

Auto-reader Incubator for Self-Contained Biological Indicators



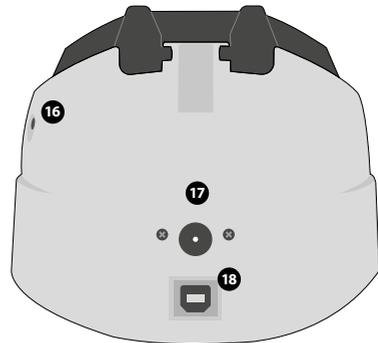
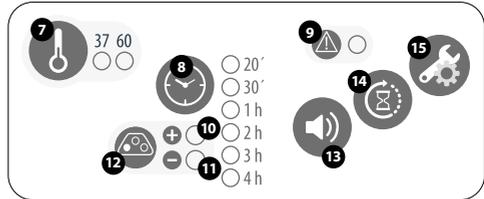
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Warning: this product contains dry natural rubber

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Composition



Use description

The Auto-reader incubator has been designed for the incubation and automatic readout of Self-Contained Biological Indicators (SCBIs).

The auto-reader allows easy and rapid detection of positive and negative Biological Indicators (BIs). Microorganisms contained within the Biological Indicators vary depending on the sterilization process for which they have been designed, therefore, incubation temperatures differ depending on the indicator. Indicators for Ethylene Oxide (EO) sterilization control, should be incubated at 37 °C, while those involved in the monitoring of the rest of the sterilization processes should be incubated at 60 °C.

! Simultaneous incubation of BIs for EO processes control along with BIs monitoring the other processes, is not possible.

Six incubation programs are available: 4 hours at 37 °C, 3 hours at 60 °C, 2 hours at 60 °C, 1 hour at 60 °C, 30 minutes at 60 °C and 20 minutes at 60 °C. A positive result can also be evidenced by culture medium color change to yellow, read the instructions for use of each indicator for more information. The choice to perform or not the extended incubation to confirm by color change depends on the internal protocols of each laboratory or hospital.

Incubator allows incubation time programs selection independently for each one of three positions. The incubator not only allows results detection but also provides a printed ticket to record them.

Safety information

References

- 1 Protective Cover.
- 2 Incubation Area.
- 3 Control Panel.
- 4 Ampoule Crusher.
- 5 Cavity for paper.
- 6 Thermal Printer.
- 7 Temperature Selector.
- 8 Programs Selectors for Incubation / Time Left
- 9 Blue Attention light.
- 10 Red Light / Positive Indicator.
- 11 Green Light / Negative Indicator.
- 12 Incubation Position.
- 13 Sound Alarm Cancellation.
- 14 Reprint of Results.
- 15 Configuration / Paper Traction Button.
- 16 Hole for external temperature control.
- 17 Input for power source plug (12Volts DC).
- 18 USB Port.

Symbols

-  30 % - 80 % Operating/storage relative humidity.
-  10 °C - 30 °C Operating/storage environmental temperature.
-  Caution, warning.
-  Important, attention.
-  Direct current.
-  Waste Electrical and Electronic Equipment.
-  Batch number.



To avoid risks and damaging the equipment:

-Do not place the incubator in an environment exposed to direct sunlight or high intensity light lamps.

-Do not place the incubator near devices that emit electromagnetic fields.

-Do not use the equipment on vibrating surfaces.

-Do not pour any liquid inside.

-Do not immerse into any liquid.

-Use indoors only.

-Disconnect the power cord before cleaning.

-Do not use abrasive, corrosive cleaners or disinfectants.

-In case of technical fault, contact the manufacturer for support. Please, do not try to open or repair the incubator on your own, since this will imply the loss of product warranty and could lead to a major and irreversible damage.

-Make sure that the incubator is connected to a properly rate power cord.

To reduce the risk of using incompletely sterilized loads:

-Make sure to use each BI with its incubation and reading program:

EO with 4 hs. at 37 °C program

Safety information

STEAM with 3hs. at 60 °C program
STEAM with 1 h. at 60 °C program
STEAM with 30 min. at 60 °C program
STEAM with 20 min at 60 °C program.
VH2O2 with 2 hs. at 60 °C program
VH2O2 with 30 min at 60 °C program.

-Check that culture medium completely wets the spore carrier.

-Do not remove the BI until the equipment reports the final readout result, check the impression of the ticket.

To avoid the risk of injury, because of glass fragments generated after the glass ampoule inside the BI tube is crushed:

-Cool the BI during the indicated time before crushing the ampoule.

-Do not handle the BI excessively since this might cause the glass ampoule to burst.

-Wear safety glasses and gloves when removing the BI from the sterilizer.

-Wear safety protective glasses and gloves to crush the ampoule and to press the cap of BI.

To avoid a potentially hazardous situation:
 Avoid contact with the hot surface of the metal incubator block.

To avoid BIs from absorbing fluorescent residues: Avoid BIs direct contact with chemical indicators or tapes.



Do not use this product in a manner not specified in this manual, otherwise the protection provided by the product might be affected.

Do not replace the power supply cord for other not provided within the product.

Only qualified personnel can access the inside of the incubator and its components. Parts or components inside the machine should not be manipulated by the user.

Power supply specifications

Input parameters	Operating conditions	Units
Voltage range	(100-240)	Volts
Frequency	50/60	Hertz
Current	0,5	Ampers
Output parameters	Operating conditions	Units
Voltage	12	DC Volts
Current	2	Ampers

It is recommended to use a UPS instead of stabilizers, since the former has two functions: it stabilizes and provides a continual power source during energy cutoff.

Environment operating conditions

Environmental conditions	Functional conditions	Units
Altitude	3500 (máx.)	Meters
Operation temperature	10-30	°C
Relative Humidity	30-80	%
Installation/overvoltage	Category II	
Degree of contamination	2	
Storage temperature	10-30	°C
Voltage	12	DC Volts

Serial/Batch Number

For easy identification, each auto-reader has a unique serial number and a batch number printed on a label found at the bottom of the auto-reader and on its packaging. Please, register your serial number and batch number in this manual for future reference:

Serial number: _____

Batch number: _____

Instructions for use

Check that the time setting is appropriate for the BIs to be incubated in each position.

To change the time program, press the button  of the correspondent position as many times as necessary to choose the right setting.

5- Wait for the temperature of the machine to be stable. Once is stable, the indicator of the desired temperature will remain steady.



Do not place any biological indicator in read positions until the incubator does not confirm temperature stability.

The incubator will keep running the incubation program during all reading process. The system does not allow the incubation program to be modified once the reading is started, except it has been completed.

6- Reading can be initiated when the temperature blue light remains stable indicating that incubation temperature was met. Then an automatic testing of the status of the incubation positions of the biological indicators will be performed. The indicating lights of each position will be turned on to show the result: green light will show a satisfactory result while red light will indicate error.

When the device detects an error in any position, it will print a ticket indicating date, time and positions with error. To guarantee the reliability of the results, these positions will be deactivated avoiding their use. To make this clear, red light in that position will remain blinking indefinitely to indicate that the position has been disabled.



For the correct performance of the automatic check, it should be done with the protective cover closed.



Read BI's instructions for use. Before placing the vials in the incubator, press the top to seal the tube. Crush the internal ampoule (using the ampoule crusher within the box of BIs or the one located within the incubation area of the incubator) and make sure that the liquid has completely wet the spore carrier placed at the bottom of the biological indicator plastic tube.



Do not remove or change placement of BI once the reading process has begun. If this occurs, results may be invalidated.



Use a non-sterilized biological indicator as a positive control every time a processed indicator is incubated. For more information refer to the *Positive Control* section of this user guide.

7- Place the rapid BI in a reading position, close the protective cover and wait for the result. Reading will start automatically. Immediately after placing the BI in a position, the auto-reader will emit a sound alarm indicating that reading has successfully began and status position light will turn on and will blink until the result is informed.

NOTE: If the incubator does not run automatically, it might indicate that the incubator temperature is not steady yet (check the temperature indicating light to remain steady) or that the incubation position is disabled due to an error in the initial autotest.

8- When a positive result is detected, the red light and the audible alarm will turn on. This will indicate that the sterilization process to which the BI was subject, has failed. 30 seconds after removing the BI from the incubation position, the alarm and the red light will turn off automatically and the position will be available to start a new reading. The negative BIs will be informed with a green light in the corresponding position, this will indicate that the sterilization process to which it was subject has been successful. The green light will remain on for up to 30 seconds after the BI is withdrawn from the reading position. The incubator will inform results within 20 min. (60° C), 30 min. (60 °C), 1 h. (60 °C), 2 hs. (60 °C), 3 hs. (60 °C) or 4 hs. (37 °C), according to the program selected. These periods of incubation are the time-limits used by the equipment to inform the fluorescence final readout.

9- Every time a positive result is detected, it will be informed through the printing of the corresponding ticket and with an audible alarm. The alarm can be cancelled by pressing the button .

10- To register the tickets, take the paper and press up for the paper to be cut with the serrated edge of the printer.

