

Mini Auto-reader

User Manual



PREFACE

Dear users:

Please read this Manual before any operation and keep it for further reference. If it is lost, please contact the local agent for another copy.

DISCLAIMER

All the data, pictures, test results and printing files are for reference and operation only, can NOT be used for clinic and maintenance evaluation.

If the software and hardware is upgraded, no other notice will be made. The figures, hardware units or specification may inconsistent with this manual. All the authorized alteration are been tested and compatible with previous version.

More information, please visits our website or contact us directly.

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1. Brief introduction

1.1 Product Features

1.2 Application Scope

Mini rapid biological reader is suitable for the sterilization effect of steam/VHP/LTSF/EO sterilizer. It can monitor the survival of *Bacillus stearothermophilus* spores in the rapid biological indicator. It should be used with the recommended special indicator.

The reader is used to cooperate with 58°C / 37°C (the temperature can be adjusted according to different requirements of the indicator) constant temperature incubation indicators. The final negative / positive incubation results were automatically obtained by reading the fluorescence changes of the special indicator in VH₂O₂ 20min / steam 20min / LTSF 60min / steam 60min / steam 180min / EO 240min.

In the design of mini rapid bio reader, the application requirements of visual PH color interpretation are considered. The reader is allowed to continuously incubate the special indicator at 58°C / 37°C for 24-48 hours. The final negative / positive incubation results can be determined by visual interpretation of PH color change.

Compared with the visual PH color change interpretation, the fluorescence intensity interpretation method has the advantages of high sensitivity, fast response and small error.

The equipment does not support the sterilization result test of other traditional long time incubation indicators except the special indicator.

1.3 SN No.

Mini Rapid Readout Auto-Reader has the only one SN number to identify on the bottom.

1.4 Operating Conditions

Fig.1: power adapter parameters

Items	Requirements
Input	AC: 100~240v, 1.5A, 50/60Hz
Output	DC: 12V, 300mA~6000mA

Fig. 2: Auto-Reader parameters

Items	Environmental Requirement
Ambient Temp.	5•c~35•c
Ambient RH	□ 95% (>85% non condensing)
Ambient Pressure	700~1060 HPa
Power Supply	DC 12V
Current	[max]DC 1.8A
Storage Temp.	5-45•c
Storage RH	10%~90% non-condensation

1.5 Explanation of symbols:

C* Error, operation or test result error, see details “7.2 System error - Chart 6: System error and solutions.

E* Error, Operation error or incubation error, see details “7 Trouble shooting-chart 5: Common error.”



Testing.



Positive, fluorescence result is positive.



Negative, fluorescence result is negative.



WARNING: error.

2. Safety Information

2.1 Service Life and Warranty

Service life is 5years; warranty is 1 year starts from delivery.

2.2 Safety Information

- WARNING:** Please read the user's manual carefully, especially for safety information.
- WARNING:** Indoor application only.
- WARNING:** when the reader is out of service, please read the manual carefully before any troubleshooting, or contact manufacturer for consultancy.
- WARNING:** After the DC power plug is unplugged, please make sure that the power plug and power adapter are matched with the device before inserting it again. It is forbidden to use the power supply that does not match the device.
- WARNING:** Please use the right power cord and power adapter.
- WARNING:** Power cable without national certification is forbidden to use.
- WARNING:** Do not immerse the reader in any liquid or splash on the reader. Warning: do not open the cover.
- WARNING:** Clean the reader according to the manual. Warning: shut off the power before cleaning.
- WARNING:** After sterilization, the indicator needs to be cooled off after taken out (stay in room temperature for 10 to 15 minutes to cool off). Before cooling off, do not shake indicator or break it.
- WARNING:** Confirm the indicator has cooled off to room temperature before plugging into reader.
- WARNING:** Wear protective goggles and gloves when breaking the indicator.
- WARNING:** Please break the glass ampule according to instruction; do not use your fingers to squeeze the glass ampule.
- WARNING:** Do not roll over the indicator between your fingers; do not wet the spore strip; do not open the indicator's cap.
- WARNING:** To avoid the reader from sunshine or other strong light source.
- WARNING:** To avoid the reader from the machine with strong electromagnetic field.
- WARNING:** Do not touch, remove or change the place of the indicator until incubation cycle is complete.
- WARNING:** Do not use reader on uneven surface.
- WARNING:** Put indicator in a safe place and away from chemical indicator, chemical tape or other material containing Fluorescence component.
- WARNING:** During incubation, the result of incubation (+ / -) sign on the operation panel indicates that the indicator should not be touched, removed and turned before the test is completed, and do not change the incubation slot.

