# 3M™ Attest™ Auto-reader 490H

GB Operator's Manual

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# 3M™ Attest™ Auto-reader 490H

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**Read and understand all safety information before using this product.**

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# PREFACE

## Manual Revision History

| Date | Revision | Reason for Revision |
|---|---|---|
| November, 2013 | A | Initial Issue |
| September, 2014 | B | To add network switch requirements to the WebApp section. |
| April, 2015 | C | Various specification edits/updates. 490H Web App Configuration Page: Added rows for secondary DNS and MAC address. BI Activation instructions: added option to activate 1295 BI using Attest™ BI Activator. |
| March, 2017 | D | Revised to reflect reduced time for final fluorescent result. Applicable to 3M™ Attest™ Auto-reader 490H software version 4.0.0 or greater. |

## Content Disclaimers

### Pictorial Disclaimer

Sample printouts, graphics, displays and screens are for information and illustration purposes only, and shall not be used for clinical or maintenance evaluations. Data shown in sample printouts and screens do not reflect actual test results.

### Hardware Disclaimer

The 3M™ Attest™ Auto-reader 490H hardware specifications are subject to change. The system images, hardware components and hardware specifications included in the manual may not match the system installed. Any changes or modifications to the authorized system installation have been verified as compatible with the functionality outlined in this document.

# INTENDED USE

The 3M™ Attest™ Rapid Readout Biological Indicator System for Vaporized Hydrogen Peroxide Sterilization provides rapid and reliable routine monitoring of vaporized hydrogen peroxide sterilization processes in health care facilities. The system is comprised of an incubator/reader with embedded software, the 3M™ Attest™ Auto-reader 490H, and a biological indicator, the 3M™ Attest™ Rapid Readout Biological Indicator 1295.

# INDICATIONS FOR USE

The 3M™ Attest™ Auto-reader 490H is designed to incubate and automatically read the 3M™ Attest™ Rapid Readout Biological Indicator 1295 at 60°C for a final fluorescent result at 24 minutes.

# PRODUCT DESCRIPTION

The 3M™ Attest™ Rapid Readout Biological Indicator System for Vaporized Hydrogen Peroxide Sterilization provides rapid, reliable routine monitoring of hydrogen peroxide vapor sterilization processes performed in health care facilities. The system is comprised of a biological indicator and an incubator/reader (3M™ Attest™ Auto-reader 490H) with embedded software. The 3M™ Attest™ Auto-reader 490H is designed to incubate and automatically read 3M™ Attest™ Rapid Readout Biological Indicators 1295 at 60°C for a final fluorescent result at 24 minutes.

The 3M™ Attest™ Auto-reader 490H is also designed to allow for further incubation of positive control 3M™ Attest™ Rapid Readout Biological Indicators 1295 for a final positive visual pH color change result at 24 hours. It is recommended that processed BIs be transferred to a humidified incubator for further incubation. A final negative visual pH color change result is assessed after 7 days. This further incubation is optional and not intended for routine use.

A positive fluorescence reading or a positive visual pH color change result indicate a sterilization process failure. However, due to the high sensitivity of the fluorescent result, there is no advantage to continuing to incubate processed 3M™ Attest™ Rapid Readout Biological Indicators 1295 once the fluorescent result has been documented.

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

# WARRANTY

The 3M™ Attest™ Auto-reader 490H has a one year limited product warranty. The US warranty, remedy and limitations are described in the Price Quote form and in the Direct Price Pages. For countries outside of the US, any warranty is established by the subsidiary with responsibility for service of the 3M™ Attest™ Auto-reader 490H.

## Serial Number

For easy identification, each 3M™ Attest™ Auto-reader 490H has a unique serial number printed on a label found on the back of the unit and displayed on the left side of the upper row of text on the LCD display when the user depresses the button. Please record your serial number in this manual for future reference: _____.

# SAFETY AND PRECAUTIONS

The 3M™ Attest™ Auto-reader 490H and its related devices and accessories are designed to provide safe and reliable service when used according to the instructions provided. Please read, understand, and follow all safety information contained in the instructions for use included with the 3M™ Attest™ Auto-reader 490H and the 3M™ Attest™ Rapid Readout Biological Indicator 1295 devices prior to use. Use this equipment only for the purpose described in this Operator's Manual. **Retain these instructions for future reference.**

The unit is designed to be used only with the Power Supply module and Ethernet cable supplied by 3M. If this product is used in a manner not specified, the protection provided by the product may be impaired.

## Explanation of Single Word Consequences

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

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

## Warnings and Safety Precautions

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

| **WARNING:** To reduce the risk associated with hazardous voltage |
|---|
| Use indoors only. |
| Do not use the equipment if it is not working properly or if it has suffered any damage. |
| Use only the power supply specified for this product and certified for the country of use. |

| **CAUTION:** To reduce the risk of injury or instrument damage |
|---|
| Do not spill liquid onto or into the instrument. Do not immerse the unit in liquid. |
| Always unplug the 3M™ Attest™ Auto-reader 490H and allow to cool before cleaning. |
| Clean external surfaces using only the instructions provided by the manufacturer. |
| Do not open the instrument housing – there are no user serviceable parts. The instrument must be returned to the manufacturer for repair. |
| Wear safety glasses and gloves when activating the 3M™ Attest™ Rapid Readout Biological Indicator 1295. |

| ⚠ **WARNING:** To reduce the risk associated with incorrect results |
|---|
| Instrument is to be used by operators familiar with the device, device functionality, and Operator's Manual. |
| Do not place the instrument in environment exposed to sunlight or strong incandescent light. |
| Do not place instrument close to any device that emits a strong electro-magnetic field. |
| Do not use on a vibrating surface. |
| Activate and incubate 3M™ Attest™ Rapid Readout Biological Indicators 1295 within 1 hour of the completion of the sterilization cycle. |
| Do not incubate a 3M™ Attest™ Rapid Readout Biological Indicator 1295 if, after processing and before BI activation, it is observed to have a broken media ampoule. Retest the sterilizer with a new biological indicator. |
| Incubate the 3M™ Attest™ Rapid Readout Biological Indicator 1295 only in the 3M™ Attest™ Auto-reader 490H i.e., match the pink cap color of the 1295 BI with the pink color-coded configuration sticker surrounding the 3M™ Attest™ Auto-reader 490H incubation wells. |
| Do not remove the 3M™ Attest™ Rapid Readout Biological Indicator from the incubation well until the (+) or (-) symbol on the LCD display indicates the test is complete. |

| ⚠ **Caution:** To reduce the risk associated with incorrect results |
|---|
| To avoid the possibility of the 3M™ Attest™ Rapid Readout Biological Indicator 1295 vial absorbing fluorescent residue from a chemical indicator or tape, place the 3M™ Attest™ Rapid Readout Biological Indicator vial so it does not come in direct contact with chemical indicators or tape. |

## HEALTH AND SAFETY INFORMATION

### Device Safety Compliance

The 3M™ Attest™ Auto-reader 490H complies with the following standards as demonstrated by the CB Scheme Certificate and test report issued by Underwriters Laboratories (UL):

- IEC 61010-1 (2010) 3rd Edition. Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements
- IEC 61010-2-010: 2014 3rd Edition. Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials

The 3M™ Attest™ Auto-reader 490H is listed as Laboratory equipment and carries the UL mark with adjacent indicators "C" and "US" based on compliance to the standards UL 61010-1, CAN/CSA C22.2 No. 61010-1 and CAN/CSA C22.2 No. 61010-2-010.