NOTE: If the paper for ticket printing runs out, the attention blue light will flash rapidly. To replace the paper, follow the instructions in *Replacing the roll paper in the printer*. The incubator will save the last 3 results, for re-printing, follow the *Reprinting of the last results* instructions.

```
RAPID READOUT INCUBATOR
SERIAL NUMBER: XXXX XXXX
PROGRAM: X h / XX °C
DATE: DD/MM/AA
START TIME: HH:MM
READOUT TIME: HH:MM
SAMPLE TUBE: XXXX
POSITIVE
```

POSITIVE

```
RAPID READOUT INCUBATOR
SERIAL NUMBER: XXXX XXXX
PROGRAM: X h / XX °C
DATE: DD/MM/AA
START TIME: HH:MM
READOUT TIME: HH:MM
SAMPLE TUBE: XXXX
NEGATIVE
```

NEGATIVE

```
RAPID READOUT INCUBATOR
SERIAL NUMBER: XXXX XXXX
PROGRAM: X h / XX °C
DATE: DD/MM/AA
START TIME: HH:MM
READOUT TIME: HH:MM
SAMPLE TUBE: XXXX
CANCELED
```

CANCELED

Instructions for use

Remaining incubation time

The auto-reader allows verifying the remaining incubation time in every reading position by ticket printing. Whenever a reading process is in course, press and hold the button  for 3 seconds, a ticket will then be printed informing reading position, incubation program and remaining incubation time. To verify remaining incubation time of 2 or more readings in course press 2 buttons  simultaneously; the device renders a ticket informing remaining incubation time of all positions.

RAPID READOUT INCUBATOR
SERIAL NUMBER: XXXX XXX
DATE: DD/MM/AA
TIME: HH:MM

TUBE 1:
PROGRAM: X h / X°C
REMAINING TIME: HH:MM h

Positive Control



The positive control should belong to the same batch of the processed BI.

Use a non-sterilized biological indicator as a positive control every time a processed indicator is incubated.

Incubate the processed biological indicator and the indicator used as positive control as specified in the instructions.

Press the cap to seal the tube and crush the ampoule, make sure the media completely wets the carrier. Write a C (for control) and the date on the label. The positive control can be placed in any position of the incubator. The positive control should belong to the same batch of the processed BI. It is a good practice to use a positive control, this helps ensuring:

- Correct temperature is reached.
- Viability of spores has not been altered due to improper storage temperature, humidity, or proximity to chemicals.
- Capability of the media to promote rapid growth and fluorescence generation.
- Proper functioning of the incubator.

Interpretation of results

Rapid Readout

The indicator used as positive control should show a positive result (red light ). The processed BI results are not valid until the biological indicator used as positive control shows a positive result . A processed BI with a positive result, indicates a failure in the sterilization process. A negative result, (green light ) after 20 min. (60 °C), 30 min. (60 °C), 1 h. (60 °C), 2 hs. (60 °C), 3 hs. (60 °C) 4 hs. (37 °C) according to the used program, indicates that the sterilization process was effective. Take action on any positive result immediately. Always retest the sterilizer and do not use the sterilizer for processing loads until 3 consecutive BI results are negative.

Visual Readout

The Rapid readout system allows the confirmation of results by color change after 48 hours or 7 days incubation analysis (if 7-day readout is made, an humidified incubator will be required to avoid media dry out). If the sterilization process was not successful, the growth media contained in the indicator will turn to yellow, as it is shown in Instruction for Use of BIs. If the sterilization process was successful, the media will remain unchanged.



The color of the growth media in the BI used as positive control must turn to yellow during the process of incubation for the results to be valid. Record the positive ones and discard them immediately as shown in the biological indicators instructions for use.

Disposal

Dispose BIs after use, according to your healthcare and safety regulations. Positives BIs can be sterilized (see BI instructions for use). It is not possible to reuse a BI.

Audible alarm

An audible alarm will sound every time a positive result is detected by the incubator. The alarm allows the user to immediately detect a positive result without the need to visually control the equipment. The alarm can be cancelled by pressing the button .

Instructions for use

Cancellation of a reading

When a BI is removed from its position during incubation process, an audible alarm will sound to indicate that the tube should be returned to the corresponding position. If the indicator is not re-introduced into the reading position after 10 seconds of being withdrawn, the reading will be cancelled and the cancelation will be informed through the printing of a ticket.

Temperature monitoring

The incubator contains an internal temperature control. If the temperature falls outside of the specified range (37 ± 2 °C or (60 ± 2) °C, the blue temperature led light will start to twinkle. Temperature can be externally monitored by using a thermometer. The auto-reader has a special hole for placing the thermometer which is located at the right side of the device.

