate the pump certificate, turn and press the control knob to select Yes.

NOTE

If **No** is selected, the autotest sequence begins. When autotest is finished, continue with step 9 of this section.

The following screen displays. By default the language is English.



- 4. Do one of the following:
 - To use English, turn and press the control knob to select **No**. Continue to step 6.
 - To use a language other than English, turn and press the control knob to select **Yes**. The **Language** screen displays:



Turn and press the control knob to select a language.

NOTE

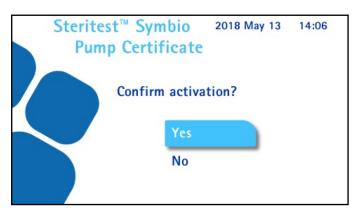
The language can also be changed later using the **Configuration** menu. See **Configuring the Steritest**[®] **Symbio Pump**.

5. Press the ()) button to continue. The following screen displays:

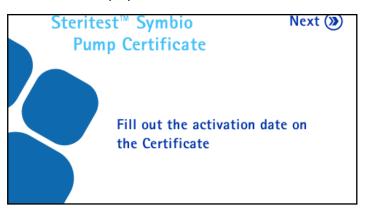


6. To set date, format, and time, turn the control knob to go from a field to another. To modify a value, push the control knob to enter the value field, turn the control knob to change the value, and press the control knob to confirm the value.

 Press the button to continue. The Steritest[®] Symbio Pump Certificate screen displays:



- 8. Do one of the following:
 - To confirm activation of the certificate of conformity:
 - Turn and press the control knob to select Yes. The countdown to the next calibration is set to 12 months, and the following screen displays:



- Fill out the activation date on the certificate of quality that was delivered with the Steritest[®] Symbio Pump.
- Press the button to move to next step (autotest sequence).
- To skip activation:
 - Turn and press the control knob to select **No**. The autotest sequence begins automatically.

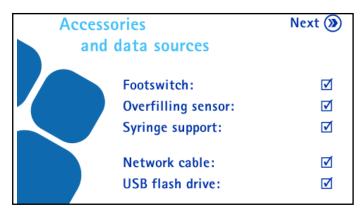
NOTE

For information about changing the frequency of calibration and for deactivating the calibration countdown and alerts, see <u>Configuring the</u><u>Steritest® Symbio Pump, Pump Information</u>.

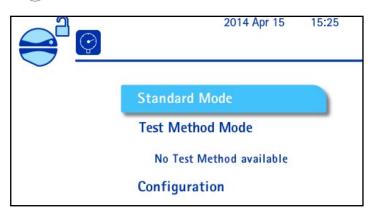
The **Autotest** screen displays. The autotest procedure starts, and the pump head opens. The screen also displays the serial number of the pump and the number of days before the next scheduled calibration.



When the autotest is complete, the following screen displays. A \checkmark symbol in a check box indicates that an accessory or data source is connected to the communication hub.



9. Press the (\mathbf{y}) button to continue. The main screen displays:



10. To continue, see <u>Using the Main Screen</u>.

Starting the Pump after Initial Startup

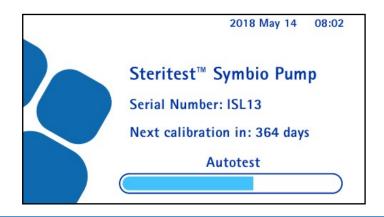
- 1. Switch on the communication hub by pressing the on/off switch (position I).
- Press the (b) button on the pump control panel. The screen displays the range of Steritest[®] devices. This is followed by the welcome screen:



NOTE

The Steritest[®] products image can be replaced by another image. See the **Steritest[®] Symbio Software User Guide**.

After a few seconds, the **Autotest screen** displays. The autotest procedure starts and the pump head opens. The screen also displays the serial number of the pump and the number of days before the next scheduled calibration.

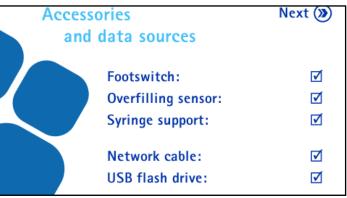


NOTE

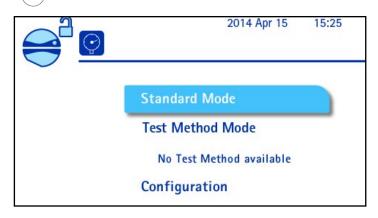
Starting 45 days before the scheduled calibration date, a calibration schedule alert displays at the top right of the Main screen.

For information about changing the frequency of calibration and for deactivating the calibration countdown and alerts, see <u>Configuring the</u><u>Steritest® Symbio Pump, Pump Information</u>.

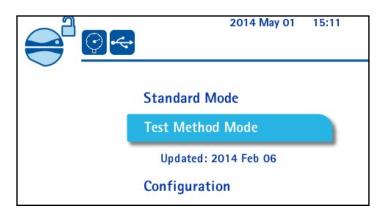
When the Autotest is complete, the following screen displays showing the status of the optional accessories and data sources. A \checkmark symbol in a check box indicates that an accessory or data source is connected to the communication hub.



3. Press the \bigcirc button to continue. The main screen displays.



Using the Main Screen



Use the Main screen to:

- Use the pump in the Standard Mode (see <u>Using the Pump in Standard</u> <u>Mode</u>)
- Use the pump in the Test Method Mode (see <u>Using the Pump in Test Method</u> <u>Mode</u>)
- Configure the pump (see <u>Configuring the Steritest</u>[®] <u>Symbio Pump</u>)

The following information is visible at the top of this screen:

- The date and time
- A calibration reminder if the calibration is scheduled in less than 45 days or is overdue
- Status and configuration of the pump and accessories

The following table explains the pump and accessories status and configuration symbols:

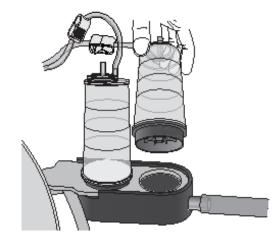
	Status	Icon
Pump head	The pump head is open.	
Pressure mode	The pressure monitoring mode is activated in Standard Mode.	
	The pressure regulation mode is activated in Standard Mode.	
Ethernet network	The communication hub is connected to an active network or directly to the computer using a network cable.	E E E E E
USB flash drive	A USB flash drive is connected to the communication hub.	•~~
Footswitch (optional)	The footswitch is connected to the communication hub, and Start/Stop mode is selected.	
	The footswitch is connected to the communication hub, and Continuous mode is selected.	
Syringe support (optional)	The syringe support is connected to the communication hub and activated.	
	The syringe support is connected to the communication hub but not activated.	- The second
Liquid waste overfill sensor (optional)	The liquid waste overfill sensor is connected to the communication hub.	
	The liquid waste overfill sensor detects that the liquid has reached the maximum filling level.	

Starting the Filtration of a Sample

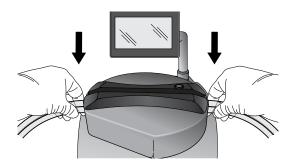
From the main screen, turn and press the control knob to select either **Standard Mode** or **Test Method Mode**.

Installing the Steritest[®] Device

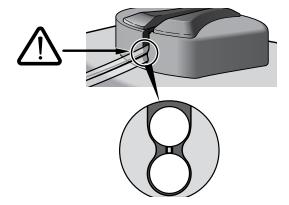
1. Remove the Steritest[®] device from its packaging and place the two canisters on the drain tray.



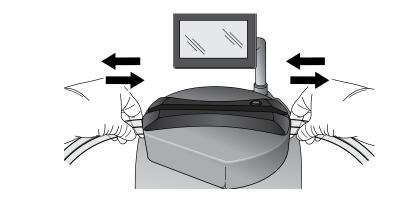
2. Install the tubing in the pump head. At the same time, gently pull the tubing and engage it fully in the cover.



3. Ensure that the two tubing hoses are positioned on either side of the bosses on the right and left sides of the cover.



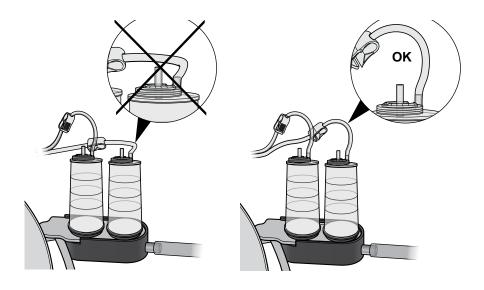
4. Slide the tubing from left to right and right to left to ensure that it is correctly positioned.



NOTE

If the tubing does not slide freely, repeat the operation.

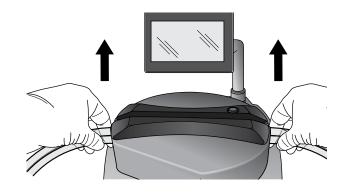
5. Ensure that the tubing connected to the canister is not under tension. If necessary, slide the tubing to the right in the pump head.



6. Close the pump head by pressing the 🏈 button.

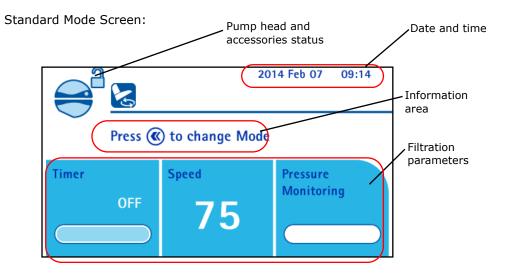
NOTE

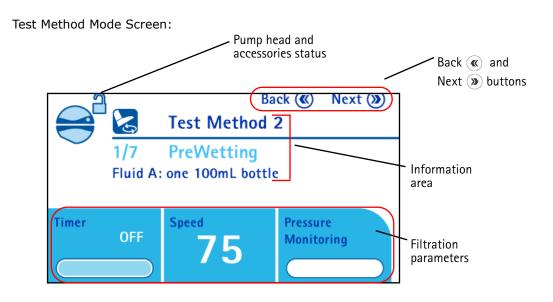
The pump head can be closed only after **Standard Mod**e or **Test Method Mode** has been selected. 7. To remove the tubing from the pump head, press the 🖉 button to open the pump head. Pull the tubing gently to release it.



Using the Standard Mode and Test Method Mode Screens

Both the **Standard Mode screen** and the **Test Method Mode screen** are composed of 4 main areas:





Date and Time (Standard Mode Screen only)

This area displays the current date and time.

Back (and Next) Buttons (Test Method Screen only)

Use these buttons to navigate through the screens

Pump Head and Accessories Status

The following table explains the symbols that indicate the status and configuration of the pump and accessories:

	Status	lcon
Pump head	The pump head is open.	
	The pump head is being closed.	
	The pump head is ready.	000000000000000000000000000000000000000
	The pump head is running (animated icon).	00000000000
Footswitch	The footswitch is connected to the communication hub, and Start/Stop mode is selected.	
	The footswitch is connected to the communication hub, and Continuous mode is selected.	E
Syringe support	The syringe support is connected to the communication hub and activated. The valve is closed.	
	The syringe support is connected to the communication hub and activated. The valve is open.	
	The syringe support is connected to the communication hub but not activated.	The second
Liquid waste overfill sensor (optional)	The liquid waste overfill sensor is connected to the communication hub. Visible only in Standard Mode.	
	The liquid waste overfill sensor detects that the liquid has reached the maximum filling level.	

