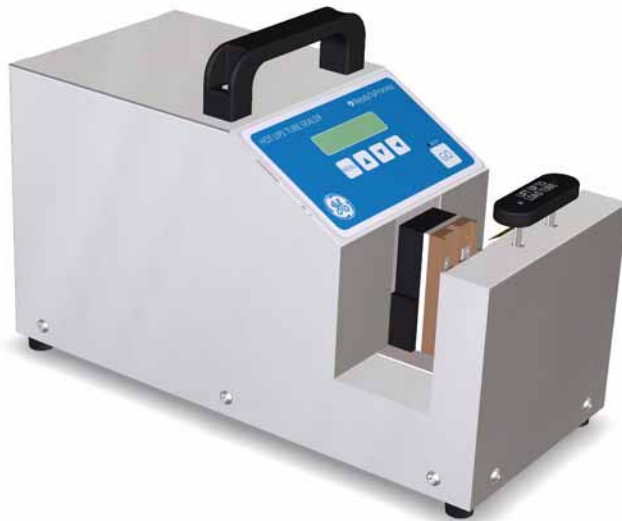


GE Healthcare
Life Sciences

HOT LIPS TUBE SEALER™

Operator Manual



Released

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1 Introduction

1.1 Important user information

Read this before using HOT LIPS TUBE SEALER



All users must read the entire *STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER Operating Instructions* before installing, using or maintaining the instrument. Always keep the Operating Instructions at hand when using HOT LIPS TUBE SEALER.

Do not operate HOT LIPS TUBE SEALER in any other way than described in the user documentation. If you do, you may be exposed to hazards that can lead to personal injury and you may cause damage to the equipment.

Intended use

HOT LIPS TUBE SEALER is an automated instrument designed to seal thermoplastic tubing. HOT LIPS TUBE SEALER shall not be used in any clinical procedures, or for diagnostic purposes.

Safety notices

This user documentation contains WARNINGS, CAUTIONS and NOTICES concerning the safe use of the product. See definitions below.

1 Introduction

1.1 Important user information

Warnings

**WARNING**

WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury. It is important not to proceed until all stated conditions are met and clearly understood.

Cautions

**CAUTION**

CAUTION indicates a hazardous situation which, if not avoided, could result in minor or moderate injury. It is important not to proceed until all stated conditions are met and clearly understood.

Notices

**NOTICE**

NOTICE indicates instructions that must be followed to avoid damage to the product or other equipment.

Notes and tips

Note: A Note is used to indicate information that is important for trouble-free and optimal use of the product.

Tip: A tip contains useful information that can improve or optimize your procedures.

Typographical conventions

Software items are identified in the text by ***bold italic*** text. A colon separates menu levels, thus ***File:Open*** refers to the ***Open*** command in the ***File*** menu. Hardware items are identified in the text by **bold** text (e.g., **Power** switch).

1.2 Regulatory information

This section lists the directives and standards that are fulfilled by HOT LIPS TUBE SEALER.

Manufacturing information

The table below summarizes the required manufacturing information. For further information, see the EC Declaration of Conformity document.

Requirement	Content
Name and address of manufacturer	GE Healthcare Bio-Sciences AB, Björkgatan 30, SE 751 84 Uppsala, Sweden
Name and ID of notified body	INTERTEK SEMKO AB, NB 0413

International standards

Standard	Description	Notes
EN 61010-1, IEC 61010-1, UL 61010-1, CAN/CSA-C22.2 no. 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use	EN harmonized with 2006/95/EC
EN 61326-1	EMC emissions and immunity requirements for measurement, control and laboratory use	Harmonized with 2004/108/EC
EN ISO 12100:2010	Safety of machinery. General principles for design. Risk assessment and risk reduction.	Harmonized with 2006/42/EC

1 Introduction

1.2 Regulatory information

CE conformity

Directive	Title
2006/42/EC	Machinery Directive (MD)
2006/95/EC	Low Voltage Directive (LVD)
2004/108/EC	ElectroMagnetic Compatibility (EMC) Directive

CE marking



The CE marking and the corresponding Declaration of Conformity is valid for the instrument when it is:

- used as a stand-alone unit, or
- connected to other CE-marked instruments, or
- connected to other products recommended or described in the user documentation, and
- used in the same state as it was delivered from GE Healthcare, except for alterations described in the user documentation or explicitly authorized by GE Healthcare.

