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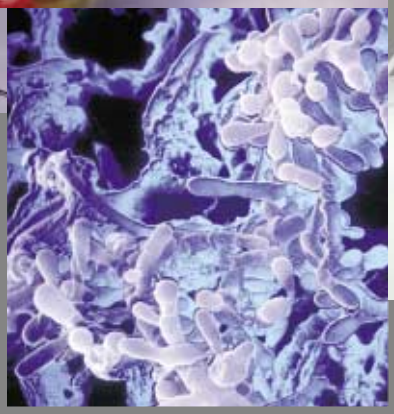


Gelatin Membrane Filter Method:

For quantitative, validatable air monitoring in isolators and clean rooms

We think small in air sampling to retain 99.9995% of Bacillus subtilis niger and 99.94% of T3 coli phages

In order to accurately detect microbiological contamination without compromising the sterility or laminar-flow in isolators and clean rooms, you've got to think small, as if you were a little microbe yourself. Sound crazy? Not really. As any successful business person or military officer will tell you – to successfully defeat your enemy or toughest competitor, you've got to think like they think and then come up with a plan to defeat them. In clean rooms and isolators, the enemy is microscopic bacteria that can shut down your process.

We think smart.
Rather than try to be all things to all people, we focus on what we do best. We are separation specialists in the detection and collection of microorganisms in liquid media and air via membrane filtration.

We think small.
Thinking small at Sartorius means being as thorough as humanly possible. By paying attention to many of the "smaller" aspects of the air monitoring process, we can make a big difference in the "cleanliness" of your clean room and the "isolation performance" of your isolators.

Monitoring air quality in clean rooms & isolators is easy when you think small.
The relentless existence and propagation of microorganisms is a small fact of life QA|QC managers and validation specialists must deal with. And growing regulatory requirements make it critical to employ a reliable air monitoring system and an accepted validatable test method that eliminates any adverse effects on the test area.

The MD8 airscan air monitoring unit is specifically designed to work with the highly preferred Gelatin Membrane Filter Method. This innovative system is extremely easy to use and easy to install. It requires minimal space inside the critical test area. It meets or exceeds all regulatory requirements and has been optimized to eliminate false positive and false negative results.

So, if you're looking for an easy detection method and precise results down to 99.9995%, think smart, think small, think Sartorius.

MD8 airscan
Flow rate and sampling time are selectable for your desired air sample volume. And the number of microorganisms detected can be directly correlated to your sampled air volume.

Gelatin filter disposables for sampling airborne microorganisms and viruses.

The Gelatin Membrane Filter Method: safe, reliable and validatable.
It's no small fact that this unique air monitoring method has distinct advantages over other methods for the collection of airborne microorganisms. For starters, the filter surface can be positioned in the direction of the air flow in the test area. Further, the flow rate through the filter can be matched to the velocity of air being sampled. This is known as isokinetic sampling and is the accepted method to ensure accurate sampling of both large and small particles.

The calibrated MD8 airscan unit is designed to operate outside the test area, making the Gelatin Membrane Filter Method ideal for air monitoring in isolators and clean rooms (classes A & B).

Our smart design will turn you inside out with these unique benefits.
The only sampling equipment required in the test area are the presterilized gelatin filter, its holder and a short length of connecting hose. Hence, from an "inside perspective", you'll benefit from:

- The small footprint
- Flexibility to position filter as needed
- In-situ sterilization of filter holder and connecting hose
- No particle emission or turbulence
- Presterilized, H_2O_2-safe disposable gelatin membranes

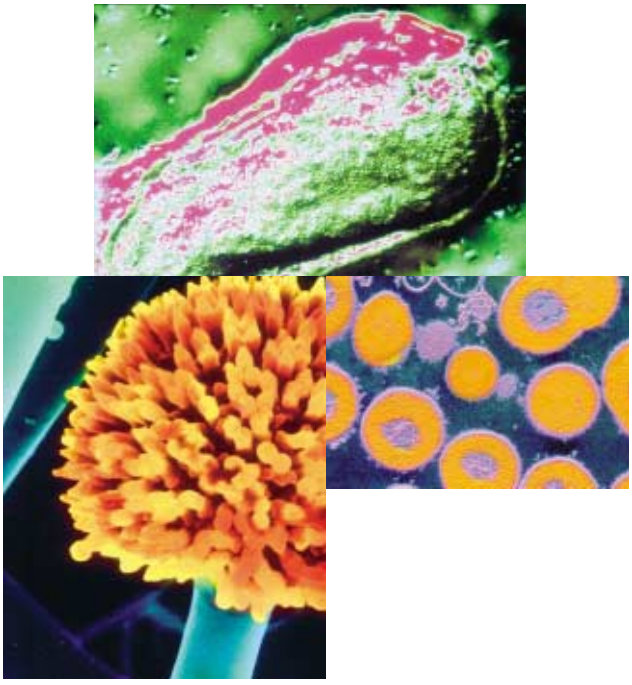
From an "outside perspective", you'll benefit from:

- No risk of secondary contamination
- No corrosion problems for the air sampler from the sterilizing agents
- Assured safety with connection of a filter system between the isolator or clean room and the air sampler
- Fast, easy calibration of the air sampler with an optional calibration unit specifically designed to meet validation requirements.

A little gelatin can retain a lot more microbes than you think.
The unique properties of Sartorius gelatin membrane filters provide unequalled bacteria retention levels as high as 99.9995% for Bacillus subtilis niger. Their ability to measure extremely low bacteria counts via high flow rates makes them ideal for validation and monitoring of critical, sterile areas in pharmaceutical plants.

The membranes' 3.0 µm pore size and large surface area enables you to achieve an impressive 1 m^3 air sample rate in under 8 minutes. Finally, the inherent high moisture content of the gelatin membrane filters helps to prevent any drying out of collected microorganisms during a relevant and meaningful sampling period.

So the next time you need to ensure "cleanliness" in the clean room, think smart, think small, think Sartorius.



For maximum flexibility in your process we offer two choices.

The Direct Method
After sampling with the MD8 airscan, the gelatin membrane filter is placed directly on an agar nutrient plate. The gelatin dissolves on the moist surface so that the microorganisms are in direct contact with the nutrients. The plates are incubated, and the colonies are counted (see photo below).

The Indirect Method
The gelatin filter can be dissolved for special evaluations:

- When inhibitors (e.g., disinfectants or antibiotics) are present in the air being sampled.
- When very high colony counts are to be expected.
- When the microorganisms collected are to be incubated on several different agar media at the same time.

Following sampling, the gelatin is dissolved in a sterile solution. The solution is then membrane-filtered, and the filter disk is placed on an agar nutrient medium. After incubation, the colonies are evaluated.

Thinking small yields big results in these critical application areas.
The MD8 airscan in conjunction with the Gelatin Membrane Filter Method is an ideal solution for quantitative, validatable air monitoring in isolators and clean rooms, especially in the following critical applications:

- At pharmaceutical filling stations. Very rapid filling lines for liquids or powders in isolators, as well as pharmaceutical research, development and quality control (e.g., for sterility testing).
- For biological research, especially when working with viruses.
- In hospitals using isolators for filling pharmaceutical products such as cytotoxic drugs, or for working with other biohazardous material such as human pathogenic bacteria and viruses.
- In the food and beverage industry for aseptic filling.
- In veterinary research.

Whenever you need to absolutely, positively know the quality of the air around you, think smart, think small, think Sartorius.

We think small in isokinetic sampling conditions to obtain the right balance of small and large particles.
When monitoring clean rooms and isolator equipment with laminar-flow installations, clean benches and air conditioning equipment, it is absolutely necessary that sampling be conducted under isokinetic conditions. This requires that the air intake rate of the air sampler be equal to the laminar flow rate and the sampling head of the gelatin membrane filter be positioned perpendicularly to the air stream.

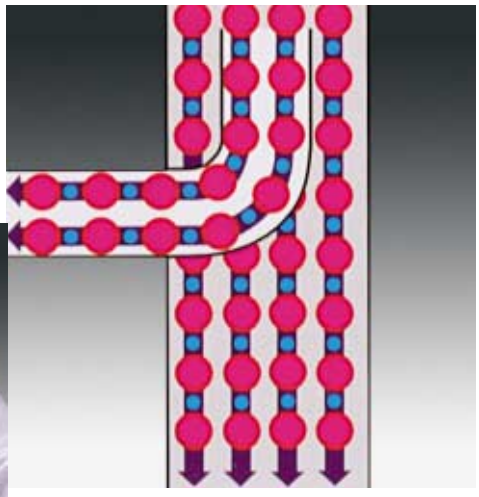
If sampling is done at a rate lower than the laminar air flow, too many large particles will be collected on the filter surface due to the effects of inertia.

If, conversely, sampling is done at a rate higher than the laminar air flow, too many smaller particles will be collected on the filter surface.

In either case, the results will not be representative of the particle distribution actually present in the laminar flow system during sampling and, hence, will not be accurate.

The unique properties of the gelatin membrane filter, combined with the flexible hose design of the MD8 airscan and its selectable flow rate and sampling time feature make the Gelatin Membrane Filter Method ideally suited to isokinetic sampling.

Direct Transfer Method
Direct transfer of gelatin membrane to agar plate for fast, accurate detection of microorganisms.



Isokinetic Sampling
Sampling head perpendicular to the air flow and with the same velocity as the laminar flow.

Specifications

MD8 airscan Air Sampler.
The air sampling rate can be set in steps of 0.1 m^3 within the range of 2.0 m^3/hr to 8 m^3/hr. The max. deviation is 5% within the temperature range of 15°C – 35°C.

Calibration Unit.
Calibration of the MD8 airscan is done by connecting the two units inline and measuring the air volume through the calibration unit at two different flow rates. Flow rates for the MD8 airscan can then be adjusted to match those on the calibration unit.

Gelatin Filter Units.
Gelatin filter (water soluble)
Pore size: 3 µm
Diameter: 80 mm
Thickness: ≈ 250 µm
Max. temperature: 60°C
Water content: 46 % to 49 %
Air flow rate:
approx. 2.7 l/min per cm^2 at Δp = 0.7 psi

Filtration area
38.5 cm^2

Limiting conditions
Room temperature, max. 30°C;
Relative humidity: 85%

Materials
Gelatin filter & Cyrolite® holder

Retention rates
a) For Bacillus subtilis niger: 99.9995% (at 0.25 m/s inlet velocity)
b) For coli phages: T1 phage, 99.9 % (at 0.3 m/s and 50% rel. humidity); T3 phage, 99.94 % (at 0.3 m/s and 80%)

Size
93 mm diameter,
16 mm height

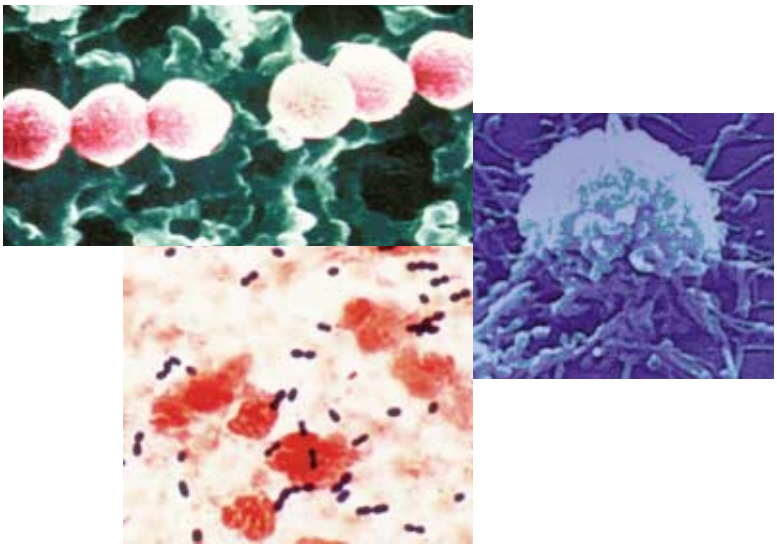
Sterilization
Presterilized by γ–irradiation

Ordering Information

MD8 airscan and Adapters.
16746 MD8 airscan, 230 V/50 Hz
16747 MD8 airscan, 115 V/60 Hz
16748 MD8 airscan, 110 V/50-60 Hz
Each version can be switched from 50 to 60 Hz and back
17801 Adapter (enables gelatin filter units to be fitted on the MD8 inlet)

Gelatin Filter Units.
Sterile and individually packed
17528-080 ACD (pack of 10)
Each unit in a single polyethylene bag
17528-080 BZD (pack of 10)
Each unit in three polyethylene bags
17528-080 VPD (pack of 10)
Each unit packed in three polyethylene bags, but label on innermost bag

Calibration Unit.
167 40 Calibration unit
176 55 Filter holder
176 57 Complete set of connectors
170 85 PVC hose (2 meters)



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