If a sterilization process has been aborted, it may be still possible that the GKE Bowie-Dick-Simulation-Test, the GKE batch monitoring system or a package indicator show still successful colour change, even if the plateau period of the sterilization time did not run completely through.

Reason:

All chemical indicators for steam sterilization processes should change only to the final colour, if condensing steam is present and the temperature-time-integral (F_0-value is achieved during the process. Typical temperature-times in steam sterilization are listed below:

Temperature	A colour change to the end point must not occur during this time	A colour change to the end point shall have occured after this time
121° C	≤ 10 min.	≥ 15 min.
134° C	≤ 1,5 min.	≥ 3 min.

If a sterilization process is stopped, after the sterilization time has been reached at the beginning of the plateau period, (e.g. after an emergency stop or electricity shut down), it may be possible that the end point of the chemical indicator has been reached and/or a biological indicator is killed without running the full sterilization time.

During the air removal fractionated vacuum cycles and temperature come-up time the sterilization starts already and after stop a safety procedure in all sterilizers is carried out before the door can be opened again which typically takes 15 – 20 minutes running through the following steps:

1. All times when steam is above 100° C during the fractionated vacuum
2. Come up Time above 100° C
3. Time before sterilizer stops
4. Time until the process remains on stop before pressure release
5. Time during the sterilizer is running down below 100° C

Going through these steps, in most cases the total temperature-time-integral (F_0-value) has been reached and the sterilization process is complete.

The exact test of biological or chemical indicators is only possible using a so-called square-wave resistometer described in EN ISO 18472. These sterilizers are able to carry out exact temperature-time-windows to be able to set correct F_0-values for testing. Tests carried out in standard hospital sterilizers are completely misleading and cannot determine if a sterilizer is working according to a specification or not.

GKE has in their test laboratories those test resistometers. All chemical indicators are tested according to the EN ISO 11140-1 specifications and all biological indicators are tested to the EN ISO 11138-1 specifications.

The below chart explains the F-value: