



# User Manual

## SYMS III Sealing Machine

### for CBS™ High Security straws, CBS™ High Security tubes and CBS™ High Security vitrification straws

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**Read this manual thoroughly before using the SYMS III**

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# Contents

## Contents

<b>SYMS III sealing machine .....</b>	<b>1</b>
<b>1 Warnings and precautions for use.....</b>	<b>4</b>
<b>2 Introduction.....</b>	<b>5</b>
2.1 Indication .....	5
2.2 List of symbols .....	5
2.3 Contraindications and side effects.....	6
2.4 Protection and safety .....	7
2.5 Installation safety requirements .....	7
Installation .....	7
Warning.....	7
2.6 Transportation and storage .....	7
<b>3 SYMS III.....</b>	<b>8</b>
3.1 Overview.....	8
3.2 Sealing station .....	9
3.3 Protective cover.....	10
3.4 Touch screen control .....	10
3.5 Holders .....	11
CBS™ straw holder (removable).....	11
CBS™ tube holder.....	11
<b>4 Initial commissioning .....</b>	<b>12</b>
4.1 Sealing machine Installation.....	12
Electrical connection.....	12
Holder installation.....	12
Switching on the machine.....	13
4.2 Access to settings .....	14
Audio setting.....	15
Setting the language .....	15
<b>5 Operating procedure .....</b>	<b>16</b>
5.1 Manual mode.....	16
CBS™ High Security straws .....	16
CBS High Security tube.....	17
CBS™ High Security Vitrification Straw .....	17
5.2 Automatic mode.....	18
CBS™ High Security straws .....	18
CBS™ High Security tube.....	19
CBS™ High Security vitrification straw .....	19
5.3 Temperature holding and cooling time .....	20
<b>6 Care and Maintenance.....</b>	<b>21</b>
6.1 Jaw cleaning .....	21

- 6.2 Maintenance.....23
- 6.3 Accessories and spare parts .....23
  - 6.3.1 Accessories..... 23
  - 6.3.2 Spare part required ..... 23
- 6.4 Changing the jaws .....23
- 7 Risk management ..... 25
  - 7.1 Jaw cleaning .....25
  - 7.2 Opening the cover .....25
  - 7.3 System error .....26
    - Jaw centering ..... 26
- 8 Technical specifications ..... 27
  - 8.1 General characteristics .....27
  - 8.2 Operating conditions.....27
  - 8.3 Power supply .....27
- 9 Important information..... 28
  - 9.1 Order.....28
  - 9.2 Terms of Warranty for New Equipment.....28
  - 9.3 Disclaimer .....28
  - 9.4 Contact .....28

# 1 Warnings and precautions for use

Before use, we recommend the following:

- Please read this user manual carefully, as it is designed to help you get to know the SYMS III sealing machine and ensure your complete satisfaction,
- Before using the machine for the first time, visually check its overall condition, the presence of the spare parts mentioned in paragraph 6.3 and the holders, and its functionality

This user manual presents the individual components of the sealing machine as well as the part numbers, which are required when ordering spare parts (see section 6.3 Accessories and Spare parts).

The SYMS III sealing machine must be used exclusively for sealing the following CRYO BIO SYSTEM products:

- Sterile products:
  - 0.3 and 0.5 ml CBS™ High Security straws
  - CBS™ High Security tubes
  - CBS™ High Security straws.
- Non-sterile products:
  - 0.3 and 0.5 ml CBS™ High Security straws
  - CBS™ High Security tubes.

Only the systematic use of the appropriate filling nozzles for the 0.3 and 0.5 ml CBS™ High Security straws and application of Cryo Bio System's recommendations for the use of the CBS™ High Security tube, the High Security Vitrification straw guarantee the sealing of products sealed with the SYMS III sealing machine.

Please refer to the following instructions for the products to be sealed

- IFU-000018 Sterile CBS™ High Security Tube
- IFU-000012 CBS™ High Security Vitrification Straw
- IFU-000010 CBS™ High Security Straw (semen)
- IFU-000013 CBS™ High Security Straw (embryo and semen)
- IFU-000254 Non-sterile CBS™ High Security Tube

The tightness of the seal for all CBS™ High Security products listed above, is guaranteed by three key sealing parameters adapted to their constituent material: temperature, intensity and duration of pressure between the two SYMS III jaws.

Caution, the inside and outside of the sealing area of CBS™ High Security products must always remain clean and dry.

The seal substrate must be suitable for the product to be sealed (see 3.5 Substrates).

Do not operate the vacuum sealer (without the presence of CBS™ High Security straw, CBS™ High Security tube or CBS™ High Security Vitrification Straw ).

Adhere to the safety indications on the nameplate. Install the sealing machine on a level and steady surface.














## 2 Introduction

### 2.1 Indication

The SYMS III sealing machine is a medical device accessory that can be used in an MSC hood and is intended to seal, by a "thermal" process, CBS™ High Security straws 0.3 ml, 0.5 ml, CBS™ High Security tubes as well as CBS™ High Security Vitrification straws in applications such as:

- Epidemiological research departments
- Biological material banks
- Serum libraries
- Cell and gene therapy units
- Pharmaceutical companies producing vaccines (live cells)
- Conservatories of genetic heritage (animal, plant, microbiological)
- Reproductive biology laboratories
- Gamete and gonadal tissue banks.

### 2.2 List of symbols

LOGO	Description
	Device catalog number
	Device serial number
	"ON" button (power connection)
	"OFF" button (power disconnection)
	Manufacturer's name and address
	Manufacturing date
	Class I CE-marked medical device
	Read the manual carefully prior to use
	Fragile, handle with care
	Observe the direction of the arrows for the packaged device during transport or storage.
	Keep the device packed when transporting or storing it away from rain and in a dry place.
	Electrical and electronic devices are collected separately
	Respect the temperature limits for storage and transport

### **2.3 *Contraindications and side effects***

No contraindications or residual adverse effects or risks identified with the use of SYMS III.

Any serious incident related to the device should be reported to CBS at the following address: [materiovigilance@imv-technologies.com](mailto:materiovigilance@imv-technologies.com) and to the competent authority of the Member State in which the user is established.

## **2.4 Protection and Safety**

- SYMS III is a Class I medical device accessory according to Regulation (EU) 2017/745
- Electrical protection class: Class II product
- Degree of pollution 2.

## **2.5 Installation safety requirements**

### **Installation**

The equipment has to be connected to a suitably earthed and conforming electrical system (NFC 15-100 for France).

The SYMS III sealing machine is powered with low voltage by means of an external electrical supply system. Voltage and frequency must be compliant with the indications on the nameplate.

The power cord must be in perfect condition. In the event of visible defects, immediately disconnect the sealing machine from the mains supply. Have the cord replaced by a specialist or contact Cryo Bio System' customer service.

### **Warning**

The pressing and sealing time characteristics are invariable settings must not be changed by the user under any circumstances.

For any use not in accordance with the recommendations in this manual, the safety of the device may not be guaranteed.

The equipment must not be opened.

Any electrical changes and/or repair work must be carried out by a qualified professional and supervised by a technician working for Cryo Bio System After-Sales Service.

## **2.6 Transportation and Storage**

Disconnect the machine from the mains supply.

The device and accessories must be stored and transported in the original packaging to avoid any damage.

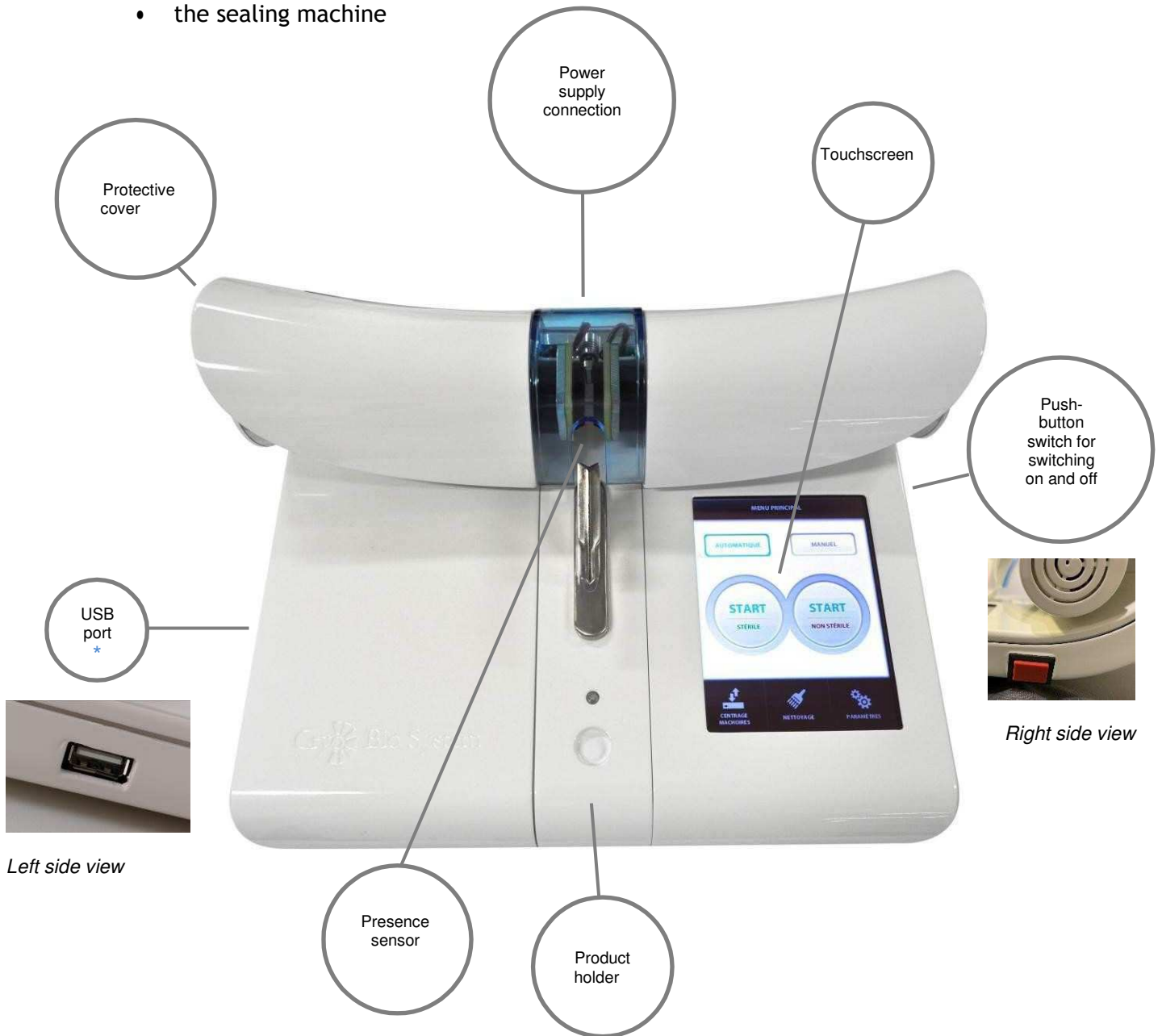
Store the device in a dry place between 5 and 30°C and humidity <80%. Avoid impacts and shocks when transporting the SYMS III.

