



Getinge Assured

Sterility and Wash Monitoring Products

Eliminate the risk of false and misleading test results

Central sterile department precautions can be made easier and more effective with Getinge Assured sterility and wash monitoring products to document and verify equipment and process performance.

Getinge Assured

In the face of intensive scrutiny, Getinge's entire Assured product line will provide your facility with an extra measure of sterility assurance. The Assured product portfolio provides your institution confirmation that it is leaving nothing to chance to ensure better patient outcomes.

Proven certainty with biological testing

Getinge's enhanced purple-to-green chemistry is complemented by the industry's most reliable and FDA-cleared approach to biological testing. These principles are based on actual *Geobacillus Stearothermophilis* spore growth to eliminate the potential of a false reading. Getinge products monitor for true spore growth and never rely on an enzyme as an early predictor of the final outcome.

If sterilization failure occurs, Getinge AccuFast technology may provide positive biological evidence of that failure in as soon as three to five hours of incubation. The operator can immediately confirm a positive test by removing the vial from the incubator and visually observing the color change of the media to yellow. To meet the USFDA/RIT protocol, the recommended incubation time is 10 hours.

How Getinge's purple to green chemical indicator eliminates uncertainty

When it comes to ensuring effective steam sterilization, Getinge's exclusive purple-to-green technology dramatically reduces the potential indication of a premature false pass. That is because our sterilant specific ink technology requires an interaction with steam for the correct length of time and temperature to achieve a color change from purple to green.

By comparison, traditional migrating indicators used in a pre-vacuum cycle can prematurely indicate a pass condition very early in the exposure phase of a sterilization cycle.

Getinge Assured sterilant-specific technology monitors much longer into the exposure phase than typical migrating indicator technology. Additionally, Getinge Assured products provide an extended window into the cycle that helps reveal intermittent problems. In contrast, migrating indicators may deem a load to have passed based on a brief snapshot of cycle time.

Our test strips are not affected by variations in position, orientation or gravity. Furthermore, they provide additional diagnostic capabilities to uncover potential issues such as superheated steam/overexposure and wet steam/excess condensation conditions. Once the test has successfully been completed, the ink cannot revert in color as with pH indicator ink chemistry.

Getinge Assured advanced product portfolio

Wash Monitoring

Wash Monitors

Easy to use Wash Monitors consist of a metal strip with a synthetic test soil for routine monitoring of automated wash processes. The test is inserted into a Wash Monitor Holder that mirrors an instrument with difficult to reach and clean areas.

The synthetic test soil (red diamond) is nonhazardous and simulates human blood and tissue. When inserted into the Wash Monitor Holder, the test soil is partially obscured to simulate the joint of a surgical instrument. It measures chemistry efficacy and direct impingement/water spray. The removal of all test soil indicates effective cleaning.

The Wash Monitor reads cycle time, temperature, detergent concentration and direct impingement. Wash Monitors comply with the AAMI and AORN guidelines and provide a safe and effective tool for cleaning verification.

Order Number	Description
61301606765	Wash Monitor, 25
61301606766	Wash Monitor, 50
61301606767	Wash Monitor, 100



Ultrasonic Wash Monitor

Easy to use Wash Monitors consist of a metal strip with synthetic test soil for routine monitoring of an ultrasonic wash process. The test is inserted into a Wash Monitor Holder and placed into an ultrasonic cleaner.

The synthetic test soil (blue diamond) is nonhazardous and simulates human blood and tissue. It does not include human or animal derived blood, which could be introduced back into the cleaning process. The removal of all test soil indicates effective cleaning. Ultrasonic Wash Monitors examine cycle time, temperature, detergent concentration and cavitation.

Order Number	Description
61301606764	Wash Monitor U — Ultrasonic, 50



Wash Monitor Holder

Designed for use with the Getinge Assured Wash Monitor and Getinge Assured Ultrasonic Wash Monitor for routine monitoring of automated wash processes.

The Wash Monitor is inserted into the holder, simulating a contaminated surgical instrument. The Wash Monitor holder is then placed inside the washer-disinfector or ultrasonic cleaner. Removal of all test soil indicates effective cleaning.

Order Number	Description
61301606768	Wash Monitor Holder, 1 Holder

TOSI®

TOSI® (Test Object Surgical Instrument) provides a highly repeatable and reliable method for evaluating the cleaning effectiveness of automated instrument washers, single chamber washers, index washers and under-counter washers.

Nonhazardous soil is chemically engineered to mimic the challenging adhesive properties of human blood and mounted on a stainless steel plate that is grooved to replicate the uneven surfaces of surgical instruments.

The plate is contained in a plastic holder with a graduated gap (nooks and crannies) replicating the areas on a surgical instrument — which are often blocked from direct spray action, such as hinges and box locks.

