CLEANING
STERILIZATION

VH202

Monitoring of Room Disinfection Processes

GKE indicators for easy and efficient monitoring of room disinfection processes

Information Room Disinfection

Application

Evaporated or sprayed hydrogen peroxide (H_2O_2/H_2O) solutions are used to disinfect rooms, i.e. patient rooms, operating rooms, ambulances, personal locks, isolators, but also conference rooms, gyms, military vehicles, airplanes or animal stables. This disinfection process has a germicidal effect.

This disinfection process is used, for example, in isolators whose inner surfaces are made with suitable materials and small gaps and angles, where it is usually known which germs shall be inactivated.

Equipment/Process Information

Equipment units of different manufacturers either vaporize H_2O_2/H_2O or produce aerosols in many ways. In some of them, aqueous H_2O_2 solution is simply forced at high pressure through a nozzle and other units use ultrasound to create aerosols from the liquid. Others evaporate the H_2O_2 solution onto a hot plate. After evaporation, the vapor can partially re-condense as an aerosol by cooling. The most commonly used machines are portable and can be used in various locations.

All methods produce a gas or suspended aerosols whose droplets are so small that they do not immediately fall to the ground but remain in the air for a long time. Aerosols disperse in the air, i.e. the droplets are spread in all directions. The aim is to ensure that even hard-to-reach areas and the ceiling of the room come into contact with the aerosol droplets or the evaorated H_2O_2.

Handling

Depending on the size of the room to be disinfected, the amount of H_2O_2/H_2O to be spread in the unit is set. Usually it starts after a delay of about one minute so that the user can leave and close the room. Then the H_2O_2/H_2O distribution is carried out at a defined exposure time. Afterwards the room is ventilated and can be entered again.

Open Questions

Some material surfaces react catalytically with hydrogen peroxide to form water and oxygen. No information exists to what extent the presence of such materials limits the processes.

The penetration depth of the disinfecting effect, e.g. in splits, textiles or in other fabriques etc. is low and objectively difficult to measure. Due to this uncertainty, wipe disinfection cannot be replaced, but only supplemented.

When disinfecting a room with equipment, such in a hospital room, the situation is unclear. There are hidden and hard-to-reach areas. There is a large number of different materials and surface structures in the room where unknown germs have to be inactivated. Research in those processes has not been completed. Since 2020 the standard EN 17272 has been established and describes a method how manufacturers can define the effectiveness of their processes.

Resistance dependance of Biological Indicators

In contrast to all other known sterilization processes, where basically the germ used determines the resistance of the biological indicator, the resistance of biological indicators in VH2O2 sterilization and room disinfection processes depends on more influencing variables, making the whole discussion more complex.

The following influencing variables are known:

1. Selection of the germ
In the food industry *B. subtilis* or *B. atrophaeus* and in the healthcare sector *G. stearothermophilus* is mainly used providing different D-values.

2. Production method of the biological indicators
By different cultivation and sporulation of the germ, the resistance can be considerably influenced, even if the same bacterial strain is used.

3. Carrier material of the BI
H_2O_2 react chemically or catalytically with the carrier to form intermediates that better inactivate the germ. Alternatively, H_2O_2 decomposes into oxygen and water without reacting with the biological indicator. The market offers carriers made of glass fibre, stainless steel, PET foil and Tyvek. Different carriers strongly change the resistance of the biological indicator.

4. Surface structure of the carrier material used
Roughness of the surface or porosity of the carrier material change the surface, either distributing the germs better or shielding them in porous systems.

5. Purification of the suspension
Organic and inorganic impurities in the suspension originating from spore production should be articularly thoroughly removed. Remaining peptides could otherwise shield the germs, for example, and therefore prevent inactivation.

6. Inoculation on the spore carriers
Germs should be applied to the surface on a single layer (monolayer inoculation) to prevent that overlapping layers are shielding H_2O_2 access to underlying layers.

7. Biological indicator packaging
Germ-tight packaging consists either of non-woven cellulose fibres, PE fibres or combinations of both. H_2O_2 can already react with cellulose fibres and reduce the H_2O_2 concentration inside the packaging. Therefore, cellulose packaging is not recommended in VH2O2 processes. It is also recommended to use naked biological indicators to monitor room disinfection processes. However, there is the problem afterwards of an aseptic transfer into the growth medium solution for the assessment of the biological indicator.

GKE produces specially purified spore suspensions for room disinfection, taking into account the above variables and making them particularly suitable for monitoring of these processes. All GKE biological indicators comply with the standard EN ISO 11138 series, the European and American Pharmacopeia (EP + USP). The specifications for population and D-value are stated in a certificate of analysis, which is included in each package.

Biological Indicators

All biological indicators are prodcued according to EN ISO 11138 and supplied with a certificate stating population and D-value according to GKE test conditions and all requirements (see page 3). The biological indicators are inoculated on different carrier materials with a specially purified suspension.

Spore Strips

The biological indicators consist of *G. Stearothermophilus* bacteria spores inoculated on different carriers with the size of 6 x 38 mm and packaged individually (in Tyvek envelope of 94 x 65 mm) or in bulk in a blister box. All spore strips can be also used inside of process challenge devices (PCD).

Art.-No.	Quantity	Packaged	Carrier	Product Code	Population
332-407	100	individually	Stainless Steel	B-V-ST-SS-10-4	10^4
332-507	100	individually		B-V-ST-SS-10-5	10^5
332-607	100	individually		B-V-ST-SS-10-6	10^6
332-608	40	bulk			
332-601	100	individually	PET	B-V-P-SS-10-6	
332-604	40	bulk*			
332-602	100	individually	Glas fiber	B-V-G-SS-10-6	
332-605	40	bulk*			
332-603	100	individually	Tyvek	B-V-T-SS-10-6	
332-606	40	bulk*			

* not in stock, available on request.

Spore Discs

The *G. Stearothermophilus* bacteria spores are inoculated on discs with 7 mm diameter (available with different carriers) and are packaged individually (in Tyvek envelopes of 60 x 65 mm) or in bulk in a blister box.

Art.-No.	Quantity	Packaged	Carrier	Product Code	Population
332-417	100	individually	Stainless Steel	B-V-ST-DIS-SP-10-4	10^4
332-517	100	individually		B-V-ST-DIS-SP-10-5	10^5
332-617	100	individually		B-V-ST-DIS-SP-10-6	10^6
332-615	110	bulk			
332-612	100	individually	PET	B-V-P-DIS-SP-10-6	
332-614	110	bulk*			
332-616	100	individually	Glas fiber	B-V-G-DIS-SP-10-6	
332-611	110	bulk*			
332-618	100	individually	Tyvek	B-V-T-DIS-SP-10-6	
332-613	110	bulk*			

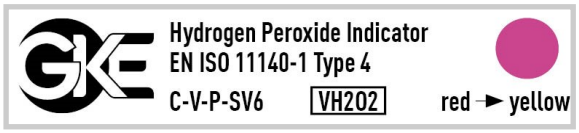
* not in stock, available on request.

Chemical Indicators

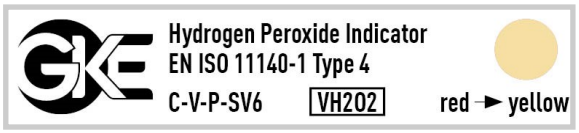
Self-adhesive Type 4 Indicators

These indicators in accordance with EN ISO 11140-1 Type 4 only provide information about successful room disinfection at the location (e.g., in rooms or isolators) where they were placed. They can be documented after use and e.g. adhered into a paper documentation.

The indicators are available on card with 16 self-adhesive indicators and in two different versions whose colour change occurs at different times. This means that even for processes with different exposure times, temperatures and concentrations, appropriate indicators for monitoring are available.

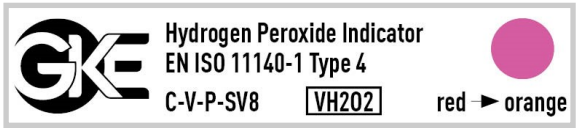


Indicator Starting Colour

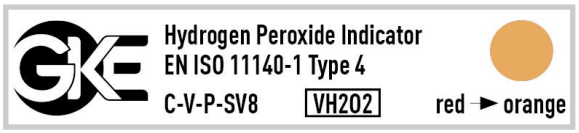


Indicator End Colour

Art.-No.	Product Code	Quantity
214-250	C-V-P-SV6	160
214-251		400
214-253		3.200



Indicator Starting Colour



Indicator End Colour

Art.-No.	Product Code	Quantity
214-260	C-V-P-SV8	160
214-261		400

Benefits

- Simple distribution of indicators in the room.
- Fast result due to visual evaluation and precise colour change.
- No H_2O_2 residue on the indicator after use.
- Self-adhesive, easy adhesion and documentation.

Accessories Biological Indicators

Incubators

The dry-bath incubator is used to incubate biological indicators. After incubation time, the colour of the pH indicator in the growth medium solution shows the result. A microbiological laboratory is not required; there are no additional waiting times.

The incubation temperature is shown in the display. The aluminum block for growth medium tubes is available separately. The power supply includes a CE marking for the low voltage directives. The incubator runs at 12 V DC. A separate power supply with variable voltage input 100 - 240 V AC is enclosed with each incubator.

Art.-No.	Product Code	Application
610-110	I-57	Incubator to incubate *G. stearothermophilus* biological indicators, Incubation temperature: 57°C
610-112	I-V-T	Incubator with variable temperature selection (30-60 °C) and programming of the incubation time.
610-115	I-AB-CM	Aluminum block to insert 12 growth media tubes (Diameter: 16,5 mm)

Growth medium

Test tubes aluminum with screw cap (diameter: 16,1 mm) filled with TSB and pH-indicator. The test tubes have optimized dimensions and volume to fit all kind of spore strips and discs. If germs are growing the pH-indicator changes its colour and allows a quick evaluation of the result.

Art.-No.	Quantity	Product Code	Application
223-010	10	B-S-V-CM	Growth medium tubes to transfer *G. stearothermophilus* biological indicators
223-100	100		

LITERATURE

EN 17272 - Chemical disinfectants and antiseptics -
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Whole room disinfection with hydrogen peroxide mist to control Listeria monocytogenes in food industry related environments
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