

MD8 Airscan®

Active sampling of airborne viruses, bacteria, yeasts and fungi



Product Information

Monitoring ambient air in cleanrooms and controlled areas in the (c)GMP environment for viable microorganisms is a routine task in the pharmaceutical | biotechnology industry. As a rule, collection of data and subsequent analysis of the results permit trends to be recognized early and problems (OOS*) with bioburden levels exceeding the limits to be prevented.

Active Air Monitoring in Cleanrooms and Controlled Areas

Active monitoring of viable airborne microorganisms is an important instrument for ensuring product quality and safety. Sampling of at least 1 m³ of air is required by regulation standards. In this procedure, care must be taken that turbulence is not caused by, for example, devices such as active air samplers and that sampling is performed isokinetically. The following areas need to be monitored using active sampling of airborne microorganisms:

In the pharmaceutical | biotechnology industry:

- Cleanrooms (grades A–D; ISO classes 5–9)
- Sterility testing isolators
- Filling lines
- Controlled areas, e.g. quality control (QC) laboratories
- Warehouses | raw materials depots
- Personnel airlocks and aseptic transfer chambers for material

* Out of specification

In the food and beverage industry:

- Manufacturing areas and production-related areas
- Quality control (QC) laboratories
- Warehouses | raw materials depots

Diagnostics | Medicine:

- Cleanroom or controlled area
- Filling lines
- Manufacturing areas and production-related areas
- Quality control (QC) laboratories
- Warehouses | raw materials depots

Technical Specifications

Disinfection | Sterilization

Stainless steel sampling heads (bayonet and TC versions)

- IPA (70%)
- Ethanol (70%)
- Peracetic acid (1%)
- Dismozon® (1%)
- Sodium hypochlorite (5%)
- Formaldehyde (4%)
- Flowpath can be disinfected or sterilized | inline with vaporized hydrogen peroxide

Command unit

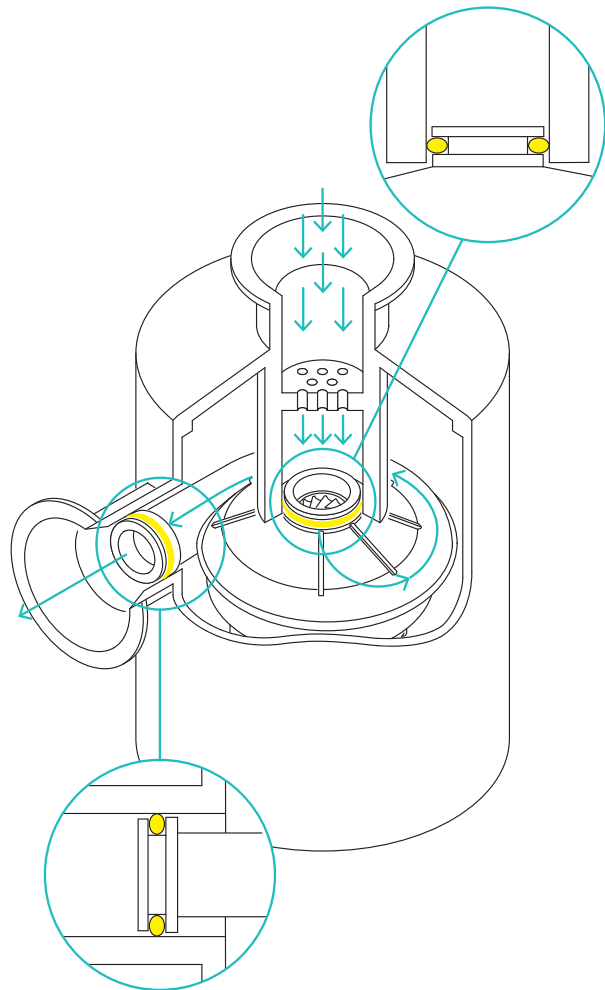
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Specifications of the Stainless Steel Sampling Heads, Bayonet and TC Versions

- Electropolished stainless steel: AISI 316L (German equivalent standard) 1.4404 or better

Quality Control

As Sartorius is a recognized supplier of products and services for the pharmaceutical industry, product quality and safety are its number one priorities. To meet stringent quality requirements, 100% final testing of the MD8 Airscan® is performed in manufacturing among the quality control checks carried out. In addition, every stainless steel sampling head is calibrated and adjusted after assembly.



