TECHNICAL BULLETIN

ConFirm™ Rapid Read 20-Minute Biological Monitoring System

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1 INTRODUCTION

This Technical Bulletin illustrates the principles of operation and the performance of the ConFirm™ Rapid Read 20-Minute Biological Indicators.

Steam Sterility Assurance Monitoring

The most common sterilization process utilized in health care facilities for the terminal sterilization of reusable medical devices is moist heat sterilization. Moist heat sterilization, also called steam sterilization, utilizes vaporized steam under high pressures to create lethal conditions within a steam sterilizer.

To monitor and confirm the lethality of a sterilization process, several trade organizations and governmental agencies have developed recommended practices when utilizing steam sterilization to sterilize medical devices in healthcare. The most referenced recommendations are published by the Centers for Disease Control (CDC), the Association for the Advancement of Medical Instrumentation (AAMI), the Association for peri-Operative Registered Nurses (AORN.) Though the recommendations may differ slightly, all agree that in addition to physical and chemical monitoring devices, steam sterilization processes must be routinely assessed using an appropriate biological challenge.

Biological indicators (BI) and process challenge devices (PCD) are utilized to confirm the ability of steam sterilizers to kill large populations of highly resistant bacterial spores. The CDC guidance for Infection Control states that “spores used in BIs are more resistant and present in greater numbers than are the common microbial contaminants found on patient care equipment, and so the demonstration that the biological indicator has been inactivated strongly implies that other potential pathogens in the load have also been killed.”

All three organizations recommend weekly, preferably daily, verification of the steam sterilization process. Additionally, a biological indicator should be placed in an instrument/challenge pack that provides a challenge equivalent to that of a device that would be processed within the load. ANSI/AAMI ST79, *Comprehensive guide to steam sterilizers and sterility assurance in health care facilities*, provides detailed instructions on the materials and construction of the biological indicator test pack to be used when monitoring steam sterilization processes. In emergency situations, healthcare facilities will sometimes run abbreviated steam sterilization cycles, with little to no dry time, for quick turn of medical devices. These cycles are referred to as Immediate Use Steam Sterilization Cycles (IUSS) and must also be routinely monitored using an appropriate biological challenge pack.

In addition to routine monitoring of the sterilizer’s performance, biological indicators and instrument/challenge packs should be used for monitoring sterilization loads which have an implantable device. The load containing the implantable device is quarantined while awaiting the results of the biological indicator.

ANSI/AAMI ST79 also identifies the need to perform qualification testing of the steam sterilizer when it is first installed, relocated and whenever a major repair has been completed.

The ConFirm™ Rapid Read 20-Minute Biological Indicators have been designed to meet the requirements of these organizations for routine monitoring, load monitoring, and qualification of steam sterilization processes for which they are labeled.

2 PRODUCT

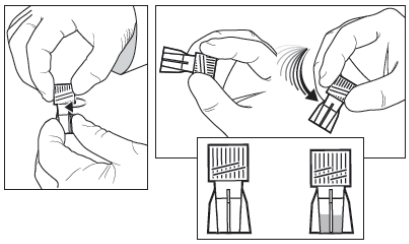
USE APPLICATION

The ConFirm™ Rapid Read 20-Minute Biological Indicatoris used for routine monitoring, qualification testing, load monitoring and product testing of steam sterilization cycles (See Table 1 for validated cycles). When used in conjunction with the ConFirm™ Rapid Read 20-Minute Incubator/Reader, the Incubator provides a fluorescent result within 20 minutes.

The ConFirm™ Rapid Read 20-Minute Incubator/Reader is used to incubate and automatically read ConFirm™ Rapid Read 20-Minute Biological Indicators at 57°C for a fluorescent result within 20 minutes.

DEVICE DESCRIPTION

The ConFirm™ Rapid Read 20-Minute Biological Indicators (BI) are self-contained biological indicators consisting of a high population of Geobacillus stearothermophilus spores and a defined media. A wraparound cap label provides information on the lot and expiration date of the BI for manual documentation. Alternatively, a barcode printed on the label can be scanned to retrieve the same information for electronic documentation. The label is also printed with a process indicator for steam as defined by ANSI/AAMI/ISO 11140-1.



The defined media contains a purple indicator dye and is held within the cap using a laminated film/foil. The twist cap design provides a smooth one step process to release the media from the cap and seal the BI from contamination. A simple flick of the wrist releases the media from the cap to the base of the vial.

The BI is intended to be incubated and final results read by the ConFirm™ Rapid Read 20-Minute Incubator/Reader within 20 minutes.

