Letter from Bosch Healtcare Solutions GmbH
to our sales partners

Brief der Bosch Healthcare Solutions GmbH
an die Vertriebspartner

Deutsche und portugiesische Sprachversion siehe unten

Dear Vivatmo User,

Due to the current Corona crisis, we are receiving an increasing number of queries related to the virus filtration rate of Vivatmo oxycaps (disposable mouthpieces). We would therefore like to issue the following information:

During the entire service life of three (Vivatmo me) or five years (Vivatmo pro), the bacteria and virus filter of the mouthpiece (99.9978% BFE and 99.960% VFE) counteracts any contamination of the inner workings of the device. Test reports on this can be found in the appendix.

In addition, after the bacteria and virus filter the exhaled air passes through a drying filter, which removes moisture from the exhaled air flowing through it and thus counteracts the growth of microorganisms in the device. The use of a valve in the gas pipe system also prevents the inhalation of air from the unit. This reduces the probability of infection to a minimum. Based on these measures, the product can be classified as low microbiological risk.

To prevent infection, we recommend wearing disposable gloves (CE category II), as well as disposing of mouthpieces immediately after measurement.

Yours sincerely,

Bosch Healthcare Solutions GmbH

Registered Office: Waiblingen, Registration Court: Amtsgericht Stuttgart HRB 728499
Managing Director: Marc Meier, Markus Thürsam
BOSCH und die Bildmarke sind registrierte Marken der Robert Bosch GmbH, Stuttgart

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Sehr geehrte Vivatmo-Nutzer,

aufgrund der aktuellen Corona-Krise erreichen uns vermehrt Anfragen zur Virenfiltrationsrate der Vivatmo *oxycaps (*Einweg-Mundstücke), daher möchten wir Ihnen wie folgt mitteilen:

Einer Verkeimung des Geräte-Innenlebens wird während der gesamten Nutzungsdauer von drei (Vivatmo *me*) bzw. fünf Jahren (Vivatmo *pro*) durch den Bakterien- und Virenfilter des Mundstückes (99,9978 % BFE und 99,960 % VFE) entgegengewirkt. Diesbezüglich finden Sie Testreports im Anhang.

Zudem ist dem Bakterien- und Virenfilter ein Trocknungsfilter nachgeschaltet, welcher der durchströmten Ausatemluft die Feuchtigkeit entzieht und damit dem Wachstum von Mikroorganismen im Gerät entgegenwirkt. Über den Einsatz eines Ventils im Gasleitungssystem, wird weiterhin verhindert, dass Luft aus dem Gerät inhaliert werden kann. Dadurch wird die Wahrscheinlichkeit von Infektionen auf ein Minimum reduziert. Ausgehend von diesen Maßnahmen, ist das Produkt als mikrobiologisch risikoarm einzustufen.

Als Infektionsprävention empfehlen wir das Tragen von Einweg-Handschuhen (CE-Kategorie II) sowie die Entsorgung der Mundstücke direkt nach der Messung.

Mit freundlichen Grüßen,

Bosch Healthcare Solutions GmbH

Registered Office: Waiblingen, Registration Court: Amtsgericht Stuttgart HRB 728499
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Carta da Bosch Healthcare Solutions GmbH
aos parceiros de vendas

Caro utilizador do Dispositivo Vivatmo,

Devido à atual pandemia causada pelo virus Covid-19, temos recebido alguns pedidos referentes à capacidade de filtragem dos bocais descartáveis Oxycaps para o Dispositivo Vivatmo. Desta forma emitimos a seguinte informação:

Durante a vidad útil do Vivatmo Me (3 anos) ou Vivatmo Pro (5 anos), os bocais Oxycap têm a capacidade de filtrar virus e bactérias de 99.9978% BFE and 99.960% VFE, neutralizando qualquer contaminação para o funcionamento do dispositivo. Os relatórios de teste podem ser encontrados em anexo.

