

# Sterilization Monitoring





# FOR OVER THREE DECADES



has been at the forefront of healthcare innovation, dedicated to revolutionizing medical device sterilization. Established in 1987 by visionary scientists in the heart of Texas, ASP's journey of groundbreaking achievements began with the invention of the **STERRAD™** Sterilizer with hydrogen peroxide gas plasma technology. This pioneering technology, granted FDA clearance in 1993, set the gold standard for sterilization, redefining safety, speed, and efficiency in the Sterile Processing departments worldwide.

ASP's commitment to excellence has been unwavering. We've continued to push boundaries, introducing specialized sterilization cycles for medical instruments and endoscopes, pioneering advanced biological indicators, and unveiling cutting-edge solutions like **ALLClear™** Technology.

Our passion for patient safety extends beyond sterilization, with the introduction of automated endoscope reprocessing systems that adhere to the highest industry standards.

In 2023, ASP embarks on a new mission, intensifying our focus on Sterility Assurance. Our new line of Steam Sterilization Monitoring products, represents a pivotal step in **protecting patients during their most critical moments**. As leaders in Infection Prevention, ASP remains steadfast in our commitment to ensuring **equal protection for all patients**.

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**WE INVITE YOU TO JOIN US  
ON THIS TRANSFORMATIVE  
JOURNEY AS WE CONTINUE  
TO SHAPE THE FUTURE OF  
HEALTHCARE SAFETY  
AND EXCELLENCE.**

# Sterilization Monitoring

IN DIVERSE HEALTHCARE SETTINGS, THE SIGNIFICANCE OF STEAM STERILIZATION FOR SAFETY CANNOT BE OVERSTATED. WHETHER IN A SPRAWLING UNIVERSITY HOSPITAL OR AN AMBULATORY SURGERY CENTER, BOTH FACE MOUNTING PRESSURE FOR QUICK STERILE INSTRUMENT TURNAROUND, MAKING PROMPT STERILIZATION RESULTS CRUCIAL.

ASP OFFERS A COMPREHENSIVE RANGE OF SOLUTIONS DESIGNED TO STREAMLINE YOUR STERILIZATION MONITORING PROCESS.



**YOUR PARTNER IN**

**INFECTION PREVENTION**

**STERILITY ASSURANCE**

**EQUAL PROTECTION FOR ALL**

# BIOTRACE™ INSTANT READ STEAM BIOLOGICAL INDICATOR SYSTEM

## Sterility Assurance in just 7 Seconds

The BIOTRACE™ Instant Read Steam Biological Indicator System provides results in just 7 seconds, enhancing workflow efficiency by removing delays and supporting an uninterrupted workflow, ensuring speed, precision, and confidence in every cycle.

PRODUCT # 73430



Attached protective cover

Two independent readout positions

Indicator light showing the unit is ready for readout

Temperature & stability indicator light

Integrated ampoule crusher (BI activator) on the back



Connect the BI Reader with the BIOTRACE™ Assist Application. An intuitive mobile app that connects via WiFi or Bluetooth to deliver real-time updates on incubation progress and BI Reader status.

BIOTRACE™ Instant Read Steam Biological Indicators have been designed for instant and fast monitoring of vacuum assisted and gravity displacement steam sterilization cycles at 132-135°C.

PRODUCT # 73110

COMPLIANCE ✓  
ISO 11138-1  
ISO 11138-3  
FDA



Spore carrier inoculated with a minimum of 10<sup>6</sup> viable Geobacillus stearothermophilus bacterial spores



Plastic colored cap and a barrier permeable to steam



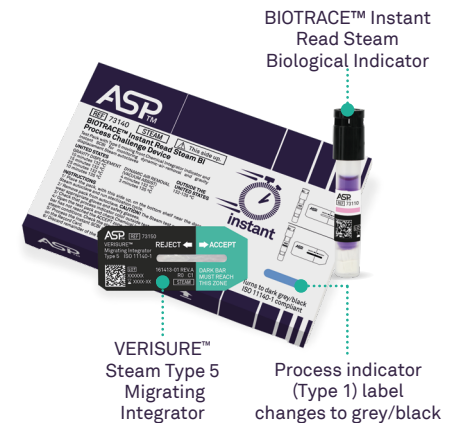
Process indicator on vial label changes from pink to brown when exposed to steam

Glass ampoule contains culture medium

The BIOTRACE™ Instant Read Steam Biological Indicator Process Challenge Device combines speed, accuracy, and confidence in every cycle. The reader provides immediate readout, empowering healthcare professionals to make quick, informed decisions without compromising patient safety.

