



# CONTROL 5

## Steam Integrator

Class 5 Integrating Indicator  
as classified by ANSI/AAMI/ISO 11140-1:2005

### Technical Bulletin

#### Device Description

Control 5 Steam Sterilization Integrator is a single use class 5 Integrating Indicator as classified by ANSI/AAMI/ISO 11140-1:2005. It integrates three essential criteria for proper steam sterilization: time, temperature, and steam. When processed along with a load it indicates, with a margin of safety, whether the proper steam sterilization criteria have been achieved.

#### Product Design

The Control 5 Integrator consists of aluminum foil coated with a pressure sensitive adhesive. The aluminum foil has an embossed cavity at one end filled with a steam sensitive chemical. The dry heat melting point of the chemical is higher than the normal steam sterilization temperature. The presence of steam lowers the melting point of the chemical. A wicking strip is attached to the foil. One end of the wicking strip is in contact with the chemical and the rest runs along the length of the foil. The whole assembly is covered with steam sensitive plastic laminated to paper with printed graphics and cut out windows. The window overlies the wicking strip while the

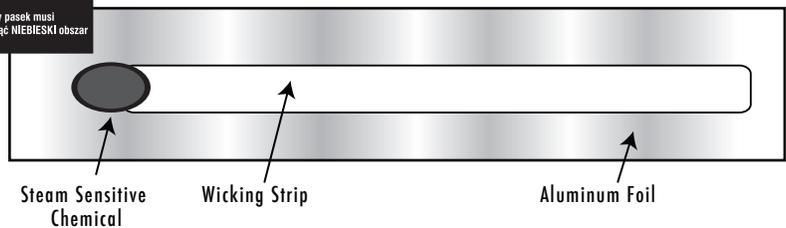
laminated graphics and the foil totally seal the chemical and the wicking strip inside.

During the sterilization process the steam penetrates the plastic cover, lowering the melting point of the chemical. The rate at which the chemical melts is determined by the vapor transmission rate of the plastic cover and the temperature. When the chemical melts the wicking paper soaks up the chemical. With time the chemical moves up the wicking strip, turning it dark. When the dark bar enters the accept window the sterilization criteria are satisfied.

#### Device Top View



#### Device Without Top Cover



#### Indications for Use

Use Control 5 Integrator in 121-134°C gravity, flash or pre vacuum cycles.

#### Precautions

Do not use Control 5 Integrator to monitor dry heat, ethylene oxide, or other low temperature sterilization processes.

#### Contraindications

None.

## Performance of Control 5 Integrators

Control 5 integrators were tested in a BIER (Biological Indicator Evaluator Resistometer) vessel at various time and temperature intervals in order to estimate the time required at each temperature

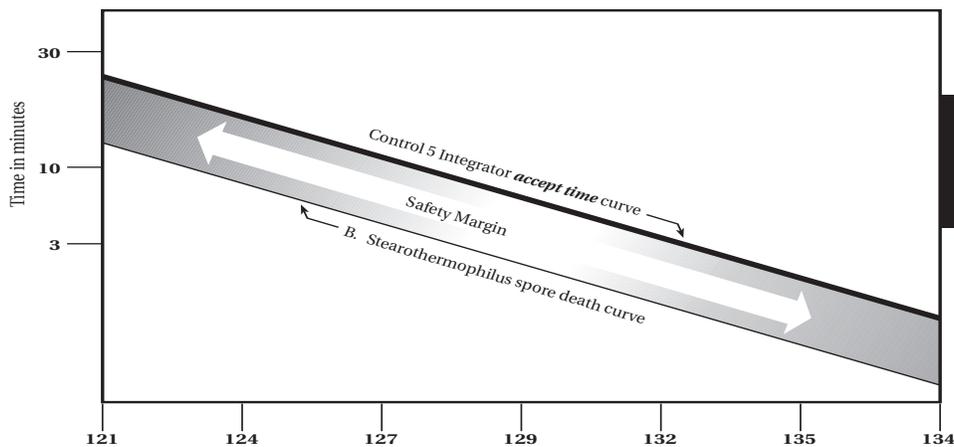
to reach the accept window. The following are the mean time (calculated from the test results) required at each temperature for the integrators to reach the accept window:

Temperature	Time in Minutes for SteriScan Integrator to Reach Safe Mark	Thermal Death Time in Minutes of Bacillus Stearothermophilus Spores
121 °C	23.58	11.8
128 °C	5.5	2.39
135 °C	1.8	0.48

The performance (time required to reach the accept mark at various temperatures) of Control 5 Integrator and the thermal death time of Bacillus stearothermophilus spores are plotted in the graph shown below. It is evident from the graph that the Control 5 Integrator parallels the spore death curve in the normal sterilization range with a margin of safety. It is clear from the data contained in the table and the graph that

Control 5 Integrator provides additional safety in ensuring proper sterilization.

The Control 5 Steam Sterilization Integrator provides an instant evaluation of the Sterilization process with the accuracy of a biological indicator.



**Control 5 is a  
Class 5 Indicator**

### Instructions for Use

1. Place a Control 5 Integrator in the center of each pack or load and process according to sterilizer manufacturer's directions.
2. Adequate sterilization conditions are reached when the dark bar has completely travelled through the reject window and has entered the accept window.
3. If the dark bar does not reach the accept window, reprocessing is required.
4. Use in 121-134 °C gravity, flash or pre vacuum cycles. Control 5 in the presence of steam will respond to time and temperature. Do not store near heat source.

### Interpreting Results



If the dark bar has not reached the *accept* window adequate sterilization conditions are not satisfied. Material should be reprocessed.