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SURGICAL MASK PERFORMANCE

European standard requirements examined

The European Centre for Disease Prevention and Control (ECDC) has estimated that, on average, healthcare associated infections occur in one hospitalised patient in 20; that is to say 4.1 million patients a year in the European Union, and that 37,000 deaths are caused every year as a result of such infections [1].

These infections are often caused by the introduction of pathogens within patients during surgical procedures. Infective agents can be transmitted during surgical procedures in operating theatres and other medical settings in several ways. One of the important sources are the noses and mouths of the surgical team.

When breathing, speaking, coughing or sneezing, a person releases smaller or larger amounts of droplets of secretions from the mucous membranes in the mouth and nose. Those droplets quickly evaporate and leave nuclei suspended in the air. Nuclei can subsequently spread through the air to a susceptible site such as an open operating wound or sterile equipment, or can be inhaled if dimensions are very small.

Contaminated particles or dust can also be at the origin of an infection transmission.

Mechanisms of transmission

Depending on the size of droplets or particles the risk and the way the contamination can be transmitted is different.

If we try to classify the particles or droplets which are found in the environment, two classes appear:

1. *Particles or droplets whose size is superior to 5 µ (>5µ)*
   Large particles or droplets can contain microorganisms from the source site, but they sediment very quickly in the immediate surrounding (<1 metre). The transmission of infection is therefore principally by contact – soiled surfaces, objects or hands [2]; that is, contact with ORL and ocular mucous membrane e.g. Meningococcus, flu or VRS.

2. *Particles or droplets whose size is inferior to 5 µ (<5 µ)*
   A part of the droplets of saliva or secretions from upper respiratory tract emitted during coughing, speaking and sneezing of an infected patient can have a size smaller than 5µ and are particularly dangerous for humans because they can be inhaled and easily reach the bronchioles. They are relatively resistant and a high viability in the environment is possible. Moreover, they can be transported by air flux for long distances rending the inhalation by a host very likely.

   Very hazardous pathogens such as tuberculosis, varicella and measles can be transmitted in this way and require a protection which is more comprehensive than the simple face surgical mask for the wearer.

Surgical mask – definition

A surgical mask is a medical device covering the mouth, nose and chin ensuring a barrier that limits the transmission of an infective agent between the hospital staff and the patient. It was originally developed to contain and filter large droplets of microorganisms expelled from the mouth and nasopharynx of healthcare workers during surgery, thereby providing protection for the patient [3].

The main objective of wearing a surgical mask is to protect the direct environment of the wearer from contamination. Contagious patients are also invited to wear surgical masks if there is a high risk of spreading a disease.

In certain situations where additionally the protection of the wearer against splashes of potentially contaminated liquids is required, masks that are equipped with eye or face protection that guard against the projection of biological fluids – masks with a waterproof layer, for example – can be used.

It has to be underlined that surgical masks are not designed or certified to seal tightly against the face or to prevent inhalation of small airborne contaminants. During inhalation these pass through gaps between the face and the facemask and the material of the mask itself. It means that a surgical mask is not a respirator and does not provide respiratory protection.

Composition and shapes

Surgical masks are mostly disposable devices, generally based on non-woven material.

Cellulose material, synthetic fibres such as polypropylene (especially spun bonded polypropylene available in a variety of weights: 18g/sqm, 20g/sqm, 25g/sqm), constitute the main compositions available on the market.

Some of them also contain latex but since this component can be allergenic a lot of suppliers sell surgical masks by indicating clearly 'latex free'.

Surgical masks can be bought in different colours – blue and green surgical masks are well known, but other colours and even patterns are possible, especially good for contagious children patients.

They are available in three general configurations [4]:

- A 'paper shield' that may be pleated, which has two ties for around the head and a flexible nose bridge
- A 'flat or pleated shield' that has ear loops
- A molded cup shape held in place by an elastic cord around the head

Surgical facemasks normally comprise three layers – a barrier layer, such as polypropylene, usually separates the inner and outer layers.

The most common European design is flat and pleated with horizontal ties and a metal strip shaped over the nasal bridge.

Masks can be found in various shapes with different features and are selected according to personal protection needs and personal preference of style and fit.

Flat-fold tie-on, duck bill, cone shaped, flat-fold with shields, and duckbill with shields are the most common styles worn in the operating room.

