

NPPTL COVID-19 Response: Beyond Shelf Life/Stockpiled Respirator Assessment

Manufacturer: Kimberly-Clark

Model Tested: PFR95-174

Date Tested: May 23, 2020

Report Prepared: May 23, 2020

These findings pertain to the Kimberly-Clark, model PFR95-174 submitted for testing, and may not be applicable to other stockpile facilities and/or under different environmental storage conditions. The maximum and minimum filter efficiency was 97.49% and 95.77%, respectively. All twenty respirators measured more than 95% efficiency. No shelf life was designated for this model by the NIOSH approval holder.

NIOSH regulation sets the minimum quality and performance requirements for the approval of respirators (42 CFR 84). **NIOSH does not have requirements for shelf life or storage conditions for particulate-only APRs.** The approval holder (i.e. the entity that is granted the approval from NIOSH) is responsible for understanding how their products' design or performance may be affected by various use or storage conditions and must provide instruction for establishing the proper use, storage, and maintenance procedures for their approved products, which may include designating a shelf life. FFR or particulate filter packaging (such as the box) often includes NIOSH-approved user instructions, label information, and recommendations on shelf life. Additionally, some approval holders also disseminate recommendations related to storage and shelf life through resources such as user and web notices. The respirators tested in this study were generally not designed for long-term storage.

Based on research conducted by NIOSH and this limited testing, NIOSH does not have enough information to definitively know the level of protection that may be provided by respirators that 1) are stored for prolonged periods of times; 2) are stored under various storage conditions; or 3) have exceeded the approval holder's designated shelf life. Users of respirators that have exceeded the designated shelf life should be forewarned to avoid a false sense of confidence; these devices may not provide the same level of protection as those that have not exceeded the designated shelf life. We recommend contacting the approval holder(s) of the respirators in the stockpile with specific questions regarding the use of product beyond the manufacturer- designated shelf life.

The results provided in this letter are specific to the subset of NIOSH-approved N95s, past their designated shelf life, that were provided to NPPTL for evaluation.

These results will be added to the CDC guidance for [Stockpiled N95 Filtering Facepiece Respirators Beyond the Manufacturer-Designated Shelf Life](#).

Evaluation of Stockpiled and Beyond Manufacturer-Designated Shelf Life N95s



Test: TEB-APR-STP-0059

Manufacturer: Kimberly-Clark

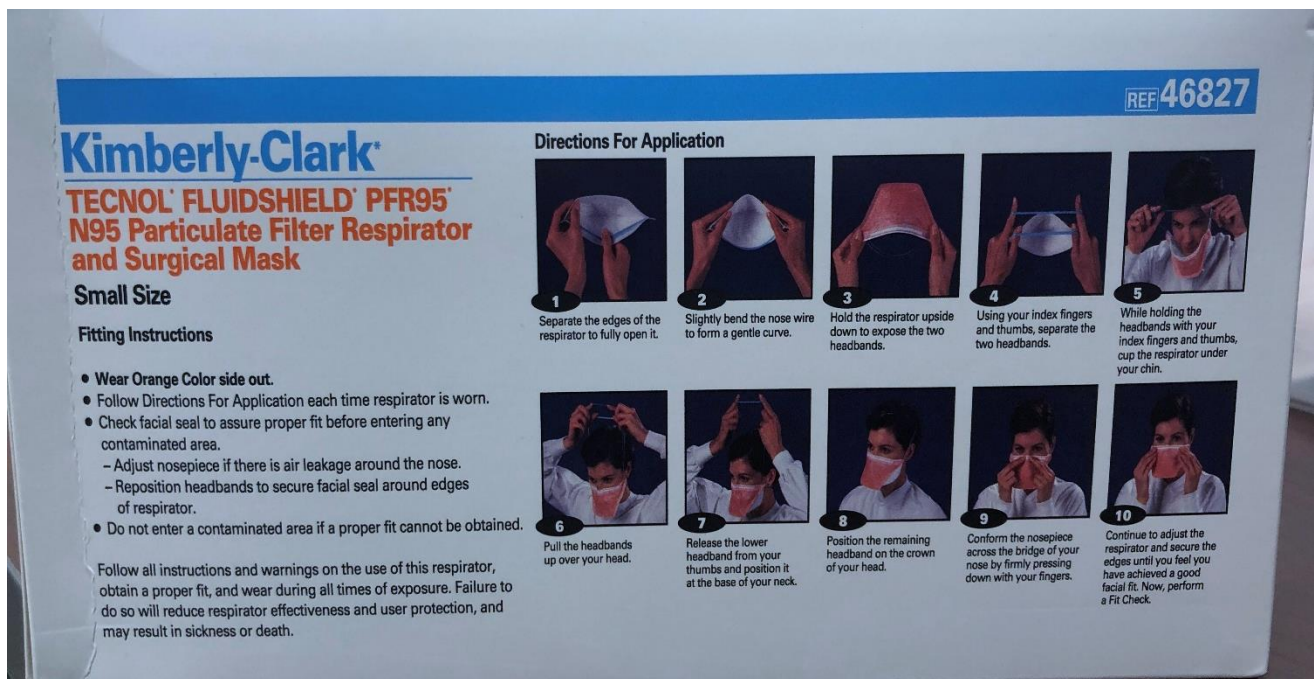
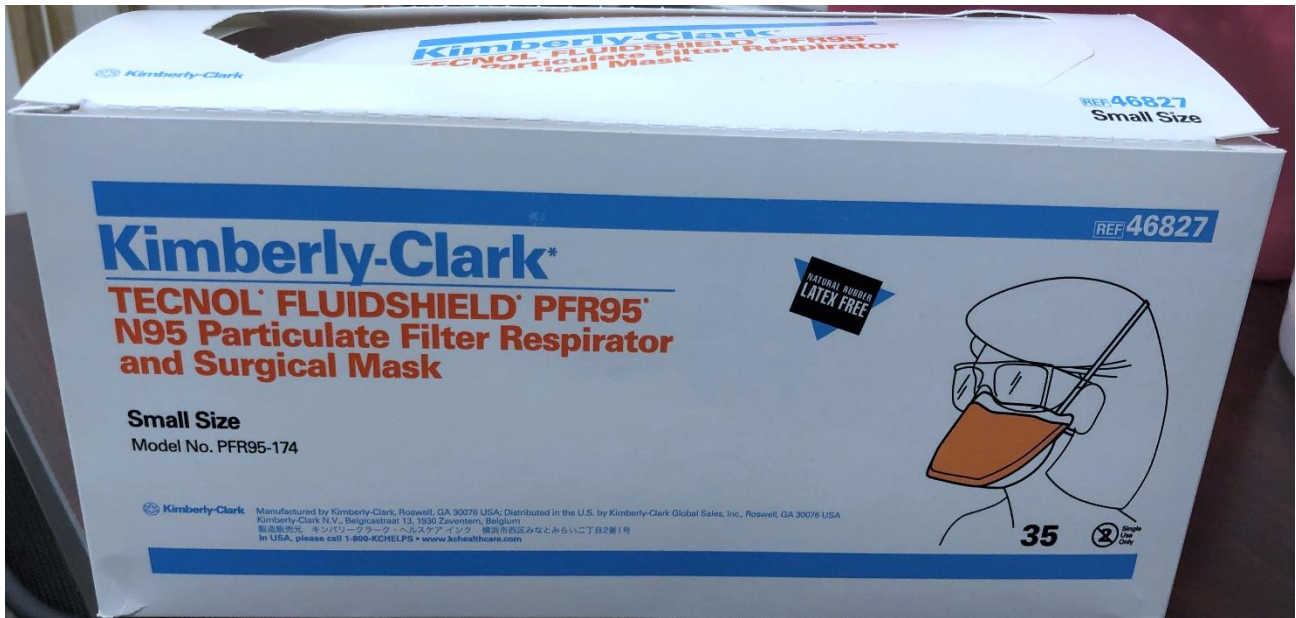
Item Tested: PFR95-174