2.3 Common Operating Error

Improperly power supply; Wrong adapter. Shake the indicator before cooling off.

Insert the indicator into reader before cooling off. Break the glass ampule before cooling off.

Break the glass ampule without protective goggles and gloves.

Take, move or change the indicator during incubation.

Do incubation on uneven surface. Polluted indicator.

2.4 Risk of Injury

Fig. 3: operating error and risk of injury

Items	Risk of injury
Improperly power supply	Overheat, damaged, fire set by short circuit, display abnormal, touch control abnormal.
Vigorously shake the indicator before cooling.	Hurt or infect users because of the burst of glass ampule
Insert the indicator before cooling.	Hurt or infect users because of the burst of glass ampule
Broke the glass ampule before cooling.	Hurt or infect users because of the burst of glass ampule
Broke the glass ampule without safety glasses and gloves.	Hurt or infect users because of the burst of glass ampule
Touch the indicator during incubation cycle.	Test result error or lose data.
Do incubation during vibrating.	Test result error or lose data.
Place the indicator vial with other fluorescence material.	Test result error

2.5 Solutions

Shut off the power supply to stop temperature keeping going up if overheat occurred or improper working of temp-control units.

When glass ampule burst happened, DO check the user if they get hurt or infected. Clean the wounds or infected skin first, then back to collect all the waste and do the treatment according to the applicable regulation or stipulation.

If the skin was contact with any indicator liquid, DO wash the skin with large quantity of water and treat the wound by the regulation of hospitals. Minor wound applied the above method. Please go and see the doctor if any severe injury occurred.

2.6 Attention in particular cases

If the power is temporarily shut down during incubation cycle, please remove the indicator to regular incubator to see the result.

When the power supply is back on, the new indicator need to be used rather than the last one.

Keep everything stable when incubation starts. If the reader needs to be moved, keep it steady without power off.

3. Features and Working Principle

3.1 Working Principle

Mini Rapid Readout Auto-Reader adopts spectrum analysis technology to monitor the fluorescence changes of the *Bacillus Stearotherophilus* and *Bacillus Subtilis* with special enzyme to rapidly judge whether there is surviving spores.

3.2 Overall structures



Fig. 1: open duct cover

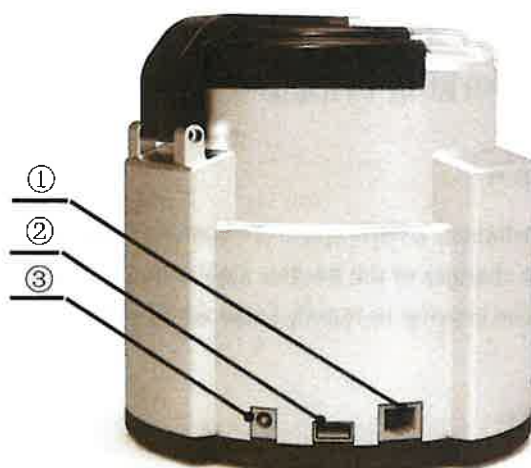
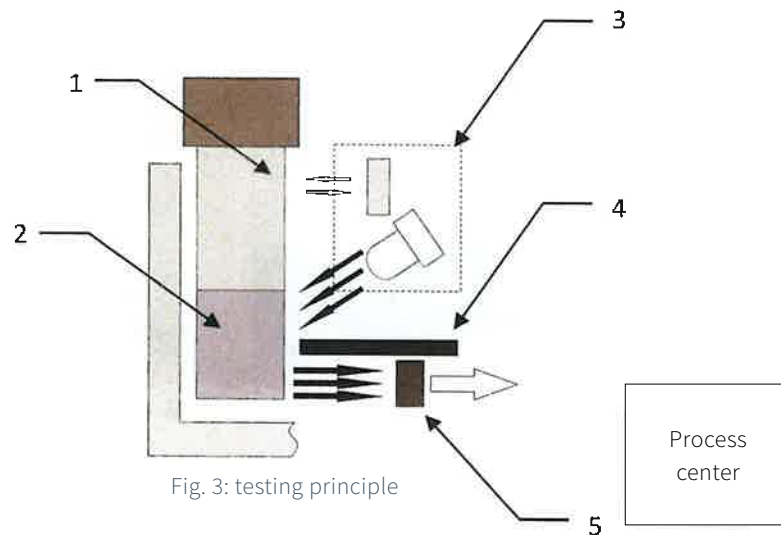


Fig. 2: Back connector

- 1. Ethernet Port
- 2. USB port
- 3. Power outlet

3.3 spare parts and its working principle

**Function of spare parts:**

Heating unit: provide proper temperature.

