Efficacy testing of airborne surface disinfection procedures according to EN 17272

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Background

For over 100 years, airborne disinfection processes have been employed as an alternative to complement manual surface disinfection methods involving spraying or wiping (1). The advantage of these airborne methods is that they can potentially reach all of the surfaces in a room. Recently, developments have seen various active substances and techniques added to the mix, including methods that use hydrogen peroxide, peracetic acid, or ozone. Just like conventional disinfection procedures, all of these methods need to be tested for efficacy. However, the established methods for testing chemical surface disinfectants do not adequately reflect how these products are being used in practice.

Generally, these kinds of processes are used as complements to “standard” surface cleaning and disinfection, and they cannot replace these methods. They may be used in areas such as isolation rooms and operating theatres, as a useful addition to the routine disinfection process.

Test Principles

In principle, gaseous agents, such as ozone, hypochlorous acid, or hydrogen peroxide, cannot be tested using previously established methods for surface disinfectants applied with a wipe, foam, or spray. In the early 1980s, a practical French standard testing method was established: the NF T 72-281 (2). This method was refined and published as DIN EN 17272 in June 2020 (3). However, the test rooms according to EN 17272 do not fully simulate such as patient rooms or operating theatres as they are not furnished for example; therefore, the test results obtained in accordance with DIN EN 17272 are not directly transferable to real-life applications.

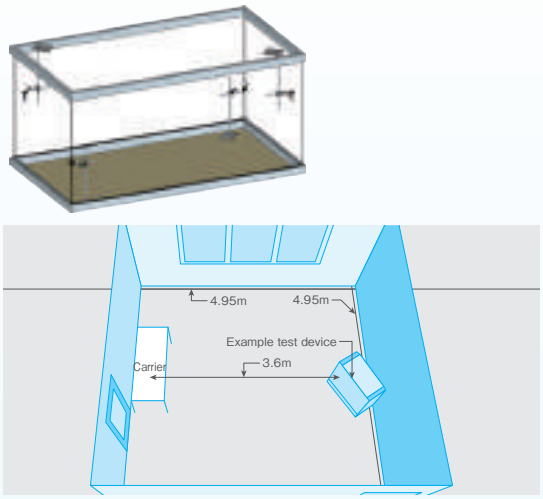
The aim of the testing process is to obtain reproducible results to assess the general efficacy of the test and allow to compare different application conditions and procedures. For this reason, the standard recommends that additional checks be performed to verify the suitability of the test for the specific local application conditions.

Determination of Efficacy

To determine the efficacy, the test follows a practical model in which an application device is used to distribute active substances in a room. The test looks at either a combination of a device and an active substance solution or a generator that directly generates the active substance.

A mixture of test organisms/viruses and an organic load is applied to a stainless steel test carrier, dried, and then exposed to the disinfection process. The number of surviving test organisms or infectious virus particles is then determined and compared with the untreated control. The resulting logarithmic reduction factor (Rf) reflects the decline in living test organisms and, therefore the efficacy of the treatment. In the case of viruses, the decline in infectiousness is measured using the $TCID_{50}$ (Tissue Culture Infectious Dose) process. Three process challenge devices for each process and test organism are affixed at defined heights and distances in the room so that the inoculated side is facing away from the release source.

Figure 1 shows a diagram of a test room setup.



Note. Example layout of the room used for testing the air disinfection device. Carriers were placed on a table 3.6 m away the test device, as shown. This figure is adapted from “Virucidal efficacy of an ozone-generating system for automated room disinfection“ by Steinmann J et al. J Hosp Infect. 2021 Oct;116:16-20, Table 1.

Fig. 1: An actual test room.

Table 1.
Selection of test organisms and required reductions.

Endpoint	Test organisms	Required reduction factor
Bactericidal	*Staphylococcus aureus*	5
	Enterococcus hirae	5
	Escherichia coli	5
	Pseudomonas aeruginosa	-
	Acinetobacter baumannii	5
	Proteus hauseri	-
Fungicidal	*Candida albicans*	4
	Aspergillus brasiliensis	4
Yeasticidal	*Candida albicans*	4
Sporicidal	*Bacillus subtilis*	4
Mycobactericidal	*Mycobacterium terrae*	4
	Mycobacterium avium	4
Tuberculocidal	*Mycobacterium terrae*	4
Virucidal	*Murine Norovirus*	4
	Adenovirus Type 5	4

In practice, a distinction is made depends on the time, which is the reaction time from the point of the effective concentration is reached to the end of the test. In laboratory tests, the time at which the process challenge device is removed marks the end of the reaction time. The carriers can be removed as soon as the process time specified by the manufacturer has elapsed or after a decontamination phase specified by the device. Under the mandatory conditions of the standard, the reaction time must be less than 15 hours. However, this is generally a challenge for many test organisms.

Distribution Test

A new aspect of EN 17272 is the distribution test. In this test, four carriers inoculated with *Staphylococcus aureus* are placed in the corners of the test room: two in opposite corners, and two secured on the ceiling. In each corner, one process challenge device is positioned vertically, facing away from the source, while another is placed horizontally, facing the ceiling (if mounted on the ceiling) or the floor. In test conditions, the tested procedure must achieve a reduction of at least five log levels. The distribution test can be performed at the same time as the actual test or as a preliminary test under identical test conditions.

Conclusion and Summary

During the COVID-19 pandemic, interest in automated room disinfection procedures increased significantly. In an automated room disinfection process with ozone as the active substance, for example, tests have demonstrated efficacy against bacteriophage Φ6 and bovine coronavirus as a surrogate for SARS-CoV-2 (4, 5).

For testing airborne chemical disinfection procedures, EN 17272 is a highly practical method, carried out in a similar way to a controlled field test. The method is a good way to standardize efficacy testing for airborne disinfection procedures and increases the safety of the disinfection as an infection prevention measures.

References

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日本語要約

EN 17272に準拠した空中からの環境表面消毒手順の有効性試験

医療施設の環境整備において、100年以上前からスプレーや清拭などマニュアル消毒の代替、あるいは補完として空間消毒が採用されてきた。現在は一般的にあくまで補助としての使用に限定され、隔離病室や手術室において日常的に行われる環境表面の洗浄・消毒に追加して実施される場合もある。近年では過酸化水素、過酢酸、オゾンといった様々な有効成分や技術の開発が進められている。従来のマニュアル消毒と同様、空間消毒も有効性試験を必要とするが、オゾン、次亜塩素酸、過酸化水素のように蒸気化して使用する薬剤は、拭き取りやスプレー式等従来の表面消毒剤に用いる試験方法は適していない。

1980年代初期、フランスの消毒標準試験法であるNF T 72-281(3)が確立された。この試験法はその後改良され、2020年6月にDIN EN 17272として発表された。しかしEN 17272で記されている試験の部屋は、病院用家具が設置されておらず病室や手術室を完全にシミュレートされていない。そのためEN 17272では現場ごとの検証を推奨している。

試験では、供試菌またはウイルスと有機負荷の混合物を試験デバイス（ステンレス製）に塗布し、乾燥させたものを消毒プロセスにさらす。試験液として、試験溶液を塗布したアプリケーションデバイスか試験液を発生させる装置のどちらかを用いることができる。これらを用いて消毒後、生残菌数またはウイルス数を測定し、未処理の対照と比較、そこでの対数減少係数（Rf）により有効性を評価する。試験では3つのプロセスチャレンジデバイスと供試菌を試験液から離れて設置されるように高さや距離が定められている。反応時間は消毒装置で設定されている処理時間となり、長くても15時間未満と決められている。

EN 17272では分布試験も実施される。黄色ブドウ球菌を摂取した4デバイスを試験室の隅（対角のコーナーに2つ、天井に2つ）に設置し消毒プロセスを行う。この試験では、5log以上の減少を達成しなければならない。分布試験は本試験と同時実施、または同一の試験条件下で予備試験として実施することもできる。

COVID-19パンデミックの際、自動室内消毒法に対する関心が著しく高まった。オゾンを用いた自動空間消毒では、バクテリオファージΦ6およびSARS-CoV-2の代用品としての牛コロナウイルスに対する有効性が試験で実証された。

空間化学消毒手順において、EN 17272は有効性試験を標準化する良い方法であり、感染対策としての消毒の安全性を高めることができる。