

Institut Schwarzkopf GbR, Mangelsfeld 16, 97708 Bad Bocklet

Herrn Dr. Sha He / 何沙(博士) Geschäftsführer / CEO DigPanda GmbH Luisenstr. 75 80798 München SCourt Advisor's Office

Ansprechpartner: **PD Dr. Andreas Schwarzkopf** Tel.: 09708 70 596-0 Fax: 09708 70 596-860 <u>a.schwarzkopf@institutschwarzkopf.de</u>

25.03.2021

Disinfection by H₂O₂-Fog using mobile PUDU Model "Puductor-2" roboter in Hospital rooms – Expert Statement

Dear Dr. Sha He,

in the matter mentioned above on February 26nd 2021 a realistic practical test was carried out in the intensive care unit of the hospital in Bad Brückenau. The test was performed used bioindicators and contact tests, to be able to examine the effectiveness.

The recommendation of the federal institute for infection prevention, commission for Hospital Hygiene and Infection Prevention, "Requirements of Hygiene at cleaning and disinfection of surfaces" (2004) is used as legal basis, as well as the RKI listing for proceeds of disinfection ordered by health authority officials, 2013.

Furthermore, contents of EN 17272:2020 were taken into account, which were already met by the misted substance, the hydrogen peroxide preparation Diosol® 9.7%.

For comparison, an established procedure listed by the Robert Koch Institute under certain conditions for the official disinfection, represented here by a device, the Diosol Generator®, was used according to the manufacturer.

The on-site tests were carried out by the cooperation institute Hygieneinstitut Mainfranken, Maßbach. The production and evaluation of the bioindicators was in the responsibility of the Laboklin GmbH, an accredited laboratory in Bad Kissingen.

Geschäftssitz: Otto-von-Bamberg Str. 10 97717 Aura a. d. Saale www.institutschwarzkopf.de Geschäftsstelle: Mangelsfeld 16 97708 Bad Bocklet Tel.: 09708 70 596-0 Fax: 09708 70 596-739 info@institutschwarzkopf.de

1. Material

1.1 Bioindicators

Enterococcus faecium was used as a test germ.

Enterococcus faecium is a fairly environmentally stable bacterium, that can survive up to 30 minutes even at 60 °C. In addition, it is comparatively antibiotic-resistant and has spread in southern Germany with the formation of the multi-resistant variant VRE. The bioindicators were deployed with an initial bacterial count of 2 10E+7 Colony-forming units (CBE)/ indicator plate (see 1.2)

1.2 Production of the indicator surfaces

The bacteria were taken from a bouillon with late-logaritmic inoculum and suspended in mucin. The mixture was applied to stainless steel germ carriers. The same has been done in the case of transport controls. Subsequently, the respective starting germ count from the bouillon mix was determined and documented by means of standard dilution methods.

1.3 Spore stripes with Geobacillus stearothermophilus

Since the Robert Koch Institute only recognizes a killing of 1 E+ 7, corresponding test strips (DioSpore Controller ®) have been designed and were used here.

2. Operating times

The experiment took place in a room of 45 cubic meters.

The "Puductor-2" fogged a total of 180 ml of the hydrogen peroxide product for 30 minutes, the Diosol generator ® misted 4 ml per cubic meter of room content plus recommended safety surcharge for 14.5 min, according to the manufacturer.

3. Results

Both the Diosol generator and the "Puductor-2" achieved a reduction factor of at least 3 (corresponding to 99.9%) at all measuring points, and the "Puductor-2" even at least a reduction factor of 6 (99,9999 %, see appendix).

In the case of DiSpore contollers (\mathbb{R}) , the "Puductor-2" reaches the reduction factor (RF) 7 (= 1 E+7 = 99.99999 %) and therefore a result in accordance with the requirements of the RKI-list.

4. Discussion and conclusion

Water peroxide has long been successfully used in dentistry as a disinfectant for root canals. The fog for surface disinfection was used in Germany from about 2006 for area disinfection, for the time being in the food industry and in experimental animal breeding. Later, the field of application was further developed into the health care system, and in 2013 the procedure was listed by the Robert Koch Institute under strict conditions.

With the pandemic appearance of SARS CoV-2, hydrogen peroxide was also used to fight these viruses. This happened and happens during the disinfection of waste water (1). Due to the long experience of use in dentistry, an effect on mucous membranes is also assumed (2). Since SARS CoV-2 lasts different lengths of time on different surfaces, various disinfection methods were investigated and hydrogen peroxide was considered effective (3, 4).

By meeting the requirements of the RKI list, the requirements of the Commission for Hospital Hygiene and Infection Prevention (KRINKO, 5) for RKI are met automatically.

However, since hydrogen peroxide can be effective and even sporocidal, class "limited virucidal plus" (i.e. including the uncovered viruses noro-, rota- and adenoviruses) an effect on enveloped viruses (influenza, corona, etc.) was and must be assumed. The concentration of 7.9% of the preparation tested here when used in conjunction with the "Puductor-2" shall be considered sufficient. The application of quantity depends in relation to the room size in cubic metres and, in the case of regular use in a health service facility, is required to provide appropriate validation. In this case, the space in the room must be defined and the exact sequence must be shown in a work instruction.