## 3 SYMS III

### 3.1 Overview

The SYMS III unit is composed of:

- the sealing machine



\* Only used for a software update. Any use, without a specific information notice from Cryo Bio System, is forbidden.



- An external power supply with a power cord.



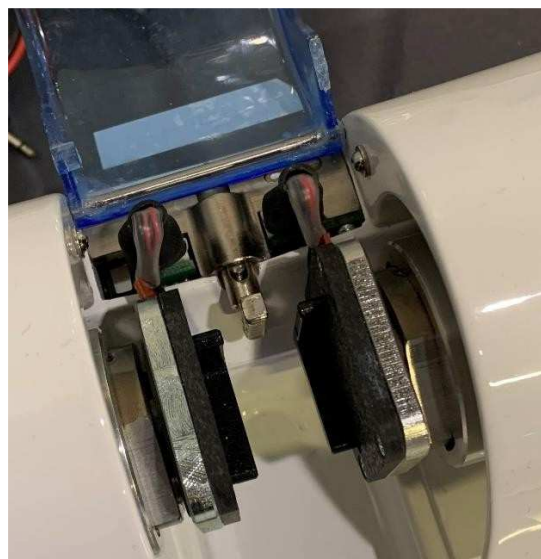
The mains plug must comply with the legislation of the country in which the device is marketed.

### 3.2 Sealing station

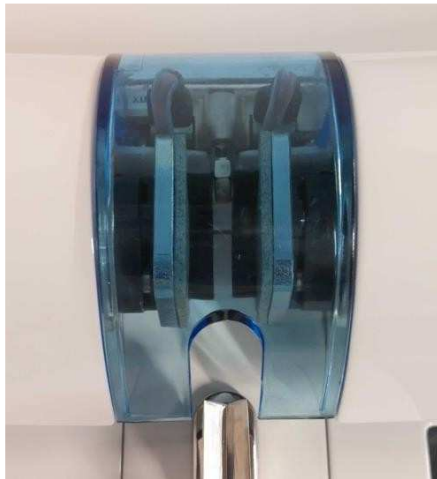
Front view



Top view

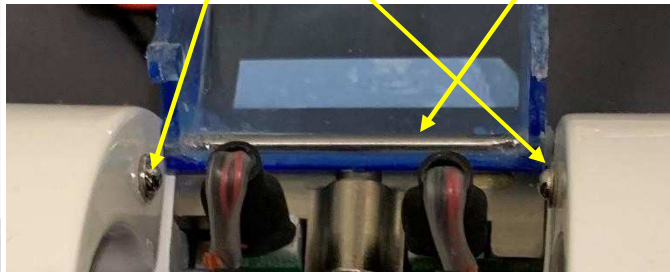


### 3.3 Protective cover



The safety cover pivots on a stainless steel shaft that cannot be removed.

2 locks to keep the cover closed



When the SYMS III sealing machine is in operation, opening the protective cover immediately causes an audible signal to be emitted, a warning message to be displayed on the touch screen and the machine to be switched off.

