solventum

Case study

A comparison of the performance of three integrating indicators against the ISO stated value performance requirements for Type 5 integrating indicators at 121°C

Abstract

Background: ISO 11140-1:2014 specifies performance requirements for CIs, including Type 5 integrating indicators. This study evaluated three different steam integrating indicators to the Stated Value performance requirements of ISO 11140-1:2014 for Type 5 steam integrating indicators at 121°C.

Method: For each product evaluated, sets of six integrators/lot were tested in a steam resistometer compliant to ISO 18472 to determine the Stated Value at 121°C. This Stated Value was compared to the minimum value specified in the ISO standard for this temperature. The test methodology has been reviewed by BSI Assurance UK Ltd.

Results: Stated Values were determined for the three lots of 3M™ Comply™ SteriGage™ Integrators and the two lots of 3M™ Attest™ Integrators. The Stated Value for each lot exceeded the 16.5 minute minimum value specified in the ISO standard. The 121°C Stated Value for three lots of the Terragene Integron® IT26-C Integrating Indicator did not meet the ISO 11140-1 requirement.

Conclusion: The lots of 3M™ Comply™ SteriGage™ Steam Chemical Integrator and the lots of 3M™ Attest™ Steam Chemical Integrators 1243 evaluated satisfied the Stated Value performance requirements of ISO 11140-1:2014 for Type 5 steam integrating indicators at 121°C. The lots of Terragene Integron® IT26-C Integrating Indicators tested in this study failed to satisfy the Stated Value performance requirements of ISO 11140-1:2014 for Type 5 steam integrating indicators at 121°C.

Introduction

A variety of monitoring tools, including chemical, physical, and biological indicators, are used as part of an effective sterilization quality assurance program. ISO 11140-1:2014 (*Sterilization of health care products—CIs, Part 1: General requirements*) specifies the labeling requirements, performance requirements, and test methods "for indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances, and which are used to monitor the attainment of one or more of the process parameter(s) specified for a sterilization process".[1]

ISO 11140-1:2014 categorizes chemical indicators (CIs) into six types. Internal CIs verify sterilant has penetrated to the point of placement inside containers, wrapped packs or peel pouches.

While Type 3, 4, 5 and 6 indicators can all be used as internal CIs, sterile processing personnel find Type 5 steam integrating indicators particularly robust and convenient for several reasons, including:

- They are the only type of CI that is designed to react to all critical process variables and for which the Stated Values are generated to be equivalent to, or exceed, the calculated performance requirements for biological indicators;
- They can be used to monitor a variety of steam sterilization cycles over the entire range of temperatures used in health care facilities.

The ISO standard establishes performance requirements that are intended to ensure that the indicators provide the correct level of challenge to the sterilization process. This is accomplished by specification of Stated Values, which define the conditions required for the CIs to show a pass or fail result in a sterilization process. Type 5 steam integrating indicators require Stated Values to be established at a minimum of three different temperatures across the entire range of steam sterilization cycles, 121°C (250°F) and 135°C (275°F) and at one or more equally spaced temperature points in between. Having these three Stated Values confirms that Type 5 CIs integrate over the full temperature range. To assess the indicator's performance at a Stated Value, manufacturers test the indicators in two different test conditions or Test Points. At Test Point 1, the Stated Value conditions, the indicator must reach its end point or show a Pass result. At Test Point 2, the temperature is set 1°C lower and the exposure time 15% shorter than the Stated Value conditions, the indicators must not reach their end point or must show a Fail result. The 2014 version of the ISO standard moved Test Point 2 (the "failing" test point) closer to the Stated Values, making it a more challenging requirement to satisfy.

The Stated Value for Type 5 integrating indicators for steam must be greater than 16.5 minutes at 121°C (250°F) and greater than 1.2 minutes at 135°C (275°F).[1] The relationship of the Type 5 integrating indicator to a calculated biological response is a feature of the Type 5 that makes it more robust than the other CI types defined in the standard. The relationship to a biological response is first established by the requirement for a minimum Stated Value of 16.5 minutes at 121°C. The 16.5 minute minimum was established based on calculations derived from biological indicator resistance specifications. (See Annex C of ISO 11140-1 for details). So, a comparison of Type 5 integrating indicators and their compliance to the ISO CI standard should start with the integrator's performance at 121°C.

