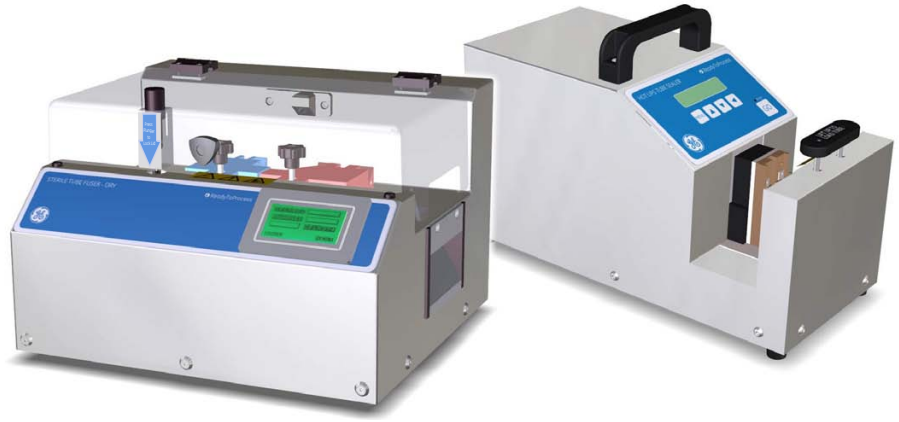
STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER™

Operating Instructions

Original instructions



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1 Introduction

Purpose of the Operating Instructions

The Operating Instructions provide you with the instructions needed to handle STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER in a safe way.

Prerequisites

In order to operate STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER safely and according to the intended purpose the following prerequisites must be met:

- You should be acquainted with the use of general laboratory equipment and with handling of biological materials.
- You must read *Chapter 2 Safety instructions, on page 15*.
- The system should be installed according to the instructions in *Chapter 3 Installation, on page 39*.
- You must read *STERILE TUBE FUSER - DRY Operator Manual* (87-4500-21) and *HOT LIPS TUBE SEALER Operator Manual* (87-4500-07).

In this chapter

1.1 Important user information

Read this before using STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER

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

Do not operate STERILE TUBE FUSER - DRY or 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

STERILE TUBE FUSER - DRY is an automated instrument designed to produce sterile joints of thermoplastic tubings. HOT LIPS TUBE SEALER is an automated instrument designed to seal thermoplastic tubing.

STERILE TUBE FUSER - DRY and 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.

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

Introduction

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

Manufacturing information

The table below summarizes the required manufacturing information. For further information, see the EU Declaration of Conformity (DoC) document.

Requirement	Content
Name and address of manufacturer	GE Healthcare Bio-Sciences AB, Björkgatan 30, SE 751 84 Uppsala, Sweden

Conformity with EU Directives

This product complies with the European directives listed in the table, by fulfilling the corresponding harmonized standards.

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

CE marking

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

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

International standards

Standard	Description	Notes
EN/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 standard is harmonized with EU directive 2006/95/EC
EN/IEC 61326-1 (Emission according to CISPR 11, Group 1, class A)	Electrical equipment for measurement, control and laboratory use - EMC requirements	EN standard is harmonized with EU directive 2004/108/EC
EN ISO 12100	Safety of machinery. General principles for design. Risk assessment and risk reduction.	EN ISO standard is harmonized with EU directive 2006/42/EC

FCC compliance

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: *The user is cautioned that any changes or modifications not expressly approved by GE could void the user's authority to operate the equipment.*

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Regulatory compliance of connected equipment

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

Environmental conformity

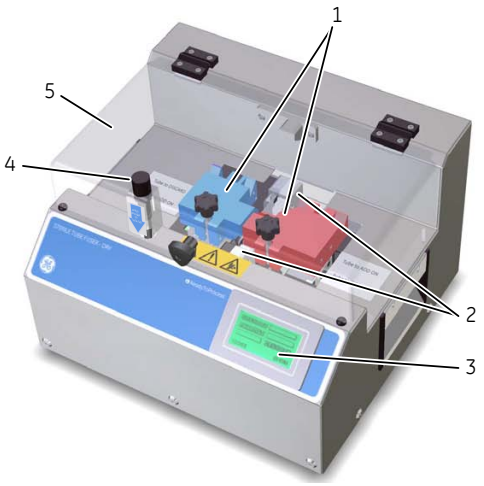
This product complies with the following environmental regulations.

Requirement	Title
2011/65/EU	Restriction of Hazardous Substances (RoHS) Directive
2012/19/EU	Waste Electrical and Electronic Equipment (WEEE) Directive
Regulation (EC) No 1907/2006	Registration, Evaluation, Authorization and restriction of CHemicals (REACH)
ACPEIP	Administration on the Control of Pollution Caused by Electronic Information Products, China Restriction of Hazardous Substances (RoHS).

1.3 STERILE TUBE FUSER - DRY

Main parts

The illustration below shows the main parts of STERILE TUBE FUSER - DRY.



Part	Description
1	Tubing holders (blue and red)
2	Blade holders
3	Touch screen
4	COVER LOCK button
5	Cover or Lid

Rear panel

The illustration below shows the rear panel of STERILE TUBE FUSER - DRY.

Part	Function
1	Ventilation fan
2	Key lock
3	Power switch
4	Data jack
5	Fuse holder
6	Power connector

1.4 HOT LIPS TUBE SEALER

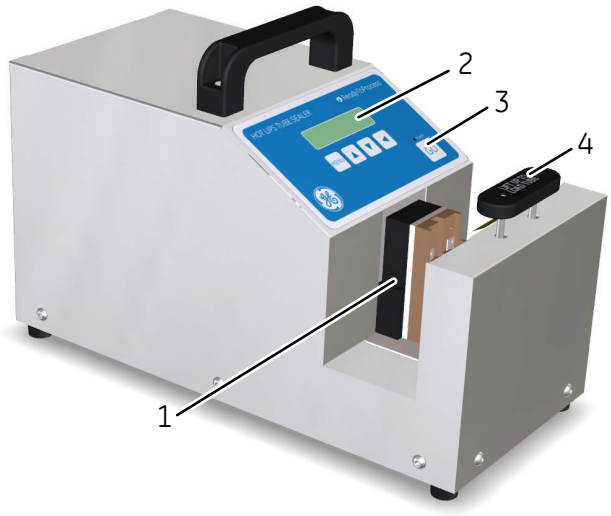
Introduction

HOT LIPS TUBE SEALER is an instrument used for heat sealing of thermoplastic tubing. It is useful for sealing feed, harvest and sample tubing connected to bags or other containers, for storage and transportation. HOT LIPS TUBE SEALER is designed to seal a wide range of tubing diameters. Major uses are in bioprocessing and in aseptic applications.

HOT LIPS TUBE SEALER is equipped with an embedded software for control and supervision.

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

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 Associated documentation

Introduction

This section describes the documentation associated with STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER.

Supplied documentation

In addition to the Operating Instructions, the STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER instruments are supplied with the respective Operator Manual:

Document	Contents
STERILE TUBE FUSER - DRY Operator Manual (supplied with STERILE TUBE FUSER - DRY)	How to use the system, including concepts, methodology, operation and troubleshooting. These documents are also available as online help.
HOT LIPS TUBE SEALER Operator Manual (supplied with HOT LIPS TUBE SEALER)	

Related documentation

STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER Tube Data Management Tool User Manual is supplied with an installation kit (available upon request).

The installation kit enables the user to:

- extend the STERILE TUBE FUSER - DRY or HOT LIPS TUBE SEALER instrument to support different tubing types.
- manage the factory loaded tubing types.

For more information, see *Section 7.2 Compatible tubing for STERILE TUBE FUSER - DRY, on page 94* and *Section 7.3 Compatible tubing for HOT LIPS TUBE SEALER, on page 96*.

For ordering information, see *Section 7.5 Further information, on page 99*.

2 Safety instructions

About this chapter

This chapter contains safety information and describes symbols and labels that are attached to STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER. In addition, the chapter describes emergency procedures, and provides recycling information.

All users must read this chapter before using STERILE TUBE FUSER - DRY or HOT LIPS TUBE SEALER, and observe the safety information at all times during use.

In this chapter

2.1 Safety precautions

Introduction

Before installing, operating, maintaining and inspecting the instrument, you must be aware of the hazards described in the user documentation. Follow the instructions provided to avoid personal injury or damage to the equipment.

The safety precautions in this section are grouped into the following categories:

- General precautions
- Using flammable liquids
- Personal protection
- Installing and moving the instrument
- System operation
- Maintenance

General precautions

STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER

WARNING

Perform a risk assessment for any risks due to the process or process environment. Evaluate the effect the system and the processes where it is used have to the classification of the hazardous area. The process might cause the area to increase or the zone classification to change. Implement the risk reduction measures needed, including use of personal protection equipment.

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

Do not operate STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER in any other way than described in the user documentation.

WARNING

Operation and user maintenance of STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER should be performed by properly trained personnel only.

WARNING

Only use spare parts and accessories that are approved or supplied by GE for maintaining or servicing the system.

NOTICE

STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER are class A products, 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.

STERILE TUBE FUSER - DRY

CAUTION

Do not attempt to connect liquid filled tubing used STERILE TUBE FUSER - DRY. This will void the warranty.

Using flammable liquids

STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER

WARNING

STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER are not designed to fuse and seal tubing containing flammable fluids. STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER are not approved for work in a potentially explosive atmosphere.

Personal protection

STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER

WARNING

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

WARNING

Hazardous substances. When using hazardous chemical and biological agents, take all suitable protective measures, such as wearing protective glasses and gloves resistant to the substances used. Follow local and/or national regulations for safe operation and maintenance of the system.

WARNING

Spread of biological agents. The operator has to take all necessary actions to avoid spreading hazardous biological agents in the vicinity of the instrument. The facility should comply with the national code of practice for biosafety.

Installing and moving the instrument

STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER

WARNING

Power cord. Only use power cords delivered or approved by GE.

WARNING

Protective ground. The instruments must always be connected to a grounded power outlet.

WARNING

Access to power switch and power cord. The Power switch must always be easy to access. The power cord must always be easy to disconnect.

CAUTION

Disconnect all tubing, hoses and cables before moving the unit.

System operation

STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER

WARNING

Do not drop objects into the unit. If an object has been dropped into the unit, disconnect the power supply before lifting the object out of the unit.

WARNING

The instrument must never be used if any safety functions are out of order. Contact your GE service operator for more information.

WARNING

Inspect all connections and tubing before start and replace any defective parts.

CAUTION

Ensure that all tubing, hoses and cables are placed so that the risk for tripping accidents is minimized.

CAUTION

Only use tubing that is compatible with the instruments.

CAUTION

Remove any spillage on the floor immediately to minimize the risk for slipping accidents.

CAUTION

Leave space around the unit for proper ventilation.

Note: *Improper use of tube data may cause damage to the unit and is not covered under the warranty.*

For a list of tubing types that have been tested for

- STERILE TUBE FUSER - DRY, refer to *Section 7.2 Compatible tubing for STERILE TUBE FUSER - DRY, on page 94*
- HOT LIPS TUBE SEALER, refer to *Section 7.3 Compatible tubing for HOT LIPS TUBE SEALER, on page 96*

STERILE TUBE FUSER - DRY

WARNING

In setup mode of STERILE TUBE FUSER - DRY, with the Programming lock key horizontal, the instrument can be run without the cover in place. The blade poses a burn hazard if the weld process is started in this mode. Use caution when in setup mode and keep clear of the blade and blade assembly.

WARNING

Pinch hazard when using STERILE TUBE FUSER - DRY. There are movable parts under the protective cover. Do not try to open the protective cover during the welding.

WARNING

Hot surfaces of STERILE TUBE FUSER - DRY. The cutting blade reaches 400°C during the heating cycle. Do not try to open the protective cover during the welding.

WARNING

Do not touch the blade of STERILE TUBE FUSER - DRY until it cools down. Always allow the blade to cool down for 30 seconds before accessing the blade.

WARNING

In case of power failure and instrument reset, STERILE TUBE FUSER - DRY unlocks the COVER LOCK. Do not touch the blade for approximately one minute till it cools down.

WARNING

The blade must be properly pushed down into its blade holders to enable the temperature sensor to measure the correct blade temperature.

CAUTION

The cutting blade of STERILE TUBE FUSER - DRY is a thin piece of stainless steel. It does not have a sharpened edge but can cause cuts if handled improperly. Be sure to read and understand the procedure of how to install and remove the blade.

CAUTION

Do not attempt to connect liquid-filled tubing using STERILE TUBE FUSER - DRY, or allow liquid to spill into the instrument.

CAUTION

Holders must not be mounted on the STERILE TUBE FUSER - DRY during initial alignment of the system.

NOTICE

Make sure that the COVER LOCK button is down during the entire welding and aligning operation.

NOTICE

Cover must be closed for the instrument to operate. The cover interlock will only allow it to be opened when it is safe. The COVER LOCK button pops out to indicate that the cover is released and can be opened.

HOT LIPS TUBE SEALER

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.

CAUTION

If there is liquid in the tubing when using HOT LIPS TUBE SEALER it will evaporate as it comes into contact with the heater pads. If the tube is full of liquid, the liquid can be released during the weld and can cause a spill in or around the equipment.

CAUTION

Depending on which tubes that are used in HOT LIPS TUBE SEALER, hazardous gases may be emitted. Make sure to use the instrument in a room with proper ventilation.

NOTICE

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 that the temporary clamps or plugs are secure.

Maintenance

STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER

WARNING

Electrical shock hazard. All repairs should be done by service personnel authorized by GE. Do not open any covers or replace parts unless specifically stated in the user documentation.

WARNING

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

WARNING

If a fuse requires repeated replacement, do not continue to use the instrument. Contact an authorized service engineer.

Refer to *Section 7.1 Specifications, on page 93* for information about the fuse types and rating.

WARNING

For continued protection from fire hazard, replace only with same type and rating of fuse.

CAUTION

Change the blade after every cut to avoid sterility issues.

HOT LIPS TUBE SEALER

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.

Troubleshooting

STERILE TUBE FUSER - DRY

NOTICE

Errors 1 through 12 can not be confirmed without causing damage to the equipment. Error 13 can be user confirmed if necessary.

Reference information

STERILE TUBE FUSER - DRY

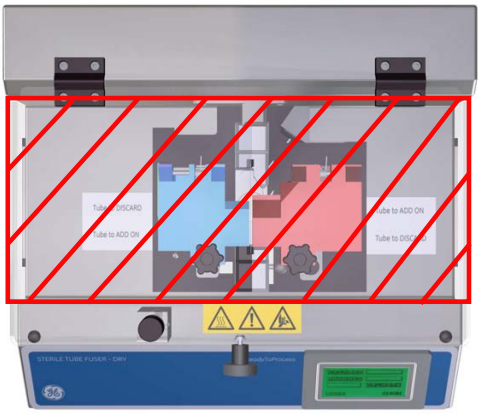
NOTICE

Only use PTFE coated cutting blades (BLADES-IR/50) specified for use with STERILE TUBE FUSER - DRY. For optimal use, do not reuse blades.

2.2 Danger zone

STERILE TUBE FUSER - DRY

The following diagram shows the danger zone on STERILE TUBE FUSER - DRY. This danger zone should be kept clear of obstructions during operation.



WARNING

Hot surfaces of STERILE TUBE FUSER - DRY. The cutting blade reaches 400°C during the heating cycle. Do not try to open the protective cover during the welding.

HOT LIPS TUBE SEALER

The following diagram shows the danger zone on HOT LIPS TUBE SEALER. This danger zone should be kept clear of obstructions during operation.

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.

2.3 COVER LOCK for STERILE TUBE FUSER - DRY

Introduction

The COVER LOCK button is located on the lid of STERILE TUBE FUSER - DRY, see *Section 1.3 STERILE TUBE FUSER - DRY, on page 10*.

If the COVER LOCK button is...	then the lid is...
down	locked.
up	unlocked.

To lock the cover, press and hold the COVER LOCK button for a few seconds until you hear a CLICK sound.

NOTICE

Make sure that the COVER LOCK button is down during the entire welding and aligning operation.

COVER LOCK button illustration

COVER LOCK button down - locked lid	COVER LOCK button up - unlocked lid
	

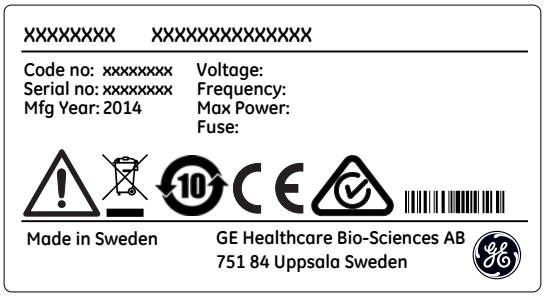
2.4 Labels

Introduction

This section describes the system label and the safety labels on STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER.

System label illustration

The illustration below shows an example of a system label.



System label description

Label	Description
Code no	• STERILE TUBE FUSER - DRY: 28999602 • HOT LIPS TUBE SEALER: 28411704
Serial no	Instrument serial number
Mfg Year	Manufacturing year
Voltage	100-120/220-240 V AC
Frequency	50/60 Hz
Max Power	• STERILE TUBE FUSER - DRY: 350 VA • HOT LIPS TUBE SEALER: 3.3 A

Label	Description
Fuse	• STERILE TUBE FUSER - DRY: 2 x T4.0 AL 250V • HOT LIPS TUBE SEALER: 2 x T3.15 AL 250V
	**Warning!** Read the user documentation before using the system. Do not open any covers or replace parts unless specifically stated in the user documentation.
	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.
	This symbol indicates that the product contains hazardous materials in excess of the limits established by the Chinese standard SJ/T11363-2006 Requirements for Concentration Limits for Certain Hazardous Substances in Electronics.
	The system complies with applicable European directives. Refer to *Section 1.2 Regulatory information, on page 7*.
	The system complies with the requirements for electromagnetic compliance (EMC) in Australia and New Zealand.

