İNÖNÜ ÜNİVERSİTESİ
TURGUT ÖZAL TIP MERKEZİ

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 – Turkey**
Test Date	: 05.10.2020-12.10.2020
Report Date	: 20.10.2020

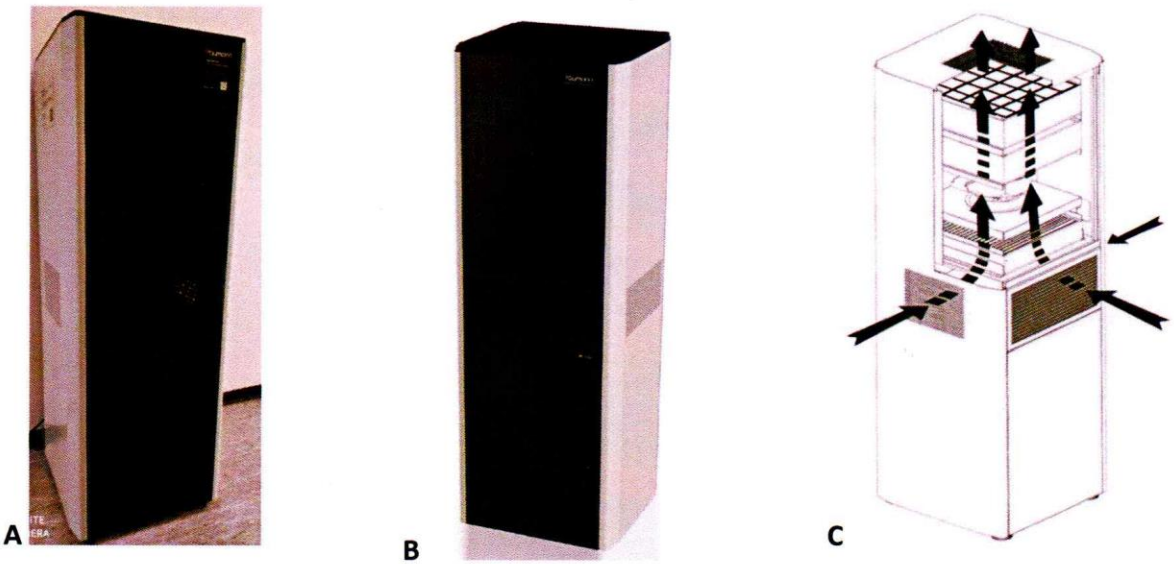

Figure 1: Device's Visuals: **A.** Front and right sides of the device, **B.** Front and left sides of the device, **C.** Schematic illustration of the device and air flow directions.

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.

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TEST MATERIALS

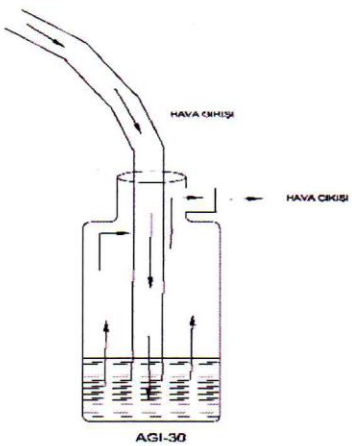
Test Transport Mediums	Universal Viral Transport Medium (Universal Transport Medium™, Copan Diagnostics Inc., US). Transport medium for viral growth in cell culture. Recommended medium for transport and storage of viruses including SARS-CoV-2, by US Food and Drug Administration (FDA).* *https://www.copanusa.com/sample-collection-transport-processing/utm-viral-transport/
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	RealStar® SARS-CoV-2 RT-PCR Kit v1.0 (altona Diagnostics GmbH, Germany) Target Sequence(s): E and S genes of SARS-CoV-2 virus Lot No:023906, Ref No: 821003 Diagnostic Performance* Limit of Detection (LOD): 1-10 viral particle; Sensitivity: 92% (95%CI: 81, 97); 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

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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.

