REF: 120.003.0001

User Manual Quick Read-Out Incubator 3.0

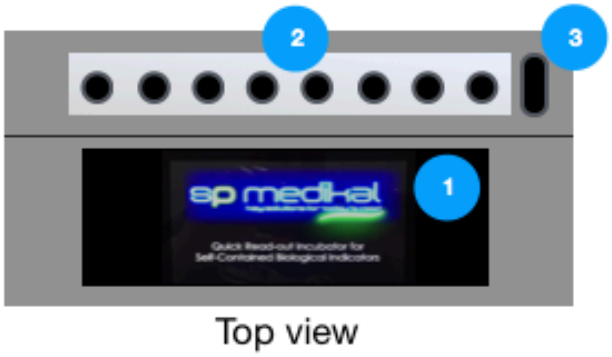
STEAM V2H20 FORM EO

Auto reader for incubation and read-out of Rapid Biological Indicators

- **Suitable for 3 hours, 1 hour and 20 minute SCBI's**
- **7 inch Colored Touch Screen,**
- **Built-in thermal direct printer**
- **USB connection**
- **Built-in Barcode reader**
- **Status indicator lights**

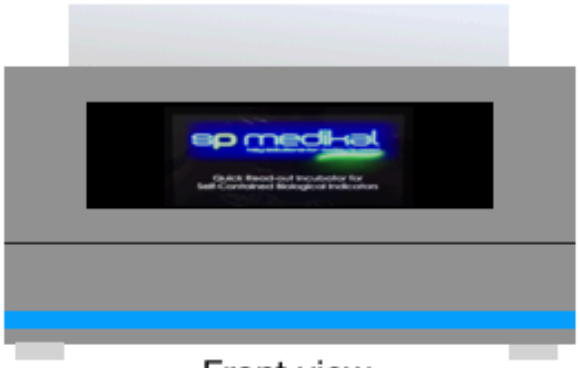
List of content

Components location

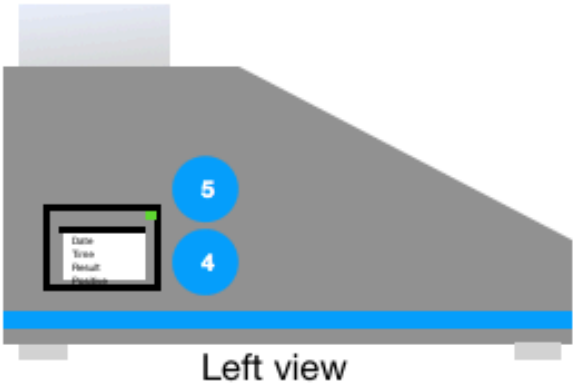


Top view

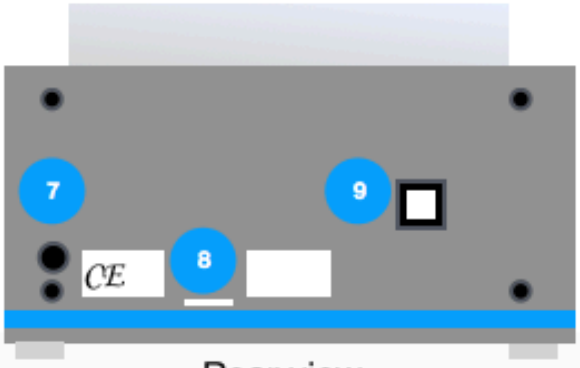
1 7" Color Touch Screen
2 SCBI Incubation wells (8 pieces)
3 SCBI Crusher
4 Thermal Printer
5 Printer status light
6 Incubator status light
7 Power inlet 12V - DC
8 Micro SD Port
9 USB Port
10 QR reader



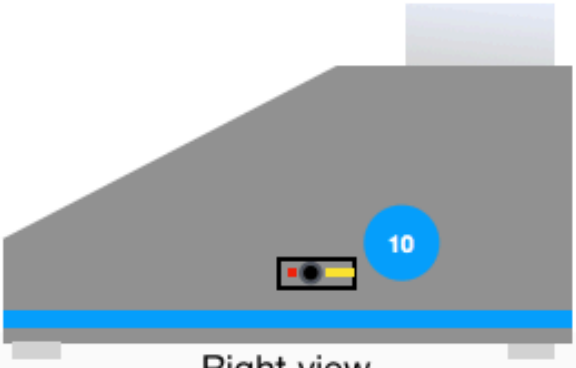
Front view



Left view



Rear view



Right view

Safety information

The QR incubator and its accessories have been designed to provide safe and reliable service when used with the instructions provided. Read, understand, and follow all safety information in this User manual included with the QR incubator as well as the Rapid Biological Indicator Instructions before use.

