INTERNAL TEST REPORT ON REPEATED 14 CYCLES ISOPROPANOL DISINFECTION OF BreaSAFE ANTI-COVID-19 / FFP2 NR respirators

Customer: NANO4FIBERS PARDAM BreaSAFE

Project: **Isopropanol disinfection of BreaSAFE respirators**

Status of the Project: Phase 1 - 14 disinfection cycles- Isopropanol
Report No: BreaSAFE ANTI-COVID-19/FFP2 NR _0120

Product: **BreaSAFE ANTI-COVID-19 / FFP2 NR**

Technology: Filtration Efficiency: TSI 8587A
Other tools: Isopropanol bottle spray
Dryer
Respirator holder and pot

Starting date: 16.7.2020

Person in charge:

PARDAM s.r.o. Tomáš Hřebíček
Jan Buk
Jana Růžičková

Prepared by: Jan Buk
Date: July 17th 2020

Goal of the Project

The goal of the project is to VERIFY presumed lifetime (filtration efficiency) of the respirators after repeated disinfection by Isopropanol and to prove that nanofiber membrane **NnF MBRANE PA6$_{ag}$** used in this product can withstand disinfection cycles by Isopropanol.

PARDAM NANO4FIBERS declares that Respirator **BreaSAFE ANTI-COVID-19 / FFP2 NR** can be safely used for 14 days when treated daily by Isopropanol to prevent cross contamination.

Isopropanol is used to disinfect the cover PES layers of respirator by spraying which may, during the use, capture microorganisms than can be potential risk of contamination.

Nanofiber membrane **NnF MBRANE PA6$_{ag}$** is laminated between two PES protective layers. The membrane has incorporated active silver nanoparticles physically embedded into the fibers and that inactivate various microorganisms.

The main concern of customers is focused on maintaining filtration efficiency of the respirator even after 14 disinfection cycles applied to respirator.

For this study Isopropanol was used as disinfection agent but Ethanol is also recommended for disinfection of **BreaSAFE** respirators.

Disinfection efficiency of Isopropanol of against wide scale of viruses was proven by many authors (Harnoss, 2018; Malik, 2006; Platt, 1985). According to Harnoss (Harnoss, 2018) Isopropanol solution has high antimicrobial efficacy and is broadly accepted and used for preoperative skin antisepsis in Europe and the USA. Due to its excellent disinfection efficiency it was chosen as an disinfection agent into domestic disinfection for COVID elimination recommended by WHO (Guide to Local Production:WHO-recommended Handrub Formulations).

Malik, Y.S., Maherchandani, S. & Goyal, S.M. 2006, "Comparative efficacy of ethanol and isopropanol against feline calicivirus, a norovirus surrogate", *AJIC: American Journal of Infection Control,* vol. 34, no. 1, pp. 31-35.

Platt, J. & Bucknall, R.A. 1985, "The disinfection of respiratory syncytial virus by isopropanol and a chlorhexidine-detergent handwash", *Journal of Hospital Infection,* vol. 6, no. 1, pp. 89-94.

Harnoss, J.C., Assadian, O., Kramer, A., Probst, P., Müller-Lantzsch, C., Scheerer, L., Bruckner, T., Diener, M.K., Büchler, M.W. & Ulrich, A.B. 2018, "Comparison of chlorhexidine-isopropanol with isopropanol skin antisepsis for prevention of surgical-site infection after abdominal surgery", *British journal of surgery,* vol. 105, no. 7, pp. 893-899.