**Caution:** Do not touch the jaws and/or connectors when the cover is open.

### 3.4 Touch screen control

The "MAIN MENU" has three areas:

1. Sealing modes
  - Automatic
  - Manuel

*The selected mode remains highlighted.*
2. Status of solder containers
  - Sterile products
  - Non-sterile products
3. Handling and parameters
  - Jaw centering
  - Cleaning
  - Settings



### 3.5 Holders

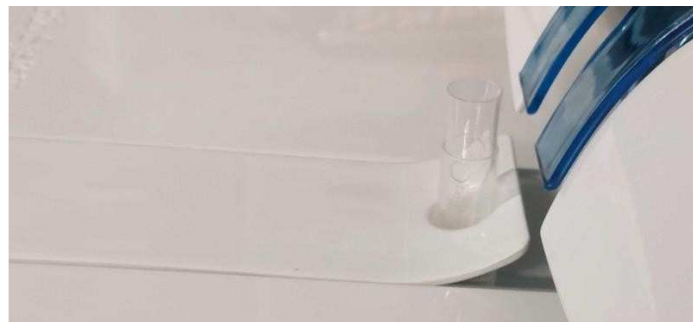
Two types of holder are delivered with the SYMS III sealing machine to ensure optimal sealing of all products offered by Cryo Bio System:

- CBS™ straw holder for 0.3 and 0.5 ml CBS™ High Security straws and for CBS™ High Security vitrification straws
- CBS™ tube holder for CBS™ High Security tubes.

#### CBS™ straw holder (removable)



#### CBS™ tube holder



## 4 Initial Commissioning

Reminder:

The SYMS III sealing machine is set up to seal only the sterile and non-sterile CBS™ High Security products specified on page 4.

### 4.1 *Sealing machine Installation*

#### Electrical Connection

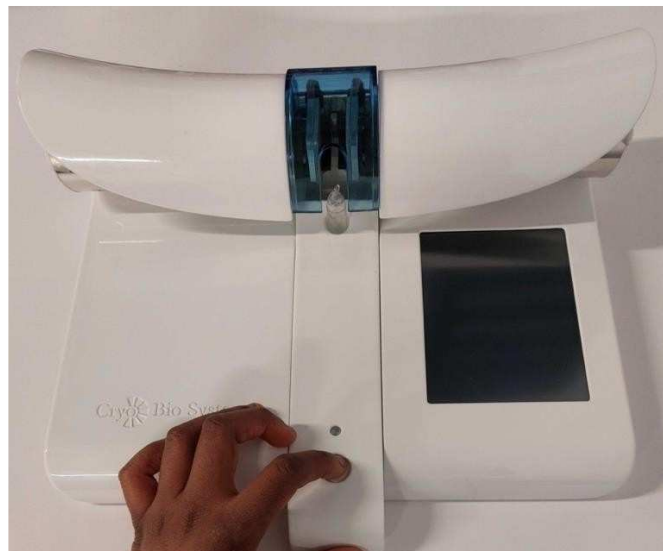
Connect the power supply by connecting:

- Mains connection
- The 4-pin connector on the back of the sealing machine.



#### Holder installation

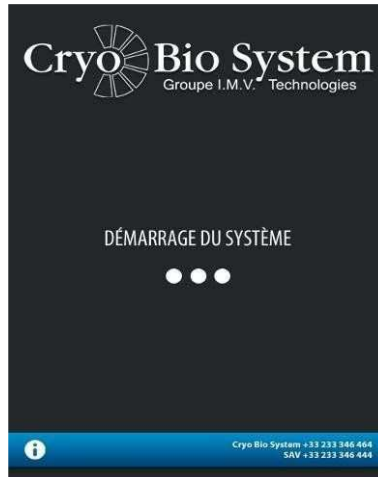
Place the CBS™ straw holder or CBS™ tube holder corresponding to the type of product to be sealed.



Make sure the equipment is on a stable work surface.

## Switching on the machine

A short press on the red push button enables the power to be switched on. The following screen appears for about 3 seconds:



The next screen offers the possibility to clean the jaws:



At each start-up, make sure that the sealing jaws are clean and show no trace of biological samples or visible wear (L-shaped part of each jaw). The choice on the first start-up screen depends on this visual check.

If cleaning is required following the user's visual check, select "YES" and the following screens will appear in sequence:

- "CLEANING"
- "MAIN MENU"



See section 6.1 "Cleaning the jaws".

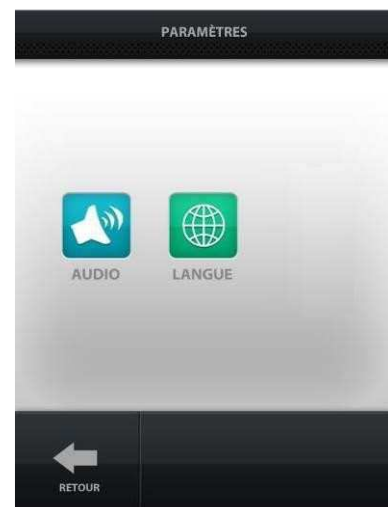
If no cleaning is required following the user's visual check, select "NO" and the "MAIN MENU" will appear:



## 4.2 Access to settings

The "SETTINGS" menu contains the standard settings:

- Audio
- Language
- Back



## Audio setting

By default, audible signals are enabled. These alerts can be disabled by selecting the "SETTINGS" menu in the "MAIN MENU", then "AUDIO".