The 3M™ Attest™ Auto-reader 490H complies with the CE mark related to the Low Voltage Directive (LVD) 2006/95/EC as confirmed in the Declaration of Conformity.

The 3M™ Attest™ Auto-reader 490H complies with the RoHS Directive, Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The 3M™ Attest™ Auto-reader 490H complies with the WEEE Directive, Directive 2012/19/EU of the European Parliament and of the Council of 04 July 2012 on waste electrical and electronic equipment (WEEE).

### EMC Compliance

The 3M™ Attest™ Auto-reader 490H complies with the following EMC standards as confirmed in the Certificate of Compliance generated by 3M:

- IEC 61326-1:2012/EN 61326:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
- EMC requirements of the CE mark EMC Directive 2004/108/EC.

The 3M™ Attest™ Auto-reader 490H complies with the Australian and New Zealand electrical safety and electromagnetic compatibility requirements as confirmed in the Supplier's Declaration of Conformity that is linked to the Australian/New Zealand RCM (Regulatory Compliance Mark).

**Note:** This equipment has been tested and found to comply with the limits for a Class A digital device pursuant to Part 15, Subpart B, 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 device meets all requirements of the Canadian Interference-Causing Equipment Regulations.

## EXPLANATION OF PRODUCT AND PACKAGING LABEL SYMBOLS

| | |
|---|---|
| ⚠ | Attention - Refer to the instructions for use |
| Li | Waste Electrical and Electronic Equipment (WEEE) and EU Battery Directive. This symbol indicates that both the device and the lithium ion battery contained therein need to be disposed of properly. |
| c UL us | UL Listed to US and Canadian Safety Standards |
| CE | Mark of Conformity to European Directives |
| ⎓ | Direct current |
| | Compliant to all applicable ACMA regulatory arrangements (RCM) |
| | Manufacturer |
| REF | Catalog number |
| EC REP | Authorized representative for the European Community |
| SN | Serial number |

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# SPECIFICATIONS

## Power Supply Specifications

| Power supply | Operating Condition | Units |
|---|---|---|
| Voltage Range | 100-240 | Volts AC |
| Frequency | 50/60 | Hertz |
| Current | 0.6 | Amps |

## Environmental Operating Conditions

| Environmental Condition | Operating Condition | Units |
|---|---|---|
| Altitude | 3000 (max) | Meters |
| Operating Temperature | 16 – 40 | ºC |
| Storage Temperature | -10 to 50 | ºC |
| Operating Relative Humidity | 20-80 (non-condensing) | % |
| Voltage Range | 12 | Volts DC |
| Frequency | DC | |
| Current | 1.2 | Amps |
| Installation/Over Voltage | Category II | |
| Pollution Degree | 2 | |

# INSTRUCTIONS FOR USE – INITIAL SET-UP

## Choose Location

Place 3M™ Attest™ Auto-reader 490H on a firm and level surface, away from sunlight and incandescent light. To save counter space, units may be stacked two high.

**WARNING:**

- Do not place the instrument in environment exposed to sunlight or strong incandescent light.
- Do not place instrument close to any device that emits a strong electro-magnetic field.
- Do not use on a vibrating surface.

## Select & Install Correct Power Plug

The 3M™ Attest™ Auto-reader 490H power supply comes with multiple blade configurations. Install the blade configuration appropriate for your country into the power supply and plug into appropriate AC grounded outlet.

**WARNING:** Use only the power supply specified for this product and certified for the country of use.

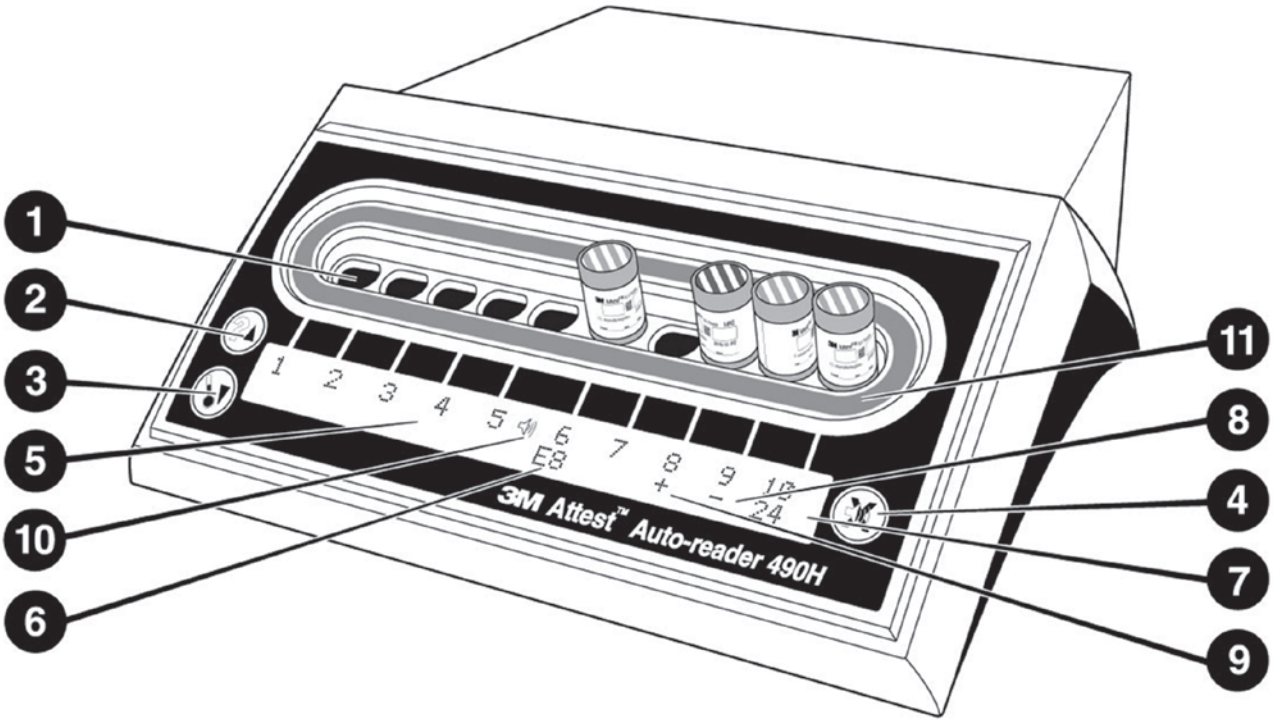
## Wait 30 Minutes Before Using

Once plugged in, allow a 30 minute warm-up period before placing 3M™ Attest™ Rapid Readout Biological Indicators 1295 into the incubation wells. The C1 caution code will disappear when proper incubation temperature is reached.

