

SYMS III[®] MANUAL SEALER



For CBS[™] High Security straws, CBS[™] High Security tubes
and HSV High Security Vitrification Straw

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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,
 - HSV 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.

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 unit 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 HSV 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.

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2.2 Protection and Safety

Electrical Safety Standards

- 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.

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



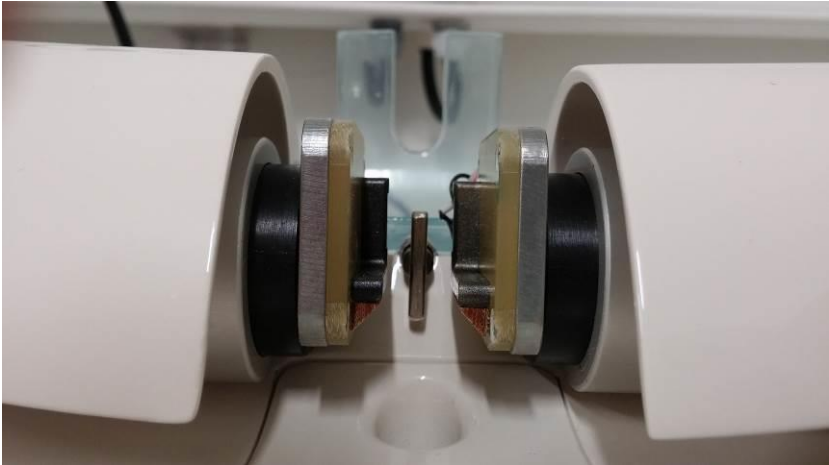
** Use only for a software update. Any use, without Cryo Bio System's specific information instructions, is forbidden.*

- the external power supply and cord.

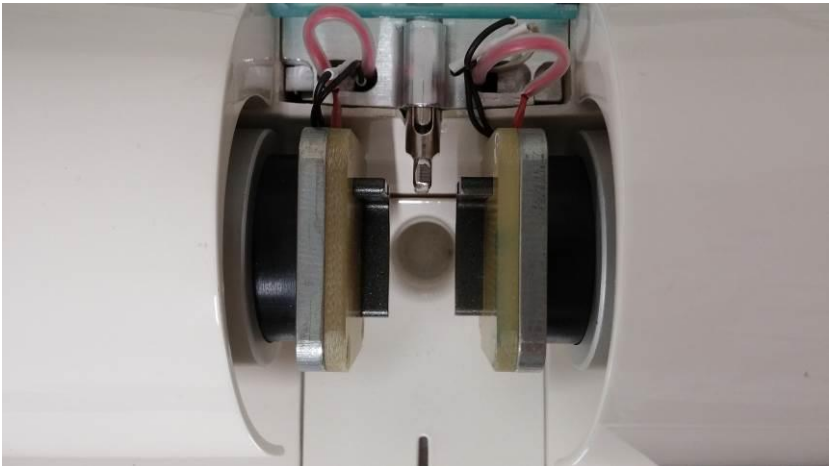


3.2 Welding unit

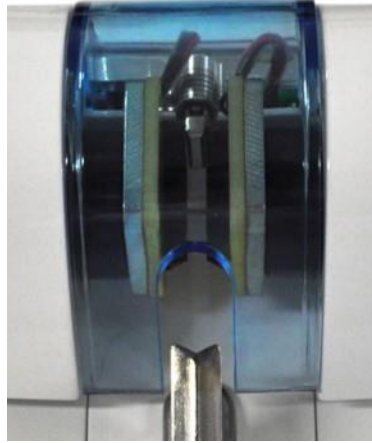
Front view



Top view



3.3 Protective cover



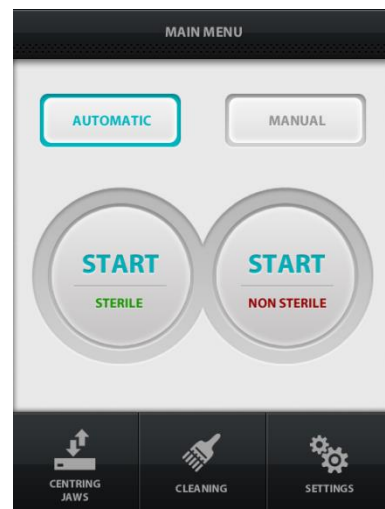
When the SYMS III® sealer is operating, removing the protective cover will immediately trigger an audible warning signal. An alert message will be displayed on the screen and the unit will shut down.