PRODUCT # 73140

COMPLIANCE ✓  
ISO 11138-1  
ISO 11138-3  
ISO 11140-1  
AAMI ST79



BIOTRACE™ Instant Read Steam Biological Indicator

VERISURE™ Steam Type 5 Migrating Integrator

Process indicator (Type 1) label changes to grey/black

\*See IFU for validated steam cycles.

# BIOTRACE™ AUTO READ PRO BIOLOGICAL INDICATOR (BI) READER

## Real-Time Monitoring at Your Fingertips

The BIOTRACE™ Auto Read Pro Biological Indicator Reader offers a 3.5" user-friendly, intuitive touchscreen LCD display, providing real-time information on incubation progress and temperature settings, ensuring ease of use and effective monitoring of biological indicators.

 Automatic Readout	 12 Simultaneous Incubator Wells	 Built-in Ampoule Crusher	 Built-in Thermal Printer
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# BIOTRACE™ AUTO READ MINI BIOLOGICAL INDICATOR (BI) READER

## Compact Design

The BIOTRACE™ Auto Read Mini Biological Indicator Reader is a compact tabletop automatic reader, designed for easy placement anywhere within your facility due to its small and space-efficient size.

 Automatic Readout	 3 Simultaneous Incubator Wells	 Built-in Ampoule Crusher	 Built-in Thermal Printer
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# BIOTRACE™ AUTO READ STEAM BIOLOGICAL INDICATORS

## Rapid Readout

Achieve a readout in as little as 20 minutes, minimizing downtime and enabling efficient sterilization process monitoring.\*

BIOTRACE™ Auto Read Steam Biological Indicators have been designed for quick and easy monitoring of vacuum assisted and gravity displacement steam sterilization cycles at 132-135 °C (269.6-275 °F).

Chemical Indicator  
Type 1  
NOT EXPOSED  
EXPOSED

*Geobacillus stearothermophilus*  
spores



PRODUCT # 73100

COMPLIANCE ✓  
ISO 11138-1  
ISO 11138-3



PRODUCT # 73105

COMPLIANCE ✓  
ISO 11138-1  
ISO 11138-3

# BIOTRACE™ AUTO READ STEAM BIOLOGICAL INDICATOR PROCESS CHALLENGE DEVICES

The BIOTRACE™ Auto Read 20 Steam Biological Indicator Process Challenge Device (BI PCD) ensures reliable sterilization with compliant design, rapid 20-minute readout, and dual verification methods, providing healthcare professionals with instant visual confirmation and peace of mind.

A 60-minute BI PCD\* is also available for extended cycle coverage.



**Achieve Rapid Readout and Quick Device Turnaround in as little as 20 minutes**



**Compact design significantly reduces material usage and waste and requires less storage space**



**Instant Visual Confirmation via Integrating Indicators through PCD**

Each Auto Read Steam BI PCD includes:

- ▶ BIOTRACE™ Process Challenge Device Record Card
- ▶ VERISURE™ Steam Type 5 Migrating Integrator
- ▶ BIOTRACE™ Biological Indicator

\*See IFU for validated steam cycles.



PRODUCT # 73130

COMPLIANCE ✓

ISO 11140-1  
ISO 11138-1  
ISO 11138-3  
ANSI/AAMI ST79



PRODUCT # 73135

COMPLIANCE ✓

ISO 11140-1  
ISO 11138-1  
ISO 11138-3  
ANSI/AAMI ST79



STEAM

# VERISURE™ MULTI-VARIABLE INDICATOR TYPE 4 STEAM

VERISURE™ Steam Type 4 Multi-Variable Chemical Indicator is a multi-variable process indicator intended for monitoring steam sterilization processes within loads.

- ✓ Monitors steam sterilization efficacy within loads.
- ✓ Type 4 indicator changes from yellow (unprocessed) to dark brown/black (processed).
- ✓ Suitable for gravity displacement and dynamic air removal/vacuum assist cycles.
- ✓ Perforated for full-size or split usage.

