ANALYSIS REPORT

CLEANING EFFECTIVENESS OF FROUMANN PROFESSIONAL AIR CLEANING DEVICE

FOR SARS-CoV-2 VIRUS IN AEROSOLS

Device Tested	**: FROUMANN PROFESSIONAL AIR CLEANING DEVICE**
Manufacturer	**: ELSON HAVA TEKNOLOJİLERİ SANAYİ AŞ., 26110 Eskişehir – Türkiye**
Test Date	: 01.12.2020-20.12.2020
Report Date	: 23.12.2020

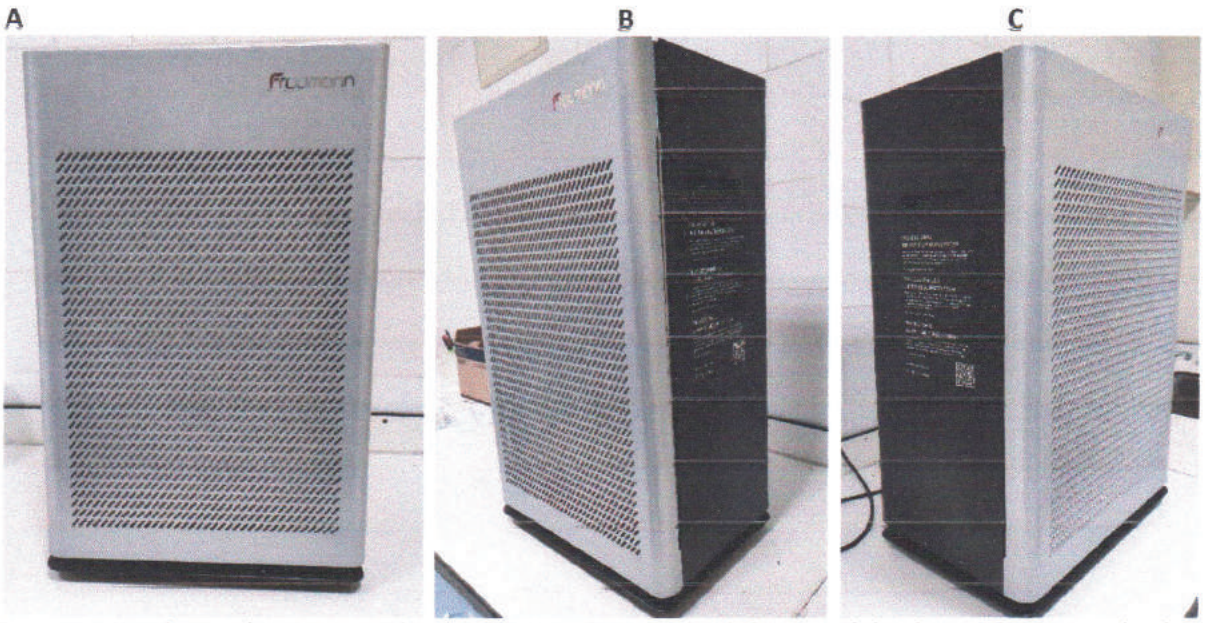


Figure 1: Device's Visuals: **A.** Front side of the device, **B.** Front and left sides of the device, **C.** Front and rights sides of the device

TEST LABORATORY

Institution	Inonu University Turgut Ozal Medical Center
Level	Clinical Microbiology Diagnostic Laboratory, Molecular Microbiology Laboratory, Biosafety Level-2
Licenser Authority	Health Ministry, Republic of Turkey
License Date	27.01.2017
License No	418/02
Test Laboratory	Authorized and accredited COVID-19 Diagnostic Laboratory Member of MOTAKK and QCMD External Quality Control Programs
Authorizing Institution	Microbiology Reference Laboratory and Administration of Biological Products Department, Health Ministry, Republic of Turkey
Authorization Date	20.03.2020
Test Conditions	Biosafety Level-2 Medical Microbiology Laboratory conditions, with controlled and air-lock entrance, continuous and externally-visualized negative air pressurized, and enforced with UV-C. Experiments were performed in Class-2B Biosafety cabinet with total atmospheric exhaust.