TOSI complies with the new AAMI and AORN guidelines, as well as ASTM Guide D7225.

Order Number	Description
61301606695	TOSI Test, 30
61301606696	TOSI Test Rack, 3



Temperature-Sensitive Label

Self-adhering temperature recording labels for use in washer-disinfectors, cage washers and cart washers indicate when the surface temperature reaches a desired level. Available in single temperature monitoring of 180°F or three temperature monitoring for 160°F, 170°F or 180°F temperature cycles.

Waterproof label features temperature-sensitive elements that produce a non-reversible white to black color change at respective rated temperature.

Order Number	Description
61301603615	Temperature Sensitive Tape — Label 1 — Temperature 180°F, 24
61301603616	Temperature Sensitive Tape — Label 3 — Temperature 160°F, 170°F, 180°F, 16



Bowie-Dick Test Pack

Mini Bowie-Dick Test Pack

The single-use device detects the presence of residual air in pre-vacuum steam sterilizers operating at 132°C and 134°C for 3.5 minutes. The indicator card within the Mini Bowie- Dick Test Pack demonstrates a uniform color change from purple to green when proper sterilization conditions are met and no air is present.

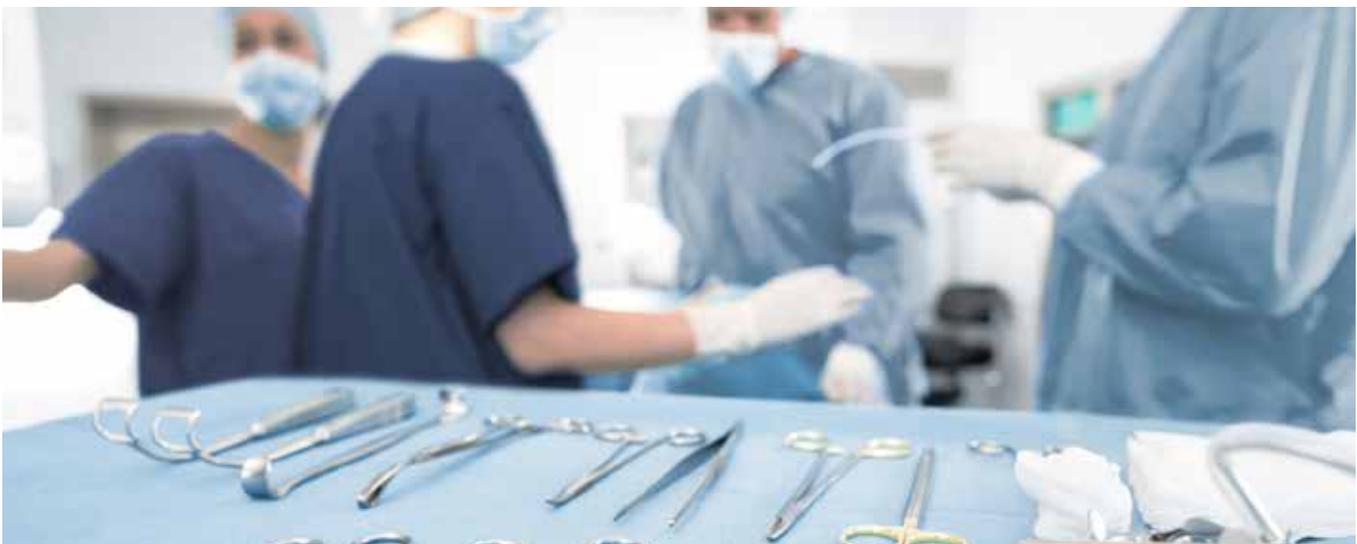
- ANSI/AAMI/ISO 11140-5 and ANSI/AAMI/ISO 11140-1:2014, Type 2 compliant
- Test pack is the size of a playing card and completely recyclable, post sterilization
- No toxic heavy metals, lead, latex or other pollutants used in the manufacturing process
- Reduced weight, waste, space, and environmental impact
- Minimizes errors and judgment calls due to unique ink technology, resulting in a complete color change
- Can be kept as a permanent record, sterilant specific indicator ink does not revert

Order Number	Description
61301606667	Mini Bowie-Dick Test Pack, 30

S.M.A.R.T. Pack II Test Pack

The environmentally-friendly disposable air removal test pack is designed to produce the challenge presented by the Bowie-Dick towel pack. S.M.A.R.T. Pack II provides a daily operational check for mechanical air removal in steam sterilizers. Its unique pattern design in the test sheet center makes it easy to interpret results. A satisfactory cycle is indicated by a complete color change from blue to black of all reactive ink.