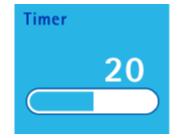
Information Area

This area is used for the display of different messages:

- Information and instructions regarding test method step (in Test Method Mode)
- Alert messages and error messages

Filtration Parameters

Timer



The timer function stops the pump automatically after a preset filtration time. The timer value can vary from off (not used) to 999 (see **Using the Pump in Standard Mode**).

NOTE

The timer default value is **off**.

Speed

The pump speed value can vary from 1 to 150.



NOTE

The default speed value is 75.

Pressure

The Steritest[®] Symbio Pump constantly monitors the pressure inside each Steritest[®] canister and indicates when pressure goes above normal working conditions. Colored bars and audible beeps indicate the pressure level. A white bar indicates that the pump head is not running.



Symbol	Pump pressure
Pressure Monitoring	When the pump is running and the pressure in the canisters is lower than the high pressure alert level, the color bar is green.
High Pressure	 When the pressure in the canisters reaches the high pressure alert level: A beep sounds. The color bar becomes orange. The display reads High Pressure.
Over Pressure	 When the pressure in the canisters reaches the canister maximum guaranteed pressure: A second beep sounds; it is higher and louder. The color bar becomes red. The display reads Over Pressure.

As soon as the pressure returns to the normal operating range, the color bar returns to green.

NOTE

This pressure alarm works with but does not replace the Steritest[®] red plugs safety function. Operation of the Steritest[®] device should never prevent the red safety plugs from popping off in the event of overpressure inside the canister. See <u>Safety Mechanisms, Steritest[®] Red Plugs</u>.

There are two pressure measurement modes. Select a pressure measurement mode in the **Configuration menu** (see <u>Configuring the Steritest</u>[®] <u>Symbio</u> <u>Pump</u>):

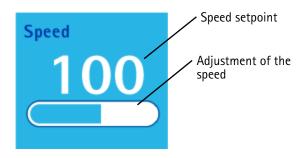
• **Pressure monitoring mode**: The pump indicates the pressure level in the canisters. Warnings indicate if the pressure is too high.

WARNING

In this mode, when over pressure is reached, stop the pump manually.

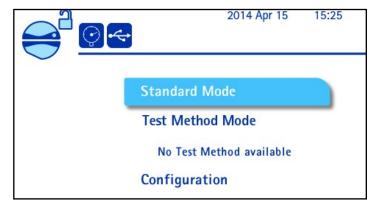
• **Pressure regulation mode**: The pump indicates the pressure level in the canisters. When the pressure level is too high, the pump automatically reduces the speed to stabilize the pressure at a normal level.

The speed value adjustment is represented by a color bar below the speed set point. If the bar is not completely filled with blue, the pump is reducing speed to reduce the pressure level in the canisters. The speed value blinks until the pump speed returns to the set value.

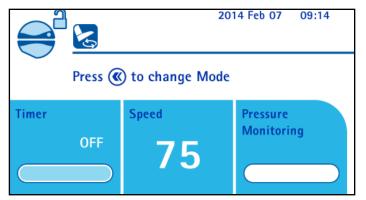


Using the Pump in Standard Mode

1. Access the main screen:



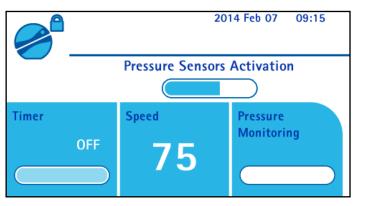
 Turn and press the control knob to select Standard Mode. The Standard Mode screen displays:



- Install the Steritest[®] device (see <u>Using the Steritest[®] Symbio Pump,</u> <u>Installing the Steritest[®] Device</u>).
- 4. Press the () button to close the pump head.

During the locking procedure of the pump head, the eigenplus eig

When the pump head is closed, the *solution* icon displays. The activation procedure of the pressure sensors starts.



When the pressure sensors are activated, the pump is ready to start. The *sicon* displays.

NOTE

To access the **Configuration** menu without going out of the **Standard Mode** when the pump head is closed and the pump not running, press the (>>>) button on the pump control panel.

5. To start the pump, press the control knob or use the footswitch (if connected).

NOTE

If the pump head is not closed, the message "Close pump head before starting pump" displays on the information area of the screen.

The pump starts, and the *set* icon with the a moving dot displays.

- To stop the pump, press the control knob or use the footswitch (if connected).
- When test is complete, press the button on the pump control panel to open the pump head.
- 8. When the pump head is open, remove the Steritest[®] Device.
- Do one of the following:
 - To run more tests in Standard Mode, go back to step 3 of this section.
 - To return to the main screen, press the (\mathbf{K}) button.

Modifying Speed in Standard Mode

The rotation speed can be changed by turning the control knob when the pump is running or when it is not running. It can also be changed during the pump head closure and the activation of the pressure sensors. Turn the control knob clockwise to increase the speed.

Turn the control knob counterclockwise to reduce the speed.

Using the Timer in Standard Mode

To adjust the value of the timer:

1. Press and hold the control knob until the value of the timer is blinking.

NOTE

The timer value cannot be adjusted when the pump is running.

When using the timer, only the pressure monitoring mode is available. If the pressure regulation mode is activated at the same time the timer is activated, a message displays: "Using the Timer will switch the Pressure Measurement System from Regulation to Monitoring." Turn and press the control knob to select **Continue**.

 Turn the control knob clockwise to increase the timer value. Turn the control knob counterclockwise to decrease the timer value. Press the control knob to confirm the value.

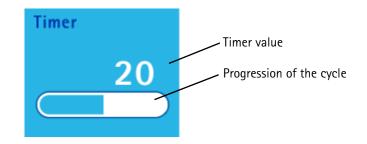
NOTE

The timer value varies from off (deactivated) to 999.

Between 0.5 and 9.9, the display is 1 digit and 1 decimal point. Between 10 and 999, the display is 2 or 3 digits without a decimal point.

3. To start the pump, press the control knob or the footswitch (if connected).

The pump starts. A progress bar shows the remaining time in the **Timer** area. When the progress bar is full blue, the cycle is complete, and the pump stops.

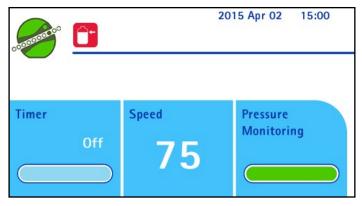


NOTE

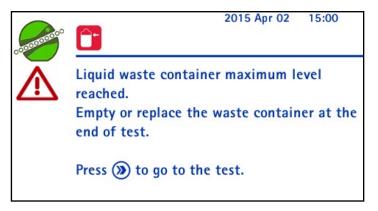
To stop the pump before the end of the timer value, press the control knob. A message asking if filtration should resume with remaining time displays. To stop the pump, turn and press the control knob to select **No**.

Using the Waste Overfill Sensor in Standard Mode

In Standard Mode, when the maximum liquid waste level is reached, the waste overfill sensor icon changes from blue to red. An alert beep sounds from the pump. An orange LED lights up on the waste overfill sensor. The pump continues to run.



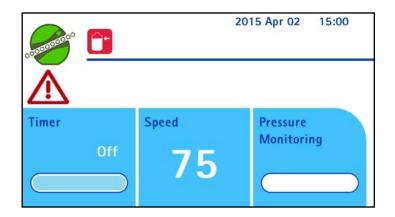
When the pump is stopped manually, the overfill alert screen displays:



The red waste overfill sensor icon and the warning symbol remain on the screen until the waste receptacle is emptied or replaced.

NOTE

The test in progress can be finished before the waste container is emptied or replaced.



Once the waste receptacle is emptied or replaced, the warning symbol is no longer displayed on the Standard Mode screen, the waste overfill sensor icon returns to blue, and the orange LED no longer lights up on the waste overfill sensor.

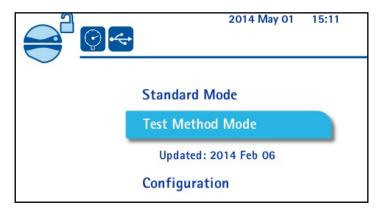
Using the Pump in Test Method Mode

The **Test Method Mode** is available only if test methods have been loaded in the pump. Test methods are created and transferred to the Steritest[®] Symbio Pump using the Steritest[®] Symbio Software. The software and software user guide are available at

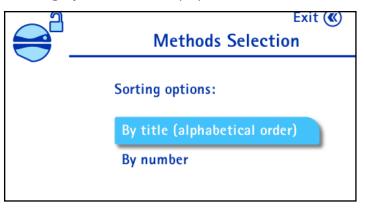
www.millipore.com/steritest-software.

To use the pump in **Test Method Mode**:

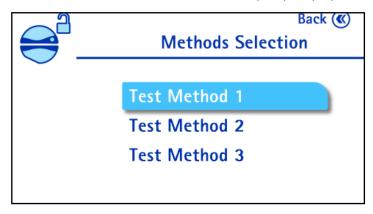
1. Access the main screen.



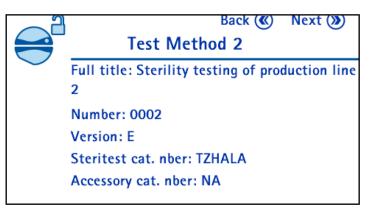
 Turn and press the control knob to select the Test Method Mode. The Methods sorting options screen displays:



3. Turn and press the control knob to select the preferred test methods sorting option. The list of the test methods stored in the pump displays:



4. Turn and press the control knob to select a test method. The details of the selected test method display:



NOTE

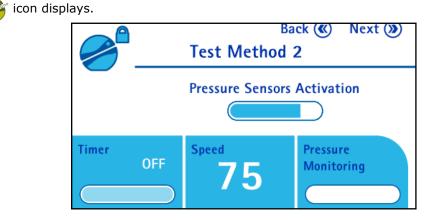
Ensure that the version of the selected test method is up to date.

5. Press the (\mathbf{y}) button to continue. The **Test Method Mode** screen displays. The name of the test method displays at the top of the screen, and the number and name of the test method step displays in the information area along with a comment, if one has been entered.

	Back (() Next ()) Test Method 2
	1/7 PreWetting Fluid A: one 100mL bottle
	Timer Speed Pressure OFF 75 Monitoring
NO	TE Use the >>> and <
6.	Install the Steritest [®] device (see <u>Using the Steritest[®] Symbio Pump,</u> Installing the Steritest [®] Device).
7.	Press the 🧭 button to close the pump head.
NO	TE During the locking procedure of the pump head, the $eellip$ icon blinks.
Wŀ	nen the pump head is closed, the 🥕 icon displays. The activation procedure

When the pressure sensors are activated, and the pump is ready to start, the

of the pressure sensors starts:



- 8. Follow the instructions on the screen for the first step of the test method.
- When the first step is completed, press the (\mathbf{y}) button to move to the 9. second step of the Test Method.

NOTE

In steps in which the pump is supposed to run, if the *button* is pressed when the pump has not begun to run, the following message displays: "No pumping performed in this step. Switch to next step?" Turn and press the control knob to select **Yes** to go to the next step.

- Continue to press the button to move through all steps of the test method.
- 11. When the last step is complete, press the *button* on the pump control panel to open the pump head. The screen returns to the list of the Test Methods available on the pump.
- 12. When the pump head is open, remove the tubing.
- 13. Do one of the following:
 - To run more tests in Test Method Mode, go back to step 4 of this section.
 - To return to the main screen, press the (\mathbf{K}) button.

Changing Pump Speed While Running a Test Method

The filtration parameters for each step are predefined in the test method; however, it is possible to change the speed of the pump. Speed can be changed if the pump is running or not running.

To change the pump rotation speed:

- 1. Turn the control knob.
 - If the timer is not activated a confirmation message displays. Turn and press the control knob to select **Yes** to change the speed.
 - If the timer is activated, a message indicating that modifying the speed will deactivate the timer, displays. Turn and press the control knob to select **Continue** to change the speed.

NOTE

The pump stops if it is running when the knob is turned.

- 2. Do one of the following:
 - If the pump was running when the knob was turned, it starts up again. Turn the control knob clockwise to increase the speed or counterclockwise to decrease the speed.
 - If the pump was not running when the knob was turned, turn the control knob clockwise to increase the speed or counterclockwise to decrease the speed. To start the pump, press the knob.

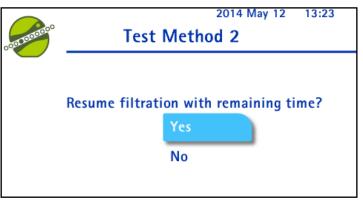
The pump runs at the new speed. This speed is valid only for the current step of the test method; in the next sequence in the test method, the pump operates at the predefined speed.

Changing the Timer Setting While Running a Test Method

The filtration parameters for each step are predefined in the test method, and the preset timer value cannot be changed. However, it is possible to stop the pump before the end of the timer value.

To stop the pump before the end of the timer value:

1. When the pump is running, press the control knob. The pump and the timer countdown stop and the following screen displays:



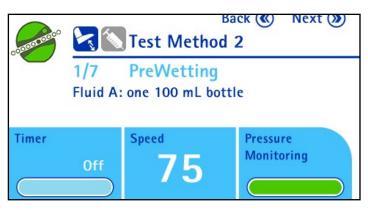
2. Turn the control knob to select **No**. Press the control knob to stop the pump before the end of the timer sequence.

Changing the Pressure Mode While Running a Test Method

The filtration parameters are predefined in the test method; the pressure mode cannot be changed.

Using the Waste Overfill Sensor in Test Method Mode

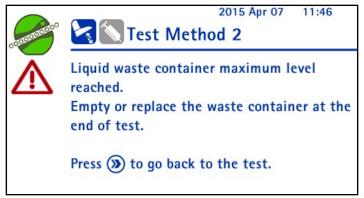
In Test Method mode, the waste overfill sensor icon is not displayed on the screen next to the title:



When the waste overfill container is full, the red waste overfill sensor icon displays on the screen below the pump head icon. An alert beep sounds from the pump. An orange LED lights up on the waste overfill sensor. The pump continues to run.



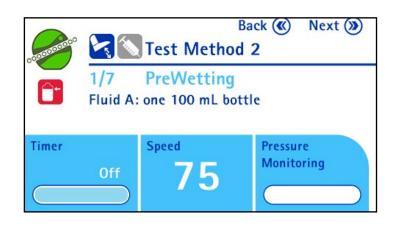
When the pump is stopped, the overfilling alert screen displays:



The red waste overfill sensor icon remains on the screen until the waste receptacle is emptied or replaced.

NOTE

The test in progress can be finished before the waste container is emptied or replaced.



Once the waste receptacle is emptied or replaced, the red waste overfill sensor icon no longer displays on the Test Method mode screen and the orange LED no longer lights up on the waste overfill sensor.

Entering Standby Mode

If no action is performed on the Steritest[®] Symbio Pump for 15 minutes while the pump head is open, the pump enters in standby mode.

The screen saver is displayed on the pump with the following message: "Press the knob to wake me up or shut me down." The default screen saver image is a blackand-white version of the Steritest[®] devices graphic. This can be replaced with a custom image (See the **Steritest[®] Symbio Software User Guide**).

To exit standby mode, press the control knob.

NOTE

If no action is performed for 60 minutes while the pump head is open, the pump switches off automatically.

Switching Off the Pump

To switch off the pump:

Press and hold the button on the control panel for a few seconds. The following screen displays, followed by the screen with the view of the Steritest[®] devices range or the custom image if one has been added:



NOTE

When the pump is switched off, the pump head remains in its current position. After the pump is switched off, the cover can be removed only if the pump head was open when the pump was switched off.

If the pump will not be used for an extended period, or if maintenance is required, switch off the main power supply using the main on/off switch (position O) on the front of the communication hub and disconnect it from power source.

Safety Mechanisms

Steritest[®] Red Plugs

Two red safety plugs are delivered with the Steritest[®] devices. They are installed on the vents on the tops of the canisters, and they pop off if overpressure occurs in the canisters.

The pressure measurement system of the Steritest[®] Symbio Pump works with but does not replace the Steritest[®] red plugs safety function. Operation of the Steritest[®] device should never prevent the red safety plugs from popping off in the event of overpressure inside the canister.

- If the red plugs pop off while pump is operating with a pressure below the High Pressure alert level, remove both red plugs to release the pressure and then put them back on the canister vent. If the problem persists, perform a verification of the pressure sensors (See <u>Configuring the Pump, Pressure Sensors</u> <u>Test</u>).
- If a red plugs pops off while pump is operating at the High Pressure alert level, remove both red plugs and place the vial upright on the table to prevent liquid from being transferred into the canister and filling it completely. Wait until the alert message disappears, which means that canister pressure is returning below the High Pressure alert level. Put both red plugs back on the canister vents and continue pump operations.
- If the red plugs have not popped off when the **High Pressure** alert is displayed, reduce speed or stop the pump until the message disappears. If the alert message does not disappear, remove both red plugs to release the pressure and ensure that the clamps close to the canisters are not closed. Then, put the red plugs back on the canister vents.
- If the red plugs have not popped off when the **Over Pressure** alert is displayed, manually stop the pump and remove the red plugs to release the pressure and ensure that the clamps close to the canisters are not closed. The message disappears, which means that canister pressure is returning below the High Pressure alert level. The equipment is returning to normal pressure conditions and can resume testing operations.

High Temperature

If the internal temperature of the pump reaches the alert level while it is running, a message appears in the information area of the screen:



High internal temperature, you can continue to use the pump.

• If the maximum operating temperature has not been reached, the test in progress can be completed. Once the test is completed and the pump head is opened, a message appears in the information area of the screen, asking the user to wait for the pump signal before starting new tests. This allows the temperature to decrease below the alert level.



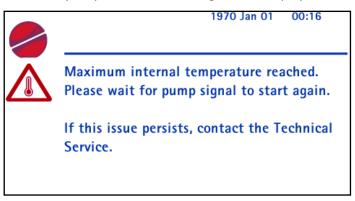
Please wait for pump signal to start again.

When the pump can resume testing operations, the following message displays and a beep sounds intermittently for ten seconds.



Internal temperature ok. Pump ready to use.

• If the maximum operating temperature is reached during the test in progress, the pump automatically stops and the following screen displays:



The test cannot be completed. No action on the pump is possible until the temperature returns to an acceptable value (except switching it off). When the internal temperature returns to an acceptable value, the following message displays and a beep sounds intermittently for ten seconds. The pump can resume testing operations.



Internal temperature ok. Pump ready to use.

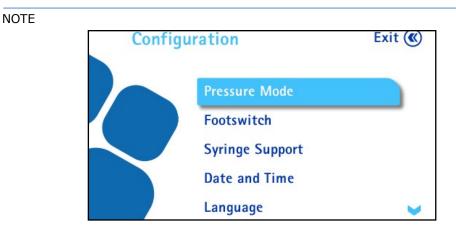
Configuring the Steritest® Symbio Pump

To configure the pump:

- 1. Access the main screen.
- 2. Turn and press the control knob to select **Configuration**. The



Configuration menu displays.



The **Configuration** menu can also be reached directly from the **Standard Mode** by pressing the (\mathbf{y}) button when the pump head is closed and the

pump not running.

From the configuration menu, the following functions can be configured:

- · Pressure Mode: select the pressure measurement system
- Footswitch: select the footswitch mode
- Syringe Support: activate the syringe support
- Date and Time: set the date and the time
- Language: select the language of the pump
- **Pump Information**: view pump information
- Alarm Volume: set the volume of the pump alarm

- Brightness: set up the brightness of the screen
- Methods Transfer: transfer test methods to the pump
- Network Configuration: configure the network for test method transfer
- Pressure Sensors Test: check the pressure sensors
- 3. Turn and press the control knob to access a menu.

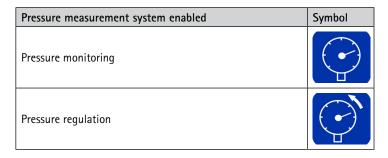
Pressure Mode

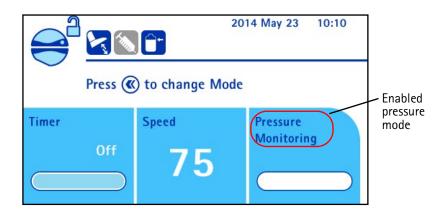
Use the Pressure Mode menu to choose the pressure measurement mode used in Standard Mode. The two options are pressure monitoring and pressure regulation.

NOTE

In the Test Method Mode, the pressure mode is predefined for each step during the creation of the test method using the Steritest[®] Symbio Software.

The enabled pressure measurement mode is indicated by a symbol displayed on the top left of the Main screen, and by the pressure mode name in the pressure information area on the use screen.



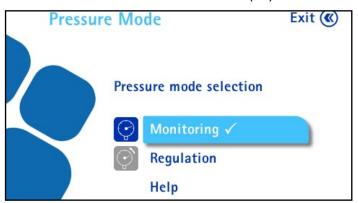


To select the pressure measurement mode used in the Standard Mode:

NOTE

See details on the pressure modes in <u>Using the Standard Mode and Test</u> <u>Method Mode Screens, Filtration Parameters.</u>

1. In the **Configuration** menu, turn and press the control knob to select **Pressure Mode**. The **Pressure Mode** screen displays:



2. Turn and press the control knob to select a pressure mode. A \checkmark symbol indicates the enabled mode.

The pressure regulation mode is not compatible with the timer function or with the optional syringe support accessory. If the timer function or the syringe support accessory is activated when switching from pressure monitoring to pressure regulation mode, a message indicating that the timer or the syringe support accessory will be deactivated displays. Turn and press the control knob to select **Continue** or **Cancel**.



3. Press the $(\boldsymbol{\ll})$ button to return to the **Configuration** menu.

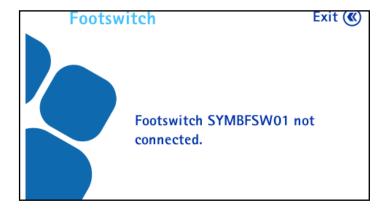
Footswitch

The footswitch is an optional accessory (see **Installing the Pump, Overview of Optional Accessories**). Use the footswitch menu to select the operating mode of the footswitch.

To select the operating mode of the footswitch:

1. In the Configuration menu, turn and press the control knob to select Footswitch.

If the footswitch is not connected to the communication hub, the following screen displays (to connect the footswitch, see **Installing the Communication Hub**):



If the footswitch is connected to the communication hub, the following screen displays:



Two operating modes are available:

Footswitch Mode	
Start/Stop Press the footswitch once to start the pump. Press again to stop the pump. Press it a third time to restart the pump. If the timer is activated (the timer value is set to anything but off) and the footswitch is pressed to stop the pump before the end of the set value, a confirmation screen asks if the filtration should resume with remaining time or if the timer value should be canceled and the pump stopped.	
Continuous The pump runs as long as the foot remains on the footswitch. If the timer is activated (the timer value is set to anything but off) and the footswitch is released before the timer reaches the end of the set value, the pump continues to run until the set value	
is reached, even if the footswitch is pressed again. To stop the pump before the end of the timer value, press the control knob. A confirmation screen asks if the filtration should resume with the remaining time or if the timer value should be canceled and the pump stopped.	

2. Turn and press the control knob to select the desired footswitch operating mode.

NOTE

- The enabled operating mode is indicated by an icon at the top left of the main screen and use screen.
- 3. Press the (\mathbf{K}) button to return to the **Configuration** menu.

Syringe Support

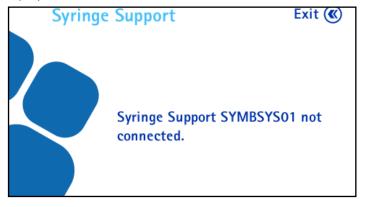
The syringe support is an optional accessory (see **Installing the Pump**, **Overview of Optional Accessories**). Use the syringe support menu to activate or deactivate the syringe support.

To activate or deactivate the syringe support:

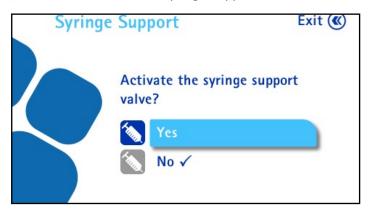
1. In the **Configuration** menu, turn and press the control knob to select Syringe Support.

If the syringe support is not connected to the communication hub, the following screen displays (to connect the syringe support, see **Installing the Communication Hub**):

If the syringe support is connected to the communication hub, the following screen displays:



2. Turn and press the control knob to select **Yes** to activate the syringe support, or **No** to deactivate the syringe support.



The syringe support is not compatible with the pressure regulation mode. If the pressure regulation mode is activated when activating the syringe support, a confirmation screen displays that provides the opportunity to deactivate the pressure regulation mode:

The status of the syringe support is indicated by an icon at the top left of the main screen and use screen. (See <u>Using the Pump, Using the Standard</u> <u>Mode and Test Method Mode Screens, Pump Head and Accessories</u> <u>Status</u> for status icon descriptions).

3. Press the (\mathbf{K}) button to return to the Configuration menu.

Date and Time

To set the date and time:

 In the Configuration menu, turn the control knob to select Date and Time. The Date and Time screen displays.



- 2. Turn the control knob to go from a field to another. To modify a value, press the control knob to enter the value field, then turn the control knob to change the value of the field. Press the control knob to confirm the value.
- 3. Press the (\mathbf{K}) button to return to the **Configuration** menu.

Language

To set the language:

 In the Configuration menu, turn and press the control knob to select Language. The Language screen displays.



NOTE

The available languages are German, English, Spanish, French, Italian, Portuguese, Japanese, Simplified Chinese, Turkish, and Russian.

- 2. Turn and press the control knob to select the desired language.
- 3. Press the (\mathbf{K}) button to return to the **Configuration** menu.

Pump Information

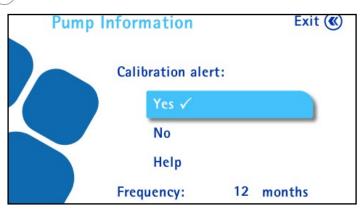
To access the **Pump Information** screen:

1. In the **Configuration** menu, turn and press the control knob to select **Pump Information**. The **Pump Information** screen displays.



This screen provides information about the pump:

- Serial number
- Firmware version installed on the pump
- Date of the last update of the test methods contained in the pump (If no test method has been loaded to the pump, the message is "No test method available.")
- Next calibration date
- 2. Do one of the following:
 - To return to the **Configuration** menu, press the $(\boldsymbol{\ll})$ button.
 - To deactivate/activate the calibration alert and change the frequency, press the () button. The **Pump Information** screen displays.



When the calibration alerts are deactivated, the question regarding the activation of the pump certificate no longer appears, and the calibration countdown and alerts are hidden.

- Turn and press the control knob to activate or deactivate the calibration alerts and countdown.
- To modify the calibration frequency, turn the control knob to select the calibration frequency value. Push the control knob to enter the value field, turn the control knob to change the value, and press the control knob to confirm the value.

NOTE

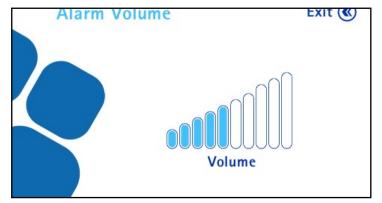
The calibration frequency can be modified only if the calibration alerts and countdown are activated. It can be changed to between 6 and 12 months.

• Press the (\mathbf{x}) button to return to the **Pump Information** screen.

Alarm Volume

To set the volume of the pump alarm:

 In the Configuration menu, turn and press the control knob to select Alarm Volume. The Alarm Volume screen displays.

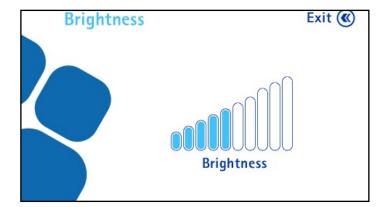


- 2. Turn the control knob clockwise to increase the volume and counterclockwise to decrease the volume.
- 3. Press the (\mathbf{K}) button to return to the **Configuration** menu.

Brightness

To set the brightness of the pump screen:

 In the Configuration menu, turn and press the control knob to select Brightness. The Brightness screen displays.



- 2. Turn the control knob clockwise to increase the brightness and counterclockwise to decrease the brightness.
- 3. Press the (\mathbf{K}) button to return to the **Configuration** menu.

Methods Transfer

To use the pump in Test Method Mode, it is necessary to previously create test methods and transfer them from the computer to the pump using the Steritest[®] Symbio Software. Use this menu to transfer Test Methods from the Steritest[®] Symbio Software to the pump.

NOTE

The Steritest[®] Symbio Software is not intended to replace the user's quality management system (QMS), which should be in place to comply with good manufacturing practices.

The software helps users to create and modify test methods in word processing format, and to update the Steritest[®] Symbio Pump.

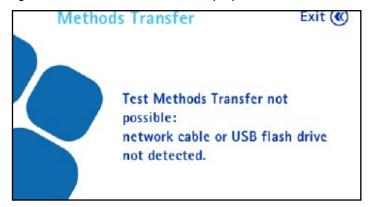
This software is only a support/guide to the operator work during the testing steps on the pump. The operator may modify the test parameters (speed and timer) on the pump.

The recording, verification, and validation of the test methods transferred shall comply with the user's quality system.

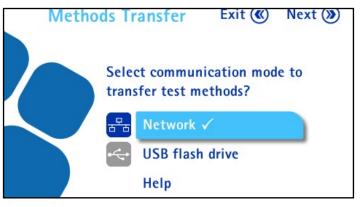
This system does not manage electronic records under 21CFR11, EU GMP Annex 11 regulations, or GMP predicate rules.

In the **Configuration** menu, turn and press the control knob to select **Methods Transfer.**

• If the communication hub is not connected to an active network or directly to the computer using the network cable or to a USB flash drive, the following **Methods Transfer** screen displays:



 If the communication hub is connected to an active network or directly to the computer using the network cable or to a USB flash drive, the following Methods Transfer screen displays:

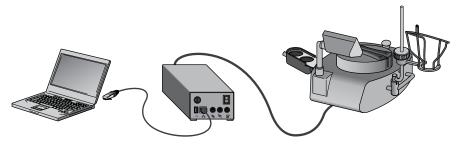


Transfer Using a Network Cable

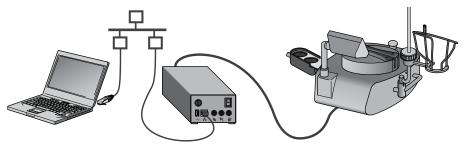
To transfer test methods from the Steritest[®] Symbio Software to the pump using a network cable:

 Ensure that the communication hub is connected to an active network or directly to the computer (see <u>Network Configuration</u>).

Direct connection between pump and computer:

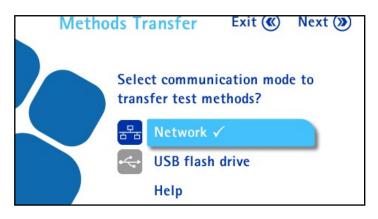


Network connection between pump and computer:



To ensure that test methods are not modified during pump use, the pump must be in one of the two following states when it is receiving test methods:

- Pump is ON in Configuration / Methods Transfer / Network / File Transfer screen
- Pump is **OFF**, but the communication hub is **ON**
- 2. Do one of the following:
 - If the pump is **ON**, continue to step 3.
 - If the pump is **OFF**, and the communication hub is **ON**, go to step 6.
- Access the Configuration menu from the main screen. In the Configuration menu, turn and press the control knob to select Methods Transfer. The Methods Transfer screen displays.



4. Turn and press the control knob to select **Network**.

5. Press the *b* button to continue. The **File Transfer** screen displays. The pump is ready to receive test methods from the Steritest[®] Symbio Software.



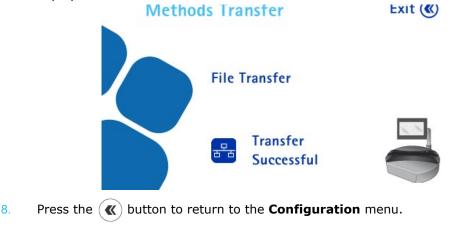
- 6. In the Steritest[®] Symbio Software, click the **Connect** command to connect the software to the pump. From the drop-down list, select the pump to be updated.
- Select the transfer file to be transferred and confirm the transfer (see the Steritest[®] Symbio Software User Guide).

NOTE

Transferring test methods to the pump erases its current content.

The transfer starts.

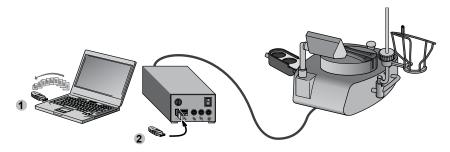
If the pump is **ON**, a progress bar shows the progression of the transfer on the pump screen. When the transfer is complete, the following screen displays:



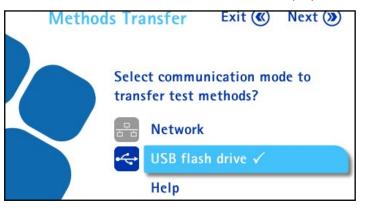
Transfer Using a USB Flash Drive

To transfer test methods from the Steritest[®] Symbio Software to the pump using a USB flash drive:

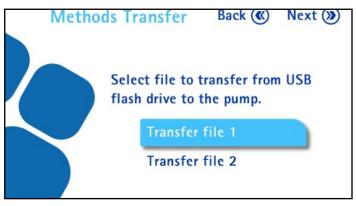
- Transfer the transfer file containing the test methods to a USB flash drive using the Steritest[®] Symbio Software (see the Steritest[®] Symbio Software User Guide.)
- 2. Connect a USB flash drive to the USB port on the communication hub.



- 3. Access the **Configuration** menu from the main screen.
- 4. In the **Configuration** menu, turn and press the control knob to select **Methods Transfer**. The **Methods Transfer** screen displays.



- 5. Turn and press the control knob to select **USB flash drive**.



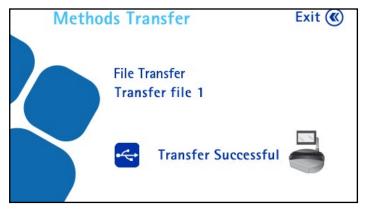
7. Turn and press the control knob to select the transfer file to be transferred from the USB flash drive to the pump.

NOTE

Transferring test methods to the pump erases its current content.

8. Press the *button* to start the transfer. The file transfer screen displays, and the transfer starts. A progress bar shows the progression of the transfer.

When the transfer is complete, the following screen displays.

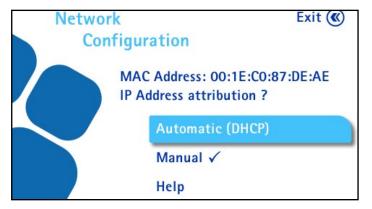


9. Press the $(\boldsymbol{\ll})$ button to return to the **Configuration** menu.

Network Configuration

Use this menu to configure the network to ensure proper communication between the pump and the computer.

- 1. Access the **Configuration** menu from the main screen.
- In the Configuration menu, turn and press the control knob to select Network Configuration. The Network Configuration screen displays.



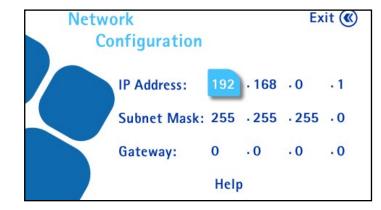
By default, the address attribution type is Automatic (DHCP). The IP address of the pump is automatically assigned by a DHCP server. No specific action is required to configure the connection.

NOTE

Refer to the **Steritest**[®] **Symbio Software User Guide** and contact your local network administrator to perform network configuration.

- Do one of the following:
 - Turn and press the control knob to select **Automatic (DHCP)**. No other action is required.
 - Turn and press the control knob to select Manual.

When the manual address attribution type is enabled, the following screen displays. Continue to the next step.



NOTE

The values shown are the default values. Modifications should be made by the local network administrator.

- 4. Turn the control knob to go from one field to the next. To modify a value, push the control knob to enter the value field, turn the control knob to change the value of the field, and press the control knob to confirm the value.
- 5. Press the (\mathbf{K}) button to return to the **Configuration** menu.

Pressure Sensors Test

Checking the Pump Pressure Sensors

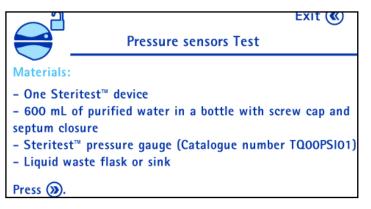
Use this menu to check the proper functioning of the pump pressure sensors.

NOTE

This verification should be done every six months.

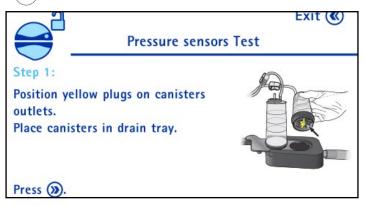
1. Access the **Configuration** menu from the main screen.

 In the Configuration menu, turn and press the control knob to select Pressure Sensors Test. The Pressure Sensors Test screen displays.



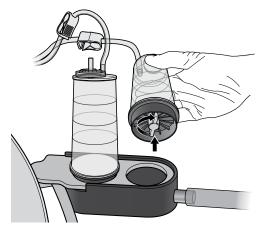
The materials needed to perform the verification of the pressure sensors are listed on the screen. Gather these materials.

3. Press the (\mathbf{y}) button to continue. The following screen displays:

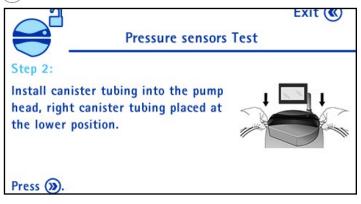


Unpack a Steritest[®] device.

Place the two yellow plugs on the canister outlets, and place the canisters on the drain tray.

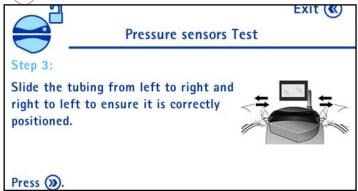


4. Press the (\mathbf{y}) button to continue. The following screen displays:

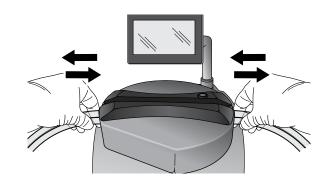


Install the tubing in the pump head (see <u>Using the Steritest[®] Symbio Pump</u>, <u>Installing the Steritest[®] Device</u>).

5. Press the (\mathbf{y}) button to continue. The following screen displays:



Slide the tubing from left to right and right to left, to ensure that it is correctly positioned.

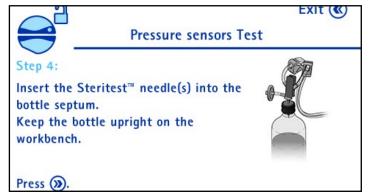


NOTE

If the tubing does not slide freely, repeat the operation.

6. Press the () button to continue. The following screen displays:

Insert Steritest[®] needle adapter into a sterile water bottle (volume > 500 ml).



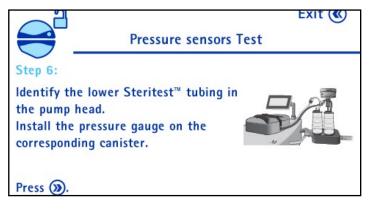
NOTE

Keep the bottle upright on the workbench.

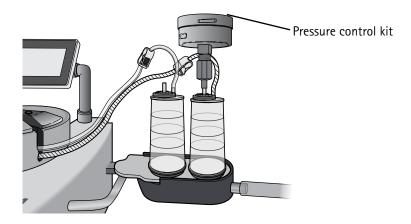
7. Press the () button to continue. The following screen displays.

	Pressure sensors Test	Exit
Step 5: Select the pressu	re sensor to verify:	
Sensor No. 1 (lo		
Sensor No. 2 (u	pper tubing)	

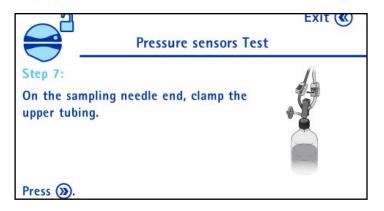
 Turn and press the control knob to select **Sensor number 1** (lower tubing). The following screen displays:



Identify the lower Steritest[®] tubing in the pump head. Install the pressure control kit for Steritest[®] Pumps (See <u>Accessories and Replacement Parts</u>) on the corresponding canister.



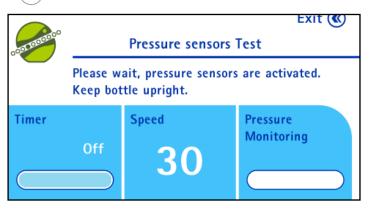
9. Press the () button to continue. The following screen displays:



On the bottle side, clamp the upper tubing to avoid transferring liquid to the untested ${\tt Steritest}^{\tt @}$ canister.



10. Press the (\mathbf{y}) button. The following screen displays:



The pump head closes, and the pump starts at a fixed speed of 30.

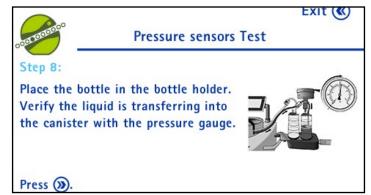
After the pump has started, do not handle the tubing for 30 seconds. This allows the air to be transferred and the pressure measurement to stabilize.

NOTE

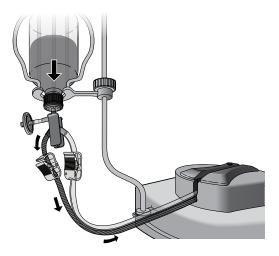
Keep the bottle on the workbench.

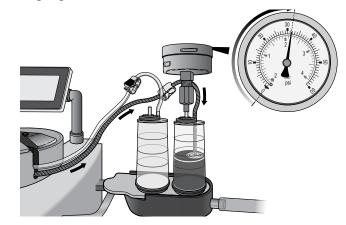
The instructions on the pump screen indicate when to move to next step.

The following screen displays:



Turn the bottle upside down and place it in the bottle holder.





The liquid is transferred to the tested canister, and the pressure on the pressure gauge increases.

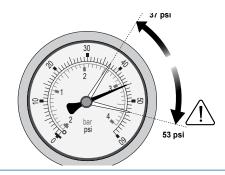
CAUTION

If the pressure reaches 53 psi (3.6 bar) and the pump does not automatically stop, press the control knob to abort the test. See <u>Pressure</u>. <u>Sensors Test Issues, Overpressure</u>.

NOTE

If no pressure is detected after about 30 seconds, the test stops. See **Pressure Sensors Test Issues, No Pressure Increase Detected**.

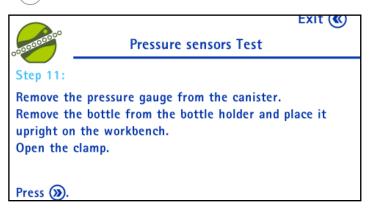
11. As soon as the pump stops, read the pressure on the pressure gauge. The pressure should be between 37 psi (2.5 bar) and 53 psi (3.6 bar).



NOTE

If the pressure is not between 37 psi (2.5 bar) and 53 psi (3.6 bar). See **Pressure Sensors Test Issues, Pressure Outside The Acceptable Range**.

12. Press the (\mathbf{y}) button. The following screen displays:

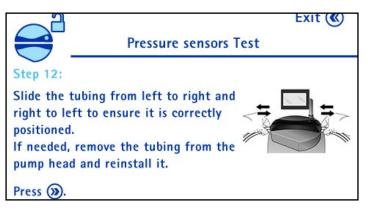


Remove the pressure control kit for Steritest $^{\ensuremath{\mathbb{R}}}$ Pumps to release the pressure in the canister.

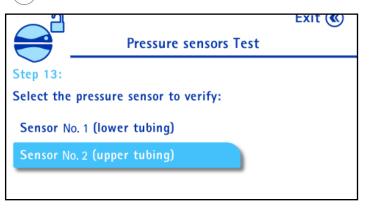
Remove the bottle from the bottle holder basket and place it upright on the workbench.

Open the clamp on the bottle side.

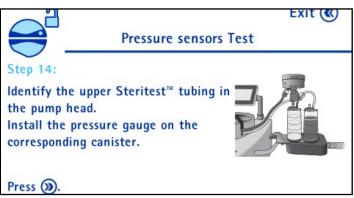
13. Press the (>>>> button. The pump head opens, and the following screen displays:



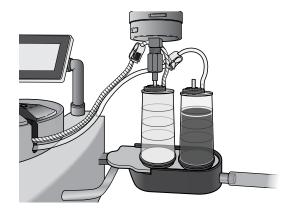
Slide the tubing from left to right and right to left to ensure that it is correctly positioned. If the tubing does not slide freely, remove the tubing from the pump head and reinstall it. 14. Press the (\mathbf{y}) button. The following screen displays:



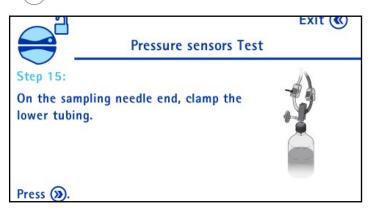
 Turn and press the control knob to select **Sensor number 2** (upper tubing). The following screen displays:



Identify the upper Steritest[®] tubing in the pump head. Install the pressure control kit for Steritest[®] Pumps on the corresponding canister.



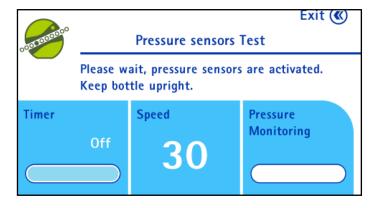
16. Press the () button. The following screen displays:



On the bottle side, clamp the lower tubing to prevent transferring liquid to the canister from the untested tubing.



17. Press the (\mathbf{y}) button. The following screen displays:



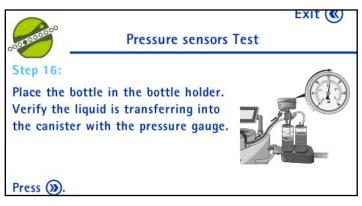
The pump head closes, and the pump starts up at a fixed speed of 30.

NOTE

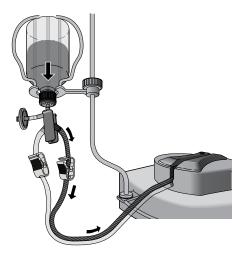
After the pump has started, do not handle the tubing for 30 seconds. This allows the air to be transferred and the pressure measurement to stabilize. Keep the bottle on the workbench.

The instructions on the pump screen indicate when to move to next step.

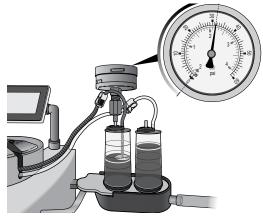
18. The following screen displays:



Turn the bottle upside down and place it in the bottle holder.



The liquid is transferred to the tested canister, and the pressure on the pressure gauge increases.



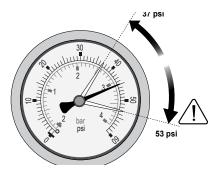
CAUTION

If the pressure reaches 53 psi (3.6 bar) and the pump does not automatically stop, press the control knob to abort the test. Refer to **Pressure Sensors Test Issues, Overpressure**.

NOTE

If no pressure is detected after about 30 seconds, the test stops. See **Pressure Sensors Test Issues, No Pressure Increase Detected**.

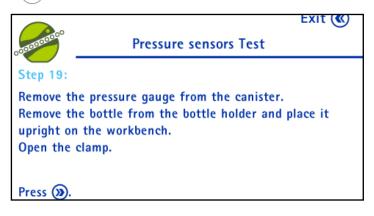
19. As soon as the pump stops, read the pressure on the pressure gauge. The pressure should be between 37 psi (2.5 bar) and 53 psi (3.6 bar).



NOTE

If the pressure is not between 37 psi (2.5 bar) and 53 psi (3.6 bar), refer to **Pressure Sensors Test Issues, Pressure Outside the Acceptable Range**.

20. Press the (\mathbf{y}) button. The following screen displays:

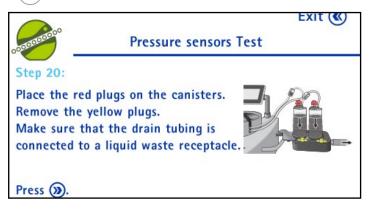


Remove the pressure control kit for Steritest[®] Pumps to release the pressure in the canister.

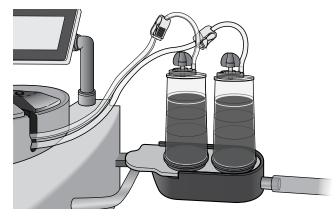
Remove the bottle from the bottle holder basket and place it on the workbench.

Open the clamp on the bottle side.

21. Press the (\mathbf{y}) button. The following screen displays:

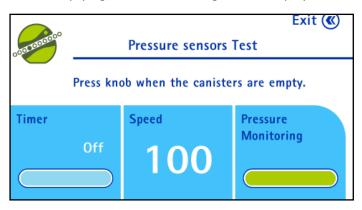


Place the red plugs on the canister vents.

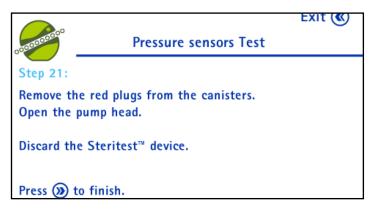


Remove the canisters from the drain tray, remove the yellow plugs from the canister outlets, and put the canisters back into the drain tray.

Ensure that the drain tray waste tubing is connected to a waste container



23. Press the control knob to stop the pump when the canisters are empty. The following screen displays:



Remove the red plugs from the canister vents.

Press the 🧼 button to open the pump head.

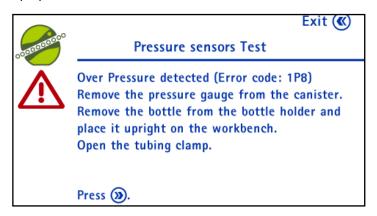
Discard the Steritest[®] device.

24. Press the (\mathbf{y}) button to return to the configuration menu.

Pressure Sensor Test Issues

Overpressure

1. During the pressure sensors test, if the pressure in the canister exceeds 53 psi, manually stop the pump by pressing the control knob. The following screen displays:



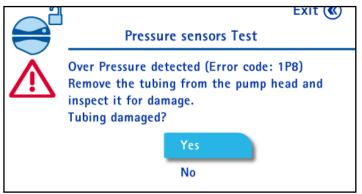
Remove the pressure control kit for Steritest[®] Pumps from the tested canister.

Remove the bottle from the bottle holder and place it upright on the workbench.

Open the tubing clamp.

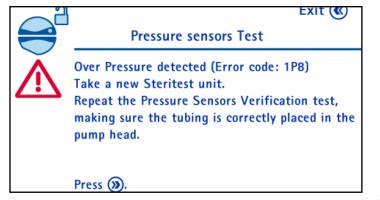
2. Press the (\mathbf{y}) button.

The pump head opens and the following screen displays:

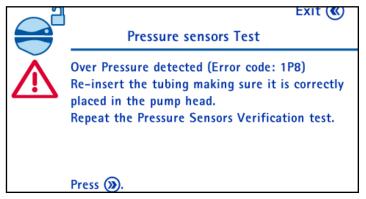


Check the tubing and do one of the following:

- If the tubing is damaged:
 - Turn and press the control knob to select Yes. The following screen displays:

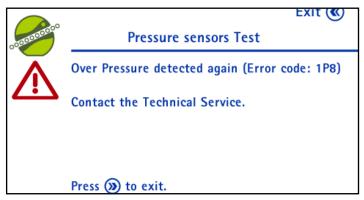


- Discard the Steritest[®] device and install a new one. Press the button.
- Restart the pressure sensor test procedure as explained in Configuring the Pump, Pressure Sensors Test.
- If the tubing not damaged:
 - Turn and press the control knob to select **No**. The following screen displays:



- Re-install the tubing in the pump head.
- Press the button. The selection screen for the pressure sensor to verify displays with the last sensor tested selected.
- Press the control knob to confirm and restart the procedure from step 7 (step 5 on the pump screen) or step 15 (step 13 on the pump screen) of the <u>Pressure Sensors Test</u> procedure.

If the pump must be stopped manually again during the test, the following message displays. The verification procedure cannot be completed.



If this happens:

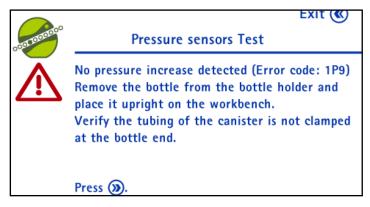
- Remove the pressure control kit for Steritest[®] Pumps from the tested canister.
- Remove the bottle from the bottle holder and place it upright on the workbench.
- Open the tubing clamp.
- Press the (>>>) button to open the pump head and return to the Configuration menu.
- Contact Technical Service.

NOTE

Until the pressure sensors issue has been resolved, the pressure level in the canisters should be assessed exclusively through the use of the red plugs.

No Pressure Increase Detected

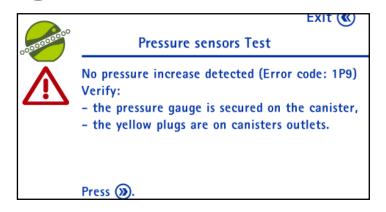
During the pressure sensors test, if no pressure increase is detected after about 30 seconds in the tested canister, the test stops and the following screen displays:



Remove the bottle from the bottle holder and place it upright on the workbench.

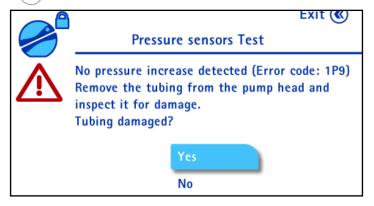
Ensure that the tubing of the tested canister is not clamped at the bottle end.

1. Press the (\mathbf{y}) button. The following screen displays:



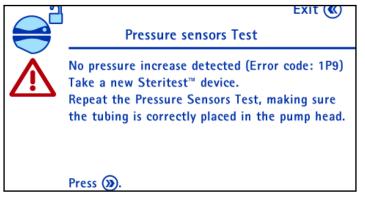
Ensure that the pressure gauge is secured on the canister and that the yellow plugs are on the canister outlets.

2. Press the (\mathbf{y}) button. The following screen displays:

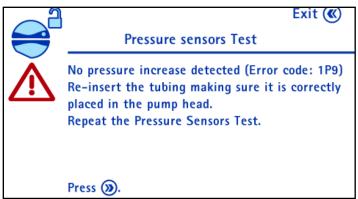


Check the tubing and do one of the following:

- If the tubing is damaged:
 - Turn and press the control knob to select Yes. The following screen displays:

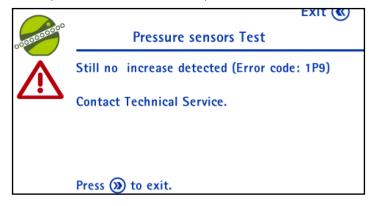


- Discard the Steritest[®] device and unpack a new one. Press the button.
- Restart the pressure sensor test procedure as explained in <u>Configuring</u> the Pump, Pressure Sensor Test.
- If the tubing is not damaged,
 - Turn and press the control knob to select No. The following screen displays:



- Re-install the tubing in the pump head.
- Press the control knob to confirm and restart the procedure from step 7 (step 5 on the pump screen) or step 15 (step 13 on the pump screen) of the <u>Pressure Sensors Test</u> procedure.

If the same issue occurs again during the test, the following message displays, and the verification procedure cannot be completed:



If this happens :

- Remove the pressure control kit for Steritest[®] Pumps from the tested canister.
- Remove the bottle from the bottle holder and place it upright on the workbench.
- Open the tubing clamp.
- Contact Technical Service.

NOTE

Until the pressure sensors issue has been resolved, the pressure level in the canisters should be assessed exclusively through the use of the red plugs.

Pressure Outside the Acceptable Range

During the pressure sensors test, if the pressure reading on the pressure gauge when the pump stops is below 37 psi or higher than 53 psi, do the following:

- Ensure that the pressure control kit for Steritest[®] Pumps is calibrated.
- Repeat the test. If the problem persists, contact technical service and have a certified technician calibrate the pressure sensors.

Maintenance

Safety Precautions

- Never use solvents or abrasives that could damage the equipment's surfaces.
- Do not put liquids directly in contact with the internal parts of the pump or the equipment's electrical components.
- Do not turn the pump upside down.

Ongoing Maintenance

Clean the pump and accessories after each use. See <u>Cleaning the Pump</u>.

NOTE

It is important to autoclave the drain tray components and the drain tubing after each use.

- Perform the pressure sensor verification every six months. See <u>Pressure</u> <u>Sensors Test</u>.
- The Steritest[®] Symbio Pump should be serviced by a certified technician annually. This servicing includes a check of the operating performances and calibration of the pressure sensors. Contact our sales representative or Technical Service for more information about the service agreements.

Preparing the Pump for Shipment

Follow these steps to prepare the pump for shipping for servicing or any other reason.

- 1. Press the (\mathbf{b}) button to switch the pump on.
- 2. Enter the Standard Mode.
- 3. Press the () button to close the pump head.
- 4. With the pump head in its closed position, press and hold the () button on the control panel for a few seconds to switch off the pump.

NOTE

This allows the pump head to remain closed when the pump is off.

- 5. Switch off the communication hub by pressing the on/off switch (position O). Disconnect it from power source.
- 6. Disconnect the communication hub pump connection cord from the pump power inlet.

- 7. Turn the pump display to its transportation position (horizontal).
- Retrieve the original pump box and protective foam or the optional Steritest[®] Symbio pumps shipment case (see <u>Accessories and Replacement Parts</u>).
- 9. Place the pump and the communication hub in the box or shipment case using the protective foam.
- 10. Seal the box with packing tape.

Cleaning the Pump

Recommended Cleaning Agents

The compatibility of the following cleaning agents with the Steritest[®] Symbio Pump has been verified.

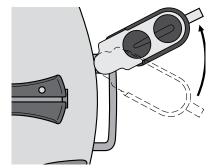
	Cleaning Product	Validated dilution
	Ethanol (<30%)	
1	Didecyldimethylammonium chloride (<1%) Propanol (<1%)	Ready to use
	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	
	(<1,5%)	
2	Isopropyl alcohol 70%	Ready to use
3	Ethanol 70%	Ready to use
4	Sodium hypochlorite	250 ppm
	Peracetic acid at (5 to 15%)	
5	Acetic acid at (5 to 15%)	2.5%
	Hydrogen peroxide (15 to 30%)	
	Ethanol (25 to 50%)	
	Polyhexamethylene biguanide hydrochloride (<2,5%)	
6	N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine	Ready to use
	(<2,5%)	
	Didecyldimethylammonium chloride (<1%)	

Disassembling the Pump

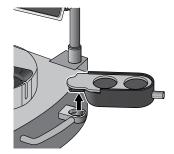
The pump must be disassembled for cleaning.

- 1. Ensure that the pump head is open.
- 2. Press the (b) to shut down the equipment. The cover disengages from the automatic closure system.
- 3. When shutdown is complete, switch off the communication hub using the on/ off switch (position O) and disconnect the hub from the power source.

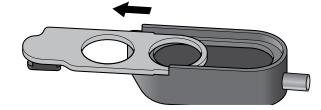
4. Turn the drain tray to the removal position.



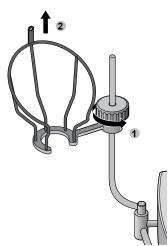
5. Remove the drain tray from the pump.



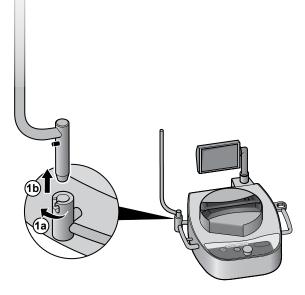
6. Disassemble the two parts of the drain tray.



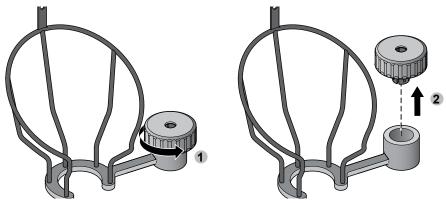
7. Remove the bottle holder basket from the bottle holder support rod.



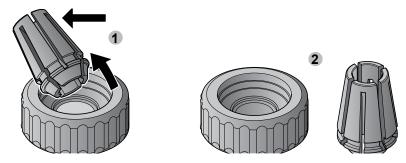
8. Remove the bottle holder support rod from the pump.



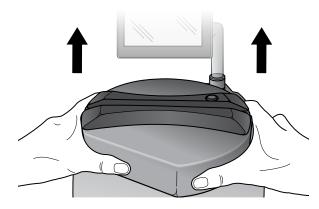
9. To disassemble the bottle holder fastening system, completely unscrew and remove the screw:



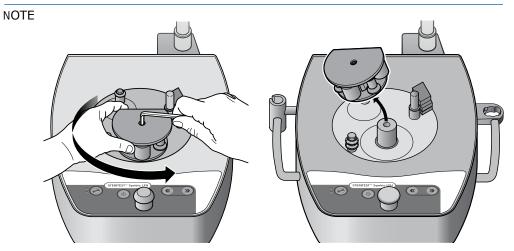
10. Remove the plastic screw clip from the screw.



11. Remove the pump head cover by pulling it off with both hands.



12. If necessary, remove the rotor mounting screw from the pump head using a 4mm hex wrench, and remove the rotor from the pump head.

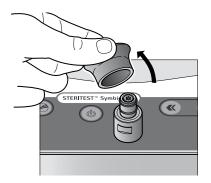


It is not necessary to remove the pump head rotor unless there has been an accidental spill.

13. Pull the control knob off to remove it.

NOTE

It may be necessary to pull hard.



Cleaning the Pump

To clean the pump:

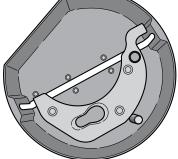
- 1. Disassemble the pump components (see **<u>Disassembling the Pump</u>**).
- 2. Switch off the communication hub using the on/off switch (position O) and disconnect the hub from the power source.

NOTE

It is not necessary to remove the pump head rotor unless there has been an accidental spill.

- 3. Clean the exterior surfaces of the pump with a nonwoven wipe moistened with one of the recommended cleaning agents listed in this section.
- Clean the protective cover of the pump head with a nonwoven wipe moistened with one of the recommended cleaning agents listed in this section.

Optional: Autoclave the protective cover at 121 °C for 30 minutes or 134 °C for 10 minutes.



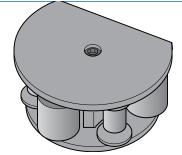
- 5. Clean the exterior surfaces of the pump head rotor with a nonwoven wipe moistened with one of the recommended cleaning agents listed in this section.
- 6. Clean the inside of the pump head rotor with a soft brush dipped in one of the recommended cleaning agents listed in this section.

NOTE

Do not fully wet the ends of the rollers; wipe them only.

CAUTION

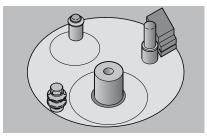
Do not autoclave the pump head rotor. Never immerse the pump head rotor in a liquid cleaning agent or alcohol.



7. Clean the control knob with a nonwoven wipe moistened with one of the recommended cleaning agents listed in this section. Rinse with clean water.

Optional: Autoclave the control knob at 121 °C for 30 minutes or 134 °C for 10 minutes.

8. Clean the pump head with a nonwoven wipe moistened with one of the recommended cleaning agents listed in this section.



9. Clean the drain tray support and drain tray container with a nonwoven wipe moistened with one of the recommended cleaning agents listed in this section. Rinse with clean water.

Completely disassemble the drain tray components. Autoclave the drain tray support, the drain tray container, and the drain tubing for 121 °C for 30 minutes or 134 °C for 10 minutes.

NOTE

Perform this operation daily. Spare drain trays are available (see <u>Accessories</u> <u>and Replacement Parts</u>).

 Clean the bottle holder parts using a nonwoven wipe moistened with one of the recommended cleaning agents listed in this section. Rinse with clean water.

Optional: Autoclave the bottle holder parts (disassembled) at 121 °C for 30 minutes or 134 °C for 10 minutes.

- 11. Clean the optional Steritest[®] holder for sterile bags and the Steridilutor[®] vent chamber using a nonwoven wipe moistened with one of the recommended cleaning agents listed in this section. Rinse with clean water.
- 12. Clean the optional Steritest[®] carrying tray and Steritest[®] rack using a nonwoven wipe moistened with one of the recommended cleaning agents listed in this section. Rinse with clean water.

Optional: Autoclave the tray and the rack at 121 °C for 30 minutes or 134 °C for 10 minutes.

NOTE

Refer to the ampoule breaker and syringe support user guides for cleaning recommendations.

Decontamination Procedure in an Isolator

- 1. Remove the bottle holder from the pump.
- 2. Disconnect the drain tubing from the isolator table.
- 3. Remove the drain tray from the pump.
- Remove the protective cover from the pump head (see <u>Disassembling the</u> <u>Pump</u>).
- 5. Remove these parts from the isolator.
- Disassemble the bottle holder and the drain tray (see <u>Disassembling the</u> <u>Pump</u>).
- 7. Clean these parts with a nonwoven wipe moistened with one of the recommended agents listed in this section, then rinse them with clean water.
- 8. Autoclave these parts at 121 °C for 30 minutes or 134 °C for 10 minutes.

NOTE

The drain tray and bottle holder should be completely disassembled for autoclaving.

9. Return these parts to the isolator. Hang them or place them on a shelf in the isolator.

NOTE

The drain tray and bottle holder should be completely disassembled during decontamination in the isolator.

10. Clean the pump with a nonwoven wipe moistened with one of the recommended agents listed in this section.

NOTE

It is not necessary to remove the rotor from the pump head unless there has been an accidental spill.

11. Start the decontamination procedure.

NOTE

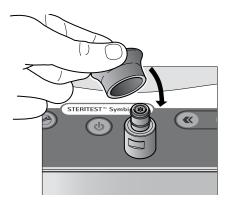
The pump and its accessories are compatible with vaporized hydrogen peroxide (VHP) and peracetic acid decontamination cycles.

12. When the decontamination procedure is complete, reassemble the pump (see **Reassembling the Pump**).

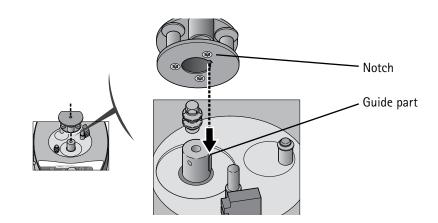
Reassembling the Pump

To reassemble the pump:

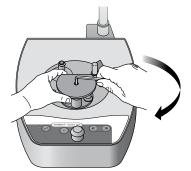
- 1. Ensure that the communication hub is disconnected from the power source.
- 2. Reattach the control knob by pushing it onto the post.



3. If the pump head rotor has been removed, reinstall it by aligning the notch in the rotor with the guide part.



4. Insert the pump head rotor mounting screw and tighten using a 4mm hex wrench.

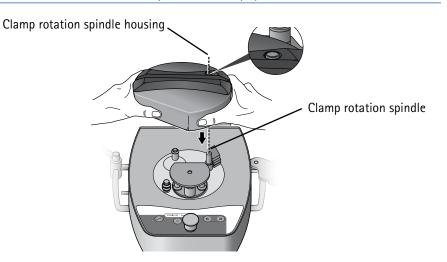


- 5. Install the protective cover on the pump head:
 - Position the cover over the pump head and engage the clamp rotation spindle with its housing in the cover.

• Adjust the cover position to align the pump rotor with its housing, and then push on the cover.

NOTE

The cover can be installed only when the equipment is switched off.



6. Ensure that the cover is firmly seated on the pump.

NOTE

The gap between the pump and the protective cover is about 2 mm (.079 in.).

- Connect the communication hub to power source and switch it on using the on/off switch (position I).
- 8. Press the (0) button to switch the pump on.

Reassembly is correct if the Autotest sequence initialization is successfully passed.

9. Install the bottle holder and the drain tray (see <u>Installing the Bottle</u> <u>Holder</u> and <u>Installing the Drain Tray</u>).

Troubleshooting

If a pump error occurs, a message displays on the pump screen with the name of the problem, the error code, and the procedure to solve it. Follow the instructions on the screen. It may be necessary to restart the pump. If the error persists, contact Technical Service and provide the error code.

If an error occurs with the error code RM7, do the following:

- 1. Open the pump head and remove the tubing from the pump head.
- 2. Close the pump head (without tubing) and start the pump. If the issue persists, contact Technical Service.
- 3. If the pump runs correctly, stop the pump.
- 4. Press the () button to open the pump head.
- 5. Re-insert the tubing, making sure it is correctly placed in the pump head.
- 6. Redo the test.

NOTE

For very small volumes, performing a pre-wetting step is highly recommended.

For other issues, refer to the following table. If any issue persists, contact Technical Service.

Symptom	Possible cause	Remedy
T he second second	The pump is not connected to power source.	Ensure that the pump is connected to the communication hub, and that the communication hub is connected to power source.
The pump doesn't start when the control panel on/off button is pressed.		Switch the communication hub on by pressing the on/off switch on the front of the communication hub (position I).
	The communication hub is OFF.	If the light on the communication hub on/off switch is off when the switch is on (position I) and the communication hub is connected to power source, check the communication hub fuses.
There is no	An unexpected	
response from	error has occurred	Switch the pump off and switch it on
the pump	in the pump	again.
software.	software.	

The pump head protective cover cannot be removed when the pump is off.	The pump head was not open when the pump was switched off.	Switch the pump on. Once the autotest procedure is complete, switch the pump off again. Wait until the shutting down process ends and the LCD screen switches off. Try again to remove the pump head.	
	The drain tubing is pinched.	Ensure that the drain tubing is not pinched	
The liquid doesn't flow correctly from the drain tray.	The drain tubing is in contact with the liquid contained in the waste container.	Ensure that the tubing does not touch the liquid in the waste container and that the waste container is open or correctly vented.	
	The drain tray is clogged.	Clean the drain tray container and support and ensure that the yellow plugs are not on the canister outlets.	
	The drain tray is lower than the waste container.	Position the drain tray higher than the waste container.	
	The tubing between the drain tray and the waste container is bent or looped.	Ensure that the tubing between the drain tray and the waste container is straight, without any bends or loops.	
The liquid is not evenly distributed between the two	The tubing to one of the canisters is pinched or clamped or damaged.	Open the pump head and check the state of the tubing. Reinstall tubing following the procedure described in Installing the Steritest [®] Device .	
canisters.	Filtration speed is too high.	Reduce the filtration speed.	
Accessories and/or data sources are not recognized by the pump.	Accessories and/ or date sources are not connected to a power source.	Ensure that the accessories or data sources are connected properly to the communications hub, and that the communication hub is connected to a power source.	
The waste overfill sensor alerts go on and off randomly (red icon, beep, orange LED).	The evacuated liquid is flowing inside the rigid container in front of the sensor position.	Move the evacuation tubing away from the sensor position.	

Accessories and Replacement Parts

Description	Quantity per pack	Catalog Number
Steritest® Symbio Pump		
Steritest [®] Symbio LFH Pump Kit, 2 media	1	SYMBLFH01WW*
Steritest® Symbio ISL Pump Kit, 2 media	1	SYMBISL01WW*
Steritest [®] Symbio FLEX Pump Kit, 2 media	1	SYMBFLE01WW*
Steritest [®] Symbio FLEX BQ Pump kit, 2 media	1	SYMBFLE01BQ
Steritest® Symbio Pump Services		
Steritest® Symbio pumps validation protocol (A4 format)	1	SYMBA4VP1
Steritest® Symbio pumps validation protocol US (letter format)	1	SYMBLTVP1
NOTE: Contact our sales representative or Technical Service for more information a	about our application support, v	alidation services, maintenance, and
repair services.		
Steritest® Symbio Pump Accessories		
Steritest [®] Pump footswitch	1	SYMBFSW01
Steritest [®] glass ampoule breaker	1	SYMBABR01
Steritest [®] pumps syringe support	1	SYMBSYS01
Steritest® Symbio waste overfill sensor for solid containers	1	SYMBWFS01
Pressure control kit for Steritest® pumps	1	TQ00PSI01
Steritest [®] holder for sterile bags and Steridilutor vent chamber	1	SYMBSVB01
Steritest [®] Symbio communication hub holder for isolators	1	SYMBCHI01
Steritest® Symbio communication hub holder for hoods	1	SYMBCHH01
Steritest [®] Symbio pumps universal shipment case	1	SYMBSCA01
Steritest [®] Symbio pump feet for use in isolator	4	SYMBFEE01
Steritest [®] Symbio pump feet, height 23 mm (used in laminar flow hood)	4	SYMBFEE02
Steritest [®] Symbio connection cable extension with Tri-Clover clamp	1	SYMBXTC01
Steritest [®] Symbio drain tray support for 2 canisters, FLEX pump, high integration	1	SYMBDSF02
Steritest® carrying trays for 5 canisters	8	SYMBCAN08
Steritest [®] rack to hold up to 4 canister carrying trays	2	SYMBRACK2
Steritest [®] Symbio FLEX optional handles	2	SYMBFHA01
Steritest [®] Symbio FLEX high integration kit for round cutout	1	SYMBFHR01
Steritest® Symbio FLEX high integration kit for oval cutout	1	SYMBFHV01
Replacement parts		
Steritest [®] Symbio bottle holder (basket and support rod)	1	SYMBBTH01
Steritest® Symbio bottle holder basket (with fastening screw)	1	SYMBCBH01
Steritest® Symbio accessories support rod	1	SYMBASR01
Steritest® Symbio accessories fastening screw	1	SYMBAFS01
Steritest® Symbio accessories fastening screw clip	1	SYMBFSC01
Steritest [®] Symbio 2 media drain tray container	1	SYMBDTC01
Steritest® Symbio 2 mean tray support for 2 canisters, LFH pump	1	SYMBDSH01
Steritest [®] Symbio drain tray support for 2 canisters, ISL pump	1	SYMBDSL01
Steritest [®] Symbio drain tray support for 2 canisters, FLEX pump, low integration	1	SYMBDSF01
Steritest [®] Symbio drain tray support for 2 canisters, FLEX pump, how integration	1	SYMBDSF02
Steritest [®] Symbio drain tray support O-rings	5	SYMBDSR02
Steritest® Symbio drain tray support express coupling	1	SYMBSEC01
Steritest [®] Symbio complete drain tray for 2 canisters, LFH pump	1	SYMBDTH01
Steritest [®] Symbio complete drain tray for 2 canisters, LFR pump	1	SYMBDTL01
Steritest [®] Symbio complete drain tray for 2 canisters, ISE pump Steritest [®] Symbio complete drain tray for 2 canisters, FLEX pump, low integration		51 MDU I LUI
Steritest Symplo complete drain day for 2 callisters, FLEX pump, IOW INtegration	1	SYMBDTF01

Description	Quantity per pack	Catalog Number
Drain tubing for Steritest [®] pumps, silicone, 1.5 meters	1	SYMBTBG01
Steritest® Symbio control knob	1	SYMBKNB01
Steritest® Symbio communication hub	1	SYMBCHB01
Steritest® Symbio communication hub fuses kit, 6.3A	2	SYMBHFK6A
Steritest® Symbio communication hub fuses kit, 3.15A	2	SYMBHFK3A
Pump head cover for Steritest [®] Symbio 2 media	1	SYMBHEC01
Power cord for North America, Central America, Mexico	1	FTPF02471
Power cord for Europe	1	FTPF01866
Power cord for United Kingdom, Ireland, Malaysia, Singapore, Hong Kong	1	SIMCABLE1
Power cord for Denmark	1	SIMCABLE2
Power cord for South Africa	1	SIMCABLE3
Power cord for Switzerland	1	SIMCABLE4
Power cord for China	1	SIMCABLE5
Power cord for India	1	SIMCABLE6
Power cord for Japan	1	SIMCABLE7
Power cord for Australia, New Zealand, Argentina	1	SIMCABLE8
Power cord for Italy	1	SIMCABLE9
Power cord for Brazil	1	SIMCABLE11
Steritest [®] Symbio flat seal for ISL pump	1	SYMBFSI01
Steritest [®] Symbio flat seal for FLEX pump	1	SYMBFSF01
Software (Available at www.millipore.com/steritest-software)		
Steritest® Symbio Software	_	-
Consumables		
Steritest® devices, culture media and rinsing fluids	-	Visit our website or contact our sales representative.
Documentation (Available at www.millipore.com/steritest-symbio)		
Steritest® Symbio Pumps User Guide	1	PF16598
Steritest® Symbio ISL Pump Installation Guide	1	PF16599
Steritest® Symbio FLEX Pump Installation Guide	1	PF17222
Steritest® Symbio Pumps Isolator Installation Checklist	1	PF17360
Steritest [®] Symbio Software User Guide	1	PF16600
Steritest® Symbio Pump Startup Quick Guide	1	PF16601
Steritest [®] Symbio Pump User Interface Quick Guide	1	PF16602
Steritest® Symbio Software Quick Guide	1	PF16603
Steritest® Symbio Communication Hub Holder for Hoods Installation Quick Guide	1	PF17287
Steritest® Glass Ampoule Breaker User Guide	1	PF17206
Steritest® Syringe Support User Guide	1	PF17207
Steritest® Canisters Carrying Trays and their Rack User Quick Guide	1	PF17451

* Country code to be defined at ordering step.

Symbols Referenced

CE	 The presence of this logo on the product testifies the compliance of the Steritest[®] Symbio Pump with the following European Union directives: Electromagnetic compatibility 2014/30/EU Low voltage directive 2014/35/EU Restriction of the use of certain Hazardous Substances in electrical equipment (RoHS) 2011/65/EU
	 In accordance to the European Union Directive 2012/19/EU on Waste Electric and Electronic Equipment (WEEE), the presence of this logo on the product indicates that it should not be disposed of in the normal waste stream but collected separately. Go to www.millipore.com/weee for details on how to ensure proper treatment of the product in different countries.

Standard Product Warranty

The applicable warranty for the products listed in this publication may be found at: www.millipore.com/ec/cp3/terms (within the "Terms and Conditions of Sale" applicable to your purchase transaction).

Technical Assistance

MilliporeSigma 400 Summit Drive Burlington, MA 01803

For more information: visit www.millipore.com/techservice



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