TCR TECORA
POLLUTION CHECK

LABORATORY

In Compliance with:
EN 14683 · EN ISO 9237
ASTM F2100 · ASTM F2101

Product passed by
SURFACE DISINFECTION PROCESS

Bioaerosol Sampling System

BFE BioKit

Virus • Bacteria • Fungi • Spores • Protozoa • Pollen • Algae

Bioaerosol Sampling System

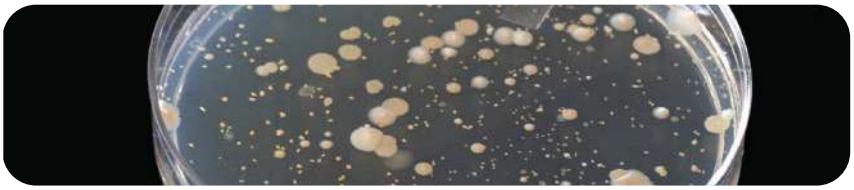
Bioaerosol is a component of Particulate Matter (PM) in the atmosphere and consists of airborne particles that have a biological origin.

Bioaerosol is a mix of:

- Microorganisms (viruses, bacteria, fungi and their spores, algae and protozoa);
- Pollen;
- Fragments of animals, insects, plants;
- Derived substances (toxins and allergenes) produced by any living species.

Bioaerosol study involves a lot of application fields (allergology, industrial aerobiology, cultural heritage, bioclimatology, physics and chemistry of the atmosphere, ecology, epidemiology, biological pollution, microbiology, plant pathology, biological terrorism, indoor/outdoor air quality).

EN 14683 describes testing methods for medical facial masks intended to limit the transmission of infectious agents between patients and clinical staff during surgeries and other medical contexts with similar requirements.



APPLICATIONS

Pharmaceutical · Cosmetics · Health · Filter Test
Military · Air Quality · Clean Rooms · Food

QUALITY GUARANTEE

Made in Italy

Produced with
AISI 316

Bioaerosol

The study of the microbial content of air has become increasingly significant in recent years when the need for "contamination-free" environments has become more evident.

Bioaerosol includes several types of primary bioaerosol particles (PBAP primary biological aerosol particles), with diameter ranging from a few nanometers (viruses), some micrometers (e.g. bacteria, pollen), >10-100 micrometers (e.g. fungi and spores), which are found in atmospheric particulates.

Knowing the dimensional distribution of bioaerosol allows to evaluate its aerodynamic behavior in the atmosphere (atmospheric residence time, transport phenomena and deposition) and the potential health effects (deposition in different sections of the respiratory system).

Bioaerosol is sampled according to size by multi-stage impactors.

Bioaerosol is collected on an impact surface, consisting of a membrane, a fattened saucer or culture soil, and is studied using specific analysis techniques (microscope analysis; laboratory analysis for immunological, biological and chemical tests; culture based methods for viable and culturable bioaerosols).

INNOVATION MADE IN ITALY

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KIT: EN 14683

(Annex B: BFE Test) - ASTM 2101
Medical face masks Requirements and test methods

- Microprocessor data management;
- High accuracy and precision in the measurement of air flow and volume;
- HEPA filter at the exhaust end of the vacuum pump;

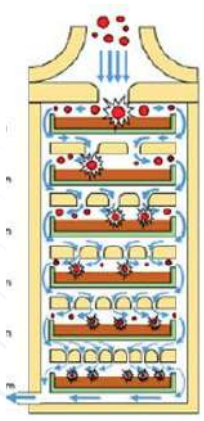
Viable Multistage Cascade Impactor. Principle of operation.

The human respiratory system tract is an aerodynamic classifying system for airborne particles.
The Viable Multistage Impactor (Andersen type), based on the particle inertial impaction principle, simulates the human respiratory tract (extrathoracic, tracheobronchial, alveolar). The micro holes in each of the 6 impactor stages act as nozzles that, in function of the diameter and impaction distance, let the collection of particles within a certain aerodynamic size range, with a characteristic efficiency impaction curve.
The specific design of the viable multistage impactor ensures the deposition of particles onto the impaction surface and lets bioaerosol viability by using a suitable collection media.

NIOSH Manual of Analytical Methods - 5 th Edition - Sampling and characterization of Bioaerosol - 2017

Cut points (d_{50})

- 7,0 μm
- 4,7 μm
- 3,3 μm
- 2,1 μm
- 1,1 μm
- 0,65 μm



1° Stage D_{50} = 7 μm
2° Stage D_{50} = 4.7 μm
3° Stage D_{50} = 3.3 μm
4° Stage D_{50} = 2.1 μm
5° Stage D_{50} = 1.1 μm
6° Stage D_{50} = 0.65 μm

The well-known particle bounce effect is minimized in the Viable Particle Sampler by collecting the bioaerosol directly on a sticky agar surface used as the impaction surface.

