

An Overview of Airborne Disinfection

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Every critically controlled sector, be it a factory, hospital or laboratory, should have hygiene procedures in place to a guarantee safe and secure environment for production and its workers.

Hygiene is, above all, a state of mind.

If the particulate level is maintained by filtration and pressure differences in the rooms the level of cleanliness can be guaranteed by following a 3 stage hygiene procedure: cleaning, disinfecting surfaces at high risk and disinfecting surfaces by airborne disinfection, a procedure also known as "terminal disinfection".



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What is Airborne Disinfection?

When talking about Airborne Disinfection, it is important to emphasize that this technique does not treat the air itself. Other techniques exist to do this, such as air filtration, photocatalysis etc.

This technique has been used for a long time but mainly in France. Other European countries have been content to use conventional or direct spraying methods.

The increasing desire of operators to find safer methods, so that they no longer have to be in direct contact with the chemical products, has led them to move towards the use of the Airborne Disinfection technique. Why?

- This is a means of disinfecting surfaces using the air as a medium for disinfectants.
- It is a disinfectant method which can reach all surfaces, including those previously considered to be inaccessible (surfaces out of reach, hidden areas or even areas which are usually enclosed).
- It is a disinfectant procedure that can be carried out with no human presence (therefore without risk to an operator) and can be run during production downtime (thereby saving time).



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What standards govern this method of disinfection?

The standard NF-AFNOR T 72-281, version 2009, sets out the validation method for the bactericidal, fungicidal and sporicidal disinfection of surfaces by airborne means. A European standard has been proposed but has not yet been implemented.

This standard also covers the Combination Product. Indeed, it would make no sense to consider validating a disinfectant product without including its method of application.

The test method used is stainless steel or glass supports, seeded and exposed to a source of inoculum, placed at a distance of between 3 to 4.20m from the disinfectant emission source and at a height of 1m. The exposure time is left to the operator's discretion, as long as it is less than 12 hours.

The reduction rate of micro-organism populations required is:

- 5 logarithm reduction for bactericidal disinfection (99.999% mortality)
- 4 logarithm reduction for fungicidal and yeasticidal disinfection (99.99% mortality)
- 3 logarithm reduction for sporicidal disinfection (99.9% mortality)

This standard shows that we're really talking about disinfection, even decontamination, but not sterilization in the purest sense of the term, that is to say, the standard used for sterilization in autoclaves must show a reduction of 12 Log.

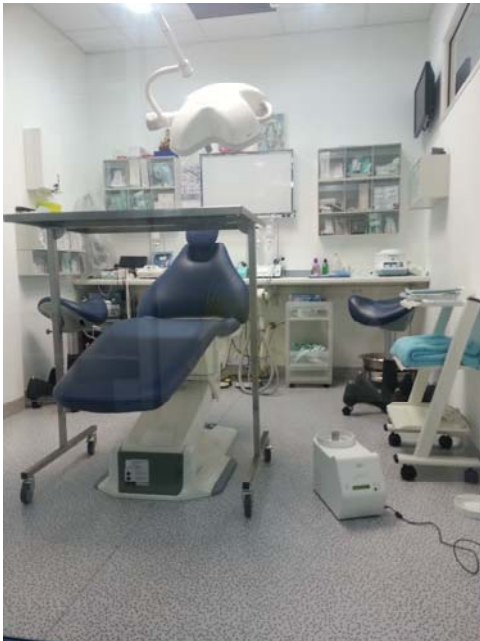


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What can be treated by Airborne Disinfection?

- Airborne contamination: these will be first deposited by a purely physical process (the agglutination of aerosol particles and micro-organisms), and then treated with the disinfectant.
- Accessible surfaces which are routinely treated: they should have already been cleaned and possibly disinfected but this process will consolidate this procedure.
- Surfaces previously considered to be inaccessible: All the difficult, or even impossible, to reach surfaces that it is absolutely essential to disinfect.
- The surfaces of equipment, material and consumables: Most material, machinery and equipment have not been designed with disinfection in mind. It is therefore very important to be able to do so using this method. Similarly, taking consumables into a cleanroom necessitates going through an airlock which must be completely disinfected.



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What are the features that make this method so effective?

- It can handle any room volume and even multiple-rooms.
- It uses an effective product with a spectrum of activity compatible with the micro-organisms found in the area to be treated.
- It is a non-persistent medium that leaves no residue to avoid the contamination of any future production.
- It uses a non-corrosive, or at least a very mild, medium during diffusion leaving no toxic residue for operators when they reuse any of the treated areas.
- It uses an efficient diffusion device (re: size of droplets emitted), to achieve optimum efficiency with the product being used.
- It has a downtime compatible with local production and working constraints.
- It makes possible a means of monitoring the proper diffusion of the product (especially in areas inaccessible to manual treatment) and microbiological monitoring for the air and surfaces.



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Environmental factors which have an impact on the process

a. Room Temperature:

Room temperature will have an effect on the homogeneity of the diffusion of the product in the area being treated.

At a temperature lower than 10°C the product will be emitted as very fine droplets into the bottom of the space being treated and will leave condensate.

Conversely, at a temperature above 30°C the mist emitted will rise to the upper region of the space being treated and surfaces in the the lower part will not be evenly disinfected.

The impact of this parameter will vary depending on the delivery method used. The new standard takes this parameter into account and specifies that a constant temperature should be maintained for the duration of the validation procedure.

b. Room Humidity:

The relative humidity of the area to be treated will have an impact depending on the methods and especially the products used. The AFNOR standard already suggests an optimum humidity level for tests (between 50 and 75% RH), but also emphasizes the necessity of maintaining a constant humidity level between tests.

The efficiency of formaldehyde gas or hydrogen peroxide is dependent on the ambient humidity which should not be less than 60% and not greater than 90%. These products are, in fact, only effective when combined with water.

"Ready to use" aqueous solutions make sure there is sufficient moisture present to make the products formulated with aldehydes or peroxide effective.

Some technologies need a pre-wetting phase before the diffusion of formaldehyde or hydrogen peroxide to meet these minimum requirements.



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c. Sealing the premises:

It is very difficult to make an area completely airtight. It should be noted that the smaller the droplets used, the more effective the seal must be. One has to be more vigilant with a vapour system than with a micro-droplet system.

In general the doses recommended take into account the reality in the field, namely with a "relative" isolation of the area to be treated.

d. The Topography of the Premises:

The shape of the building and way the space is laid out (partitions, doors etc.) should be taken into consideration in order to achieve effective disinfection.

For example, the contact time will depend on the estimation of the time needed to distribute the product through the volume of space to be treated.

The location of the product dispersion source will depend on the placement of any partitions, doors and machine fairing outlets.

Finally, the type of device chosen and the number of devices used will also depend on the topography of the area.

e. Ventilation systems:

We know that filtration is an effective way to clean the air and that premises are usually equipped with ventilation systems. Any ventilation systems in place must be turned off during the diffusion period and while the disinfectant is in contact with the surfaces. Even drafts from air outlets can be detrimental to the even distribution of the product within the operating space.



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Means of propulsion

To distribute a disinfectant liquid throughout an area it is necessary to use an adequate means of propulsion, usually a device (we intentionally do not discuss disinfection with sprays, which belongs to the classic method of conventional spraying).

1 - Venturi System:

This procedure is now the most common and uses a nozzle and compressed air, which can be supplied either by an external pipe, or by a built-in compressor.

In this process a liquid-air mixture is forced through a very small hole to create the droplets.

This method generates droplets of 5 to 25 μ depending on the quality of the nozzles and the efficiency of the compressor.

There is no exact calibration and there is a varying gradient depending on the distance from the apparatus (large droplets fall close to the device, resulting in a wetting effect, the fine droplets are diffused into the more distant parts of the area without necessarily having the most effective concentration).

This method can use both ready-made formulas as well as formulas which must be diluted.

Advantages	<ul style="list-style-type: none">Simple designInexpensiveNot too complicatedWell known and widely used method.
Disadvantages	<ul style="list-style-type: none">The droplet size is not constantFluctuating flowThe bottle needs to be refilledWetting effect particularly in small areasThe nozzles can get cloggedNoisyCannot be used to treat very small areas

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2 - Hot Gas Method:

The method generates vapour which acts as a carrier for the disinfectant. It uses only concentrated hydrogen peroxide. It takes into account the relative humidity of the area to be treated either by varying the amount of H₂O₂ released, or by first drying the rooms before re-humidifying them. Once the vapour has been deposited on the surfaces, the difference in temperature between the medium and the surface causes micro-condensation to occur. It is these micro-droplets that render the disinfectant effective. In both cases, the particles are evenly distributed by external fans. Naturally, the hot steam tends to rise and sinks with difficulty without this method of mixing the air.

Advantages	Comprehensive and traceable system Proven effectiveness Very fine droplet size Robust and reliable
Disadvantages	Very expensive Needs a skilled operator High risk of corrosion Requires the use of fans Cannot be used to treat either very small or very large areas.



