

Steam Sterilization Assurance System Side-by-Side Comparison

Biological Indicators

Features	3M™ Attest™ Super Rapid Readout System	Terragene® Bionova® Super Rapid Readout System	Terragene® Bionova® Ultra Rapid System	Important considerations
BI FDA cleared	Yes 1491: K173584 ¹ 1492V: K173437 ²	Yes BT222: K163646 ³ BT223: K163646 ³	Yes BT224: K191021 ⁴	Biological indicators are regulated as Class 2 Medical Devices in the United States.
Time to final result	24 minutes ^{1,2}	BT222: 1 hour ³ BT223: 30 minutes ³	20 minutes ⁴	Load should be allowed to cool before handling. (AAMI ST79, Section 10.3.1). ⁵
BI optional visual pH color change result	Yes 1491: 24 hours ¹ 1492V: 48 hours ²	Yes ³ BT222: 48 hours ³ BT223: 48 hours ³	Yes BT224: 48 hours ⁴	Optional visual result facilitates periodic verification of the early-readout, as recommended in AAMI ST79, Section 13.5.3.1. ⁵
BI indications for use	1491: ¹ Gravity Cycles • 270°F / 132°C 3 or 10 minutes • 275°F / 135°C 3 or 10 minutes 1492V: ² Dynamic-air-removal (Prevac + SFPP) • 270°F / 132°C 3 and 4 minutes • 275°F / 135°C 3 minutes	BT222: ³ Gravity Cycles • 250°F / 121°C 30 minutes • 270°F / 132°C 15 and 25 minutes • 275°F / 135°C 10 minutes Dynamic-air-removal (Vacuum Assist) • 270°F / 132°C 4 minutes • 275°F / 135°C 3 minutes BT223: Gravity Cycles • 270°F / 132°C 3 or 10 minutes • 275°F / 135°C 3 or 10 minutes	BT224: ⁴ Gravity Cycles • 270°F / 132°C 10, 15 and 25 minutes • 275°F / 135°C 10 minutes Dynamic-air-removal (Vacuum Assist) • 270°F / 132°C 4 minutes • 275°F / 135°C 3 minutes	AAMI ST79, Section 13.5.3.1, recommends selecting a BI that is suitable for use in the specific sterilization cycle. ⁵
BI design	Self-contained BI with glass media ampoule. Process indicator dot on BI cap.	Self-contained BI with glass media ampoule. Chemical indicator line on label.	Self-contained BI with glass media ampoule. Chemical indicator line on label.	Process indicator allows easy differentiation between test and control BIs.
2-D barcode on BI	1491: Yes 1492V: Yes	BT222: No BT222-T: Yes ⁶ BT223: No	BT224: No	A barcode can help simplify record keeping and minimize transcription errors.
ISO 11138 compliant	1491: Yes ⁷ 1492V: Yes, ⁸ BSI Kitemark™ Certificate KM657624. ⁹	BT222: Yes ¹⁰ BT223: Yes ¹¹	BT224: Yes ¹²	AAMI ST79, Section 13.5.3.1, recommends use of BIs that comply with ISO 11138-3. ⁵

