



User manual

SYMS III sealer

for CBS™ High Security straws, CBS™ High Security tubes
and CBS™ High Security Vitrification Straw

Edition: 07/05/2019

Read this manual carefully before using SYMS III

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1 Foreword

Before using, we recommend that you read these operating instructions carefully in order to familiarize yourself with the SYMS III sealer and obtain total satisfaction.

These operating instructions present the sealer's various components as well as their item numbers, essential for ordering spare parts (see 6.2 Spare Parts and Accessories).

The SYMS III sealer cannot be used to seal any products other than those specified on the list below:

- Sterile products:
 - CBS™ High Security 0.3 ml and 0.5 ml straws,
 - CBS™ High Security 2 ml straws,
 - CBS™ High Security tubes,
 - CBS™ High Security vitrification straws.
- Non-sterile products:
 - CBS™ High Security 0.3 ml and 0.5 ml straws,
 - Co-X High Security 0.3 ml and 0.5 ml straws,
 - CBS™ High Security tubes.

To guarantee the seal integrity of products sealed with the SYMS III, only use filling nozzles and tips specifically designed for use with CBS™ High Security 0.3 and 0.5 ml straws, and follow Cryo Bio System's recommendations for using the CBS™ High Security tube, HSV High Security Vitrification Kit and CBS™ High Security 2 ml tissue straw.

Please refer to below notices for products to be sealed by the product:

- IFU-000018 Sterile Tube CBS™
- IFU-000012 Sterile Vitrification Straw VHS CBS™
- IFU-000010 Sterile Sperm Straw CBS™
- IFU-000013 Sterile Embryo and Sperm Straw CBS™
- IFU-000016 Sterile Tissu CBS™
- IFU-000254 Non Sterile Tube CBS™
- IFU-000011 Non Sterile Co-X Straw

Caution: Only products at room temperature can be sealed with the SYMS III sealer.












2 Introduction

2.1 Applications

The SYMS III sealer is a benchtop active medical device that can be used under a laminar flow cabinet. It uses a thermal process to seal CBS™ High Security 0.3 ml, 0.5 ml and 2 ml straws, CBS™ High Security tubes as well as CBS™ High Security Vitrification straws in applications related to:

- Epidemiological research departments
- Biobanks
- Serum banks
- Cellular and gene therapy units
- Vaccine-manufacturing pharmaceutical companies (living cells)
- Gene banks (animal, vegetal, microbiological)
- Reproductive biology laboratories
- Gamete and gonadal tissue banks.

2.2 Liste des symboles

LOGO	Référence ISO	Désignation
	ISO 7000-2493	Device catalog number
	ISO 7000-2498	Device serial number
	ISO 7000-5007	'ON' Button (power connection)
	ISO 7000-5007	'OFF' Button (power disconnection)
	ISO 7000-3082	Name and address of manufacturer
	ISO 7000-2497	Manufacturing date (JJ-MM-AAAA)
	Annex XII 93/42/CEE directive	EC Class I medical device
	ISO 7000-M002	Notice must be read before use
	ISO 7000-0621	Fragile, manipuler avec soin
	ISO 7000-0623	Keep package in this way up during storage or transport
	ISO 7000-0626	Keep package away from rain, and in a dry conditions during storage and transport.
	Annex IX of DEEE 2012/19/UE directive	This EE device is subject to separate collection

2.2 Protection and Safety

- SYMS III is a class I medical device in compliance with 93/42/EEC directive.
- Electrical Protective Class: Class I product requiring installation with properly protected earth connection.
- Pollution degree 2.

2.3 Setup Safety Requirements

Setup

Safe use of this unit requires its connection to a grounded, compliant electrical source. The SYMS III sealer is powered by a low voltage external power supply. The voltage and frequency must comply with the instructions in the rating plate. The power cable must be in perfect condition. If the cable looks damaged in any way, turn off the power supply to the sealer immediately. Call a specialist to replace the cable or contact the Cryo Bio System Technical Service Department.

Cautionary note

Sealing and press time specifications must never be modified by the user under any circumstances.

Failure to obey the recommendations of these operating instructions may compromise the protection provided by the equipment.

The device must not be opened.

Any change and/or electrical repairs may only be carried out by a qualified individual under the supervision of a Cryo Bio System technician.

Recommendations

The seal integrity of all CBS™ High Security Products listed on page 3 is guaranteed thanks to three key sealing settings specifically adapted to the products' constituent materials: the temperature, force and pressure time between the two SYMS III jaws. Caution: The area in and around the CBS™ High Security product sealing area must be kept clean and dry.

The sealing support must be adapted to the product to be sealed (see 3.5 Supports).

Do not operate the sealer when empty (without a CBS™ High Security Straw, CBS™ High Security Tube or HSV High Security Vitrification Straw present).

Follow the safety instructions on the rating plate.

Make sure the sealer is mounted on a flat, stable support.

2.4 Transport and Storage

Unplug the unit from the power source.

Store and transport the unit and its accessories in the original packaging to prevent any damage.

Store the unit in a dry place at a temperature between 5 and 30°C and hygrometry <80%.