Use this equipment only for the purposes described in the User Manual. Keep these instructions for future reference.

The unit is designed for exclusive use with the supplied power module. If alternative power supplies are use, the protection provided with that product may be impaired.

WARNING: Indicates a hazardous situation which, if not avoided, could result in serious injury or even death.

CAUTION: Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

Warnings and safety precautions

The following cautions and warnings must be followed in order to avoid unsafe actions that could result in personal injury or damage to the instrument.

WARNINGS: To reduce the risks associated with dangerous voltages, follow these instructions:

- For indoor use only.
- Do not use the incubator if it is not working properly or if it has mechanically damage.
- Use only the power supply supplied with this Incubator.

CAUTION: To reduce the risk of injury or damage to the Incubator.

- Do not spill any liquid on or into the Incubator.
- Do not immerse the Incubator in any liquid.
- Always unplug the Incubator and allow it to cool down before cleaning.
- Clean external surfaces only with slightly damp cloth (no chemicals or detergents).
- Do not open the Incubator case: it contains no parts that you can repair. The incubator must be returned to the manufacturer for repair.
- Wear gloves and safety glasses when activating the Rapid Biological Indicator and read its instructions embedded in the manufacturer's box.
- Allow Rapid Biological Indicator to cool for the recommended amount of time before activating. Over-activating or manipulating the biological indicator before cooling may cause the glass vial to explode.

WARNING: To reduce the risks associated with incorrect results:

The incubator should be used by an operator familiar with the device, the functionality of the device, and the Users Manual.

- Do not place the instrument in an environment exposed to light or strong incandescent light.

- Do not place the instrument near a device that emits strong electromagnetic radiation.

- Do not use the instrument on a surface subject to vibrations. This could lead to erroneous results in the interpretation of the status of the biological indicator by the incubator.

- Do not incubate a Rapid Biological Indicator if, after processing and before activating the BI, the vial of culture medium is found to be broken. Repeat the test in the sterilizer with a new biological indicator.

- Allow Rapid Biological Indicator to cool for the recommended time interval before activating it.

- Do not remove or change the placement of the Rapid Biological Indicator once it has been placed in a well.

- Do not remove the Rapid Biological Indicator from the incubation well until the incubation progress bar on the touch screen is red or green, if you remove the biological indicator before the incubator of its respective result, you will lose the incubation time that leads so far.

- Avoid moving the incubator or causing bumps while it is in the process of reading and analyzing a biological indicator. This can cause inaccurate results from the incubator.

- Keep the transparent cap closed and only open it when removing or inserting a biological indicator into a well. This will prevent dirt and / or particulate material from entering the cavities where the sensors are located.

CAUTION: To reduce the risks associated with incorrect results.

- The biological indicator must be incubated no later than 7 days after being processed in the respective sterilizer. Consider reducing this time to a minimum (respecting the cooling time that the biological indicator should have after leaving the sterilizer.

- Avoid shocks or vibrations to the incubator during the reading process.

- Do not allow residues to enter the interior of the wells: when you fracture the biological indicator, make sure not to tear the sticker that it has, this material can detach from the biological indicator and deposit sit inside the cavity of the incubator when removing it. This could affect the sensors. If you detect dirt inside the cavities, contact an authorized technical service. Do not attempt to clean the cavities as it may cause irreparable damage to the electronic systems of the equipment.

Power supply specifications

Input Parameters	Values
Voltage range	100-240 V AC
Frequency	50-60 Hz
Current	1,4 Ampere

Output parameters	
Voltage	12V DC
Current	5 Ampere

Environmental conditions

Humidity	20-80 % RH
Altitude	max 3500 meter
Operation temperature	16-35 °C
Installation / over-voltage	Category II
Degree of contamination	2
Storage temperature	0-50 °C

Location selection

Place the QR Incubator on a firm, level surface away from sunlight and incandescent light sources.

IT IS ESSENTIAL THAT THE INCUBATOR IS NOT ON A SURFACE SUBJECT TO VIBRATION OR SHOCK OF ANY KIND. This could lead to misleading results from the incubator.