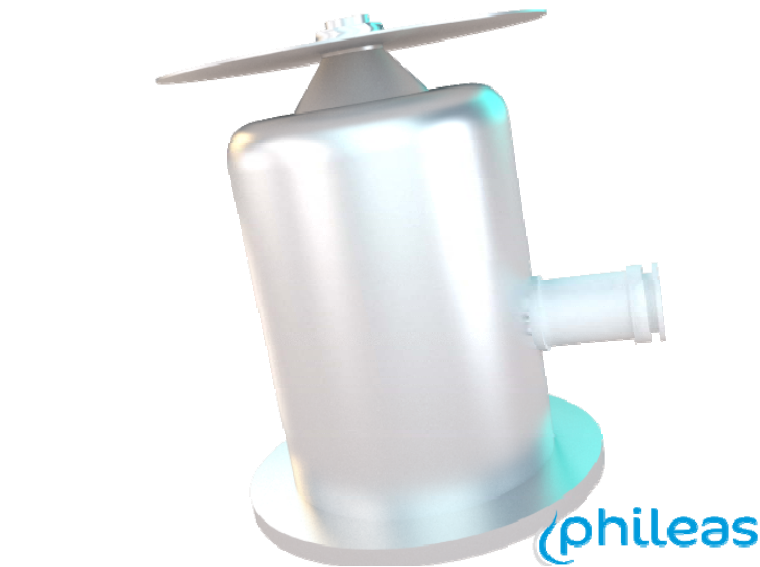
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3-"Dry" mist or the Venturi two-piece nozzle system:

This cold process uses compressed air and relies on a specific quality of the spray nozzles that emit two jets that intersect one another. It produces perfectly calibrated particles between 7 and 12 μ in size and uses a mixture of peroxyacetic acid in concentrated form. The dilution percentage is calculated as a function of the relative humidity of the treatment area for the intended purpose (for even distribution and maximum efficiency).

Advantages	Proven effectiveness Calibrated and fixed droplet size Table of calculations for water flow No electrical connection required Robust and reliable
Disadvantages	Quite expensive Complicated to assemble and move Very fragile nozzles which clog easily Requires an external supply of compressed air The volume of water to be added must be calculated depending on the Relative Humidity (RH) of the room before each treatment If RH > 70%, no treatment is possible.



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4 - Centrifugation System:

It's a well know fact that most processes using nozzles suffer from the risk of clogging.

This system uses centrifugal force to produce droplets of excellent quality with a more uniform droplet size of between 5 and 10 μ , with no risk of clogging.

A peristaltic pump ensures a constant liquid throughput.

A high-speed rotating disc or plate creates fine, accurately calibrated droplets.

It is the natural kinetic energy of the droplets that distributes them evenly throughout a given volume.

Advantages	Very easy to use and a highly mobile system Proven effectiveness Calibrated droplet size No special skill required Can handle all volumes
Disadvantages	Traceability only with the large appliances Fragile diffusion head



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Categories of Products used

1 - Formaldehyde Gas:

Formaldehyde exists as a solid (sublimation) or liquid (spray) to be released in gaseous form by heating. Its effectiveness has long been recognized in the veterinary field (often combined with potassium permanganate). It was introduced into the hospital and industrial sectors many years ago without having undergone proper validation. Today, this method of disinfection has been largely abandoned because of its proven toxicity, with the exception of sensitive sectors such as L3 or L4 laboratories.

2 - Liquid Products:

Liquid products alone are not part of an integrated diffusion method and must be used with a suitable device. The choice of product (ready-to-use or concentrate to be diluted with water) depends on the method of dissemination and economic criteria. The hospital and industrial sectors usually use ready-to-use products because they allow the reproducibility of results, are easy to use, safe and avoid any dilution errors.

The choice of active ingredients will depend on the objective (desired spectrum of activity). For example, sporicidal treatment will only be effective with four active ingredients: glutaraldehyde, hydrogen peroxide (with or without added peracetic acid), potassium monopersulfate and chlorine dioxide.

Aldehyde Solutions:

They have a very broad spectrum of activity covering bactericidal, fungicidal and sporicidal treatment (if glutaraldehyde is included in the formulation). They achieve an efficacy equivalent to that of the gaseous formaldehyde method but with a shorter contact time, much faster recovery of the treated area and with no risk of sustained release for the staff.

According to the International Agency for Research on Cancer (IARC) Formaldehyde is classified as a Category 1 product and now has the same restriction of use as products classified as known carcinogens to humans. Therefore, few manufacturers continue to produce it and even fewer operators use it due to restrictions related to the use of carcinogenic substances. This product is not prohibited, but the user must demonstrate to the Ministry of Labour, that there is no acceptable alternative.