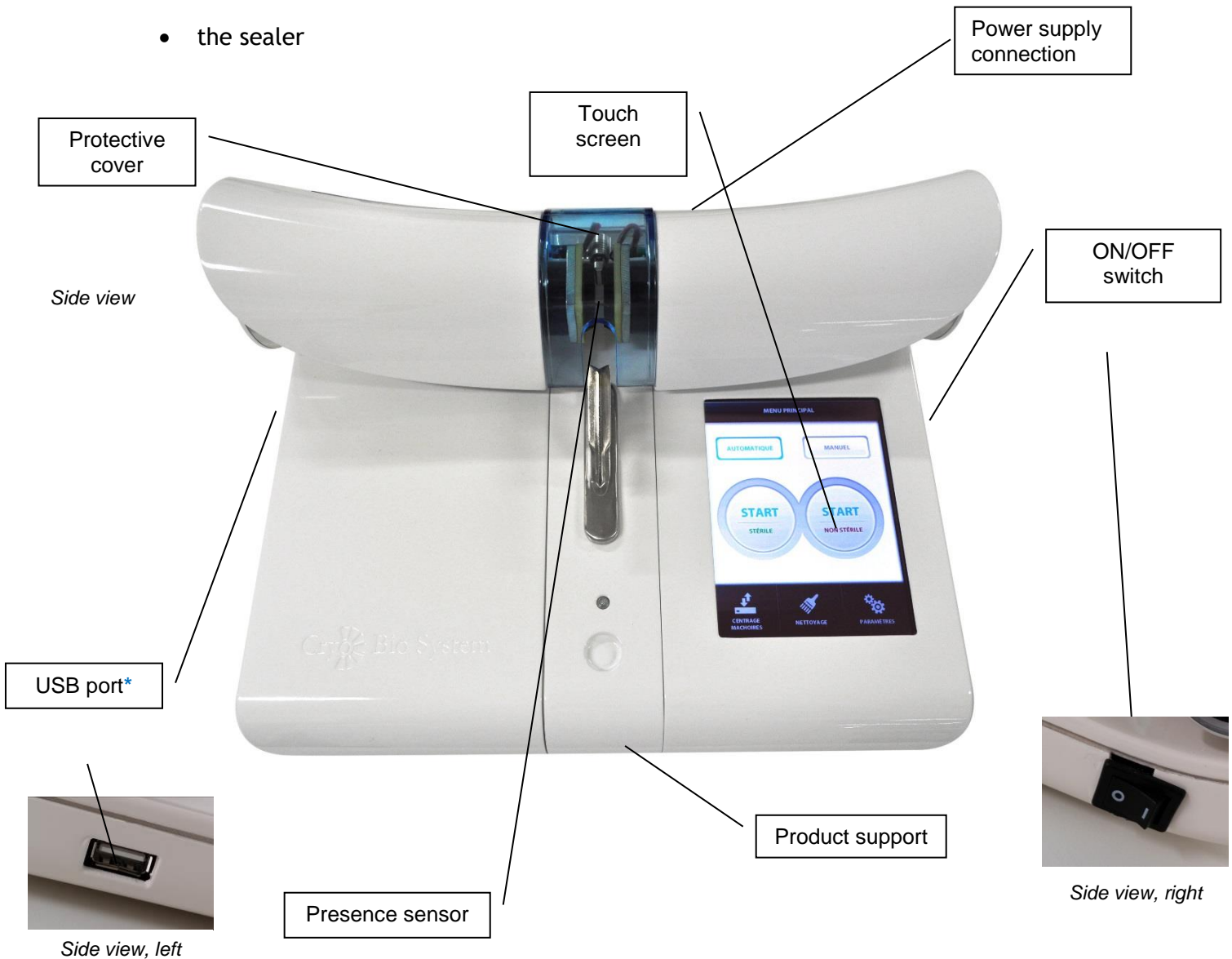
Avoid any shock or jolts while transporting the SYMS III.

3 SYMS III

3.1 Overview

The SYMS III unit consists of the following:

- the sealer



*** Use only for a software update. Any use, without Cryo Bio System's specific information instructions, is forbidden.**

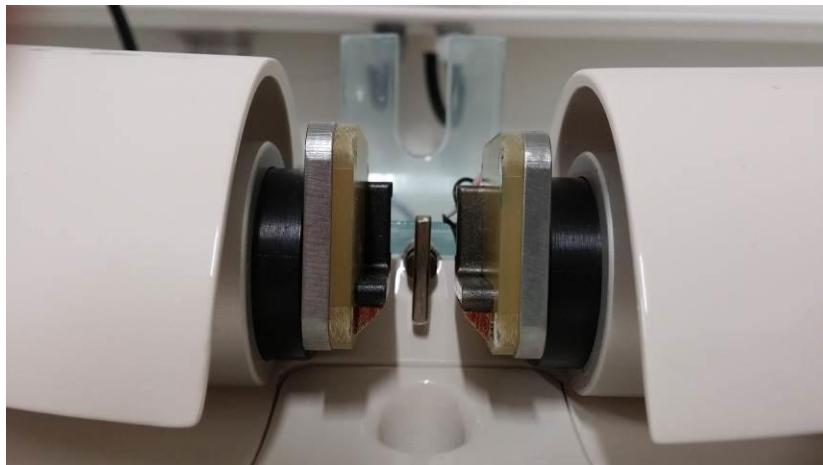
- the external power supply and cord.