3.4 Controller Touch Screen

The "MAIN MENU" consists of three areas:

1. Sealing Modes
 - Automatic
 - Manual

The selected mode remains highlighted.
2. Soldering 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 and HSV 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

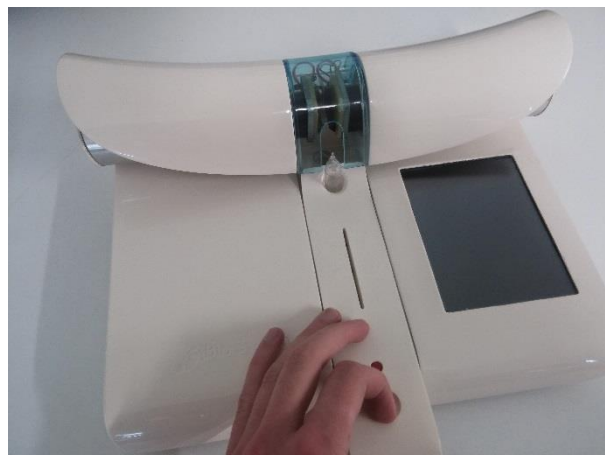
Connect to power supply as follows:

- 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 HSV straw support or the CBS™ tube support, depending on the type of product to be sealed.

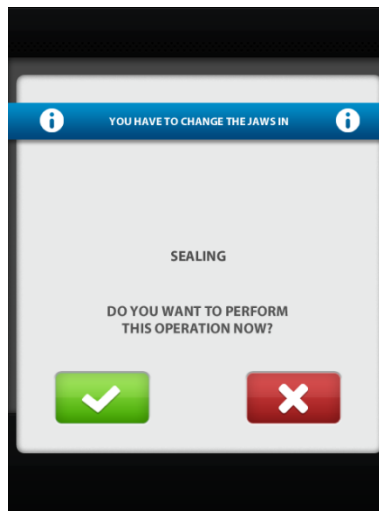


Turning on the Sealer

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

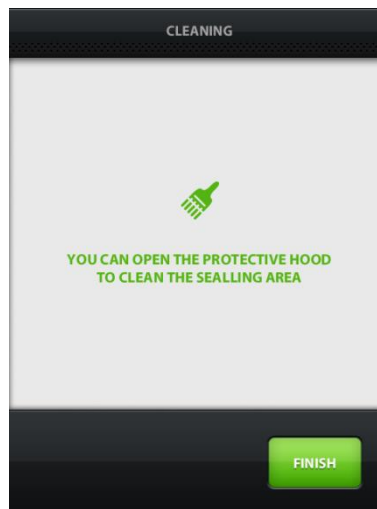


The following screen offers the option of cleaning the jaws:



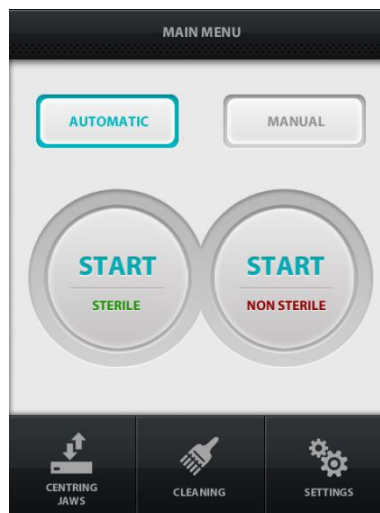
If 'YES' is selected, the following screens will appear in successive order:

- "CLEANING"
- "MAIN MENU"



Cf. Subsection 6.3 “Cleaning the jaws”.