https://www.who.int/gpsc/5may/Guide_to_Local_Production.pdf

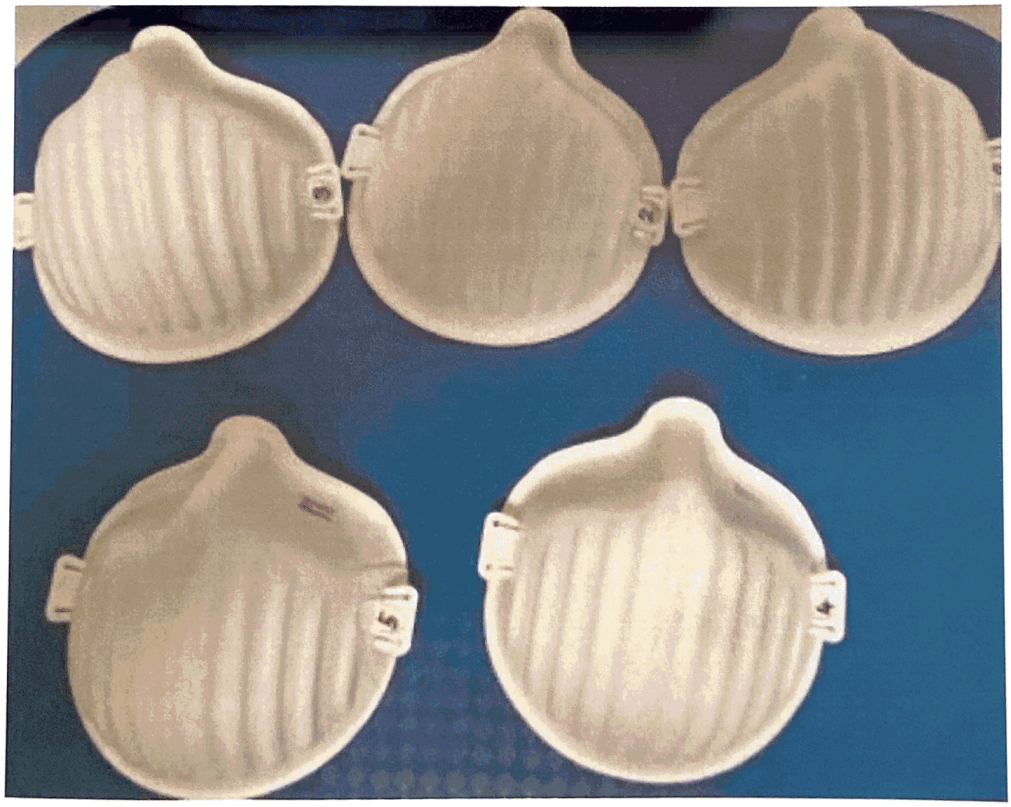
1) DESCRIPTION OF THE TEST

1) 5 **BreaSAFE ANTI-COVID-19 / FFP2 NR** respirators were randomly selected from different production batches for testing
2) 5 respirators were measured on TSI in the state (AR – as received)
3) Isopropanol was applied by spray to both (inner and outer) sides of respirator ensuring whole surface was sprayed evenly.
4) Respirators were left for 5 minutes to dry on the air
5) Respirators were inserted in a Dryer and left for 5 minutes to dry at 50°C
6) This process was repeated 14 times within one day
7) Respirators were measured on TSI in a state (AC – After conditioning)

Results of filtration efficiency and pressure drop were compared on samples AR and AC. Those parameters were measured in accordance to EN 149 on calibrated and certified device installed by ECM ECO Monitoring CZ.

2) TESTING:

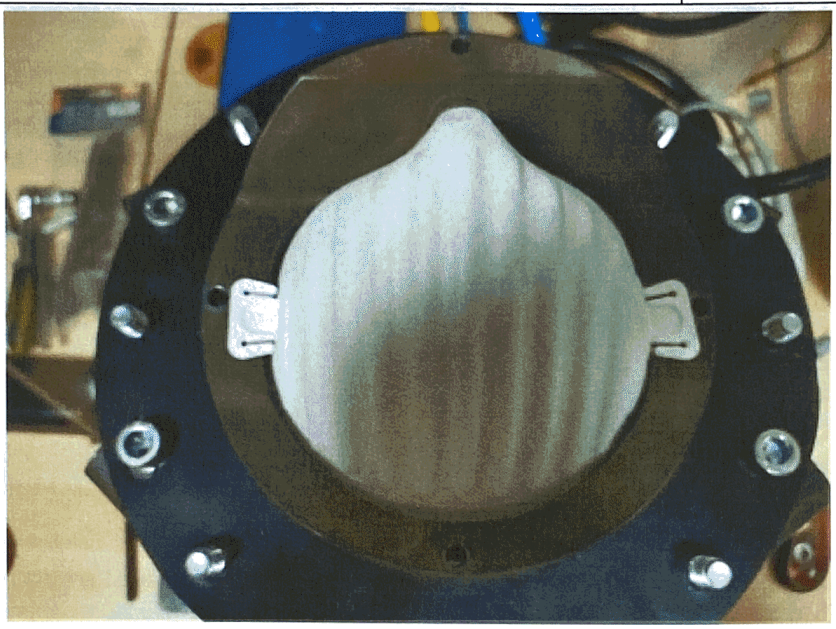
1) 5 **BreaSAFE ANTI-COVID-19 / FFP2 NR** respirators were randomly selected from different production batches for testing