Photoelectricity unit: check if the indicator is inserted and launch UV of proper wave length.

Light isolation unit: shield other lights besides fluorescence, assure the accurate test result and provide fluorescence transmitting channel.

Photoelectric sensor: converse the optical signal into electrical signal Process center: data calculation and data treatment.

3.4 Visual and sound alarm system

Alarm system adopts visual and sound alarm function, including: screen, light changing, buzzer.

4. Technical Characteristic

4.1 Performance

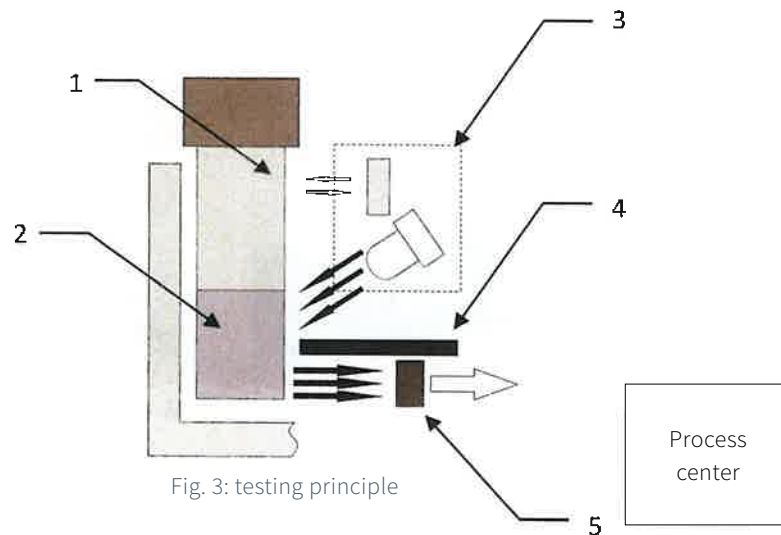


Fig. 3: testing principle

1. Rapid test

Positive readout at 20 minutes (models for steam and VH_2O_2 20mins), 1 hour (model for steam and LTSF 1 hour), 3hours (model for steam 3 hours), 4 hours (model for EO 4hours)

2. Data process and save

After the incubation, the reader automatically saves the incubation results, which can be easily viewed on the app; and can be exported through the USB interface or Ethernet interface on the machine body, so as to facilitate the user to query, edit and print the historical records on other devices, or to print the results in real time through the reader equipped with a printer.

3. Traceability

During the incubation process, the reader can be connected with computer through the Ethernet port, and the indicator and operator related information can be input by the reader related app. The information can be included in the saved final incubation results, and can be queried, edited and printed through the previous "data processing and preservation".

Note: the incubation traceability information can only be entered after the indicator starts to incubation.

4. Visibility

Touch screen, user interface visual is available.

4.2 Parameters

Fig. 4: parameters

Items	Specification	Details
Power Adapter	~100V-240V 50/60Hz	Input
	DC12V 3A	Output
Power Supply	DC12V 3A	
Ambient Temp.	10~40°C	
Ambient RH	<95%	>85% no moisture
Ambient Pressure	700~1060 HPa	
Incubation Temp.	58°C/37°C	Factory setting is 58°C
Testing time needed	20MIN/30MIN/60MIN/240MTN	20mins readout for 20mins steam and VH ₂ O ₂ type BI; 1 hour readout for 1 hour steam BI and LTSF BI; 3 hours readout for 3 hours steam BI; 4 hours readout for 4 hours EO BI
Dimension (W*D*H)	160mm x 60mm x 65mm	W*D*H
Number of Incubation Slots	3	
N.W.	Around 830 g	Adapter excluded
G.W.	Around 1.2kg	Package included

5. Dimension & Weight

5.1 Appearance



Fig. 4: External view

5.2 Weight

N.W.: 0.83kg, one reader.

G.W.: around 1.2 kg, package included.

6. Instruction for use

6.1 Inspection before use

6.1.1 Preparation before power on:

1. Confirm no indicator in slot before power on;
2. Confirm the proper ambient temperature and RH, no vibration and strong light;
3. Confirm a proper adapter.

6.1.2 Initialization inspection

After power on, confirm no error code display and allow a 30 minutes warm-up period before placing indicator into the incubation slots.

If there is, please solve the problem according to “Chapter 7 troubleshooting guide 5”.

