



STERAFFIRM™ CONTROL TUBES FOR STEAM FOR EXPOSURE PARAMETERS 121°C (250°F) FOR 15 MINUTES TECHNICAL DATA

GENERAL DESCRIPTION

The Steraffirm Control Tubes for Steam are chemical indicators for steam sterilizers working below 126°C (258°F). Each Steraffirm Sterilizer Control Tube consists of a 45 x 5 mm (2 x 0.2") borosilicate glass tube sealed at both ends. One end is color coded with a black spot to facilitate identification of the unboxed indicator. The tube contains approximately 200 µl of heat sensitive red liquid which changes color from red to green at various times and temperatures which are integrated by the device. Steraffirm Control Tubes for Steam conform to International Standard ISO 11140-1 Class 4 and European Standard EN867-1 Class D.

APPLICATION

The Steraffirm Control Tube for Steam is designed to monitor steam sterilization cycles. The Control Tube should be placed in the slowest to heat area of the load in an appropriate test device similar to items being processed in a steam sterilization cycle. The sensitive solution in each control tube heat changes red through amber to green after exposures of 121°C (250°F) for 15 minutes. The Steraffirm Control Tubes for Steam have a permanent color change from red to green when the parameters stated on the product instructions are achieved. Since the Steraffirm Control Tubes for Steam consist of sealed vials containing heat sensitive solution, chemicals from the indicator do not normally come in contact with any items the control tubes are adjacent to during the cycle. The control tubes should not be exposed to temperatures in excess of 200°C (392°F). The Steraffirm Control Tubes for Steam are for Life Sciences applications and international use and are not approved for use in healthcare facilities in the United States.

FEATURES

Color change from red to green after exposure to specified parameters

Permanent color change following exposure

Lot number and expiration on each box

Conforms to EN 867-1 Class D and ISO 11140-1 Class 4

BENEFITS

Easy to interpret, instant readout after the cycle

The processed Control Tubes may be stored for record purposes

Enhances traceability

Meets critical standards as multi-parameter indicator

TECHNICAL PROPERTIES

The Steraffirm Control Tube is designed to be used in steam sterilizers. The tube solution changes red through amber to green following temperature/exposure time parameters:

100°C (212°F) for 100 minutes

105°C (221°F) for 62 minutes

115°C (239°F) for 25 minutes

120°C (248°F) for 16 minutes

125°C (257°F) for 10 minutes

130°C (266°F) for 6.5 minutes

Temperature +/- 0.5°C (+/- 0.9°F) and Time +/- 10%.

Excessive exposure to high temperatures/long times may result in color fading. Do not expose to temperatures in excess of 200°C (392°F). Do not expose the Control Tubes to naked flames, excessive internal pressure could cause the fracture and failure of the tube.

The heat sensitive liquid, which is the indicating medium, contains 0.08 mg dyes, 4.0 mg reagents with the remainder as water. None of the substances used in the formulation is a known carcinogen. The liquid is non-flammable. The liquid component is an irritant, and in the case of a tube breakage the liquid should be washed from the skin using copious quantities of cold water. In the case of contact with the eyes, irrigate with tepid water or an approved eye irrigation solution, until the eye irritation is cleared. If the liquid is ingested, wash out mouth thoroughly with water, give plenty of water to drink, and seek medical advice.

Sweep up broken glass particles, and dispose of the glass particles in a sharps container or other safe receptacle. Mop up spillage with absorbent material and cold water, and wear protective gloves.

DIRECTIONS FOR USE

Place a Steraffirm Control Tube for Steam in a process challenge device in the slowest to heat area of the load of items to be sterilized. The Control Tubes for Steam for use at 121°C (250°F) can be used to monitor liquid cycles. The control tube may be placed in a test bottle of the solution to be sterilized and placed in the slowest to heat area of the sterilizer. After the sterilizing cycle, the control tube should be allowed to cool and should be inspected. A color guide in the instructions provides an instant visual check of the results. If the color of the heat sensitive liquid in each control tube has not changed to green, the process should be considered suspect and the items should be re-sterilized using a fresh control tube. The Steraffirm Control Tubes for Steam should only be used to monitor steam sterilization cycles operating at the performance tolerances stipulated on the control tube packaging. The processed control tubes may be stored for record purposes in cool dark conditions, or disposed of as waste. See the instructions enclosed in the product packaging for detailed use-directions.

STORAGE CONDITIONS

Store the Steraffirm Control Tubes for Steam in cool, dark, dry conditions before and after use.

SERVICE

Sales

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

ORDERING INFORMATION

Description	Quantity	Reorder Number
Steraffirm Control Tubes for Steam For exposure parameters 121°C (250°F) for 15 minutes	100/Box	PCC024

For further information, please contact:

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