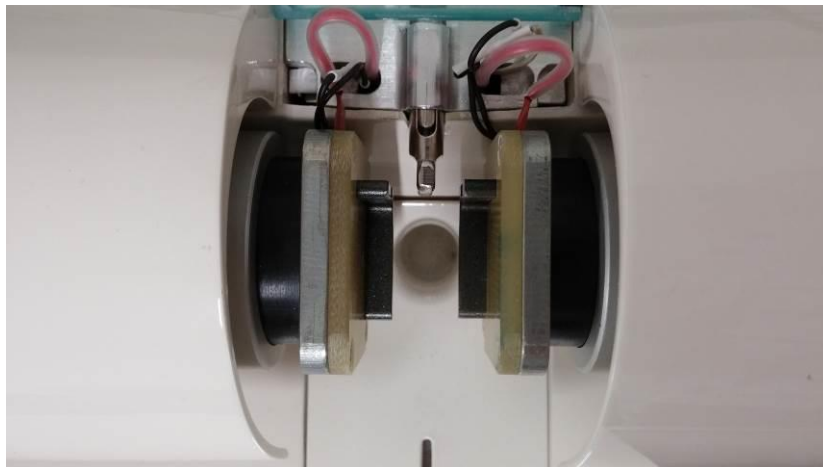
Earth plug must be compliant with the legislation where the device is marketed.

3.2 *Welding unit*

Front view



Top view



3.3 Protective cover



When the SYMS III sealer is operating, removing the protective cover will immediately trigger an audible warning signal. An alert message will be displayed on the screen and the unit will shut down.

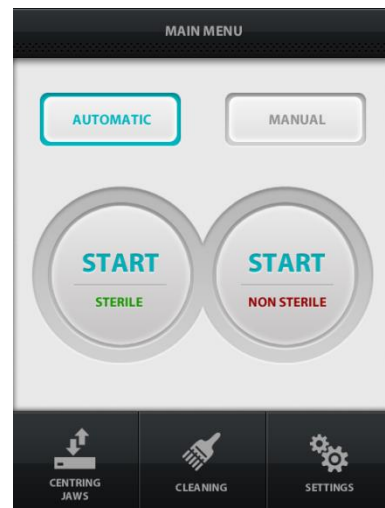
Warning: Do not touch the jaws and/or connectors when the cover is open.

3.4 Controller Touch Screen

The "MAIN MENU" consists of three areas:

1. Sealing Modes
 - Automatic
 - Manual

The selected mode remains highlighted.
2. Sealing containers status
 - Sterile products
 - Non-sterile products
3. Handling and parameters
 - Jaws centring
 - Cleaning
 - Settings



3.5 Supports

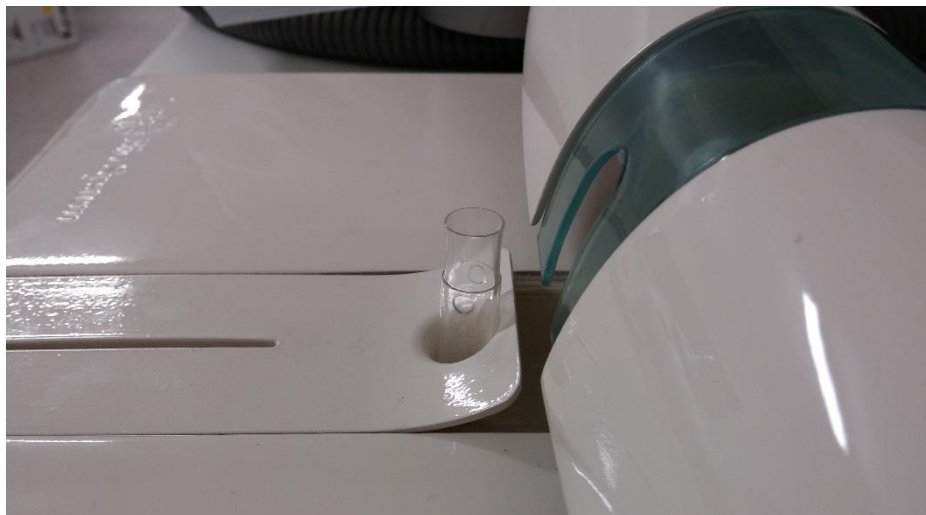
Two types of supports are delivered with the SYMS III sealer to provide optimal sealing of all products offered by Cryo Bio System:

- CBS™ straw support for CBS™ High Security 0.3, 0.5 and 2 ml straws and the HSV High Security Vitrification straw.
- CBS™ Tube Support for CBS™ High Security tube.

CBS™ Straw support (removable)



CBS™ tube support™



4 Initial Startup

Reminder:

The SYMS III sealer is configured solely for sealing CBS™ High Security sterile and non-sterile products (specified on page 3).

4.1 *Sealer Setup*

Electrical Connection

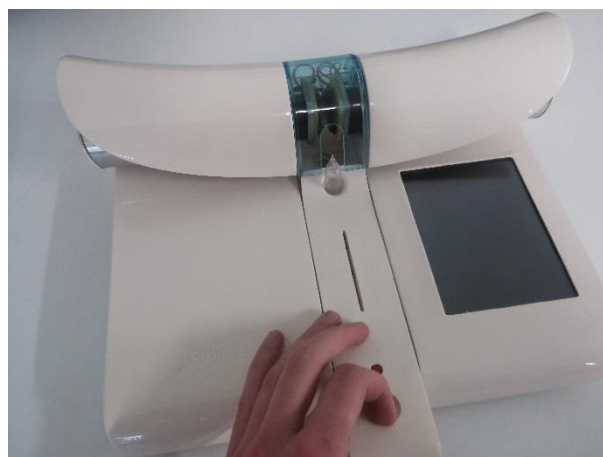
Connect to power supply as follows:

- Connect the plug to the power source
- Connect the 4-pin connector to the back of the sealer.