6.2 Safety symbols instruction

Improper operation may harm the user and reader. Please operate the reader according to following specifications strictly.

1. Do not break the glass ampule before cooling to avoid ampule burst.
2. Wear safety glasses and gloves when taking out the indicator from the sterilizer.
3. Wear safety glasses when breaking the indicator.
4. Holding the indicator by its cab and break it at the breaking mouth. Do not break indicator with your fingers, do not roll over the indicator.
5. Carefully not dropping the indicator.

6.3 Operation methods and matters need to be attended

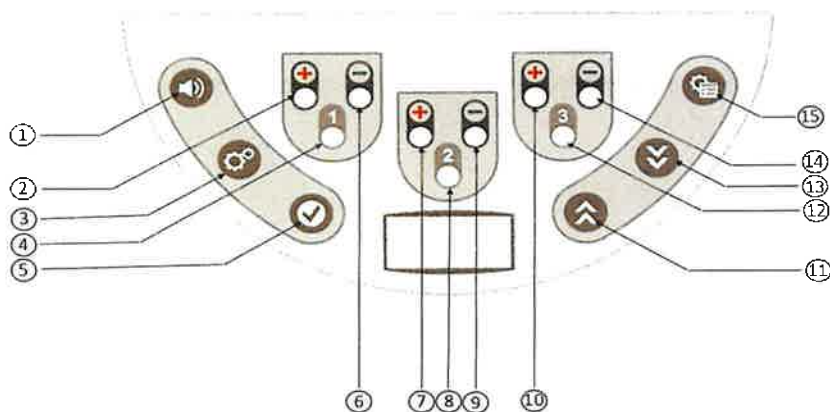


Fig.6: Operation panel

- | | |
|--|---|
| 1. Sound control button | 9. No.2 well negative indication light |
| 2. No.1 well positive indication light | 10. No.3 well positive indication light |
| 3. Setting button | 11. Page up button |
| 4. No.1 well indication light | 12. No.3 well indication light |
| 5. Confirm button | 13. Page down button |
| 6. No.1 well negative indication light | 14. No.2 well negative indication light |
| 7. No.2 well positive indication light | 15. Active scanner |
| 8. No.2 well indication light | |

Mini Reader's working flow:

1. Inspect and connect adapter with power supply.
2. Do not place indicator in the slots and shut down the cover. Connect adapter with reader.
3. Temperature setting,: click the “12

Matters to be attention

1. *DO NOT open the dust cover in the temperature-rise period of heating body; put down the dust cover immediately after indicator is inserted; DO NOT open the dust cover during incubation process in case of problem alarm from the device and imprecise inspection result.*
2. *DO NOT insert indicator in inconstant temperature during the heating body temperature is rising. Otherwise device fault and alarm will occur.*
3. *Please inspect one piece of unexposed indicator for the first daily usage, to attest gemma survival and device normal running. Unexposed indicator is a positive control.*
4. *Please re-insert the indicator 30s later if pulling out the indicator for checking during indication process, or the incubation will be canceled automatically.*
5. *Please operate the above operation when the icon  on the top of interface 7 occurs (no positive, negative or alarm before incubation completes) after inserting operation completes.*
6. *The two sets in above work flow, item 8 are already set in factory.*

7. Trouble shooting

Please refer to the manual for troubleshooting. Do not dispose or disassemble the device at liberty.

The digital tube display, the buzz prompt and the operation panel indicator light can indicate the measurement status and abnormal situation of each detection channel, and indicate in the form of error code below the channel sign. Please follow the instructions in this manual to operate.

When fault or error occurs, if the voice alarm function is turned on, display screen's back light and indication lamps will flicker, meanwhile the sound alarm will working at the same time; If voice alarm function is turned off, only display backlight and indication lamps flashing reminders are available.

7.1 Common error

Fig. 5: Simple malfunction modes and troubleshooting

Fault Phenomenan	Probable Reasons	Troubleshooting
Reader cannot initiate	No power supply or without connection with power adapter	Check whether there is alternating current supply 100V-240V 50/60Hz on the socket by test pencil or multimeter. Check whether the connections between power adapter & socket and device are correct and stable.
No indication on display screen	No power supply or power supply system error in the interior device	Check whether the wire is correct connected on device. (refer to the above item). Please call service center if power connection is correct.
No display or start beep on the nixie tube display	Reader not powered Reader internal power system failure	Check whether the power supply connection of the reader is correct (refer to the previous one). If the power connection is correct, please contact the authorized service center.
Traceability system off-line	Without internet or incorrect IP address	Connect the device and local traceability information system by stable internet wires. Set the online target IP of traceability system as the IP indicated on the device setinterface (this address is gained automatically by device). Please contact the authorization center.