## Special Considerations

**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.

# INSTRUCTIONS FOR USE – WELLS, BUTTONS, & DISPLAY INTERPRETATION




Please familiarize yourself with the face of the 3M™ Attest™ Auto-reader 490H:

### Wells

1. Incubation/Reader Wells – The 3M™ Attest™ Auto-reader 490H has ten incubation wells.

### Buttons

2. Information / Up Arrow Button
3. Temperature / Down Arrow Button
4. Buzzer Alarm OFF / Enter Button

### Information Display

5. LCD display – Display is backlit
6. LCD display – Example of Error Message for well #6
7. LCD display – Example of Remaining Incubation Time, in minutes, for well #10
8. LCD display – Example of Negative ( - ) BI result for well #9
9. LCD display – Example of Positive ( + ) BI result for well #8
10. LCD display – Alarm Enabled Indicator

### Color-Coded Configuration Indicator

11. Incubation well configuration sticker is color-coded pink

## INSTRUCTIONS FOR USE – 3M™ ATTEST™ AUTO-READER 490H CONFIGURATION

**Note:** Ideally, the 3M™ Attest™ Auto-reader 490H should be empty (i.e., have no incubating BIs) when it is reconfigured.

Press the and buttons on the front of the 3M™ Attest™ Auto-reader 490H simultaneously for 3 seconds to enter configuration mode. Once in configuration mode, use the Up and Down buttons to set the 3M™ Attest™ Auto-reader 490H clock and audible alarm as desired. The button acts as an "Enter" key and moves the flashing cursor to the next changeable setting.

### Setting the 3M™ Attest™ Auto-reader 490H Clock

The 3M™ Attest™ Auto-reader 490H date and time are displayed in this format: YYYY-MM-DD HH:MM, with the time displayed using a 24 hour clock. To change the year, if necessary, push the up or down buttons to set desired year, then press to advance to the month, adjust as necessary and press to advance to the day. Use the button to move to the time and set the hours and minutes.

### Setting the Audible Alarm Function

Move across the top row of text by pushing the button. The flashing "B" in Buzzer indicates this is a changeable setting. It is recommended this be set at "Buzzer Enabled" to audibly alert the operator to a positive BI but it may be set to "Buzzer Disabled" by using either the up or down button. **Note:** If Buzzer Disabled is selected, and the change is accepted, the speaker icon ( ) will disappear from the LCD panel and the alarm will be disabled for all positive 3M™ Attest™ Rapid Readout Biological Indicators, error codes, and caution code alarm warnings.

**Note:** The 3M™ Attest™ Auto-reader 490H display backlight flashes whenever an audible alarm sounds. Disabling the audible alarm does NOT disable the LCD display backlight flashing.

Press to select the desired option and advance to the Accept screen.

### Accept Screen

Use the up or down buttons to toggle between Yes and No, press to accept changes (Yes selected) or retain current settings (No selected) and exit the configuration mode. The LCD panel will return to the standard display.

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# INSTRUCTIONS FOR USE – READOUT PROCEDURE

## Instructions for Biological Indicator (BI) Activation and Incubation

**CAUTION:** To avoid the possibility of the 3M™ Attest™ Rapid Readout Biological Indicator 1295 vial absorbing fluorescent residue from a chemical indicator or tape, place the 3M™ Attest™ Rapid Readout Biological Indicator vial so it does not come in direct contact with chemical indicators or tape.

**WARNING:** To reduce the risk associated with incorrect results

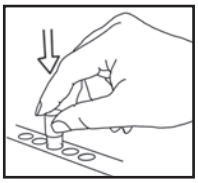
Do not incubate a 3M™ Attest™ Rapid Readout Biological Indicator 1295 if, after processing and before BI activation, it is observed to have a broken media ampoule. Retest the sterilizer with a new biological indicator.

Activate and incubate 3M™ Attest™ Rapid Readout Biological Indicators 1295 within 1 hour of the completion of the sterilization cycle.

Incubate the 3M™ Attest™ Rapid Readout Biological Indicator only in the 3M™ Attest™ Auto-reader 490H i.e., match the pink cap color of the 1295 BI with the pink color-coded configuration sticker surrounding the 3M™ Attest™ Auto-reader 490H incubation wells.

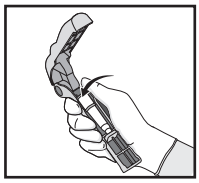
**CAUTION:** Wear safety glasses and gloves when activating the 3M™ Attest™ Rapid Readout Biological Indicator 1295.

Follow this procedure for every 3M™ Attest™ Rapid Readout Biological Indicator (BI) to be read.

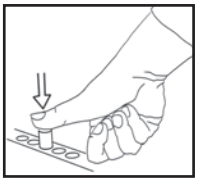


While wearing safety glasses and gloves, **PLACE** BI in color-coded 3M™ Attest™ Auto-reader 490H well. Note that BI vial is keyed for specific orientation in well (flat back of BI faces back of 3M™ Attest™ Auto-reader 490H).

**or**

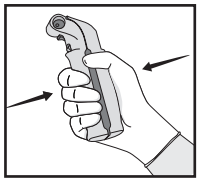


While wearing safety glasses and gloves, **PLACE** BI in Attest™ Biological Indicator Activator.

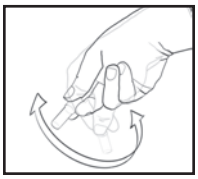


**CLOSE** BI cap and **CRUSH** media ampoule by firmly pushing vial straight down in incubation well.

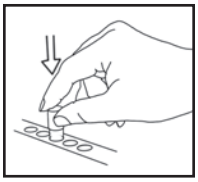
**or**



**CLOSE** and **SQUEEZE** Attest™ Biological Indicator Activator to close BI cap and crush media ampoule.



Immediately remove BI, visually **VERIFY** the glass ampoule (containing growth media) has been crushed, and **FLICK** BI to ensure purple growth media flows to the growth chamber at the bottom of the vial.



