27th May, 2020

General information on powered air-purifying respirators (PAPR) approvals with regard to filter performance

CE certified PAPR have been tested on the basis of EN 12941 and EN 12942. With regard to the filtering performance, the EN standards define, in addition to the filter penetration, a total inward leakage of the PAPR system.

The maximum achievable performance for a PAPR with a loose fitting headpiece (e.g. hood, helmet, visor etc.) is TH3 which corresponds to a maximum total inward leakage of less than 0.2% (under laboratory conditions).

The maximum achievable performance for a PAPR with a tight fitting headpiece (e.g. full face mask, half mask etc.) is TM3 which corresponds to a maximum total inward leakage of less than 0.02% (under laboratory conditions).

EN143:2000+A1:2006 standardizes particle filters for breathing masks (not for PAPR) throughout Europe and divides them into different classes (P1, P2, P3).

With regard to the penetration requirements, both standards, EN 143 and EN 12941/ 12942, refer to the same test procedures according to EN 13274-7. Within the scope of these tests, the filters are tested with 2 different aerosols (a liquid aerosol consisting of paraffin oil droplets and a solid aerosol consisting of NaCl particles). EN 143 allows a maximum penetration of 0.05% for both aerosol types for a filter classification according to P3.

For the X-plore 8000 particulate filters it can be confirmed that the results of these tests are far below the maximum penetration value of 0.05% of EN 143 for P3 filters. So although filters for PAPR aren't classified as P1, P2 and P3, the efficiency of Dräger X-plore 8000 particulate filters meet the requirements regarding penetration for a P3 filter according to EN 143.

For the PAPR approved acc. to 42CFR84, the approval scheme differs from the European approval scheme, because NIOSH argues that a respirator's performance is largely dependent on its fit to an individual user. Therefore, in contrast to the EN approval, the total inward leakage is not taken as reference for the filter performance within the NIOSH approval.

The particle filters, however, have been tested in acc. with NIOSH Standard Test Procedure TEB-APR-STP 0001. This test procedure allows a maximum filter penetration of 0.03% for a liquid DOP aerosol which has been safely met by the X-plore 8000 HE filter.

In addition, 42CFR84 requires in subpart K that filter series HE, PAPR100-N, and PAPR100-P, for powered air-purifying respirators must demonstrate a minimum efficiency level of 99.97%, which exactly corresponds to the requirement given in the standard test procedure TEB-APR-STP0001. Dräger can confirm that our filters 'Dräger X-plore 8000 Filter P R SL' and 'Dräger X-plore 8000 HE' are identical except for the color of the housing. The results of the standards mentioned above can therefore be applied to both filters.

We would like to emphasize that, in our view, the total leakage approach of EN 12941/12942 gives a more realistic picture with regard to user protection than filter leakage alone. The reason for this is that user protection depends not only on filter performance but also on the tightness of the entire system. This also includes leakages at headpieces, connections and hoses etc..

Information regarding the use of PAPR particle filters beyond one shift

In a medical workplace environment, there are two aspects that determine how long a filter can be used: one is the filter load and the other is the infection control policy of the respective organization.

When a PAPR system is exposed to biological aerosols, such as viruses or bacteria, filter loading typically plays no role in filter replacement. Rather, the infection control policy of the respective organization plays a role here, which must be developed on the basis of national regulations.

On behalf of the Federal Ministry of Labour and Social Affairs and the Federal Ministry of Health, the German Committee for Biological Substances issued a recommendation on 7 May, 2020 on organizational measures for occupational safety in connection with the occurrence of SARS-CoV-2 and on the resource-saving use of protective equipment. (Source: Robert Koch Institute, publication of the German Committee for Biological Substances)

In this recommendation it was stated that for filters made of a glass fibre material used in the healthcare service, moisture penetration from the inhaled ambient air and dust application to the filters can be a negligible factor. Likewise, no accumulation of viruses by propagation on the filter material can be assumed. From experience in other areas of application, the use of dry filters is therefore also possible beyond one shift over several days.

Dräger can confirm that the X-plore 8000 particle filters are made of a glass fibre material.

In the event that an organization decides to use the filter beyond one shift, Dräger recommends not removing the filter from the PAPR unit but leaving it in the unit to avoid contamination behind the sealing area of the filter.

Additionally, we inform that a plug is available to close the hose connection on the unit side. Dräger recommends to close the hose connection on the unit side after use, in order to prevent any inside contamination of the unit. Furthermore, with regard to material compatibility, it was tested that the outside of the X-plore 8000 PAPR can be wiped with Incides N disinfection wipes.

A risk assessment must be carried out by your organization to determine whether these possibilities with regard to the handling of the unit are sufficient to ensure hygienic handling of a used unit with installed filter. Dräger cannot make any recommendations in this respect.

Once a filter has been removed from the device, Dräger's statements regarding the reuse of filters and their disinfection possibilities remain valid. Link

Regarding the disinfection possibilities of the other X-plore 8000 components (e.g. hoses, carrying system, hoods), the instructions for use of these must be observed.

If cleaning and disinfecting agents other than those mentioned therein are used, material damage or a shorter service life of the products cannot be ruled out. The responsibility for this lies with the customer.

In general, appropriate personal protective equipment must be worn during the preparation of the device.