

	Technical Information	730-148-EN		V03
	Use of chemical indicators for steam sterilization processes in programs with longer plateau period then the indicated SV	Created	26.07.2017	JM
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Requirements for chemical indicators according to EN ISO 11140-1

The requirements for chemical indicators (CI) for use in steam sterilization processes are described in the standard EN ISO 11140-1. One requirement is that the CI must be provided with an indication of the temperature at which and the time after which it reaches the final colour. This information is called "Stated Value", abbreviated "SV", colloquially also called "SV value".

For steam sterilization processes at 134°C, GKE only offers CI type 5 and 6 with an SV of 3 min for standard and 18 min for prions, while other market participants also offer these CI partly with an SV of 4, 5, 6 or 7 min. GKE wants to make indicator selection easier for users and not to engage in indicator inflation. Competitors criticize that if sterilization plateau times are longer than 3 min, CI with correspondingly longer SV must also be used.

The sterilization process must inactivate all germs on or in an instrument load. If biological indicators that have higher resistance than the germs of the load are inactivated, the load is safely sterilized. All biological indicators are safely killed in a steam sterilization process at 134°C with a maximum plateau time of 1 min, so that this proven plateau time is more than sufficient to safely sterilize the load. Therefore, a sterilization plateau time of 134°C, 3 min is more than sufficient. All longer sterilization times are no longer needed today and only cost additional energy and sterilizer capacity cycle times. In the past, processes with longer plateau times were used because it was not known that inadequate air removal hinders steam penetration and therefore longer sterilization plateau times than 3 min were used.

Today, longer sterilization plateau times are sometimes used, but type 5 or 6 CIs with SV of 3 min can still be used, as these fully guarantee sterility. The sterilization plateau time is recorded in the sterilizer documentation anyway and times longer than 3 min are not process-relevant. Therefore, the use of CIs with SVs > 3 min is not necessary and the use of only one CI simplifies handling in the AEMP (CSSD).

Information on the Stated Value (SV)

Typical SV information is e.g. "121 °C, 15 min or 134 °C, 3 min".

To consider a CI for monitoring a steam sterilization process, it must be ensured that the sterilization program at least reaches or exceeds the temperature-time window indicated with the SV. Therefore, a specification such as "134 °C, 3 min or longer" is often found.

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Process technical reasons

Chemical indicators for steam sterilization processes may only reach the final colour if the CI surface comes into contact with water (usually through steam condensation). Therefore, EN ISO 11140-1 also contains the requirement that a CI for steam sterilization processes must not reach the final colour in dry heat at 140 °C even after 30 min.

Chemical indicators therefore also show, among other things, the presence or absence of water at the location where they are placed (e.g. in a package, in a PCD, in a cotton pack, etc.). Therefore, a CI provides the information if the steam has penetrated the indicator location. In the validation standard EN ISO 17665-1, this is called "air removal and steam penetration".

If steam penetration is successful and the CI is reached by the steam and moistened by condensation, it changes colour in the times indicated by the SV.

If steam penetration is not successful, the CI does not come into contact with steam. In this case, it remains dry - irrespective of the program time - and therefore does not reach the final colour even in programs with holding times far beyond the SV.

A CI therefore monitors steam penetration, but only within the minimum program time according to the SV specification. The actual temperature-time integral is monitored by the sterilizer and documented on the sterilizer printout of the batch.

Steam sterilization processes must perform two important process variables to produce sterile goods:

1. Achieving the temperature-time integral
Provide the minimum required temperature-time integral as described above, e.g. 134°C; 3 min, also called F_0 -value

and

2. Generation of steam condensate at the most difficult to sterilize location in the load. Penetration of steam to the most difficult to reach locations in the load, e.g. channels of lumen instruments such as arthroscopes. Therefore, the sterilizer must replace the air in the channels with steam using an air removal program. Therefore, sterilizers are tested after start-up and warm-up with the so-called Bowie-Dick test without load. If the air is not replaced by steam at these most difficult locations, it cannot condense into water. Only hot water, neither pure steam nor hot air, sterilize at temperatures of 121 to 134°C.