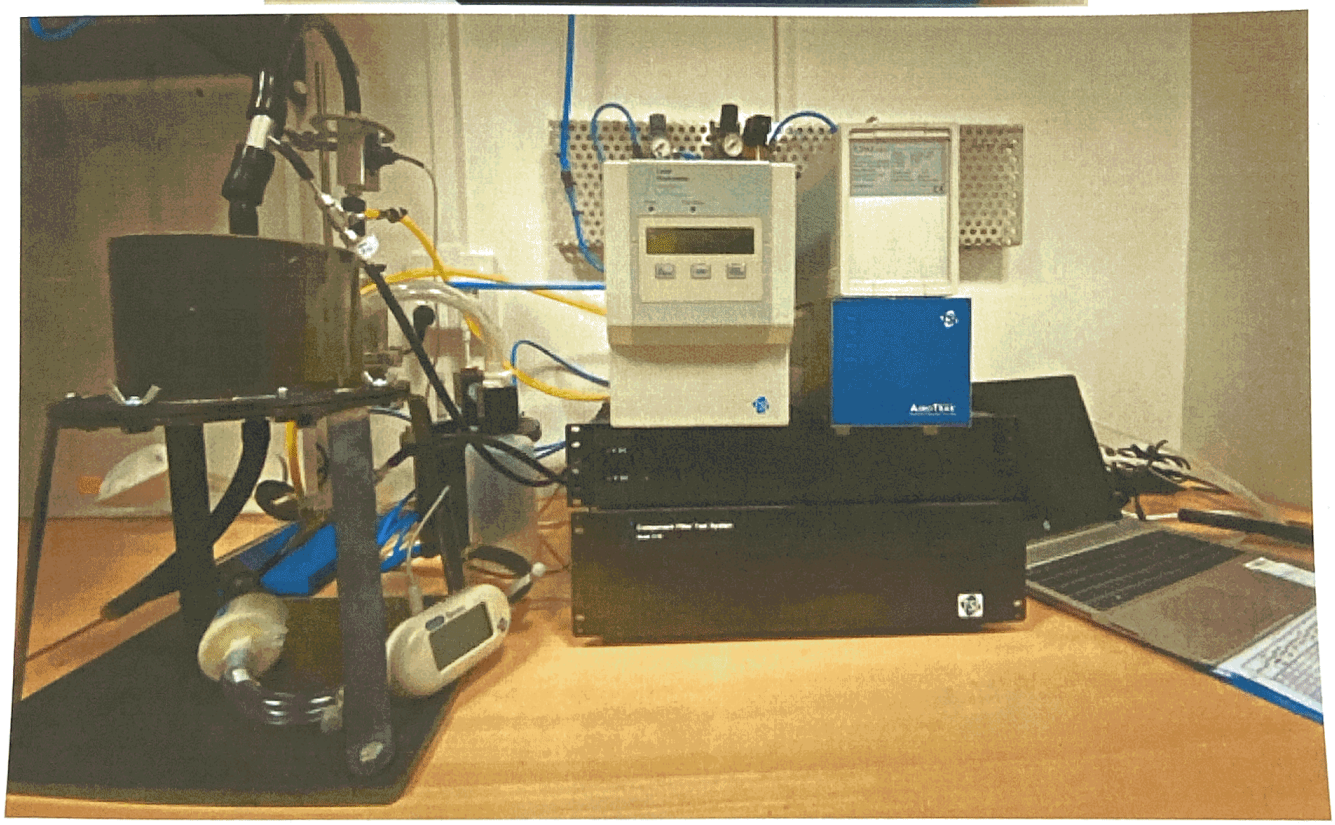


2) 5 respirators were measured on TSI in the state (AR – as received)