Safety label description

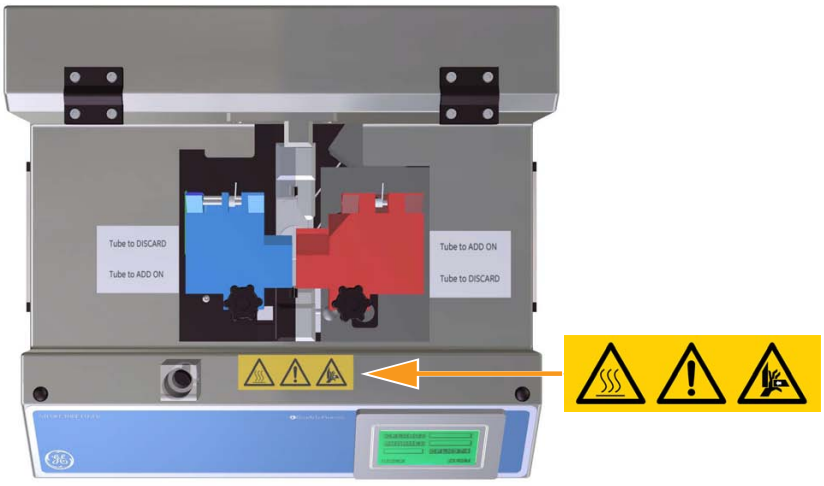
The safety labels are described in the table below. Make sure that you fully understand the potential hazards indicated by the labels.

Label	Description
	Indicates a hot surface and that care must be exercised to prevent injury.

Label	Description
	Indicates a pinch hazard and that care must be exercised to prevent injury.

Safety labels on STERILE TUBE FUSER - DRY

The safety labels are located on STERILE TUBE FUSER - DRY as illustrated below. The labels warn the user of risk of personal injury.



Safety labels on HOT LIPS TUBE SEALER

The safety labels are located on HOT LIPS TUBE SEALER as illustrated below. The labels warn the user of risk of personal injury.


XXXXXXXX XXXXXXXXXXXXX
Code no: xxxxxxxx
Serial no: xxxxxxxx
Mfg Year: 2014
Voltage:
Frequency:
Max Power:
Fuse:
Made in Sweden
GE Healthcare Bio-Sciences AB
751 84 Uppsala Sweden

2.5 Emergency procedures

Introduction

This section describes how to do an emergency shutdown of STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER. The section also describes the result in the event of power failure.

Emergency shutdown of STERILE TUBE FUSER - DRY

Switch off the power by pressing the power switch to the "**O**" position.

The power switch is located at the rear of the instrument, see the illustration below.

Emergency shutdown of HOT LIPS TUBE SEALER

Switch off the power by pressing the power switch to the "**O**" position.

The power switch is located at the rear of the instrument, see the illustration below.

If an emergency situation occurs when clamping tubing, the clamping operation is immediately interrupted if the **GO** button is released.

Power failure

If the power to the...	then the tubes may not be completely...
STERILE TUBE FUSER - DRY fails during the welding operation	welded. Action: Re-initiate the welding process by following the instructions displayed on the Touch Screen.
HOT LIPS TUBE SEALER fails during the sealing operation	sealed. Action: Re-initiate the sealing process.

2.6 Recycling procedures

Introduction

This section contains information about the decommissioning of STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER.

Decontamination

The equipment shall be decontaminated before decommissioning and all local regulations shall be followed with regard to scrapping of the equipment.

Disposal, general instructions

When taking STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER out of service, the different materials must be separated and recycled according to national and local environmental regulations.

Recycling of hazardous substances

STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER may contain hazardous substances. Detailed information is available from your local GE representative.

Disposal of electrical components

Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized GE representative for information concerning the decommissioning of your equipment.

2.7 Declaration of Hazardous Substances (DoHS)

根据SJ/T11364-2006《电子信息产品污染控制标识要求》特提供如下有关污染 控制方面的信息。

The following product pollution control information is provided according to SJ/T11364-2006 Marking for Control of Pollution caused by Electronic Information Products.

电子信息产品污染控制标志说明
Explanation of Pollution Control Label

该标志表明本产品含有超过SJ/T11363-2006《电子信息产品中有毒有害物质的限量要求》中限量的有毒有害物质。标志中的数字为本产品的环保使用期，表明本产品在正常使用的条件下，有毒有害物质不会发生外泄或突变，用户使用本产品不会对环境造成严重污染或对其人身、财产造成严重损害的期限。单位为年。

为保证所申明的环保使用期限，应按产品手册中所规定的环境条件和方法进行正常使用，并严格遵守产品维修手册中规定的期维修和保养要求。

产品中的消耗件和某些零部件可能有其单独的环保使用期限标志，并且其环保使用期限有可能比整个产品本身的环保使用期限短。应到期按产品维修程序更换那些消耗件和零部件，以保证所申明的整个产品的环保使用期限。

本产品在使用寿命结束时不可作为普通生活垃圾处理，应被单独收集妥善处理。

This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard SJ/T11363-2006 Requirements for Concentration Limits for Certain Hazardous Substances in Electronic Information Products. The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the toxic or hazardous substances or elements contained in electronic information products will not leak or mutate under normal operating conditions so that the use of such electronic information products will not result in any severe environmental pollution, any bodily injury or damage to any assets. The unit of the period is “Year”.

In order to maintain the declared EFUP, the product shall be operated normally according to the instructions and environmental conditions as defined in the product manual, and periodic maintenance schedules specified in Product Maintenance Procedures shall be followed strictly.

Consumables or certain parts may have their own label with an EFUP value less than the product. Periodic replacement of those consumables or parts to maintain the declared EFUP shall be done in accordance with the Product Maintenance Procedures.

This product must not be disposed of as unsorted municipal waste, and must be collected separately and handled properly after decommissioning.

有毒有害物质或元素的名称及含量
Name and Concentration of Hazardous Substances

产品中有毒有害物质或元素的名称及含量
Table of Hazardous Substances' Name and Concentration

部件名称 Component name	有毒有害物质或元素 Hazardous substance					
	铅 Pb	汞 Hg	镉 Cd	六价铬 Cr6+	多溴联苯 PBB	多溴二苯醚 PBDE
28-9996-02	X	0	0	0	0	0
28-4117-04	X	0	0	0	0	0

0: 表示该有毒有害物质在该部件所有均质材料中的含量均在SJ/T11363-2006标准规定的限量要 求以下

X: 表示该有毒有害物质至少在该部件的某一均质材料中的含量超出SJ/T11363-2006标准规定的限量要求

- 此表所列数据为发布时所能获得的最佳信息

0: Indicates that this toxic or hazardous substance contained in all of the homogeneous materials for this part is below the limit requirement in SJ/T11363-2006.

X: Indicates that this toxic or hazardous substance contained in at least one of the homogeneous materials used for this part is above the limit requirement in SJ/T11363-2006.

- Data listed in the table represents best information available at the time of publication.

3 Installation

Precaution

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.

In this chapter

3.1 Site requirements

STERILE TUBE FUSER - DRY

Parameter	Requirements
Electrical power	100-120/220-240 V AC ±10%, 50 to 60 Hz
Transient overvoltages	Overvoltage category II
Operating temperature	0°C to 30°C
Humidity	20% to 80%, non-condensing
Pollution degree	2
Altitude	Maximum 2000 m

HOT LIPS TUBE SEALER

Parameter	Requirements
Electrical power	100-120/220-240 V AC ±10%, 50 to 60 Hz
Transient overvoltages	Overvoltage category II
Operating temperature	2°C to 32°C
Humidity	2% to 80%, non-condensing
Pollution degree	2
Altitude	Maximum 2000 m

Requirements on instrument placement

The following requirements apply to both STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER.

- There should be at least 0.6 m of space around the instrument for easy access to the whole equipment, both for normal operation and for maintenance and service operations.

- The danger zone (see *Section 2.2 Danger zone, on page 26*) should be kept clear of obstructions.
- The instrument is designed for normal laboratory environments and must be protected from splashes or dusty operations.
- The instruments are equipped with ventilation fans. Make sure that the air flow is not blocked.

3.2 Unpacking

Follow the instruction below to unpack the instrument.

Step	Action
1	Remove the instrument from the shipping container.
2	Remove any tape and packaging material from the instrument.
3	Check the equipment for any apparent damage before starting installation. Document any damage carefully and contact your GE representative.

3.3 Transport

STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER are designed to be portable and can be moved to different locations. Moving should only be performed by qualified personnel.

3.4 Connections

Connect the supplied power cord into the rear of the instrument and to a grounded power outlet specified in *Section 3.1 Site requirements, on page 40*.

WARNING

Protective ground. The instruments must always be connected to a grounded power outlet.

4 Operation

Precaution

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.

