



BHC SUCTION CANISTERS Virus Filter Efficiency

Thank you for your recent inquiry regarding Bemis Health Care's Suction Canisters virus filter efficiency, and its ability to minimize aerosolizing of the virus from the canister. We understand the increased concern most recently related to COVID-19, but at this time, we are not aware of any actual testing against the COVID-19 bacteria. However, the following information may help you with regards to Bemis Suction Canisters, and testing that has been performed.

Bemis Suction Canisters

Bemis manufactures two different lids for our canisters, each with a different shutoff mechanism.

- **Bemis Hi-Flow Canisters** (green lid) use a *mechanical shutoff mechanism* to shut the vacuum off when the canister is full of fluid. The cover then has a separate filter on the vacuum line to prevent contamination of the vacuum line.
- **Bemis Hydrophobic Canisters** (red lid) use a *hydrophobic media* to shut the vacuum off when the canister is full of fluid. This hydrophobic media acts as a filter, while there is a second filter in place to prevent premature shut off.

HEPA

Bemis products have not been tested against the HEPA standard, but please keep in mind that HEPA means it will need to filter out 99.97% of the particles 0.3 micron in diameter. The HEPA standard does not evaluate the filtration of bacteria or viruses.

Bacterial Testing

Both canister types have undergone bacteria filtration testing against Staphylococcus Aureus, Escherichia Coli and Pseudomonas Aeruginosa. The Hi-Flow and Hydrophobic containers tested their filtration efficiency at 99.9998% and 99.9999%, respectively.

The bacteria tested included:

1. Staphylococcus Aureus: 0.1 to 0.25 micron in width by 1 to 1.5 micron in length (Source: Britannica)
2. Escherichia Coli: 1-2 micron long with radius of 0.5 micron (Source: NCBI)
3. Pseudomonas Aeruginosa: 0.5 to 0.8 micron by 1.5 to 3 micron (Source: NCBI)

Virus Testing

The hydrophobic filter media used in the Bemis Hydrophobic Canisters has undergone filtration testing against a representative virus (bacteriophage jX174). The tested filtration efficiency was >99.9%.

The virus tested included:

1. Bacteriophage jX174: 0.017 micron (Source: Bionumbers)

COVID-19

As we all understand, many questions exist regarding COVID-19. From what we have found online, the estimated diameter of the COVID-19 bacteria is approximately 0.125 micron. (Source: National Library of Medicine)

For more information regarding **Bemis Hi-Flow and Hydrophobic Suction Canisters**, please visit our website at www.bemishealthcare.com or click <https://www.bemishealthcare.com/products/suction-canisters/>



Title: Declaration of Conformance

Author: David Howell

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Declaration of Conformance

Bemis Suction Canisters, Suction Liner System and Specimen Adaptor conform to the applicable Essential Requirements of EC Council Directive 93/42/EEC as amended by Directive 2007/47/EC according to Annex VII concerning Medical Devices.

Device Classification: Class I (Non-sterile, non-measuring) Rule 1

Route to Compliance: Annex VII

Standards Applied; ISO 10079-3 2014

Manufacturer: Bemis Manufacturing Company, 300 Mill St. Sheboygan Falls, WI 53085 USA

Quality Management Representative: John Cutting Telephone 920-467-4621

Authorized Representative: EMERGO EUROPE, Prinsessegracht 20, 2514 AP The Hague, The Netherlands

Product Type, Model Numbers and Description

Rigid Suction Canisters and Kits		
Model Number	Product Trade Name	Description
006772-901	BEMIS HI-FLOW	3000cc Hi-Flow Rigid Canister with 18" Tubing
0502-100-000	FLUID SAFE	3000cc Hi-Flow Rigid Canister with 18" Tubing
3002 055	BEMIS HI-FLOW	3000cc Hi Flow Rigid Canister
3025 055	BEMIS HI-FLOW	3000cc Hi-Flow Rigid Canister with 18" Tubing
424410	BEMIS HYDROPHOBIC	800cc Hydrophobic Rigid Canister
424410 10	BEMIS HYDROPHOBIC	800cc Hydrophobic Rigid Canister
434410	BEMIS HYDROPHOBIC	1200cc Hydrophobic Rigid Canister
484410	BEMIS HI-FLOW	1200cc Hi-Flow Rigid Canister
484410 12	BEMIS HI-FLOW	1200cc Hi-Flow Rigid Canister
485410	BEMIS HI-FLOW	1200cc Hi-Flow Rigid Canister with 18" and 6' Tubing
494410	BEMIS HI-FLOW	2000cc Hi-Flow Rigid Canister
5450-851-012	BEMIS HYDROPHOBIC	2000cc Hydrophobic Rigid Canister
72200024	BEMIS HI-FLOW	3000cc Hi-Flow Rigid Canister
8002 055	BEMIS HI-FLOW SOLO	800cc Hi-Flow Rigid Canister
8002K 055	BEMIS HI-FLOW SOLO	800cc Hi-Flow Rigid Canister with 6' Tubing
883001	BEMIS HI-FLOW	1200cc Hi-Flow Rigid Canister
AQL-BEMIS	BEMIS HI-FLOW	3000cc Hi-Flow Canister with tubing & specimen adaptor
B1605	BEMIS HI-FLOW	1200cc Hi-Flow Rigid Canister
MCANISTER1	BEMIS HI-FLOW	800cc Hi-flow Rigid Canister

Suction Liner System		
Model Number	Product Trade Name	Description
1500	BEMIS QUICK-FIT	1500cc Quick-Fit Outer Canister
1500SC	BEMIS QUICK-FIT	1500cc Quick-Fit Outer Canister with Stopcock
1504	BEMIS QUICK-FIT	1500cc Quick-Fit Suction Liner
3000	BEMIS QUICK-FIT	3000cc Quick-Fit Outer Canister
3000SC	BEMIS QUICK-FIT	3000cc Quick-Fit Outer Canister with Stopcock
3004	BEMIS QUICK-FIT	3000cc Quick-Fit Suction Liner



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Specimen Adaptor

Model Number	Product Trade Name	Description
533510	BEMIS SPECIMEN ADAPTOR	Specimen Adaptor
533810	BEMIS SPECIMEN ADAPTOR	Specimen Adaptor
7209824	BEMIS CANISTER ACCESSORIES KIT	Specimen Adaptor Kit with 4 pieces of 18" Tubing
72203257	BEMIS SINGLE JUMPER CABLE PROCEDURE KIT	Specimen Adaptor Kit with 1 piece of 18" Tubing

We declare that Bemis Suction Canisters, Suction Liner Systems and Specimen Adaptor meet the provisions of the EC Council Directive 93/42/EEC as amended by Directive 2007/47/EC according to Annex VII concerning Medical Devices and the Essential Requirements which apply to them.

Company Representative: David P. Howell

Title: Corporate Counsel

Signature: _____

Date: _____

9-5-19