## Setting the language

By default, the touch screen menus are displayed in French. The language can be changed by selecting the "SETTINGS" sub-menu of the main menu, then "LANGUAGE". Four languages are then available: English, French, Spanish and Chinese; plus an optional factory loaded language from among the following: Italian, German, Portuguese, and Russian.



## 5 Operating procedure

*Preamble:* After each seal, the jaws are automatically re-centered (moved back and forth).

**Caution:** Do not touch the jaws and/or connectors when the cover is open.

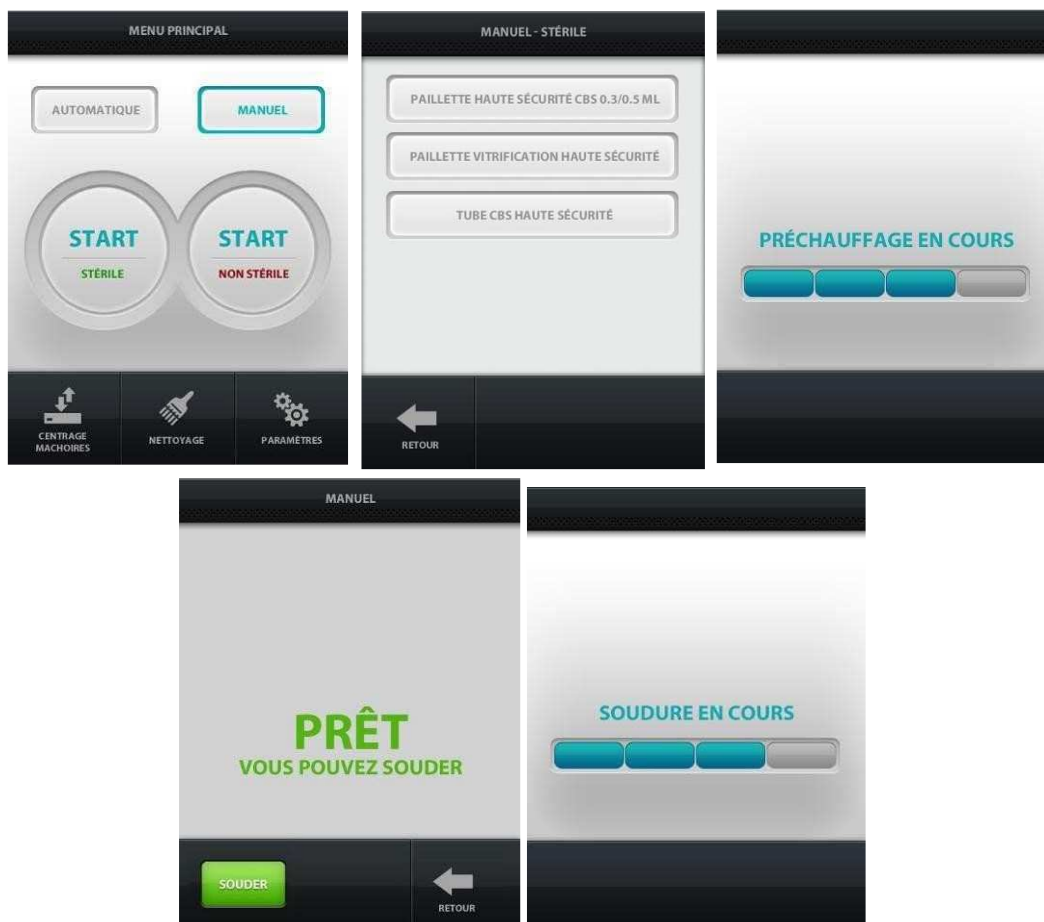
### 5.1 Manual mode

Manual sealing is carried out as soon as two conditions are met:

- The presence sensor must detect a container (CBS™ High Security products specified on page 3)
- The operator must press the "SEAL" button.

#### CBS™ High Security straws

1. Select "MANUAL" in the main menu
2. Select "**STERILE**" or "**NON-STERILE**"
3. Select the type of CBS™ High Security straws to be sealed
4. Wait for the warm-up time
5. The "Ready to seal" screen appears
6. Place the product on the appropriate holder
7. Slide it until it actually touches the sensor
8. Press "SEAL"
9. Proceed in the same way to seal the other end of the straw (steps 6 to 8).





## CBS High Security tube

Proceed as for the CBS™ High Security straw by selecting "CBS High Security tube" in step 3 and using the appropriate holder for the CBS™ High Security tube in step 6.