In this chapter

4.1 STERILE TUBE FUSER - DRY

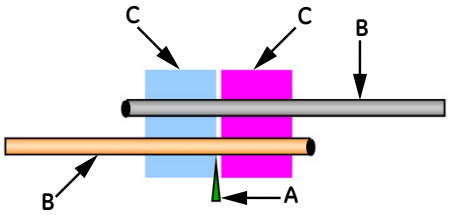
Operation overview

The STERILE TUBE FUSER - DRY is used to weld together thermoplastic tubing in a sterile manner. Each piece of tubing is connected on one end to a container, bag or process equipment. The other end is sealed by a clamp, plug, or other closure.

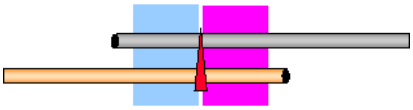
- See *Section 7.2 Compatible tubing for STERILE TUBE FUSER - DRY, on page 94* for all approved tubing types. It is not possible to seal non-thermoplastic materials such as PTFE or silicone.
- The STERILE TUBE FUSER - DRY can handle various tubing diameters specified in *Section 7.2 Compatible tubing for STERILE TUBE FUSER - DRY, on page 94*.

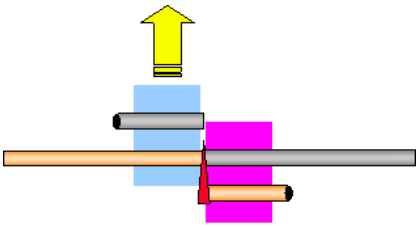
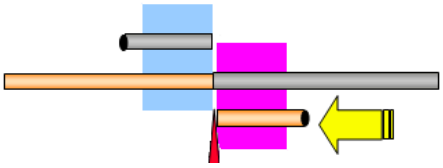
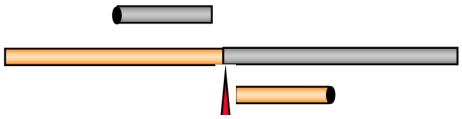
Schematic operation

Stage	Description
1	The cutting blade (A) is installed. It retracts into the instrument.
2	The tubing (B) is placed in the holders (C). Arrows (B) indicate the part of tubing to be connected.



3	The cutting blade heats up and when heated it cuts through both tubing pieces.



Stage	Description
4	The Tubing holders slide the cut tubing into alignment. The hot cutting blade is held against the cut tubing to ensure sterility. 
5	The cutting blade returns to the start position and the tubing is simultaneously pushed together to form the connection. 
6	The connected tubing is removed and the used cutting blade and cut tubing ends are discarded. 

Prior to use

Prior to use, the instrument should be tested by making a few trial welds which should be examined. If the sample welds are not acceptable, contact Service.

Fusing tubes

WARNING

Hot surfaces of STERILE TUBE FUSER - DRY. The cutting blade reaches 400°C during the heating cycle. Do not try to open the protective cover during the welding.

WARNING

Pinch hazard when using STERILE TUBE FUSER - DRY. There are movable parts under the protective cover. Do not try to open the protective cover during the welding.

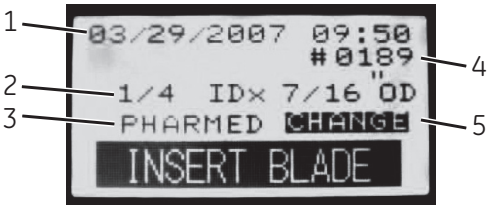
WARNING

In case of power failure and instrument reset, STERILE TUBE FUSER - DRY unlocks the COVER LOCK. Do not touch the blade for approximately one minute till it cools down.

NOTICE

Cover must be closed for the instrument to operate. The cover interlock will only allow it to be opened when it is safe. The COVER LOCK button pops out to indicate that the cover is released and can be opened.

Start instrument and set tubing brand and dimension

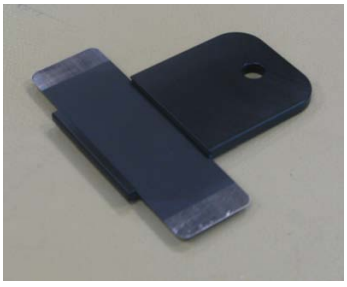
Step	Action
1	Switch on the power to STERILE TUBE FUSER - DRY by pressing the power switch to the "**I**" position. *Result:* Close the lid and lock by pressing COVER LOCK button in order to proceed further. On successful initialization, the display shows the ***INSERT BLADE*** screen.  The display shows current date and time (1) and instrument ID number (4).
2	Check that desired tubing dimension (2) and tubing brand (3) are shown.

Step	Action
3	Optional, change tubing brand (3): • Press the ***CHANGE*** button (5). • Press the desired tubing type on the new display. If no tubing types appear on the first screen, press the ***NEXT*** button to open the second screen. ***Note:*** *If you have already inserted the blade and wish to change the tubing type, simply remove the blade to get the* ***INSERT BLADE*** *screen.* ***Note:*** *If the tubing has been inserted you must remove the tubing, cycle power to the instrument, and then remove the blade to get the* ***INSERT BLADE*** *screen.*
4	Optional, change tubing dimension: Use a Tubing holder with the desired dimension. The tubing dimension is then automatically entered in the instrument. To change a Tubing holder, see *Changing Tubing holder, on page 52*.

Insert a cutting blade

CAUTION

The cutting blade of STERILE TUBE FUSER - DRY is a thin piece of stainless steel. It does not have a sharpened edge but can cause cuts if handled improperly. Be sure to read and understand the procedure of how to install and remove the blade.

Step	Action
1	Place the STERILE TUBE FUSER - DRY blade in Installation/Removal Tool as shown below. 

Step	Action
2	Use Installation/Removal Tool to install the blade by pressing the top of the tool with the palm of the hand. During the blade installation, secure the blade within the tool by compressing with thumb as shown in the image below.

3	Press Installation/Removal Tool with palm of your hand until the blade is fully inserted into mounted position. Remove Installation/Removal Tool.
4	Close the STERILE TUBE FUSER - DRY lid and press the COVER LOCK button, for location see *Section 1.3 STERILE TUBE FUSER - DRY, on page 10*. Once you press the COVER LOCK button, the blade automatically retracts into the instrument.
5	Wait for the cover interlock to release.

Insert tubing and start welding

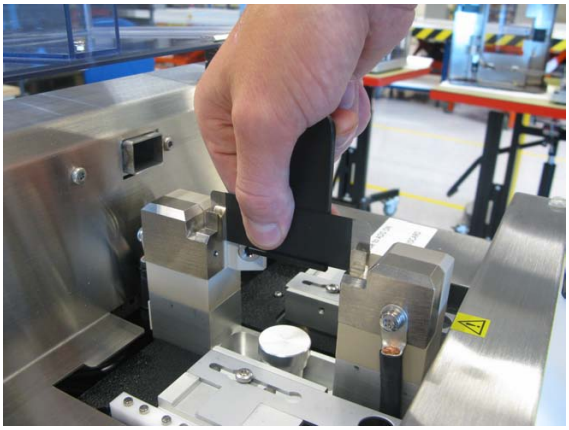
Step	Action
1	Clean the outside of the tubing area to be connected using a suitable disinfectant. 70% ethanol or isopropanol can be used as a suitable disinfectant.
2	Place the tubing firmly in the holders. The tubing ends must protrude out beyond each holder.
3	Close the blue (left) holder first and slide it towards the red (right) holder. Clamp it down securely.
4	Close the red holder and tighten the clamp.
5	Close the cover.

Step	Action
6	Press and hold the COVER LOCK button for a few seconds to sequence the program.

Remove connected tubing and turn off the instrument

CAUTION

The cutting blade of STERILE TUBE FUSER - DRY is a thin piece of stainless steel. It does not have a sharpened edge but can cause cuts if handled improperly. Be sure to read and understand the procedure of how to install and remove the blade.

Step	Action
1	On successful completion of the cycle, the display shows a ***WELD COMPLETE*** message and the cover interlock releases.
2	Open the cover.
3	Remove the used cutting blade with Installation/Removal Tool. Secure the blade within the tool by compressing with thumb as shown in the image below.  ***Note:*** *For optimal operation, do not reuse cutting blades.*
4	Open the red Tubing holder, then the blue Tubing holder.

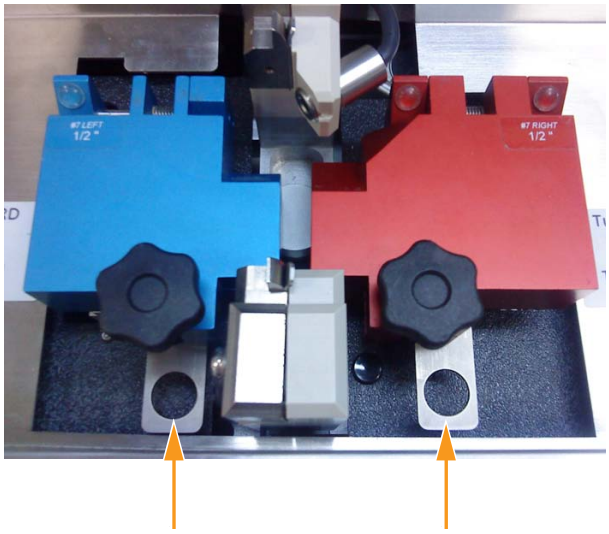
Step	Action
5	Remove the connected tubing and discard the cut ends. ***Note:*** *Inspect the weld carefully before use, see Inspecting weld quality, on page 54.*
6	Close the cover and press the COVER LOCK button to reset the instrument.
7	Optional: Start at step 3 in *Start instrument and set tubing brand and dimension, on page 48* to make additional tubing welds. Each weld cycle takes about 2 minutes.
8	Switch off the power to STERILE TUBE FUSER - DRY by pressing the power switch to the "**O**" position.

