F&P **Optiflow**

Optiflow Nasal High Flow: Daily-use for multiple patients

Confidence to multi-use your nasal high flow system with the FDA-cleared daily patient use Optiflow Oxygen Kit and filtered nasal interface.

When used with a filtered nasal interface, AA403 is multiple patient use for a maximum of 24 hours after set up. Cleaning and disinfection is required between each patient, the AA403 can be cleaned and disinfected up to a maximum of 30 times.









AA403 Optiflow Oxygen Kit

When used with an FDA cleared hydrophobic filter and interface, the AA403 cleaning and low-level disinfection have been validated. Cleaning and disinfection validation testing was completed as per the standards: Advancement of Medical Instrumentation (AAMI) TIR30:2011 and AAMI TIR12 by an independent, US Based laboratory – Nelson Laboratories, Salt Lake City, Utah. Testing includes realistic, worst-case inoculation of test samples with representative test soils. Reprocessing is completed as per the instructions for use and the residual soil is extracted and measured.



Cleaning

Test	Result
Carbohydrate test	0.28 μg/cm²
(Maltodextrin)	(acceptance criteria < 1.8 μg/cm²)
Micro BCA protein test	0.11 μg/cm²
(Albumin)	(acceptance criteria < 6.4 μg/cm²)

Note: the acceptable residual carbohydrate and protein levels for flexible endoscopes are 1.8 and 6.4 μ g/cm² respectively.

Disinfection

Test		Result	
Bioload reduction	K. pneumoniae	Log 6.9 reduction 99.999988% (Beyond detection limit)	
	P. aeruginosa	Log 6.3 reduction 99.999939%	
	E. coli	Log 6.7 reduction 99.99998% (Beyond detection limit)	
	S. aureus	Log 7 reduction 99.999989% (Beyond detection limit)	

AA031J Optiflow Filtered Nasal Interface with CO₂ Sampling

(featuring a pleated hydrophobic high efficiency particulate air filter)

The AAO31J interface filter has been tested as per and in accordance with standards for particulate, bacterial and viral filtration efficiency according to ISO 23328-1 and a method adapted from ASTM F2101. Testing was undertaken at a qualified, independent facility that develops specific protocols in line with ISO or ASTM standards to simulate the types of challenges that a filter may be subjected to in clinical settings.

The filter media's hydrophobic properties enable it to repel fluids that may accumulate during the delivery of humidification. The hydrophobicity ensures filtration efficiency is maintained to prevent the risk of contamination that may be caused by fluid passing through the system.

Test Method Test Material		Size	Filtration Efficiency
ASTM F2101-14 (bacterial)	Staphylococcus Aureus Bacteria	3.0 <u>+</u> 0.3 μm	99.999%
ASTM F2101-14 (viral)	Phi X174 Virus	3.0 <u>+</u> 0.3 μm	99.996%
ISO 23328-1	Sodium Chloride Particles	0.26 µm	99.974%





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