MicroGard® II

Key Facts & Insights

JAEGER™

MicroGard® II filter - What you need to know

The use of disposable in-line filters for pulmonary function testing (PFT) has become standard practice in most facilities worldwide. Hospital acquired infections are one of the reasons why the cost of healthcare is increasing. In respiratory care the use of validated pulmonary filters is an efficient measure to prevent contamination. Not only do they prevent contamination of the equipment by potential pathogen transmission via the patient's exhaled air but also patient cross contamination. Furthermore, filters protect the staff from coming in direct contact with the exhaled air during the breathing maneuvers.

With regard to the COVID-19 pandemic, both the European Respiratory Society (ERS) and the American Thoracic Society (ATS) recommend pulmonary filters as a prerequisite when performing pulmonary function tests in order to comply with the strict requirements for infection prevention.[1]

This paper reviews the characteristics of the MicroGard® II filter with particular regard to mandatory infection prevention and technical requirements in pulmonary function testing.

Content

MicroGard® IIC with disposable mouthpiece during DLCO measurement

Introduction

When using filters on pulmonary function equipment, their impact on various parameters needs to be considered to ensure correct measurement results. Above all, these include:

- filter efficiency
- airflow resistance
- effective dead space of filter
- compliance with equipment

Efficiency versus resistance

The relation between thickness and area of the filter material determines the resistance the patient is experiencing on inhalation and exhalation. The challenge is to achieve an optimal balance between the best possible filtering effect and an acceptable resistance.

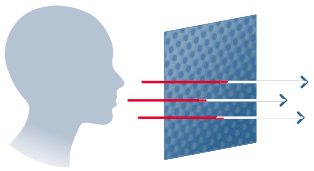
Bacterial Filtration Efficiency (BFE) and Viral Filtration Efficiency (VFE) are correlated to the basis weight of the filter media, which is also correlated to the flow resistance, referred as the delta P (ΔP). As the weight increases, the filtration efficiencies are higher and so is the delta P. The scientific challenge therefore is to obtain the best possible BFE and VFE without causing an excessive delta P.

MicroGard® IIC with disposable mouthpiece during body plethysmography

The MicroGard® II filter has been designed to address this trade off, achieving a high measurement quality with an optimum performance balance.

MicroGard® II airflow resistance:

< 100 Pa*s/L @ 14 L/s
(< 1,02 cmH2O*s/L)



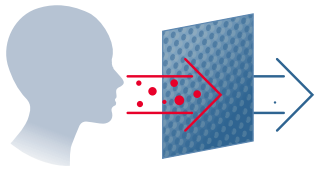
Airflow resistance for the complete breathing circuit:

According ATS[2] the total resistance to airflow @ 14 L/s must be <150 Pa*s/L (<1.53 cmH2O*s/L). The total resistance must be measured with any tubing, valves, pre-filter, etc. included that may be inserted between the subject and the spirometer.

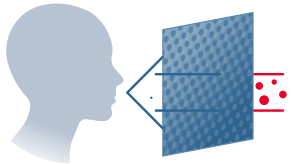
The total resistance for MicroGard® II filter + Vyntus™ Ultrasonic Sensor (USS) + FlowPath Valve (FPV) is <150 Pa*s/L (<1.53 cmH2O*s/L).

Filter efficiency against cross contamination:

The viral and bacterial efficiency is > 99.9999% (based on tests from external certified test lab[3])



MicroGard® II combines a high pathogen filter efficiency with a low total resistance of <150 Pa*s/L at an air flow of 14 L/s, which is according to the ATS recommended maximal limit.



Dead space

The minimal dead space contribution (only 55ml's) of the MicroGard® II filter helps Jaeger Diagnostic products achieve compliance with dead space recommendations put forth by the European Respiratory Society (ERS) and the American Respiratory Society (ATS).

Compliance testing with equipment

MicroGard® II filter is approved by the Food and Drug Administration (510(k) K111408) and the National Medical Products Administration (NMPA) 20152082110. In addition, MicroGard® II filter is fully compliant with the Medical Device Regulation (EU) 2017/745 (MDR).

Pulmonary filters are CE-certified medical devices of class IIa. In pulmonary function testing (PFT), they are used in combination with other CE-marked medical devices such as spirometers. It is mandatory for the manufacturer to demonstrate the conformity for the combination of different CE-marked medical devices.

Combination of CE-labelled medical devices

The interfaces of the individual components (medical devices) are to be examined, e. g. according to the standard EN 60601-1, and the whole system / treatment unit should be assessed based on a risk analysis, e.g. in accordance with the EN 14971 standard.

