



Gelatine Membrane Filter Method

For Quantitative, Validatable
Air Monitoring in Isolators
and Clean Rooms

Simplifying Progress

SARTORIUS

We Think Small in Air Sampling ...

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. Sounds 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.

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.

The gelatine 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).

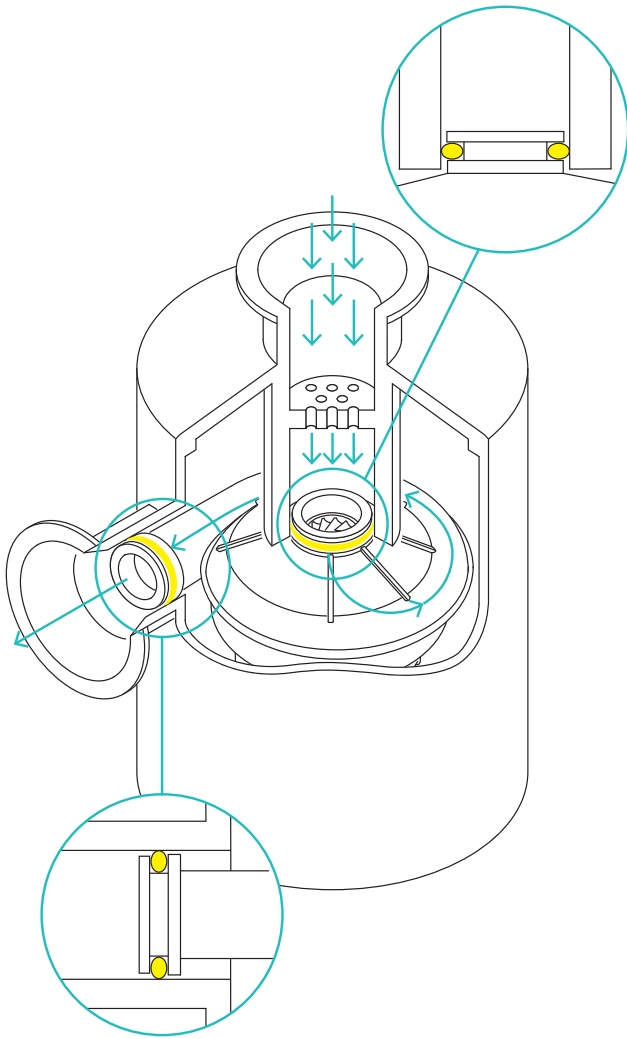
Our smart design will turn you inside out with these unique benefits.

The only sampling equipment required in the test area are the presterilized gelatine 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 gelatine 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
- The flowpath can be decontaminated inline with vaporized hydrogen peroxide
- 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.



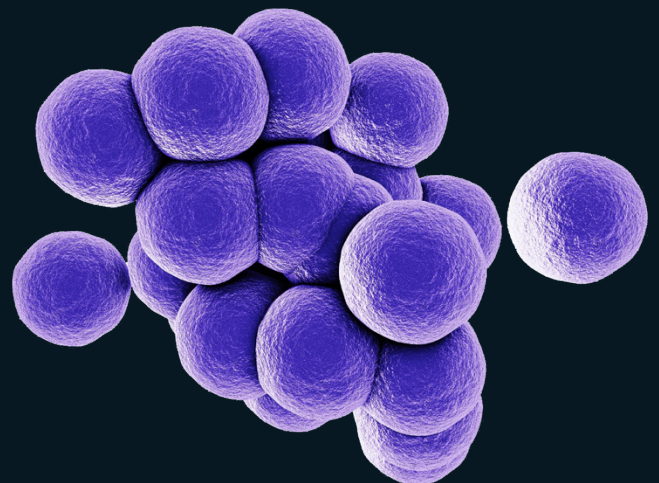
... to Retain 99.9995% of Bacillus Subtilis Niger and 99.94% of T3 Coli Phages

A little gelatine can retain a lot more microbes than you think.

The unique properties of Sartorius gelatine 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 m³ air sample rate in under 9 minutes. Finally, the inherent high moisture content of the gelatine 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.



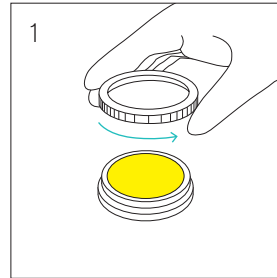


Two Choices for Maximum Flex

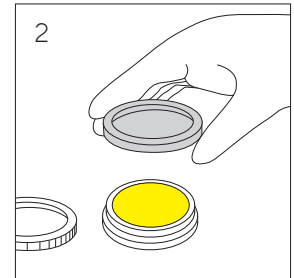


The Direct Method

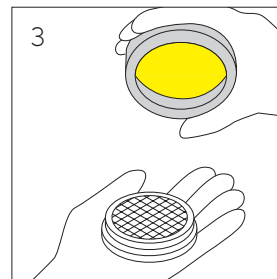
After sampling with the MD8 airscan, the gelatine membrane filter is placed directly on an agar nutrient plate. The gelatine dissolves on the moist surface so that the microorganisms are in direct contact with the nutrients. The plates are incubated, and the colonies are counted.