Process Challenge Devices

Features	3M™ Attest™ Super Rapid Readout System	Terragene® Bionova® Super Rapid Readout System	Terragene® Bionova® Ultra Rapid System	Important considerations
PCD design	1496V: ¹³ Wrapped pack containing paper index cards, record keeping sheet, and 1492V BI. 41482V: ¹⁴ Wrapped pack containing paper index cards, record keeping sheet, 1492V BI, and a moving-front Type 5 integrator.	PCD222-2: ¹⁵ Cardboard box containing porous cards, BT222 SCBI, and Type 5 integrator printed on record card. PCD222-C: ¹⁶ Cardboard box containing porous cards, self-adhesive record card, BT222 SCBI, and IT26-C moving-front Type 5 integrator.	PCD224-2: ¹⁷ Cardboard box containing porous cards, BT224 SCBI, and Type 5 integrator printed on self-adhesive record card. PCD224-C: ¹⁸ Cardboard box containing porous cards, self-adhesive record card, BT224 SCBI, and IT26-C moving-front Type 5 integrator.	Loads containing implants should be monitored with a PCD containing a BI and a Type 5 integrating CI (AAMI ST79, Section 13.5.4). ⁵
PCD equivalent in challenge to AAMI 16-towel PCD	Yes ¹³	Yes ³	Yes ⁴	Required by FDA and recommended by AAMI ST79. ⁵
PCD indications for use	1496V / 41482V: ^{13,14} Dynamic-air-removal • 270°F / 132°C 4 minutes • 275°F / 135°C 3 minutes	PCD222-2 / PCD222-C: ³ Gravity Cycles • 250°F / 121°C 30 minutes • 270°F / 132°C 15 and 25 minutes • 275°F / 135°C 10 minutes Dynamic-air-removal (Vacuum Assist) • 270°F / 132°C 4 minutes • 275°F / 135°C 3 minutes	PCD224-2 / PCD224-C: ⁴ Gravity Cycles • 270°F / 132°C 10, 15 and 25 minutes • 275°F / 135°C 10 minutes Dynamic-air-removal (Vacuum Assist) • 270°F / 132°C 4 minutes • 275°F / 135°C 3 minutes	Ensure adequate inventory for high volume cycles.
PCD includes a type 5 integrator	1496V: No ¹³ 41482V: Yes ^{14,19}	PCD222-2: ¹⁵ Yes, purple → green integrator printed on record card PCD222-C: ¹⁶ Yes, IT26-C moving front style	PCD224-2: ¹⁷ Yes, purple → green integrator printed on record card. PCD224-C: ¹⁸ Yes, IT26-C moving front style.	Loads containing implants should be monitored with a PCD containing a BI and a Type 5 integrating CI. (AAMI ST79, Section 13.5.4). ⁷
Type 5 CI in PCD satisfies ISO 11140-1:2014 performance requirements	1496V: N/A 41482V: Yes ^{19,20} 3rd party certification: BSI Kitemark™ Certificate KM 657533. ²¹	PCD222-2: Yes ¹⁵ PCD222-C: Yes ¹⁶ Not always ²⁰	PCD224-2: Yes ¹⁷ PCD224-C: Yes ¹⁸ Not always ²⁰	Loads containing implants should be monitored with a PCD containing a BI and a Type 5 integrating CI. (AAMI ST79, Section 13.5.4). ⁷
2-D barcode on PCD	Yes	No	No	A barcode can help simplify record keeping and minimize transcription errors.

Incubators/Readers

Features	Attest Super Rapid Readout System	Terragene® Bionova® Super Rapid Readout System	Terragene® Bionova® Ultra Rapid System	Important considerations
Dual Sterilization Modality Incubation Capability	Yes, 3M™ Attest™ Auto-reader 490 having software version 4.0.0 or greater and 3M™ Attest™ Mini Auto-reader 490M can simultaneously incubate both 3M™ Attest™ steam and VH2O2 BIs. ^{2,22}	No, FDA clearance for Terragene Bionova® IC10/20FR Reader Incubator is for steam BIs only. ³	Yes, Terragene Bionova® Reader Incubators IC10/20FRLCD and Mini-Bio incubate at 60°C and 37°C and are FDA cleared to incubate steam, VH2O2, and EO BIs. ⁴	The use of only one incubator can save space and improve efficiency.
Incubation Wells require configuration by end-user	No, all incubation wells of Attest Auto-readers 490 and 490M incubate at 60°C and provide a result in 24 minutes.	Yes, user must set the incubation temperature and reading program applicable to the BI type. ²⁵	Yes, user must select incubation program and temperature appropriate for the indicator for each readout position. ²⁶	Preconfigured incubation wells can help reduce the risk for use error.

Incubators/Readers (cont.)

