



STERAFFIRM™ CONTROL TUBES FOR DRY HEAT FOR EXPOSURE PARAMETERS 160°C (320°F) FOR 60 MINUTES TECHNICAL DATA

GENERAL DESCRIPTION

The Steraffirm Control Tubes for Dry Heat are chemical indicators for Hot Air Ovens working at 160°C (320°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 green 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 Dry Heat conform to International Standard ISO 11140-1 Class 6 and European Standard EN867-1 Class D.

APPLICATION

The Steraffirm Control Tube for Dry Heat is designed to monitor dry heat sterilization cycles. The Control Tube should be placed in the center of the load in an appropriate test device similar to items being processed in a dry heat cycle. The sensitive solution in each Control Tube for dry heat changes red through amber to green after exposures of 160°C (320°F) for 60 minutes or 170°C (338°F) for 31 minutes. The Control Tubes for dry heat have a permanent color change from red to green when the parameters stated on the product instructions are achieved. Since the Control Tubes for dry heat 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 Dry Heat 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 6

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 dry heat ovens. The tube solution changes red through amber to green following temperature/exposure time parameters:

145°C (293°F) for 158 minutes
150°C (302°F) for 115 minutes
155°C (311°F) for 83 minutes
160°C (320°F) for 60 minutes
165°C (329°F) for 43 minutes
170°C (338°F) for 31 minutes
175°C (347°F) for 22 minutes
180°C (356°F) for 16 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. If used at temperatures below 140°C (284°F) in dry heat, the control tubes may not yield the same end point results as a moist heat exposure at an equivalent time and temperature.

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 Dry Heat in a process challenge device in the center of the load of items to be sterilized. 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 Dry Heat 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 Dry Heat 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 Dry Heat For exposure parameters 160°C (320°F) for 60 minutes	100/Box	PCC027

For further information, please contact:

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