



MULTICRITICAL PROCESS VARIABLE INTEGRATOR STRIP For Monitoring Steam Sterilisation Processes (CLASS / TYPE 5)

Rodwell Part No. AC981A (885-0340)

OEM Code: TST-5SE



Product Description

Excelsior multi critical process variable indicator strips contain no lead or other toxic heavy metals. The Indicator strips are manufactured to monitor whether sterilisation conditions were met at the point of placement of the strip. The strips are intended for use in steam sterilisers operating at 121°C and up to 135°C. Class/Type 5 integrating indicators react to all critical variables (time, temperature and moisture) and reach an end point indicating exposure to sterilisation conditions at defined by Excelsior Scientific's stated values.

Physical Properties

| | |
|----------------------------|--|
| Process | Steam |
| Indicator Strip Dimensions | 19mm x 64mm |
| Packaging | 250 Strips / Package |
| Chemical Indicator | Initial Colour: Pink Signal Colour: Dark Chemical Indicator Inks contain no lead or other toxic heavy metals |

Indications for Use

Class / Type 5 Integrating indicator stated values

- 121°C, 16.5 minutes (pre-vacuum)
- 135°C, 1.2 minutes (pre-vacuum)

Instructions for Use

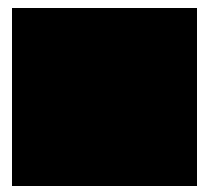
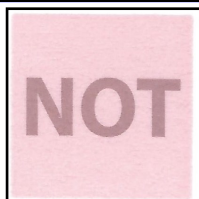
Use a strip in each pack, peel pouch or tray intended for steam sterilisation. Process packages/items as instructed in the autoclave/steriliser validation or manual.

Upon exposure to high temperature steam, the chemical indicator will transition from a shade of pink to dark. The transition colour may vary depending on the load configuration, length and conditions of exposure. A colour transition from pink to dark provides indication of exposure to high temperature steam. If the signal colour is not achieved this may suggest ideal exposure conditions were not met. Review the exposure conditions and investigate the steriliser malfunction.

The chemical reaction which causes the colour transition is a steam specific reaction and is irreversible.

| | |
|---------------------|--|
| Result Availability | Immediately following exposure to high temperature steam process |
|---------------------|--|

| | |
|-----------|--------------------------------------|
| Unexposed | Exposed to steam 121°C, 16.5 minutes |
|-----------|--------------------------------------|



*Colours shown are representations of printed ink initial and signal colours but may vary from actual use.

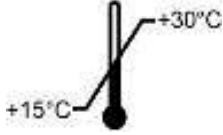







Colour Transition is dependent upon load configuration, cycle parameters and may vary. A colour transition from the Initial colour to a shade of the signal colour which results in the word "NOT" being completely concealed is considered an acceptable transition. If the word "NOT" remains visible, check cycle parameters and equipment function.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical Indicators- Part 1: General Requirements for Type 5 Multi-critical Process Variable Indicators.

Storage and Shelf Life

| | | | |
|---|--|--|-------------------------|
|  | 15°C to 30°C |  | Keep away from sunlight |
|  | 20% to 80% relative humidity |  | Keep Dry |
| Shelf Life | 3 years from the date of manufacture. The date of manufacture is based on the day the indicating ink is applied to the substrate. The remaining shelf life upon receipt will be shorter than 3 years |  | Don not reuse |
|  | Keep away from sterilants. Do not use after expiration date. | | |

Disposal

Discard as general waste.