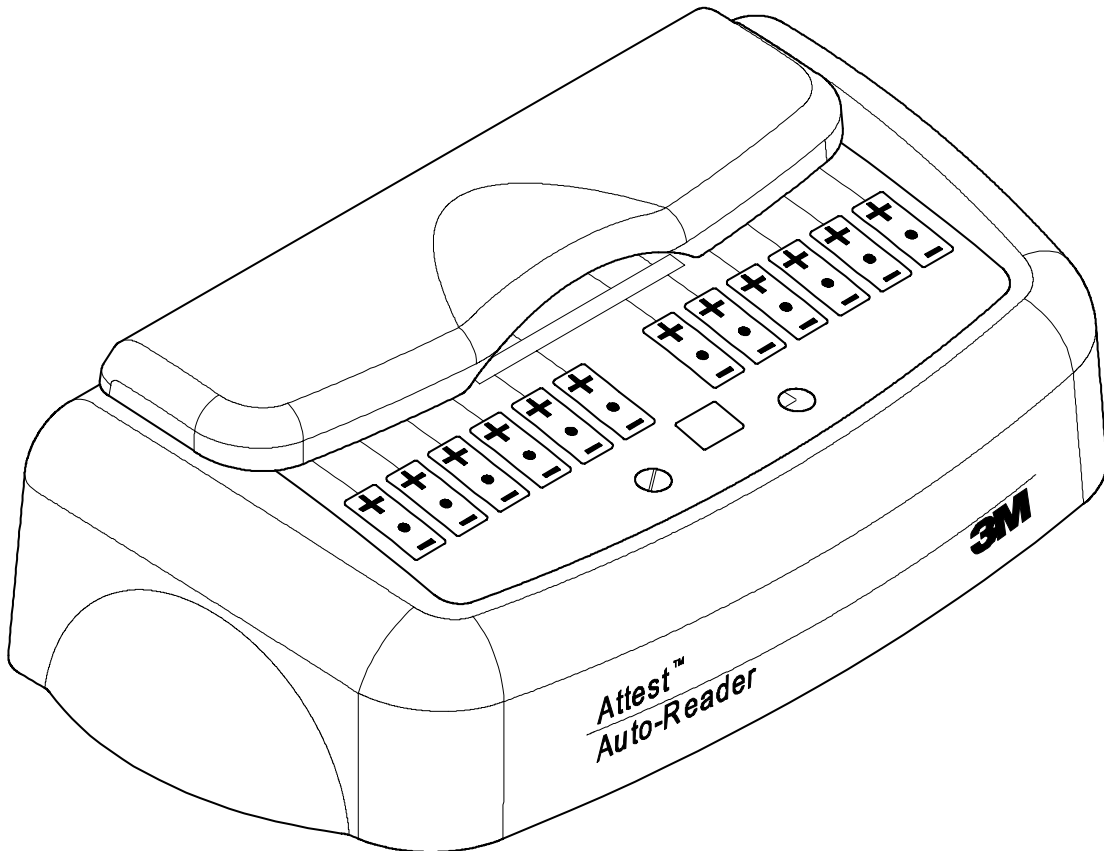


3M™ Attest™ 290 Auto-reader

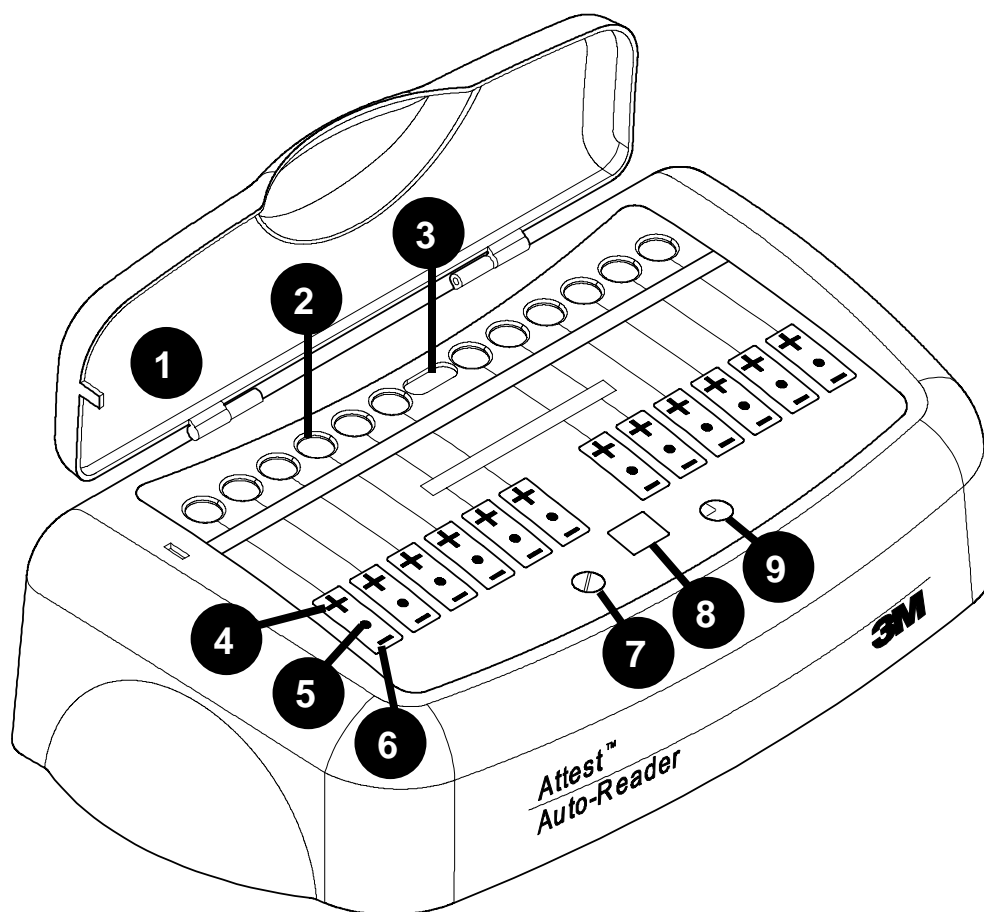
Operator's Manual



Read and understand all safety information before using this product.

3M

INTENDED USE



- | | |
|--|---------------------------------------|
| 1. Cover | 6. Green Light Negative (-) Indicator |
| 2. Incubation/Reader Wells | 7. Buzzer Alarm OFF Button |
| 3. Crusher Well | 8. Digital Display Panel |
| 4. Red Light Positive (+) Indicator | 9. Time Remaining Button |
| 5. Yellow Light (•) Test In Progress Indicator | |

Intended Use

The 3M™ Attest™ 290 Auto-reader is designed to incubate and automatically read the 3M™ Attest™ 1291 Rapid Readout Biological Indicators (RRBI) and/or 3M™ Attest™ 1292 Rapid Readout Biological Indicators at 60°C for a final negative fluorescence reading at 1 hour for 1291 or 3 hours for 1292.

The 3M™ Attest™ 290 Auto-reader is also designed to allow for further incubation of the 3M™ Attest™ 1291 RRBI and/or 3M™ Attest™ 1292 RRBI for a final negative, visual pH color change of the growth media at 24 hours for 1291 and 48 hours for 1292.

A positive fluorescence reading or a visual color change indicates a steam sterilization process failure.

Other biological indicators (BIs), are not compatible with this device and cannot be used.

The unit is designed to be used only with the Power Supply module supplied by 3M.

