TCR TECORA
POLLUTION CHECK

OUTDOOR
AIR QUALITY

In Compliance with:
EN 14683

Product passed by
SURFACE
DISINFECTION
PROCESS

Bioaerosol Sampling System

BFE BioKit

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

APPLICATIONS

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

Bioaersol Sampling System

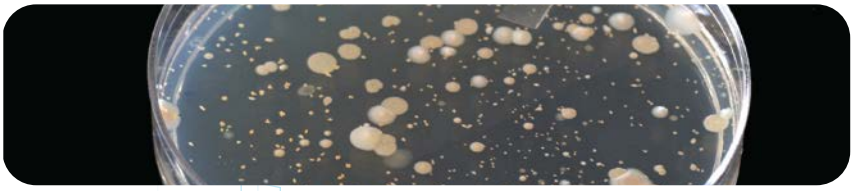
Bioaerosol is a component of the suspended particulate matter in the atmosphere and is composed by particles of biological source.

Bioaerosol is a mix of:

- Microorganism (virus, bacteria, fungi and their spores, algae and protozoa);
- Pollen;
- Micro parts of animals, insects, plants;
- Derived substances (toxins and allergenes) produced by every 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.

The EN standard 14683 describe the test methods to verify the facial mask for surgical use to restrict the transmission of infective agents during surgical procedures beteween patient and surgeon or other situations where this device has to be used.



Bioaerosol

The study of microbial content in ambient air it has become increasingly important over the last years in wich is emerged the needs of environments "contamination free". Bioaerosol includes different type of so called "Pirmary bioaerosol" (PBAP primary biological aerosol particles) with an aerodinamic diameter ranging from few nanometers (virus) to some micrometers (bacteria, pollen, etc) in between 10 to 100 micrometers (fungi and spores) , that are conveyed in the particulate suspended matter. To know the dimensional distribution of the bioaerosol allows to evaluate the aerodinamic behaviour in the atmospere (suspension time on air, transport and deposition phenomena) and the potential effects on human health (deposition in the different tracts of the respiratory system.
Bioaerosol is sampled as a function of the dimensions by a multi stage impactor. Bioaerosol is collected on an impact surface that consists of a membrane, a greased coated plate or biological colture plate and is studied by different analytical techniques (microscope investigations, analysis for immunologycal, biologycal and chemical test, coltural tecniques for living cells).

INNOVATION MADE IN ITALY

TCR TECORA
POLLUTION CHECK

KIT: EN 14683

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

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

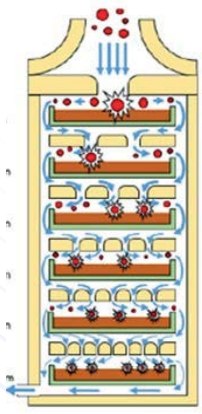
Multistage cascade impactor Principle of Operation

From the standpoint of respiratory deposition, the human respiratory system act as aerodinamic airborne particle classifier.
The multi stage impactor, based on the particle inertial impaction principle, simulate the human respiratory tract (extrathoracic, tracheobronchial, alveolar). The micro holes in each of the 6 impactor planes act as nozzles that, in function of the diameter and impaction distance, permit the caption of a dimensional range of particles, with a particular and charateristic efficiency impaction curve.
The special design of the multi stage impactor assure the depositon of the desired particle classes that are suspended in the ambient air.

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

Cut points (d_{50})

- 7,1 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 "bouncing effect" of the cascade impactor is mitigated by using of a petri plate with Agar that hold the particles avoinding rebounding or resuspension.

Particle nebulyzer

Cod : AC99-120-0000SP

- Aerosol generator compatible with all type 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 to test holder and differential pressure intakes);
- Aerosol generator connector, 6 stages impactor and n° 4 side connectors (optical particle counter option).

Extraction Condenser

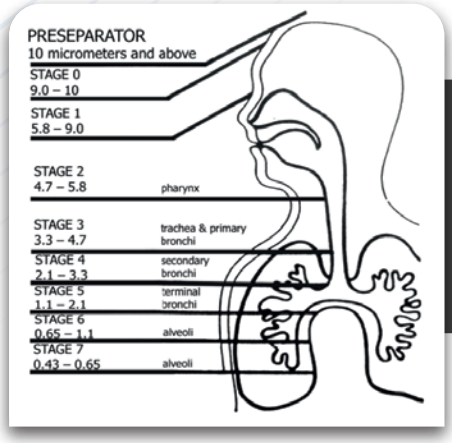
Cod : AC99-120-0003SP

- PYREX glass Condenser;
- PYREX glass Condensation vessel.

