

Gas-Chex® Sterilization Indicator Strips

Technical Data Sheet

Introduction:

Propper Gas-Chex Sterilization Indicator Strips are chemical indicators designed to monitor all critical sterilization parameters of Ethylene Oxide (EO or EtO) gas sterilization in Healthcare facilities and industrial applications.

Propper Gas-Chex Strips monitor the following critical parameters of the process: EO gas concentration, exposure time, temperature, and humidity. If any of the critical parameters will be insufficient, the indicator will not change to the green end-point color.

Product description:

Gas-Chex indicator strips are 4in paper strips that have “gas-chex” phrase printed with indicator ink. The indicator is designed to be placed inside sterilization packaging in the area judged to be the most difficult for EO gas to penetrate. It should be examined when the pack is opened. If “gas-chex” is green, sterility conditions have been reached. If “gas-chex” is not green, sterility is in doubt and pack should be reprocessed.

Instructions for use and typical end-point indicator color change are printed on the product boxes.

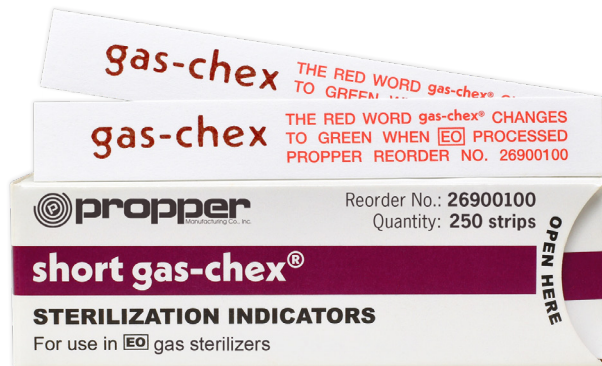


FIGURE 1. PROPPER MANUFACTURING COMPANY gas-chex® STERILIZATION INDICATORS STRIP UNIT BOX.



FIGURE 2. LEFT IMAGE SHOWS UNPROCESSED LOOSE INDICATOR STRIP.
RIGHT IMAGE SHOWS PROCESSED LOOSE INDICATOR STRIP.

Performance:

Stated values are indicator performance parameters determined in a special testing sterilizer – Resistometer (BIER vessel). For Gas-Chex strips stated values are as follows:

- 54°C, 42 min, EO 600 mg/l, RH 60±10%
- 37°C, 75 min, EO 600 mg/l, RH 60±10%

- 55°C, 36 min, EO 736 mg/l, RH 50±10%
- 37°C, 73 min, EO 736 mg/l, RH 50±10%

- 55°C, 35 min, EO 759 mg/l, RH 50±10%
- 37°C, 73 min, EO 759 mg/l, RH 50±10%

The performance parameters of Gas-Chex Sterilization Indicator strips meet the requirements of FDA Guidance for Industry for Integrating Indicators. The indicator performance is equivalent to the performance of biological indicators.

Interpretation of results:

Gas-Chex indicator strips have an easy-to-remember color scheme: **Red** for **Stop** (pack was not yet processed or the process was inadequate), and **Green** for **Go**. Any shade of green is considered a Pass result. If at the end of sterilization, the color of the indicator is not green (ie. red, yellow, or brown color) the result is Fail.

Ink safety testing:

The indicator ink has been tested in cytotoxicity study using live cell culture. It was found that the indicator does not affect cells in the study. The results are presented in PIR 84-6, "Safety Testing of Proper Gas-Chex EO Indicator Strips".

Shelf-life and storage conditions:

- Shelf-life: 3 years
- Storage conditions before use: RH: below 60%, protect from direct light and excessive humidity. Temperature 15-30°C 32° (59-86°F).
- Storage conditions excursion limits:
 - RH 60%-65% - up to 1 week
 - Temperature 30°C-35°C - 1 week
- Storage conditions after use for record keeping: RH: below 60% protect from direct light and excessive humidity. Temperature 15-30°C (59-86°F).
- Record keeping: Gas-Chex indicators strips have stable color change and can be stored for record keeping after processing. Excessive humidity or exposure to light may cause some color degradation.

Product Order Information:

- Reorder No.: 26900100 – Box of 250 Gas-Chex® 4" Strips - Ethylene Oxide