**PLACE** the activated BI into a 3M™ Attest™ Auto-reader 490H well and observe 3M™ Attest™ Auto-reader 490H LCD display to confirm correct placement of the BI. If the BI is correctly seated, the 3M™ Attest™ Auto-reader 490H LCD display will show ***, **, * and then remaining minutes of incubation directly below the incubating BI.

**RECORD** BI result.

**WARNING:** Do not remove the 3M™ Attest™ Rapid Readout Biological Indicator 1295 from the incubation well until the (+) or (-) symbol on the LCD display indicates the test is complete.

# INSTRUCTIONS FOR USE – ADDITIONAL INFORMATION

## BI Placement

Remaining incubation time, in minutes, will be displayed on the LCD display to indicate the 3M™ Attest™ Rapid Readout Biological Indicator is incubating in the reader well and should not be touched. The time remaining display indicates the result is not available and incubation is in progress.

**Do not remove 3M™ Attest™ Rapid Readout Biological Indicator until the (+) or (-) symbol on the LCD panel indicates the test is complete.** Once the result is determined, it is continuously displayed on the LCD panel until 10 seconds after the BI has been removed from the incubation well.

**Note:** After the first minute of incubation, if 3M™ Attest™ Rapid Readout Biological Indicator is inadvertently removed before the incubation period is complete, an alarm will sound and a C2 Caution code will be displayed on the LCD panel under that well. **You must return the 3M™ Attest™ Rapid Readout Biological Indicator to the reader well within 10 seconds or the results will be lost.**

**WARNING:** Do not remove or change placement of 3M™ Attest™ Rapid Readout Biological Indicator once it is placed into a well. Doing so may result in loss of results and the 3M™ Attest™ Rapid Readout Biological Indicator test may be invalid.

# INSTRUCTIONS FOR USE – POSITIVE CONTROL

## Positive Control

Activate and incubate at least one non-processed 3M™ Attest™ Rapid Readout Biological Indicator 1295 to use as the positive control each day that a processed 3M™ Attest™ Rapid Readout Biological Indicator 1295 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 incubation well. The positive control should be the same part number and have the same lot number as the processed 3M™ Attest™ Rapid Readout Biological Indicator in the unit.

The positive control biological indicator helps confirm:

- correct incubation temperatures are met (heater block reading of 60°C +/-2°C);
- 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 3M™ Attest™ Auto-reader 490H components.

# INSTRUCTIONS FOR USE – INTERPRETATION OF RESULTS

## Fluorescent Results

After placing a 3M™ Attest™ Rapid Readout Biological Indicator into an incubation well, the 3M™ Attest™ Auto-reader 490H LCD display will show ***, **, * and then the remaining minutes of incubation directly below the incubating BI to indicate that incubation/reading is in progress. The 3M™ Attest™ Rapid Readout Biological Indicator should not be removed or touched when the display indicates remaining incubation time.

A (+) will display on the LCD panel directly under the BI and an alarm will sound (if the sound feature is enabled) as soon as a positive 3M™ Attest™ Rapid Readout Biological Indicator result is detected.

At the end of the specified incubation time, if a negative 3M™ Attest™ Rapid Readout Biological Indicator result is detected, a (-) will display on the LCD panel directly under the incubating BI. The final negative fluorescent result (-) for a processed 3M™ Attest™ Rapid Readout Biological Indicator 1295 indicates an acceptable sterilization process.

After either the (+) or (–) symbol is displayed, and the result is recorded, the 3M™ Attest™ Rapid Readout Biological Indicator can be removed from the well. Do not re-incubate BIs as the result will not be valid.

The positive (unprocessed) control 3M™ Attest™ Rapid Readout Biological Indicator 1295 must provide a positive fluorescent result (+). Processed 3M™ Attest™ Rapid Readout Biological Indicator results are not valid until the positive control reads fluorescent positive (+).

With a processed 3M™ Attest™ Rapid Readout Biological Indicator, a positive (+) result indicates a sterilization process failure. Act on any positive test results immediately. Determine the cause of the positive 3M™ Attest™ Rapid Readout Biological Indicator and retest the sterilizer following current facility policies and procedures.

### Optional Visual pH Color Change Result

3M™ Attest™ Rapid Readout Biological Indicators 1295 for Vaporized Hydrogen Peroxide Sterilization may be further incubated for a visual pH color change. Due to the high sensitivity of the fluorescent result, there is no advantage to continuing to incubate 3M™ Attest™ Rapid Readout Biological Indicators 1295 after the fluorescent result has been determined and documented. This optional further incubation is not intended for routine use but may be used for special studies.

In the case of a positive control BI, a yellow color change of the growth media will appear within 24 hours. Any observation of a yellow color within the vial indicates a positive result. The pH color change result can be recorded and the BI discarded as soon as the yellow color is observed and the result recorded.

For processed 3M™ Attest™ Rapid Readout Biological Indicators 1295, the use of a humidified incubator is recommended to avoid media dry out. If a visual pH color change result is desired, transfer the processed 1295 BI to a humidified incubator after the fluorescent result has been determined in the 3M™ Attest™ Auto-reader 490H. A media color change from purple to yellow indicates a sterilization process failure. A negative pH color change result, i.e., media remains purple, can be assessed at 7 days.

## INSTRUCTIONS FOR USE – DISPOSAL

Instrument contains a lithium battery. Dispose of instrument in accordance with federal, state, and local requirements.

## FEATURES OF THE 3M™ ATTEST™ AUTO-READER 490H

### Audible Alarm

An audible alarm will sound, the LCD display backlight will flash, and a (+) symbol will be displayed on the LCD panel directly under the incubating BI when a positive result is detected. An alarm will also sound if a 3M™ Attest™ Rapid Readout Biological Indicator is removed from the 3M™ Attest™ Auto-reader 490H well before a final result has been detected. Data will be lost if the 3M™ Attest™ Rapid Readout Biological Indicator is not replaced in the incubation well within 10 seconds.

### Alarm On/Off

The audible alarm for positive results can be turned off for a particular 3M™ Attest™ Rapid Readout Biological Indicator. This is accomplished by pressing the “Buzzer Alarm OFF” button after the alarm has sounded. This will turn off the alarm for that BI only. Any positive 3M™ Attest™ Rapid Readout Biological Indicator results subsequently detected in other wells will result in the alarm sounding. Removing the 3M™ Attest™ Rapid Readout Biological Indicator will reactivate the alarm for that well. Pressing the “Buzzer Alarm OFF” button will not silence the alarm for error or caution code alarm warnings. To disable the alarm, see configuration section.