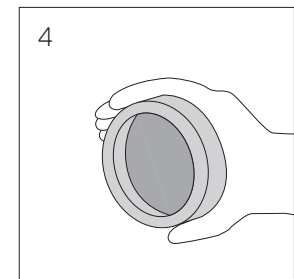
1 Detach the cap of the disposable with a gentle anti-clockwise twist.



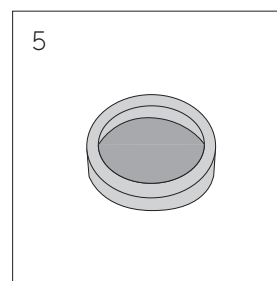
2 Gently touch an inverted 90 mm nutrient media plate onto the gelatine membrane filter lying on its gridded base.



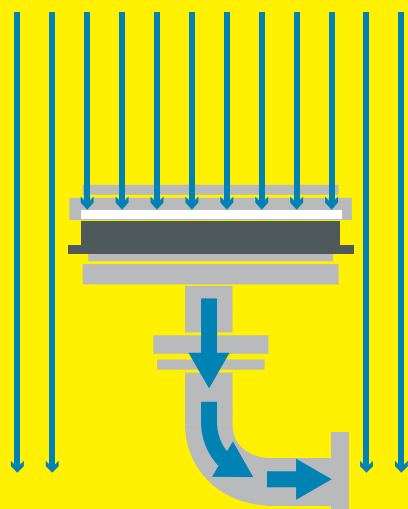
3 The gelatine filter adheres to the nutrient media in a matter of seconds and lifts off the gridded base. Transfer is touch-free and does not require forceps.



4 Due to its hygroscopic nature, the filter dissolves onto the surface of the nutrient media plate without any loss of microorganisms.



5 Incubate the nutrient media plate at the required temperature.





The Indirect Method

The gelatine 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.
- When time is of the essence and a rapid test such as PCR is adopted

Thinking small yields big results in these critical application areas. The MD8 airscan in conjunction with the gelatine 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 gelatine 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 gelatine membrane filter, combined with the flexible hose design of the MD8 airscan and its selectable flow rate and sampling time feature make the gelatine membrane filter method ideally suited to isokinetic sampling.

Your Benefits

- Non-Stop Active Viable Air Monitoring for at Least 8 Hours With a Reduced Risk of False Positive Results Due to Sampling Errors

The EU Good Manufacturing Practice (GMP) Annex-1 specifies that “any risk caused by interventions of the monitoring operations is avoided”. Unlike settle plates that need to be changed after 4 hours, an example of an intervention during operation, our unique gelatine membrane affords up to at least 8 hours of uninterrupted sampling. Unlike conventional plates, our agar-free gelatine membrane filters do not dry out, and there is no-risk associated with the prolonged exposure of a nutrient source within your clean room. Given that any recovery of 1 cfu or greater in a grade A clean room requires an investigation according to the Annex-1, you can’t be too careful.

- Multiple configurations are available to suit any microbiology testing need, including Gelatine Membrane filters in Biosafe® bags for its aseptic transfer, via a Biosafe® port, into isolators, RABS and clean rooms with the need for numerous disinfection steps.



Technical Specifications

MD8 airscan Air Sampler

The air sampling rate can be set in steps of 0.1 m³ within the range of 0.01 – 9.99 m³/hr. The max. deviation is 5% within the temperature range of 15 °C – 35 °C.

Gelatine Filter Units

Gelatine 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 cm² at Δp = 0.7 psi

Filtration area

38.5 cm²

Operating 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%)

Sterilization

Presterilized by γ-irradiation

Ordering Information

Description	Order No.
Set of: Command unit (16746-01--COM); Connection cable 3 m (69898530A); Sampling Head with Triclamp (16746-01--SHT); Filter holder for Gelatine filters (17801); Tri-clamp Connector S-F (17659---003)	16746SHTCOM
Set of: Command unit (16746-01--COM); Connection cable 3 m (69898530A); Sampling Head with Bayonet (16746-01--SHB); Filter holder for Gelatine filters (17801)	16746SHBCOM
Gelatine filter units - pack of 10 (sterile and individually packed)	
Each unit in a single polyethylene bag	17528--80----ACD
Each unit in three polyethylene bags	17528--80----BZD
Each unit packed in three polyethylene bags, but label on innermost bag	17528--80----VPD
Gelatine filters in Biosafe® bags	17528-----BFV






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