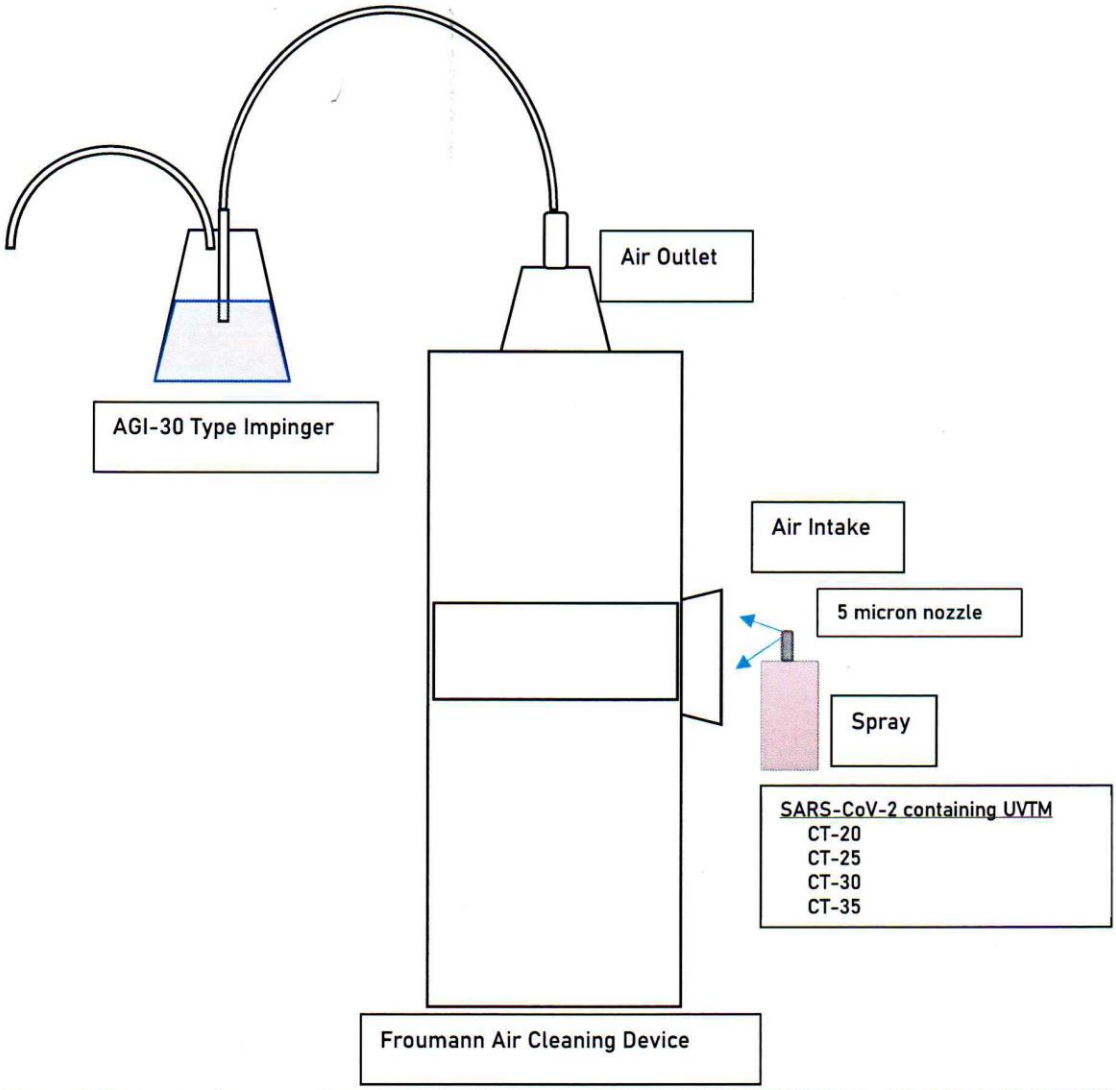

Figure 3: Test setup for aerosolized SARS-CoV-2 virus in FROUMANN PROFESSIONAL AIR CLEANING DEVICE. The device was tested in 1st, 3rd, and 5th levels of air flow. According to the data of the manufacturer, 250 m3/h, 360 m3/h, and 600 m3/h air flow volumes could be achieved in 1st, 3rd, and 5th air flow levels, respectively.

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 suspension included SARS-CoV-2 virus at ct20, ct25, ct30 and ct35 concentrations in 10 ml volume of UVTM were produced. Final RT-PCR confirmation was carried out.