## CBS™ High Security vitrification straw

Proceed as for the CBS™ High Security straw by selecting "CBS™ High Security vitrification straw" in step 3.

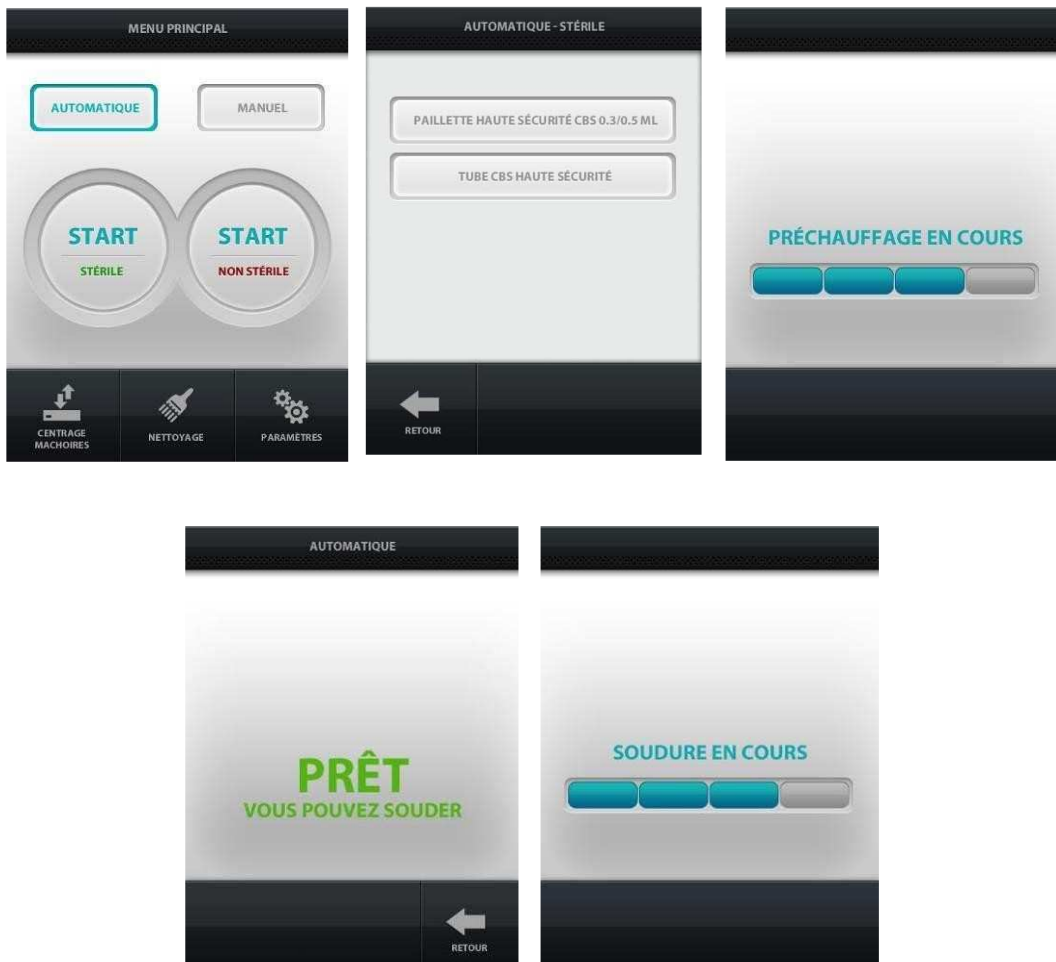
→ **Caution:** the CBS™ High Security vitrification straw can only be sealed in "MANUAL" and "STERILE" mode

## 5.2 Automatic mode

The automatic sealing process starts as soon as the presence sensor detects one of the containers compatible with the SYMS III sealing machine.

### CBS™ High Security straws

1. Select "AUTOMATIC" in the main menu
2. Select "**STERILE**" or "**NON-STERILE**"
3. Select the type of CBS™ High Security straws to be sealed
4. Wait for the warm-up time
5. The "Ready to seal" screen appears
6. Place the product on the appropriate holder
7. Apply the product against the detector
8. The product is automatically sealed
9. Proceed in the same way to seal the other end of the straw (steps 6 to 8).



### **CBS High Security tube**

Proceed as for the CBS™ High Security straw by selecting "CBS High Security tube" in step 3 and using the appropriate holder for the CBS™ High Security tube in step 6.

### **CBS™ High Security vitrification straw**

**Automatic mode not operational for this product.**

### ***5.3 Temperature holding and cooling time***

The following data is given as an indication and was measured when using the SYMS III device at an ambient temperature of 20°C.