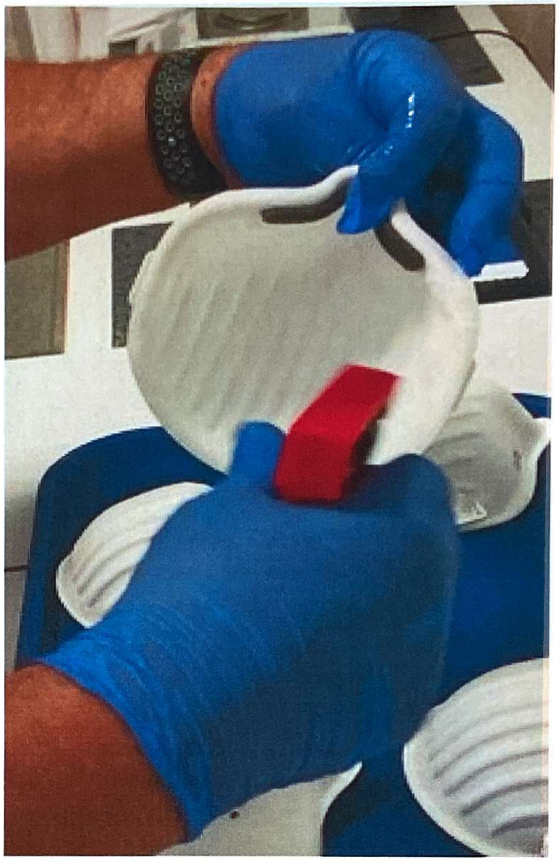
a. Respirator was placed into the measuring form and adjusted with bolts into the form as shown on the picture below.
b. The respirator was then sealed in the measuring chamber to ensure that the measurement will not be influenced by ambient air or pressure loss of the chamber.
c. All respirators were measured under conditions according to **ČSN EN 149+A1**

Parameters	
Air flow	94 l/min
Paraffin mean size particle distribution	400 nm





3) Isopropanol p.a. spray was applied to both (inner and outer) sides of respirator ensuring whole surface was sprayed evenly.



4) Respirators were left for 5 minutes to dry on the air
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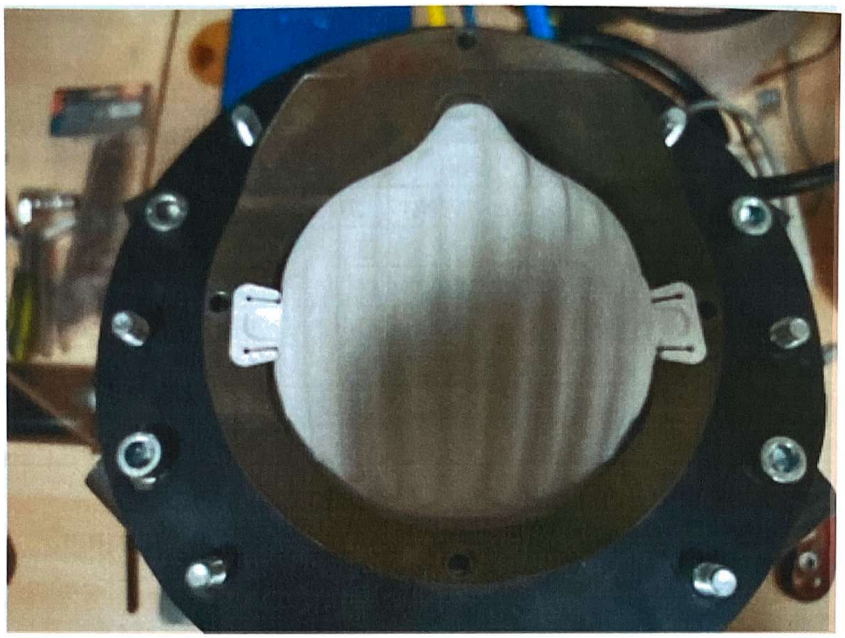
7) Respirators were measured on TSI in a state (AC – After conditioning)



3) SUMMARY OF TESTS:

