CardioPulmonary Review

MicroGard® II

Next generation Pulmonary Filter with validated filter and equipment performance

MicroGard® IIB

MicroGard® IIC

The use of pulmonary filters is becoming more and more a mandatory requirement in Respiratory Care departments throughout the world to be able to comply with the more stringent hygiene standards in hospitals. Hospital acquired infections are one of the reasons why the cost of healthcare is increasing and in the Respiratory Care field the use of validated pulmonary filters is an efficient measure to prevent contamination. Pulmonary filters do not only prevent contamination of the equipment by potential pathogen transmission via the patient's exhaled air but also prevent patient cross contamination. Furthermore it protects the staff from coming in direct contact with the exhaled air during the breathing manoeuvres.

CareFusion has been manufacturing the MicroGard® filter for over a decade. The MicroGard® filter has been used in combination with pulmonary instrumentation from CareFusion's strong brands JAEGER, SensorMedics® and Micro Medical. The growing demand for cost control and increased hygiene guidelines for medical devices were key drivers for the development of the new MicroGard® II filter.

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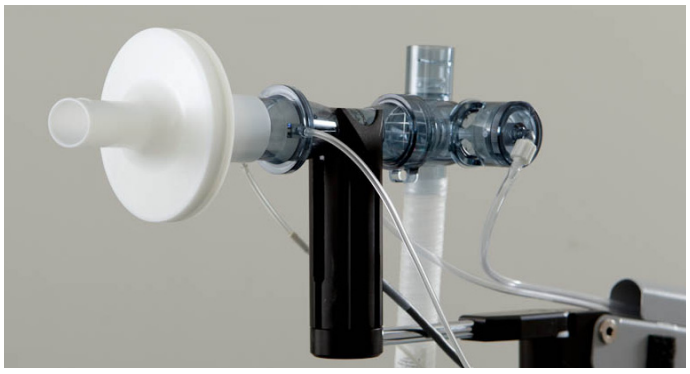
Introduction

The use of pulmonary filters on lung function equipment has an impact on the characteristics of the equipment. Filter dead space, resistance and filter material properties all play an important role in this. Filter properties depend on the right balance between thickness and area of the filter material. This determines the resistance the patient is experiencing, when exhaling and inhaling through the filter. A viral or bacterial efficacy of 99.9999% can be obtained but most likely the resistance will be unacceptably high. The MicroGard® II has been designed to optimise this trade off and is the only filter that has gone through a full verification and validation process together with the Medical Equipment it is used on hence we can guarantee optimum measurement performance of the CareFusion's JAEGER, SensorMedics® Vmax and Micro Medical Pulmonary Instrumentation. As stated, filters do influence the equipment's characteristics and where applicable our linearization tables for the flow sensors are corrected to generate the most accurate measurement results when the MicroGard® II filter is used. This level of accuracy cannot be guaranteed when other, none validated, filters are used in combination with CareFusion equipment.

MicroGard® IIB Pulmonary Laboratory Setting with Filter by MasterScreen

A new manufacturing facility has been created to ensure an optimum manufacturing environment for the filter production. When you order the CareFusion MicroGard® II filter, you get a product that has been produced using the highest quality materials, stringent manufacturing standards, and extensive quality control measures. Quality systems in CareFusion Respiratory Systems division at our manufacturing facilities are certified to meet ISO 9001 and EN 46001 standards. The MicroGard® II filter material has been tested for Biocompatibility[i].



MicroGard® IIB Pulmonary Laboratory Setting with Filter by Vmax

Independent Testing[ii]

A recently performed series of scientific tests of the MicroGard® II filters was carried out at Nelson[ii] Laboratories, Salt Lake City, Utah, USA and Health Protection Agency Porton Down, UK.

Nelson Laboratories performed hundreds of bacterial removal efficiency tests every week using standardised operating procedures (SOP). The use of SOP's are for both the manufacturer and the customer a proof of reliable independent testing to verify the filter's performance. The Standard Operating Procedure used comprises the following key elements:

- A constant flow of aerosol at a rate of 30 litres per minute
- A mean particle size must be maintained at 3.0 +/- 0.3 µm in accordance with ASTM F2101[iii]
- An additional test at a rate of 750 litres per minute at HPA
- Testing several filter samples to ensure the efficiency is consistent between different filters.

The Health Protection Agency, Porton Down (HPA) has the ability to test the efficiencies of many types of microbiological filters using their small test rig facility. This rig is based on an apparatus developed originally by Henderson and Druett[iv] to study experimental airborne infection, where a suspension of micro-organisms in aqueous solution is nebulised by a 3-jet Collision spray forming a fine aerosol containing viable micro-organisms.

Filter Material

The proprietary filter material used in the MicroGard® II is a special blend of polymers with a highly stable electrostatic charge due to its unique composition. The filter material consistently achieves high efficiencies by deploying both the electrostatic charge as well as mechanical mechanisms to remove airborne particles. The high efficiency of the charged material allows for a more open matrix of fibres, this results in a minimal restriction to the airflow. Most filtration materials use surface loading as the primary means of removal. With the material used in the MicroGard® II product, the fibre matrix results in depth loading, where particles are captured throughout the entire filter material, not just on the surface. The filter material is composed of polymer fibres that will not support the growth of mould mildew, fungus or bacteria. This material also is resistant to degradation over time and is able to withstand extreme temperature and humidity.

Bacterial/Viral Efficiency

It is important to know that the viral filtration efficiency was performed using the bacteriophage virus which, at 0.027 microns, is one of the smallest known viruses. It is considered to represent a severe challenge to the filter material due to its diminutive size and morphology. In comparison, the HIV virus is 0.042 microns while the Hepatitis C is 0.03 microns. Bacteria such as Tuberculosis, by contrast, are much larger in size than viruses.

Filter Variations

The MicroGard® II comes in 2 filter variations.

1. The MicroGard® IIB with integrated oval mouthpiece; the unique positioning support (design patent pending DE202010009616U1) on the integrated oval mouthpiece is assisting the patient with the correct positioning of the teeth/lips to avoid air leakage around the lips.

2. The MicroGard® IIC with round connector for use in combination with a separate mouthpiece.

MicroGard® IIC in combination with the Free Flow Mouthpiece

The picture above shows the unique free flow mouthpiece. This mouthpiece ensures that the tongue is not affecting the measurements. This mouthpiece can improve the reproducibility between measurements especially with lung resistance related measurement.

The filter performance specifications are identical.

Flow Rate

It is crucial for the clinician to be aware that the bacterial filtration efficiency (BFE) and viral filtration efficiency (VFE) are correlated to the basis weight of the filter media, which is also correlated to the flow resistance, referred as the Delta P (ΔP). As the base weight increases, the filtration efficiencies are higher and so is the Delta P. The scientific challenge therefore is to obtain the best possible BFE and VFE efficiency without jeopardising a higher Delta P.

Specifications of the MicroGard® II Filter

Measurement Quality with optimum performance balance

- Inspiratory Resistance: <0.04 kPa/LPS at 1 L/S (<0.4 cmH2O/L/s at 1 L/S)
- Expiratory Resistance: <0.04 kPa/LPS at 1 L/S (<0.4 cmH2O/L/s at 1 L/S
- Filtering Efficiency: %BFE >99,999 (Nelson Test Lab at 30 L/min)[ii] %VFE >99,9924 (Nelson Test Lab at 30 L/min)[ii] %BFE & %VFE >96% (Health Protection Agency Test Lab at 750 L/min
- Filter effective dead space volume: 55 mL, including adapters and housing

Conclusion

Based upon the scientific test results conducted by Nelson Laboratories and Health Protection Agency, the MicroGard® II Filter proves to have the combination of greatest filtration efficiency with lowest resistance (Delta P) to airflow. Based on CareFusion's validation and verification processes MicroGard® II does not compromise equipment measurement characteristics. We recommend using only MicroGard® II filters in combination with CareFusion JAEGER MasterScreen, SensorMedics® Vmax and Micro Medical pulmonary instrumentation.

Ordering information

V-892381	MicroGard® IIB 50 pack
V-892382	MicroGard® IIB 100 pack
V-892384	MicroGard® IIC 50 pack
V-892385	MicroGard® IIC 100 pack
V-861449	Silicon adapter oval for volume calibration MicroGard® IIB
852740	Silicon sleeve (60 mm) for volume calibration MicroGard® IIC
MFA1010	Adapters MicroGard to MicroMedical, pack of 10
MFA1050	Adapters MicroGard to MicroMedical, pack of 50

i NAMSA has performed the following tests:
- ISO Intracutaneous Study - Extract
- Murine Local Lymph Nody Assay (LLNA) -(SC and DMSO Extracts)
- Cytotoxicity Study Using the ISO Elution Method (1X MEM Extract)

ii Nelson Report 10003754 - Viral Filtration Efficiency Test (VFE) at an Increased Challenge level GLP Report
Nelson Report 10003754 - Bacterial Filtration Efficiency Test (BFE) at an Increased Challenge level GLP Report
HPA Report 53/10 An evaluation of filtration efficiencies against bacterial and viral aerosol challenges.

iii ASTM F2101

iv HENDERSON, D. W. (1952): An apparatus for the study of airborne infections.
J. Hyg. Camb. 50, 53-67
DRUETT, H. A. (1969). A mobile form of the Henderson apparatus.
J. Hyg. Camb. 67, 437-448.

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V-781711
Version 01.00

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