The ConFirm™ Rapid Read 20-Minute Incubator/Reader is designed for exclusive use with the ConFirm™ Rapid Read 20-Minute BI. This compact, tabletop incubator functions at 55-60°C and consists of two independent heating blocks, each containing four numbered wells for incubation of processed or control ConFirm™ Rapid Read 20-Minute BIs. Each well is designed to “fit” the specific shape of the BI. An LCD screen provides user prompts, test results or error messages that might occur during operation. Test results may be downloaded from the incubator to an optional printer or to a computer for electronic documentation.

INTERPRETATION OF CHEMICAL INDICATORS

Interpretation of the steam process indicator on BI:

The process indicator for steam is located on the wraparound label on the BI cap. This process indicator is a Type 1 chemical indicator as defined by ANSI/AAMI/ISO 11140-1:2014. The indicator will start pink and change to brown following exposure to steam.

Table 1. Validated steam sterilization cycles

SKU	Sterilization Cycles
RR20BI **ConFirm™ Rapid Read 20-Minute BI**	Dynamic Air Removal: • 270°F/132°C 4-minute Prevacuum Steam • 270°F/132°C 4-minute Steam-Flush Pressure-Pulse Steam • 275°F/135°C 3-minute Prevacuum Steam • 275°F/135°C 3-minute Steam-Flush Pressure-Pulse Steam Gravity: • 250°F/121°C 30-minute Gravity Steam • 270°F/132°C 15-minute Gravity Steam

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3 TECHNOLOGICAL REVIEW OF EARLY DETECTION SYSTEM

The ConFirm™ Rapid Read 20-Minute BI has been designed to allow confirmation of negative growth within 20 minutes of incubation in conjunction with the dedicated ConFirm™ Rapid Read 20-Minute Incubator/Reader.

The ConFirm™ Rapid Read 20-Minute BI utilizes spores of *Geobacillus stearothermophilus*. Following sterilization, the BI is activated and incubated using the ConFirm™ Rapid Read 20-Minute Incubator/Reader. Any viable spores present will begin to germinate upon contact with the defined media containing the fluorescent substrate 4-methylumbelliferyl-α-D-glucopyranoside (MUD). The enzyme α-glucosidase reacts with the MUD to produce a fluorescent signal. A general schematic of the reaction between α-glucosidase and its substrate is illustrated in Figure 1.

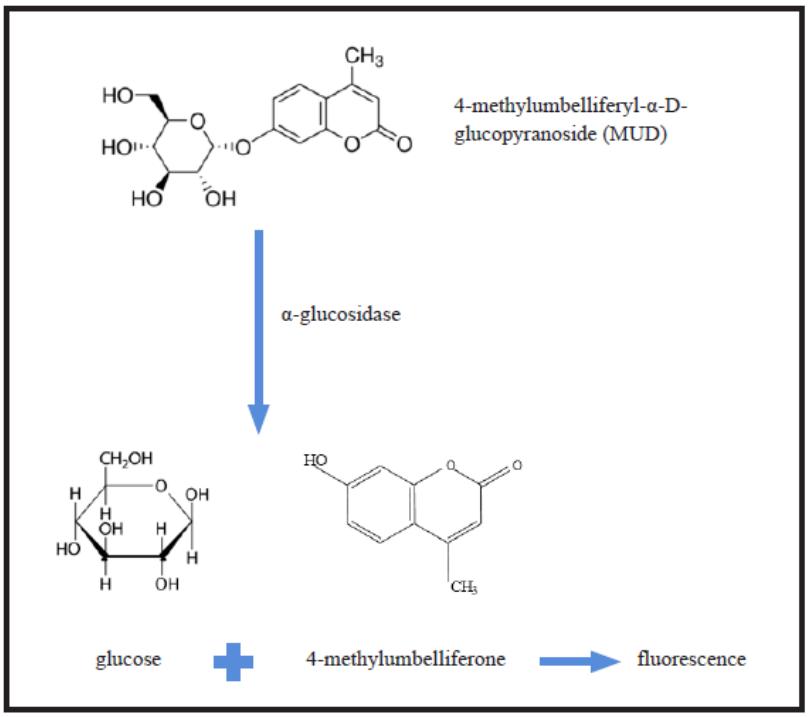

Figure 1: General reaction schematic of the α- glucosidase activity on the substrate MUD

If the BI was properly sterilized, no viable *Geobacillus stearothermophilus* spores are present in the BI, and there is, therefore, no increase in fluorescence. A positive growth response read by the ConFirm™ Rapid Read 20-Minute Incubator/Reader results from the presence of α-glucosidase, indicating inappropriate sterilization of the BI. The fluorescent signal that is generated from the reaction between α-glucosidase and MUD is read by the ConFirm™ Rapid Read 20-Minute Incubator/Reader.

Each well of the ConFirm™ Rapid Read 20-Minute Incubator/Reader has its own individual LED and detector to monitor the potential fluorescence generated as a result of the reaction with α-glucosidase. When a growth response has been detected or when the required incubation time has elapsed, the incubator indicates the results to the user either by audible and visual means for a growth response or by visual means (optional audible alarm available) for a no growth response.