Expiration Date: None Provided


Manufacture Date: None Provided

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	12.4	2.85	2.85	97.15
2	85	12.9	3.03	3.03	96.97
3	85	12.6	3.01	3.01	96.99
4	85	12.9	3.80	3.80	96.20
5	85	12.9	3.15	3.15	96.85
6	85	13.5	3.13	3.13	96.87
7	85	12.8	3.22	3.22	96.78
8	85	12.9	3.44	3.44	96.56
9	85	12.9	2.93	2.93	97.07
10	85	14.0	2.92	2.92	97.08
11	85	12.3	2.51	2.51	97.49
12	85	13.7	3.39	3.39	96.61
13	85	12.8	2.94	2.94	97.06
14	85	12.9	3.22	3.22	96.78
15	85	13.0	4.23	4.23	95.77
16	85	13.1	3.48	3.48	96.52
17	85	13.9	3.45	3.45	96.55
18	85	13.7	3.46	3.46	96.54
19	85	12.4	2.75	2.79	97.21
20	85	13.5	2.96	2.96	97.04
Minimum Filter Efficiency: 95.77			Maximum Filter Efficiency: 97.49		


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Kimberly-Clark
 1400 Holcomb Bridge Road
 Roswell, GA 30076 USA
 www.kchealthcare.com
 In USA call 1-800-KCHELPS.



This respirator is approved only in the following configuration:

TC-	Protection ¹	Respirator		Cautions and Limitations ²
84A-0005	N95	PFR95-174	PFR95-274	A B C J M N O P
		X	X	

1. PROTECTION:

N95-Particulate Filter (95% filter efficiency level) effective against particulate aerosols free of oil; time use restrictions may apply.

2. CAUTIONS AND LIMITATIONS:

- A. Not for use in atmospheres containing less than 19.5 percent oxygen.
- B. Not for use in atmospheres immediately dangerous to life or health.
- C. Do not exceed maximum use concentrations established by regulatory standards.
- J. Failure to properly use and maintain this product could result in injury or death.
- M. All approved respirators shall be selected, fitted, used, and maintained in accordance with MSHA, OSHA, and other applicable regulations.
- N. Never substitute, modify, add, or omit parts. Use only exact replacement parts in the configuration as specified by the manufacturer.
- O. Refer to users instructions, and/or maintenance manuals for information on use and maintenance of these respirators.
- P. NIOSH does not evaluate respirators for use as surgical masks.

Small Size
REF 46827

Description: The FLUIDSHIELD* PFR95* Mask is NIOSH approved (TC-84A-0005) as an N95 particulate filter respirator. It provides 95% filtration efficiency of 0.3 micron particles. It meets the CDC Guidelines for TB exposure control.

Intended Use: The FLUIDSHIELD* PFR95* Mask is intended for use by operating room personnel and other health care workers to protect both patients and health care workers from transfer of microorganisms, blood and body fluids, and airborne particulate materials.


Use Instructions: 1. Before use, the wearer must be trained by the employer in proper respirator use in accordance with applicable safety and health standards. 2. If the respirator becomes damaged or breathing becomes difficult, leave the area. Discard and replace the respirator.

Warning: When properly worn, FLUIDSHIELD* PFR95* Mask reduces potential exposure to blood and body fluids as well as airborne microorganisms. **This product does not completely eliminate the risk of contracting disease or infection.**

Reminder: It is important to fit check the respirator each time it is worn. Consult the facility's Respiratory Protection Program for further instruction.

U.S. Pat. Nos.: 4,920,960; 5,322,061; D347,713
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LOT
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