TEST MATERIALS

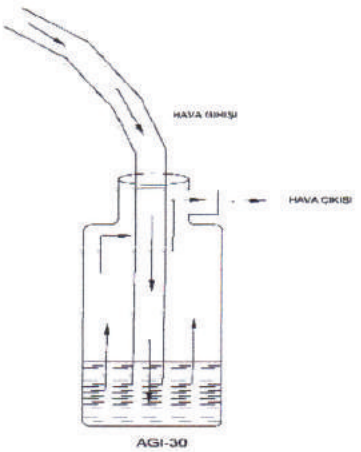
Test Transport Mediums	Universal Viral Transport Medium (Universal Transport Medium™, Copan Diagnostics Inc., US). Transport medium for viral growth in cell culture. Recommended medium for transport and storage of viruses including SARS-CoV-2, by US Food and Drug Administration (FDA).* *https://www.copanusa.com/sample-collection-transport-processing/utm-viral-transport/
RNA Extraction Kit	EZ1 ® Virus Mini Kit v2.0 (Qiagen GmbH, Germany) Lot no: 166030599, Ref no: 955134 One of recommended RNA extraction kits by Centers for Disease Control and Prevention (CDC), and World Health Organization* *https://www.who.int/docs/default-source/coronaviruse/whoinhouseassays.pdf?sfvrsn=de3a76aa_2
qRT-PCR Kit	genesig® Real Time PCR Coronavirus COVID-19 Kit v1.0 (Primerdesign Ltd., UK) Lot Code: JN-02780-0192. Belgeler: IVD, CE Diagnostic Performance* Limit of Detection (LOD): 1-10 viral particle; Sensitivity: 100% (95%CI: 93, 100); Specificity: 100% (95%CI: 96, 100). *World Health Organization. *https://www.finddx.org/wp-content/uploads/2020/07/FIND_SARS-COV2_molecular-assay-evaluation-results_03Jul2020.pdf
Real-Time PCR Device	Rotor-Gene Q HRM 5 Plex (Qiagen GmbH, Germany) Serial No: R0414319
Biosafety Cabinet	NUAIRE Biological Safety Cabinets. Series: 22; Serial No: 15050090500; Class-2A/B3 Calibration Approve: Unitest, Report No: 2019073162 Validation Approve: BC Laboratories, Validation Date: 18.02.2020

TEST METHODS

A-COLLECTION OF THE VIRAL PARTICLES EXHOUSTED FROM THE DEVICE

To collect the viral particles exhausted from the device, an AGI-30 type liquid impinge was used.

Figure 2: AGI-30 type impinger



AGI-30 type impinger is one of the most widely-used methods for collection of the viral particles in aerosols.

The efficacy of this method on the collection and capture of the viruses in the air droplets was reported to be higher about 10-fold than the polycarbonate filters.*

*Verreault D, et al. Microbiol Mol Biol Rev, 2008, 72: 413-444
*Tseng C, et al. J Aerosol Sci, 2005, 36: 593-607

B-TEST STAGES

Test Setup of the Device

To measure the filtering performance of the device tested for SARS-CoV-2 virus in aerosols, the experiment setup showed below was used.