Thermal paper specifications

Recommended paper: JUJO AF50KSE3 or similar.

Paper width : 58 mm

Maximum paper thickness: 60 g/m²

Maximum diameter size: 23 mm

Replacement of the paper roll



The printer uses thermal paper rolls.



1. To replace the paper roll, pull the handle of the printer's door. Open the printer's cover and remove the spent roll.



2. Place the new paper roll with the outer side up.



3. Close the printer cover by pressing on the sides of the lid.

NOTE: You can check the correct paper replacement by pressing , this button will force the advance of the paper a few centimeters.

Reprinting of results

The incubator allows reprinting of the last 3 results by fluorescence readout. For printing the results, press the button  for 3 seconds.

Care and cleaning

Clean the outer surface of the incubator with a damp cloth moistened with a small amount of detergent. Do not clean interior components. If additional cleaning of the internal components of the equipment is required, contact your distributor or manufacturer.



Always unplug the auto-reader and allow it to cool before cleaning. Do not immerse the unit in liquid.

NOTA: The auto-reader does not need routine maintenance.

Firmware update

The auto-reader allows updating the firmware periodically (program that controls the device and defines its different features) through the use of a firmware update utility. This software verifies, by using the internet, the latest

Instructions for use

firmware version available for the auto-reader; downloads it and installs it in a few seconds without the loss of any device data.

Update procedure

Before starting the process, turn off the incubator for five seconds, then turn it on and follow these steps:

- 1-Connect the incubator to a PC using a USB cable and make sure to have an internet connection.
- 2-Open the firmware update utility.
- 3-Select the device and press Start button to update.
- 4-Wait until the software indicates that the upgrade process is complete. The auto-reader prints an update confirmation ticket. If it was already up to date, it will print nothing.

NOTE: This process must be repeated every time a new firmware version is available, this will be informed in the website.

Setup Mode

The auto-reader has a setup mode from which, the device time zone and the print language can be set up. To enter Setup mode, turn on the incubator while holding down the button . The red and green LEDs in the three positions will remain on, indicating that the device is in this mode. The printer will render a ticket indicating that it is in Setup Mode.

To change the time zone and the print language, follow the instructions below. When finished, restart the incubator to exit Setup mode.

Modification of time zone

The time zone modification function allows changing the time zone of the device to suit the time zone of your country. To make this change, the incubator must be started in Setup mode (see *Setup Mode*), then press the  button. The current time will be printed to set a reference.

To subtract hours, press the button  as many times as necessary. To add hours, press the button  as many times as necessary. After 2 seconds, a ticket will be printed informing the selected time.

To confirm the change hold down the  button for 3 seconds. To discard the changes, unplug the incubator from the power source.

Modification of printing language

This functionality allows changing the language in which the incubator printer renders the tickets.

To make this change, the device must be started in Setup mode (see *Setup Mode*), then press the button .

The current language and list of available languages will be printed to establish a reference. Press the button  to scroll up and  to scroll down. After 2 seconds, a ticket will be printed informing the selected language.

To confirm the change, press and hold the button  for 3 seconds. To discard the change, unplug the incubator from the power source.

Time setting mode

Change the time using the firmware update utility

Connect the auto-reader via the USB port to a PC and start-up the program. Select the Auto-reader and press the Clock Sync button, the auto-reader will be synchronized with the PC's clock. Synchronization can only be done as long as there is not an ongoing reading.

Troubleshooting chart

Fault	Possible cause	Action
The incubator does not start.	Power source is not connected.	Check that the power source is connected to the power supply according to its characteristics and that the plug is connected to the incubator.
The incubator gives an error in one position during "Autotest".	A BI is placed in the position at the moment of starting the incubator.	Check that every position is empty at the moment of starting the incubator.
The incubator gives an error in the "Autotest".	Dust particles might be obstructing the light path between the sensors.	Ensure cleanliness of the incubation position. Use of air is recommended. Do not use solid objects that could damage internal components. Restart the incubator.
The incubator does not run a BI reading. The red light of that position is blinking.	The "Autotest" gives an error in that position, which becomes disabled.	Make sure that the position is empty when starting the incubator. Restart the incubator.
The incubator does not run a BI readout in any position.	The incubation temperature is not stable.	Wait for temperature to be stable.
The incubator does not allow changing the incubation program.	Ongoing reading.	Wait for the reading of corresponding position to finish.
The printer does not print and Attention indicator light blinks quickly.	The printer cover is not tightly locked. Printer without paper.	Check that the cover is tightly closed. Place a new paper roll in the right direction.
The printer releases unprinted paper.	Paper roll is placed in the wrong direction.	Check the paper roll direction.