PRODUCT # 73165

COMPLIANCE ✓  
ISO 11140-1



# SEALSURE™ INDICATOR TAPE 18MM TYPE 1 STEAM

SEALSURE™ Steam Indicator Tape 18mm is designed as a steam sterilization exposure monitor.

- ✓ Securely seals sterilization packs.
- ✓ Provides visual assurance to SPD and/or staff.
- ✓ Distinguishes between exposed and non-exposed packs.
- ✓ Innovative lead-free yellow chemical indicator turns dark brown or black after steam sterilization.
- ✓ Adheres to various packaging materials (cloth, paper, plastic) and leaves no residues.
- ✓ Latex-free.

PRODUCT # 73170

COMPLIANCE ✓  
ISO 11140-1



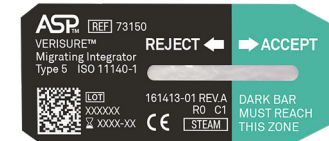
STEAM



# VERISURE™ INTEGRATORS TYPE 5 STEAM

The VERISURE™ Type 5 Steam Migrating Integrator is engineered to monitor steam sterilization processes at 121°C and 132°C to 135°C. During the sterilization process, the pellet undergoes a melting transformation, resulting in a visible bar that travels along the wick. This movement indicates the ACCEPT or REJECT status, which is determined by sterilization conditions that can change with variations in steam quality, time, and temperature.

Migrating Integrator **PRODUCT # 73150**



COMPLIANCE ✓  
ISO 11140-1

VERISURE™ Steam Type 5 Migrating Integrator with Extender for easy accessibility within surgical tray.

Migrating Integrator with Extender **PRODUCT # 73155**



COMPLIANCE ✓  
ISO 11140-1

VERISURE™ Steam Type 5 Migrating Integrator Process Challenge Device (PCD) has been designed for rapid and easy monitoring of dynamic air removal and gravity air displacement processes. The PCD poses a challenge to the steam sterilization process by demonstrating resistance equivalent to the ANSI/AAMI ST79 16 towel pack.

Migrating Integrator Process Challenge Device **PRODUCT # 73160**



COMPLIANCE ✓  
ISO 11140-1  
ANSI/AAMI ST79

VERISURE™ Steam Type 5 Ink Integrator has been designed for the monitoring of dynamic air removal and gravity displacement steam sterilization processes, printed with a Type 5 Chemical Indicator which changes color from yellow (unprocessed) to black (processed).

Ink Integrator **PRODUCT # 73156**



COMPLIANCE ✓  
ISO 11140-1

STEAM

# VERISURE™ BOWIE-DICK TEST

The VERISURE™ Bowie-Dick Test Pack and the VERISURE™ Bowie-Dick Test Card have been specifically crafted to evaluate the effectiveness of air removal during pre-vacuum steam sterilization cycles.\*

The VERISURE™ Bowie-Dick Test Pack is a Type 2 chemical indicator that includes an easy-to-read chemical indicator sheet. Placed between porous materials (and reticulated foam - only in US version), it's enclosed with crepe sterilization wrap. The pack features a Type 1 Process Indicator label for clear visual assurance. In addition, the US model contains an Early Warning Sheet with a circular chemical indicator, allowing rapid detection of air removal failures during the sterilization cycle.

**Bowie-Dick Test Pack** PRODUCT # US 73180  
PRODUCT # EU 73181

COMPLIANCE ✓

ISO 11140-1  
US model ISO 11140-5  
EU model ISO 11140-4

Vacuum-assisted Cycles:  
4 min. at 132°C | 3.5 min. at 134 °C



Color Changing  
Process Indicator

NOT EXPOSED

EXPOSED

Color Changing Indicator Early Warning  
Detection Sheet and Test (only in US model) Sheet

NOT EXPOSED EXPOSED

The VERISURE™ Bowie-Dick Test Card features a Type 2 Chemical Indicator System which changes from purple (unprocessed) to green (processed) and is to be used daily before running the first load of the day. Cycle information can be recorded on the back of the card, allowing for ease of permanent record.