Power connection

Connect the power cord to the power outlet. Connect the power outlet to the QR incubator and plug the power cord into the AC power outlet. Leave a space of at least 10 cm from the wall. Do not move the Incubator periodically and especially not during use.

It will be observed that the touch screen will immediately turn on and the equipment will start its operation.

In the first screen, you can see the version of the software that the equipment has.

At the side a thermal direct printer is located an indication light is present. If the light on the printer is flashing it means that the thermal paper must be loaded or that the printer cover is not properly closed. Otherwise, the light will remain steady lit up.

WARNINGS:

Do not place the incubator in an environment exposed to sunlight or strong incandescent light.

Do not place the instrument near a device that emits strong electromagnetic radiation.

Do not use the instrument on a surface subject to vibrations.

Once connected, wait for a 40 minute warm-up period (depending on environment temperature) before placing the biological indicators in the incubation wells. A message "CONDITIONING TEMPERATURE" will appear on the screen of the equipment. When the incubation temperature has been reached, the equipment will change screens and you can start incubating according to the instructions given later in this manual. DO NOT introduce any biological indicators while the temperature is conditioning.

Special considerations

It is recommended that the unit be left on to avoid having to wait for warm-up periods. You can turn off the unit if you expect that you will not be using it for a long period of time like a few days.

WARNING:

Use only the power supply specified for this product and certified for the country where it is used.

Do not get the Incubator wet or hot. If any liquid is spilled on the incubator, unplug it and dry immediately. Prior to start up, it must be verified that the equipment is completely dry and with empty cavities. If necessary, contact the authorized technical service. Inserting objects into the cavities can cause irreparable damage to sensors or electronic parts.

The equipment will start taking the last configuration of the incubation program and temperature used.

General Description of the QR Incubator

The Quick Read-Out incubator allows the incubation and analysis of results of the following self-contained biological indicators:

- Biological indicators for steam , plasma and Formaldehyde sterilization processes a
    - 20 minutes,
    - 1 hour
    - 3 hours.

- Biological indicators for sterilization processes by Ethylene Oxide at 3 or 4 hours.

It also allows to disable positions to incubate self-contained biological indicators by colorimetry only.

The Quick Read-Out Incubator allows to incubate in two temperatures: 37 ° C for Ethylene Oxide or 60 ° C for the other sterilization methods.

Pre-face:

The QR Incubator provides you with a fast and reliable periodic monitoring for steam, hydrogen peroxide, low temperature steam with formaldehyde (VBTF) and ethylene oxide sterilization processes in healthcare facilities.

The QR Incubator is designed to automatically incubate and read the STEAM, VH2O2, FORM Rapid Biological Indicators at 60 ° C and EO Rapid Biological Indicators and 37 ° C respectively to obtain a definitive negative fluorescence reading in 20 minutes, 1, 2, and 3 hours according to the reference of the biological indicator used.

Note: **The simultaneous incubation of biological indicators for the control of processes by Ethylene-Oxide together with biological indicators for the control of the other processes is not possible due to the difference in incubation temperature.**

The QR incubator has also been designed to allow subsequent incubation of rapid biological indicators for STEAM, VH2O2, FORM and EO to obtain a negative pH visible color change result at 24 for steam and 48 hours (EO) according to the characteristics of the biological indicator. This subsequent incubation is optional and is not intended to be performed on a routine basis.

A positive fluorescence reading or a visible pH color change indicates a failure in the sterilization process. However, due to the high sensitivity of the fluorescence result, there is no advantage to continue incubating the processed rapid biological indicators once the fluorescence result has been documented. The choice to perform the extended incubation for confirmation by color change or not depends on the internal protocols of each laboratory or hospital.

Sterintech™ SCBI's are calibrated on the QR Incubator in order to provide the most reliable test results.

The incubator will give a printed ticket when obtaining a result (positive or negative) where the most relevant data of the incubation process will be recorded.

The incubator has a built-in “Crusher" that allows fracturing the biological indicator to begin the incubation process. You can see the location of it on page 3.

Start up

Place the Incubator on a flat, firm, vibration-free surface, away from sunlight, away from very intense artificial sources of light, away from hot or cold air currents, away from sources of heat and excessive humidity. Position the equipment so that disconnecting the plug from the power supply is not difficult or deformed. Leave a space of at least 10 cm from the wall. Do not move the incubator periodically and especially not during its use.

Failure to comply with the above recommendations could affect the result that the team issues.