Particle nebulyzer
Cod : AC99-120-0000SP

- Generating Aerosol from all kinds of liquids, suspensions and solutions;
- Integrated pump (no compressed air required);
- Adjustable Nebulyzing and dilution air (dry) flow;

6 Stage impactor
Cod : AC99-120-0002SP

- Functioning principle: Inertial impaction;
- Required Flow: 28,3 l/min (1 CFM);
- Direct sampling on 90 mm petri plates;
- Made of corrosion resistant material.

Aerosol Chamber
Cod : AC99-120-0001SP

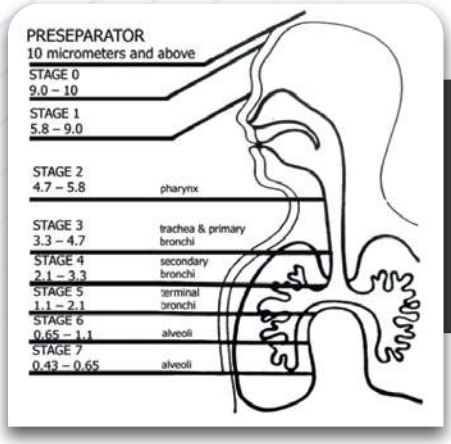
- Pyrex tempered glass, dimensions 600 mm x 80 mm Ø;
- Upper flange of PTFE (HEPA filter included);
- Lower flange of PTFE (included: mask sample holder);
- Connections to: aerosol generator, 6 stage impactor and n° 4 additional side connectors (i.e. for optical particle counter: optional).

Extraction Condenser
Cod : AC99-120-0003SP

- PYREX glass Condenser;
- PYREX glass Condensation vessel.

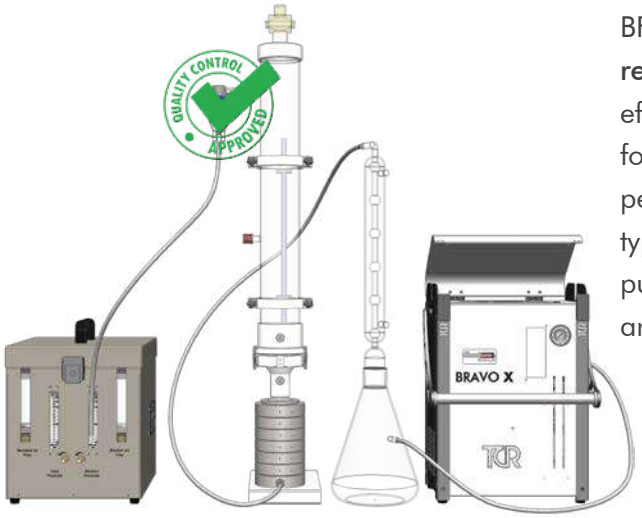
Electronic Flow Control Sampler
Cod : AA99-000-0030SP [Bravo Basic H]
Cod : AA99-000-0740SP [Bravo X BIO]
(differential pressure)

- Automatic flow regulation;
- Flow range: 0.5 to 70 l/min
- Available models: Basic H or X-BIO
- HEPA filter (pump exhaust) included



The picture shows the deposition effects inside the respiratory tract divided in extrathoracic, tracheo-bronchial and alveolar region.
The particles with higher aerodynamic diameter stops in the first tract while the submicronic particles cross the lung airways to stop in the alveolar region.

BFE - Pneumatic Diagram EN14683 (Annex B)



BFE Bio Kit, allows to be in **compliance with all the requests for BFE % efficiency test** (Bacterial filtration efficiency) and **breathability test**(Pa/cm²). It is also done for ASTM F2101 and EN 9237 for measuring the permeability of fabrics to air and is applicable to most types of fabrics, including industrial fabrics for technical purposes, nonwovens and made-up textile articles that are permeable to air.

Facial BFE Mask

These operating phases can be repeated more time. The system design and material composition allows all service and maintenance operations required for every sampling batch.

- Fill in the aerosol generator with the bacteria suspension to nebulize;
- Set up the multi stage cascade impactor and connect the sampling pipe;
- Connect the atomization chamber to the impactor;
- Connect the condenser at the impactor output suction line;
- Connect the output of the condenser to the sampler, setting a 28,3 l/min flow;

- Download report USB;
- Flowmeter and Differential Pressure reader integrated;
- Multiple repetition of tests with aid of configured functions.

Table 1 — Performance requirements for medical face masks

Test	Type I [a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm²)	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

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BREATHABILITY and PEARMEABILITY (differential pressure)
EN14683 (Annex C) • ASTM F2100 • EN ISO 9237

The determination of differential pressure is performed under a specific constant flow condition and taking in account temperature and humidity during the test.