Positioning the Support

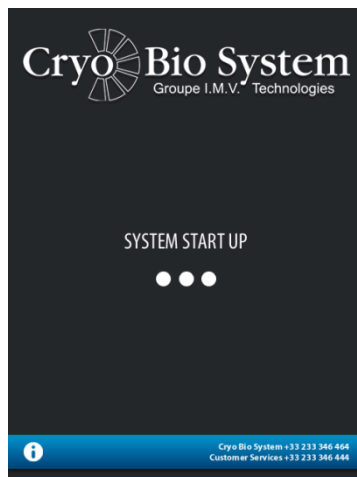
Install either the CBS™ straw and CBS™ High Security Vitrification straw support or the CBS™ tube support, depending on the type of product to be sealed.



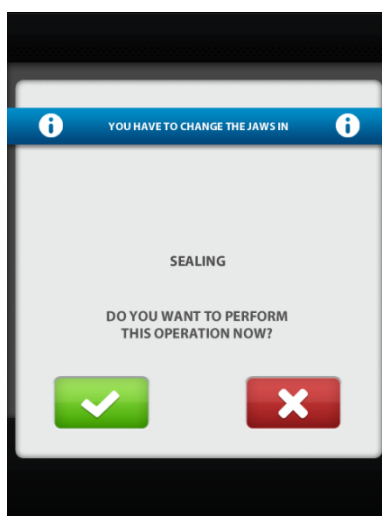
Make sure that the equipment is placed on a steady worktop.

Turning on the Sealer

Switch the ON/OFF button to the "I" position.
The following screen will display for about 3 seconds:

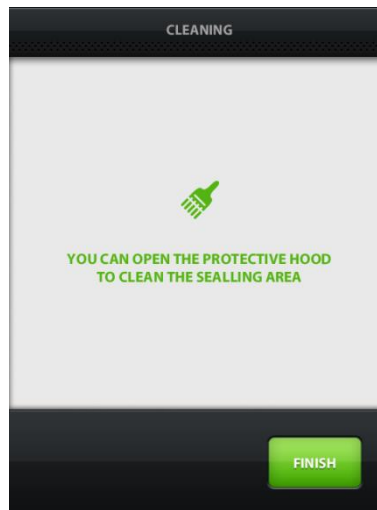


The following screen offers the option of cleaning the jaws:



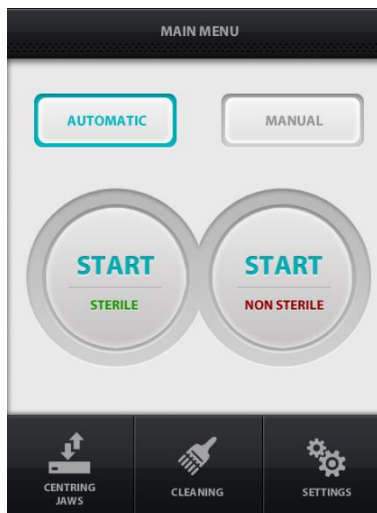
If 'YES' is selected, the following screens will appear in successive order:

- "CLEANING"
- "MAIN MENU"



Cf. Subsection 6.3 “Cleaning the jaws”.

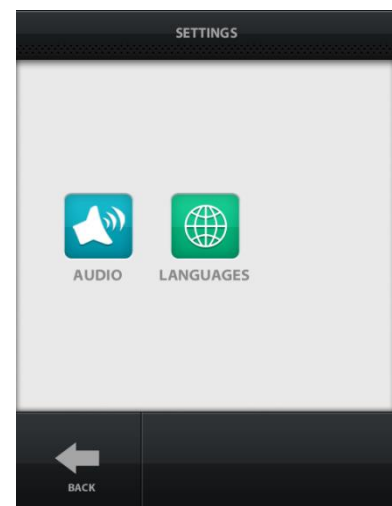
If “NO” is selected, the “MAIN MENU” will appear:



4.2 Settings

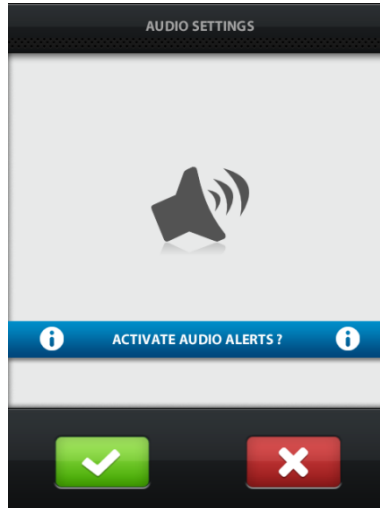
The "SETTINGS" menu groups the standard settings:

- Audio
- Language
- Back



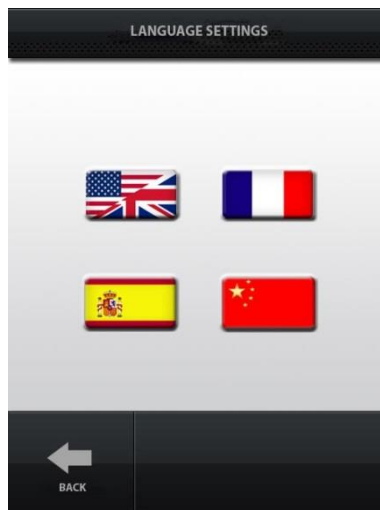
Audio Settings

By default, audible warning signals are turned on. These alerts can be turned off by selecting the "SETTINGS" menu in the "MAIN MENU", then "AUDIO".