5. Literature

1) Mohan SV, Hemalatha M, Kopperi H, Ranjith I, Kumar AK. SARS-CoV-2 in environmental perspective: Occurrence, persistence, surveillance, inactivation and challenges. Chem Eng J. 2021 Feb 1;405:126893. doi: 10.1016/j.cej.2020.126893. Epub 2020 Sep 4. PMID: 32901196; PMCID: PMC7471803.

2) Caruso AA, Del Prete A, Lazzarino AI. Hydrogen peroxide and viral infections: A literature review with research hypothesis definition in relation to the current covid-19 pandemic. Med Hypotheses. 2020 Nov;144:109910. doi: 10.1016/j.mehy.2020.109910. Epub 2020 Jun 1. PMID: 32505069; PMCID: PMC7262503.

3) Kampf G, Todt D, Pfaender S, Steinmann E. Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents. J Hosp Infect. 2020 Mar;104(3):246-251. doi: 10.1016/j.jhin.2020.01.022. Epub 2020 Feb 6. Erratum in: J Hosp Infect. 2020 Jun 17: PMID: 32035997; PMCID: PMC7132493.

4) Janik E, Bartos M, Niemcewicz M, Gorniak L, Bijak M. SARS-CoV-2: Outline, Prevention, and Decontamination. Pathogens. 2021 Jan 23;10(2):114. doi: 10.3390/pathogens10020114. PMID: 33498679; PMCID: PMC7911301.

 5) Recommendation of the Commission on Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI). Hygiene requirements for cleaning and disinfection of surfaces.
Federal Health BI - Health Research Health Protection 2004 47:51–61
DOI 10.1007/s00103-003-0752-9

Kind regards

A. John And

PD Dr. med. A. Schwarzkopf Specialist in Microbiology and Infectious Epidemiology Publicly appointed and sworn expert for hospital hygiene

Attachment



Privatdozent Dr.med. Andreas Schwarzkopf

Mangelsfeld 16

97708 Bad Bocklet

Labor-Nr.: 2103-Y00286

BEFUNDBOGEN: Ermittlung Reduktionsfaktor

(nicht akkreditierte Leistung, Gerätenamen aktualisiert)

Untersuchte Einrichtung	Franz von Prümmer Klinik Bad Brückenau
Entnahmeort	Keine Angabe
Entnahme-Datum	04.03.2021
Probennehmer	HIM – Hans Gölinitz
Probeneingang	04.03.2021
Prüfbeginn	04.03.2021
Prüfende	08.03.2021
Probenmaterial	Edelstahlplättchen, Testanschmutzung Enterococcus faecium
Transportkontrolle	2,0 x 10 ⁷ KBE E. faecium

Baumusterprüfung DIGPANDA Puductor 2			
H ₂ O ₂ 7,9% / 30 min Laufzeit / 1300ml 45m ³			
1	Perfusor	RF 6	
2	Boden rechts hinten	RF 7	
3	Schublade Monitor	RF 5	
4	Versorgungsleiste rechts	RF 7	
5	Verbandwagen	RF 6	
6	Fensterbank	RF 7	

Aer	osol Generator <u>Diop</u>	
H ₂ O ₂ 7,9% / Einstellung 60m ³ / 150 ml		
7	Perfusor	RF 6
8	Boden rechts hinten	RF 4
9	Schublade Monitor	RF 3
10	Versorgungsleiste rechts	RF 6
11	Verbandwagen	RF 7
12	Fensterbank	RF 6

24.03.2021 Ausgangsdatum

Dr. C. Simon Unterschrift Befundfreigabe

Junion

LABOR FOR KLINISCHE DIAGNOSTIK GMEH & CO. KS Staubenstr. 4 - 97688 Bad Kissingen Tel. (0971) 7 20 20 Stempel Prüfflabör

Steubenstraße 4 • 97688 Bad Kissingen • Tel.: 0971/72020 • Fax: 0971/68546 • Geschäftsführender Gesellschafter: LABOKLIN Verwaltungs-GmbH • RG. Schweinfurt HRA 3631 Bankverbindung: Sparkasse Bad Kissingen (BLZ 793 510 10) Kto.-Nr. 311 596 19, IBAN: DE09 793 510 1000 311 596 19, SWIFT/BIC: BYLADEMIKIS, BCEE Luxembourg Kto.-Nr. 1507/3600-5, IBAN: LU95 0019 1507 3600 5000, SWIFT/BIC: BCEELULL, Salzburger Sparkasse Kto.-Nr. 122 762, IBAN: AT43 2040 4012 0012 2762, SWIFT/BIC: SBGSAT23XXX e-Mail: info@labOktint.cm VO3t.ID DE200897624