Changing Tubing holder

The Tubing holders can be quickly changed to connect different diameter tubing. The Tubing holders must be changed as a pair (left and right Tubing holders must be the same size).

The Tubing holders are coded so that the instrument automatically reads the Tubing holder type and selects the appropriate program.

Step	Action
1	Open the cover.

Step	Action
2	For each Tubing holder: • Push the Locking tab towards the rear of the instrument to unlock the Tubing holder (arrows).  • Lift out the Tubing holder.
3	Select desired Tubing holder pair (the pair must match).
4	Place each Tubing holder on its platform. ***Note:*** *Ensure that the alignment pins under the Tubing holder are placed into holes in the platform.*
5	Pull the locking tabs towards the front of the instrument to lock the Tubing holders.

Handling of liquid filled tubing

CAUTION

Do not attempt to connect liquid-filled tubing using STERILE TUBE FUSER - DRY, or allow liquid to spill into the instrument.

It is not possible to weld together tubing that is filled with liquid. Pump out the excess fluid before welding tubing. Stop liquid from re entering by clamping the tubing. All clamps must be placed outside the lid.

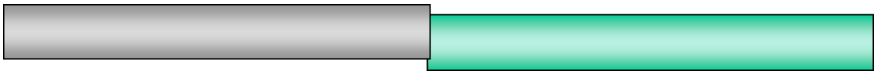
Inspecting weld quality

STERILE TUBE FUSER - DRY is designed to make reproducible and reliable connections, however it is still critical to inspect the weld prior to use.

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

Axial alignment

Check that the tubing is axially aligned. If the tubing is offset, then the weld will be weaker on one side. Do not use such welds. Contact Service to realign the instrument.

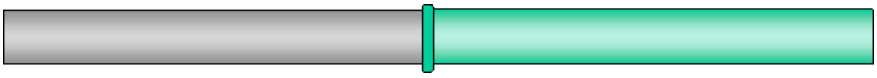


Uniform weld

Check that you see a flange all around the weld. This indicates that the weld is uniform in the radial direction. If you do not see a flange all the way around, then discard the weld. Check for the following and weld again.

- Ensure correct tubings are used.
- Ensure correct holders are used.
- Ensure approved tubing size and formulation are used.
- Insert a new blade.
- Ensure holders are closed and properly latched.

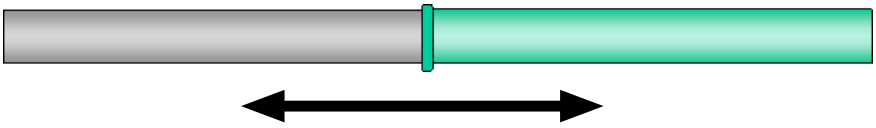
If you are unable to get a uniform flange, contact Service for help.



Good tensile strength

Pull gently at the weld and make a gentle twist. Make sure that the tubes are properly clamped in both sides of the weld in order not to compromize the sterility of the tube if any ruptures emerges.

The tubing should not come apart or start to crack.



4.2 HOT LIPS TUBE SEALER

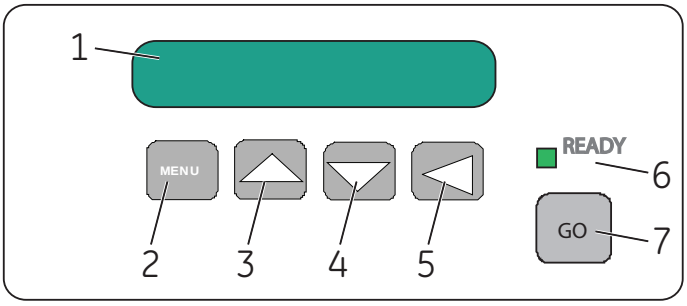
Operation overview

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.

- Refer to *Section 7.3 Compatible tubing for HOT LIPS TUBE SEALER, on page 96* HOT LIPS TUBE SEALER for all approved tubing types. It is not possible to seal non-thermoplastic materials such as PTFE or silicone.
- HOT LIPS TUBE SEALER can handle various size tubing diameters specified in *Section 7.3 Compatible tubing for HOT LIPS TUBE SEALER, on page 96* HOT LIPS TUBE SEALER.

Control panel

The operating controls are located on the front panel of the instrument.



Part	Description
1	LCD display
2	**MENU** button
3	Cursor up button
4	Cursor down button
5	Enter button
6	**READY** indicator
7	**GO** button

Sealing tubes

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.

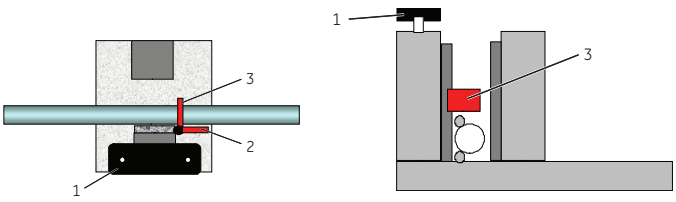
WARNING

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

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.

Step	Action
1	Switch on the power to HOT LIPS TUBE SEALER by pressing the power switch to the "**I**" position. *Result:* The LCD display shows ***INITIALIZING*** and sealing jaws moves to the load position. INITIALIZING PLEASE WAIT When initialization is complete, the The LCD display shows ***INSERT TUBING***, the tubing type, and the tubing dimension (i.d. × o.d. in inches). The **READY** light also turns on. INSERT TUBING CFLEX 3/8 × 5/8

Step	Action
2	To change tubing type and tubing dimension: • Press the **MENU** button. SELECT TUBING CFLEX 3/8 × 5/8 • Press the up or down cursor buttons until the desired tubing type and diameter are displayed. • Press enter button. The parameters for the selected tubing are loaded. A beep confirms that loading is complete. • Press the **MENU** button to abort the selection and retain the original setting.
3	Lift the **LIFT UP TO LOAD TUBE** handle upwards (1). *Result:* The red Safety flag turns from position (3) to position (2) to allow insertion of the tubing. The illustrations below show the instrument from the top (left) and from the right-hand side (right). 
4	Place the tubing between the jaws resting on the stainless steel platform.
5	Press the **LIFT UP TO LOAD TUBE** handle (1) and verify that the red Safety flag is on top of the tubing (3).

Step	Action
6	• Press and hold the **GO** button. • Release the **GO** button when a beep is heard. If the **GO** button is released before the jaws have closed to the preset sealing position, the jaws open again. The jaws close to squeeze the tubing. The **READY** light goes out. Once the jaws are closed, the sealing begins. The LCD display shows the progress of the cycle and the time in seconds for each step:

Step	LCD display	Step	LCD display
1	HEATING TEMP = xxx °C	4	SEALING..... .....XX s
2	SOAKING TIME TO GO .....XX s	5	WAITING .... RELEASE IN ....XX s
3	COOLING ..... TEMP = XXX °C	6	OPENING.... SEAL COMPLETE

When the seal cycle is complete, the instrument opens to the release position and the sealing jaws are cool enough to touch.

7 When the **READY** light turns on, remove the tubing.

REMOVE TUBING
CFLEX 3/8 × 5/8

8 If another tube sealing is desired, press the **GO** button and the instrument resets. Follow the instructions (Sealing tubes) from step 3 and onwards.

Note:

Each seal cycle takes about 2 to 3 minutes depending on the tubing type and dimension.

9 Inspect the seal carefully before use, see *Inspecting seal quality, on page 59*.

Step	Action
10	When no more tube sealing is desired, switch off the power to HOT LIPS TUBE SEALER by pressing the power switch to the "**O**" position.

Handling of filled tubing

NOTICE

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 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 the tubing is sealed. The liquid is displaced by the specially contoured jaws and the seal area is free of liquid or bubbles.

Note: *No clamps, plugs or seals should be inside the danger zone of the instrument, see* *Section 2.2 Danger zone, on page 26**.*

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. A common cause for a poor seal is that the wrong tubing type and/or dimension have been set during tubing sealing.

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

Check seal

Check that:

- the seal has smooth and uniform edges.

- the seal has uniform width.

- the seal has no splitting or cracking.
- there are no bubbles (arrow in figure indicates a trapped bubble).

- the plastic has melted through and that the seal is homogeneous.

Note: *If the seal is wider on top, then it was not centered properly in the sealer jaws.*

Cutting sealed tubing

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.