<b>Data</b>	<b>Time</b>
Jaw holding time at temperature before switching off	About 30 minutes
Cooling time of jaws to 39°C	About 25 minutes

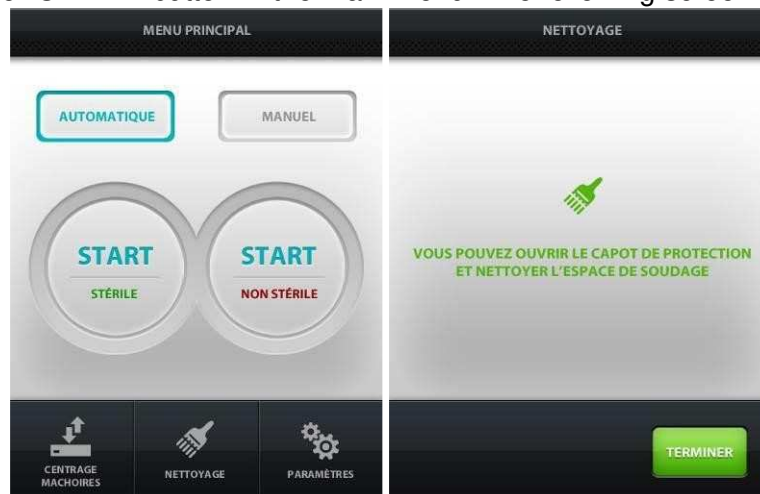
## 6 Care and Maintenance

### 6.1 *Jaw cleaning*

Regular cleaning of the sealing jaws is recommended, particularly following accidental soiling during the sealing operation for CBS™ High Security straws, CBS™ High Security vitrification straws and CBS™ High Security tube.

The "CLEANING" function allows the jaws to be held apart for cleaning.

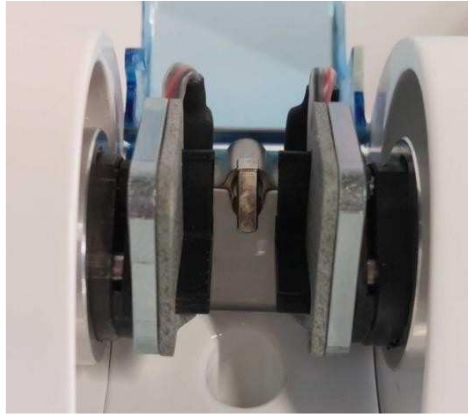
1. Select the "CLEAN" button in the main menu. The following screen is displayed:



2. Switch off the power to the equipment
3. Open the protective cover



4. Clean the jaws with a cotton swab soaked in distilled water or alcohol
5. Dry with a cotton swab or a dry cloth



6. Close the protective cover
7. Switch the equipment back on (jaws reposition)



## 6.2 Maintenance

Apart from the sealing jaws, the main mechanical and electrical parts of the SYMS III sealing machine require no special maintenance.

**Reminder:** Only an authorized Cryo Bio System Specialist or Cryo Bio System Technician is authorized to perform repairs on the SYMS III sealing machine.

## 6.3 Accessories and Spare parts

### 6.3.1 Accessories

Description	Reference	Indication and method of replacement
CBS™ straw and CBS™ High Security vitrification straw holder	025590	Components to hold the sealing device and ensure an optimal seal. Refer to section 4 to replace them.
CBS™ tube holder	025591	

### 6.3.2 Spare parts

Description	Reference	Indication and method of replacement
Sealing jaw assembly	026550	Component that ensures the sealing. Refer to paragraph 6.4 to replace it.

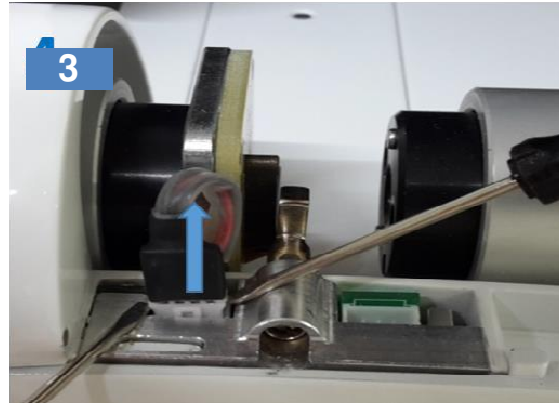
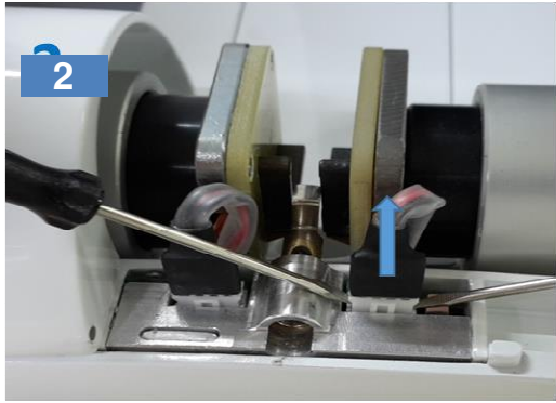
## 6.4 Changing the jaws