**Bowie-Dick Test Card Kit** PRODUCT # US 73190  
PRODUCT # EU 73195

COMPLIANCE ✓

ISO 11140-1  
US model ISO 11140-5  
EU model ISO 11140-4

The Bowie-Dick Test Card Kit includes:

- ▶ VERISURE™ Bowie-Dick Test Cards (120 qty)
- ▶ Reusable test card holder



Test Card uniformly changes from purple to green when properly processed.



NOT EXPOSED



EXPOSED

**Test Card (Refill)** PRODUCT # US 73191  
PRODUCT # EU 73196

COMPLIANCE ✓

ISO 11140-5

\* See IFU for validated steam cycles.

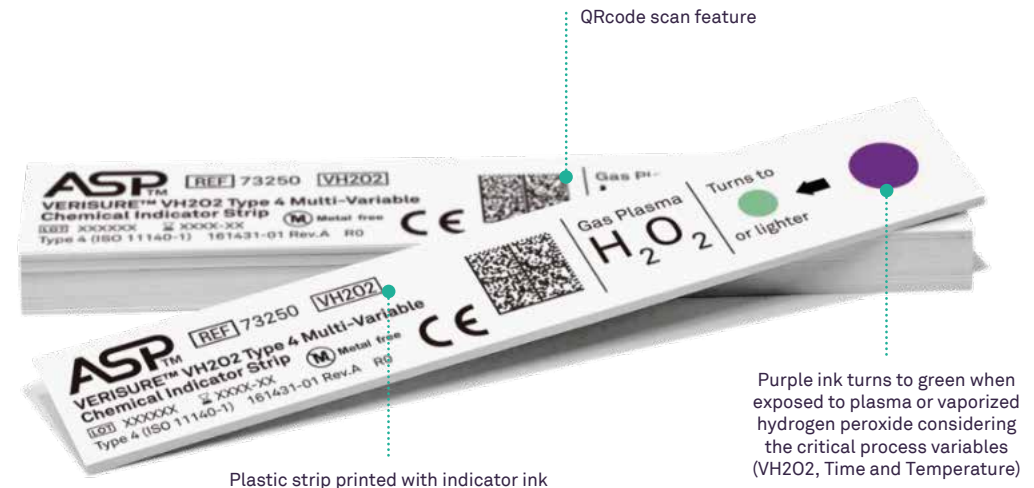
# VERISURE™ MULTI-VARIABLE INDICATOR TYPE 4 VH2O2

## VERISURE™ VH2O2 Type 4 Multi-Variable Chemical Indicator Strip

VERISURE™ VH2O2 Type 4 Multi-Variable Chemical Indicator Strip are single-use chemical indicators that consist of plastic strips printed with indicator ink. These indicators have been designed to monitor plasma or vaporized hydrogen peroxide sterilization processes within loads, ensuring an adequate exposure to the sterilizing agent during the sterilization process.

Innovative highly sensitive purple ink was developed to turn to green or lighter when the indicator is exposed to plasma or vaporized hydrogen peroxide considering the critical process variables which provides additional quality assurance.

- Size: 4.13 x 0.71 - 105 mm x 18 mm
- Heavy metal free
- Compliance: FDA / CE marked / ISO 11140-1 Type 4
- Shelf life: 5 years
- Packaging (250/bag | 2 bags7case)



PRODUCT # 73250

COMPLIANCE ✓  
ISO 11140-1

H2O2



# BIOTRACE™ AUTO READ 4H BIOLOGICAL INDICATOR ETO



**BIOTRACE™ Auto Read 4H EtO Biological Indicator** are single-use Self-Contained Biological Indicators (SCBI) that consist of a polypropylene tube, a spore carrier inoculated with a population of *Bacillus atrophaeus* ATCC® 9372 spores and a glass ampoule containing culture medium, enclosed with a plastic colored cap and a barrier permeable to ethylene oxide. Each SCBI has a process indicator on label that changes from brown/bordeaux to green when exposed to ethylene oxide.

- Simultaneous incubation of SCBIs for monitoring EO processes along with SCBIs for monitoring other sterilization processes is not possible.
- Compliance: ISO 11138-1, ISO 11138-2, FDA
- Shelf life: 2 years

PRODUCT # EU 73300

COMPLIANCE ✓  
ISO 11138-1  
ISO 11138-2

# VERISURE™ MULTI-VARIABLE INDICATORS TYPE 4 ETO

**VERISURE™ EtO Type 4 Multi-Variable Chemical Indicator Strip** are single-use chemical indicators that consist of punched paper double strips printed with indicator ink. These indicators have been designed to monitor ethylene oxide sterilization processes within loads, ensuring an adequate exposure to the sterilizing agent during the sterilization process. Innovative highly sensitive purple/brown ink was developed to turn to green when the indicator is exposed to ethylene oxide considering the critical process variables which provides additional quality assurance.