Acrescentando à informação anterior, de que após filtrar bacte´rias e virus, o ar exalado passa por um outro filtro de secagem, que remove a humidade do ar neutralizando o possivel crescimento de microrganismos nos dispositvo. A existência de uma valvula nos Sistema de tubulação de gás, também Evita a inalação de ar da unidade, reduzindo a probabilidade de infecção oa mínimo. Com base nestes pressuposto o dispositivo pode ser classificado de baixo risco microbiológico.

Para prevenir a infecção recomendamos a utilização de luvas descartáveis (categoria CE II) bem como o descartar dos bocais oxycap imediatamente após utilização.

Com os Melhores Cumprimentos,

Bosch Healthcare Solutions GmbH

Registered Office: Waiblingen, Registration Court: Amtsgericht Stuttgart HRB 728499
Managing Director: Marc Meier, Markus Thürsam
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NELSON LABORATORIES

Sponsor:
Heike Vogel
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GERMANY

Bacterial Filtration Efficiency (BFE) at an Increased Challenge Level GLP Report

Test Article: C7.2 Samples BFE125
Study Number: 937247-S01
Study Received Date: 27 Dec 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0009 Rev 09

Summary: This procedure was performed to evaluate the BFE at an increased challenge level of the test article. A suspension of *Staphylococcus aureus*, ATCC #6538, was delivered to the test article to determine filtration efficiency. A challenge level of greater than 10^6 colony forming units (CFU) was pumped through a nebulizer using a peristaltic pump at a flow rate of 5 liters per minute (L/min) and fixed air pressure. The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) in parallel. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. The mean particle size (MPS) control was performed at a flow rate of 28.3 L/min.

This test procedure was modified from Nelson Laboratories, LLC (NL), standard BFE procedure in order to employ a more severe challenge than would be experienced in normal use. This method was adapted from ASTM F2101. NL has not performed validation using the flow rate performed in this testing, however, adequate controls are included to verify the reliability of this study. All test method acceptance criteria were met.

Challenge Flow Rate: 5 L/min
Area Tested: Entire Test Article
Side Tested: Mouth Piece
Challenge Level: 4.9×10^6 CFU
Mean Particle Size (MPS): ~3.1 µm

Results:

Test Article Number	Total CFU Recovered	Filtration Efficiency (%)
1	2.6×10^1	99.99947
2	9.3×10^1	99.9981
3	1.1×10^2	99.9978

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Challenge Level
T = Total CFU recovered downstream of the test article

Study Director Trang T. Truong, B.S.

19 JAN 2017
Study Completion Date

937247-S01

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Test Method Acceptance Criteria: The average MPS of the challenge aerosol at 28.3 L/min must be maintained at 3.0 ± 0.3 µm. The average BFE challenge level must be ≥1 x 10^6 CFU/test article when the flow rate is ≥30 L/min.

Procedure:

Challenge Preparation: Approximately 100 mL of soybean casein digest broth (SCDB) was inoculated with *S aureus*, ATCC #6538, and incubated with mild shaking for 24 ± 4 hours at 37 ± 2°C.

Challenge Procedure: The bacterial culture suspension was aerosolized using a nebulizer and delivered to the test article at a constant flow rate. The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into AGIs. The challenge was delivered for a 1 minute interval followed by a 1 minute vacuum cycle to clear the aerosol chamber. Positive control runs were performed (no medium in the test article holder) prior to the first test article, after every 5-7 test articles, and after the last test article to determine the average number of viable particles being delivered to each test article. The MPS of the challenge aerosol was determined using a six-stage Andersen sampler.

Assay Procedure: The titer of the AGI assay fluid was determined using standard plate count and/or membrane filtration techniques.

Plating: An aliquot of the test articles assay fluid was dispensed onto a soybean casein digest agar (SCDA) plate and spread using a sterile rod. The assay fluid was allowed to soak into the agar, and then inverted.

Membrane Filtration: A sterile filter funnel was placed on a manifold. A sterile 0.45 µm membrane was aseptically removed from the packaging and centered over the base of the funnel. An appropriate volume of the assay fluid was poured into the sterile filter funnel. The vacuum was applied to the apparatus in order for the assay fluid to be filtered under light suction. The membrane was then rinsed to ensure that all organisms were impinged onto the membrane. The membrane was removed from the filter funnel and placed onto the surface of a SCDA plate.

All plates were incubated at 37 ± 2°C for 48 ± 4 hours prior to counting.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	09 Jan 2017
Phase Inspected by Quality Assurance: Challenge Procedure	11 Jan 2017
Audit Results Reported to Study Director	16 Jan 2017
Audit Results Reported to Management	17 Jan 2017

Scientists	Title
Adam N. Meese	Supervisor
Trang T. Truong	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Quality Assurance

18 JAN 2017
Date

NELSON LABORATORIES

Sponsor:
Heike Vogel
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GERMANY

Viral Filtration Efficiency (VFE) at an Increased Challenge Level GLP Report

Test Article: C7.2 Samples VFE125
Study Number: 937246-S01
Study Received Date: 27 Dec 2016
Test Procedure(s): Standard Test Protocol (STP) Number: STP0010 Rev 10

Summary: This procedure was performed to evaluate the VFE at an increased challenge level of the test article. A suspension of ΦX174 bacteriophage was delivered to the test article to determine filtration efficiency. A challenge level of greater than 10^6 plaque-forming units (PFU) was pumped through a nebulizer using a peristaltic pump at a flow rate of 5 liters per minute (L/min) and a fixed air pressure. The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) in parallel. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber. The mean particle size (MPS) control was performed at a flow rate of 28.3 L/min. The VFE at an Increased Challenge Level test procedure was adapted from ASTM F2101.

This test procedure was modified from Nelson Laboratories, LLC (NL), standard VFE test in order to employ a more severe challenge than would be experienced in normal use. NL has not performed validation using the flow rate performed in this testing, but adequate controls are included to verify the reliability of this study. All test method acceptance criteria were met.

Challenge Flow Rate: 5 L/min
Area Tested: Entire Test Article
Side Tested: Mouth Piece
Challenge Level: 2.0×10^6 PFU
Negative Monitor Count: <1 PFU
Mean Particle Size (MPS): ~2.7 µm

Results:

Test Article Number	Total PFU Recovered	Filtration Efficiency (%)
1	5.1×10^2	99.974
2	8.0×10^2	99.960
3	5.0×10^2	99.975

The filtration efficiency percentages were calculated using the following equation:

$$\%\,VFE = \frac{C - T}{C}\, x\, 100$$

C = Challenge Level
T = Total PFU recovered downstream of the test article

Study Director Trang Truong Trang T. Truong, B.S.

16JAN2017
Study Completion Date

937246-S01

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Test Method Acceptance Criteria: The average MPS of the challenge aerosol at 28.3 L/min must be maintained at 3.0 ± 0.3 µm. The average VFE challenge level must be ≥1 x 10^6 PFU/test article when the flow rate is ≥30 L/Min.

Procedure:

Challenge Procedure: The viral culture suspension was aerosolized using a nebulizer and delivered to the test article at a constant flow rate. The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into AGIs. The challenge was delivered for a one minute interval followed by a one minute vacuum cycle to clear the aerosol chamber. Positive control runs were performed (no medium in the test article holder) prior to the first test article run, after every 5-7 test articles, and after the last test article to determine the average number of viable particles being delivered to each test article. The MPS of the challenge aerosol was determined using a six-stage Andersen sampler.

Plaque Assay Procedure: The titer of the AGI assay fluid was determined using standard plaque assay techniques. Approximately 2.5 mL of molten top agar was dispensed into sterile test tubes and held at 45 ± 2°C in a waterbath. An aliquot of the assay fluid from the test article was added to the sterile test tubes along with approximately 0.1mL of an *E. coli* culture. The contents were mixed and poured over the surface of bottom agar plates. The agar was allowed to solidify on a level surface and the plates were incubated at 37 ± 2°C for 12-24 hours.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	09 Jan 2017
Phase Inspected by Quality Assurance: Counting Procedure	13 Jan 2017
Audit Results Reported to Study Director	13 Jan 2017
Audit Results Reported to Management	13 Jan 2017

Scientists	Title
Adam Meese	Supervisor
Trang Truong	Study Director

Data Disposition: The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Quality Assurance

16 Jan 2017
Date