Regulatory compliance of connected equipment

Any equipment connected to HOT LIPS TUBE SEALER should meet the safety requirements of EN 61010-1/IEC61010-1 or relevant harmonized standards. Within the European Union, connected equipment must be CE-marked.

Recycling



This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of equipment.

1.3 Safety precautions

All users must read this section and the **Safety instructions** chapter in *STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER Operating Instructions* before using **HOT LIPS TUBE SEALER**, and observe the safety information at all times during use.



WARNING

The end user must ensure that all installation, maintenance, operation and inspection is carried out by qualified personnel who are adequately trained, understand and adhere to local regulations and the operating instructions, and have a thorough knowledge of the entire system and process.



WARNING

Hot surfaces of HOT LIPS TUBE SEALER. The jaws reach over 200°C during the heating cycle. Do not touch the jaws during operation.



WARNING

Pinch hazard when using HOT LIPS TUBE SEALER. The jaws are moving during clamping and calibration. Keep away from the jaws when clamping tubes and during the calibration procedure.



WARNING

Before starting **HOT LIPS TUBE SEALER** please make sure that no objects/ tubes are kept in between the heating jaws or moving path.

1 Introduction

1.3 Safety precautions



WARNING

Disconnect power. Always disconnect power from the instrument before performing any maintenance task.



WARNING

Depending on which tubes that are used, hazardous gases may emit. Make sure to use the instrument in a room with proper ventilation.



WARNING

Always use appropriate personal protective equipment during operation and maintenance of HOT LIPS TUBE SEALER.



CAUTION

Only use tubing that is compatible with the instruments. Refer to Appendix A for a list of tubing types that have been tested.



CAUTION

Do not spill liquid into HOT LIPS TUBE SEALER. This can cause serious damage and will void the warranty.




NOTICE

This is a class A product, input power > 1 kW, intended for professional use. In a domestic environment it may cause radio interference, in which case the user might be required to take appropriate measures.



NOTICE

Leave space around the unit for proper ventilation.



NOTICE

High pressures can be generated if the liquid in the seal area has no place to go when it is clamped down by the sealing jaws. Make sure that the liquid can be displaced up or downstream of the seal and ensure that the temporary clamps or plugs are secure.

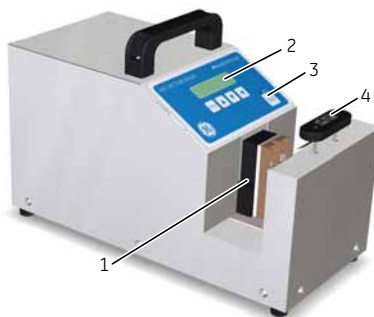
1.4 HOT LIPS TUBE SEALER

Introduction

The HOT LIPS TUBE SEALER is a fully automated unit designed to seal thermoplastic tubing. The machine is useful for sealing feed, harvest and sample tubing connected to bags or other containers, for storage and transportation. The unit is designed to seal a wide range of tubing diameters. See Appendix A for all approved tubing. Major uses are in bioprocessing and in aseptic applications.

Main parts

The illustration below shows the main parts of HOT LIPS TUBE SEALER.



Part	Description
1	Moving jaw
2	LCD display
3	GO button
4	LIFT UP TO LOAD TUBE handle (tube loading handle)

Rear panel

The illustration below shows the rear panel of HOT LIPS TUBE SEALER.



Part	Description
1	Power switch
2	Fuse holder
3	Power connector
4	Key lock
5	Data jack

1.5 Features

- True thermal seal provides tamperproof protection
- 100-120/220-240 V~ (autoswitching)
- Compact, portable
- No compressed air or cooling water needed
- Automated, validatable, 2 to 3 minutes sealing cycle

HOT LIPS TUBE SEALER is a portable unit for heat sealing thermoplastic tubing. The leakproof and tamper proof seal is ideal for ensuring that inoculum, products, media or buffers do not leak through tubing clamps, hemostats, or plugs suitable for shipment, storage and cGMP operations.