Features	3M™ Attest™ Super Rapid Readout System	Terragene® Bionova® Super Rapid Readout System	Terragene® Bionova® Ultra Rapid System	Important considerations
Large and small capacity compatible incubators available	Yes, 3M™ Attest™ Biological Indicators 1491 and 1492V may be incubated in 3M™ Attest™ Auto-readers 490 (10 well) or 490M (4 well). ^{23,24}	No, BT222 and 223 are FDA cleared for incubation only in IC10/20FR Reader Incubator (12 well). ^{3,25}	Yes, BT224 is FDA cleared for incubation in IC10/20FRLCD (12 wells) or in the Mini-Bio (3 wells). ^{4,26,27}	Select a reader with sufficient capacity to incubate both control and test BIs.
Reader detects BIs with intact media ampoules	BI activator provided with each Attest Auto-reader 490 and 490M. 490: E11 error code alerts user if BI cap is not fully depressed, prompting user to re-activate BI. ²³ 490M: Yes, C6 caution code alerts user if purple growth media is not detected in BI growth chamber. ²⁴	No. User crushes ampoule using ampoule crusher or in crusher on IC10/20FR Reader. Reader does not detect uncrushed ampoules. ²⁵	IC10/20FRLCD: No, user uses ampoule crusher or crusher on incubator. Incubator does not detect uncrushed media ampoules. ²⁶ MiniBio: No, user uses ampoule crusher or crusher on incubator. Incubator does not detect uncrushed media ampoules. ²⁷	Media needs to cover spore carrier to support growth and permit reader to detect viable organisms.
Incubator displays remaining time to result	Yes, Attest Auto-readers 490 and 490M prominently display time remaining to result. ^{23,24}	No, but user can print a ticket which states remaining incubation time. ²⁵	IC10/20FRLCD: No, but user can press icon and a new screen will open and display remaining incubation time. ²⁶ MiniBio: No, but user can print a ticket which states remaining incubation time. ²⁷	A time display can help staff plan and communicate timing of implant and load release to the OR and department teammates.
Incubator has On-board Printer	No, but Attest WebApp (3M™ Attest™ Auto-reader 490) ²³ and Attest Connect software (3M™ Attest™ Auto-reader 490M) ²⁴ can be used to print a BI record.	Yes, IC10/20FR includes a printer. The printer uses thermal paper rolls. ²⁵	Yes, IC10/20FRLCD and Mini-Bio have printers. The printers use thermal paper rolls. ^{26,27}	
Incubator stores archived data history and results	490: Auto-reader stores results for the last 100 incubated BIs. ²³ User can access using WebApp. 490M: Auto-reader stores 1,250 results. Users can access using Attest Connect. ²⁴	Incubator saves the last 12 results. ²⁵	IC10/20FRLCD: Stores the last 208 results and user can access on LCD. ²⁶ MiniBio: Incubator allows reprinting of the last three results. ²⁷	Access to historic data can be helpful in situations in which result was not documented.
Firmware updates	490: Upgrades done by authorized Solventum representative. 490M: User can check for updates and download latest firmware using Attest Connect. ²⁴	User can check for updates and download latest firmware using Bioupdate Software. ²⁵	IC10/20FRLCD: User can download using firmware update utility Bionova Bioupdate. ²⁶ MiniBio: User can download using firmware update utility Bionova Bioupdate. ²⁷	
Connection to facility network or PC	490: Ethernet cable (supplied) to facility network. ²³ 490M: USB cable (supplied) to PC. ²⁴	USB port may be connected to PC. ²⁵	IC10/20FRLCD: Yes, ethernet cable. ²⁶ MiniBio: USB cable (supplied) to PC. ²⁷	
Instrument tracking software connectivity	Yes, Attest Auto-reader 490 interface with industry leading instrument tracking platforms.	Yes, to Bionova® Traceability Software. ²⁵	IC10/20FRLCD: Yes, to Bionova® Traceability Software. ²⁶ MiniBio: Yes, to Bionova® Traceability Software. ²⁷	Connectivity to a comprehensive CSSD software platform allows facilities to document sterilization cycle and BI results electronically in one system.

Support

Features	Attest Super Rapid Readout System	Terragene® Bionova® Super Rapid Readout System	Terragene® Bionova® Ultra Rapid System	Important considerations
Local direct sales, clinical, and service support	Yes, Solventum has resources in over 60 countries.	Limited ²⁸	Limited ²⁸	Availability of sales, in-service, troubleshooting, and service support/resources.

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