The jaws have a minimum service life of 3,000 sealing operations. Once this threshold is reached, you must replace them in order to guarantee the quality of the seal by following the procedure below:

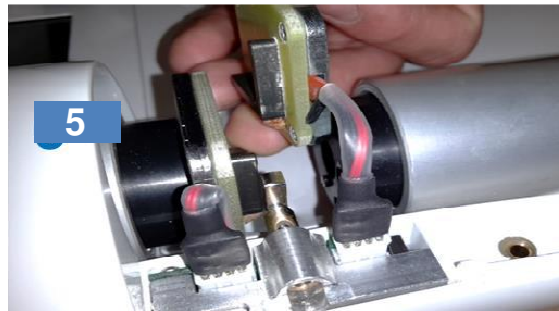
1. Open the protective cover



2. Lift the first connector, holding its base (with a finger or a screwdriver), then remove the jaw.
3. Lift the second connector, holding its base (with a finger or a screwdriver), then remove the jaw.



4. Insert the first connector of the new jaw with locator and fit the jaw into place.
5. Insert the second connector of the other new jaw with locator and fit the jaw into place.



6. Close the protective cover



7. Switch the equipment back on (jaws reposition)

In case of premature degradation, contact Cryo Bio System Customer Service.



## 7 Risk management

### 7.1 *Jaw cleaning*

The jaws can only be cleaned if the jaw temperature is below 40°C in order to avoid any burns.



### 7.2 *Opening the cover*



As soon as the protective cover is opened, a warning screen appears and a continuous "beep" is heard. Once the cover is closed, the "MAIN MENU" appears.

### 7.3 System error



In the event of a system error, a warning screen will appear and 3 beeps will sound every 2 minutes. The sealing machine locks automatically.

Restart the sealing machine.

If the alert persists, contact Cryo Bio System's Technical Service (+33 2 33 346 444).

#### **Jaw centering**

Pressing the touch button at the bottom left of the "Main Menu" screen, checks the correct centering of the jaws in relation to the straw/tube holder and the presence sensor.

## **8 Technical specifications**

### **8.1 *General Characteristics***

- Dimensions  
Length: 335 mm  
Width: 250 mm  
Height: 105 mm
- Weight: 3.3 kg.

### **8.2 *Operating Conditions***

- Indoor use at room temperature
- Operating environment: the device must not be used at altitudes above 2,000 m, nor in explosive or corrosive atmospheres.

### **8.3 *Power Supply***

External power supply:

Supply voltage: 100 - 240 V Supply  
frequency: 50 - 60 Hz Rated power  
consumption: 120 W max  
12 V output with a 4-pin mini DIN connector

Sealing unit

Voltage: 12 - 15 V

## 9 Important Information

### 9.1 Order

For spare part orders, please refer to the paragraph: “6.3 Accessories and Spare Parts” of this manual.

### 9.2 Terms of Warranty for New Equipment

Cryo Bio System warrants its equipment to be free of defects in materials, workmanship or design for a period of one year, running from the date stated on the certificate of warranty. Parts and labor are free of charge during this period.

Defects must occur within twelve months from the warranty's effective date, and subject to the equipment being used in keeping with the user manual.

The warranty is voided in the following cases:

- if the defect arises from an unauthorized operation on the equipment
- if the defect arises from improper use respective to the technical specifications and user manual
- if the malfunction is caused by force majeure.

In virtue of the above, Cryo Bio System accepts to repair or replace any parts that can no longer be used for reasons attributable to the company throughout the period of warranty.

The application of this warranty, namely total or partial repair and replacement of the equipment delivered, will not extend the period of warranty.


Disputes arising from the interpretation and/or execution of the terms of warranty are governed by French law. The competent court is the Court of Alençon, including in the event of third party appeals and multiple respondents.

### 9.3 Disclaimer

Cryo Bio System accepts no responsibility for any damage caused by external influences, as well as inappropriate operations and usage that do not fall within the recommendations set out in this user manual.

Please refer to the application areas (see 2.1 Applications, 3.3 Protective cover, 5 Operating mode, 6. 1 Jaw cleaning) and the electrical specifications (see 8.3 Power supply) in this manual.

### 9.4 Contact

 Cryo Bio System  
ZI n°1 Est 61300 Saint Ouen sur Iton - France  
Tel. +33 (0)233 346 464  
Fax +33 (0)233 341 198  
Customer service tel. +33 (0)233 346 444  
Fax. Customer Service +33 (0)233  
341 198 [contact@cryobiosystem-  
imv.com](mailto:contact@cryobiosystem-imv.com)



Decree No. 2012-617 of 2 May 2012 on the management of waste batteries and accumulators and electrical and electronic equipment

Date first put on the EU market: 01/2015.

Notes: