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|  | <b>Technical Information</b>   |  | <b>730-157-EN</b> | <b>V03</b>    |
|   | <b>GKE Chemical VHPO indicators with different SV and dose indications</b> |  | Created           | 13.05.2019 CP |
|   |  |  | Changed           | 13.02.2023 UK |
|   |  |  | Checked           | 14.02.2023 UK |
|   |  |  | Released          | 14.02.2023 UK |
|   | <b>File No.: 1.4</b>   |  |                   |               |

## 1 Introduction

The chemical indicator standard EN ISO 11140-1 requests, that all chemical indicators require information about the pass/fail colour changes. In most cases the minimum so-called "stated value" (SV) has to be written on the chemical indicator to show pass conditions. The traditional SV can only be determined if the sterilization agent concentration remains constant during the sterilization plateau period. In hydrogen peroxide sterilization processes however only extreme small H<sub>2</sub>O<sub>2</sub> concentrations are used and, in most cases, totally consumed over time, so that almost no H<sub>2</sub>O<sub>2</sub> remains at the end of the sterilization process. The colour change of a chemical indicator or a kill of a biological indicator is not only time- but also concentration- and temperature dependent. Therefore, it is not possible only to talk about the time when using the SV but the colour change is dependent on concentration over time. This is called a concentration-time integral or "dose" and describes the minimum amount of H<sub>2</sub>O<sub>2</sub> gas required to achieve the colour change to a pass result of chemical indicator (CI) or a kill of a biological indicator (BI).

Different doses can be described using a theoretical average concentration over time.


## 2 Description of Test Method

Test sterilizer (resistometer) used

The VHPO resistometer has an internal chamber volume of 80 l and has been modified by GKE so that different volumes of H<sub>2</sub>O<sub>2</sub> can be injected. The concentration of VHPO in the gas phase can be modified by changing either the concentration of the injected liquid H<sub>2</sub>O<sub>2</sub>/H<sub>2</sub>O concentration or the volume of the liquid injected into the chamber. The solution volume is injected in the sterilizer chamber after the air has been removed before evaporation. The resistometer has a built-in detector measuring the VHPO and water concentration throughout the process.

The process itself consists of three steps that include

- conditioning by vacuum, heat up to 50 °C and air removal
- injection of H<sub>2</sub>O<sub>2</sub>/H<sub>2</sub>O and subsequent diffusion
- ventilation & drying.

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An exemplary process curve is shown in figure 1.

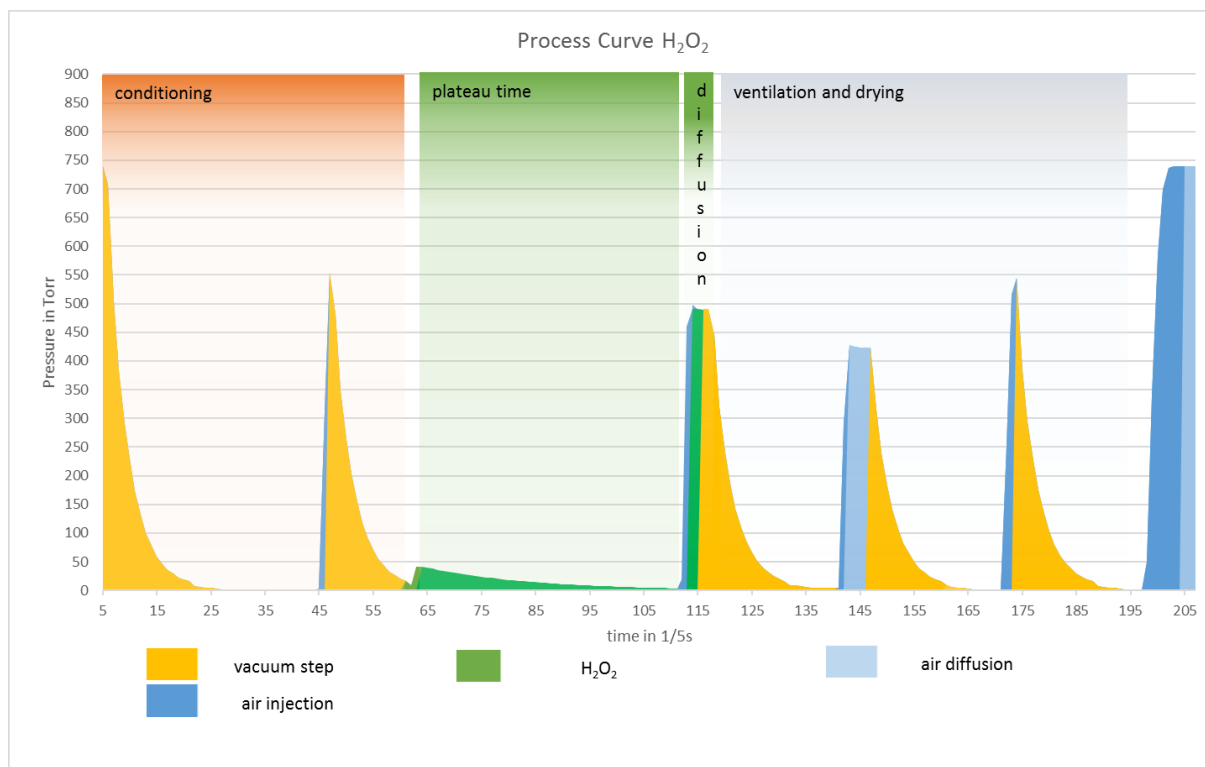



Fig. 1: Exemplary process curve for hydrogen peroxide with conditioning phase (red), plateau phase and diffusion (green) as well as ventilation and drying (grey).

Processes with different doses can be produced by modifying the plateau time (depicted in green in figure 1). The longer the plateau time is the higher the dose gets. This information is only valid if not all H<sub>2</sub>O<sub>2</sub> is used during the plateau period. To obtain a comparable statement on different indicator difficulties, the initial amount of hydrogen peroxide is varied within the process by injecting different volumes of the solution into the chamber. A 50% hydrogen peroxide solution is used.

Since all other variables and their parameters are kept constant during the process and only the plateau time is changed, indicators can be exposed to different doses of VHPO. Biological and chemical indicators may show different reactions depending on the dose of VHPO applied (e.g. different colour changes for chemical indicators or different survival populations for biological indicators).

### 3 GKE H<sub>2</sub>O<sub>2</sub> Indicators

Sterilization processes with real load configurations may consist of different packaging materials with different surgical instruments having various geometric shape and deviant surface structures. The real load configuration therefore directly affects the local concentration of H<sub>2</sub>O<sub>2</sub> gas, since the consumption of different packaging materials and instruments influence the concentration within the VHPO sterilization chamber at a

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different position. If multiple chemical indicators are placed among different positions in the chamber, different colour shapes may be observed depending on the local concentration of VHPO at each position.

This observation is quite often misinterpreted by customers with the assumption, that the indicator would have a malfunction and is not changing the same way when several indicators are put at different locations in the chamber

GKE offers four different chemical indicators for hydrogen peroxide sterilization processes where different doses of H<sub>2</sub>O<sub>2</sub> are required for the indicator to change to the final colour. The table below lists all GKE Type 4 indicators with the doses and colour changes.










| Art. No.                      | Product Code | Dose                          | Colour Change   |   | GKE-Production since | Shelf life<br>(02/2023) | Sensitivity |
|-------------------------------|--------------|-------------------------------|---|---|----------------------|-------------------------|-------------|
|                               |              |                               | Starting colour/ Fail   | Final colour/ Pass  |                      |                         |             |
| 214-250<br>214-251<br>214-253 | C-V-P-SV6    | 2.6 mg/L,<br>2 min,<br>50°C   |  |  | 05/2021              | 1,5 years               | 1           |
| 214-241<br>214-243            | C-V-P-SV7    | 2.6 mg/L,<br>8 min,<br>50 °C  |  |  | 03/2018              | 3 years                 | 2           |
| 214-260<br>214-261            | C-V-P-SV8    | 2.6 mg/L,<br>15 min,<br>50 °C |  |  | 11/2021              | 1,5 years               | 3           |
| 214-221<br>214-223            | C-V-P-SV9    | 3.8 mg/L,<br>20 min,<br>50 °C |  |  | 09/2011              | 3 years                 | 4           |

Table 1: GKE H<sub>2</sub>O<sub>2</sub> Indicators with dose

The last column of the table lists increasing sensitivity levels (1 = easy to 4 = difficult) corresponding to an increasing SV.

As there are no standards for H<sub>2</sub>O<sub>2</sub> test sterilisers and for biological or chemical H<sub>2</sub>O<sub>2</sub> indicators yet, the GKE doses are not comparable with other CI or BI on the market, as

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each company has its own H<sub>2</sub>O<sub>2</sub> test method, which are not comparable with each other. The H<sub>2</sub>O<sub>2</sub> sterilisation processes themselves are also not standardised and differ greatly from each other.

Chemical and biological indicators provide valuable information about the sterilization process. It is important to validate the sterilization process and follow the guidelines and EN-ISO standard 22441 for validation and routine monitoring.

The development of type 5 indicators for hydrogen peroxide sterilization processes is not yet possible. Indicators according to EN ISO 11140-1 type 5 are intended to simulate the resistance characteristics of a biological indicator. A requirement for this statement would be a known BI resistance (ISO 11138 series) as a result of intensive resistometer (ISO 18472) testing. A standardized resistometer for H<sub>2</sub>O<sub>2</sub> does not exist either, which makes the production of type 5 indicators impossible.

This is because the colour change of a type 4 chemical indicator does not match with a biological indicator. When the hydrogen peroxide concentration increases, the resistance of a biological indicator decreases, and the colour change of the chemical indicator also has the same tendency. However, there is a notable difference compared to other sterilisation processes (e.g. steam): The process strongly depends on the [VH<sub>2</sub>O<sub>2</sub>] and [VH<sub>2</sub>O] concentration.