Features include keypad selectable programs for virtually all types and sizes of thermoplastic tubing. No adaptors or accessories are required over the entire size

range. The portable lightweight unit has a carrying handle and can be plugged into any 100-120/220-240 V~ power outlet making it usable anywhere in the plant or laboratory. No compressed air or cooling water is required.

1.6 Disclaimer

The HOT LIPS TUBE SEALER has been tested to produce seals of sufficient quality and strength. It is believed to be adequate for the intended application. Under no circumstances can data in this manual be submitted to any regulatory agency in support of a clinical product, without specific written permission from the manufacturer.

The manufacturer is not liable for any loss incurred due to the use of this equipment.

It is the responsibility of the end user to verify and validate the suitability of this device for a specific application. Seals should be carefully inspected before use.

1 Introduction

1.6 Disclaimer

2 Principles of operation

Introduction

The HOT LIPS TUBE SEALER is used to seal tubing permanently. This is done by clamping the tubing to be sealed in a precise position between two heated jaws. The molten tubing is pressed together and cooled under high pressure resulting in a permanent, leak-proof, butt seal.

Compatible tubing

Only thermoplastic tubes listed in Appendix A can be used for the sealing operation. See Appendix A for all approved tubing types. It is not possible to seal materials such as PTFE or silicone as these materials are not thermoplastic.

Sealing method

The HOT LIPS TUBE SEALER can handle various size tubing diameters specified in Appendix A without the need for any additional holders or adaptors. The machine squeezes the tubing to be sealed to a precise thickness based on the material of the tubing and its diameter. The tubing is then melted by heat and cooled under pressure to form a seal. This unique "mold-free" process permits different sizes and materials to be sealed without requiring specific dyes. The low thermal mass of the heated jaws can be readily air-cooled in a matter of minutes eliminating the need for cooling water or refrigeration.

Safety function

The jaws of the HOT LIPS TUBE SEALER can exert several tons of pressure. During the clamping operation, the **GO** button must be pressed and held down until the jaws have closed completely (indicated by a beep). If the button is released prematurely, the jaws will immediately go to the full open position. Furthermore, the jaws will not heat until they are in closed position. In the closed position, it is not possible to bring anything into contact with the heated jaws.

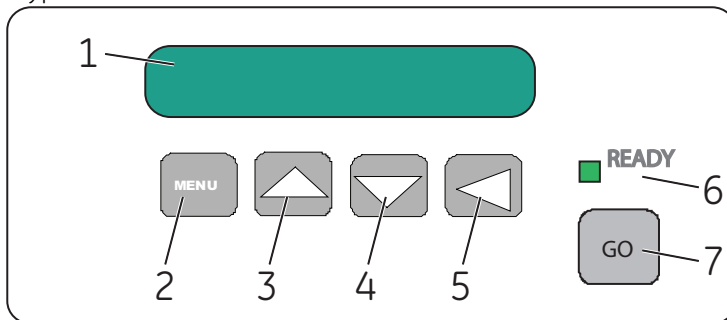
2 Principles of operation

Released

3 Operation

3.1 Controls

The main power switch is located at the rear of the unit. The operating controls are located on the front panel of the unit. Functions are accessed using the front keypad:



Part	Description
1	LCD display
2	MENU button Press the Enter button to go to Tubing Selection Menu. Press MENU button to abort selection and return to normal display.
3	Cursor up button Moves up through the selection list.
4	Cursor down button Moves down through the selection list
5	Enter button Enter function. Accepts new selection
6	READY indicator
7	GO button Advances to next step in the sealing process. Only active when READY light is lit.