For the choice of a surgical mask, size and flexibility for easy and frequent use are key factors.

Effectiveness over time

During the wearing of a surgical mask its effectiveness can decrease as a function of time.

A previous study indicated a significant difference in efficiency between different masks during wearing. The best masks contained more fabric, were softer and were pleated, while the worst were stiffer, smaller and not pleated. Reusable cotton fabric masks are as effective as synthetic fabric masks when made to a good design [5].

A mask wet with exhaled moisture has increased resistance to flow, is less efficient at filtering bacteria and has increased venting. Current recommendations are that a new surgical mask is used for each surgical case and that they should be changed when wet.

A study made by Maria Helena Barbosa and Kazuko Uchikawa Graziano [6] concerning the influence of wearing time on efficacy of disposable surgical masks as microbial barriers shows that disposable surgical masks with 95% BFE (Bacterial Filtration Efficiency) are efficient microbial barriers up to wearing time and, therefore, they are indicated for every critical invasive procedure. Another conclusion, however, is that their bacterial filtration efficacy decreases significantly after four hours.

Assessment and standardisation

In Europe, surgical masks have to meet the requirements of the standard EN 14683 [7] which defines the technical requirements for this type of product. The standard defines surgical masks as a "medical device covering the mouth, nose and chin providing a barrier to minimise the direct transmission of infective agents between staff and patient." The masks capture the infective components that are exhaled by the wearer of the mask without hindering his or her breathing.

In a hospital, this type of surgical mask is worn by:

- Doctors and nurses to prevent the patient and the environment from being contaminated
- The contagious patient to prevent both the people in his or her environment and the environment itself from being contaminated
- Relatives and visitors who are in contact with the patient

Surgical masks have to be labelled with a CE mark and meet the construction, design and performance requirements as described in standard EN 14683. The performance levels of the mask will be tested on the finished product. The mask will be classified according to the different test results.

> "masks capture the infective components that are exhaled by the wearer without hindering his or her breathing"

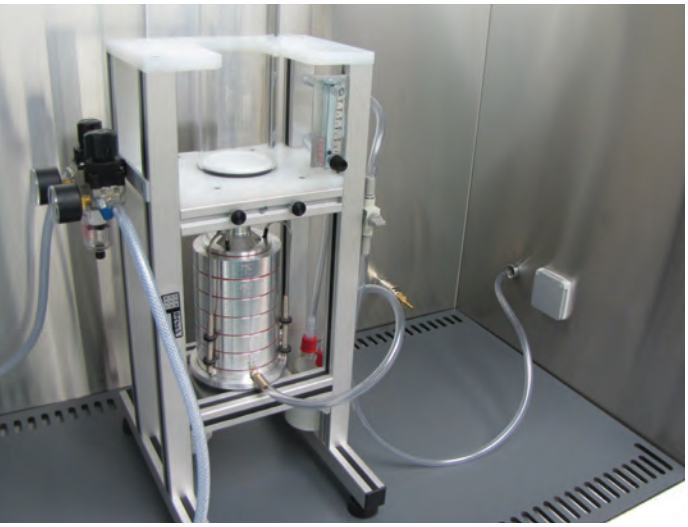
Please note: surgical masks should not be confused with protective inhalation facemasks to protect the wearer against inhaling solid or liquid particles, e.g. protection against a influenza pandemic. These facemasks have to meet other requirements, as defined in standard EN 149 [8] (Classification FFP1, FFP2 or FFP3).

The performance levels of the surgical masks are evaluated on the basis of three criteria included in standard EN 14683:

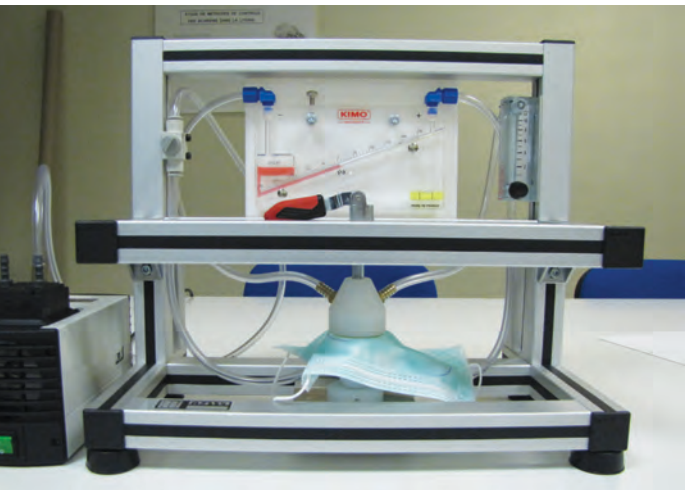
1. *BFE (Bacterial Filtration Efficiency)*
   The BFE measures the percent efficiency at which the facemask filters bacteria passing through the mask.