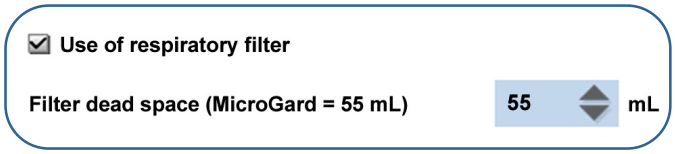
Our products and systems continue to be compliant with EU MDR. If two medical devices are used together, a validation of their combined use is required. MDR Annex I, Chapter II, Section 14.1 states: "If the device is intended to be used in combination with other devices or equipment, the whole combination ... shall be safe and shall not impair the specified performance ..."

MicroGard® II is the only filter that has gone through a full verification and validation process together with the medical equipment of Jaeger PFT products it is used on. If a device of the Jaeger respiratory diagnostics line is to be combined with a filter, an optimum measurement performance can therefore only be guaranteed with MicroGard® II. Where applicable the linearization tables for the flow sensors are corrected to generate the most accurate measurement results. This level of accuracy cannot be ensured when other non-validated filters are used instead.

Validated SentrySuite™ software corrections particularly tailored to MicroGard® II

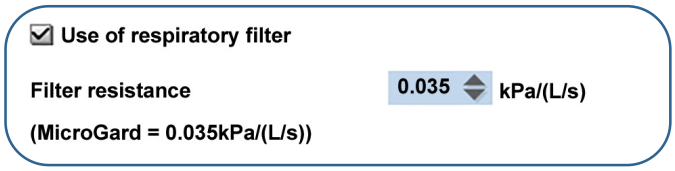
SentrySuite™ includes multiple correction factors specific to the MicroGard® II:

- Correction of the filter's dead space for all lung volume (TLC) measurements



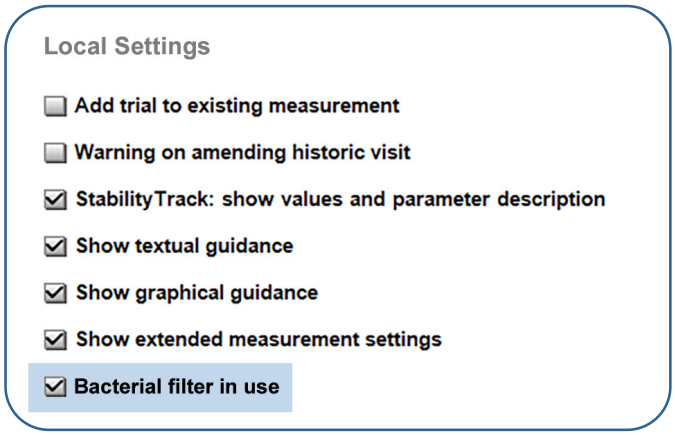
SentrySuite™ software program settings within measurement programs Bodyplethysmography, FRC N2 Washout, FRC Rebreathing and Diffusion SB

- Correction of the filter's resistance for the measurement of specific airway resistance within bodyplethysmography and impulse oscillometry (IOS)



SentrySuite™ software program settings within measurement programs Impulse Oscillometry and Bodyplethysmography

- BTPS (body temperature, pressure, saturated with water vapor) correction to aide in stability and minimization of drift

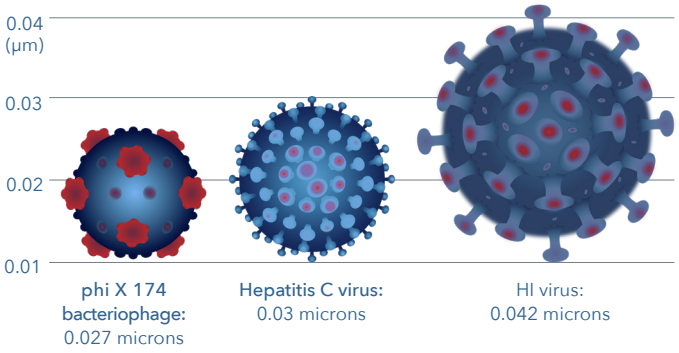


SentrySuite™ software, configuration, global settings

In ultrasound based PFT devices such as Vyntus™ BODY and Vyntus™ ONE, the MicroGard® II filter is an integral part of the whole measurement system, as well as polytubes downstream of the filter which ensure a predictable flow pattern.

Efficiency testing

Jaeger Medical continuously performed bacterial and viral filter efficiency tests at external certified test laboratories.[3] The viral filtration efficiency testing was performed using the bacteriophage phi X 174 as a surrogate for viruses. It represents a significant challenge to the filter material due to its diminutive size and morphology.



Size comparison of different viruses

In comparison, the Hepatitis C virus is 0.03 microns while the HIV virus is 0.042 microns. COVID-19 is reported to have a particle size of 0.08 – 0.16 microns, significantly larger than the bacteriophages used by the test laboratories in the effectiveness tests. Bacteria such as Mycobacteria tuberculosis, by contrast, are much larger in size than viruses.

Bacterial & viral filtration efficiency at low & high flows

MicroGard® II is the only filter that passed the bioburden test in combination with Jaeger PFT equipment regarding the accumulation of the bacterial population in accordance with the DIN EN ISO 11737-1. After insertion of 9.3 x 10^9 CFU (colony forming unit) of B. atrophaeus into the measuring system, 99.9999973% of the bacteria were stopped by the MicroGard® II filter.

For the viral filtration efficiency a cross-contamination rate of 99.6851% was achieved using a high flow rate of 750 LPM[6].

In two distinct setups, the daily use of the PFT equipment was simulated by[4].

- **30 minutes of low flow (120 L/min = 2 L/s)** equivalent to the expiration in 60 minute tidal breathing as present in bodyplethysmography, N2 washout, He wash-in, diffusion, and slow spirometry
- **20 times at high flow (720 L/min = 12 L/s) for 5 seconds** equivalent to multiple flow/volume trials of 20 subjects

MicroGard® IIB in pulmonary laboratory

The warm air supply and germ injection setup was validated to deliver a constant high amount of bacteria to the PFT equipment. After 90 and 180 working days[4], the amount of bacteria in the PFT equipment was tested. The ratio between detected bacteria and infused bacteria was less than 0.001% in all tests and setups. More than 99.999% of the infused bacteria could not be detected in the PFT system.

The results of these bacterial filtration efficiency tests justified the prolongation of the reprocessing cycles for Jaeger PFT systems. MicroGard® filters allows for a prolonged reprocessing cycle of parts downstream of the filter. **Cleaning and high level disinfection is required only twice a year for many of the Jaeger PFT products.** Please consult the reprocessing instructions for your device to determine the required interval.

Hygienic requirements during COVID-19

ERS: Lung function testing during COVID-19 pandemic and beyond

"Test should always be carried out with a high specification disposable in-line bacterial and viral filter in place (We recommend filters with minimum proven efficiency for high expiratory flow of 600 to 700 L/min). Use of disposable combined mouthpieces / sensors is not recommended at this time. The exception would be where an additional filter can be added to the patient circuit and not degrade the measurements." [5]

As a disposable in-line filter, MicroGard® II meets the ERS requirements for the COVID-19 pandemic. The viral filtration efficiency of the MicroGard® II filters was performed using the bacteriophage virus with a size of 0.027 microns as a surrogate. The COVID-19 virus is reported to have a particle size of 0.08 – 0.16 microns.

MicroGard® IIB and IIC, disposable noseclip and mouthpiece

Filter material

The proprietary filter material used in the MicroGard® is polypropylene, a particular blend of polymers with a highly stable electrostatic charge. It consistently achieves high efficiencies by deploying both 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 fibers, resulting in a minimal restriction to the airflow. Most filtration materials use surface loading as the primary means of removal. With the material used in MicroGard®, the fiber matrix enables depth loading, where particles are captured throughout the entire filter material, not just on the surface.

Controlled manufacturing

MicroGard® II is produced in Germany using the highest quality materials, stringent manufacturing standards, and extensive quality control. The Quality System at the manufacturing facility in Höchberg is certified to meet DIN EN ISO 13485 standard. The filter material has been tested for biocompatibility.

Lifetime simulation

Transport and storage validation tests showed that the MicroGard® II filter maintains it´s filter efficiency criteria over a lifetime of three years.

Conclusion

Based upon the scientific test results conducted by external laboratories[3], the MicroGard® II filter proves to have the combination of greatest filtration efficiency with lowest resistance (Delta P) to airflow. Repeated multiple validation and verification testing show that the use of MicroGard® filters does not compromise equipment measurement characteristics. To ensure correct measurement results, Jaeger respiratory diagnostics devices should only be used in combination with the precisely matched MicroGard® filters. The use of MicroGard® with these devices allows for prolonged cleaning cycles.

MicroGard® IIC with disposable mouthpiece flex during bodyplethysmography

REFERENCES

[1] Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement. American Journal of Respiratory and Critical Care Medicine Volume 200 Number 8, October 15 2019.

[2] ATS Standardization of Spirometry [ATS 2005, p. 332].

[3] "Bacterial Filtration Efficiency (BFE) at an Increased Challenge Level GLP Report", Nelson Laboratories, UT, Salt Lake City, Study Numbers: 1722703-S01, 1638260-S01, 1487569-S01, 1412078-S01.
"Viral Filtration Efficiency (VFE) at an Increased Challenge Level GLP Report", Nelson Laboratories, UT, Salt Lake City, Study Numbers: 1722702-S01, 1638259-S01, 1487570-S01, 1412080-S01.

[4] Laboratories of senetics healthcare group GmbH & Co. KG has performed the following tests:
- Simulation of a daily usage of a spirometer with filter attachment for 180 calendar days - 2019-10-24.
- Validation Report High Flow Filtration Efficacy -2021-11-29.

[5] Recommendation from ERS Group 9.1 (Respiratory function technologists /Scientists) Lung function testing during COVID-19 pandemic and beyond.

[6] UK Health Security Agency, Test Reports: 24-009, 24-024

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