Understanding EN 17272:2020
The New Automated Airborne Disinfection Standard

EN 17272:2020 is the new European test standard for automated airborne disinfection systems intended to provide a standardised challenge against which manufacturers can test their automated airborne disinfection process to claim defined antimicrobial activity. The standard is based on the long-standing French standard NFT 72-281, but contains additional test requirements such as distribution assessment, airborne disinfection contact (ADC) time, specific test organisms and enclosure test volumes.

This paper discusses the background to the development of the standard and provides guidance on its application.

An automated airborne disinfection process is defined as a process that diffuses a product in the form of a gas, vapour or aerosol from a device without the need for human intervention. Well-known examples of such technology are hydrogen peroxide vapour disinfection systems and formaldehyde fogging units. However, the standard also applies to lesser well-known technologies such as total release foggers – canisters of product placed into an enclosure and activated to release the product - and ozone surface disinfection systems.

In France, technologies that deliver a biocidal product to a surface via the air have been subject to standardised testing for many years. The standard NFT 72-281 was originally developed and introduced in the 1980's and was subsequently updated several times up until its latest revision in 2014.

In 2010, the European disinfectant standards writing body CEN recognised the need for a European standard to evaluate the efficacy claims of the growing number of automatic disinfection systems intending to disinfect the surfaces of large and small enclosures such as pharmaceutical manufacturing isolators and facilities and hospital operating theatres and wards; and embarked on a project to develop a standard. Using the existing and industry-accepted French NFT 72-281 standard as a base, a task force of experts, led by France, developed a new standard – EN 17272 – over many years. The standard is a cross-working group standard providing the requirements to support claims in the Medical area, Veterinary area and Industrial / Food area. Whilst heavily based on the NFT 72-281:2014 standard, the new standard aimed to address some of the limitations identified in the NFT 72-281 and clarify areas of the standard such as enclosure volume.

WHAT ARE THE FOUR KEY DIFFERENCES BETWEEN EN 17272 AND NFT 72281 ?

Distribution Test

NFT 72-281:2014 requires the microbiological carrier to be placed a defined distance from the automated airborne disinfection device relative to the size of the enclosure in which the testing is being carried out. The carriers are positioned vertically, at a height of between 1.0m and 1.5m from the ground, facing away from the device. Whilst this set-up provides an indication that the disinfectant and its delivery technology are able to achieve a certain level of microbiological reduction in front of the device at a height of 1.0 – 1.5m, it does not provide any confirmation that the same level of microbiological reduction would be achieved behind the device, or in the corners of the enclosure, or on surfaces that may be horizontal – particularly those facing towards the floor. Automated airborne disinfection systems are commonly marketed as being able to decontaminate all exposed surfaces or as whole room disinfection systems. The NFT 72-281 test did not provide a means to evaluate such a claim. A distribution test has been incorporated into EN 17272 to challenge the efficacy of automated airborne disinfection systems at the extremities of an enclosure and in conditions where the effects of gravity or conditions of reduced distribution may affect the process. In total 8 carriers, each containing > 1×10^6 CFU of *Staphylococcus aureus* are located in the corners of the enclosure. Two carriers are located in one top corner of the enclosure – one carrier is facing towards the wall and one carrier is facing towards the ceiling.

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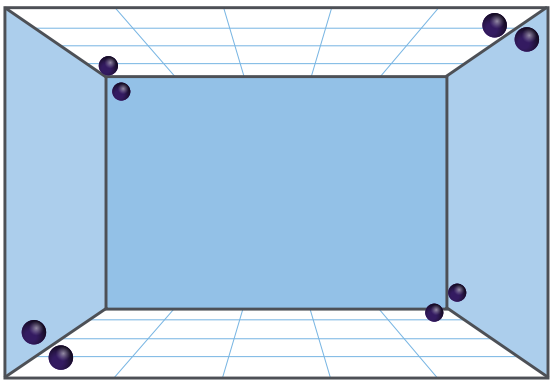
Another two carriers are located in the top corner of the enclosure diagonally opposite the first two carriers – again, one facing the ceiling and one facing the wall. Two carriers are located in the bottom corner of the enclosure across from the carriers in the top corners – one carrier is facing the floor and one carrier is facing the wall. The final two carriers are located in the bottom corner of the enclosure diagonally opposite the other set of bottom corner carriers – again, one facing the floor and one facing the wall. The position of the carriers is presented in the following diagram *(fig 1)*:



Distance from corners = 50 cm (15cm for small enclosures)

Figure 1.

The automated airborne disinfection system must attain a >5 log reduction on each of the eight carriers. If the required log reduction is not achieved on all carriers, the system cannot claim to pass the standard. The cycle used to conduct the distribution test must be identical to the cycle used in the core efficacy test and the application device must stay in the same location within the test enclosure.