- Compliance: ISO 11140-1:2014 standard Type 4 and cleared by the FDA.
- Shelf life: 5 years
- CE marked



PRODUCT # EU 73350

COMPLIANCE ✓  
ISO 11140-1



## Readers and Accessories

Product #	Product Description	Packaging*
73400	BIOTRACE™ Auto Read Pro Biological Indicator Reader	1 reader per case
73410	BIOTRACE™ Auto Read Mini Biological Indicator Reader	1 reader per case
73430	BIOTRACE™ Instant Read Steam Biological Indicator Reader	1 reader per case
73451	Thermal Printer Paper Pro Reader (50 mm diameter)	6 rolls per case
73450	Thermal Printer Paper Mini Reader (23 mm diameter)	3 rolls per case

## Biological and Chemical Indicators

Product #	Product Description	Modality	Packaging*
73100	BIOTRACE™ Auto Read 20 Biological Indicator	STEAM	50 BIs per box / 2 boxes per case
73130	BIOTRACE™ Auto Read 20 BI Process Challenge Device	STEAM	25 PCDs + 25 BIs (controls) per case
73105	BIOTRACE™ Auto Read 60 Biological Indicator	STEAM	50 BIs per box / 2 bags per case
73135	BIOTRACE™ Auto Read 60 BI Process Challenge Device	STEAM	25 PCDs + 25 BIs (controls) per case
73140	BIOTRACE™ Instant Read Steam BI Process Challenge Device	STEAM	25 PCDs and 25 BIs (controls) per case
73110	BIOTRACE™ Instant Read Steam Biological Indicator	STEAM	50 BIs per box / 2 boxes per case
73150	VERISURE™ Type 5 Migrating Integrator	STEAM	250 CIs per bag / 2 bags per case
73155	VERISURE™ Type 5 Migrating Integrator w/ Extender	STEAM	100 CIs per bag / 2 bags per case
73160	VERISURE™ Type 5 Migrating Integrator Process Challenge Device	STEAM	25 PCDs per case
73156	VERISURE™ Type 5 Ink Integrator	STEAM	200 CIs per bag / 2 bags per case
73165	VERISURE™ Type 4 Multi-Variable Chemical Indicator	STEAM	500 CIs per bag / 2 bags per case
73180	VERISURE™ Bowie-Dick Test Pack US Model	STEAM	20 per case
73190	VERISURE™ Bowie-Dick Test Card Kit US Model	STEAM	120 Cards per case + 1 Holder
73191	VERISURE™ Bowie-Dick Test Card US Model	STEAM	120 Cards per box / 2 boxes per case
73170	SEALSURE™ Indicator Tape 18mm	STEAM	50 meters per roll / 4 rolls per case
73181	VERISURE™ Bowie-Dick Test Pack EU Model	STEAM	20 per case
73195	VERISURE™ Bowie-Dick Test Card kit EU Model	STEAM	120 Cards per case + 1 Holder
73196	VERISURE™ Bowie-Dick Test Card EU Model	STEAM	120 Cards per box / 2 boxes per case
73250	VERISURE™ Type 4 Multi-Variable Chemical Indicator Strip	VH202	250 per bag / 2 bags per case
73300	BIOTRACE™ Auto Read 4H Biological Indicator	EtO	50 per box / 2 bags per case
73350	VERISURE™ Type 4 Multi-Variable Chemical Indicator Strip	EtO	500 per bag / 2 bags per case

\*the minimum order quantity is one case.

# Sterilization Monitoring



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▶ PROTECTING PATIENTS DURING THEIR MOST CRITICAL MOMENTS.™

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Important information: Prior to use, refer to the complete instructions for use supplied with the device(s) for proper use, indications, contraindications, warnings and precautions. Capitalized product names and ALLClear™ are trademarks of ASP Global Manufacturing GmbH.

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