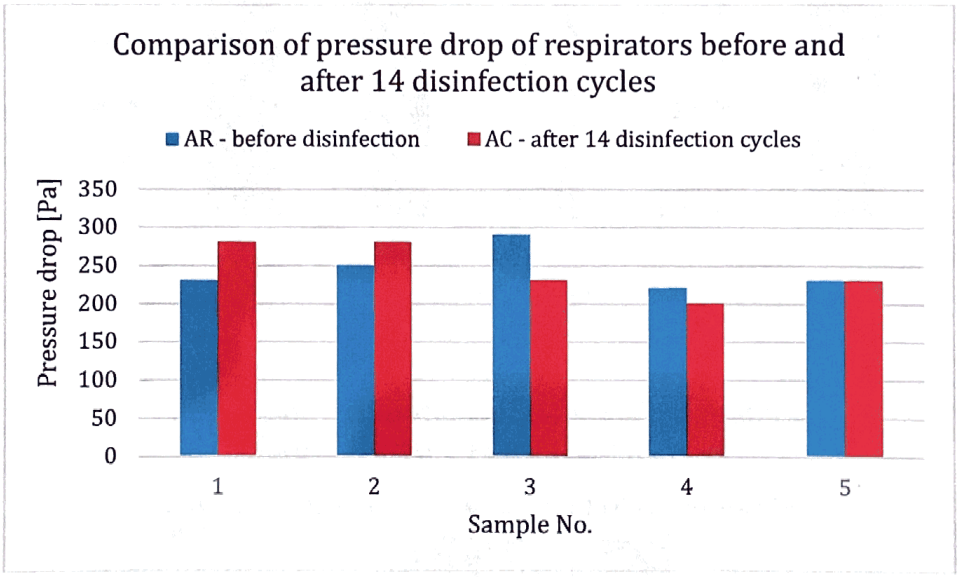
- Tests were performed in a standard condition (room temperature) - 21°C RH 45%
- Measurements on TSI proceeded without problems. Only Respirator No.5 was slightly broken when inserting into the respirator holder. Plastic rubber holders need to be bended to fit respirator into the holder. There was a small damage noticed on one holder (*hole fixed by hot glue*) which slightly influenced the result (see image).

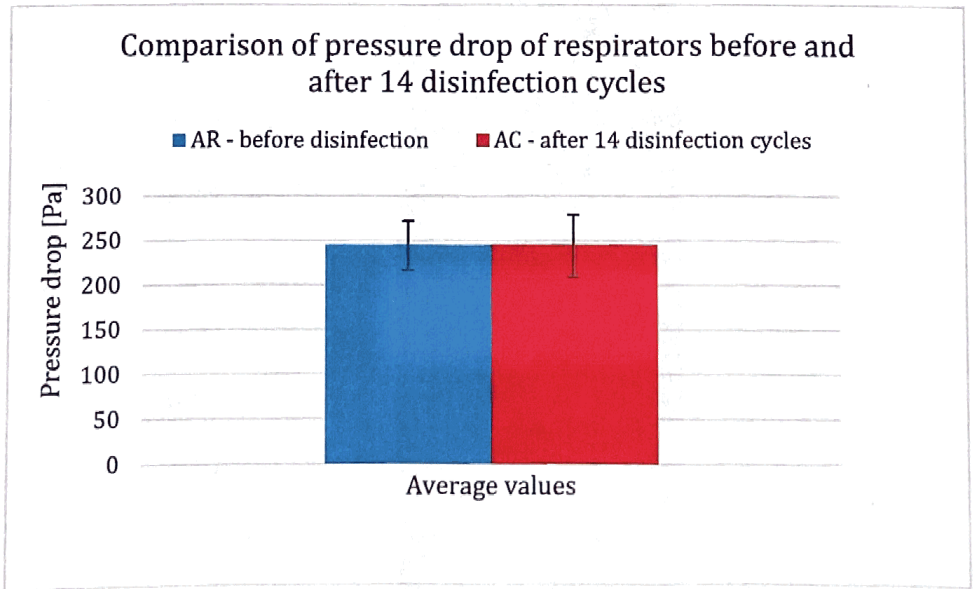
- Disinfection proceeded without any noticeable problems. Respirators were not soaked by Isopropanol, but both sides of respirator were wet,
- 14 disinfection cycles were repeated within one day as there is no need to run the tests for 14 days, which saves lot of time – *once respirator is dry, isopropanol can be applied again to simulate the disinfection process.*