Types of MD8 Airscan® Stainless Steel Sampling Heads

Stainless steel sampling head with bayonet connector

Specially designed as a “stand-alone” version”

- Type of connector: Bayonet
- Flow capacity: Maximum flow rate capacity: up to 7 m³/h; adjustable in increments of 0.1 m³/h
- Saves the calibration data and actively regulates air flow
- Order No. for sampling head: 16746-01--SHB
- Order No. for bayonet package version: 16746SHBCOM

Contents of package version:

- Command unit with 3 m connecting cable
- Stainless steel sampling head with bayonet flange connector
- Aluminum filter holder*

Stainless steel sampling head with Tri-Clamp connector

Specially designed for integrating into lines

- Type of connector: Tri-Clamp, 50.5 (TC 50.5)
- Maximum flow rate capacity: up to 7 m³/h; adjustable in increments of 0.1 m³/h
- Saves the calibration data and actively regulates air flow
- Order No. for sampling head: 16746-01--SHT
- Order No. for Tri-Clamp package version: 16746SHTCOM

Contents of package version:

- Command unit with 3 m connecting cable
- Stainless steel sampling head with Tri-Clamp connector
- Stainless steel adapter, for connection of TC 50.5 to filter holder
- Aluminum filter holder*

MD8 Airscan® Command Unit

- Plastic material PA6 with 30% glass fiber
- RS-232 interface port for connecting a printer
- 2 status LEDs for displaying operating status and errors
- Stores the test results
- Order No. of the command unit: 16746-01--COM



*The filter holder is also available in an AISI 316L stainless steel version (German equivalent standard 1.4404).

General Information

| | Sampling Head with Bayonet Connector | Sampling Head with Tri-Clamp Connector (TC 50.5) |
|--|--------------------------------------|--|
| Dimensions (L×W×H) in mm inches | 128×112×137 ~5×4.4×5.4 | 128×112×154 ~5×4.4×6 |
| Weight in kg lb | 2.6 ~6 | 2.6 ~6 |
| Power supply | | |
| Only through MD8 Airscan® command unit | | |
| Material | | |
| Gaskets | Silicone | Silicone |
| Surfaces | Stainless steel | Stainless steel |

Ambient Conditions

| | Unit | Specification |
|--|--|--------------------|
| Installation site | | |
| Usual laboratory spaces and cleanrooms as defined by ISO 5 to ISO 9; use in controlled areas: Cleanroom classification A-D | m above sea level ft. above sea level | < 3,000 < 9,843 |
| Required clearance for air exhaust outlet | mm inches | > 100 4 |
| Ambient temperature | | |
| Operation | °C | 4-40 |
| Storage and transportation | °C | 4-45 |
| Max. temperature of motor in the sampling head | °C | 65 |
| Relative humidity | | |
| Operation | % | 50-80 |
| Storage | % | 20-90 |
| Electromagnetic compatibility according to DIN EN 61326-1: Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1 | | |
| Defined immunity to interference: Suitable for use in industrial areas | | |
| Limitation of interference | Class | B |

Specifications of the Stainless Steel Sampling Heads, Bayonet and TC Versions

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| Relative humidity | | |
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| Defined immunity to interference: Suitable for use in industrial areas | | |
| Limitation of interference | Class | B |

Command Unit Specifications

| | Unit | Specification |
|--------------------|-------------|------------------------|
| Dimensions (L×W×H) | mm inches | 282×102×107 11×4×4.2 |
| Weight | kg lbs | 1.4 ~3.1 |