SAFETY INFORMATION

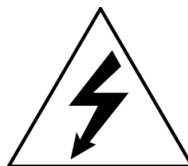
WARNING

- To avoid the risk of electric shock, which if not avoided could result in serious injury or death:
 - Do not immerse the Attest 290 Auto-reader in any liquid.
 - Use indoors only.
 - Disconnect power cord before cleaning.
 - To clean, use only a mild detergent and wipe with a damp cloth.
 - There are no user serviceable parts.
 - The Attest 290 Auto-reader must be returned to the manufacturer for repair.
 - Make sure a properly rated power cord is installed on the Attest 290 Auto-reader power supply.
- To reduce the risk of using incompletely sterilized loads:
 - Match the color on the exterior label of the incubator with the same color cap on the RRBI.
 - Do not remove RRBI until incubation cycle is complete.
 - Do not use on a vibrating surface.
- There is a glass ampule inside the plastic vial of the RRBI. To avoid the risk of injury from flying debris due to a ruptured RRBI, which if not avoided could result in serious injury or death:
 - Allow the RRBI to cool for the recommended time period before crushing.
 - Crushing or excessive handling of the biological indicator before cooling may cause the glass ampule to burst.
 - Wear safety glasses and gloves when removing the RRBI from the sterilizer.
 - Wear safety glasses when crushing the RRBI.
 - Handle the RRBI by the cap when crushing and tapping.
 - Do not use your fingers to crush the glass ampule.
 - Do not roll the RRBI between your fingers to wet the spore strip.

CAUTION

- To avoid a potentially hazardous situation, which if not avoided may result in minor or moderate injury:
 - Avoid contact with the hot surface of the metal incubator block.
- To avoid possible environmental contamination, dispose of the Attest 290 Auto-reader according to applicable governmental regulations.
- To avoid RRBI vial from absorbing fluorescent residue from a chemical indicator or tape, place the RRBI vial so it does not come in direct contact with chemical indicators or tape.

Explanation of symbols:



Caution – Risk of electric shock



Attention – Refer to accompanying documents

SAFETY INFORMATION

Power Supply Specifications

Power supply	Operating Condition	Units
Voltage Range	100-240	Volts AC
Frequency	50/60	Hertz
Current	1.2	Amps

Environmental Operating Conditions

Environmental Condition	Operating Condition	Units
Altitude	2500 (max)	meters
Operating Temperature	16-43	°C
Relative Humidity	20-80 (non-condensing)	%
Voltage Range	12	Volts DC
Frequency	DC	
Current	2.4	Amps
Installation/Over Voltage	Category II	
Pollution Degree	2	

Health and Safety Information

Device Safety Compliance

The Attest 290 Auto-reader complies with the standard IEC/EN 61010-1 as demonstrated by the CB Scheme Certificate and test report that Underwriters Laboratories Inc. (UL) generated.

The Attest 290 Auto-reader is listed as Laboratory equipment and carries the UL and c-UL marks based on compliance to the standards UL 3101-1 and CSA 22.2 No. 1010-1.92.

The Attest 290 Auto-reader complies with the CE mark related to the Low Voltage Directive 73/23/EEC as confirmed in the Declaration of Conformity.

EMC Compliance

The Attest 290 Auto-reader complies with IEC/EN 61326-1 as confirmed in the Certificate of Compliance generated by 3M.

The Attest 290 Auto-reader complies with the EMC requirements of the CE mark EMC Directive 89/336/EEC.

The Attest 290 Auto-reader complies with the Australian EMC requirements as confirmed in the Supplier's Declaration of Conformity that is linked to the C-tick mark.

Note: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide a reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at their own expense.

This Class A digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Cet appareil numérique de la classe A respecte toutes les exigences du Règlement sur le matériel brouilleur du Canada.

INSTRUCTIONS FOR USE

Operating Instructions

Start-up

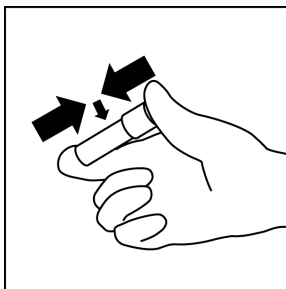
Place unit on a firm level surface. Plug unit into an appropriate AC grounded outlet.

Allow a 30 minute warm-up period before placing RRBI's into the incubation wells. The C1 caution code will disappear when proper incubation temperature is reached.