Language Settings

By default, the menus on the touch screen are displayed in French. The language can be changed by selecting the "SETTINGS" submenu in the main menu, then "LANGUAGE". Four languages are now available: English, French, Spanish and Chinese. One extra language option from the following list can be added at the factory: Italian, German, Portuguese and Russian.



5 Operating Mode

Preamble: After each sealing operation, the sealing jaws are automatically recentered (recoil and back into position).

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

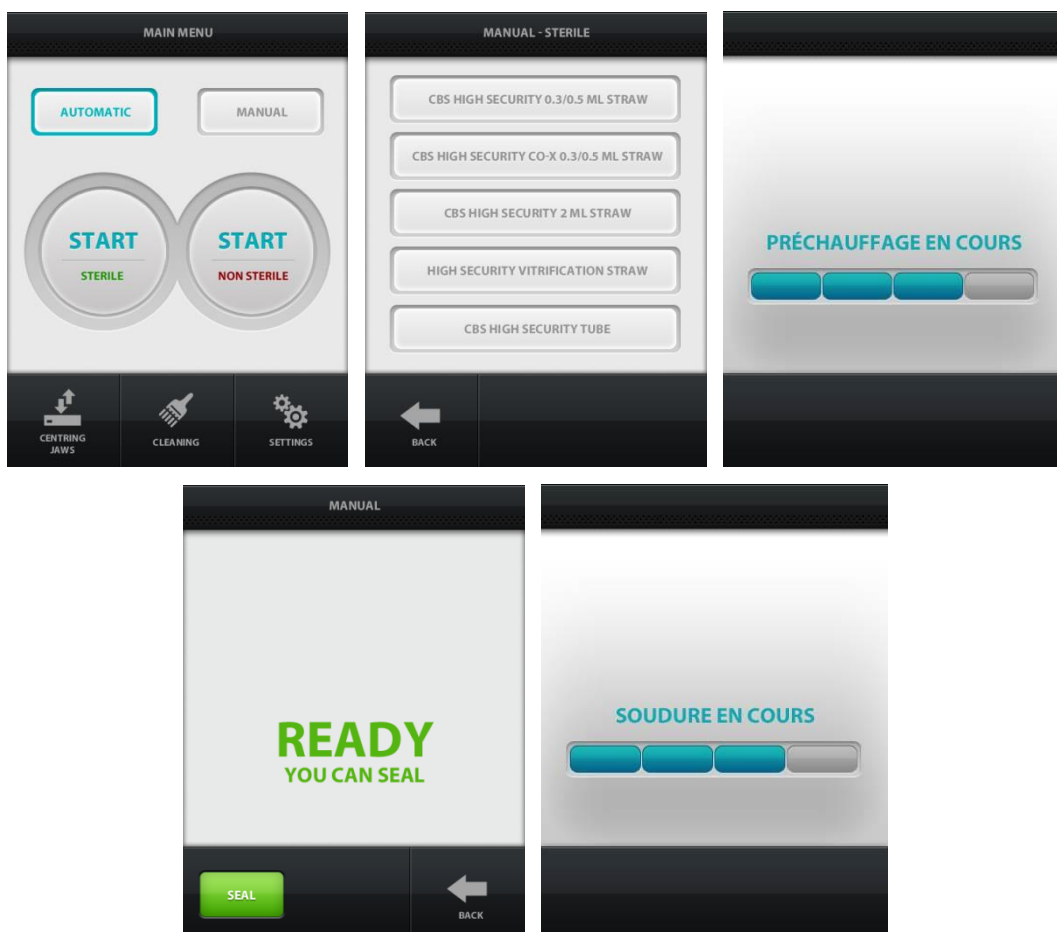
5.1 Manual Mode

Manual sealing can begin once two conditions are met:

- The presence sensor must detect a container (the 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 Straw to be sealed
4. Wait until the preheating is completed
5. Sealing can begin when “READY” appears on the screen
6. Place the product onto the proper support
7. Slide the product forward until it touches the detector
8. Push “SEAL”
9. Repeat the sealing process for the other end of the straw (Steps 6 to 8).



CBS™ High Security Tube

Proceed as with the CBS™ High Security Straw, but select “CBS High Security Tube” in Step 3 and use the support designed for the CBS™ High Security Tube in Step 6.

CBS™ High Security Vitrification Straw

Proceed as with the CBS™ High Security Straw, but select “CBS™ High Security Vitrification Straw” in Step 3.