### Stackable

To save counter space, 3M™ Attest™ Auto-readers 490Hs may be stacked two high.

### Information Button

When the Information button is pressed once the 3M™ Attest™ Auto-reader 490H displays two lines of text in the LCD display.

The top row indicates (left to right):

- 3M™ Attest™ Auto-reader 490H serial number
- 3M™ Attest™ Auto-reader 490H embedded software version (V X.Y.Z)
- Current date and time.

The bottom row indicates (left to right):

- The BI type configuration for wells 1-5 (i.e., 1295)
- The BI type configuration for wells 6-10 (i.e., 1295)

Press the information button twice and the 3M™ Attest™ Auto-reader 490H LCD display will present two additional lines of text.

The top row indicates:

- IP address (if unit is connected to an Ethernet jack).

The bottom row indicates (left to right):

- Date (YYYY-MM-DD) and time that power was supplied to the 3M™ Attest™ Auto-reader 490H.

Press the information button three times and the 3M™ Attest™ Auto-reader 490H LCD display will present the unique Media Access Control (MAC) Address for the device.

### Temperature Monitoring

The 3M™ Attest™ Auto-reader 490H contains an internal temperature self-diagnostic program. Should the temperature fall outside the specified range (60ºC +/-2ºC) an error code will be displayed. The heater block temperature may be checked by depressing the Temperature button once.

### Easy Configuration

The 3M™ Attest™ Auto-reader 490H may be configured using either the buttons located on the front of the unit or using the optional 3M™ Attest™ Auto-reader 490H Web App.

### Optional 3M™ Attest™ Auto-reader 490H Web App

If desired, the 3M™ Attest™ Auto-reader 490H may be connected to a PC via an Ethernet connection for additional capabilities:

- Remotely view current status of BIs in the 3M™ Attest™ Auto-reader 490H via networked PC or mobile hand held devices. For full functionality, the use of an HTML5 compliant browser with JavaScript enabled is required.
- Remotely view and configure 3M™ Attest™ Auto-reader 490H settings.
- View the last 100 BI records.
- Print out documentation using a local or networked printer and/or save documentation as an electronic file.*

**Note:** To access the 3M™ Attest™ Auto-reader 490H Web App within a secure network, the PC or mobile device must have access to the secure network; options include connecting via a network Ethernet cable, signing in to the facility’s wireless network, or connecting via a virtual private network (VPN).

* Refer to your facility’s record keeping policy and procedure.

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## CARE AND CLEANING

Clean the exterior surface of the 3M™ Attest™ Auto-reader 490H by wiping it with a damp cloth moistened with a mild detergent. Do not attempt to clean interior components. If additional cleaning of the wells is required, call for repair or replacement.

**Note:** The 3M™ Attest™ Auto-reader 490H does not contain any user serviceable parts or require any routine maintenance or calibration. Any malfunctions will be indicated by an error code. Refer to the Troubleshooting Guide section for error code explanations.

| |
|---|
| ⚠ **CAUTION:** Always unplug the 3M™ Attest™ Auto-reader 490H and allow to cool before cleaning. |
| Do not spill liquid onto or into the instrument. Do not immerse the unit in liquid. |
| Clean external surfaces using only the instructions provided by the manufacturer. |
| Do not open the instrument housing – there are no user serviceable parts. The instrument must be returned to the manufacturer for repair. |

## TROUBLESHOOTING GUIDE

In the event of an error code, unplug the 3M™ Attest™ Auto-reader 490H and plug it back in to initiate the self-diagnostic test. If error code re-occurs, call for repair or replacement.

The LCD display will indicate detected malfunctions by displaying a caution or error code under affected BI wells. The audible alarm, if active, sounds and the LCD display backlight flashes to alert the user to all caution (except C1) and error codes. The alarm and backlight can be silenced and extinguished, respectively, by pressing the Buzzer Alarm OFF button. Note that disabling the audible alarm does not disable the flashing LCD display backlight. Refer to the following:

| Code/ Issue | Problem | Solution |
|---|---|---|
| C1 | Unit Warm-up Caution<br>Incubation block not at temperature. | Allow a 30 minute warm-up after 3M™ Attest™ Auto-reader 490H is plugged in. (Note: 3M™ Attest™ Rapid Readout BI readings are disabled until incubator block reaches 60ºC +/- 2ºC). |
| C2 | BI Removed from Well Caution<br>3M™ Attest™ Rapid Readout BI has been removed before incubation is complete. | Replace 3M™ Attest™ Rapid Readout BI in proper well within 10 seconds to prevent loss of collected data. |
| C4 | Ambient Light Caution | Move 3M™ Attest™ Auto-reader 490H to reduced ambient light conditions. |
| E1 | Temperature Control Error<br>This error will occur if system is no longer able to control the temperature of the incubator block (60ºC +/- 2ºC ). | Unplug the unit and plug it back in to clear error.<br>If error doesn't clear, call for repair or replacement. |
| E3 | Memory Error<br>3M™ Attest™ Auto-reader 490H unable to save/read data from memory. | Unplug the unit and plug it back in to clear error.<br>If error doesn't clear, call for repair or replacement. |
| E7 | Communications Error<br>This error will occur if internal communications have failed. | Unplug the unit and plug it back in to clear error. If error doesn't clear, call for repair or replacement. |
| E8 | LED Error<br>This error occurs for a specific well if the system detects that a UV LED or Optics Detection circuit is not working. | Unplug the unit and plug it back in to clear error.<br>If error doesn't clear, call for repair or replacement. Do not use affected incubation well. |
| E11 | BI Inserted Incorrectly Error<br>Incubation time remaining will not display and fluorescent readings are not taken. | Remove BI and inspect to verify cap is fully closed, glass ampoule is crushed, and growth media is in growth chamber. If necessary, repeat BI activation steps: place & push BI down FIRMLY into incubation well; remove BI and flick it; inspect BI; and return BI to incubation well, ensuring it is seated properly. |
| E12 | Power Failure Error<br>Power to Auto-reader was off for too long to provide valid result for affected BI(s). | Ensure power supply connection to Auto-reader is secure. Retest sterilizer with a new BI. |
| E14 | Ambient Light Error (occupied well)<br>Fluorescent result will not display. | Rely on optional visual pH color change result for BI in affected well. Move 3M™ Attest™ Auto-reader 490H to reduced ambient light conditions to avoid future occurrences. To clear E14 error code, after visual pH color change result has been documented and BI has been removed, unplug the 3M™ Attest™ Auto-reader 490H and plug it back in. |
| Other | Unwanted alarm sounds when positive BI detected. | Disable alarm; refer to **3M™ Attest™ Auto-reader 490H Configuration** section for instructions. |
| Other | Alarm Sounds<br>3M™ Attest™ Rapid Readout Biological Indicator has been removed from incubation/reader well prematurely. | Replace 3M™ Attest™ Rapid Readout Biological Indicator in incubation/ reader well within 10 seconds to prevent loss of data collected. |
| Other | LCD display does not display properly. | Unplug the unit and plug it back in. If problem persists call for repair or replacement. |
| Other | Negative Control Vial<br>BI not properly activated/ media did not contact spore carrier. | Ensure BI cap is closed and glass ampoule is crushed. Flick BI until media flows to spore chamber at bottom of BI. |