Key terms

- **Critical Process Variable:** "Variable identified as being essential to the attainment of sterilization and monitored by the CI".[1] The standard defines which process variables are critical for different sterilization processes. Time, temperature, and moisture are listed as critical for steam sterilization.
- **Endpoint:** "Point of the observed change defined by the manufacturer, occurring after the indicator has been exposed to specified stated values."[1] This study evaluated moving front style Type 5 integrating indicators which show a progressive, observable change towards a pass or accept region upon exposure to critical process variables.
- **Resistometer:** A specialized test vessel capable of reproducible cycles used by manufacturers to characterize the performance of CIs. The standard states, "Resistometers allow for precise specification and control of the specific test conditions and cycle sequences in order to produce controlled, repeatable studies of the effect of process parameters on indicators."[1]
- **Stated Value (SV):** "Value or values of a critical process variable at which the indicator is designed to reach its endpoint as defined by the manufacturer."[1]

This study compared the performance of three different Type 5 steam integrating indicators to the Stated Value performance requirements of ISO 11140-1:2014 for Type 5 steam integrating indicators at 121°C.

Method

Test equipment

Testing was conducted in a steam resistometer, H&W LLC (Rochester, NY) which meets the requirements for CI testing.[2]

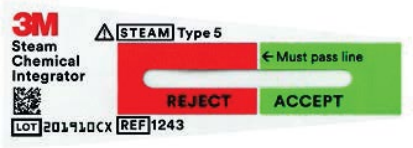
Test samples

Three different type 5 steam integrating indicators were evaluated:

1. 3M™ Comply™ SteriGage™ Steam Chemical Integrator 1243 manufactured by 3M Company, St. Paul, MN. Three lots tested.

2. Terragene Integron® Integrating Indicator IT26-C, manufactured by Terragene Corporation, Argentina. Three lots tested.

3. 3M™ Attest™ Steam Chemical Integrators 1243 manufactured by 3M Company, St. Paul, MN. Two lots tested.



Test procedure

1. The resistometer was warmed up with empty chamber cycles.

2. The chemical integrator samples were run in sets of n=6 per lot per cycle. Samples were placed flat in a perforated metal test rack. Independent temperature sensors were also placed at the front and back of each test rack. Samples were placed into the resistometer chamber immediately prior to starting the cycle and removed immediately following cycle completion.

3. 120°C cycles were run at exposure times of 8, 10, 12 and 14 minutes. The number of indicators reaching the endpoint was noted.

4. 121°C cycles were run at a range of exposure times until a condition was found at which all indicators reached the endpoint (Test Point 1).

5. The corresponding Test Point 2 (Fail Condition: Test Temperature = Test Point 1 – 1°C; Test Time = Test Point 1 – 15%) was run to verify the indicators did not reach the endpoint. If indicators reached the endpoint, Steps 3 and 4 were iterated until a Stated Value (exposure time at which all indicators reach the endpoint at Test Point 1 and do not reach endpoint at Test Point 2) was determined.

6. Resistometer test cycle printouts and independent temperature sensor data were reviewed for each cycle to confirm the resistometer was performing as required.[1, 2]

The Stated Value test methodology was reviewed by a third party, BSI Assurance UK, during their independent assessment of the compliance of 3M™ Comply™ SteriGage™ Steam Integrating Indicators to Type 5 integrating indicator requirements per ISO 11140-1:2014.[3]

Results

121°C results

Table 1 summarizes the results for the three integrating indicators when tested at varying exposure times between 8 and 14 minutes at 120°C. This testing examined the integrator's performance at the Test Point 2 temperature, or test conditions where the integrator must show a FAIL response.

(Test Point 2 reduces the exposure time by 15% and the temperature by 1°C). Actual Stated Values were determined for all lots of the 3M™ Comply™ SteriGage™ Steam Chemical Integrator 1243, 3M™ Attest™ Steam Chemical Integrators 1243 and the Terragene Integron® IT-26C Integrating Indicators. Table 2 provides the Stated Values for all integrators tested in this study.