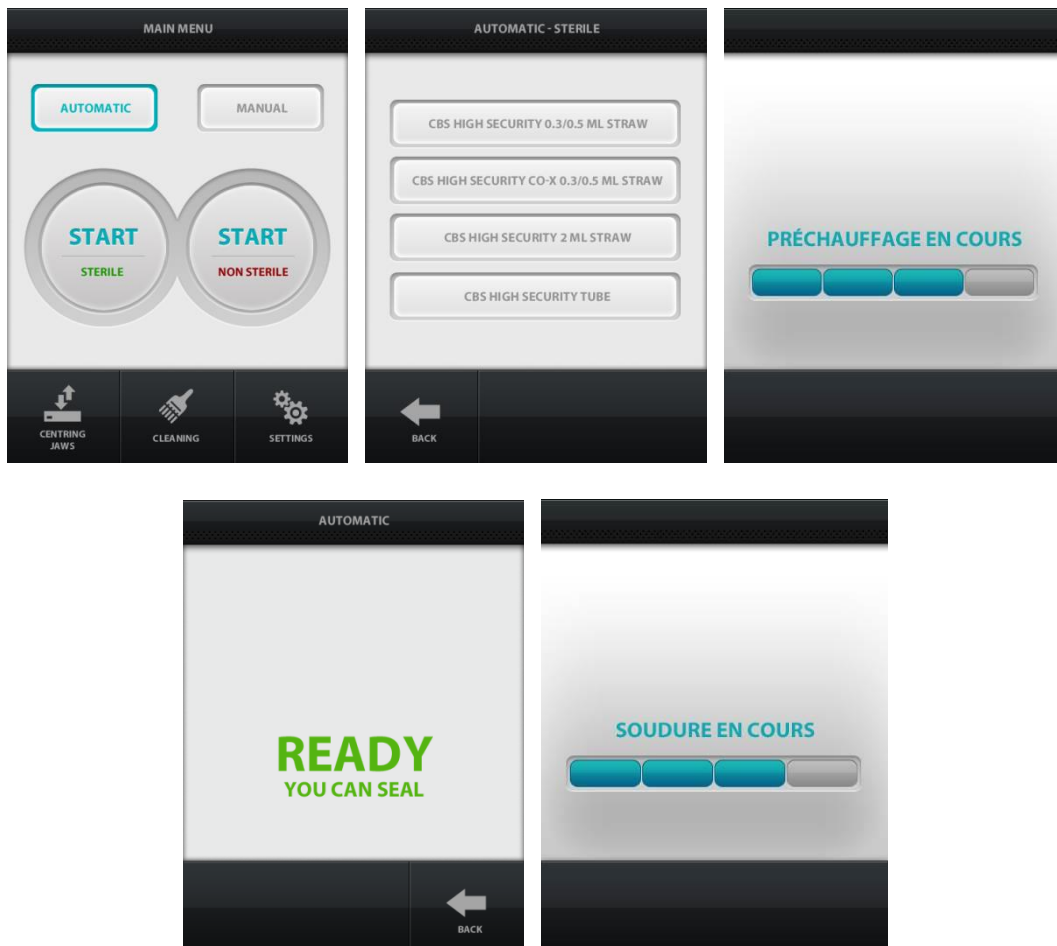
- ➔ **Caution:** the CBS™ High Security Vitrification Straw can only be sealed in “MANUAL” mode with the “STERILE” option selected

5.2 Automatic Mode

Automatic sealing will begin as soon as the presence detector detects one of the containers supported by the SYMS III sealer.

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 Straw to be sealed
4. Wait until the preheating is completed
5. You can begin sealing when “READY” appears on the screen
6. Place the product onto the proper support
7. Place the product up against the sensor
8. The product is sealed automatically
9. Repeat the sealing process for the other end of the straw (Steps 6 to 8).



CBS™ High Security Tube

Proceed as with the CBS™ High Security Straw, but select “CBS High Security Tube” in Step 3 and use the support designed for the CBS™ High Security Tube in Step 6.

CBS™ High Security Vitrification Straw

Automatic Mode will not operate for this product.

5.3 Run-up time and changeover time between modes

The following data are provided for information purposes only and were measured while using the SYMS III unit in an environment with an ambient temperature of 20°C.

Data	Time
Run-up time for HSV Straw	45 seconds
Run-up time for CBS™ Straws	49 seconds
Run-up time for CBS™ Tube	1 minute
HSV Straw/CBS™ Straws changeover time	18 seconds
HSV Straw/CBS™ Tube changeover time	10 seconds
CBS™ Straws/HSV Straw changeover time	4 seconds
CBS™ Tube/HSV Straw changeover time	4 seconds
CBS™ Tube/CBS™ Straws changeover time	4 seconds
CBS™ Straws/ Tube changeover time	4 seconds
Hold time at temperature before standby	30 minutes and 17 seconds
Tube or straw cooling time to 39°C	24 minutes and 36 seconds

5.4 Sealing time

The following data are provided for information purposes only and were measured while using the SYMS III unit in an environment with an ambient temperature of 20°C.

Container	Sealing time
For 1 prefilled CBS™ straw	15 seconds
For 1 prefilled CBS™ tube	15 seconds
For 1 prefilled HSV™ straw	5 seconds

Container	Sealing time (with laboratory technician handling time)
For 10 prefilled CBS™ straws	3 minutes and 20 seconds
For 10 prefilled CBS™ tubes	2 minutes and 30 seconds
For 10 prefilled HSV™ straws	1 minutes and 20 seconds

6 Maintenance

6.1 Servicing

There is no specific maintenance required for the main mechanical and electrical parts of the SYMS III sealer.

However, it is strongly recommended that you clean the sealing jaws regularly, especially if they become accidentally fouled while sealing the CBS™ High Security straws, CBS™ High Security Vitrification straw and CBS™ High Security tube.