| Code/ Issue | Problem | Solution |
|---|---|---|
| Other | Negative Control Vial<br>Control vial was sterilized. | Check process indicator on BI cap. Use a non-sterilized vial as a control. |
| Other | Unexplained Positive BI<br>Adhesive residue on vial. | Do not place tape or labels on vial. |
| Other | Unexplained Positive BI<br>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. |
| Other | 3M™ Attest™ Auto-reader 490H will not enter Configuration mode.<br>Pushbutton Configuration may be disabled on 3M™ Attest™ Auto-reader 490H Web App. | On 3M™ Attest™ Auto-reader 490H Web App Configuration Page, go to Pushbutton Configuration and select the **Enable** radio button. Save changes to begin using new setting. |
| Other | 3M™ Attest™ Auto-reader 490H LCD display flashes and asterisks (***) and/or E11 and/or C4 codes appear on display below unoccupied incubation wells. | Move 3M™ Attest™ Auto-reader 490H away from sunlight or sources of incandescent light. |

# OPTIONAL 3M™ ATTEST™ AUTO-READER 490H WEB APP

## Web Browser Requirements

The web interface is designed to be viewed in Internet Explorer 8.0 or higher. Earlier versions of Internet Explorer or other browsers may result in some web pages being displayed in a less-than-optimal manner. For best results, switching to Internet Explorer 8.0 or higher is recommended. For full functionality, the use of an HTML5 compliant browser with JavaScript enabled is required.

## Ethernet Connection:

Connection switch/router with auto-negotiation capability to identify the Auto-reader as operating at 10 Mbps and half-duplex, or able to be manually configured as 10 Mbps and half-duplex.

## Connecting to the 3M™ Attest™ Auto-reader 490H Web App

To use the 3M™ Attest™ Auto-reader 490H Web App, the 3M™ Attest™ Auto-reader 490H must be connected to the facility network using the supplied Ethernet cable. Consult with your facility IT personnel for assistance with network connectivity. Each 3M™ Attest™ Auto-reader 490H has a unique MAC Address which is presented on the unit's LCD display when the user depresses the Info button three times. The MAC Address is also provided at the bottom of the 3M™ Attest™ Auto-reader 490H Web App Configuration page. Communication occurs using the http protocol over Port 80. The 3M™ Attest™ Auto-reader 490H does not collect, process, store, or transmit any Protected Health Information (PHI). Web App Users may connect to the 3M™ Attest™ Auto-reader 490H Web App using a URL based upon either the 3M™ Attest™ Auto-reader 490H serial number or the IP Address. To view the 3M™ Attest™ Auto-reader 490H Web App from a wireless device such as a mobile hand-held device or a computer on a sub-net different from that to which the 3M™ Attest™ Auto-reader 490H is connected, use the IP Address URL.

**Note:** To access the 3M™ Attest™ Auto-reader 490H Web App within a secure network, the PC or mobile device must have access to the secure network; options include connecting via a network Ethernet cable, signing in to the facility's wireless network, or connecting via a virtual private network (VPN).

## A. Serial number URL

1. Connect the supplied Ethernet cable from the 3M™ Attest™ Auto-reader 490H to an Ethernet jack.
2. Depress the button once to display the 3M™ Attest™ Auto-reader 490H 6-digit serial number on the left side of the top row of text on the LCD display.
3. Enter http://attestxxxxxx, where xxxxxx represents the unit's serial number (e.g., http://attest221008) from Step 2, in the PC web browser address bar and press Enter.
4. The 3M™ Attest™ Auto-reader 490H Web App Status page will display on the PC. For future ease of use, add this page to your web browser "Favorites."

## B. IP Address URL

The 3M™ Attest™ Auto-reader 490H Web App may also be accessed using either a dynamic or static IP address.

## 1. Dynamic IP Address

A dynamic IP address is assigned when the Ethernet cable is connected from the 3M™ Attest™ Auto-reader 490H to a live Ethernet jack.

Press and release the button twice to display the dynamic IP address for the 3M™ Attest™ Auto reader 490H. Enter http://IPaddress (e.g. http://123.456.789.012) in the web browser address bar of the PC or mobile hand-held device and press Enter. The 3M™ Attest™ Auto-reader 490H Web App Status page will display.

## 2. Static IP address

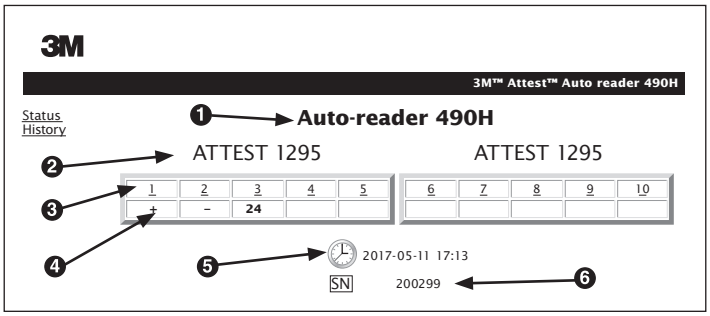
Some facility IT personnel may require devices connecting to the network to use a Static IP address. If this is the case at your facility, contact the IT department to request a Static IP address.

Record the static IP address provided by your facility IT department here: _____. You may wish to label the Ethernet jack with the assigned address. Enter http://StaticIPaddress (e.g. http://111.222.333.444) in the web browser address bar on your PC or mobile hand-held device and press Enter. The 3M™ Attest™ Auto-reader 490H Web App Status page will display.

## About the 3M™ Attest™ Auto-reader 490H Web App Pages

The 3M™ Attest™ Auto-reader 490H Web App includes four pages.

**a) Status page**




1. User-entered nickname (optional)
2. Well Configuration (1-5 and 6-10)
3. Well Number
4. BI Result/Remaining Incubation Time
5. Date and Time
6. 3M™ Attest™ Auto-reader 490H Serial Number

The Status page provides a real-time representation of the 3M™ Attest™ Auto-reader 490H LCD panel display. The current date and time and 3M™ Attest™ Auto-reader 490H serial number are also indicated on this page. From this page, the user may navigate to:

- the History page by clicking on History on the left of the screen.
- the Results Detail page by clicking on the well number of an occupied well (i.e., a well that currently has an incubating BI). Clicking on an unoccupied well takes the user to the History page.