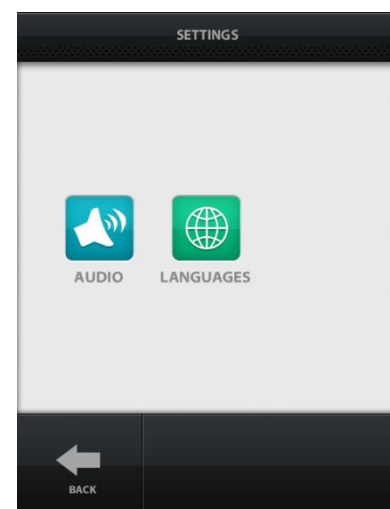
If “NO” is selected, the “MAIN MENU” will appear:



4.2 Settings

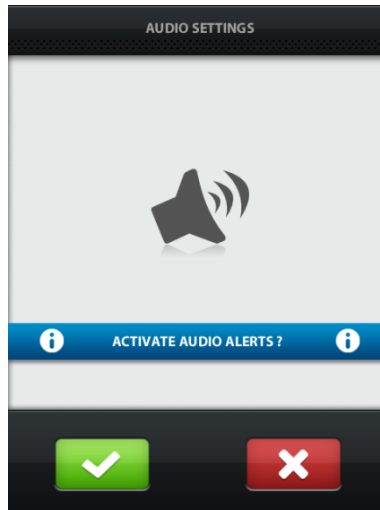
The “SETTINGS” menu groups the standard settings:

- Audio
- Language
- Back



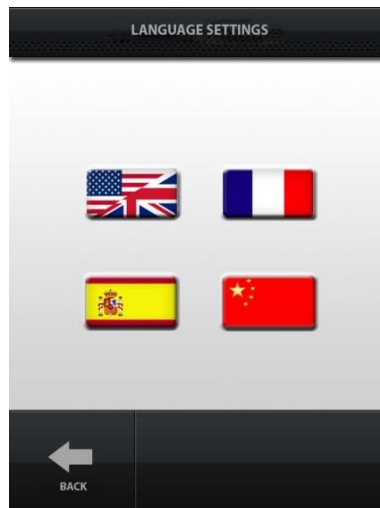
Audio Settings

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).

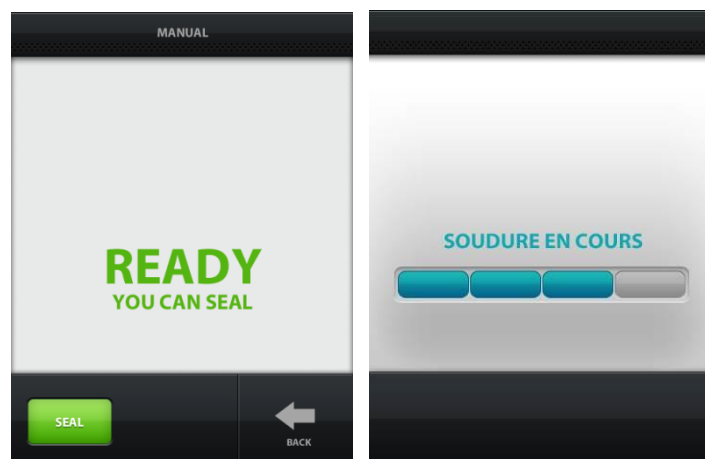
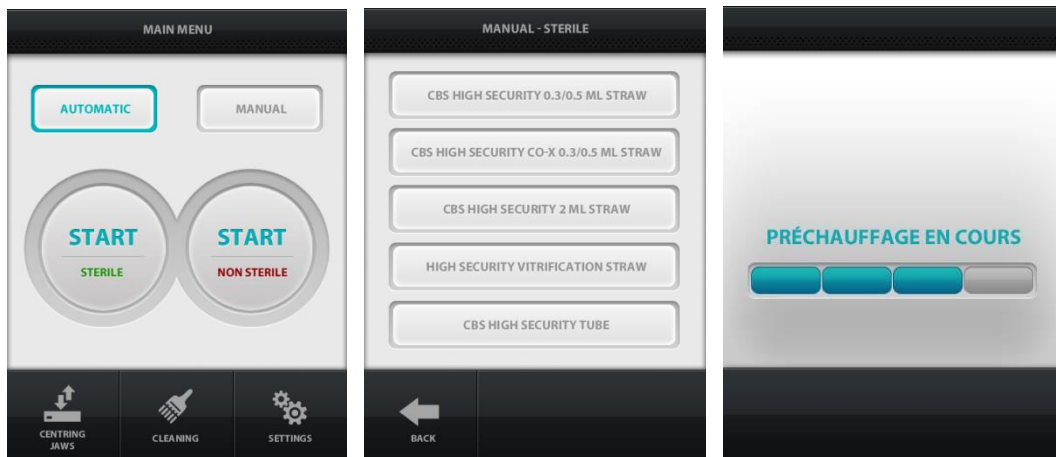
5.1 *Manual Mode*

Manual sealing can begin once two conditions are met:

- The presence sensor must detect a container (the CBS™ High Security products specified on page 4)
- 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).