Please refer to the Operator's Manual for the ConFirm™ Rapid Read 20-Minute Incubator/Reader for more detail and operation instructions.

4 BIOLOGICAL INDICATOR PERFORMANCE

CONFIRM™ RAPID READ 20-MINUTE BIOLOGICAL INDICATOR

The ConFirm™ Rapid Read 20-Minute BI utilizes an enzyme-based early-readout detection system. The performance of the ConFirm™ Rapid Read 20-Minute BI was tested using methods defined in ANSI/AAMI/ISO 11138-1:2006/R2010 *Sterilization of health care products – Biological Indicators – Part 1: General Requirements* and ANSI/AMI/ISO 11138-3:2006/R2010 *Sterilization of health care products – Biological Indicators – Part 3: Biological indicators for moist heat sterilization processes*.

A certification card containing the BI lot's population and resistance information is provided with each box of product.

ANSI/AAMI/ISO 11138-1:2006/R2010 and 11138-3:2006/R2010 specify requirements for BIs designed to monitor moist heat sterilization processes. Table 2 lists the ANSI/AAMI/ISO requirements, as well as the ConFirm™ Rapid Read 20-Minute BI specifications.

Table 2. Performance requirements for biological indicators intended for moist heat sterilization as identified by ANSI/AAMI/ISO 11138-1 and 11138-3

ANSI/AAMI/ISO 11138 Specifications	ConFirm™ Rapid Read 20-Minute BI Specifications
Indicator organism: *Geobacillus stearothermophilus*	Indicator organism: *Geobacillus stearothermophilus*
Spore population: ≥1.0 x 10^5 cfu/BI	Spore population: 1.0x10^6 to 4.0 x 10^6 cfu/BI
D-value at 121°C (250°F) ≥ 1.5 minutes	D-value at 121°C (250°F) is ≥ 1.5 minutes
Z value ≥ 6°C Note: US FDA requires Z value ≥ 10°C	Z value is ≥ 10°C

CONFIRMATION OF COMPLIANCE WITH POPULATION AND RESISTANCE PERFORMANCE SPECIFICATIONS

Test Objective: To confirm compliance with the population and resistance performance specifications of the BI.

Test Method: Three lots of ConFirm™ Rapid Read 20-Minute BIs were tested for population of viable spores and resistance within a steam resistometer. D-values were determined at 121°C, 132°C, and 135°C using Holcomb-Spearman-Karber D-value calculations. Z-value calculations were based on the slope of the curve generated from the D-values.

Resistance was also evaluated using the Survival/Kill calculations below. All-survive exposure times for the BI conformed to recommended survival times as outlined in FDA guidance for BI submissions.

Survival time = not less than ($\log_{10}$ nominal population -2) x D-value

Kill time = not more than ($\log_{10}$ nominal population + 4) x D-value

Test Results: Population and resistance test results are presented in Table 3. Survival/Kill testing was confirmed for all 3 lots evaluated and is presented in Table 4.

Table 3. Confirmation of population and resistance profiles for 3 lots of ConFirm™ Rapid Read 20-Minute BIs

Lot	Population (CFU/BI)	121°C D-value (min)	132°C D-value (min)	135°C D-value (min)	Z-value
1	2.3 x 10^6	3.1	0.8	0.7	16.7
2	2.5 x 10^6	2.5	0.8	0.6	20.0
3	2.5 x 10^6	2.6	0.8	0.7	20.0

Table 4. Confirmation of Survival and Kill Times (121°C) for 3 lots of ConFirm™ Rapid Read 20-Minute BIs

Lot	Survival Exposure time (min)	Test Results	Lot	Survival Exposure time (min)	Test Results
1	13.39	50/50	31.81	0/50	1
2	11.11	50/50	26.29	0/50	2
3	11.33	50/50	26.77	0/50	3

5 REGULATORY STATUS AND REFERENCE

REGULATORY STATUS

The ConFirm™ Rapid Read 20 Minute BI and ConFirm™ Rapid Read 20 Minute Incubator/Reader have been cleared for release into interstate commerce as Type II Medical Devices as defined by the US Food and Drug Administration.

REFERENCE

1. *Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.*
2. *ANSI/AAMI/ISO 11140-1:2014 Sterilization of health care products - Chemical indicators- Part 1: General Requirements.*
3. *ANSI/AAMI/ISO 11138-1:2006/R2010 Sterilization of health care products - Biological indicators- Part 1: General Requirements.*
4. *ANSI/AAMI/ISO 11138-3:2006/R2010 Sterilization of health care products - Biological indicators- Part 3: Biological Indicators for moist heat sterilization processes.*

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