3 Operation

3.2 Operating procedure

3.2 Operating procedure

Step	User action	Response	LCD display
1	Switch power on.	The LCD will show " INITIALIZING " and sealing jaws will move to the load position.	<div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">INITIALIZING</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">PLEASE WAIT</div>
2	Check that the tubing type and diameter displayed are correct. If not, then set to match the tubing to be sealed (Steps 2A to C).	When the diagnostic checks are complete, the unit will prompt you to insert the tubing and will display the current tubing setting. The READY light will come on.	<div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">INSERT TUBING</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">CFLEX 3/8 x 5/8</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;"> Press GO to START </div>
3	Lift the tube loading handle upwards. The red safety flag will turn to allow you to insert the tubing. Place the tubing in between the jaws resting on the stainless steel platform. Release the tube loading handle and verify that the red safety flag is on top of the tubing. Press and hold the GO button down until a beep is heard. The GO button may be released at that point.	<p>The jaws will close to squeeze the tubing. The READY light will go out. Once the jaws are closed, the sealing will begin. The LCD screen will display progress of the cycle and the time in seconds for each step.</p> <p>If the GO button is released before the jaws have closed to the preset sealing position, the step will be aborted and the jaws will open again to the load position (Step 2).</p>	<div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">CLOSING</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">HOLD BUTTON DOWN</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">HEATING</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">TEMP = xxx °C</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">SOAKING</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">TIME TO GOXX s</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">COOLING</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">TEMP = XXX °C</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">SEALING.....</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">.....XX s</div>
4	<p>Wait for the sealer jaws to open and release the sealed tubing. Remove the tubing and reset the machine for the next cycle by pressing the GO button.</p> <p>Inspect the seal carefully before use. Allow a few minutes for the seal to cool completely to anneal to maximum strength.</p>	<p>The machine will open to the release position. The sealing jaws will be cool to touch. The seal cycle is complete. The READY light will come on.</p> <p>Each seal cycle takes about 2 to 3 minutes depending on the tubing type and diameter.</p>	<div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">WAITING</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">RELEASE IN ...XX s</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">OPENING....</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">SEAL COMPLETE</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">REMOVE TUBING</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">CFLEX 3/8 x 5/8</div> <div style="border: 1px solid black; padding: 2px; margin-bottom: 2px;">Press GO to reset</div>

Released

3.3 Setting the tubing type and size

Step	User action	Response	LCD display
2A	Press the MENU button.	The LCD will show " SELECT TUBING " with the current setting displayed.	<div style="border: 1px solid black; padding: 5px; width: fit-content;"> SELECT TUBING CFLEX 3/8 x 5/8 </div>
2B	Press the cursor up button or cursor down button cursor keys until the desired tubing type and diameter are displayed.	The LCD will scroll through all the available tubing combinations.	<div style="border: 1px solid black; padding: 5px; width: fit-content;"> SELECT TUBING PVC 1/2 x 3/4 </div> <div style="border: 1px solid black; padding: 5px; width: fit-content; margin-top: 10px;"> Press ◀ to select </div>
2C	Press the Enter (▶) button to select this tubing. Press the MENU button to abort the selection and retain the original setting.	The parameters for the selected tubing are loaded. A beep will confirm load complete. This setting will be retained even when power is turned off.	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin-top: 10px;"> INSERT TUBING PVC 1/2 x 3/4 </div>

3 Operation

3.4 How to load the tubing

3.4 How to load the tubing

Precautions

**WARNING**

Hot surfaces of HOT LIPS TUBE SEALER. The jaws reach over 200°C during the heating cycle. Do not touch the jaws during operation.

**WARNING**

Pinch hazard when using HOT LIPS TUBE SEALER. The jaws are moving during clamping and calibration. Keep away from the jaws when clamping tubes and during the calibration procedure.

**WARNING**

Depending on which tubes that are used, hazardous gases may emit. Make sure to use the instrument in a room with proper ventilation.