Warning:

Do not wet, or warm the incubator. If any liquid spills on the incubator, unplug it and dry immediately. Before starting, it must be verified that the equipment is completely dry and with empty cavities.

2.Turn the Incubator on by connecting the AC end of the power supply to the power grid and then connect the other end of the power supply cord (plug) to the back of the incubator. You will notice that the touch screen will immediately turn on and the equipment will start its operation.

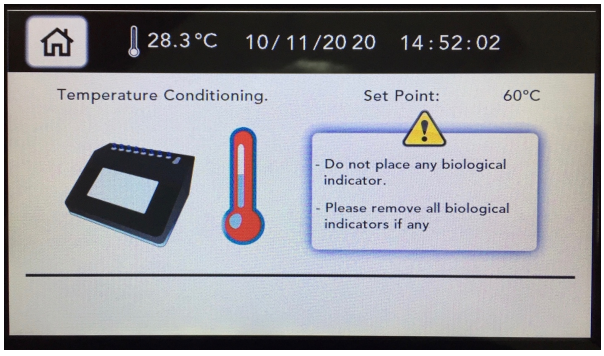
In the first screen, you can see the software version on the incubator.

Likewise, the paper indicator light on the printer will turn On, if the light becomes blinking, it indicates that the thermal paper should be loaded or that the printer cover is not properly closed. Otherwise, the light will remain fixed.

The equipment will start taking the last configuration of incubation program and temperature used.

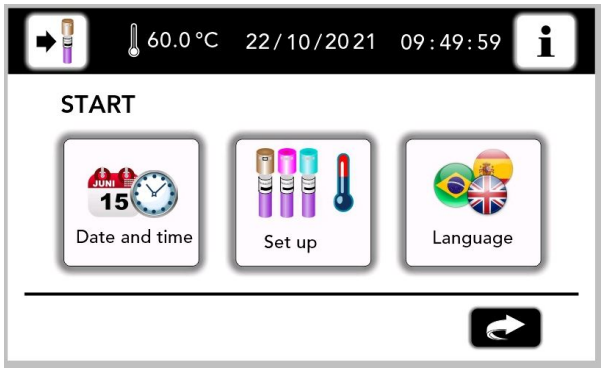
3. After the start-up screen it automatically switch to the second screen, you can see that the equipment performs an "Auto Test", it analyzes the operation of the sensors of each position.

After the initialization the incubator will automatically switch to the third screen.



4. On the third screen, the incubator will begin to condition the temperature to the pre-set temperature.

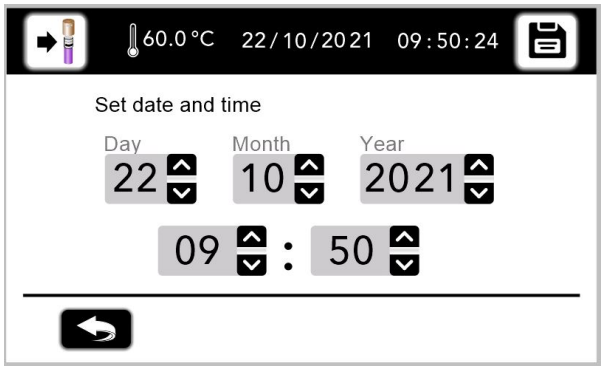
At this time you can enter the Settings menu by touching the HOME icon. You will enter the configuration menu where you can set up time and date, set up of the incubator cycles as well as language.



The home screen

If you press the FORWARD icon, the incubator switch to the second home screen which is showing a Technical Panel which is only available over a password. The description of the Technical Panel is left out of this manual as it may only be used under guidance of our technical staff.

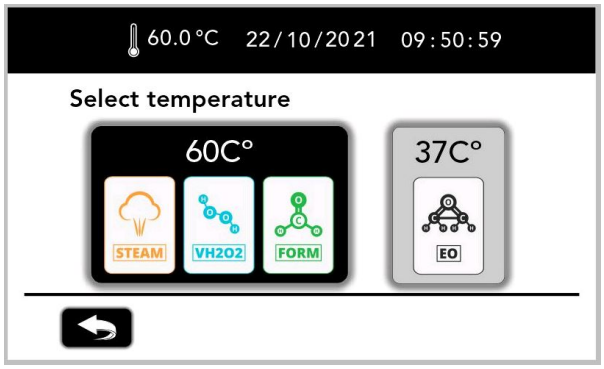
Press Return icon to return to the first Home screen



Date and time settings:

If you press the DATE AND TIME icon, the incubator will go to the following screen where you can set the date in format (DD / MM / YYYY) and time in 24 hours format.