6.2 Spare Parts and Accessories

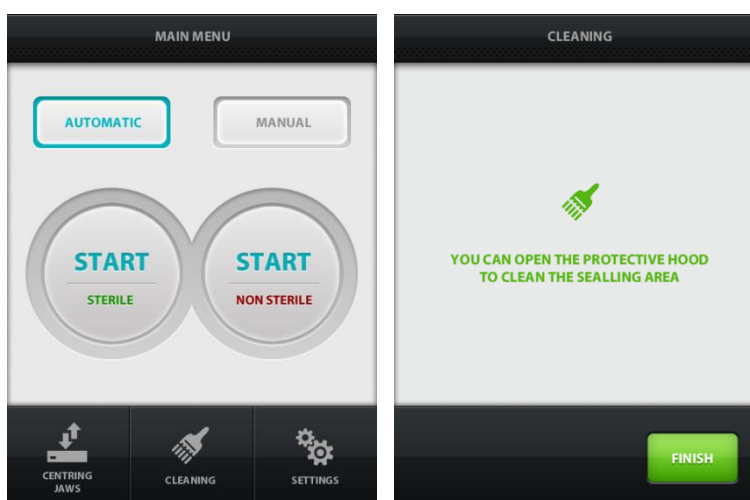
Name	Product Number
CBS™ straw and HSV Straw Support	025590
CBS™ Tube Support	025591
Protective cover	025592
Sealing jaws set	026550

Reminder: Only a certified Cryo Bio System Specialist or Cryo Bio System Technician is authorized to perform repair work on the SYMS III sealer.

6.3 Cleaning the Jaws

The “CLEANING” function keeps the jaws apart in order clean them.

1. Select “CLEANING” on the Main Menu. The following screen will appear:

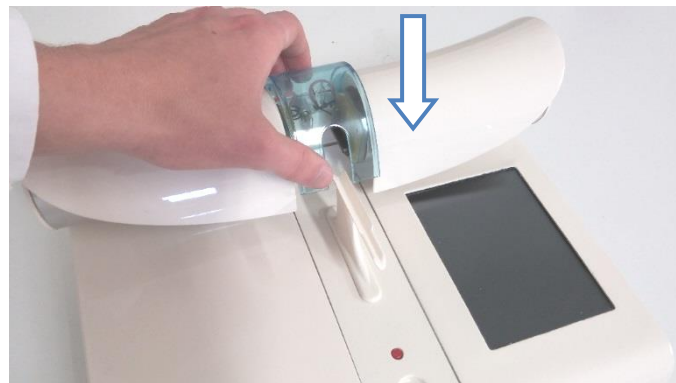


2. Turn off the equipment
3. Open the protective cover

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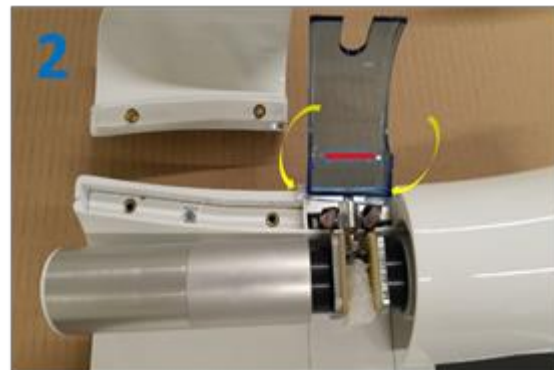
4. Clean the jaws with a cotton swab moistened with distilled water or alcohol
5. Dry with a dry cotton swab or cloth
6. Close the protective cover
7. Turn on the equipment (the jaws are repositioned).



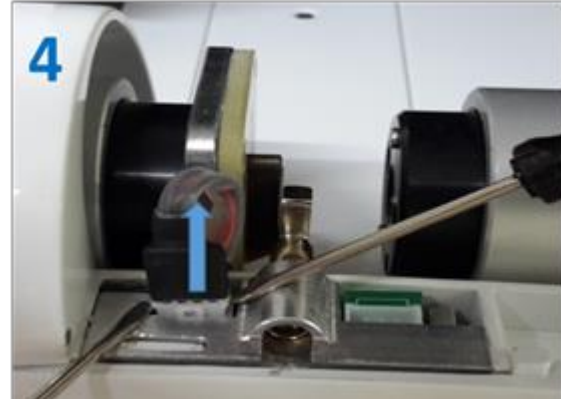
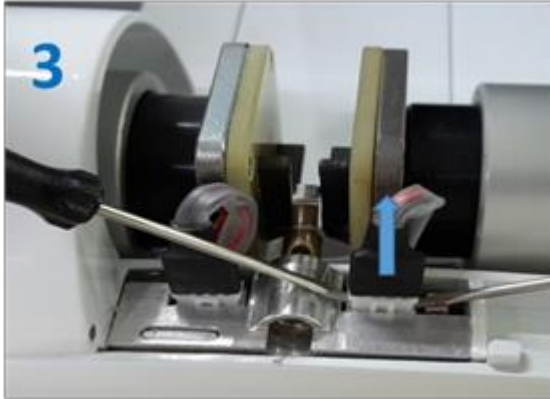
6.4 Jaws replacement

The jaws have a minimum service life of 3,000 sealing operations. Beyond this limit value, they have to be replaced to guarantee sealing quality. Proceed as follows:

1. Lift the left motor housing.
2. Move the blue Plexiglas jaw housing to the left to remove it, paying attention to the two small spindles.



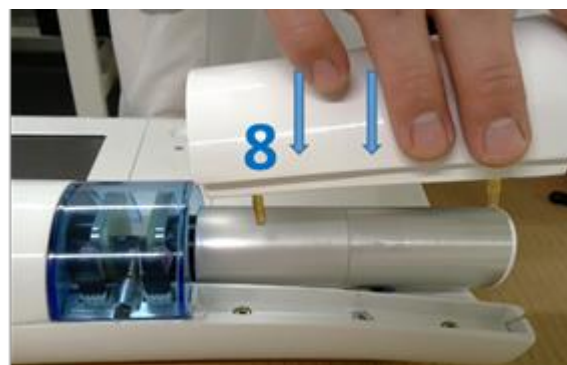
3. Lift the first connector, holding its base (with a finger or a screwdriver), then remove the jaw.
4. Lift the second connector, holding its base (with a finger or a screwdriver), then remove the jaw.



