COSMED
The Metabolic Company

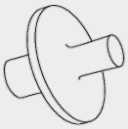
COSMED statement in response of concerns over the risk of using products during COVID-19 pandemic

Due to the current COVID-19 pandemic, we are receiving an increasing number of queries related to the use and safety of COSMED devices. We would therefore like to issue the following information and best practice guidelines:

COSMED devices have been designed to minimize the risk of infection due to contaminated components. This may include the implementation of single use items, high bacterial/viral filtration efficiency patient filters or/and unidirectional flow mechanisms (from patient to device only).

For what concern Spirometry and Lung Function Testing, COSMED strongly recommends the use of filters over single-use flowmeters to minimize the dispersion of aerosol droplets in the environment produced during forced exhalation and other lung function maneuvers. Use of high bacterial/viral filtration efficiency filters ensures device protection, avoids cross-contamination and protects patient and healthcare personnel from aerosolized droplets in the environment. Preventing aerosol spreading is fundamental to minimize lung infection diseases transmission and particularly COVID-19, as supported by main scientific organizations[1].

Bacterial and viral filtration efficiency of COSMED filters[2] are summarized in the below table:

Applicable to	REF, description	Image	Bacterial Filtration Efficiency (BFE)	Viral filtration efficiency (VFE)
Spirometry and Pulmonary Function Testing **Resting Metabolism** **Clinical CPET**	A-182-300-004 Antibacterial Filter, Round Mouthpiece A-182-300-005 Antibacterial Filter, Oval Mouthpiece		BFE: 99.999% (Staphylococcus aureus @ 30L/min) according to ASTM F2101-07	VFE: 99.999% (Bacteriophage @ 30L/min) according to ASTM F2101-07

[Table 1]

In addition, any cleaning and disinfection instructions enclosed in COSMED user manuals[3] have been validated for both material compatibility and disinfection efficacy by third-party independent laboratories. With particular regards to semi-critical components (see Table 2), the recommended disinfectant agents CIDEX® OPA and Oxivir® have been proven to be efficacious against coronavirus.[4]

To guarantee the correct level of disinfection, users must carefully follow the reprocessing instructions reported in COSMED user manuals. A most updated and comprehensive COSMED Cleaning and Disinfection Manual has been released to ease and promote correct infection prevention procedures during COVID-19 pandemic.
Alternative reprocessing methods might be equally suitable if the following criteria are met: the obtained level of reprocessing matches with Table 2; components' materials are compatible with the agents and procedures used (refer to COSMED Cleaning and Disinfection Manual). Always follow the indications, instructions and warnings provided by the supplier of the cleaning and disinfectant agent and select only disinfectants with approved efficiency (e.g. FDA clearance or CE mark).

Classification	Equipment/Device	Level of Reprocessing
Critical*	That enters sterile tissues, including the vascular system	Cleaning followed by Sterilization *Not applicable to COSMED devices
Semicritical	That comes in contact with non-intact skin or mucous membranes but does not penetrate them	Cleaning followed by High-Level Disinfection (as a minimum)
Non Critical	That touches only intact skin and not mucous membranes, or does not directly touch the patient	Cleaning followed by Low- Level Disinfection (in some cases, cleaning alone is acceptable)

[Table 2] [5]

Refer to WHO guidelines for infection prevention and control during health care when COVID-19 is suspected[6].

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References and Bibliography

[1]ERS COVID-19 resource centre (https://www.ersnet.org/the-society/news/novel-coronavirus-outbreak--update-and-information-for-healthcare-professionals);
Novel Coronavirus (COVID-19): The ATS Response (https://www.thoracic.org/professionals/clinical-resources/disease-related-resources/novel-coronavirus.php)
[2] Patient filters supplied by COSMED have not been specifically validated for removal of the COVID-2019, MERS-CoV and SARS-CoV.
However the filters are tested by independent laboratories passing BFE and VFE test using Staphylococcus Aureus (*ATCC #6538) and Bacteriophage PHI X174 (dimension about 0.025 μm) and have been validated to removal a range of clinically relevant bacteria and viruses, including, but not limited to Influenza A virus(H1N1: 0.08-0.12 μm), HIV(0.08 μm), Hepatitis C virus(0.8 μm), Adenovirus (0.07 μm), Cytomegalovirus(0.1 μm), Orthmyxovirus(0.12 μm) and Mycobacterium tuberculosis(1.0 μm). COVID-2019, MERS-CoV and SARS-CoV are Coronavirus species and its size ranges from 0.06 to 0.2 μm.
[3]Cleaning and disinfection on user manuals complies with EN ISO 17664, Processing of health care products – Information to be provided by the medical device manufacturer.
[4]https://www.asp.com/preventing-the-spread-of-coronavirus-from-contaminated-medical-devices;
https://www.hopkinsmedicine.org/hse/forms/cidexopa/opatechinfo.pdf;
https://www.epa.gov/pesticide-registration/list-n-disinfectants-use-against-sars-cov-2;
https://www.americanchemistry.com/Novel-Coronavirus-Fighting-Products-List.pdf
[5]Adapted from: Spaulding E. The role of chemical disinfection in the prevention of nosocomial infections. Proceedings of the ICNI conference. AHA; 1971. p. 247-54
[6]https://www.who.int/publications-detail/infection-prevention-and-control-during-health-care-when-novel-coronavirus-(ncov)-infection-is-suspected-20200125

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