7.2 System error

Please refer to the following content of this manual if any abnormal occurs on this device.,

The status bar at the top of display screen displays all the incubation real-time status or error code;

The status bar at the bottom of the displays device the information of thermostatic system; Please follow the instruction of this manual.

Fig. 6: System error modes and solutions

Category	Code	Malfunction mode	Display Screen	Buzzer Prompt	Indication Lamp Prompt	Troubleshooting
Device Malfunction	C1	Temp. sensor fault	C1 and error description	Buzzing 1s and stop 1s, repeating 3times	Red lamp flickers	End the current incubation and Re-start the device
	C2	Abnormal temp.-rising; temp. did not get to the set value after start up	C2 and error description			Cut the power off; Check if the power adapter is correct; Replace power supply adapter
	C3	Abnormal constant temp.: temp. exceeds constant temp. range during device incubation process.	C3 and error description			
Operation Malfunction	E1	Initial value discrepancy. Starting-up environment inspection. Environment illumination intensity is not Qualified for device running.	E1 and error description	alternate flicker between	Buzzing 1s and stop 1s, repeating 3times	Move the device indoor Keep away from strong light source.
	E2	Indicator is pulled out in incubation process	E2 and error description	Red and blue lamps	Buzzing 1s and stop 1s, repeating 5 times	Insert the same indicator within 30s. Cancel the current incubation 30s later.
	E3	Inserted indication disqualification or error	E3 and error description		Buzzing 1s and stop 1s, repeating 3times	Check if foreign matters exists inside the inspection hole; Check if the indicator is designated model.

Note: please call after-sales service center for help if problem cannot be resolved using the above solutions

Fig. 7: Normal incubation process

Conditions	Screen Reminder	Buzzer Reminder	Light Reminder
Preheating	Temperature display	--	--
Preheat complete	Temperature display	Buzzing 2s	--
Incubating	Scroll to display the countdown time and incubation temperature of corresponding slot {10s for each slot)	--	Corresponding slot blue breathing light is on, cycle 4s (2s weakened and 2s enhanced)
Positive	display "+" at the slot top	Buzzing 2s	"+" breathing light is on, cycle is 4S (2S weakened and 2S enhanced)
Negative	display "-" at the slot top	Buzzing 1s, stop 1s, Repeating 10times	"-" breathing light is on, cycle is 4S (2S weakened and 2S enhanced)

8. Maintenance

8.1 Daily Maintenance and Calibration

- **WARNING: DO NOT do cleaning and maintenance with power on.**
- Keep device cleaned and keep foreign matters away from the inspection holes and channels. Inspect the device regularly to confirm cleanness.
- Scrub the device surface using wet towel with gentle detergent.
- Scrub the inspection channels by dry in cotton swabs. Note: do not soak too much alcohol because alcohol will flow into device through the inspection channels and interfere with device performance.
- **DO NOT** use organic solvents to scrub the surface of the device.
- **DO NOT** disassembly the device, if inside maintenance needed, please contact your local distributor.
- If calibration needed, please call your local distributor.

8.2 Maintenance for long-term out of service

- Please operation as the daily maintenance if out of service in a long period. And pack the device in original package, stored in a place of environment of temp.20 °C to 40 °C, RH 30% ~ 60%.
- Please conduct device calibration after long time storage.

9. Transportation & Storage

9.1 Matters to be attention in lifting and transportation

- Avoid basking and rain;
- Upright placement;
- Handle gently and no falling;
- Highest stacking layer: 4

9.2 Storage condition, time & matters to be attention

- Storage temp. :20°C~40°C;
- Storage RH: 30%~60%RH;
- Storage life for 3 years;
- Regular inspection.

10. Unpacking and Inspection

10.1 Package

- **MINI** rapid readout Auto-reader body is packed in waterproof packaging bag. The body and power adapter are cushioning foam to prevent wear;
- Inner package foam size 240mm * 215mm * 240mm.

Note: Please return unqualified products to manufacturer and the cost will be paid by manufacturer.

10.2 Inspection Contents

- Check whether there is missing piece according to packing list;
- Check whether the device was broken;
- Check whether the power adapter parameters are correct;
- Check whether the power connection is normal.

11. Environmental Protection and Others

- Biological hazards are concerned to the device, and waste generated in the test shall be collected for centralized and unified treatment and then shall be discarded after the sterilization process.
- If the test result is positive, please sterilize other indicators in this batch again.