Measurement Parameters

| | Unit | Specification |
|---|-------------------|---------------|
| Adjustable volume: adjustable in increments of 0.01 m³ | | |
| For gelatin membrane filters | m ³ | 0.01 - 9.99 |
| For cellulose nitrate membrane filters | m ³ | 0.01 - 1.10 |
| Adjustable air flow: adjustable in increments of 0.1 m³ | | |
| With gelatin membrane filters | m ³ /h | 1.8 - 7 |
| With cellulose nitrate membrane filters | m ³ /h | 1.8 - 3 |

Interfaces

RS-232 interface port for connecting a printer

Suitable printer: Sartorius YDP30 (baud: 9600; parity: odd; data bit: 8; stop bit: 1)

Power Supply

Power Supply Unit

Type: Sartorius power supply, model 1000018304

| | Unit | Specification |
|--|--|--------------------|
| Primary | | |
| Voltage | V _{AC} | 100 - 240 ±10% |
| Frequency | Hz | 50 - 60 |
| Power consumption, max. | A | 2.0 |
| Secondary | | |
| Voltage | V _{DC} | 24 ±5% |
| Power, max. | A | 6.25 |
| Short-circuit protection: Electronic | | |
| Protection class according to DIN EN/IEC 60950-1 | | I |
| Installation site according to DIN EN/IEC 60529-1 | m above sea level ft. above sea level | < 3,000 < 9,843 |
| Installation category (overvoltage) according to IEC 60950-1 | | II |
| Contamination level according to IEC 60950-1 | | 2 |
| Connecting cable for power supply | Class | B |
| Connecting cable according to DIN EN/IEC 60320-1/C14: country-specific, 3-pin; can be plugged in at both ends | | |
| Socket according to DIN EN/IEC 60320-1/C14: 3-pin | | |
| Additional data: See label on the power supply | | |

Command Unit and Sampling Head






| | Unit | Specification |
|---|-----------------|---------------|
| Power supply for control unit: Only via Sartorius power supply, model 1000018304 | | |
| Voltage | V _{DC} | 24 ±5% |
| Power consumption | A | 5.0 |
| Power supply for sampling head: Only through command unit | | |

Ordering Information

Recommended Accessories and Consumables








Accessories

This table shows a sampling of the range of accessories that can be ordered. Please contact Sartorius for information on additional products.