5 Maintenance

Precautions

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

Electrical shock hazard. All repairs should be done by service personnel authorized by GE. Do not open any covers or replace parts unless specifically stated in the user documentation.

WARNING

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

In this chapter

5.1 Cleaning

In this section

5.1.1 Cleaning

General cleaning

Clean the system using a damp cloth with suitable disinfectant that does not affect any markings or signs, or the safety of the system.

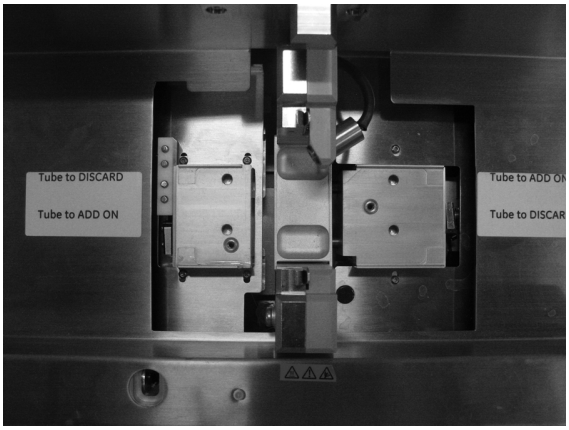
Ethanol (up to 20% as disinfectant) and a lint free cloth can also be used to clean surfaces of the instrument.

Liquid spillage cleaning

In case of spillage, mild cleaning agents should be used to clean the instrument, holders and clamps depending on the hazard level of the process chemicals/biological being used.

Step	Action
1	Switch off the instrument and disconnect power cable, before initiating the cleaning process.
2	Unlock the tube holders, open the holders and rotate 90 degree to facilitate tube removal. ***Note:*** *Do not remove external clamps clamped on fused tubes before ensuring a good weld. Refer to Inspecting weld quality, on page 54.*
3	Dismantle the tube holders from the instrument for cleaning using proper cleaning agent along with lint free cloth.

Step	Action
4	Clean the spillage area on the instrument surface with a proper cleaning agent and cotton swab.



WARNING

In case of large amount (more than about 50 ml) of liquid spillage inside the instrument, switch off the instrument and contact Service. Do not touch the instrument in power ON condition.

Lid

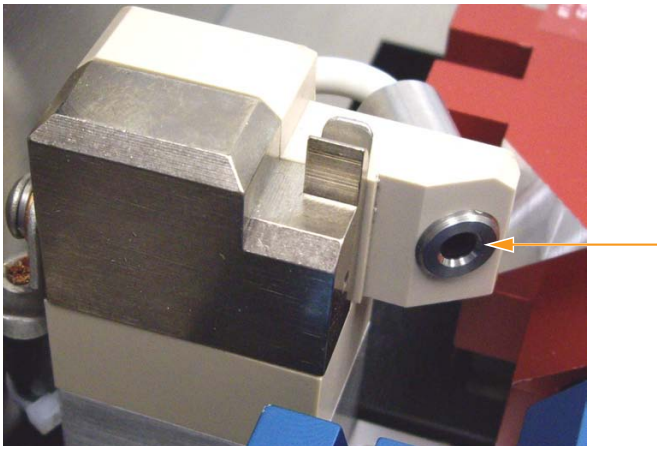
Clean the polycarbonate lid with 40% ethanol or 40% isopropanol.

Danger zone

The danger zone under the cover see *Section 2.2 Danger zone, on page 26* may be cleaned periodically, using a small handheld vacuum cleaner. Any spillage may be cleaned with a lint free cloth moistened with water or up to 20% ethanol.

Infrared sensor window

Clean the infrared sensor window (indicated by an arrow below) every 2 months. Use a lens cleaning kit to clean the sensor window.



5.1.2 Cleaning of HOT LIPS TUBE SEALER

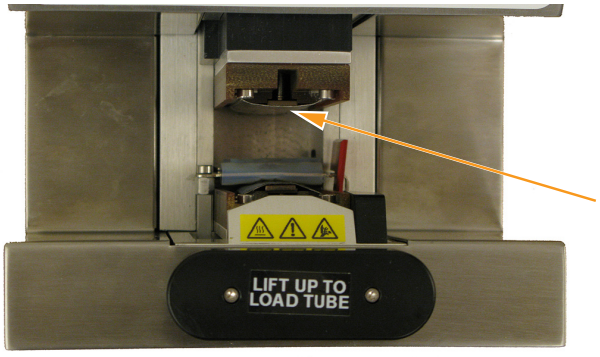
General cleaning

Clean the system using a damp cloth with suitable disinfectant that does not affect any markings or signs, or the safety of the system.

Ethanol (up to 20% as disinfectant) and a lint free cloth can also be used to clean surfaces of the instrument.

PTFE jaw covers

Wipe the black PTFE jaw covers (see arrow) with alcohol if there is any tubing residue or discoloration.



5.2 Maintenance of STERILE TUBE FUSER - DRY

All maintenance tasks on STERILE TUBE FUSER - DRY other than specified below needs to be done by a GE service representative. Contact Service.

- Replace the fuse in case of fuse failure. See *Section 5.4 Replacement of fuses, on page 80* for more information.
- Handle and store the tube holders in a safe designated place. Dropping the holders on the pin side could cause damage to holder and result in poor fit.
- Check whether the code plate underneath the left tube holder is intact, before use.
- Tighten the captive screw, if the installed tube holders are found to be slack.
- Clean the instrument surface, welding region & tube holders for any liquid spillage after tube welding operation.
- Perform safety checks on instrument and surroundings at regular intervals, once in a quarter for safe operating conditions.
- Schedule the instrument for preventive maintenance by GE service personnel. Contact Service.

5.3 Maintenance of HOT LIPS TUBE SEALER

About this section

All maintenance tasks on HOT LIPS TUBE SEALER other than specified in this section needs to be done by a GE service representative. Contact Service.

- User can replace the fuse in case of fuse failure. See *Section 5.4 Replacement of fuses, on page 80* for more information.
- It is recommended to service the instrument every six months including cleaning, Functional validation or Calibration, retest and safety check. Contact Service.

In this section

5.3.1 Tube Restrictor replacement

Introduction

The Tube Restrictors are wearable components that require periodic replacement to ensure good quality sealing of thermoplastic tubing.

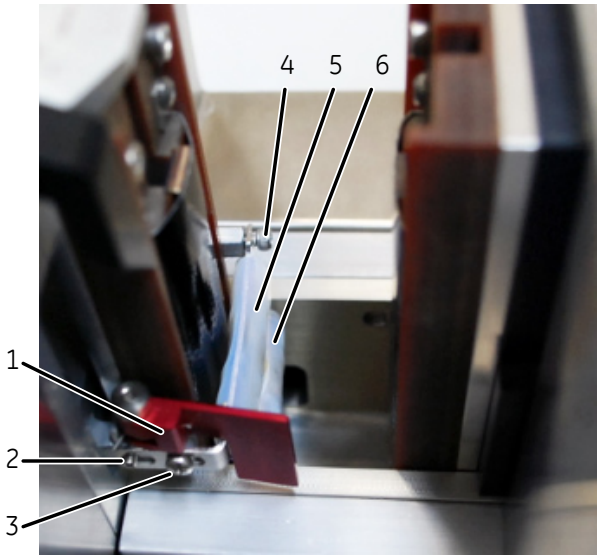
Depending on tube size and tubing formulation, approximately 40 to 60 seals can be created before the Tube Restrictors need to be replaced. It is recommended to replace the Tube Restrictors as a part of the routine maintenance of HOT LIPS TUBE SEALER.

For more information about inspecting the quality of the seal, see *Inspecting seal quality, on page 59*

Tools required

- Torx™ wrenches T8 and T10
- Needle nosed pliers

Tube Restrictor assembly illustration



Part	Description
1	Red flag indicator
2	Metal steering peg
3	Hex pan head screw(1)
4	Hex pan head screw(2)
5	Top restrictor
6	Bottom restrictor

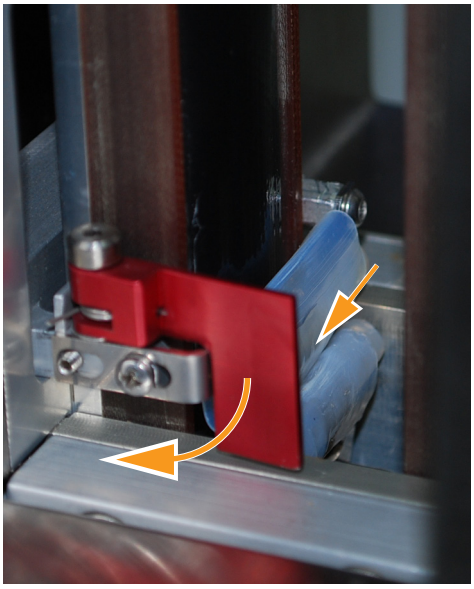
Note: *Screws may vary depending on the production year of the unit. The picture above is of an older unit where hex pan head screws were not used and is solely for illustration purposes.*

Note: *Older installations may be held in place with two button head screws in position 3 and 4, shown in the picture above. Use a Precision Phillips screwdriver and Metric Hex keys to loosen or fasten them.*

Remove the Tube Restrictors

Follow the instruction below to remove the Tube Restrictors.