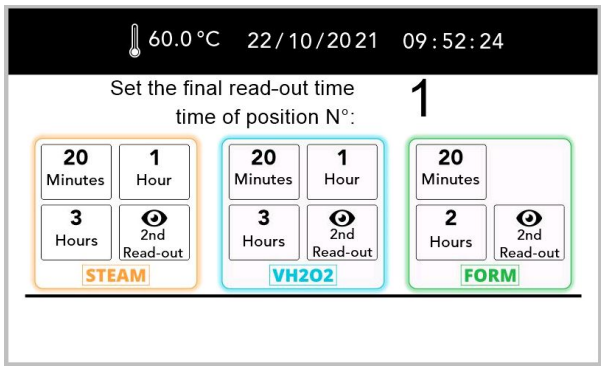
After setting the time and date , you can return to the previous screen by pressing the RETURN button



Configuration of the Sterilization Method:

By clicking on SET UP icon, you can select the sterilization method and thus temperature you wish to incubate.

As the Steam , Plasma and Formaldehyde SCBI's all using the same Bacteria the incubation temperature is the same i.e. 60 ºC. Only for Ethylene-Oxide SCBI the incubator will be set to 37 ºC as incubation temperature. NOTE: It is not possible to incubate on different temperatures at the same time.



After you selected the temperature option, by pressing the FORWARD button (on the low right corner) a screen will appear with the different options presented by the incubator:

One by one you can select the method and time for the consecutive well positions by clicking on your selection it will be confirmed by a changing color of your choice.

The position No. will change to 2 and you can enter your choice for that well. Please continue to choose your selection for the next wells. After you entered your selection for Well 8 the screen will switch back to the main screen.

Notes:

All configured values are stored in the incubator even when it is switched of from its power supply. When it is turned on again, it will take the last parameters that you programmed from it's memory.

A change of incubation program can be made only for an empty position.

The incubator will keep the selected temperature (37 ºC or 60 ºC) during the reading process. The system does not allow to modify the temperature once the reading process has begun, unless the reading is finished.

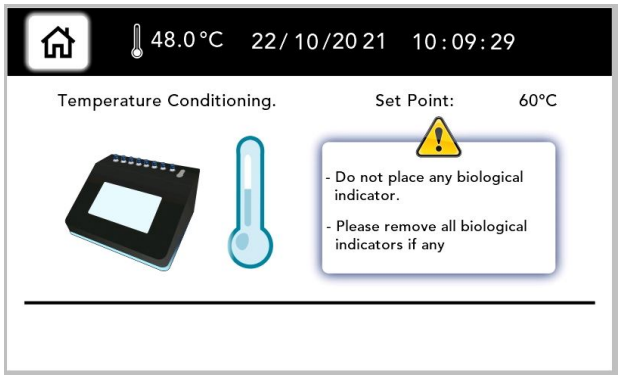
The incubator allows to select different incubation times: 20 minutes, 1 hour and 3 hours for the options of Steam, Plasma and Formaldehyde (incubation temperature of 60 °C) and 3 and 4 hours for Ethylene Oxide (temperature of incubation of 37 °C).

Growth media color change

If you wish to use the incubator as a standard , non-reading incubator , to see the color change of the growth media based upon the spores , you can select 2nd Read-out in the menu for temperature selection. The Incubator will not activate its fluorescent reader for this particular Well but keep incubating for 24 hours.

Language settings:

If you press the LANGUAGE icon, the incubator will go to the following screen where you can configure the language. A selection between English, Spanish and Portugese can be made. Your selected language will keep flashing to confirm your choice. Press the RETURN button to return to the previous screen



At this point you have finished configuring the options that the incubator has.

