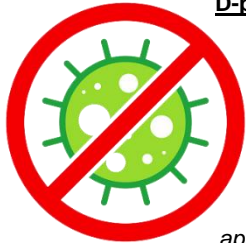




Dear Valued coVita Clients,

At coVita we strive to ensure that we utilize the industry leading infection control technologies and practices. The following information is intended to provide you with specifics about our products in relation to the concerns about the Coronavirus (**COVID-19 / SARS-COV-2**).

**UPDATES:**



**D-pieces™ Valves & OneBreath™ Mouthpieces:** Our **D-piece™** and **OneBreath™** filters have been independently tested for prevention of cross infection. We are happy to announce based on this data Bedfont concluded that bacterial and viral pathogens including (**COVID-19 / SARS-COV-2**) will effectively be removed by the **D-piece™** and **OneBreath™** filter at an efficiency rate of >99% (bacteria) and >97% (viruses).

In the tests carried out on the viral and bacterial filter contained in the **D-piece™ & OneBreath™**, the virus model used for tests (M2-Coliphage) are similar in size as the smallest human viruses (as small as 24 nanometers in diameter<sup>1</sup>), so that they can test the efficiencies of the filters for removing human viruses from air streams. The model virus (M2-Coliphage) is approximately 24-26 nanometers in size<sup>1</sup> in comparison to COVID-19 virus which is approximately 125 nanometers in size.<sup>2</sup>

**D-piece™:** one-way valve and an infection control filter can be used for a continuous 30 days in conjunction with single-patient-use SteriBreath™ mouthpieces.

**OneBreath™:** mouthpiece with an incorporated one-way valve and infection control filter is a single-patient use mouthpiece which replaces both the SteriBreath™ mouthpiece and the D-piece™ for the ultimate infection control.

**SteriBreath™ Mouthpieces:** The single use SteriBreath™ mouthpieces are individually wrapped for ease of handling and greater infection control.

**Monitor Wipes:** The wipes provided with the breath monitors have been tested by the supplier and found effective against (**COVID-19 / SARS-COV-2**), as the product shows efficacy against feline coronavirus, a surrogate coronavirus (for **COVID-19 / SARS-COV-2**). As standard practice, Bedfont® recommends that the monitors are wiped down with the alcohol-free antibacterial/viral wipes, provided with the monitor, after each breath test. According to the manufacturer, they are effective against the following pathogens (Table 1).

**Additional Information:**

**Steritouch®:** The surface of your monitor(s) (Micro+ pro, baby, basic, piCO+™ Smokerlyzers®, Gastro+™, ToxCO®) have an added material known as Steritouch®, an antimicrobial product, offers protection against a range of bacteria including E.coli, MRSA, Salmonella and Legionella, as well as black mold growth, biofilm and fungi<sup>3</sup>. Statement from Steritouch® manufacturer states “Coronavirus COVID-19 is an enveloped virus, so called because of its fatty outer membrane or ‘envelope’. Several of the active substances we use have been successfully tested against other enveloped viruses, such as Influenza, Avian flu, and SARS. It would be reasonable to imply that those same active substances would be effective against COVID-19, but at this stage testing against COVID-19 is not available<sup>4</sup>.”

**Foaming Hand Sanitizer:** The hand sanitizer provided by coVita is alcohol-free and according to the manufacturer, they are effective against the following pathogens including Human Coronavirus (Table 2). There is no information on their effectiveness specifically against COVID-19.

Keep in mind the following common-sense precautions and additional information:

- **Do not test ill individuals:** If you know or suspect (based on symptoms) that a person that you would like to offer the breath test to has COVID-19, you should probably avoid the test until they are well. This would generally be advisable for any patients exhibiting cold/flu-like symptoms, not only those with confirmed or suspected COVID-19 infections.
- **Stand off to the side for the test:** You should not stand in front of a person taking the test, as this would place you directly in the stream of air exiting the breath monitor. Stand off to the side as you administer the test regardless of whether you hold the monitor during the test or you let the test subject hold the monitor.
- **Wear gloves and/or sanitize your hands:** You can wear gloves to handle the monitor or if you do not wear gloves, be sure to wash your hands thoroughly or sanitize your hands with approved hand sanitizers when handling the monitor after a breath test. Hand washing/sanitizing would probably be a best practice under most circumstances.
- **Wipe down the monitor:** Do this before (if you do not know whether it was wiped down after the last test) and after each use with an approved sanitizer wipe, but **DO NOT SATURATE THE MONITOR WITH EXCESS LIQUID OR ALLOW EXCESS LIQUID TO POOL IN THE SEAMS OF THE MONITOR CASING, AS THIS WILL DAMAGE THE MONITOR AND VOID YOUR WARRANTY.**
- **Avoid touching face:** Avoid touching your eyes, nose, and mouth, particularly prior to washing/sanitizing your hands.

Sincerely,





Daniel M. Sibis  
Regulatory Affairs



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(Table 1) Wipe Clinical Efficacy Data

	Standard	Test Organisms	Contact Time
<b>Medical</b> Healthcare  Laboratories 	EN 16615	<i>Pseudomonas aeruginosa</i>	5 minutes
	EN 16615	<i>Staphylococcus aureus</i>	5 minutes
	EN 16615	<i>Enterococcus hirae</i>	5 minutes
	EN 16615	<i>Candida albicans</i>	5 minutes
	EN 13727	<i>E.coli</i>	5 minutes
	EN 13727	<i>Legionella pneumophila</i>	5 minutes
	EN 13727	<i>Listeria monocytogenes</i>	5 minutes
	EN 13727	<i>Pseudomonas aeruginosa</i>	5 minutes
	EN 13727	<i>Staphylococcus aureus</i>	5 minutes
	EN 13727	<i>Enterococcus hirae</i>	5 minutes
	EN 13727	Vancomycin Resistant <i>Enterococcus</i> (VRE)	5 minutes
	EN 13727	MRSA	5 minutes
	EN 13624	<i>Candida albicans</i>	15 minutes
	EN 14476	Hepatitis C (BVDV)	5 minutes
	EN 14476	Feline Calicivirus (Human Norovirus surrogate)	5 minutes
	EN 14476	Feline Coronavirus	5 minutes

	Standard	Test Organisms	Contact Time
<b>General Purpose</b> Hospitality  Industry 	EN 1276	<i>E.coli</i>	5 minutes
	EN 1276	<i>Salmonella enterica</i>	5 minutes
	EN 1276	<i>Klebsiella pneumonia</i>	5 minutes
	EN 1276	<i>Pseudomonas aeruginosa</i>	5 minutes
	EN 1276	<i>Staphylococcus aureus</i>	5 minutes
	EN 1276	<i>Enterococcus hirae</i>	5 minutes
	EN 1276	<i>Candida albicans</i>	5 minutes



**(Table 2) Foaming Instant Skin Sanitizer Efficacy Data**

**In-Vitro Antimicrobial Test Procedures and Protocols:**

1. Each test organism was grown overnight on Trypticase-soy agar slants at 35°C. Cell suspensions were prepared by adding 10mL sterile saline (0.9%) to each slant and gently scraping the slant surface. Microbial densities of each cell suspension were estimated using the viable plate count method.
2. Test product (1mL) was aseptically added to sterile test tubes and then inoculated with a 1:10 dilution of a cell suspension (100 µL) of the test organism. At selected time intervals (0.5, 1.0 and 2.0 minutes), aliquots (10 µL) were aseptically removed and transferred to a Trypticase-soy broth recovery medium (10mL). Microbial growth was monitored by the development of turbidity in the recovery medium.

**Test Results:**

Foaming Skin Sanitizer with 0.13% Benzalkonium Chloride exhibited strong germicidal activity against a variety of gram-positive and gram-negative bacteria, as well as the yeast *Candida albicans*. In most instances viable cell numbers were reduced by greater than 99.99% after a 30-second exposure period with this product.

**In-vitro Antimicrobial Efficacy for Foaming Skin Sanitizer with 0.13% Benzalkonium Chloride**

Organism Type	Test Microorganisms	Initial Inoculum (cfu/10µL)	Exposure Time (Minutes)			Reduction (percent)*
			0.5	1.0	2.0	
Gram Neg -	<i>Pseudomonas aeruginosa</i>	3.39 x 10 <sup>5</sup>	-	-	-	99.99
Gram Neg -	<i>Klebsiella pneumoniae</i>	2.76 x 10 <sup>5</sup>	-	-	-	99.99
Gram Neg -	<i>Escherichia coli</i>	15.8 x 10 <sup>5</sup>	-	-	-	99.99
Gram Neg -	<i>Salmonella typhimurium</i>	18.9 x 10 <sup>5</sup>	-	-	-	99.99
Gram Pos +	<i>Staphylococcus aureus</i> ATTC33591	21.2 x 10 <sup>5</sup>	(Methicillin Resistant / MRSA)			99.99
Gram Pos +	<i>Staph. epidermidis</i>	18.3 x 10 <sup>5</sup>	-	-	-	99.99
Gram Pos +	<i>Streptococcus faecalis</i> ATTC522A	9.8 x 10 <sup>5</sup>	(Vancomycin resistant enterococci / VRE)			99.99
Gram Pos +	<i>Streptococcus agalactiae</i>	12.1 x 10 <sup>5</sup>	-	-	-	99.99
Gram Pos +	<i>Micrococcus luteus</i>	14.4 x 10 <sup>5</sup>	-	-	-	99.99
Yeast	<i>Candida albicans</i>	12.6 x 10 <sup>5</sup>	-	-	-	99.99
Fungi	<i>Trichophyton mentogrophytes</i> (Athlete's Foot)	9.6 x 10 <sup>5</sup>	-	-	-	99.99
Gram Neg -	<i>Salmonella choleraesuis</i>	14.1 x 10 <sup>5</sup>	-	-	-	99.99
Fungi	<i>Aspergillus niger</i>	11.8 x 10 <sup>5</sup>	-	-	-	99.99
Gram Pos +	<i>Listeria monocytogenes</i>	17.9 x 10 <sup>6</sup>	(30 seconds)			0 survival CFU/mL
Gram Pos +	<i>Clostridium difficile</i>	1.1 x 10 <sup>4</sup>	(15 seconds)			0 survival CFU/mL

(\*) Indicates percentage reduction in numbers of viable cells evidenced by lack of growth in Trypticase-soy Broth medium.

(-) Indicates no survival of test organisms in the recovery medium.

<b><i>In Vitro Virucidal Tests</i></b>	<b>Results</b>
Human Coronavirus (resembles SARS-like virus family) (Microbio Test, Inc. – USA)	The product showed virucidal efficacy on all test-viruses.
Influenza virus-A H3N2 (BioScience Labs – USA)	The product showed virucidal efficacy on all test-viruses.

Unless noted, all test performed by Chembac Laboratory – USA