Ct is the value indicating the level of viral RNA amplification which is cutting the threshold of positivity. By using the Ct value, the viral concentration in a sample can be calculated in the standardized RT-PCR tests. Accordingly, the lower Ct value indicates the higher virus concentration. The reported Limit of Detection (LOD) is 1-10 copy/reaction for the PCR kit used in this experiment*.
*https://www.finddx.org/wp-content/uploads/2020/07/FIND_SARS-COV2_molecular-assay-evaluation-results_03Jul2020.pdf

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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	ct 20	Negative
	ct 25	Negative
	ct 30	Negative
	ct 35	Negative
Second Test	ct 20	Negative
	ct 25	Negative
	ct 30	Negative
	ct 35	Negative
Third Test	ct 20	Negative
	ct 25	Negative
	ct 30	Negative
	ct 35	Negative
Fourth Test	ct 20	Negative
	ct 25	Negative
	ct 30	Negative
	ct 35	Negative
Fifth Test	ct 20	Negative
	ct 25	Negative
	ct 30	Negative
	ct 35	Negative

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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	ct 20	ct39.9
	ct 25	ct40.1
	ct 30	Negative
	ct 35	Negative
Second Test	ct 20	ct38.3
	ct 25	ct40
	ct 30	Negative
	ct 35	Negative
Third Test	ct 20	ct40
	ct 25	Negative
	ct 30	Negative
	ct 35	Negative
Fourth Test	ct 20	ct39.2
	ct 25	Negative
	ct 30	Negative
	ct 35	Negative
Fifth Test	ct 20	ct38.7
	ct 25	Negative
	ct 30	Negative
	ct 35	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 5th 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	ct 20	ct25.5
	ct 25	ct35.7
	ct 30	ct39.2
	ct 35	Negative
Second Test	ct 20	ct28.2
	ct 25	ct36
	ct 30	ct39.9
	ct 35	Negative
Third Test	ct 20	ct24.25
	ct 25	ct35.3
	ct 30	ct40
	ct 35	Negative
Fourth Test	ct 20	ct26.3
	ct 25	ct37.5
	ct 30	ct40
	ct 35	Negative
Fifth Test	ct 20	ct28.7
	ct 25	ct38.4
	ct 30	ct40.5
	ct 35	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 (250 m3/h), it could filtrate all of the SARS-CoV-2 virus (complete filtration) in aerosols. The complete filtration means no viral particle is allowed**

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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 (360 m3/h), it could reduce the viral concentration in aerosols about 99% if the aerosols given were containing the highest concentration of SARS-CoV-2 virus. In case of the aerosols were containing moderate to low virus concentrations, it could filtrate all of the SARS-CoV-2 virus in outlet aerosols (complete filtration). 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 (600 m3/h), it could reduce the viral concentration in aerosols between ct5-10 concentrations, if the aerosols given were containing the highest concentration of SARS-CoV-2 virus. When the aerosols given were containing moderate concentration (ct30) of SARS-CoV-2 virus, it could reduce the virus concentration in the outlet aerosols to the very close levels of the reported Level of Detection limit of the test kit reported by World Health Organization. Finally, when the aerosols given were containing low level of SARS-CoV-2 virus (ct35), the device could filtrate all of the SARS-CoV-2 virus in the outlet aerosols (complete filtration). 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 significant proportion of the SARS-CoV-2 virus in aerosols (if aerosols given are containing very high level of the virus), and it can filter SARS-CoV-2 virus in aerosols from 90% to complete filtration levels (if aerosols given are containing moderate to low level of the virus), when it works at the highest level of air flow. Additionally, FROUMANN PROFESSIONAL AIR CLEANING DEVICE can filter about 99% of the aerosolized SARS-CoV-2 virus (if the aerosols given are containing the highest level of virus), and it can filter all the SARS-CoV-2 virus in aerosols (if the aerosols given are containing the moderate and low levels of virus) when the device is working at the third level of air flow power. Finally, FROUMANN PROFESSIONAL AIR CLEANING DEVICE can filter all detectable SARS-CoV-2 virus in the aerosols, when it is working at the first level air flow power. October 20th, 2020.

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