

# Colour reference chart for the *gke* Batch Monitoring System

for ethylene oxide sterilization processes

## PASS CONDITIONS

The batch can be released if all 4 color segments of the processed indicator are green as shown below to indicate that ethylene oxide has penetrated the PCD, and if all other critical process parameters such as temperature, pressure and sterilization time are in accordance with the cycle reference.



all color segments are green

☞ Sufficient Ethylene oxide penetration

## FAIL CONDITIONS

The example shown below clearly demonstrates an insufficient Ethylene oxide penetration which may be due to various reasons (see note below).

If this example is found after a sterilization process, the respective batch must not be released and requires re-processing.



all color segments are blue-green

☞ Insufficient Ethylene oxide penetration



all color segments are blue

☞ No Ethylene oxide penetration

### Note

A failure of the batch control test is not conclusive proof that the fault is necessarily associated to the sterilizer itself (insufficient air removal or leakages), but may well be due to external causes such as unpurged supply pipes at the start of the process, insufficient Ethylene oxide supply due to separation of Ethylene oxide and inert gas or changing temperature. Therefore batch control tests made in subsequent cycles may show different results.

## Important

If the chemical indicators already show a clear green color before usage, the indicators were improperly stored or the expiry date has passed. These indicators should not be used.

If an indicator achieves pass conditions when put unprotected in a sterilizing chamber but not within a process challenge device, this is a clear proof that the Ethylene oxide concentration is sufficient but the process is unable to penetrate Ethylene oxide in the inner lumens of hollow devices like tubes, etc.

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