Step	Action
1	Switch on the power to the HOT LIPS TUBE SEALER, by pressing the power switch to the "**I**" position, and wait for the initialization to be completed.
2	Press the Enter button on the keypad. *Result:* The rear jaw will move away from the operator.
3	Switch off the power to HOT LIPS TUBE SEALER, by pressing the power switch to the "**O**" position, and disconnect the power plug from the rear of the unit.
4	Remove Hex pan head screw 1 using a T8 Torx wrench.
5	Move and hold the Red flag indicator in a position where it does not block the top Tube Restrictor, and pull out the top Tube Restrictor. Slightly loosen Hex pan head screw 2 using a T10 Torx wrench.



Step	Action
6	Remove the bottom Tube Restrictor from the unit by pulling it up and away from the front jaw assembly using needle nose pliers.

Insert new Tube Restrictors

Follow the instruction below to insert the new Tube Restrictors.

Step	Action
7	Insert the new bottom Tube Restrictor using needle nose pliers.
8	Move and hold the Red flag indicator in a position where it does not block the new top Tube Restrictor, and insert the new top Tube Restrictor.
9	Fasten Hex pan head screw 1 using a T8 Torx wrench. Tighten Hex pan head screw 2 using a T10 Torx wrench.
10	Switch on the power to the unit, by pressing the power switch to the "**I**" position, and wait for the initialization to be completed.
11	Perform some test welds to verify functionality of the unit.

5.3.2 Functional validation and calibration

Introduction

This section describes how to perform a functional validation and a calibration of HOT LIPS TUBE SEALER.

A functional validation should be performed every six months to check that the jaw mechanism in HOT LIPS TUBE SEALER is within the specified tolerance. The functional validation is done using the Functional verification gauge, illustrated below.

If functional validation fails, the operator or service engineer manually triggers the calibration routine.

Precaution

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.

Functional validation

Follow the instruction below to perform a functional validation using the Functional verification gauge.

Step	Action
1	Start the instrument.

Step	Action
2	Wait until the **READY** light glows, then press the Enter button. *Result*: The LCD display shows ***PRESS UP =T CAL DOWN =GAUGE CAL***.

3	Press the Cursor down button to perform the Functional verification gauge validation test.
4	When ***INSERT GAUGE AND PRESS ENTER*** is shown on the LCD display, insert the Functional verification gauge, and press the Enter button.

Step	Action
5	

If...	then...
only the PASS end of the Functional verification gauge passes through the jaws without any difficulty	press the Cursor up button. *Result:* The display shows ***CAL PASSED AND RE-CYCLE POWER***. Recycle the power and start the instrument.
any part of the FAIL end of the Functional verification gauge passes through the jaws	press the Cursor down button. *Result:* The display shows ***CALIBRATION FAIL***. Calibrate to make sure that jaws are within the specified tolerance.

Calibration

Follow the instruction below to calibrate HOT LIPS TUBE SEALER.

Step	Action
1	Switch the power switch to the "**O**" position.
2	Remove the Tube Restrictors according to the procedure *Remove the Tube Restrictors, on page 71*.

Step	Action
	Make sure that there is nothing between the jaws which obstructs the jaws from closing completely against each other, as shown in the illustration below.

3 While holding down the **GO** button, switch the power switch to the "**I**" position.

4 Release the **GO** button when the LCD display shows ***READY TO CAL?***.

Step	Action
5	Verify that the tube restrictors have been removed and that nothing obstructs the jaws. Press **GO** to continue calibration. *Result:* The display shows ***CALIBRATING...*** and the jaws start closing. Make sure no objects restrict the jaws from closing completely. ***Note:*** *If **GO** button is pressed during calibration, calibration stops and LCD displays **CALIBRATION ABORTED**. Operator has to recycle power and perform the steps from beginning in order to calibrate again.*

The jaws will close to approximately 5 mm apart and then start moving together slowly. The LCD display shows the incremented position count information.

When the jaws touch, the zero calibration is complete, and the jaws will automatically retract to do a repeatability check.

If...	then...
the repeatability test completes successfully	the operation proceeds to ***CAL GAUGE TEST***.
the repeatability test fails	the operation is terminated and the LCD display shows ***CALIBRATION FAIL***. Contact Service.

Step	Action

6 When ***INSERT GAUGE AND PRESS ENTER*** is shown on the LCD display, insert the Functional verification gauge as shown and press the Enter button.

Step	Action
7	

If...	then...
only the PASS end of the Functional verification gauge passes through the jaws without any difficulty.	press the Cursor up button. *Result:* The display shows ***CAL PASSED AND RE-CYCLE POWER***. Recycle the power and start the instrument.
any part of the FAIL end of the Functional verification gauge passes through the jaws.	press the Cursor down button. *Result:* The display shows ***CALIBRATION FAIL***. Contact Service.

Please refer to *Section 5.3.1 Tube Restrictor replacement, on page 69* for more information on next steps.

5.4 Replacement of fuses

Precautions

WARNING

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

WARNING

If a fuse requires repeated replacement, do not continue to use the instrument. Contact an authorized service engineer.

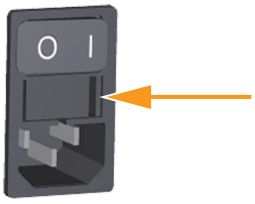
Refer to *Section 7.1 Specifications, on page 93* for information about the fuse types and rating.

WARNING

For continued protection from fire hazard, replace only with same type and rating of fuse.

Refer to *Section 7.1 Specifications, on page 93* for fuse specification.

Instructions

Step	Action
1	Disconnect the power cord from the instrument.
2	Lift out the fuse cover, located below the power switch (see arrow).
	
3	Lift out the broken fuses.

Step	Action
4	Insert new fuses.
5	Replace the fuse cover on the instrument.
6	Connect the power cord.
7	Switch on the power to the instrument by pressing the power switch to the "**I**" position.

5.5 Storage

Refer to *Section 7.1 Specifications, on page 93* for information.

CAUTION

The instrument has fragile items. Ensure that the instrument is always in upright position during transport, movement and storage. Also ensure no weight is kept on instrument or on the instrument packaging.

6 Troubleshooting

In this chapter

6.1 STERILE TUBE FUSER - DRY

General troubleshooting

Problem	Corrective action
The display is not lit.	• Check that the instrument is plugged in. • Check that the power switch is in the "**I**" position. • A fuse has blown. Refer to *Section 5.4 Replacement of fuses, on page 80* for instructions on how to replace fuses. • If problem persists, contact Service.
The instrument does not recognize that the holders are installed.	• Make sure that the holder tabs are locked (pulled out towards the front of the instrument). • Check that tubing is the correct size and firmly clamped in the holder. • Check that the holders are in the correct position and firmly seated in the instrument. • Check the holder code plate attached to the bottom of the left (blue) holder.
The instrument does not recognize that the tubing is inserted.	• Make sure you are using the correct tubing O.D. for the holder and that it is firmly clamped. • Make sure that there is tubing over the tube detector in each holder. It may be necessary to adjust the tube detector microswitches located on the posts under the holders.
The cover does not open.	Access door should only open when the COVER LOCK is released by the instrument, or if the program was unable to run to completion. • Turn off the power by pressing the power switch to the "**O**" position in order to release the cover. Wait for the blade to cool before attempting to repair the instrument.

Problem	Corrective action
The instrument malfunctions during the welding process causing the instrument to stop.	• Reset the instrument by turning the power to the instrument off and wait 10 seconds or so before turning the power on again. • Check that the holders are correctly installed and do not move in their mounts. • Make sure that the left and right holders are for same diameter tube. • Make sure the holders are locked in correctly with the locking tabs pulled out towards the front of the instrument. • Check that the tubing is of the correct size. • Check that the instrument is set to the correct tubing type. • Try using a new cutting blade. • If the instrument still does not perform properly, contact Service.

Automatic error checking

The STERILE TUBE FUSER - DRY is designed to monitor all aspects of its operation. If a step does not perform properly, the instrument does not proceed to the next step of the operation.

Step	Instrument checks
Setup	• Check that the holders are correctly installed. • Check that no tubing is present. • Check that all systems are functional. • Check that the holders are moved into alignment and checked.
Cutting blade insertion	Check that a cutting blade is inserted.
Tubing insertion	Check that the tubing is correctly inserted in the holders.

Step	Instrument checks
Operation	• Check the cutting blade temperature. An infrared sensor measures the cutting blade temperature and modulates power to control temperature. The program stops if the measured temperature differs from the set temperature. • Check that the tubing has the correct position after alignment and before welding.

Error messages

In the event an error occurs during the cycle, one of the following messages may be displayed on the LCD.

Contact Service and give the error message(s) to assist in troubleshooting the problem.