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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.

HSV High Security Vitrification Straw

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

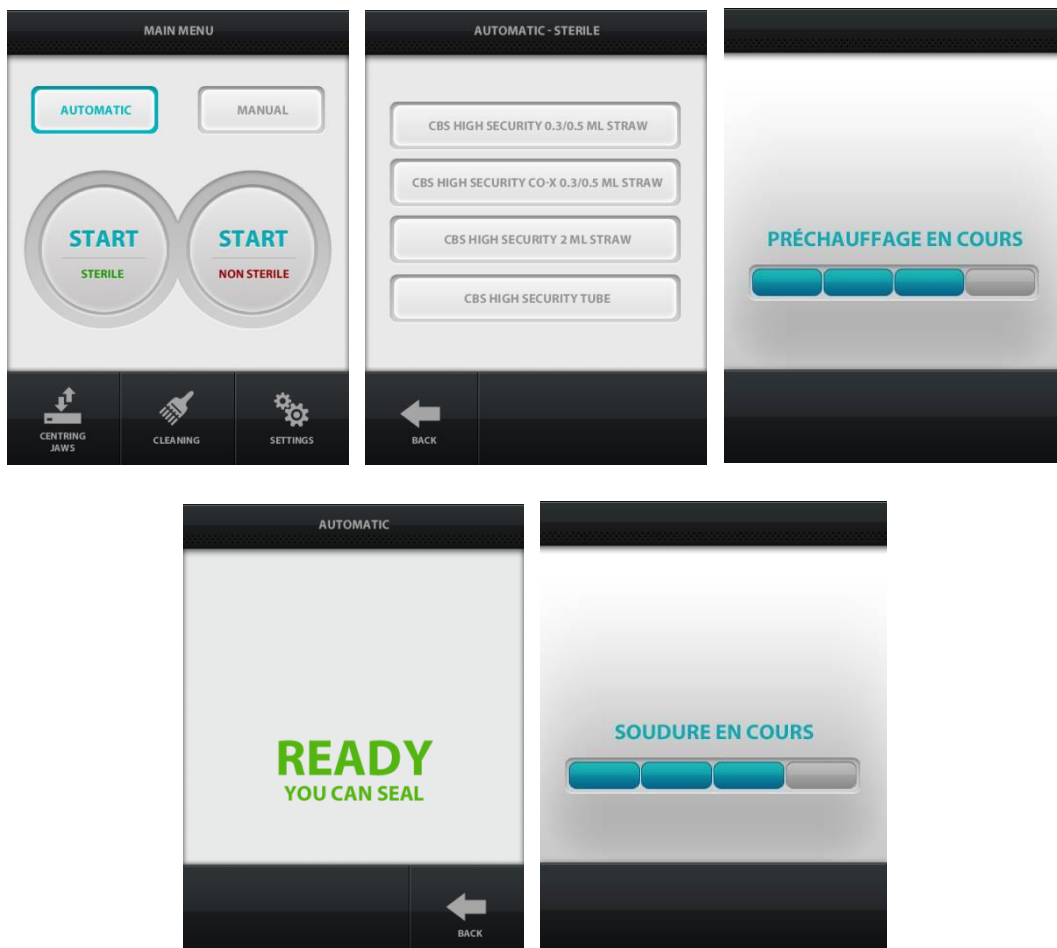
→ **Caution:** the HSV High Security Vitrification Straw can only be sealed in “MANUAL” mode with the “STERILE” option selected

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).



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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.

HSV High Security Vitrification Straw

Automatic Mode will not operate for this product.