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



7. Fit the blue Plexiglas housing back into place, paying attention to the two small spindles.
8. Fit the motor housing back into place.

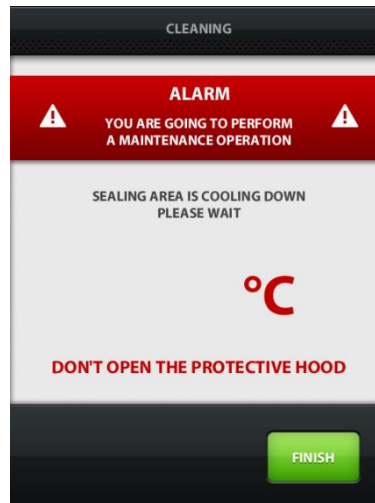


In the event of early damage, please contact Cryo Bio System's Customer Service.

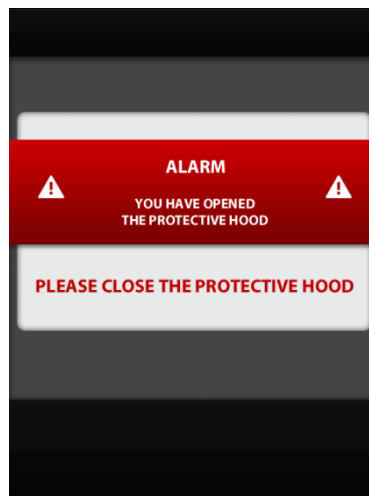
6.5 Managing Alerts

Cleaning the Jaws

The jaws can be cleaned only if their temperature is below 40°C to mitigate any burn risks.

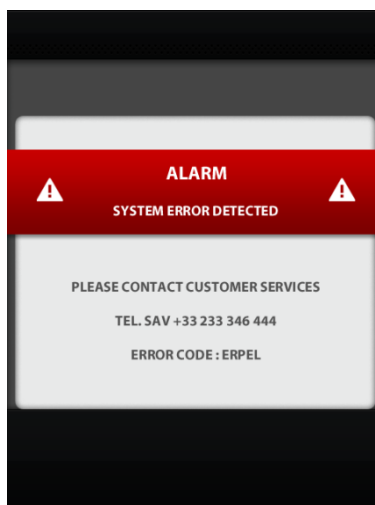


Opening the Cover



While the protective cover is open, an "ALERT" screen is displayed and an audible warning signal is generated. As soon as the cover is closed, the "MAIN MENU" appears.

System Error



When a system error occurs, an "ALERT" screen is displayed and 3 audible warning signals are generated every 2 minutes. The sealer is automatically locked.

Restart the sealer.

If the alert continues to sound, please contact a Cryo Bio System customer service technician (+33 2 33 346 444).

6.6 Centring Jaws

Press the Main Menu button at the bottom left of the screen to check that the sealing jaws are correctly centered with the straw/tube support and the presence sensor.

7 Technical Specifications

7.1 *General Specifications*

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

7.2 *Operating Conditions*

- For indoor use at ambient temperature
- Operating temperature: 5 at 30° C
- Maximum relative ambient humidity: 80%
- Operating environment: The unit cannot be used at an altitude higher than 2,000 m, or in an explosive or corrosive environment.

7.3 *Power Supply*

- External power supply
 - Supply voltage: 100 - 240 V
 - Supply frequency: 50 - 60 Hz
 - Power consumed: 120 W max
 - Output 12V with a 4-pin DIN miniconnector
- Sealer Unit
 - Voltage: 12 - 15 V

8 Important Information

8.1 Orders

To order any spare parts, please see Subsection 6.2 “Spare Parts and Accessories” in these operating instructions.

8.2 Warranty Conditions for New Units

Cryo Bio System guarantees its equipment against all malfunctions caused by faulty material, manufacturing defects or design errors for one year from the date specified on the warranty certificate.

Parts and services are free of charge during this period.

Any malfunction must occur within twelve months of the effective warranty date and while using the equipment in strict accordance with these operating instructions.

Warranty exclusions include the following:

If the malfunction is caused by an unauthorized procedure on the unit

If the malfunction is caused by a failure to comply with the technical specifications and these operating instructions

If the malfunction is caused by a situation of force majeure.

Based on the above warranty, Cryo Bio System shall repair or replace the parts that become unusable during the warranty period for reasons outlined above.

The implementation of this warranty, i.e., the repair and replacement of all or part of the delivered equipment, is not liable to extend the warranty period.

Any dispute arising from the interpretation and/or execution of these warranty conditions shall be subject exclusively to French law. The Courts of Alençon shall be the only courts of competent jurisdiction; this also applies to the introduction of third parties and multiple defendants.

8.3 Exclusion of Liability

Cryo Bio System is not liable for damages caused by outside influences or any inappropriate handling and use that does not comply with the recommendations stipulated in these operating instructions.

Please refer to the fields of application (see 2.1 Applications, 3.3 Protective cover, 5 Operating mode, 6.3 Cleaning the jaws) and electrical specifications (see 7.3 Power Supply) in these instructions.

8.4 Contact



Cryo Bio System

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Décret n° 2012-617 du 2 mai 2012 relatif à la gestion des déchets de piles et accumulateurs et d'équipements électriques et électroniques

UE First market date : 01/2015

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Notes: