COSMED statement in response of concerns over the risk of using Q-NRG/Q-NRG+ 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 Q-NRG/Q-NRG+. We would therefore like to issue the following information and best practice guidelines[1]:

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).

All levels of infection control implemented in the Q-NRG/Q-NRG+ are summarized in the below table:

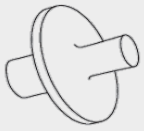
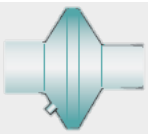
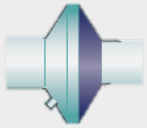
Measurement modes	Levels of infection control
VENTILATOR*	• Any parts in contact with the patient are single use. • High bacterial/viral efficiency filter is connected to the patient protecting the device from any contaminated flow. • Electropneumatic device functioning guarantees that no air flows from the device to the patient.
CANOPY	• Validated cleaning and disinfection procedures for any reusable parts. • High bacterial/viral efficiency filter is connected to the patient canopy expiratory port protecting the device from any contaminated flow. • Electropneumatic device functioning guarantees that no air flows from the device to the patient.
MASK**	• Validated cleaning and disinfection procedures for any reusable parts. • Electropneumatic device functioning guarantees that no air flows from the device to the patient.

[Table 1]

* Additional actions may be undertaken to avoid contamination of the mechanical ventilator such as: use of bacteria filter on the inspiratory and expiratory port of the ventilator. For further indications, please refer to mechanical ventilator manufacturers recommendations.

** As an alternative to the mask, test can be performed by using a high bacterial/viral efficiency filter to protect reusable parts from any contaminated flow.

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

REF, description	Image	Bacterial filtration efficiency (BFE) according to ASTM F2101-07	Viral filtration efficiency (VFE) according to ASTM F2101-07	Measurement modes
A-182-300-004 Antibacterial Filter, Round Mouthpiece		BFE: 99.999% (Staphylococcus aureus @ 30L/min)	VFE: 99.999% (Bacteriophage @ 30L/min)	CANOPY, MASK
A-182-300-007 Antibacterial Filter		BFE: 99.999% (Staphylococcus aureus @ 30L/min)	VFE: 99.999% (Bacteriophage @ 30L/min)	VENTILATOR
A-182-300-006, HME Heat Moisture Exchanger with Antibacterial Filter		BFE: 99.999% (Staphylococcus aureus @ 30L/min)	VFE: 99.999% (Bacteriophage @ 30L/min)	VENTILATOR

[Table 2]

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 3), 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 3; 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

cosmed.com
Via dei Piani di Monte Savello, 37
00041 Albano Laziale (Roma) - Italy
info@cosmed.com
+ 39 06.93.15.492
+ 39 06.93.14.580 F

ISO 9001:2015
ISO 13485:2016

disinfectant agent and select only disinfectants with approved efficiency (e.g. FDA clearance or CE mark).

Classification	Equipment/Device	Level of Reprocessing	Q-NRG/Q-NRG+ applicable parts***
Critical	That enters sterile tissues, including the vascular system	Cleaning followed by Sterilization	N/A
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)	Canopy, Mask, Flowmeter
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)	Q-NRG unit, Canopy Hose, Headcap

[Table 3] [5]

*** Single use items are not listed as they are meant to be disposed immediately after use thus not undergoing any reprocessing procedures.

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

References and Bibliography

[1] Barazzoni R et al., ESPEN expert statements and practical guidance for nutritional management of individuals with SARS-CoV-2 infection, Clinical Nutrition, https://doi.org/10.1016/j.clnu.2020.03.022

[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" section of user manuals complies with EN ISO 17664, Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices.

[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. In: Proceedings of the International Conference on Nosocomial Infections, 1970. Chicago, IL: American Hospital Association; 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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