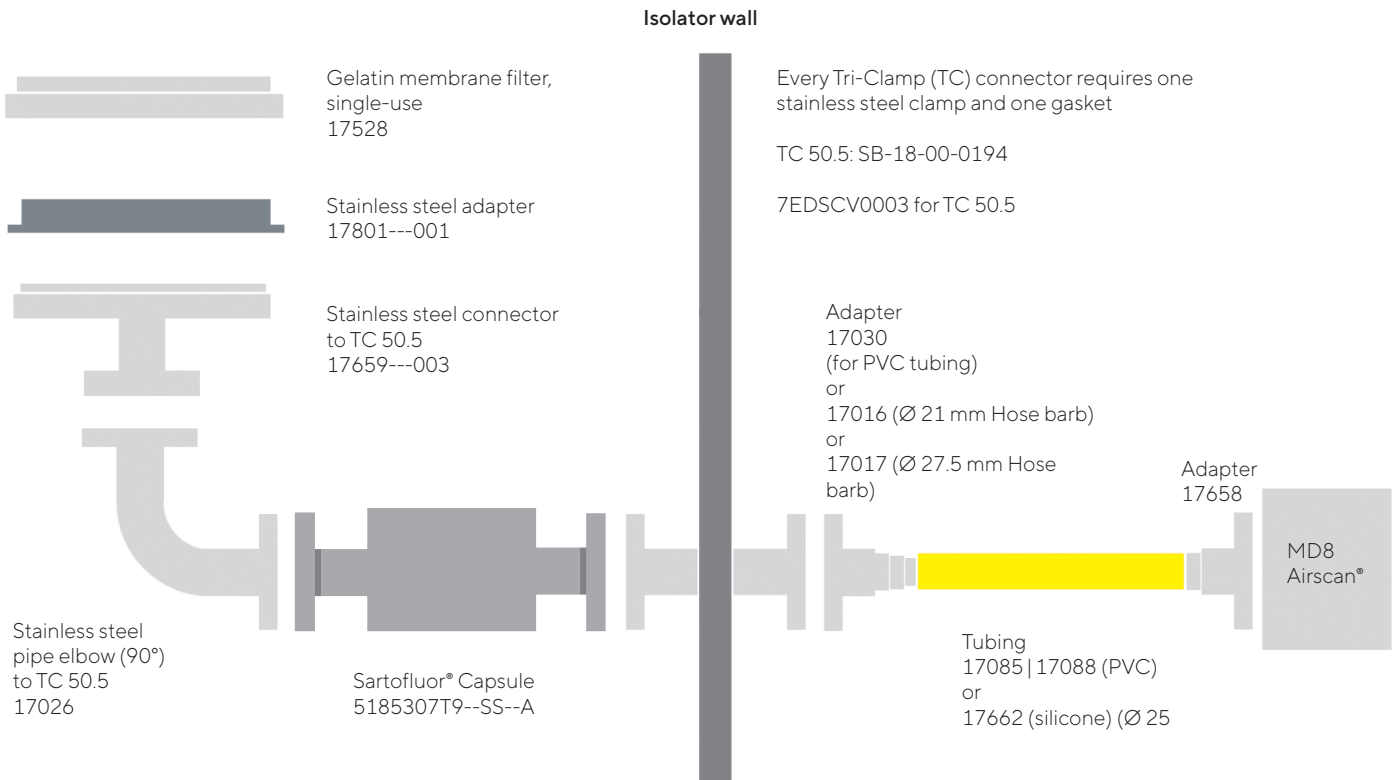
| Product | Quantity | Order Number |
|--|----------|----------------|
|  Adapter for gelatin membrane filter | 1 | 17801 |
|  Adapter, Tri-Clamp (TC 50.5) to bayonet, stainless steel | 1 | 17659---003 |
|  Adapter, bayonet to Tri-Clamp (TC 50.5), stainless steel | 1 | 1ZAD--0025 |
|  Adapter, TC 50.5 to single-step hose barbs, stainless steel. Can be used on the air outlet for conducting exhaust air outside the area. | 1 | 17016 or 17017 |
|  Clamp for 1" to 1½" Sanitary flange | 1 | SB-18-00-0194 |

Consumables

This table shows a sampling of the range of consumables that can be ordered. Please contact Sartorius for information on additional products.

| Product | Quantity | Order Number |
|---|----------|------------------|
|  Gasket for Tri-Clamp TC 50.5 connector, silicone | 2 | 7EDSCV0003 |
|  Sartofluor® capsule, sterilizing-grade air filter, 0.2 µm, 0.2 m² filter area | 4 | 5185307T9--SS--A |
|  PVC tubing, 2 m (~6.5 ft.) | 1 | 17085 |
|  PVC hose, 5 m (~16 ft.) | 1 | 17088 |
|  Silicone tubing, 1 m (~3.3 ft.) | 1 | 17662 |
|  Quick-connect cable | 1 | 69898530 |
|  Cable for YDP30 printer | 1 | YCC01-0041M3 |

Installation of the MD8 Airscan® | Isolator



Sartorius Service

We ensure the quality of your results

From equipment qualification IQ | OQ to regular maintenance: We offer you just the right choice of services to ensure that you comply with the high regulatory requirements right from the beginning, especially in GMP environments. Not only that: we will take care that your air sampler operates reliably over the long term.


Get more information at
www.sartorius.com/services

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