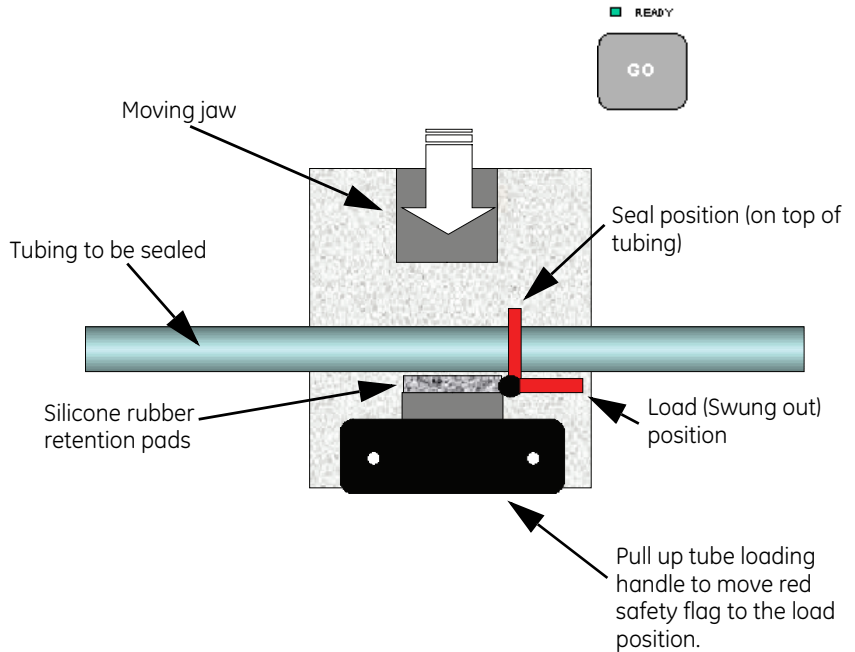
**WARNING**

Before starting HOT LIPS TUBE SEALER please make sure that no objects/tubes are kept in between the heating jaws or moving path.

**NOTICE**

Leave space around the unit for proper ventilation.

Instructions



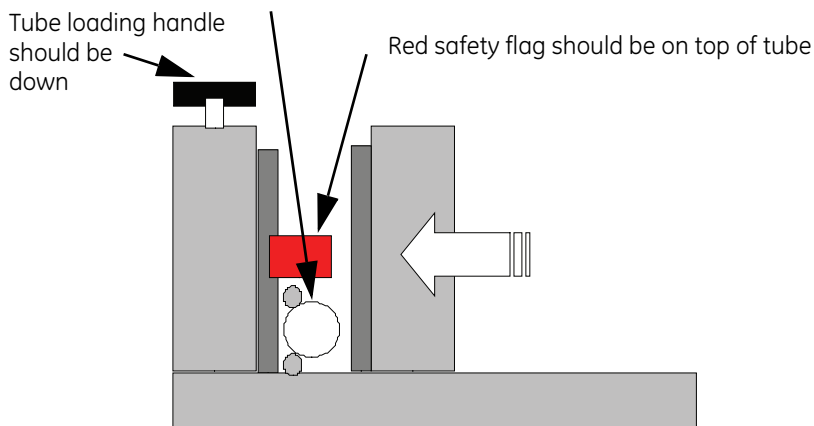
- 1 Pull up the *tube loading* handle. This will cause the *red* safety flag to move up and swing out of the way.
- 2 Place the tubing in between the sealer jaws on the stainless steel platform. All clamps, plugs and so on must be outside the stainless steel platform
- 3 Release the *tube loading* handle. The *red* safety flag should rest *on top of the tubing*.
- 4 Press and hold down the **GO** button. The jaws should start to close. Hold the **GO** button down until the jaws have closed completely (indicated by a beep). If the **GO** button is released prematurely, the jaws will open immediately and you must start again from step 2.

3 Operation

3.4 How to load the tubing

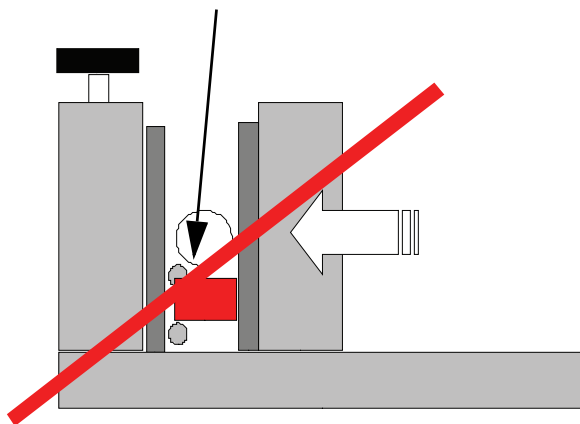
3.4.1 Proper loading of tube

Lay the tubing so it rests on the stainless steel platform.



3.4.2 Improper loading of tube

Red safety flag below tube



3.4.3 Inspecting seal quality

The HOT LIPS TUBE SEALER is designed to make reproducible and reliable seals, however it is still critical to inspect the seal prior to use. Check that the correct tubing type and diameter are set as in many cases a poor seal is the result of using the wrong tubing program.

Note: Allow the seal to cool for 2 to 3 minutes before inspection to achieve optimal strength.

Clean edges

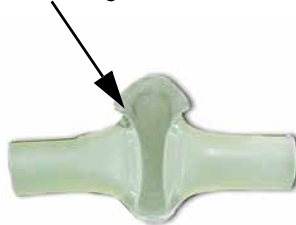
Check that the seal has smooth and uniform edges. There should be no splitting or cracking.



Uniform seal

The seal should have uniform width. Check that the plastic has melted through and that the seal is homogeneous. If the seal is wider on top, then it was not centered properly in the sealer jaws.

Deformed edge



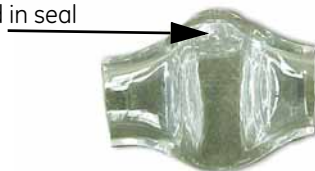
Split and ragged edge



No bubbles

There should be no bubbles or cracks in the center portion of the seal.

Bubble trapped in seal



3 Operation

3.4 How to load the tubing

3.4.4 How to handle filled tubing



WARNING

Always use appropriate personal protective equipment during operation and maintenance of HOT LIPS TUBE SEALER.



CAUTION

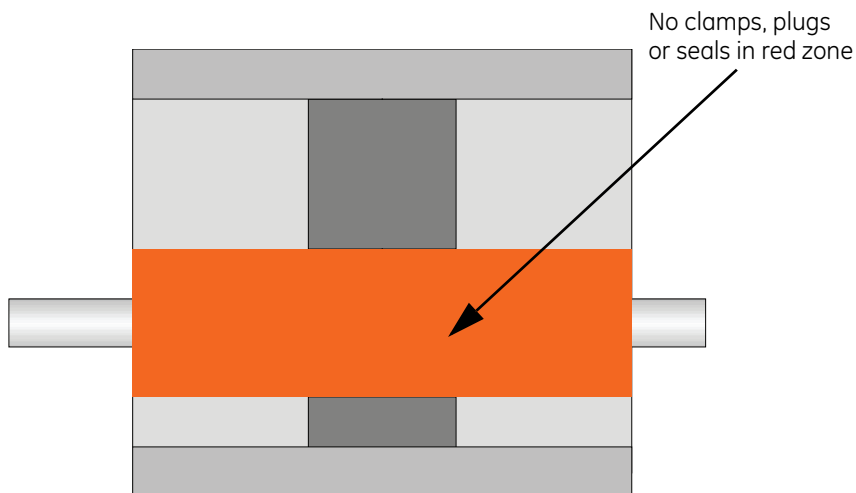
Do not spill liquid into HOT LIPS TUBE SEALER. This can cause serious damage and will void the warranty.



NOTICE

High pressures can be generated if the liquid in the seal area has no place to go when it is clamped down by the sealing jaws. Make sure that the liquid can be displaced up or downstream of the seal and ensure that the temporary clamps or plugs are secure.

The HOT LIPS TUBE SEALER can handle liquid filled tubing. Typically, a clamp or plug is used to prevent the liquid from leaking while being sealed. The liquid will be displaced by the specially contoured jaws and the seal area will be free of liquid or bubbles. Any clamps, plugs or seals should not be inside the width of the machine.



3.4.5 Cutting sealed tubing

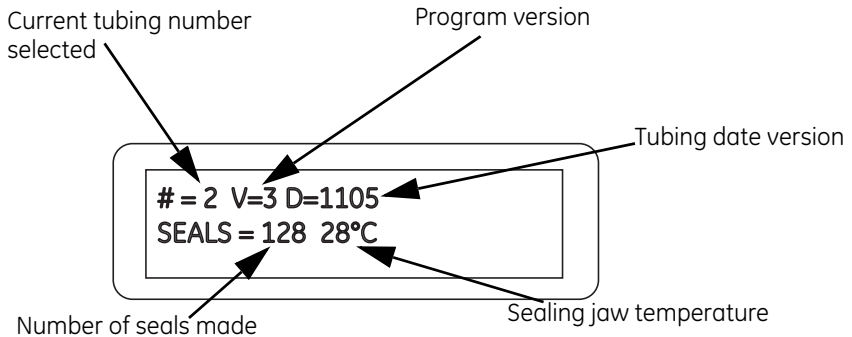
The HOT LIPS TUBE SEALER produces a seal that is wide enough to be easily cut. Simply use scissors to cut through the middle of the seal. This procedure is useful for sealing and detaching tubing from bags.

3 Operation

3.4 How to load the tubing

3.4.6 Checking the version number

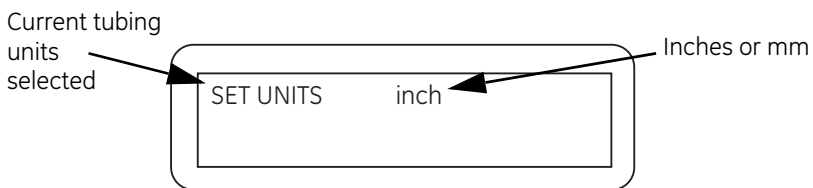
Press the Enter (◀) button and then press the Cursor down button to access the status display. The unit will first initialize and then display the current program and data revision and also the number of seals made. Press **MENU** to return to the normal operations display.



The date code of the loaded version is shown on the status display. New tubing data can be obtained from GE Healthcare and downloaded by the user. See the Maintenance section of this manual.

3.4.7 Setting tube diameter units

Tube dimensions can be displayed in inches (default) or mm. Press **MENU** and Enter buttons together to access the **UNITS** selection screen.



Press the Cursor up button to change the setting. Press the Enter button to accept the new setting or **MENU** to abort.

4 Troubleshooting

Introduction

HOT LIPS TUBE SEALER is designed to monitor all aspects of its operation. If a step does not complete properly, the unit will not proceed to the next step of the operation.

4.1 Operation steps

Step 1: Initialization

The machine retracts the jaws to the fully retracted position and then moves them forward to the start position. The previous sealer settings are loaded and the tubing type and diameter are displayed on the LCD display. The machine beeps to indicate that the initialization step has been completed correctly, and the **READY** light will come on. HOT LIPS TUBE SEALER uses position sensors and encoders to provide feedback on correct positioning. This minimizes the need for realignment.

Step 2: Clamp tubing

The unit closes the jaws to clamp the tubing to a preset thickness. If the **GO** button is released before the jaws reach the final position, the closing step is aborted and the jaws open to the loading position.

Step 3: Heat tubing

If the jaws are in the correct position, the unit initiates heating of the jaws. This is done to a preset temperature depending on the type and wall thickness of the tubing.

Step 4: Seal tubing

Tubing is maintained at a preset temperature for a preset time to seal. Then the fans are turned on to start cooling the tubing.

Step 5: Cool down

The unit is then allowed to cool to a preset temperature. This ensures that the jaws are safe to touch and that the seal is properly annealed. At the completion of the cooldown period, the machine will beep and the jaws will open automatically. Pressing the **GO** button will reinitialize the unit (Step 1).

4 Troubleshooting

4.2 General troubleshooting

4.2 General troubleshooting

For information about general troubleshooting, refer to the *STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER Operating Instructions*.