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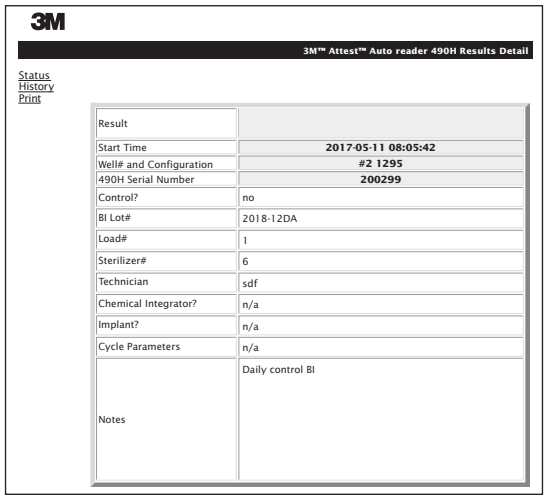
### b) Results Detail page

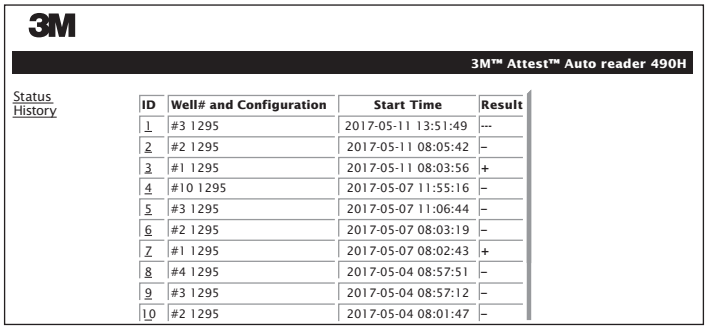



This page provides an individual record for an incubated BI. For complete documentation, the user may print a hard copy and/or save the record as an electronic file.

**Note 1:** The top four rows (highlighted in green) are populated automatically by the 3M™ Attest™ Auto-reader 490H and cannot be changed by the user. The remaining rows are completed by the user to satisfy the documentation requirements of their facility.

**Note 2:** The Results Detail page refreshes less frequently that the Status page. Until the BI result is available, the Results Detail page displays remaining minutes of incubation in the results field.

### c) History page

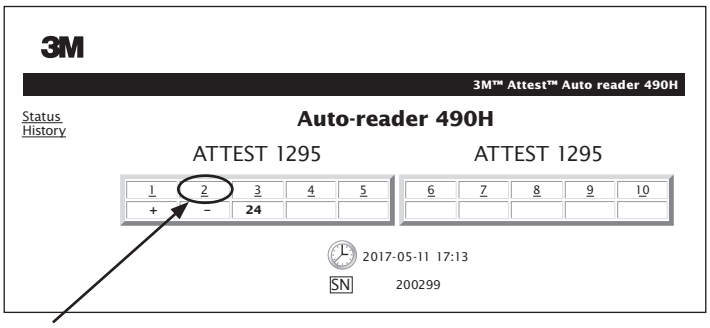



The 3M™ Attest™ Auto-reader 490H stores results for the last 100 incubated BIs on embedded software. The 3M™ Attest™ Auto-reader 490H Web App History page provides a summary of these last 100 results.

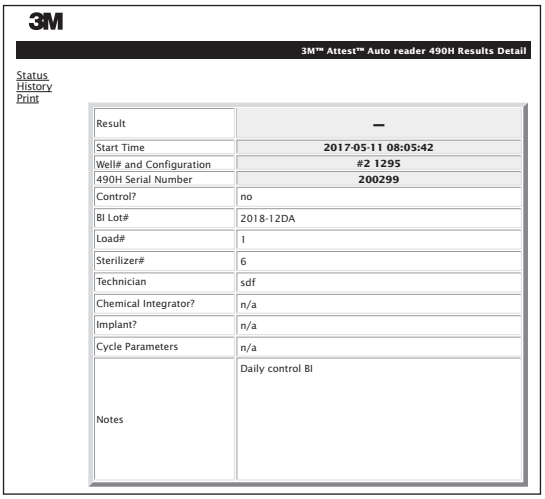
### d) Configuration page

This page allows the configuration of the network and language settings for the 3M™ Attest™ Auto-reader 490H from the 3M™ Attest™ Auto-reader 490H Web App.

## Documenting BI Results using the 3M™ Attest™ Auto-reader 490H Web App




1. **Open the Results Detail page**
   After inserting a new 3M™ Attest™ Rapid Readout BI in the 3M™ Attest™ Auto-reader 490H, it is a best practice to open the 3M™ Attest™ Auto-reader 490H Web App Results Detail page for that BI by clicking on the appropriate well number from the Status page.
2. **Enter** the specific information for that BI (e.g., BI Lot #, sterilizer #, load #, technician name, etc.) in the provided editable fields. Use the Notes section to capture information not prescribed in the provided row titles; for example, you may wish to use this field to record load items.

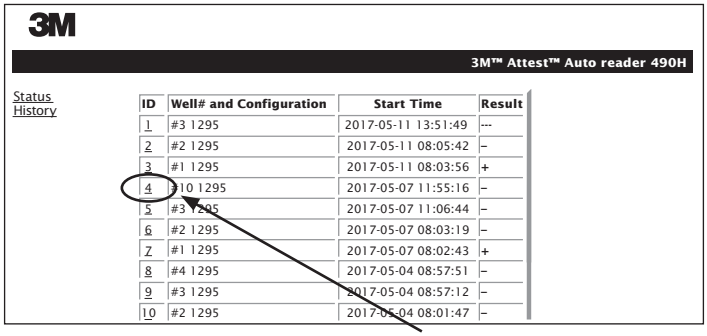



3. The entered information is **saved** automatically to temporary web browser storage on the user's PC every 60 seconds, or by leaving the Results Details page.
4. **Print/File.** Once the BI result is available, print or file the Results Detail page to create a record. The page may be physically printed and/or saved as an electronic file.

**Important! Data is only stored for the last 100 incubated BIs.**

Embedded software in the 3M™ Attest™ Auto-reader 490H saves the data from the auto-populated (i.e., green highlighted) fields. The application relies on the temporary storage in the user's web browser to save the data in the user-populated fields. In both cases, data is only stored for the last 100 records, i.e., the 101st incubated BI will overwrite the information saved for the 1st incubated BI. To retain the Results Detail information for future reference it is best practice to print the page or save to an electronic file as soon as the BI result is available.