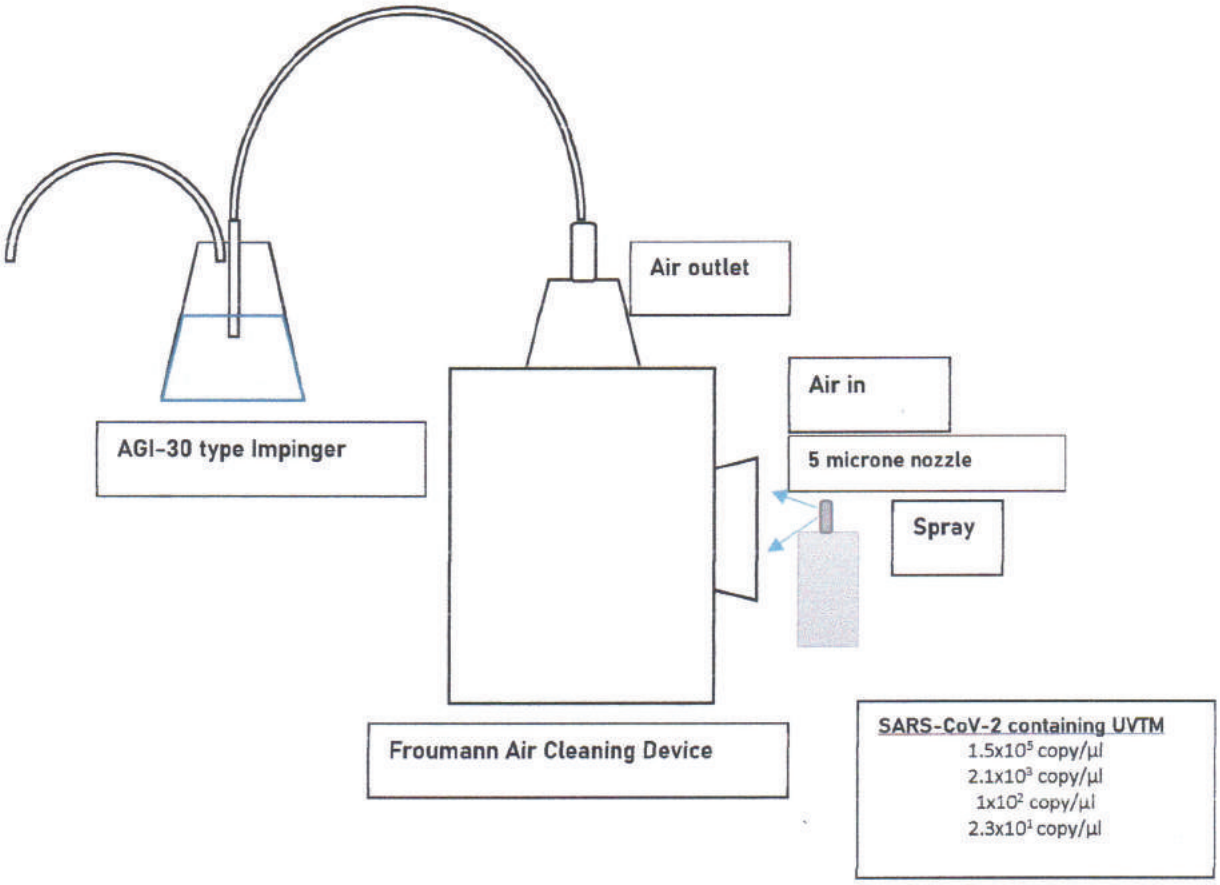


Figure 3: Test setup for aerosolized SARS-CoV-2 virus in FROUMANN PROFESSIONAL AIR CLEANING DEVICE. The device was tested in 1st, 3rd, and 5th levels of air flow.

C-PREPARATION OF SARS-CoV-2 VIRUS SUSPENSIONS

Viral suspensions including different concentrations of SARS-CoV-2 virus were prepared by pooling of the positive samples detected in the accredited laboratory mentioned above. Four viral suspensions included SARS-CoV-2 virus at $1.5x10^5$ copy/µl, $2.1x10^3$ copy/µl, $1x10^2$ copy/µl ve $2.3x10^1$ copy/µl were prepared according to the positive controls provided by the manufacturer of RT-PCR kit used in the experiment.

D-MS2 Bacteriophage Test

Due to biosecurity purpose, the cleaning capacity of the device is first tested with MS2 Bacteriophage before application of SARS-CoV-2.

MS2 Bacteriophage Plate Test

Two agar plates included bacterial growth mediums were prepared, and both of them were inoculated with bacteria at 0.5 McFarland density. The MS2 bacteriophage that was going to be used in the experiment were applied to one of these petri dishes. The phage was accepted as active when the plate that was phage applied showed no bacterial growth while bacterial growth occurred on the other.

The Cleaning Effectiveness of the Device Tested for MS2 Bacteriophage

The device was started up about ten minutes then total 10 ml MS2 Bacteriophage suspension 10^7 pfu/ml was given as aerosolized to the air intake area of the device tested for 15 min. The air exhausted from the air outlet part of the device was collected with AGI-30 type impinger. The liquid in the impinger was then applied to the bacteria inoculated growth mediums. Bacterial growth was detected in the growth mediums, and this was accepted as the proof of the effective viral filtration of the device tested.

E- FILTRATION TESTS OF THE AEROSOLIZED SARS-COV-2 VIRUS WITH FROUMANN PROFESSIONAL AIR CLEANING DEVICE

The device was tested with different concentrations of SARS-CoV-2 virus prepared in the Universal Viral Transport Medium (UVTM). Each test was repeated for five times.

A total 10 ml UVTM containing different concentrations of SARS-CoV-2 virus were applied to the air intake part of the device, with 5 micron nozzle, for 15 min. The filtered air was re-filtered with sterile deionized water in the AGI-30 impinger to collect the aerosolized virus. The virus existence in the filtration liquid was studied with the COVID-19 RT-PCR method with the kits and the devices mentioned above. The results of the tests performed in 1st, 3rd and 5th level of air flows of the device were showed in the Tables 1, 2 and 3.

Table 1. The results of the tests performed with direct application of the aerosols containing different concentrations of SARS-CoV-2 virus to the air intake part of the device.
The device was tested at the 1st level of air flow power. 10 ml SARS-CoV-2 suspension, 5 micron aerosol

	The Viral Concentration Given to the Air Intake Part of the Device	The Measured Viral Concentration in the Air Outlet Part of the Device
First Test	$1.5x10^5$ copy/µl	1.2 copy/µl
	$2.1x10^3$ copy/µl	Negative
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative
Second Test	$1.5x10^5$ copy/µl	8.4 copy/µl
	$2.1x10^3$ copy/µl	Negative
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative
Third Test	$1.5x10^5$ copy/µl	2.9 copy/µl
	$2.1x10^3$ copy/µl	Negative
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative
Fourth Test	$1.5x10^5$ copy/µl	10.2 copy/µl
	$2.1x10^3$ copy/µl	Negative
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative
Fifth Test	$1.5x10^5$ copy/µl	Negative
	$2.1x10^3$ copy/µl	Negative
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative

Table 2. The results of the tests performed with direct application of the aerosols containing different concentrations of SARS-CoV-2 virus to the air intake part of the device.
The device was tested at the 3rd level of air flow power. 10 ml SARS-CoV-2 suspension, 5 micron aerosol

	The Viral Concentration Given to the Air Intake Part of the Device	The Measured Viral Concentration in the Air Outlet Part of the Device
First Test	$1.5x10^5$ copy/µl	31 copy/µl
	$2.1x10^3$ copy/µl	12 copy/µl
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative
Second Test	$1.5x10^5$ copy/µl	18 copy/µl
	$2.1x10^3$ copy/µl	8.4 copy/µl
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative
Third Test	$1.5x10^5$ copy/µl	13 copy/µl
	$2.1x10^3$ copy/µl	Negative
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative
Fourth Test	$1.5x10^5$ copy/µl	12 copy/µl
	$2.1x10^3$ copy/µl	8.7 copy/µl
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative
Fifth Test	$1.5x10^5$ copy/µl	12 copy/µl
	$2.1x10^3$ copy/µl	Negative
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative

Table 3. The results of the tests performed with direct application of the aerosols containing different concentrations of SARS-CoV-2 virus to the air intake part of the device.
The device was tested at the 5rd level of air flow power. 10 ml SARS-CoV-2 suspension, 5 micron aerosol

	The Viral Concentration Given to the Air Intake Part of the Device	The Measured Viral Concentration in the Air Outlet Part of the Device
First Test	$1.5x10^5$ copy/µl	45 copy/µl
	$2.1x10^3$ copy/µl	1.8 copy/µl
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative
Second Test	$1.5x10^5$ copy/µl	36 copy/µl
	$2.1x10^3$ copy/µl	22.5 copy/µl
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative
Third Test	$1.5x10^5$ copy/µl	98 copy/µl
	$2.1x10^3$ copy/µl	5.5 copy/µl
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative
Fourth Test	$1.5x10^5$ copy/µl	82 copy/µl
	$2.1x10^3$ copy/µl	25 copy/µl
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative
Fifth Test	$1.5x10^5$ copy/µl	38 copy/µl
	$2.1x10^3$ copy/µl	25 copy/µl
	$1x10^2$ copy/µl	Negative
	$2.3x10^1$ copy/µl	Negative

F-EVALUATION of the RESULTS

FROUMANN PROFESSIONAL AIR CLEANING DEVICE tested for the filtering performance of aerosolized SARS-CoV-2 virus in our laboratory, with the test procedures, experiment conditions, test kits and devices mentioned above, has provided following results:

1. **When the device was working at the 1st level of air flow, it could filtrate 99-100% of all the SARS-CoV-2 virus (complete filtration) in aerosols which were containing the highest concentration of the virus. It could filtrate all the SARS-CoV-2 virus (complete filtration) in aerosols which were containing the high, moderate and low concentration of the virus. The complete filtration means no viral particle is allowed to pass through from the device, or under the Level of Detection of the test kit (1-10 copy/reaction) reported by the World Health Organization.**
2. **When the device was working at the 3rd level of air flow, it could filtrate 99-100% of all the SARS-CoV-2 virus (complete filtration) in aerosols which were containing the highest and high concentrations of the virus. It could filtrate all the SARS-CoV-2 virus (complete filtration) in aerosols which were containing the moderate and low concentration of the virus. The complete filtration means no viral particle is allowed to pass through from the device, or under the Level of Detection of the test kit (1-10 copy/reaction) reported by the World Health Organization.**
3. **When the device was working at the 5th level of air flow, it could filtrate about 99% of all the SARS-CoV-2 virus (complete filtration) in aerosols which were containing the highest and high concentrations of the virus. It could filtrate all the SARS-CoV-2 virus (complete filtration) in aerosols which were containing the moderate and low concentration of the virus. The complete filtration means no viral particle is allowed to pass through from the device, or under the Level of Detection of the test kit (1-10 copy/reaction) reported by the World Health Organization.**

G-CONCLUSION

The results of the experiments performed under the test conditions, and with the kits and devices mentioned above have indicated that FROUMANN PROFESSIONAL AIR CLEANING DEVICE can filter 99% of the SARS-CoV-2 virus given through the air intake part of the device (if aerosols given are containing very high level of the virus), when it works at the highest level of air flow. It could filtrate the all the viral particles (or below the detectable limit) when moderate or low virus containing aerosols are given at the same air flow level. When the device is working at the moderate and low air flow power; it could filtrate 99-100% of the SARS-CoV-2 in the aerosols (if the aerosols given are containing very high level of the virus), and it could filtrate the all the viral particles (or below the detectable limit) when high, moderate or low virus containing aerosols are given at the same air flow level. December 23rd, 2020.