Order Number	Description
61301605554	S.M.A.R.T. Pack II Test Pack, 30



Biological Indicators

AccuFast Biological Indicator

- After exposure to steam, the biological indicator indicates growth or no growth when incubated
- For gravity cycles at 250°F (121°C), 270°F (132°C) and 275°F (135°C)
- Color change (BI vial process indicator): Blue to black
- BI growth medium: Purple to yellow with growth
- Biological Indicator: Geobacillus Stearothermophilus
- Incubation temperature/time: 10 hours at 140°F (60°C) ± 36°F (2°C)
- ANSI/AAMI/ISO 11138

Order Number	Description
61301606636	Assured AccuFast BI, 50
61301606637	Assured AccuFast BI, 100

AccuFast Biological Test Pack

- Includes a self-contained biological indicator containing bacterial spores (Geobacillus Stearothermophilus) inside a small package of porous and nonporous materials plus an Instant Readout Integrator
- Four minutes at 270°F (132°C) and three minutes at 275°F (135°C)
- May detect a failed cycle within three to five hours of incubation
- For use with Getinge Assured 1410 and 1710 incubator
- Incubation time of 10 hours at 140°F (60°C) ± 36°F (2°C)
- Instant Readout Integrator Card: FDA Integrator
- Biological Indicator: ANSI/AAMI/ISO 11138
- Test Pack: ANSI/AAMI ST79

Order Number	Description
61301606638	Assured AccuFast BI Test Pack 5 Controls, 25
61301606639	Assured AccuFast BI Test Pack 25 Controls, 25

AccuView Biological Test Pack

- Includes a self-contained biological indicator containing bacterial spores (Geobacillus Stearothermophilus) inside a small package of porous and nonporous materials plus an Instant Readout Integrator
- Four minutes at 270°F (132°C) and three minutes at 275°F (135°C)
- Unique window design helps eliminate the potential that an empty or broken vial would require the load to be reprocessed post sterilization
- May detect a failed cycle within three to five hours of incubation
- For use with Getinge Assured 1410 and 1710 incubator
- Incubation time of 10 hours at 140°F (60°C) ± 36°F (2°C)
- Instant Readout Integrator Card: FDA Integrator
- Biological Indicator: ANSI/AAMI/ISO 11138
- Test Pack: ANSI/AAMI ST79

Order Number	Description
61301606714	Assured AccuView BI Test Pack 5 controls, 25
61301606715	Assured AccuView BI Test Pack 25 controls, 25

EO Self-Contained Biological Indicator

- Designed for biological testing of Ethylene Oxide sterilizers
- Contains 10⁶ Bacillus Atrophaeus
- Color change (Biological vial process indicator): Blue to brown
- BI growth media: Red to yellow with growth
- Incubation Time: 48 hours at 95°F to 102°F (35°C to 39°C)
- ANSI/AAMI/ISO-11138

Order Number	Description
6005500154	SteriTec EZEO, 100

EO Biological Test Pack

- Designed specifically for biological testing of EO Gas sterilizers
- Includes a self-contained biological indicator (Bacillus Atrophaeus) placed inside a diffusion resistant plastic container covered with a closure cap. Its then placed in a paper peel pouch with an Instant Readout Indicator Card
- Color change (Instant readout indicator card): Yellow to brown
- BI vial process indicator: Blue to brown
- BI growth medium: Red to yellow with growth
- Incubation time: 48 hours at 95°F to 102°F (35°C to 39°C)
- For use with the Getinge Assured 1410 Incubator
- Instant Readout Indicator Card: Process indicator
- Biological Indicator: ANSI/AAMI/ISO 11138
- Test Pack: ANSI/AAMI ST-41

Order Number	Description
61301606710	Assured EO BI Test Pack 25 Controls, 30
61301606709	Assured EO BI Test Pack 5 Controls, 30



1410 Incubator

- Designed for incubation of AccuFast and AccuView Biological Indicators and Getinge EO Self-Contained Biological Indicators
- 99°F (37°C) (Bacillus Atrophaeus), 135°F (57°C) or 140°F (60°C) Geobacillus Stearothermophilus
- Includes integrated thermometer for easy temperature reference, 13 incubation wells and an activation well for crushing the Getinge Assured SCBIs

Order Number	Description
61301606649	AccuFast 1410 Incubator

1710 Incubator

- Designed for incubation of AccuFast and AccuView Biological Indicators
- Internal thermometer continuously monitors the incubation temperature and displays it on the LCD screen
- Reduces total incubation time to 10 hours, eliminating the need to continue incubation for 12, 18, 24 or 48 hours
- Features a touch sensitive, color liquid crystal display (LCD) for interacting with a powerful, feature rich user interface
- Calibrated to 140°F ± 36°F, (60°C ± 2°C) for proper incubation of AccuFast biological indicators containing spores of Geobacillus Stearothermophilus

Order Number	Description
61301606672	AccuFast 1710 Incubator (with printer)



Chemical Indicators

ChemiSix Emulating Indicator

- For use in a pre-vacuum steam sterilization process
- Four minutes at 270°F (132°C) or three minutes at 275°F (135°C)
- Does not contain lead or toxic heavy metals
- ANSI/AAMI/ISO 11140-1, Type 6
- FDA Cleared Integrator
- Sterilant specific ink technology

Order Number	Description
61301606200	ChemiSix Emulating Indicator, 250
61301606626	ChemiSix Emulating Indicator, 500

ChemiSix Emulating Test Pack

- Monitors pre-vacuum steam sterilizers
- Four minutes at 270°F (132°C) and three minutes at 275°F (135°C)
- Emulator card becomes a permanent record (color change will not revert)
- Does not contain lead or toxic heavy metals
- Test pack is pre-assembled and ready to use
- FDA Cleared Integrator
- ANSI/AAMI/ISO 11140-1, Type 6
- Designed to react to all critical process variables of time, temperature and steam
- Sterilant specific ink technology

Order Number	Description
61301606235	ChemiSix — Emulator Test Pack, 40



ChemiSix Extended Test Pack

- For use in a pre-vacuum steam sterilization process
- 10 or 20 minutes at 270°F (132°C) and 8 or 16 minutes at 275°F (135°C)
- Emulator card becomes a permanent record (color change will not revert)
- Does not contain lead or toxic heavy metals
- Test pack is pre-assembled and ready to use
- FDA Cleared Integrator
- ANSI/AAMI/ISO 11140-1, Type 6
- Designed to react to all critical process variables of time, temperature and steam
- Sterilant specific ink technology

Order Number	Description
61301606236	ChemiSix Pack Extended Emulator Test Pack, 40

ChemiPack Integrator Test Pack

- Designed for use as a supplementary test to biological pack testing (not as a substitute) in 270°F (132°C) pre-vacuum steam sterilizers operating for three minutes or longer
- When exposed to steam, the indicator, "PASS", changes color
- May be used as a standalone test for non-implant load testing
- Integrator Card becomes a permanent record

Order Number	Description
61301605836	ChemiPack Integrator Test Pack, 40

Steam Sterilization Integrators

- Single-use wick chemical integrators for use in 250°F to 272°F (121°C to 133°C) steam sterilization processes
- Responsive to critical steam cycle parameters – steam pressure, temperature and time
- Reacts to the steam sterilization cycle parameters in a manner that is equivalent to 1X biological kill
- ANSI/AAMI/ISO 11140-1:2014, Type 5

Order Number	Description
61301658261	Steam Sterilization Integrator (Short), 250



Steam Monitor Strips

- For use in steam sterilizers operating at 132°C to 135°C (270°F to 276°F)
- Gives a visible indication that all parameters of steam sterilization conditions have been met before the color change occurred (The check marks change color to black)

Order Number	Description
61301606813	Steam Sterilization Indicator - 4", 250
61301606814	Steam Sterilization Indicator - 8", 250



Steam Sterilization Indicator Tape

Green Steam Tape

- FDA Sterilization Process Indicator (ANSI/AAMI ST79, Type 1: ISO 11140-1 Type 1) for use in 250°F (121°C) gravity sterilizers for 30 minutes or pre-vacuum sterilizers operating at 270°F (132°C) for 4 minutes and 275°F (135°C) for 3 minutes
- Green stripes turn to black when exposed to steam sterilization conditions to identify processed items
- Secure seal is easy to remove from reusable wraps



Order Number	Description
61301606668	Green Steam Tape — 3/4", 48
61301606669	Green Steam Tape — 1", 36



Documentation Products

Load Control Cards

- Compact sterilization process indicator for use in an ethylene oxide (EO) sterilizer or steam sterilizer operating at 132°C
- EO exposure changes the EO indicator spot from yellow to brown and steam exposure changes the STEAM indicator spot from light blue to black
- Record label can be affixed to the front of the card which becomes a permanent record

Order Number	Description
61301606815	Control Card for EO and Steam Sterilization, 500



Load Control Number System

Includes a lightweight label gun and load control labels that easily identify each pack by date processed, date sterilized, load number and expiration date.

Record-Keeping System

Includes envelopes and a binder for accurate documentation essential to Good Hospital Practices (GHPs) and Good Manufacturing Practices (GMPs). Separate color-coded envelopes for steam and EO gas cycles contain necessary checklists for operators. Each envelope holds all charts, data logger strips, load control cards, chemical indicators/ integrators, Bowie and Dick test sheets and biological data.

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