2. *Delta P (Breathability)*
   The Delta P is the pressure drop across a facemask, expressed in mm water or Pascal. The higher the Delta P, the more difficult the mask is to breathe through.

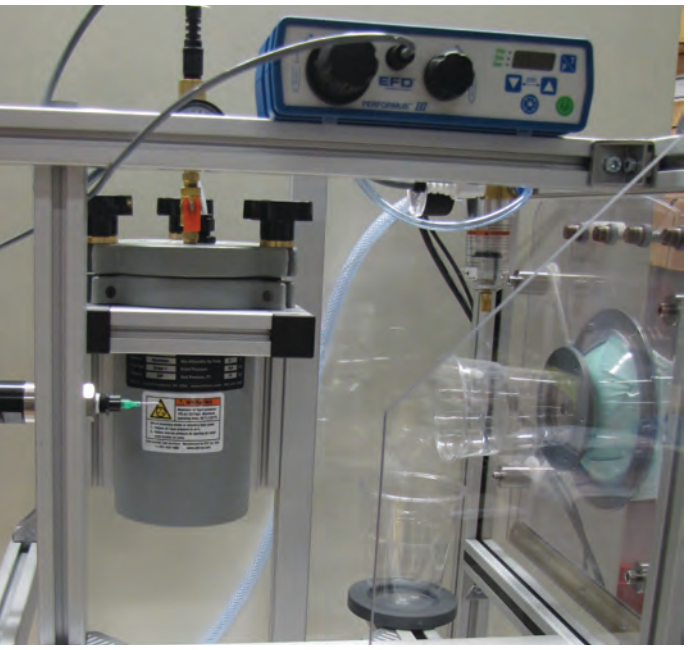
3. *The 'Splash Test'*
   The splash test measures the fluid resistance of the mask and is defined as the ability of a facemask's material construction to minimise fluids from travelling through the material, and potentially coming into contact with the user of the facemask. Fluid resistance helps reduce potential exposure to blood and body fluids caused from splashes, spray or spatter. ▷



BFE test – developed by Centexbel



Breathability test – developed by Centexbel



Splash resistance test – developed by Centexbel

Bacterial Filtration Efficiency (BFE)

Point 5.2.1 of the EN 14683 standard (description in annex B)

This method measures the effectiveness of a surgical mask in capturing aerosol droplets containing bacteria.

The filtration efficiency depends on the particles or bacteria size, the air flow passing through the mask and the surface properties of the particles.

Principle of the method:

A specimen of the mask is inserted between an impactor and the chamber where the bacterial aerosol is produced.

The bacterial aerosol (Staphylococcus aureus) arrives in the chamber « aerosol », goes through the specimen and is recuperated on Petri dishes placed in the impactor.

The efficiency of filtration of the mask is given by the percentage of bacteria that are stopped by the mask specimen, compared to a trial performed without specimen.

Depending on the type of facial mask, the required filtering levels are ≥ 95 % or 98%.

Differential pressure or breathability

Point 5.2.2 of the EN 14683 standard (description in annex C)

This method measures the pressure drop across a surgical mask under specific conditions of airflow, temperature and humidity. The differential pressure is an indicator of the breathability of the mask, expressed in a differential pressure (ΔP) in mm H_2O/cm^2 or Pascal/cm^2.

> "the differential pressure is an indicator of the breathability of the mask"

A differential pressure of viz. < 29,4 or < 49,0 Pascal/cm^2 is required for surgical masks of Type I and Type II.

The breathability of a surgical mask or its properties to let air through depends on a series of parameters such as the nature of the textile, the applied finish, the number of layers or its thickness.