NOTICE

Errors 1 through 12 can not be confirmed without causing damage to the equipment. Error 13 can be user confirmed if necessary.

Error No.	Message	Possible cause	Corrective action
ERROR 1	***INITIALIZATION FAIL***	The instrument was not able to initialize the motors and heating system within the specified time-out period.	• Check if anything is obstructing the movement of the tube holders. • Switch off the power to the instrument. • Check if COVER LOCK button is up. • Wait 2 to 3 minutes. • Switch on the power to the instrument. • Retry initialization.

Error No.	Message	Possible cause	Corrective action
ERROR 2	***HEATING TOO SLOW***	It took too long for the blade to reach the sterilization temperature.	• Try with a new blade. • Check that the blade edges are clean and unscratched. • Contact service for further assistance.
ERROR 3	***STERILIZATION FAIL***	The temperature when sterilizing the blade dropped below the set point.	• Repeat the operation with a new blade. • Call Service if the problem persists.
ERROR 5	***RETRACT MOTOR FAIL***	The blade retract operation failed to retract the blade in the specified time.	• Check for obstructions. • Switch off the power to the instrument. • Switch on the power to the instrument and follow the display messages. • If the motor fails to move, contact Service.
ERROR 6	***CUT MOTOR FAIL***	The cut operation failed to reach the cut position in the specified time.	• Switch off the power to the instrument. • Switch on the power to the instrument and follow the display messages. • If the motor fails to move, contact Service.
ERROR 7	***ALIGN MOTOR FAIL***	The align operation failed to align the cut tubes in the specified time.	• Switch off the power to the instrument. • Switch on the power to the instrument and follow the display messages. • If the motor fails to move, contact Service.

Error No.	Message	Possible cause	Corrective action
ERROR 8	***LIFTOUT MOTOR FAIL***	The blade liftout operation failed to bring the blade to the top position in the specified time.	• Switch off the power to the instrument. • Switch on the power to the instrument and follow the display messages. • If the motor fails to move, contact Service.
ERROR 9	***TEMPERATURE SENSOR FAIL***	The infrared temperature sensor has failed.	Contact Service to replace and recalibrate the infrared temperature sensor.
ERROR 10	***COVER OPEN***	Cover opened during operation.	A safety interlock stops the weld cycle if the cover is forced open or COVER LOCK fails. Contact Service to repair COVER LOCK.
ERROR 11	***PUSH MOTOR FAIL***	The X-axis motor compresses the tubes together during the weld. This error indicates that this motor failed to move correctly.	• Switch off the power to the instrument. • Switch on the power to the instrument and follow the display messages. • If the motor fails to move, contact Service.
ERROR 12	***RESET FAIL***	The instrument failed to reset to the start configurations.	Check that all tubes are removed, and that nothing is obstructing the movement of the motors.
ERROR 13	***REMOVE TUBES***	The instrument was powered up with tubes still inserted in the holders.	Remove all tubes and cycle power off/on to restart the instrument.
N/A	***ERFF***	• Time out error. • The communication cable may be disconnected, or the communication error has occurred due to noise and so on.	• Check if the cable is connected properly. • Switch off the power to the instrument. • Wait for 2 to 3 minutes. • Switch on the power to the instrument.

Error No.	Message	Possible cause	Corrective action
N/A	***ERFE***	Response error from the PC during communication with the instrument.	• Verify if the expected data is received from PC (GUI application). • Check if the communication cable is connected properly. • Restart the PC application(GUI).

6.2 HOT LIPS TUBE SEALER

General troubleshooting

Problem	Possible cause	Corrective action
The LCD display is not lit.	• The instrument is not plugged in. • The power switch is in the "**O**" position. • Instrument fuse has blown.	• Check that the instrument is plugged in. • Check that the power switch is in the "**I**" position. • If any instrument fuses has blown, refer to *Section 5.4 Replacement of fuses, on page 80* for instructions on how to replace fuses. • If problem persists, contact Service.
The seal is not satisfactory	• The tubing program is not set correctly. • Incorrect tubing is used. • The tubing is not centered in the jaws. • The motor need adjustment.	• Check that the tubing program is set correctly, by clicking on the **MENU** button and co-relating the tube inserted to the selected tubing. • Check that you are using the correct tubing. • Check that tubing is centered in the jaws. • Perform mechanical assembly calibration according to the instructions in *Calibration, on page 75* .
LCD error message: ***MOTOR OVERLOAD***	Mechanism was obstructed from complete movement.	Remove tubing and any other object from the jaws and cycle power off/on to reset the instrument.
LCD error message: ***HEATER OVERTEMP***	The heater temperature was too high due to internal malfunction.	Contact Service.
LCD error message: ***SENSOR FAILURE***	The temperature sensor has failed, or is giving invalid readings.	Contact Service.
LCD error message: ***HEATER FAILURE***	The heater did not reach set temperature within time-out period.	Contact Service.

Problem	Possible cause	Corrective action
LCD error message: ***SAFETY SWITCH TRIP***	Motor caused jaw to retract beyond a safe position. The motion is stopped and the program halted.	Try to reset by cycling power off/on. Contact Service if problem persists.

Automatic error checking

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

Step	Instrument checks
Initialization	Check that components have the correct positioning.
Clamp tubing	Check that the **GO** button is pressed until the jaws reach the final position.
Heat tubing	Check that the jaws have the correct position.
Seal tubing	Check that the sealing temperature is reached. Then the fans are turned on to start cooling the tubing.
Cool down	Check the temperature. At the completion of the cool down period, the instrument will beep and the jaws will open automatically.

7 Reference information

In this chapter

7.1 Specifications

STERILE TUBE FUSER - DRY

Parameter	Value
Supply voltage	100-120 V AC ±10% or 220-240 V AC ±10%, 50/60 Hz
Maximum current	3.3 A
Fuse specification	2 x T4.0 AL 250 V
Dimensions (W × D × H)	395 x 355 x 265 mm
Weight	16 kg
Acoustic noise level	<70 dB A
Ambient temperature	0°C to 30°C
Storage temperature	-20°C to +60°C
Relative humidity tolerance	20% to 80%, non-condensing

HOT LIPS TUBE SEALER

Parameter	Value
Supply voltage	100-120 V AC ±10% or 220-240 V AC ±10%, 50/60 Hz
Maximum power	350 VA
Fuse specification	2 x T3.15AL, 250 V
Dimensions (W × D × H)	165 × 356 × 203 mm
Weight	8 kg
Acoustic noise level	<55 dB A
Ambient temperature	2°C to 32°C
Storage temperature	-25°C to +50°C
Relative humidity tolerance	2% to 80%, non-condensing

7.2 Compatible tubing for STERILE TUBE FUSER - DRY

Introduction

STERILE TUBE FUSER - DRY is designed to join thermoplastic tubing.

Note: *STERILE TUBE FUSER - DRY cannot be used to join 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.

*Denotes the factory loaded tubing types.

Tubing dimension (I.D. x O.D. in inches) Data ver: 4.03 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**	**7/16 x 9/16**	**3/8 x 5/8**	**1/2 x 3/4**	**5/8 x 7/8**
BIOPRENE™					+		+			+	+	
C-Flex® 082*	+	+		+	+	+	+	+	+	+	+	+
C-Flex 374*	+		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.*

Change selected tubing type

The selected tubing type is shown on the touchscreen display.

For instructions on how to change the tubing type, refer to *Start instrument and set tubing brand and dimension, on page 48*.

Update tubing types

To replace the factory loaded tubing types or to add the ReadyToProcess tube sizes, refer to the *STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER Tube Data Management Tool User Manual* that is supplied with an installation kit (available upon request).

7.3 Compatible tubing for HOT LIPS TUBE SEALER

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.*

Change selected tubing type

For instructions on how to change the tubing type, refer to *Sealing tubes, on page 56*.

Update tubing types

To add the ReadyToProcess tube sizes, refer to the *STERILE TUBE FUSER - DRY and HOT LIPS TUBE SEALER Tube Data Management Tool User Manual* that is supplied with an installation kit (available upon request).

7.4 Blade contact materials for STERILE TUBE FUSER - DRY

The cutting blade is made of a special Nichrome alloy (NiCrA) that has the required electrical characteristics for resistance heating.

The tubing is in contact with a black polytetrafluoroethylene (PTFE) coating only. This coating is applied at high temperature and is suitable for food contact applications. The coating ensures minimal adhesion to the tubing during the welding and cutting cycle. This improves the quality of the weld and results in minimal smearing. The inert nature of the coating also eliminates any potential contamination.

The black, reflection-free coating also improves the infra-red emissivity of the blade making it possible to accurately estimate blade temperature with non-contact infrared sensors.

More information about the coating material may be required for cGMP validation. Please contact our Customer Service department and ask for non-disclosure forms.

NOTICE

Only use PTFE coated cutting blades (BLADES-IR/50) specified for use with STERILE TUBE FUSER - DRY. For optimal use, do not reuse blades.

7.5 Further information

For more details on ordering information and for information about spare parts and accessories, visit www.gelifesciences.com/bioprocess or contact your local GE representative.

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

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