## Using the BI History Page




To view or print an individual record, click on the ID number of the desired record to navigate to the Results Detail page for that BI.

**Note 1:** Column 1, "ID" is the assigned ID number with ID 1 representing the newest record and ID 100 representing the oldest record. For convenience, all columns are sortable; to help find a particular record, simply click once on the column heading to sort in ascending order and click a second time to reverse the order.

**Note 2:** The History page refreshes less frequently than the Status page. Until the BI result is available, the History page displays ••• in the Results column indicating incubation is still in-process.

## Using the Configuration Page

Certain set-up and configuration options are available on the password-protected 3M™ Attest™ Auto-reader 490H Web App Configuration page. Ideally, the 3M™ Attest™ Auto-reader 490H should be empty (i.e., have no incubating BIs) when it is reconfigured. Navigate to the Configuration page by entering either:

1) http://attestxxxxxx/protect/config.htm (where xxxxxx is the 6-digit unit serial number), or

2) http://xxx.xxx.xxx.xxx/protect/config.htm (where xxx.xxx.xxx.xxx is the IP address)

in the web browser address bar and pressing Enter. A security screen will appear. Fill in the fields as follows:

**User name:** manager

**Password:** Attest

and click OK.

Click on the desired radio buttons to change settings.

| | |
|---|---|
| **Language** | Selected setting indicates language in which text on 3M™ Attest™ Auto-reader 490H Web App pages will appear on the PC/mobile device screen. |
| **Pushbutton Configuration** | Selecting **Enable** ⦿ allows the user to configure the 3M™ Attest™ Auto-reader 490H from the buttons on the unit itself.<br>Selecting **Disable** ⦿ prevents the user from being able to configure the 3M™ Attest™ Auto-reader 490H from the buttons on the unit itself. |
| **Buzzer Configuration** | Selecting **Enable** ⦿ enables the audible alarm. The speaker icon will appear on the 3M™ Attest™ Auto-reader 490H LCD panel.<br>Selecting **Disable** ⦿ disables the audible alarm. The speaker icon will disappear from the 3M™ Attest™ Auto-reader 490H LCD panel. |
| **Attest Auto-reader 490H Nickname** | Naming the 3M™ Attest™ Auto-reader 490H may be useful in facilities with multiple units. The assigned nickname will appear on the 3M™ Attest™ Auto-reader 490H Web App Status page. |
| **Enable DHCP** | Default: Setting is checked indicating the Web App will use the Dynamic IP address automatically assigned when the 3M™ Attest™ Auto-reader 490H is connected to the network. Remove the check if you wish to use a Static IP address assigned by your facility IT. |
| **IP Address** | Enter Static IP address assigned by IT. |
| **Gateway** | Enter Gateway. |
| **Subnet Mask** | Enter Subnet Mask. |
| **Primary DNS** | Enter Primary DNS. |
| **Secondary DNS** | Enter Secondary DNS. |
| **MAC Address** | XX:XX:XX:XX:XX:XX<br>**(Unique MAC address assigned to device. This value cannot be changed.)** |
| **Use Computer Time** | Check this box if you wish to set the clock on-board the 3M™ Attest™ Auto-reader 490H using the computer's clock. |
| **Attest Auto-reader 490H Time** | Alternatively, leave the Use Computer Time box unchecked and complete the date and time boxes to set the 3M™ Attest™ Auto-reader 490H clock. |

After changing desired settings, click on Save Config button to save your changes. A new screen confirming the settings were successfully changed appears.

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## TROUBLESHOOTING THE 3M™ ATTEST™ AUTO-READER 490H WEB APP

| Issue | Problem | Solution |
|---|---|---|
| Unable to access 3M™ Attest™ Auto-reader 490H Web App on networked computer | 3M™ Attest™ Auto-reader 490H and/or computer not connected to network.<br>Auto-negotiation issue between the 3M™ Attest™ Auto-reader 490H and facility network switch. | Ensure 3M™ Attest™ Auto-reader 490H Ethernet cable is connected to a live jack and that connection to 3M™ Attest™ Auto-reader 490H is secure.<br>Ensure computer is connected to network.<br>If failure is with connection attempted using 3M™ Attest™ Auto-reader 490H serial number URL, try connecting using IP address URL.<br>Switch port setting must be set at 10 Mbps and half-duplex.<br>Contact facility IT or 3M if problem persists. |
| Unable to access 3M™ Attest™ Auto-reader 490H Web App on mobile device | 3M™ Attest™ Auto-reader 490H not connected to network.<br>For security reasons, facility firewall may prevent mobile devices not connected to the facility network from connecting to secure IP addresses. | Ensure 3M™ Attest™ Auto-reader 490H Ethernet cable is connected to a live jack and that connection to 3M™ Attest™ Auto-reader 490H is secure.<br>Contact facility IT for their recommendation on connecting to the secure network. Solutions may include enabling Wi-Fi on the mobile device and signing into the facility network or connecting to the facility virtual private network (VPN) on the mobile device. |
| Data entered by user on Results Detail page disappears | User entered data is written to temporary web browser storage. Browser may have cleared data. | Set web browser to accept (allow or enable) cookies.<br>As a best practice, print or save Results Detail record as soon as BI result is final. |
| BI result displayed on 3M™ Attest™ Auto-reader 490H LCD display does not appear on Results Detail page | The Results Detail page has not refreshed yet. | Use your browser to refresh the Results Detail page, or wait up to 60 seconds for the page to automatically refresh. |
| Results Detail page will not open from the Status page | The Results Detail page only opens from the Status page for occupied 3M™ Attest™ Auto-reader 490H wells. | Do not attempt to navigate to the Results Detail page from unoccupied wells on the Status page. |

## REPAIR AND REPLACEMENT

In the U.S.A., 3M™ Attest™ Auto-readers 490H 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 U.S.A., contact your local 3M Subsidiary.

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

CE

Made in the U.S.A. of globally sourced materials by 3M Health Care.

**3M Health Care**

2510 Conway Ave
St. Paul, MN 55144
1-800-228-3957
www.3M.com/healthcare

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Issue Date: XXXX-XX

EC REP **3M Deutschland GmbH**
**Health Care Business**
Carl-Schurz-Str. 1
41453 Neuss
Germany

Made in U.S.A. by

**3M Health Care**

2510 Conway Ave.
St. Paul, MN 55144
1-800-228-3957

3M.com/Medical

EC REP **3M Deutschland GmbH**
**Health Care Business**
Carl-Schurz-Str. 1
41453 Neuss
Germany

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