Electronic Flow Control Sampler

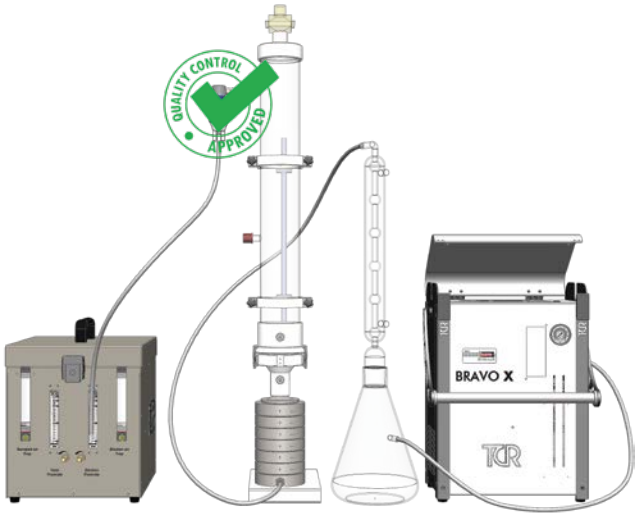
Cod : AA99-000-0030SP [Bravo Basic H]
Cod : AA99-000-0740SP [Bravo X BIO]
(differential pressure)

- 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 aerodinamic diameter stops in the first tract while the submicronic particles cross the lung airways to stop in alveolar region.

Pneumatic Diagram EN 14683 (Annex B)



BFE Bio Kit allows to be in compliance with all the requests for BFE % efficiency test (Bacterial filtration efficiency) and differen-tail pressure test(Pa/cm^2).

Facial BFE Mask

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

- Fill in the aerosol generator with liquid solution or suspension to nebulyze;
- 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/cm^2)	< 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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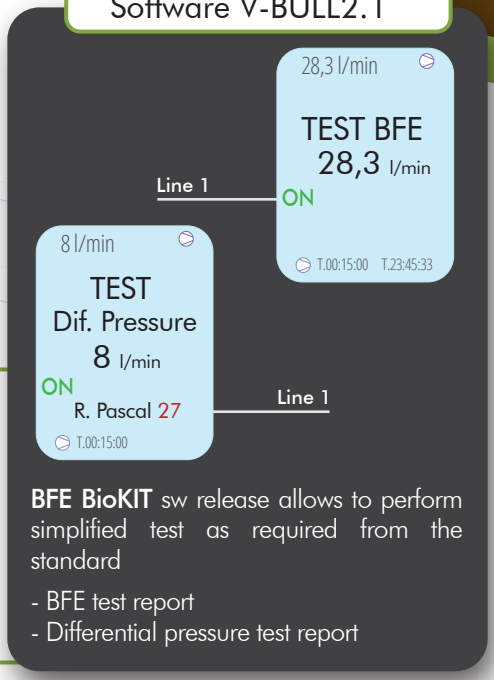
BREATHING EFFICIENCY TEST
differential pressure - Annex C - EN14683

The air permeability level when the air flows through the mask tissue is measured by a differential pressure assesment, in a specific 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 othewise specified, the test has to be performed flowing air from the internal part of the mask (part that face nose and mouth) towards outside.
Particle sampled holders to recover the sample, made of material as requested from the standard, are delivered.

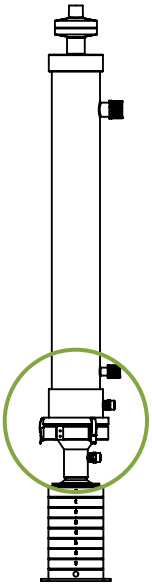
Sample holder 25 mm diameter Stainless steel AISI316 – Breathing test
Sample holder 80 mm diameter made in PTFE – BFE test (cutout part 100x100 mm)

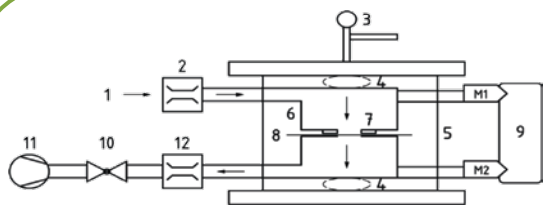
Software V-BULL2.1



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

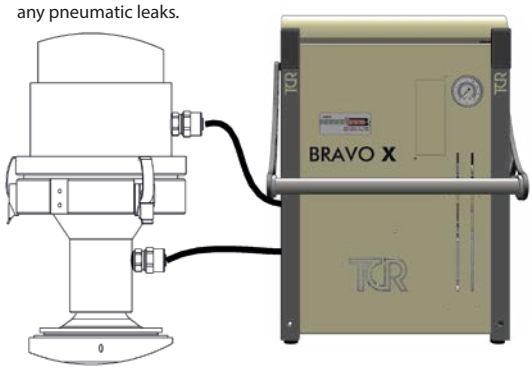
- BFE test report
- Differential pressure test report





Pneumatic Diaphragm EN 14683 (Annex C)

Lever closure to eliminate any pneumatic leaks.



BRAVO X 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 simplify the data management and settings. The output fully detailed 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.

In fact, EN 14683 standard require that the 25 mm punch test is performed in 4 hours at a temperature of 21 +/- 5 °C and with RH 85 +/- 5%

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
- Average flow and average differential pressure

TCR Call us! +39 02 3664 8635 info@tcrtecora.com www.tcrtecora.com Via delle Primule, 16 Cogliate (MB), 20815, Italy