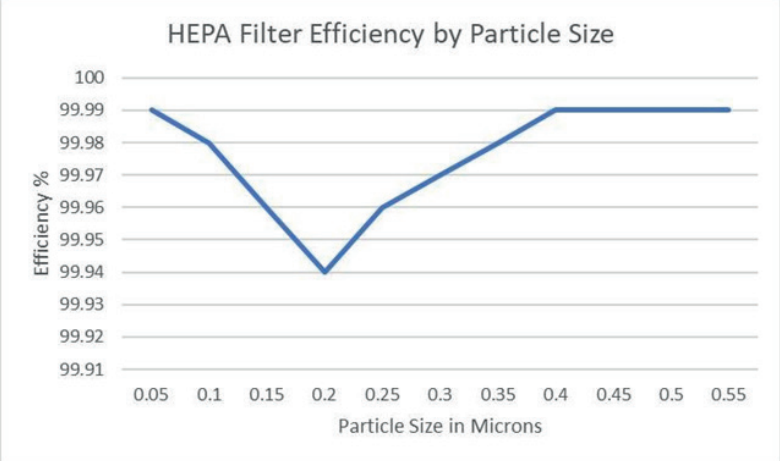
EXAUSTED AIR ASPIRATION INSTRUMENT (EAAI)

Exhausted air aspiration system for scientific instruments and "Breath Test" sampling

At this time in history, more than ever, it is crucial to make sure that the air circulating in healthcare facilities is as clean and free of pathogens as possible. When using "Breath Test" instruments, due to potentially infected exhausted air coming out of the apparatus, possible threats might spread in the surrounding environment, endangering healthcare workers and patients alike. As of the most recent research, the most effective way to eliminate the possibility of infections has proven to be the use of a high-efficiency filter(1), whose aspiration system is placed in close proximity of the instrument.

Most pathogens have a size ranging from 0.05 to 1 µm; in particular, SARS-CoV-2 measures approximately 0.125 µm in diameter. (2) ULPA (Ultra Low Penetration Air) filters, as for the European Union EN1822-2009 standard, are the most effective way to retain particles down to 0.01 µm. There is a widespread misconception about ULPA and HEPA filters, which are believed to be unable to filter particles smaller than 0.3 µm; this is due to the fact that most high-efficiency filters are tested at 0.3 µm, which is defined as the Most Penetrating Particle Size (MPPS).

Particles larger than the MPPS get easily trapped in the fibers of the filters, while smaller particles, which would intuitively just pass through it, are subject to Brownian motion, moving in a random pattern and colliding with their surroundings until they encounter the filtering fibers: this is the case for viruses such as SARS-CoV-2.(3)
U15 filters have, by definition, an efficiency higher than 99.995%, making them suitable for the filtering of air in healthcare facilities, and virtually eliminating any possibility of infection related to the use of Breath Test instruments.



The chart represents the efficiency of HEPA filters in relation to the filtered particle size. As the particle size goes down, the filter will be less likely to intercept them directly, but at the same time, their random movement makes them more likely to encounter the filtering fibers. As the particles increase in size, the particles will be easily intercepted by the fibers (4).

BS EN 1822-1 2019			ISO 29463-1 2017		
Filter class and group	Overall value		Filter class and group	Overall value	
	Efficiency (%)	Penetration (%)		Efficiency (%)	Penetration (%)
E10	≥ 85	≤ 15			
E11	≥ 95	≤ 5	ISO 15E	≥ 95	≤ 5
			ISO 20E	≥ 99	≤ 1
E12	≥ 99.5	≤ 0.5	ISO 25E	≥ 99.5	≤ 0.5
			ISO 30E	≥ 99.9	≤ 0.1
H13	≥ 99.95	≤ 0.05	ISO 35H	≥ 99.95	≤ 0.05
			ISO 40H	≥ 99.99	≤ 0.01
H14	≥ 99.995	≤ 0.005	ISO 45H	≥ 99.995	≤ 0.005
			ISO 50U	≥ 99.999	≤ 0.001
U15	≥ 99.9995	≤ 0.0005	ISO 55U	≥ 99.9995	≤ 0.0005
			ISO 60U	≥ 99.9999	≤ 0.0001
U16	≥ 99.99995	≤ 0.00005	ISO 65U	≥ 99.99995	≤ 0.00005
			ISO 70U	≥ 99.99999	≤ 0.00001
U17	≥ 99.999995	≤ 0.000005	ISO 75U	≥ 99.999995	≤ 0.000005

Filter efficiency is for most penetrating particle size (MPPS)

The table shows the comparison between the European Union EN 1822 standard and the global ISO 29463 classification for high-efficiency air filters. As shown, a U15 filter corresponds to an ISO 55U one (5).

During the sampling for the execution of Breath Tests, the patient has to blow into a sample collection system; the alveolar exhale is then placed into a container designed for its conservation.

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FIG. 1

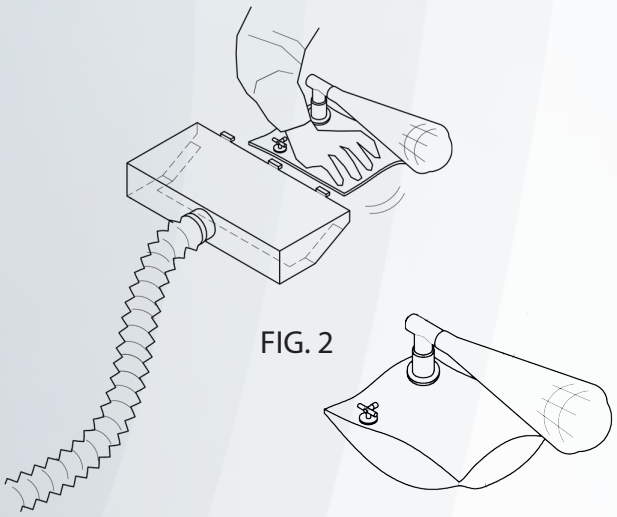

FIG. 2

In the case of Quintron Instruments USA Breath Tests equipment:

· For **AlveoSampler™** systems, a syringe, suitable for short periods of time (a maximum of 8 hours at room temperature) (FIG. 3);

· For **GasSampler™** systems, a laminated bag, suitable for short periods of time (a maximum of 8 hours at room temperature) (FIG. 2);

· For **EasySampler™** system, an apparatus of vacuum glass tubes, suitable for long periods of time (a maximum of 15 days at room temperature) (FIG. 5).

The exhale sample has to be injected into the instrument; it is analyzed, and then expelled from the back of the instrument (FIG. 1).

OTHER SAMPLING DEVICES

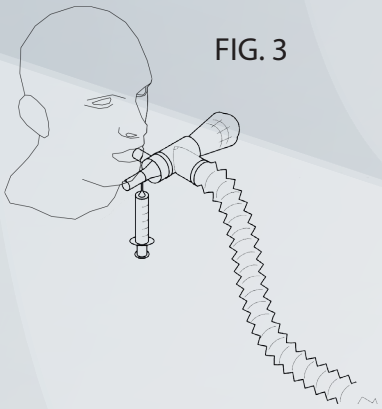

FIG. 3

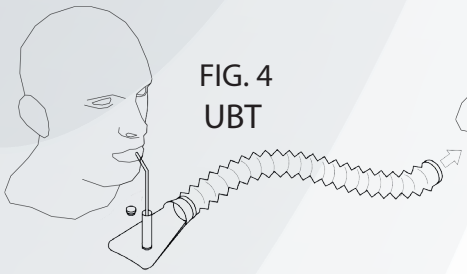

FIG. 4
UBT

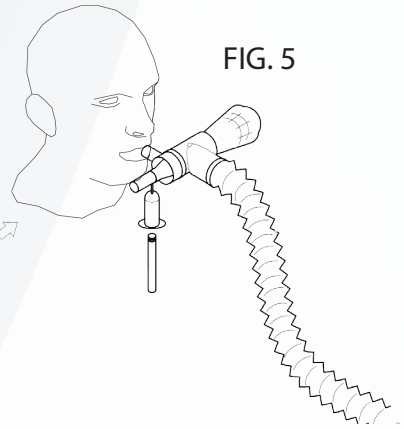

FIG. 5

EAA1-01 and EAAI-02 aspiration systems are activated during the sampling phase, and on the air coming out of the instrument. The aspiration flux, which is more than sufficient compared to the exhausted air produced by the instrument (200m^3/h versus the 3,6l/h produced by the instrument) is then redirected onto a ULPA U15 HIGH-EFFICIENCY FILTER, suitable for retaining dust particles, droplets, aerosols, bacteria, and viruses, SARS-CoV-2 included.

Please note that the use of **NON-ORIGINAL** or **ARTISANAL** sampling systems completely invalidates the CE certification of the in-vitro diagnostic medical device (included that of the instrument). This exposes the service manager, health professionals, or medical practitioners involved in the testing procedure to any civil or legal action taken by the Manufacturer, the Distributor, and the patient, in case of the onset of health issues due to the misuse of the instrument.

The above-described system is subject of the Patent Application, nr. 102020000028022 of 23/11/2020.

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