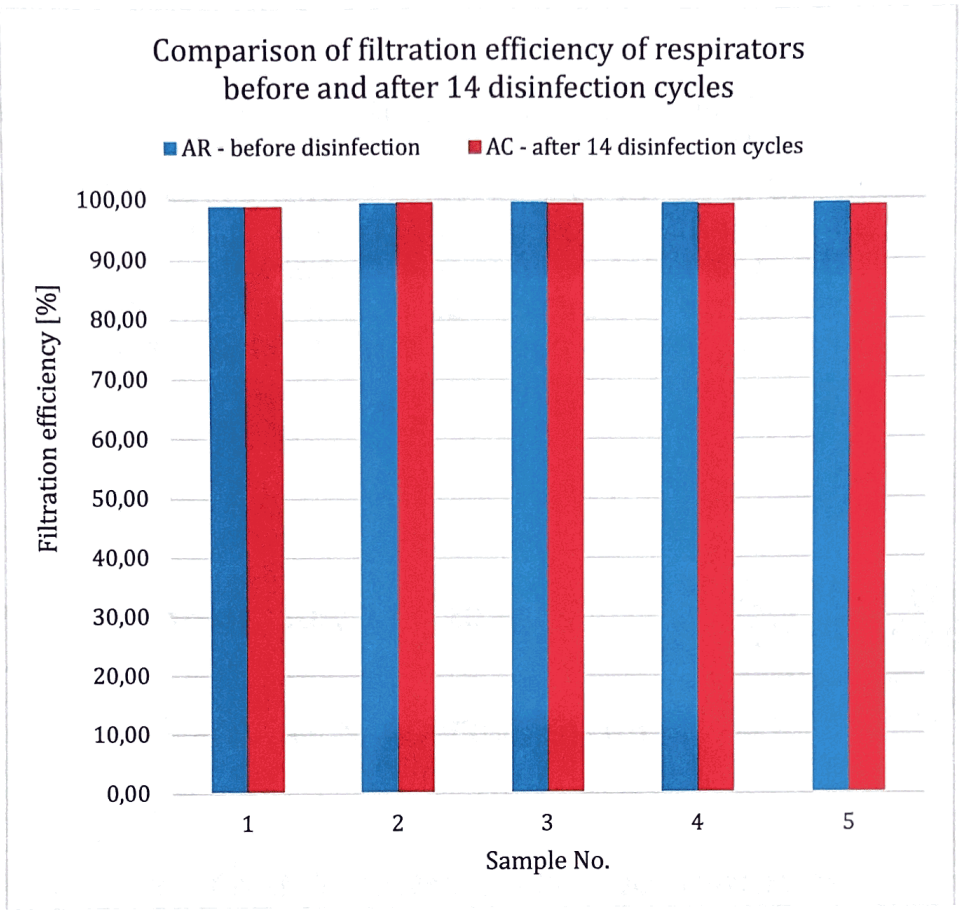
- *Results of filtration efficiency were performed also at Technical University Liberec to verify validity of internal measurements at Pardam. Samples AC were sent for measurement of disinfection treated respirators.*