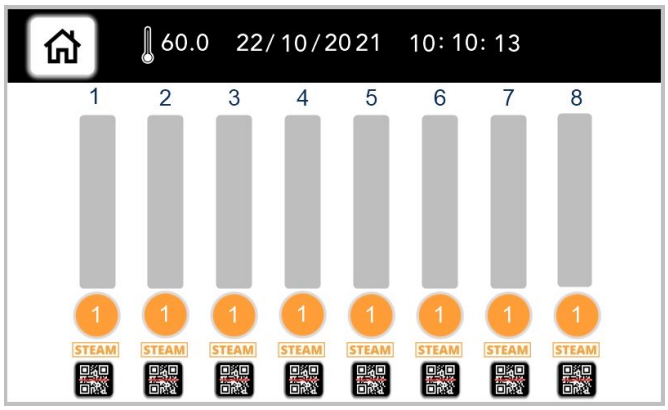
Until the actual temperature of the thermal block does reach the set "incubation temperature" the incubator will not go to the Temperature Conditioning screen.

The time to reach the incubation temperature may vary depending on the temperature of the thermal block when the equipment is turned on. If the thermal block is at an ambient temperature of 23 ° C when the equipment is turned on, the time to reach the incubation temperature may be approximately 35 minutes.

Note: Do not place any biological indicator while the incubator is heating up.

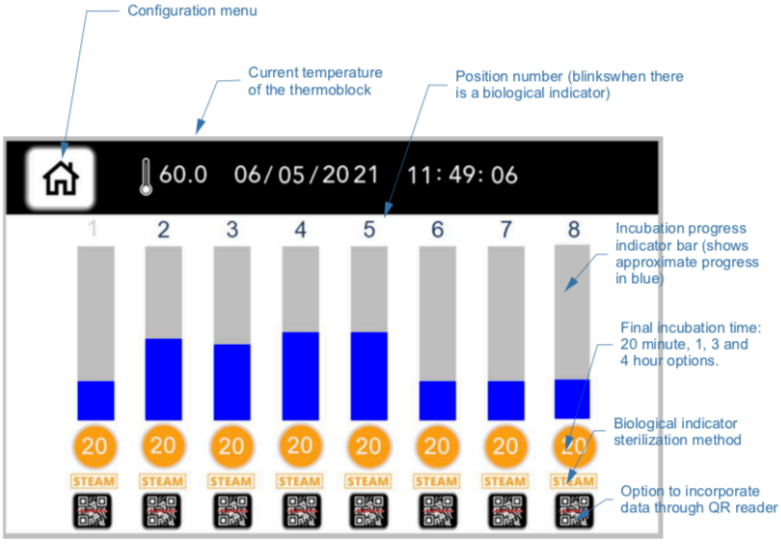
Main Incubation screen information

After the incubation temperature is reached the screen as seen on the left is displayed. You can find the information of the selected sterilization process as well as the time of incubation for each well. (in the screen all wells have been set to STEAM and 1 hour.

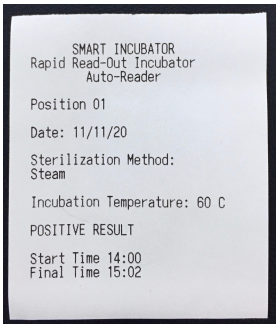


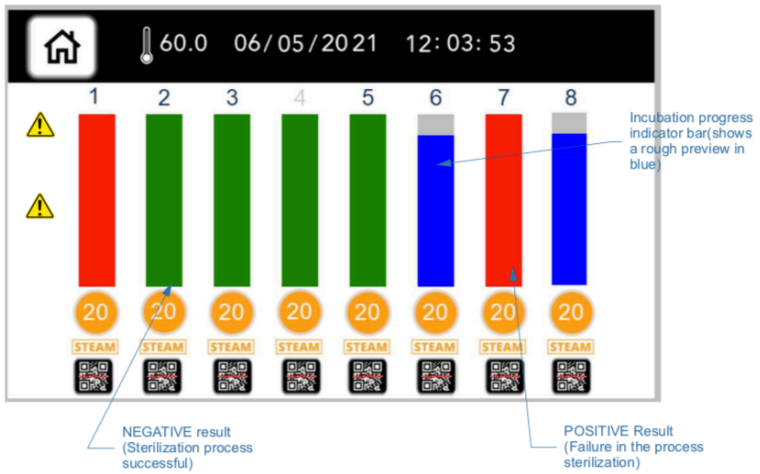
When a Biological Indicator is place it shows a blinking well number. Along with incubation time passing the incubator shows a dark blue indication as indication of the time passed.

During incubation , the LED status light at the base of the incubator will be blue. Once the incubator is giving a result for one of the wells the LED status light will change to RED or GREEN depending of the result. RED is signaling a Positive , GREEN is signaling a Negative result. The LED status light can be seen from a distance in order to get your staff's attention next to the audible alarm.