Micro-organisms

The test micro-organisms in EN 17272 are substantially similar both to those within the NFT 72-281 standard and the EN disinfectant efficacy standards. The specific microorganisms used in the test depend on the manufacturers' use claims for the technology. To claim compliance with the standard, a manufacturer must, as a minimum, pass the bactericidal, yeasticidal and distribution test requirements. Should a manufacturer wish to support a claim of, for example, activity against viruses in a hospital setting, then the manufacturer would need to pass the bactericidal, yeasticidal and virucidal requirements for the medical area along with the distribution test. The test micro-organisms and their required log reductions to support a claim of conformity are presented in the following table *(fig 2)*:

Group	Species	Required Log Reduction		
		Medical Area (PT2)	Vet. Area (PT2 & 3)	Industrial & Food Area (PT2 & 4)
Bacteria	*Pseudomonas aeruginosa*	Not applicable	5	5
	Staphylococcus aureus	5	5	5
	Enterococcus hirae	5	5	5
	Escherichia coli	5	Not applicable	5
	Acinetobacter baumanii	5	Not applicable	Not applicable
	Proteus hauseri	Not applicable	5	Not applicable
Spores	*Bacillus subtilis*	4	3	3
Fungi & Yeast	*Candida albicans*	4	4	4
	Aspergillus brasiliensis	4	4	4
Virus	Murine Norovirus	4	Not applicable	4
	Adenovirus Type 5	4	Not applicable	4
	Porcine Parvovirus	Not applicable	4	Not applicable
Mycobacteria	*Mycobacterium avium*	4	4	4
	Mycobacterium terrae	4	Not applicable	4
Bacteriophage	*Lactobacillus lactis* P001 + 8	Not applicable	Not applicable	4

Figure 2.

Specific test organisms apply for the different use areas and whilst generally, log reduction requirements are the same across the use areas, a claim of sporicidal activity requires a 4-log reduction in the medical area. Efficacy against Murine Norovirus and Adenovirus Type 5 is required to support a claim of virucidal activity within the medical and industrial areas, whilst the small non-enveloped virus *Porcine parvovirus* is required to support a virucidal claim within the veterinary area. Efficacy against *Acinetobacter baumanii* must be established as part of the testing to support a claim of Bactericidal activity within the medical area.

Enclosure volume

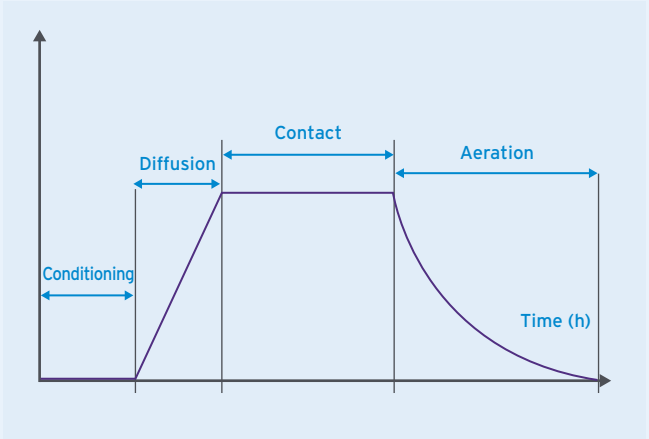
NFT 72-281:2014 was unclear and impractical in relation to the size of the enclosures in which the testing had to be carried out. The standard clearly identified that an enclosure volume of 30m^3 to 150m^3 should be used to establish an efficacy claim, but it also provided information on testing smaller enclosures down to 10m^3. Testing requirements related to small enclosures were unclear and 10m^3 is unrepresentative of small enclosures that are commonly biodecontaminated using an automated airborne disinfection system such as biological safety cabinets, isolators, pass through chambers, etc. The standard also required a manufacturer to test in a large enclosure if claiming >150m^3. This requirement was impractical, unrealistic and does not provide valuable information. Conducting a NFT 72-281 test in a large empty enclosure – if an appropriate enclosure can be found – does not assess the decontamination efficacy throughout the enclosure, only at the point the carriers are located in front of the generator. The results gained are applicable to the tested enclosure at the environmental conditions at the start of the test, they may not be transferable to another enclosure of equal volume but with a different internal configuration, construction materials and surface to volume ratio. There is little / no value in conducting the test.

EN 17272 improves the clarity of the testing requirements in relation to enclosure volume. Manufacturers intending to support a use claim in small enclosures, defined as enclosures between 0.25m^3 to 4.0m^3 must test in an enclosure within this volume range. For use claims in enclosures greater than 4m^3 manufacturers must test in a 30m^3 to 150m^3 chamber. The impractical and unvaluable requirement to test in large enclosures greater than 150m^3 has been removed.

EN 17272 recognises that testing in an empty enclosure is not equivalent to testing in an equivalent size chamber containing a load (i.e. furniture). The standard makes it clear that the intent of the standard is to provide a defined challenge to confirm that an automated airborne disinfection system can be considered efficacious, it does not validate all intended treatments with a specific automated airborne disinfection system. The standard identifies that each biodecontamination cycle / scenario is unique and that cycles must be validated in practice using appropriate biological indicators or calibrated chemical indicators. This requirement supports the position of the European Chemicals Agency (ECHA) detailed in Section 8 of the Efficacy Technical Agreement on Biocides.

Airborne Disinfection Contact (ADC) time

An automated airborne disinfection system cycle can be broken down into 4 distinct phases:



Conditioning – where the automated airborne disinfection system and the enclosure to be decontaminated are prepared or conditioned ready for the introduction of the gas, vapour or mist

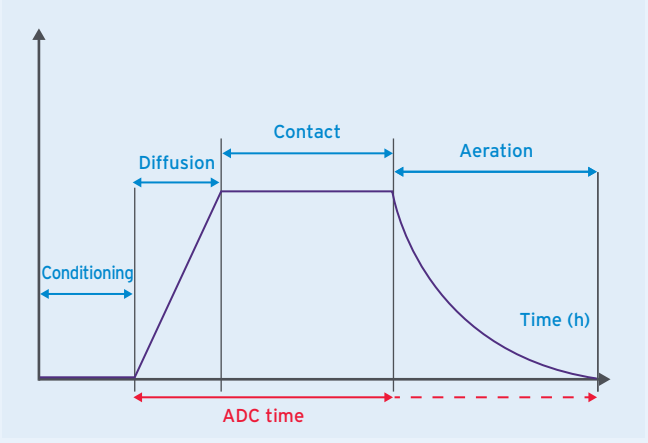
Diffusion (Gassing) – introduction of the gas, vapour or mist

Contact (Dwell) – where the disinfecting agent is left in contact with the surfaces of the enclosure and the microorganisms residing on those surfaces

Aeration – removal of the disinfectant to allow the enclosure to be re-occupied or used

The results of NFT 72-281 testing reported the contact time of the cycle, rather than the overall time the disinfectant was in contact with the enclosure surfaces. For example, system A could inject 20g/m^3 of disinfectant over a period of 1 hour and have a contact time of 10 minutes and system B could inject 20g/m^3 over a period of 15 minutes and have a contact time of 10 minutes. The cycles and their associated actual contact times with the surface are very different, but their reported contact times are identical at 10 minutes. EN 17272 introduces the concept of the Airborne Disinfection Contact time to more accurately represent the overall contact time of the disinfecting agent. The system ADC time starts from the point at which the disinfectant is first introduced into the enclosure and ends either at the initiation of aeration, or if no aeration process is used, at the point the test

coupons are removed from the enclosure. If aeration is used, the details of the aeration rate must be included in the test report.



EN 17272 Reporting

The EN 17272 standard provides instruction on the information that is to be included in the report of a test and includes:

- Identity of the testing laboratory
- Name of the product (disinfectant) and the device / process being tested
- The mechanism of the delivery process – i.e. vaporisation, misting, nebulisation, atomisation, etc.
- Disinfectant product batch number
- Device serial number
- Type of carrier used
- Distance of the device from the carriers
- Scale drawing of the test set-up
- ADC time
- Diffusion (gassing) time
- Contact (dwell) time
- Aeration time
- Aeration rate
- Quantity of disinfectant product delivered
- Exact size of the test enclosure

The test report must indicate which group(s) of organisms have been tested and identify whether the test results are "conforming" or "not-conforming" to the requirements of the test. For the distribution test a 5-log reduction must be achieved for each individual carrier.

Regulators and purchasers of automated airborne disinfection systems should request copies of the manufacturers EN 17272 test report and should review the test data to determine how the system has been tested. Manufacturers may be claiming compliance with EN 17272 based on testing against vegetative bacteria and yeast. Manufacturers looking for a system to deal with spores (such as *Clostridioides difficile*), fungi or viruses (such as SARS CoV-2) should ensure that the system has been tested against the relevant test organisms to support such claims. Users should assess the manufacturers ADC time related claims, as manufacturers may solely report the product diffusion time (sometimes referred to as application time) or the contact time, which may lead to underestimation of the overall cycle time of the system.

Conclusion

EN 17272 builds and improves on the foundation laid by NFT 72-281. The European Biocidal Products Regulation (BPR) PT 1-5 efficacy guidance document identifies the use of the European standard in the assessment of biocidal product applications involving automated airborne disinfection systems.

Bioquell's hydrogen peroxide vaporisation system has been tested to EN 17272 in large and small enclosures, for the medical, veterinary and food and industrial areas and the supports claims of bactericidal, mycobactericidal, sporicidal, fungicidal, yeasticidal and virucidal activity.

Bioquell produces a range of biological and calibrated chemical indicators that can be used to verify the performance of the airborne disinfection cycle as required in EN 17272 and the ECHA efficacy TAB.

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