Splash test

Point 5.2.3 of the EN 14683 standard

EN 14683 refers to the standard ASTM F1862 [9] 'Resistance of medical facemask to penetration by synthetic blood'. This is what is meant by a 'Splash Test' to measure a mask's performance.

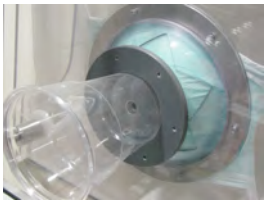
This test method is used to evaluate the resistance of medical facemasks to penetration by the impact of a small volume (~2 ml) of a high velocity stream of synthetic blood. The impact speeds and volumes of synthetic blood are chosen to simulate different scenarios in the operating theatre.

The masks are evaluated at speeds of 450, 500 and 635 cm/s. These speeds correspond to the puncturing of a small blood vessel at a vessel pressure of viz. 10.6, 16 and 21.3 kPa (80, 120 and 160 mmHg).

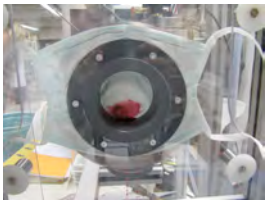
"medical facemask pass/fail determinations are based on visual detection of synthetic blood penetration"

Prior to the test, the masks are conditioned over a period of four hours in a very humid environment (85% ± 5% at 21°C ± 5° C) to simulate the conditions of use corresponding to the humidity created by the respiration of the wearer of the mask.

Medical facemasks pass/fail determinations are based on visual detection of synthetic blood penetration.



Detail of mask in the equipment



Mask after Splash Test bad result

As far as test results are concerned, surgical masks are classified in types according to the table below:

Test	Type I	Type IR	Type II	Type IIR
Bacterial Filtration Efficiency (BFE)%	≥ 95	≥ 95	≥ 98	≥ 98
Breathability (differential pressure), Pa/cm²	< 29,4	< 49,0	< 29,4	< 49,0
Splash resistance pressure (mm Hg)	not required	≥ 120	not required	≥ 120

Note Type IR and Type IIR are splash resistant types

At this very moment, standard EN 14683 is being revised and a new draft [10] has been proposed, including two additional aspects:

- The bio-burden or microbial charge of surgical masks
- The biocompatibility of surgical masks

These additional properties will be included in the tests as soon as the revision has been approved.

References

1. *Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01)*
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5. *Quesnel LB, 1975, The efficiency of surgical masks of varying design and composition, Br J Surg.; 62 (12):936-40*
6. *Barbosa MH and Graziano KU, 2006, Influence of wearing time on efficacy of disposable surgical masks as microbial barrier, Brazilian Journal of Microbiology 37:216-217*
7. *European Standard EN 14683, 2005, Surgical masks – Requirements and test methods*
8. *European Standard EN 149 + A1, 2009, Respiratory protective devices - Filtering half masks to protect against particles – Requirements, testing, marking*
9. *ASTM International Standard F1862, 2007, Standard test method for resistance of medical facemasks to penetration by synthetic blood (horizontal projection of fixed volume at a known velocity)*
10. *prEN European Standard 14683, 2012, CEN/TC 205/WG14/PG1, Medical facemasks – Requirements and test methods*

Authors

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Yvette Rogister joined Centexbel 23 years ago after one year of teaching at the University of Louvain-La-Neuve. As an engineer in chemistry she started her career as a researcher and followed a lot of projects concerning textiles and surface modifications by different processes. Later she contributed largely to the development of the laboratory of microbiology, and hygiene in relation to textiles. By participating in different standardisation committees and developing testing methods she now has extensive experience in numerous different fields including antimicrobial treatments, barrier textiles, medical textiles and medical devices.

Ing Mark Croes

After a career of almost 15 years in technical service and product development servicing the European pharmaceutical, paper and textile markets with an American specialty chemicals' manufacturer, Croes joined Centexbel ten years ago as a Technological and Innovation Consultant, supporting the activities in the field of Health and Safety in the laboratory.

Centexbel, Belgian Textile Research Centre

The Belgium based laboratory offers highly specialised technological services including customised advice, measuring and testing, certification, process innovation and product development to the manufacturers of medical and hygiene oriented textile products. The laboratory specialises in the evaluation of cleanliness and barrier properties – both particle and microbial – of medical and hygiene products.

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