When a Well is reporting a result depending on the result it will show a RED or GREEN column for that Well number in the screen (see left) and will make a print-out of that result. In the meantime the other Wells will continue to be incubated until a result is know.





Preparation of the Biological Indicator

To avoid risks of injury from glass fragments that are generated by breaking the glass vial contained within the plastic tube of the biological indicator:

- Allow the Biological Indicator to cool down during the indicated time before breaking the vial.

- Avoid excessive manipulation of the Biological Indicator before it cools, as this can cause the glass vial to explode.

- Use glasses and safety gloves when removing the Biological Indicator from the sterilizer.

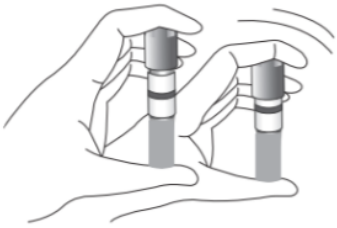
- Use glasses and safety gloves when breaking and pressing the lid of the biological indicator (if needed). Do not use your fingers when breaking the Biological Indicator ampoule.

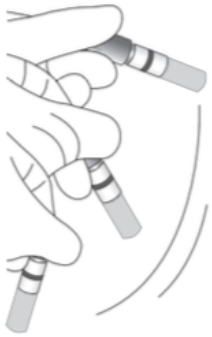
To avoid potential dangerous situations: avoid contact with the hot surface of the metal block of the incubator.

To prevent biological indicator absorbing fluorescent waste: avoid biological indicators coming into direct contact with chemical indicators or tapes.

Instructions for use:

Read the instructions of the biological indicators. Before placing them in the auto-reader, be sure to seal them by pressing the cover down (if needed). Break the ampoule contained inside (use the separate Ampoule crusher or the Crusher in the incubator) and make sure that the culture medium completely wet the spore carrier placed in the bottom of the vial by shaking the Biological indicator for a few seconds.





This is of vital importance in the rapid reading indicators of 1 hour and even more important in the biological indicators of super rapid reading of 20 minutes.

To achieve this, shake the biological indicator vigorously after having sealed it and fractured it down like a thermometer. See the images.

Make sure that the reading position you want to use is configured with the incubation program corresponding to the biological indicator you want to analyse.

Do not remove or change the biological indicator of place once the incubation and reading process has been initiated. If this occurs, the results may be invalid.

After the incubation process of the biological indicator has begun, it can not be removed from the position and then re-incubated, this would affect the result. If you remove the biological indicator after you have incubated it for a minimum period of time, you can not reuse it in a fluorescence position of the incubator. You can only re-incubate it and obtain results from it by means of colorimetry (change of color of the culture medium).

Use a biological indicator that has not been exposed to the sterilization process as a positive control, each time a processed indicator is incubated.

Place the rapid biological indicator in one position and wait for the result. The reading will start automatically. Immediately after having entered the rapid biological indicator into a cavity, the incubator will emit an audible alarm to indicate that the reading began and will show on the screen that said position has just begun an analysis of the indicator. The Well number will blink while in use.

Main incubation screen

When a positive result is detected, the advance column will turn RED and an audible alarm, this will indicate that the sterilization process to which the indicator was exposed has failed.

The negative biological indicators will be informed by placing the GREEN color advance column in the corresponding position, this will indicate that the sterilization process to which the biological indicator was exposed has been successful.

Obtaining / Interpretations the results

Fluorescence reading (fast)

The indicator used as a positive control must show a positive result (red column).

The results of the sterilized indicator are not valid until the biological indicator used as positive control gives a positive result. A sterilized biological indicator that gives a positive result indicates a failure in the sterilization process.

A negative result (green column) after 20 min. (60 ºC), 1 hour (60 ºC), 3 hours (60 ºC), 3 hours (37 ºC) and 4 hours (37 ºC) depending on the program used, indicates that the sterilization process was successful.

The presence of positive results implies that the load must be reprocessed immediately.

In view of these results, review the good practices of preparing the load and using the biological indicators. Verify the volume of load to be sterilized as well as the location of the biological indicator within said load. If the biological indicator has been used correctly, it must be interpreted that the sterilizer presents a possible failure and recommends maintenance of it.

Visual reading (colorimetric)

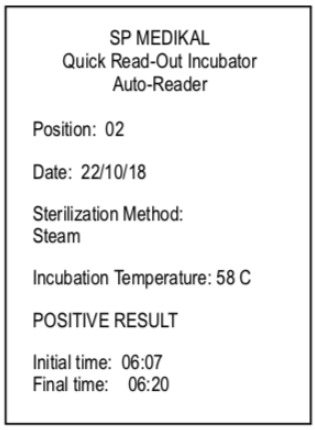
The rapid fluorescence reading system allows the confirmation of results by color of the growth media by incubation over 24 hours.

If the sterilization process was not successful, the growth medium in the indicator will turn into another color, as shown in the Instructions for Use of the biological indicators. If the sterilization process was successful, the indicator growth media will remain unchanged.

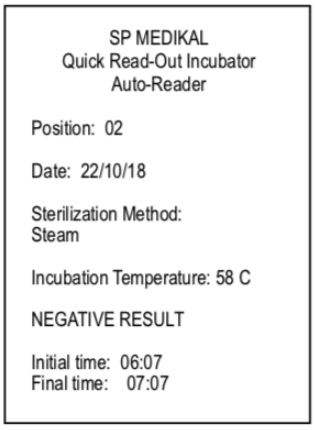
The color of the growth medium in the biological indicator used as a positive control should change during the incubation process for the results to be valid. Record the positives and discard them as per Instructions for Use for the biological indicators.

Printing the results

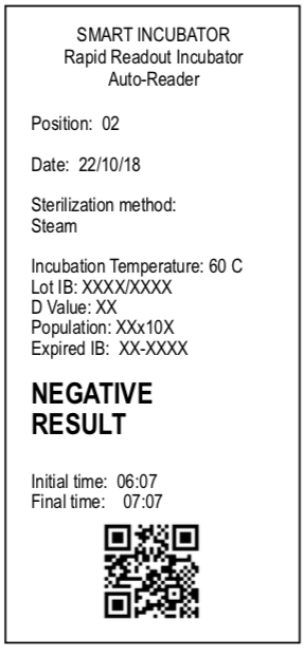
As long as the incubator obtains a result, it will print a ticket with the result obtained.



POSITIVE Result Ticket



NEGATIVE Result Ticket



Result Ticket with QR reading

Discard of Biological Indicators

Discard the biological indicators according to the sanitary regulations of your country. Positive biological indicators can be sterilized (read the Instructions for use of your biological indicators).

Warranty

SP Medikal guarantees both the quality of the material components of this product and its manufacturing process. If it is detected that the product has defects in its materials or manufacturing within the warranty period (1 year from its acquisition), the only obligation of SP Medikal will be the repair or replacement of the product.

Do not use this product in a manner not specified in this manual, otherwise the protection provided by the product could be affected and you would lose your warranty.

Do not replace the power cord nor the power supply with others not provided with the product. Only personnel authorized by SP Medikal can access the interior of the incubator and its components.

No part or component of the interior of the equipment must be manipulated by the user, it could lose its warranty and cause damage to the equipment or to the personnel that manipulates it and can lead to false test results.

Limitations of liability

SP Medikal is not responsible for losses or damages caused by the use of this equipment, due to negligence or due to strict user responsibility.

Technical assistance

For technical assistance initially contact your supplier i.e. the official SP Medikal's distributor. For direct assistance please write an email to info@spmedikal.com

Certificate of Compliance

To whom it may concern

The below mentioned incubators have been undergoing testing to comply with the standards mentioned in this certificate.

- 120.003.0001 Digital Incubator SCBI Quick Read-out

In accordance with European directives 2014/35/EU (Low voltage directive) and 2006/42/EC (EMC directive) we hereby declare that the listed products conform to the published specification and complies with the requirements of the following European Standards and to their current amendments.

BS EN 61010-1:2010 / A1: 2019 Safety requirements for electrical equipment for measurement, control, and laboratory use. General requirements

BS EN 61326-1:2021 Electrical equipment for measurement, control and laboratory use. EMC requirements. Immunity requirements for safety-related systems and for equipment intended to perform safety-related functions (functional safety). General industrial applications

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Further to these design criteria and type tests each individual unit has been undergoing 24 hours of works test and finally a works calibration to meet the 1,0 degrees Celsius accuracy.

Based upon the above mentioned tests and their results the Digital Incubator is carrying a CE-mark at the back the unit.

	Seda Kücükyilmaz	Peter M. den Uil (B. Sc.)
2 JANUARY 2023	Quality Department	Managing Partner