5 Specifications

5.1 Technical specifications

Catalog Number	28-4117-04
Performance	<p>Seals thermoplastic tubing with outer diameters from 6.4 mm (¼") to 31.8 mm (1¼")</p> <p>Typical sealing cycle takes 2 to 3 minutes</p> <p>Compact and portable</p> <p>Fully automated validatable performance</p> <p>No accessories, compressed air or cooling water needed</p> <p>Factory settings for sealing most thermoplastic tubing, see Appendix A.</p>
Dimensions	W x D x H: 165 mm x 356 mm x 203 mm (6.5" x 14" x 8")
Weight	8 kg (18 lb)
Power	100-120/220-240 V~ auto-switching 6 Amp max.
Voltage	100-120/220-240 V~ ± 10%, autoswitch
Frequency	50 or 60 Hz
Maximum power	350 VA
Fuse	2 x T3.15AL, 250 V (5x20 mm)
Overvoltage	Category 2
Max. tubing OD	See Appendix A
Main. tubing OD	See Appendix A
Sealing cycle	2 to 3 minutes (includes heating up and cooling down)
Enclosure	Indoor use only
Pollution	Degree II
EMC	FCC Part 15 Subpart B Class A and EN61326-1
LVD	IEC/EN/UL61010-1 and CAN/CSA-C22.2 No.61010-1
Relative humidity	2% to 80% non-condensing

5 Specifications

5.2 Tubing

Storage temperature -25°C to +50°C

Operating temperature +2°C to +32°C

5.2 Tubing

The HOT LIPS TUBE SEALER is preprogrammed for various tubing types, diameter and wall thickness. The compatible tubing types can be found in Appendix A.

Appendix A Compatible tubing

Introduction

The HOT LIPS TUBE SEALER is designed to seal thermoplastic tubing.

Note: HOT LIPS TUBE SEALER cannot be used to seal silicone tubing or PTFE.

Suitability is based on typical tubing material. The user must determine suitability of autoclaved, irradiated, or otherwise treated tubing.

Tested tubing brands

The tested tubing brands are listed in the table below. The ReadyToProcess™ tube sizes are marked with an x in the table.

Tubing dimension (I.D. x O.D. in inches)													
Data ver: 0809 Date: 09/11													
Tubing brand	1/8 x 1/4	3/16 x 5/16	3/16 x 3/8	1/4 x 3/8	1/4 x 7/16	5/16 x 7/16	1/4 x 1/2	3/8 x 1/2	3/8 x 5/8	1/2 x 3/4	5/8 x 7/8	3/4 x 9/8	3/4 x 5/4
BIOPRENE™							+		+				
C-FLEX™ 082	+	+		+	+	+	+	+	+	+	+	+	+
C-FLEX 374	+		x	+	+		+x		+x	+x		x	
PHARMED™ BPT	+	+					+		+	+			
SANIPURE™ 60					+				+	+			
SANIPURE BDF	+				+				+	+			
TYGON™/ PVC	+								+	+			

Note: The Tubing Brand names on the instrument screen may not look exactly the same as in the table above. The Tubing Brand names displayed on the instrument screen are abbreviations with the purpose to identify the tube material

Released

A Compatible tubing

Change selected tubing type

For instructions on how to change the tubing type, refer to Setting the tubing type and size on page 19.

Update tubing types

To add the ReadyToProcess tube sizes, order HLTS TUBE DATA MANAGEMENT TOOL (GUI).

For ordering information, refer to Appendix B.

Appendix B Ordering information

SI No.	Catalog Number	Description
1	WV003261	KIT, QK CHNGE TUBE RESTRICTOR
2	28411709	HLTS II FUNCTIONAL VERIFICATION GAUGE
3	WV001984	KEY, REPLACE 6 TUMBLER
4	29002782	HLTS TUBE DATA MANAGEMENT TOOL (GUI)

For more details on ordering information, visit:

www.gelifesciences.com/bioprocess

[Ordering information](#)

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For local office contact information, visit
www.gelifesciences.com/contact

GE Healthcare Bio-Sciences AB
 Björkgatan 30
 751 84 Uppsala
 Sweden

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GE Healthcare UK Ltd.
 Amersham Place, Little Chalfont, Buckinghamshire, HP7 9NA, UK

GE Healthcare Bio-Sciences Corp
 800 Centennial Avenue, P.O. Box 1327, Piscataway, NJ 08855-1327, USA

GE Healthcare Europe GmbH
 Munzinger Strasse 5, D-79111 Freiburg, Germany

GE Healthcare Japan Corporation
 Sanken Bldg. 3-25-1, Hyakunincho, Shinjuku-ku, Tokyo 169-0073, Japan

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