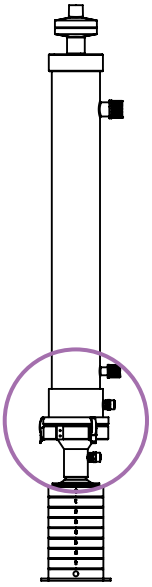
BFE BioKIT configuration allows to process automatically the BFE and differential pressure test. Unless otherwise specified, the breathability test (EN 14683 Annex C – ASTM F2100) shall be performed with the air flow direction from the inside of the mask to the outside of the mask.

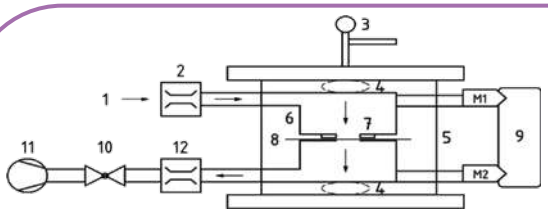
Specific sample holders, made of the material and with the dimensions required by the standard, are delivered.This system is suitable for measuring also the permeability of fabrics to air and is applicable to most types of fabrics, including industrial fabrics for technical purposes, nonwovens and made-up textile articles that are permeable to air

Sample holder 25 mm diam. Stainless steel AISI316 – Breathability (EN 14683 Annex C)

Sample holder 5 cm² - 20 cm² - 50 cm² - 100 cm² – Permeability (EN ISO 9237)

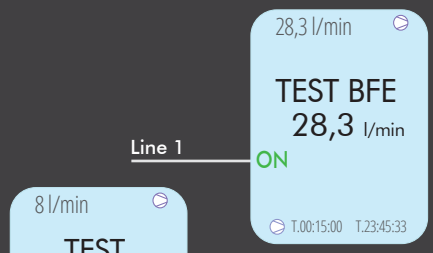
Sample holder 80 mm diameter made in PTFE – BFE test (EN 14683 Annex B; ASTM F2101)





Pneumatic Diaphragm EN 14683 EN 9237

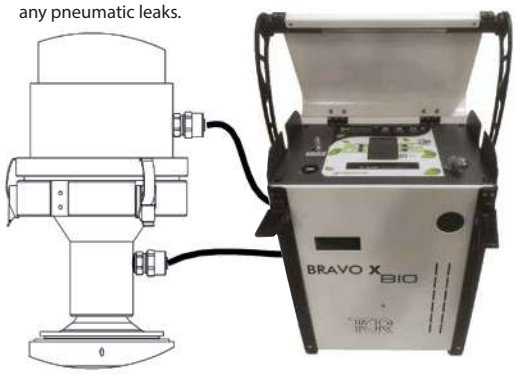
Software V-BULL2.1



BFE BioKIT sw release allows to perform simplified test as required from the standard

- BFE test report
- Differential pressure test report

Lever closure to eliminate any pneumatic leaks.



BRAVO X BIO is able to measure and record the differential pressure upstream and downstream of the mask part under test, measuring the instantaneous flow and to perform the leack check.

All logged data are saved in the internal memory of the sampler and are downloadable by USB key. Touch screen display with intuitive user friendly interface simplifies the data management and settings. The output data are fully detailed in the digital report.

The efficiency level of a respiratory mask depends on various factors such as filtration efficiency, filtration material quality, mask wearabilty compared with the various face shape.

Filtration efficiency is different from type to type of filtering material used.

Another aspect to take in account is the humidity caption level that the mask is able to retain and therefore to assure the performances for a longer period of time.

For the BFE and the breathability test each test specimen shall be conditioned at T=21 (± 5) °C and RH= 85 (± 5) % for minimum 4 h (EN 14683, ASTM F2101).

REPORT EN 14683 : 2019

Date & time: 20-03-19 - 14:18
Operator: Name
Material: Punch 1 Mask Type II
Supplier: Filter Producer
AQL: 4%
Temperature: 21 Rw : 86 %
Lot number: 384845-44
Dimension: 80 mm x 6 n
Mask side: INLET

BFE

Q= 28,36 l/min | **ET=** 00:03:00
Tot. POSITIVE= 5 | **Tot. NEGATIVE=** 1
BFE= 34% | **V=** 85.08 l/min

PDIF

Test AVG= 20 Pa | **Qp=** 8,02

- Start test date and time
- Operator name
- Type of material under test
- Mask manufacturer/material composition
- Acceptance level
- Temperature and humidity
- Mask production lot batch
- Material under test dimensions
- Side material under test
- Average flow and sampling time
- Negative and positive check results
- Filtration efficiency and volume
- Air Permeability R - Average flow

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