

DESCRIPTION

The GEX P8003 Irreversible Temperature Indicators are a self-adhering, self-activating, monitoring tool that provides a visual and irreversible record of the maximum temperature exposure. The product has a successful 20 year history of use in the radiation processing industry, and is accurate¹, flexible, non-toxic, and non-breakable indicator of maximum temperature.

The label features 16 temperature intervals (ranging from 27.5°C to 65.0°C). A color change from white to red is activated to indicate when each temperature interval event has occurred (±1°C).

TECHNOLOGY

A calibrated activation chemistry layer is applied at each temperature event location on the label. The chemicals in the indicators are calibrated to react at the labeled temperatures. The label chemistry has been proven to be reliable under high-radiation dose conditions in designed experiments¹.

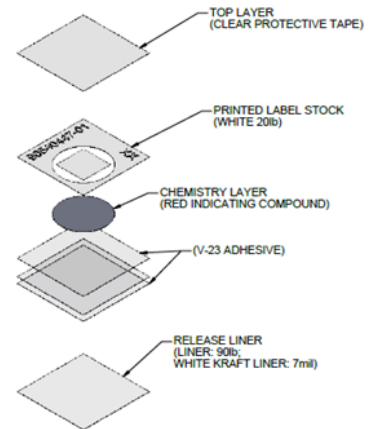
A clear, pressure sensitive adhesive protects the top of the indicator label, and the back has a permanent super-tack adhesive covered by a release liner.

This product is manufactured and qualified in large batches in a certified ISO 9001:2015 facility².

APPLICATION(S)

The Irreversible Temperature Indicator is designed for use in Gamma, Electron Beam, and X-ray radiation process applications. The temperature range of the Indicator works especially well for medical device sterilization applications. The Indicator may be used:

- To measure the maximum temperature of products and materials during radiation processing;
- During calibration irradiations where the temperature must be measured;
- In dose mapping characterization of a facility or product;
- To monitor temperature during routine irradiation processing;
- For other monitoring and measurement applications.



SPECIFICATIONS

Physical Specifications:

Product Dimensions	Packaging Specifications	Weight (10 units/package)
1.950" x 1.625" ±0.03125"	3.0"x 5.0"	0.30 lbs.

Range: 27.5°C to 65.0°C (81.5°F to 149.0°F) in 2.5°C increments.

Accuracy: ±1.0°C

Shelf Life: 2 years from the ship date. Month and Year of manufacture are printed on the product.

Certificate of Compliance: Issued with each customer order of the product.

Receiving Inspection:

The product is shipped from GEX inside of insulated shipper boxes, then with ice packs to ensure the product remains below 26.0°C (78.0°F) at all times. The product should be immediately inspected by the customer upon receipt to check the condition of the indicators.

Irreversible Temperature Indicators

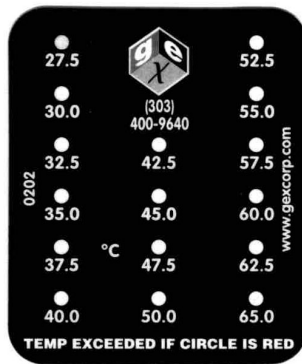
Storage:

Store the P8003 product in a cool, dry area below 26°C (78°F) at all times. Storage in a refrigerated environment 4°- 16°C (40°- 60°F) is the preferred storage method. Storage in a freezing environment at 0°C (32.0°F) has not been shown to adversely affect the functionality of the Indicator.

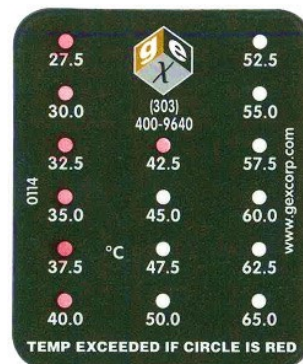
Stability:

Under the proper storage conditions, non-exposed, Irreversible Temperature Indicator activation trigger points remain a white color for at least 2 years from the date of manufacture until exposed to the trigger temperatures.

PRODUCT PHOTOS



Non-exposed example



Exposed example

USAGE

- Peel off the release liner (backing material) from the Indicator. The adhesive allows attachment of the indicator to most clean, dry surfaces.
- Attach the indicator flat against the surface being monitored.
- The maximum temperature achieved during a process is indicated with a red window.
- See 'Precautions' section below for special handling instructions.

PRECAUTIONS

- *The Indicators react immediately within the active temperature range!* Handle with care in a cool, dry area.
- The Indicator can be activated by a person's body heat. Avoid handling the indicator near activation trigger points.
- If attaching a large quantity of indicators to a product (i.e. a dose map), keep the product in a cool, dry area before irradiation.
- The adhesive on the P8003 indicator is permanent. Do not use the self-adhering backside of the Indicator to attach to anything you do not want it permanently attached to. Taping the backing along the edges of the Indicator is the suitable alternative to attach the Indicator.

HEALTH/ENVIRONMENTAL INFORMATION

Irreversible Temperature Indicators are non-toxic, non-liquid-filled, and non-breakable. Indicators can be safely discarded in general waste receptacles.

WARRANTY/GUARANTEE

Guarantee:

1-year GEX satisfaction guarantee. Product may be returned with or without reason within one year of the date of delivery.

REFERENCES

- *ISO 9001:2015 Certification*. American Thermal Instruments, www.americanthermal.com/safety-certification.
- Uttinger, V. (2013). Shelf Life Data on Select Irreversible Baseline Temperatures (Tech Report No. QF01-01). Dayton, OH: American Thermal Instruments.

RELATED DOCUMENTS

- GEX Doc# 100-219, Performance of GEX P8003 Irreversible Temperature Indicator Label.

REVISION HISTORY

DATE	CHANGE DESCRIPTION	REVISION
01/23/15	Initial release	A
05/14/19	Reference to PSU# 100-219. ECO 70443.	B