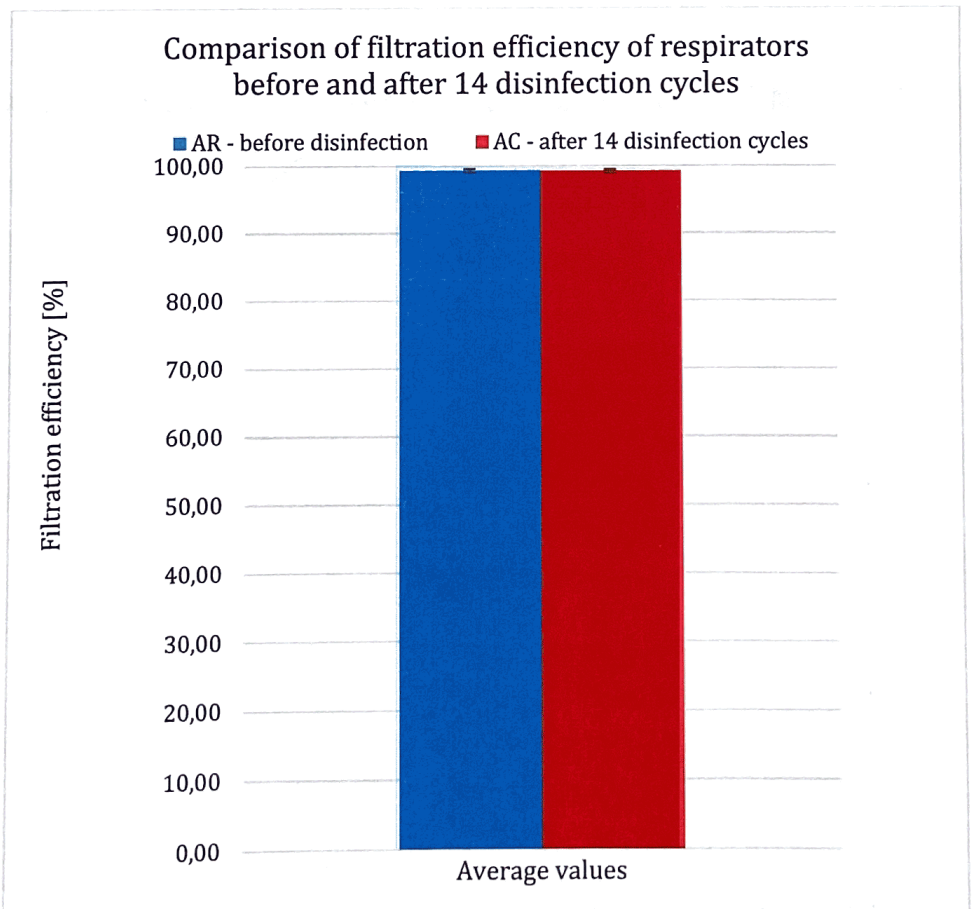
4) TEST RESULTS

Sample No.	Delta P of empty chamber [kPa]		Flow Rate [l/min]		Face Velocity [cm/s]		Resistance [kPa]		Pressure drop of the respirator [Pa]		Filtration efficiency [%]		Pressure behind the chamber before measurement [kPa]
	AR	AC	AR	AC	AR	AC	AR	AC	AR	AC	AR	AC	
1	94,70	94,50	94,23	95,29	51,53	52,10	1,11	1,15	230	280	98,90	98,82	
2	94,60	94,50	94,12	94,96	51,46	51,92	1,12	1,15	250	280	99,31	99,43	
3	94,60	94,50	94,43	94,08	51,42	51,44	1,16	1,11	290	230	99,57	99,38	
4	94,54	94,50	94,27	94,11	51,55	51,47	1,09	1,07	220	200	99,42	99,25	
5	94,60	94,50	94,12	95,31	51,46	52,10	1,15	1,10	230	230	99,31	98,97	
average	**94,61**	**94,50**	**94,23**	**94,75**	**51,48**	**51,81**	**1,13**	**1,12**	**244**	**244**	**99,30**	**99,17**	0,87






Comparison of filtration efficiency of respirators before and after 14 disinfection cycles
AR - before disinfection
AC - after 14 disinfection cycles
Filtration efficiency [%]
100,00
90,00
80,00
70,00
60,00
50,00
40,00
30,00
20,00
10,00
0,00
1
2
3
4
5
Sample No.


Comparison of filtration efficiency of respirators before and after 14 disinfection cycles
AR - before disinfection
AC - after 14 disinfection cycles
Filtration efficiency [%]
100,00
90,00
80,00
70,00
60,00
50,00
40,00
30,00
20,00
10,00
0,00
Average values

5) CONCLUSION:

From measured values it is clear, that pressure drop and filtration efficiency after 14 disinfection cycles performed by Isopropanol spray within our verification test, do not change significantly when compared with values of the samples before 14 disinfection cycles and it is probably caused by statistical fluctuation of the measured values within the statistical measurement error and the accuracy of the measuring instrument. All measured respirators show very high filtration efficiency and very small deviation of filtration efficiency and pressure drop.

In Roudnice nad Labem, July 17th 2020

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