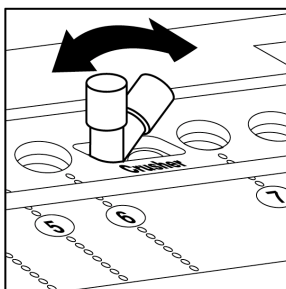
It is recommended that the unit be left on to eliminate warm-up periods. The unit may be turned off when it is anticipated that it will not be used for an extended period.

Readout Procedure

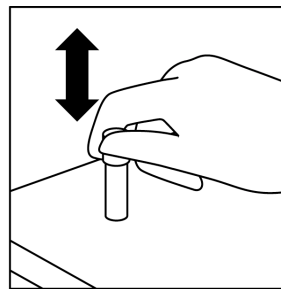
Follow this procedure for every RRBI to be read:



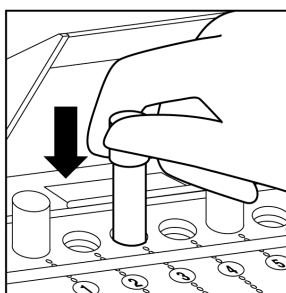
Step 1. While wearing gloves and safety glasses, **CLOSE** RRBI cap by pressing down.



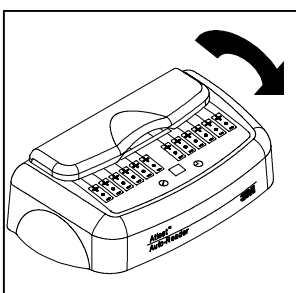
Step 2. CRUSH the glass ampule (containing growth media) in the designated crushing well built into the incubator.



Step 3. Hold the RRBI by the cap and **TAP** bottom of the vial on a tabletop until media wets spore strip at bottom of vial. Do not tap vial on unit.



Step 4. Open the cover and **PLACE** the RRBI into an incubation/reader well.



Step 5. CLOSE the cover on the Attest 290 Auto-reader and wait for either the red or green indicator light to signal the result.

WARNING

Do not remove or change placement of RRBI once it is placed into a well. Doing so may result in loss of results and the RRBI test may be invalid.

INSTRUCTIONS FOR USE

Wells are color coded to match the cap of each type of biological indicator; i.e. the 1291 RRBI with a blue cap goes into a blue well and the 1292 RRBI with a brown cap goes into a brown well.

A yellow light will come on to indicate the RRBI is incubating in the reader well and should **not** be touched. A yellow light indicates the results are not available and incubation is in progress.

Do not remove RRBI until the red (+) or green (-) light indicates the test is complete.

Note: If RRBI are inadvertently removed before the incubation period is complete, an alarm will sound and all three lights (+, •, and -), for that incubation well will light. C2 Caution code will also be displayed. You **must return the RRBI to the reader well within 10 seconds or the results will be lost.**

WARNING

Do not remove or change placement of RRBI once it is placed into a well. Doing so may result in loss of results and the RRBI test may be invalid.

All red, yellow and green lights will flash for one second when the cover is opened demonstrating they are functional.

The cover should **only** be opened when placing additional RRBI into incubation wells or when removing RRBI at the completion of the designated incubation period.

A positive result (+) will automatically be shown as soon as it is detected. The full incubation period is required before a negative result (-) is shown. The Attest 1291 RRBI requires 1 hour of incubation and the Attest 1292 RRBI requires 3 hours of incubation before a negative (-) result will be shown. The negative result will be shown automatically after completion of the required incubation time.

The processed indicator and the positive control may also be further incubated for a visual pH color change. The final negative reading (media remains purple) for a visual color change is made at 24 hours (1291) or 48 hours (1292). The positive control should show a yellow color change of the growth media. For any incubation beyond 24 hours (1291) or 48 hours (1292), RRBI should be moved to a humidified environment.

Each facility must establish final readout time in its policy and procedures. The policy should be based on manufacturer's instructions for use, scientific knowledge, current recommendation practices, applicable compliance requirements, inventory levels, and the risk to the patient if the medical device is not sterile.

INSTRUCTIONS FOR USE

Positive Control

Crush, tap and incubate at least one non-processed Attest 1291 or 1292 RRBI to use as the positive control each day that a processed RRBI is incubated and read by the unit. Write a "C" (for "control") and the date on the label. The positive control can be placed in any incubator well of the unit. The positive control should be the same part number, from the same manufacturing date and lot number as the processed RRBI in the unit.

It is good practice to use a positive control each day a sterilized RRBI is processed. This helps ensure:

- correct incubation temperatures are met.
- viability of spores has not been altered due to improper storage temperature, humidity, or proximity to chemicals
- capability of media to promote rapid growth, and
- proper functioning of Attest 290 Auto-reader components.

Interpretation of Results

Each incubation/reader well has three corresponding indicator lights: a red (+), yellow (•) and green (-) light. After placing a RRBI into a corresponding color-coded well, a yellow light will illuminate to indicate that incubation/reading is in progress.

The final negative processed RRBI reading for a fluorescence change (green light -) after 1 hour (1291) or 3 hours (1292) indicates an acceptable sterilization process. The positive control should read positive (red light +).

A red light (+), will illuminate and an alarm will sound (if the sound feature is turned on), as soon as a positive RRBI result is detected.

If the processed RRBI is further incubated for a visual pH color change, when special studies are desired, the media color change from purple to yellow will also indicate a sterilization failure. The positive control should show a yellow color change at 24 hours (1291) or 48 hours (1292). A final negative color change result (no color change), media remains purple, is made at 24 hours (1291) or 48 hours (1292).

At the end of the specified incubation time, if a negative RRBI result is detected, the green light (-) will illuminate indicating an acceptable sterilization process.

After either the green or red light comes on, the RRBI can be removed from the well. The RRBI should not be removed or touched when the yellow light is on.

Act on any positive result immediately. The positive result indicates a sterilization process failure may have occurred. Determine the cause of the positive RRBI following current facility policies and procedures. Always retest the sterilizer and do not use the sterilizer for processing loads until 3 consecutive RRBI results are negative.

The positive (unprocessed) control RRBI must provide a positive fluorescent result (red light +). Processed RRBI results are not valid until the positive control reads fluorescent positive (red light +). With the processed RRBI, a positive (red light +) result means a sterilization process failure may have occurred.

Disposal

Dispose of the used Attest RRBI according to your healthcare facility policy.

You may wish to sterilize any positive RRBI prior to disposal.

FEATURES, CARE AND CLEANING

Features

Audible Alarm

An audible alarm will sound and the positive red (+) light will illuminate for the designated incubation/reader well when a positive result is detected. This provides results in the least amount of time without the need to manually take frequent readings. An alarm will also sound if a RRBI is removed from the Attest 290 Auto-reader well before a final result has been detected. Data will be lost if the RRBI is not replaced in the reader/incubation well within 10 seconds.

Alarm On/Off

The audible alarm for positive results can be turned off or on for a particular RRBI. This is accomplished by pressing the "alarm off" button after the alarm has sounded. This will turn off the alarm for that RRBI only. Any positive RRBI results detected in other wells will result in the alarm sounding. Removing the RRBI will reactivate the alarm for that well. Pressing the "alarm off" button will not silence the alarm for error or caution code alarm warnings.

To turn alarm function off (disable), press both the "alarm off" and "time remaining" buttons at the same time. A yellow period will appear on the lower right corner of the display panel to indicate the alarm is disabled. The alarm will be disabled for all positive RRBIs, error codes, and caution code alarm warnings.

To turn the alarm function back on, press the "alarm off" and "time remaining" buttons at the same time. The yellow period on the display panel will turn off, indicating that the alarm is again active.

Time Remaining

When the "time remaining" button is pressed, the incubation time remaining for each individual incubation/reader well that contains a RRBI will be displayed. All three lights for each individual incubation/reader well will illuminate as the time remaining is displayed. The process begins with the incubation/reader well containing a RRBI on the left and proceeds to the right. The time remaining appears in hours until there is less than an hour remaining when it displays minutes remaining.

