Thopaz+ Filter Performance

Summary
Medela has conducted a series of tests to ascertain the effectiveness of the Thopaz/Thopaz+ system at retaining particles of a given size such as bacteria and viruses. Qualitative filtration efficiency tests with 500–1'000 nanometer (nm) sized bacteria showed the bacteria to be completely blocked by the test filter.[1]

Repeated quantitative laboratory filtration tests using an aerosol suspension with 27 nm particles showed effective filtration at a retention rate of 97.43 to 99.27 %.[2]
The equivalent effectiveness of Thopaz/Thopaz+ for filtering SARS-CoV-2 in a real-world clinical setting is expected to be significantly higher, based on the retention rates demonstrated with the entire system.

Note: Respiratory protection masks, used to protect the wearer from droplets, airborne particles and body fluids, have no qualified retention capability for coronavirus-sized particles. Instead they protect users from large droplets and sprays. FFP3 class respirators retain 99.95 % of 500 nm particles respectively aerosol, FFP2 respirators retain 94 % of 500 nm particles. N95 have a retention rate >95 % for 500 nm particles.[3,4]

Bacterial and Viral Filtration Testing

An article issued by the U.S. National Library of Medicine and National Institutes of Health[5] states, "Corona virions are spherical with diameters of approximately 125 nm." Bacterial and viral filtration efficiency tests are performed on filtration materials and devices that are designed to provide protection against biological aerosols, such as face masks, surgical gowns, caps, and air filters.

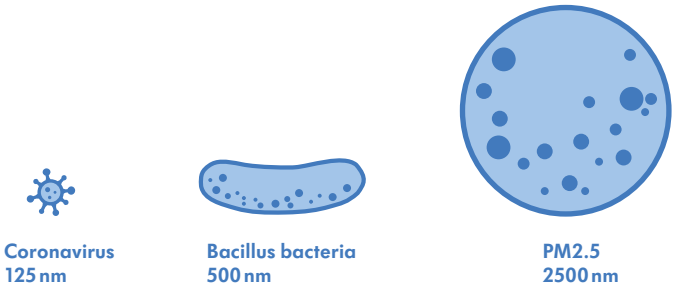

Figure 1: Coronavirus and Other Particles Sizes

Thopaz+ Filtration Efficiency for 500 nm Particles

Qualitative bacterial retention filter tests were performed using several defined bacterial strains; i.e. Staphylococcus (St.) aureus ATCC 6538 (dimensions 500–1'000 nm), Serratia (S.) marcescens no. 731 from clinical isolates (dimensions 500–800 nm in diameter and 900–2000 nm in length), Micrococcus luteus ATCC 10240 (dimensions 500–2'000 nm) and others. In summary, the test filters in multiple repeated tests were all observed to completely block several challenge bacterial strains under the applied test conditions. The test filter can therefore be regarded as impermeable for bacteria under the applied test conditions.

Thopaz+ Filtration Efficiency for 27 nm Particles

Repeated quantitative laboratory tests were performed with a bacteriophage equivalent to a Hepatitis A size virus of 27 nm. The test showed effective filtration of the aerosol-suspended bacteriophage with a retention rate of 97.43 % and 99.27 % in dry filter state and 99.58 % and 99.67 % in wet filter state.

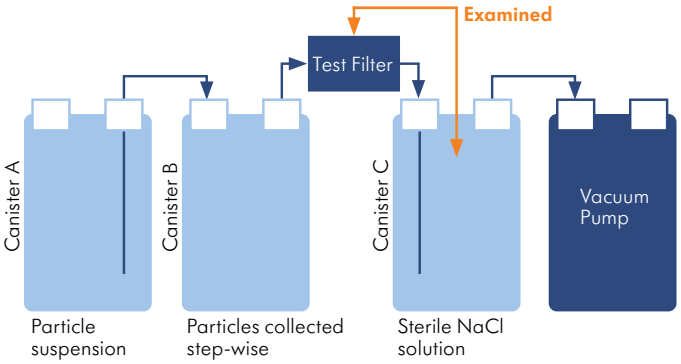

Figure 2: Schematic overview of test setup

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Thopaz+ Filtration Efficiency

Particle Size	Test Type	Filter State	Retention Rate of Filter %
27 nm particle (~size equivalent for Hepatitis A), aerosol-suspended	Retention rate of filter	Dry	97.43–99.27
27 nm particle (~size equivalent for Hepatitis A), aerosol-suspended	Retention rate of filter	Wet	99.58–99.67

Table 1: Summary of Quantitative Filter Test Results, Retention Rate of Filter Only

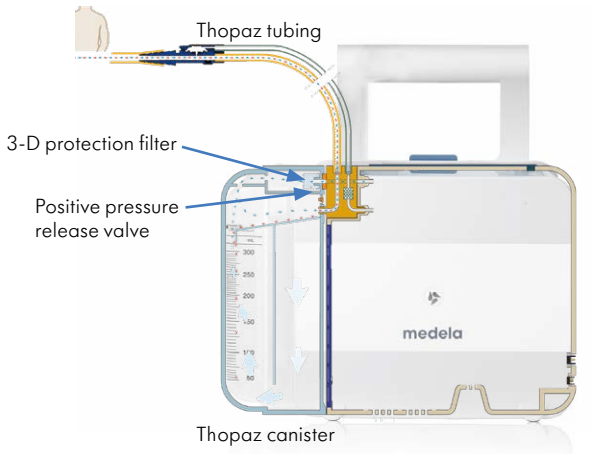
Particle Size	Test Type	Filter State	Retention Rate of Entire System %
27 nm particle (~size equivalent for Hepatitis A), aerosol-suspended	Retention rate of entire system	Dry	99.999998–99.9999998
27 nm particle (~size equivalent for Hepatitis A), aerosol-suspended	Retention rate of entire system	Wet	99.9999991–99.9999997

Table 2: Summary of Quantitative Filter Test Results, Across Entire System

Thopaz+ system

The Thopaz+ digital chest drainage system consists of a reusable pump unit and a disposable canister and tubing assembly. All drained air passes through a hydrophilic 3-D protection filter located in the canister before entering the pump to avoid cross-contamination. Drained liquids are captured in the canister itself. The filter is inherent to the canister and is disposed together with any retained particles when the canister is replaced.

Only in case of an overpressure event, caused for example by patient coughing, to prevent possible patient injury, the air exhausts unencumbered via the positive pressure release valve. ISO norm therefore requires every chest drainage system to have such a valve.



References
1 Hohenstein GmbH, Laboratory, Germany (Test report on file at Medela AG)
2 Bioexam AG, Laboratory, Switzerland (Test report on file at Medela AG)
3 Jacek Smereka, Kurt Ruetzler, Lukasz Szarpak, Krzysztof Jerzy Filipiak, Role of Mask/Respirator Protection Against SARS-CoV-2, Anasthesia & Analgesia, 2020
4 3M technical bulletin on https://multimedia.3m.com/mws/media/1791500O/comparison-ffp2-kn95-n95-filtering-facepiece-respirator-classes-tb.pdf
5 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4369385/