

RESPIRATOR SHELF LIFE, CONTINUED USE, EXPIRATION DATING AND EXCEPTIONS TECHNICAL BRIEF



ORIGIN: Moldex® Technical Services Department

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Shelf Life and Testing

All Moldex respirators are manufactured with an expiration ("use by") date. The expiration date is determined based off of internal testing and is printed on a "use by" label. We not only test the efficiency of the filter media or cartridge components, but the various other components of the respirator. The "use by" label can be found on the outside of the sealed bag or under the top flap of the box. Respirators have various components, each of which may react differently to storage times and conditions. These components include but are not limited to the filter media, straps, exhalation valves, as well the various plastic materials, including cartridges and facepieces if they are elastomeric reusable respirators.

OSHA states all respirators shall be stored to protect them from damage, contamination, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals, and they shall be packed or stored to prevent deformation of the facepiece and exhalation valve.

For more information, click the link below to review OSHA's respirator regulations:

<https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134>

For OSHA storage regulations, please refer to sections 1910.134(h)(2) and 1910.134(h)(2)(i).

We are confident that when our respirators have been stored under normal conditions, they will perform in accordance with National Institute of Safety and Health (NIOSH) or other applicable regulatory specifications, as well as our internal specifications.

If a respirator has passed its expiration date it must be discarded and not used for protection in either an industrial or healthcare environment. Once a respirator has passed its expiration date, we cannot guarantee that the respirator will perform within all the required manufacturing specifications.

Exception Regarding Fit Testing and Training

A respirator that has passed its expiration date can be used for training purposes to demonstrate donning, doffing, fit testing and use of the same model which will be used in a hazardous, or potentially hazardous environment. Please note that if you have excessive fit testing failures, they may be due to a compromised filter media or strap and the use of the expired models for training should be discontinued.

Expired respirators used for training/fit testing purposes in non-hazardous environments must be discarded after use.

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Exceptions Regarding Emergency Stockpiles

Respirators past their expiration date that have been stored in a national, state or local strategic stockpile may be eligible to be used beyond the expiration date according to the Emergency Use Authorization (“EUA”) issued March 2, 2020. The EUA states that the stockpile manager may submit a request to the FDA, with a copy of the request to the CDC for approval. If the FDA approves the specific manufacturer, model numbers and expiration dates of the respirators in the request, they may be used by healthcare personnel.

Certain respirators past their expiration date that are listed in the current EUA are now authorized for use **“if stockpiled generally in accordance with the manufacturer-recommended storage condition and distributed under conditions of this EUA.”**

NIOSH has tested certain models of Moldex respirators which have been stored in the Strategic National Stockpile and the CDC has provided use guidance for healthcare workers and can be found below:

Link to FDA EUA Guidance:

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

Link to CDC Healthcare Worker Guidance:

<https://www.cdc.gov/coronavirus/2019-ncov/release-stockpiled-N95.html>

Link to Emergency Use Authorization Notice:

<https://www.fda.gov/media/135763/download>

Relevant Reading

The FDA authorizes industrial N95 respirators for use by healthcare workers and release from national, state and local stockpiles of respirators for use beyond their expiration date.

All currently available Moldex disposable NIOSH approved respirators have been authorized for healthcare use under the EUA.

Additional Resources

Respirator Fitting Instructions:

<https://www.moldex.com/resources/instructional-resources/fitting-instructions-respiratory/>

Coronavirus Tech Brief:

<https://www.moldex.com/resources/technical-briefs/novel-coronavirus-ncov-infection/>

Respirator Fit Testing Instructions:

<https://www.moldex.com/resources/setting-respiratory-protection-program/fit-testing/>