Temperature Monitoring

The Attest 290 Auto-reader contains an internal temperature self-diagnostic program. Should the temperature fall outside the specified range (60°C +/-2°C) an error code will be displayed.

Power Cord Retaining Clip

Place the power cord through the power cord-retaining clip on the rear of the Attest 290 Auto-reader near the plug in. This will help to ensure that the power connection does not become inadvertently disconnected.

Care and Cleaning

WARNING

Always unplug the Attest 290 Auto-reader and allow to cool before cleaning. Do not immerse the unit in liquid.

Clean the exterior surface of the Attest 290 Auto-reader, with the dust cover closed, by wiping it with a damp cloth moistened with a mild detergent. Do not open the dust cover and attempt to clean interior components. If additional cleaning of the wells is required, call for repair or replacement.

Note: The Attest 290 Auto-reader does not contain any user serviceable parts or require any routine maintenance. Any malfunctions will be indicated by an error code. Refer to the Trouble Shooting Guide section for error code explanations.

TROUBLESHOOTING GUIDE

Trouble Shooting Guide

In the event of an error code, unplug the Attest 290 Auto-reader and plug it back in to initiate the self-diagnostic test. If error code re-occurs, call for repair or replacement.

The display panel will indicate malfunctions detected by a specific error code. Refer to the following:

Code	Problem	Solution
C1	Unit Warm-up Caution Incubation block not at temperature (RRBI readings are disabled until incubator block reaches 60°C +/-2°C).	Allow a 30 minute warm-up after Attest 290 Auto-reader is plugged in.
C2	RRBI has been removed before incubation complete. All three lights for affected RRBI will light and alarm will sound if active.	Replace RRBI in proper well within 10 seconds.
E1	Temperature Control Error This error will occur if system is no longer able to control the temperature of the incubator block (60°C +/-2°C).	Call for repair or replacement.
E3	Memory Error.	Call for repair or replacement.
E4	Analog-Digital Conversion Error.	Call for repair or replacement.
E7	Communications Error This error will occur if internal communications have failed.	Call for repair or replacement.
E8	Bulb Error This error occurs if the system detects that the bulb is too dim to properly read RRBI results.	Call for repair or replacement.
E9	Transport Error This error will occur if the system detects a motor failure or positioning problem.	Call for repair or replacement.

TROUBLESHOOTING GUIDE

Trouble Shooting Guide (Continued)

Code	Problem	Solution
Other	Unwanted alarm sounds when positive detected.	Turn alarm off, refer to features Section.
Other	All three lights blink and buzzer sounds. RRBI has been removed from incubation/reader well prematurely.	Replace RRBI in incubation/reader well within 10 seconds to prevent loss of data collected.
Other	Red, yellow, or green lights do not illuminate when expected such as following insertion of a RRBI or when time remaining button is pressed.	Specific light burned out. Call for repair or replacement.
Other	Negative Control Vial	
	Vial not crushed.	Crush vial before inserting into well.
	Media did not wet the spore strip.	Tap vial on table until media wets spore strip.
	Control vial was sterilized.	Use a non-sterilized vial as a control. Check chemical indicator on label.
Other	Unexplained positive	
	Adhesive residue on vial.	Do not place tape or labels on vial.
	Test vial is absorbing fluorescent residue from a chemical indicator or tape.	Place the vial so it does not come in direct contact with chemical indicators or tape.

Repair and Replacement

Attest 290 Auto-readers must be repaired at:

3M Health Care Service Center
Suite 200, Bldg. 502
3350 Granada Avenue North
Oakdale, MN 55128
1-800-292-6298
Fax: 1-800-770-8016

Outside of the USA, contact your local 3M Subsidiary.

If you have questions, call our Customer Service number: 1-800-292-6298.

3M Health Care
3M Center
Building 275-4E-01
St. Paul, MN 55144-1000
1-800-228-3957



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