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Quaternary Ammonium-Glutaraldehyde Mixtures:

These have a wide range of applications covering bactericidal, fungicidal and sporicidal treatment. They have a relatively strong odour and treated areas do not recover quickly. This mixture may also present a risk of persistence and residues (fatty deposits).

Biguanidine:

Its range of application covers bactericidal and fungicidal treatment if it is used at a high enough dose. It has no odour, rapid recovery time for the premises and has low persistence. However, a recent study has demonstrated some carcinogenic properties that will lead to the product being reclassified as a CMR.

Hydrogen Peroxide:

This can be effective for all treatments if used at the correct dosage. However, the active ingredient is unstable and often requires the addition of a chemical stabilizer, which may result in the deposition of residues.

Mixtures of Hydrogen Peroxide and Peracetic Acid:

This can be effective for all treatments (like aldehyde solutions or peroxide alone), the addition of peracetic acid reduces the dosage required. They allow for a very rapid recovery of the premises, without the risk of any persistence. However, their strong oxidizing property can cause corrosion of some fragile materials, if the product is used at certain concentrations or if the delivery method is not adjusted accordingly.

Chlorine Dioxide:

Its usage is as wide as hydrogen peroxide but it is very difficult to manufacture and especially difficult to stabilize. This product is available as two separate components which must be mixed at the time of use. This procedure carries with it a risk of user error.

Procedures for Use:

Dosage: Dosages between 6 and 15ml/m³ are the most common.

It is important to check that the dosage used does not result in too much consequential damage such as excessive wetting of surfaces, corrosion or contamination of the surfaces. *The contact time:* not specified by the standard but must be compatible with production constraints. Commonly accepted times are from 1 to 12 hours.

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The Disinfectant-Device Combination Product

A study of the methods and formulations available shows that the effectiveness of the disinfectants product will depend on the chosen diffusion process. Manufacturers of products for the disinfection of surfaces by airborne means must therefore validate the effectiveness of their formulas with a given method selected and provide a custom combination product.

This is also a requirement of the NF T 72-281 standard.

With any combination product the operator must be given proper training in the specific disinfection technique associated with it.

Validation "in the field"

NF T72-281 standard is indeed the benchmark for validation but cannot integrate the constraints of use in the field for several reasons

1 - the biological indicator preparation protocol is too complicated to implement

2 - the choice of strains. Although representative of many contaminants, they may be far removed from the so-called "factory" strains

3 - the volumes proposed by the standard (between 30 and 150m³) are not sufficiently representative of those found in the field

4 - the positioning of biological indicators at a single point does not reflect the concerns of operators in the field, especially their desire to see the product spread over the entire area.

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In conclusion, we favour the use of commercial biological indicators such as *Geobacillus stearothermophilus* on stainless steel supports that we can place in the most representative parts of the area to be treated. The advantage of this strain is that it is not pathogenic. It is also an excellent tracer for evaluating the effectiveness of hydrogen peroxide and it is cultivated at 55°C, which avoids any false positives related to mishandling.

This part of the microbiological validation can be completed using so-called "factory" strains, that is to say, those wild strains encountered on-site and subjected to the same treatment.

We can complete this validation using routine 1-100 ppm H₂O₂ chemical detection strips that can be placed at strategic locations to ensure that the disinfectant has spread to all parts of the area to be treated. The results of microbiological tests may give some indication of a correlation between the rate of H₂O₂ observed and microbiological efficacy. For the record, the maximum rate of hydrogen peroxide in the air after disinfection, and before the facilities can be reused, must be less than or equal to 1 ppm.

Study Conclusions

The disinfection of surfaces by airborne means is a process with good prospects and has the following advantages:

- the method is generally reliable
- the method is mostly easy to carry out
- the method can treat inaccessible surfaces
- the method can be used with no human presence and in production downtime

This technique has been overlooked for some time, primarily in the food industry and in hospitals, because its ease of implementation had led users to forget that it was necessary to keep up with conventional cleaning procedures and that this technique was complementary to standard disinfection procedures.

Today, thanks to ISO standards and quality assurance procedures, this process is finding its niche as an added component in hygiene procedures. With the formulas available it can be perfectly adapted to the requirements and limitations of each specific use and each sector.

Airborne Disinfection is a remarkable tool and can achieve good results in the disinfection of surfaces and premises but must be integrated into an overall hygiene process, described in detail in written procedures and checked regularly to avoid any lapses because of its ease of use. Under these conditions, this technique continues to evolve, has a great future ahead of it in the disinfection of cleanrooms and has become internationalized for use in Europe and throughout the world.

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