Table 1: Test point 2 temperature endpoint test results (# indicators showing PASS result/6 indicators tested)

		Test Point 2			
Product	**Lot #**	**120°C/ 8.0 minutes**	**120°C/ 10.0 minutes**	**120°C/ 12.0 minutes**	**120°C/ 14.0 minutes**
Comply SteriGage Steam Chemical Integrator 1243	2022-08AE	0/6	0/6	0/6	0/6
Comply SteriGage Steam Chemical Integrator 1243	202305JZ	0/6	0/6	0/6	0/6
Comply SteriGage Steam Chemical Integrator 1243	202304JV	0/6	0/6	0/6	0/6
Attest Steam Chemical Integrator 1243	2022-11PA	0/6	0/6	0/6	0/6
Attest Steam Chemical Integrator 1243	2020-11PA	0/6	0/6	0/6	0/6
Terragene Integron® Integrating Indicator IT26-C	15102	0/6	0/6	0/6	5/6
Terragene Integron® Integrating Indicator IT26-C	15100	0/6	0/6	1/6	5/6
Terragene Integron® Integrating Indicator IT26-C	16102	0/6	1/6	5/6	6/6

Table 2: Stated values at 121°C

Product	**Lot #**	**Stated value (minutes)**
Comply SteriGage Steam Chemical Integrator 1243	2022-08AE	22.0
Comply SteriGage Steam Chemical Integrator 1243	202305JZ	19.5
Comply SteriGage Steam Chemical Integrator 1243	202304JV	20.0
Attest Steam Chemical Integrator 1243	2022-11PA	21.4
Attest Steam Chemical Integrator 1243	2020-11PA	20.2
Terragene Integron® Integrating Indicator IT26-C	15102	13.9
Terragene Integron® Integrating Indicator IT26-C	15100	11.8
Terragene Integron® Integrating Indicator IT26-C	16102	10.6

Discussion

This study compared the performance of three different Type 5 steam integrating indicators to the Stated Value performance requirements of ISO 11140-1:2014 at 121°C. The three lots of the 3M™ Comply™ SteriGage™ Steam Chemical Integrator 1243 and the two lots of 3M™ Attest™ Steam Chemical Integrators 1243 tested in this study met the Type 5 integrating indicator 121°C performance requirements stipulated in ISO 11140-1:2014. The Stated Value for each lot was greater than 16.5 minutes, and the Test Point 2 temperature test results demonstrated that these integrators did not respond too quickly. The three lots of Terragene Integron® IT26-C Integrating Indicators tested in this study did not meet the Type 5 integrating indicator 121°C performance requirements stipulated in ISO 11140-1:2014. The lots tested did not meet the requirement for a Stated Value of at least 16.5 minutes at 121°C. The Test Point 2 temperature testing demonstrated that these lots reached their end point (i.e., showed a PASS result) too quickly to meet the standard's requirements. The minimum Stated Value of 16.5 minutes at 121°C would have Test Point 2 conditions of 14 minutes at 120°C. Indicators showing PASS at less than 14 minutes therefore cannot meet the ISO standard requirement for a minimum Stated Value of 16.5 minutes at 121°C.

The integrating indicator performance requirements stated in ISO 11140-1:2014 are designed to ensure that CIs provide the correct challenge to the sterilization process throughout the range of steam sterilization temperatures used in health care facilities. Integrating indicators that do not meet the minimum Stated Value requirements at 121°C do not meet the minimum requirements of the standard and therefore they do not provide an appropriate challenge to the sterilization process.

Limitations

This study did not do a full evaluation of the tested products against all the performance requirements for Type 5 steam integrating indicators specified in ISO 11140-1:2014. A full evaluation would have included testing the products at 135°C and at an additional temperature equidistant between 121°C and 135°C; conducting the 140°C dry heat test; and determining the integrating indicator temperature coefficient.

Conclusion

The three lots of the Comply SteriGage Steam Chemical Integrator 1243 and the two lots of Attest Steam Chemical Integrators 1243 tested in this study met the Type 5 integrating indicator 121°C performance requirements stipulated in ISO 11140-1:2014. The three lots of Terragene Integron® IT26-C Integrating Indicators tested in this study did not meet the Type 5 integrating indicator 121°C performance requirements stipulated in ISO 11140-1:2014.

References

1. International Organization for Standardization. Sterilization of health care products—CIs—Part 1: General requirements. ISO 11140-1:2014.
2. International Organization for Standardization. Sterilization of health care products—Biological and CIs—Test equipment. ISO 18472:2018, Table 2, Steam Resistometer Physical Conditions.
3. Kitemark™ Certificate KM 657533, Issued by BSI Assurance UK Ltd on 02/13/2019.
4. Data on File (EM-05-376600).

solventum

Solventum Medical Surgical

Phone 800-228-3957
Web Solventum.com

70-2011-7971-3