

Colour reference chart

for all **gke** Batch Monitoring Systems (BMS)
using the prion cycle (SV = 134°C, 18 min)
for steam sterilization processes

PASS RESULTS

The batch can be released if all 4 colour segments of the processed indicator are black as shown below, and if all other critical process parameters such as temperature, pressure and sterilization time are in accordance with the cycle reference.



all colour segments are black

→ sufficient steam penetration

FAIL RESULTS

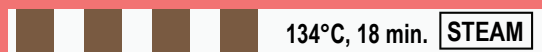
The examples shown below demonstrate insufficient steam penetration which may be due to various reasons (see note below).

If one of the results shown below is found after a sterilization process, the respective batch cannot be released and requires re-processing.



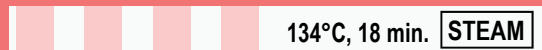
colour segments are brown at one end
and light-brownish at the other end

→ insufficient air removal
and steam penetration



all colour segments are brownish,
but not black

→ temperature achieved, but no
air removal and steam penetration



all colour segments are pink

→ insufficient temperature and no
air removal and steam penetration

Note

A failure of the batch monitoring test is not a 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 steam pipes at the start of the process (if no prior Bowie-Dick Simulation Test was performed), non-condensable gases in the external steam supply or changing temperature of the cooling water. Therefore batch monitoring tests made in subsequent cycles may show different results.

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