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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 25° 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 25° 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, HSV High Security Vitrification straw and CBS™ High Security tube.

The jaws can perform 3,000 seals. Please contact the Technical Service Department in the event of any damage or wear.

6.2 Spare Parts and Accessories

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

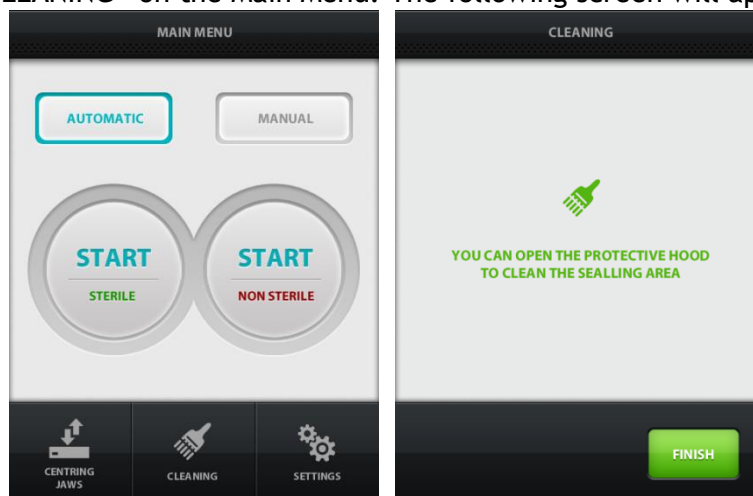
Reminder:

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. Open the protective cover



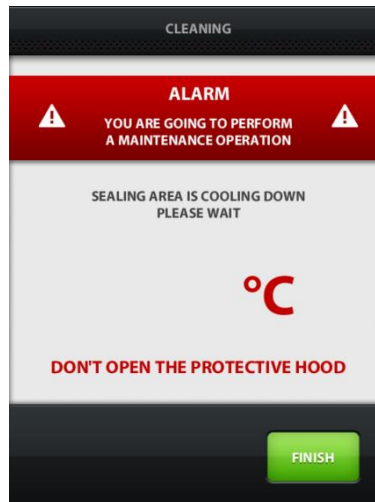
3. Clean the jaws with a cotton swab moistened with distilled water or alcohol.
4. Dry with a dry cotton swab or cloth.
5. Press the button "Finish"
6. Close the protective cover



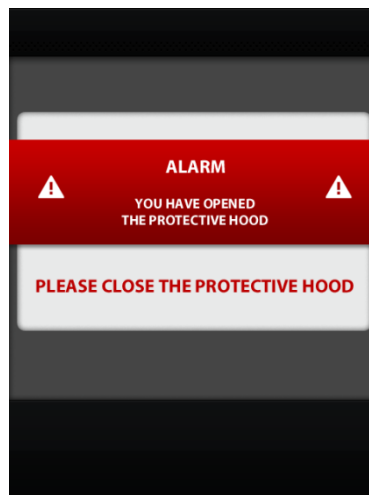
6.4 Managing Alerts

Cleaning the Jaws

The jaws can be cleaned only if their temperature is below 40° C.

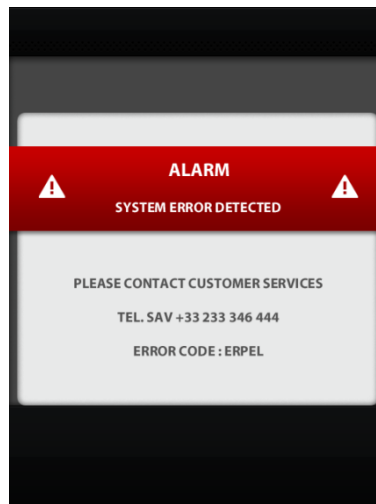


Opening the Cover



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).

6.5 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 only
- 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 Applications) and electrical specifications (see 7.3 Power Supply Power Supply) in these instructions.

8.4 *Contact*

Cryo Bio System
ZI n° 1 Est
61300 L'Aigle
Tel. +33 (0)233,346,464
Fax +33 (0)233 341 198
Tel. Customer Service +33 (0)233 346 444
Fax Customer Service +33 (0)233 849 504
contact@cryobiosystem-imv.com



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

Notes: