

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

Manufacturer: A.R. Medicom Inc.

Model Tested: M2321

Date Tested: February 17, 2021

Report Prepared: February 17, 2021

These findings pertain to the A.R. Medicom Inc., model M2321 (Lot # 112631) (TC-84A-4006) 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 97.68% and 76.07%, respectively. Nine respirators measured more than 95% filter efficiency. Eleven respirators measured less than 95% filter efficiency. There was no designated expiration date.

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 time; 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: A.R. Medicom Inc.

Item Tested: M2321

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	12.2	7.58	8.35	91.65
2	85	13.1	5.90	6.28	93.72
3	85	12.2	5.14	5.33	94.67
4	85	12.5	12.77	12.77	87.23
5	85	12.9	3.99	4.10	95.90
6	85	11.1	4.65	5.04	94.96
7	85	12.9	5.98	6.53	93.47
8	85	11.8	7.24	7.61	92.39
9	85	11.0	5.84	5.97	94.03
10	85	13.1	23.93	23.98	76.02
11	85	13.7	3.41	3.55	96.45
12	85	12.2	4.52	4.69	95.31
13	85	12.2	6.00	6.35	93.65
14	85	12.7	3.33	3.48	96.52
15	85	12.2	2.27	2.32	97.68
16	85	12.7	4.61	4.77	95.23
17	85	11.8	7.00	7.15	92.85
18	85	13.0	2.94	2.97	97.03
19	85	13.1	4.07	4.13	95.87
20	85	14.2	2.57	2.60	97.40
Minimum Filter Efficiency: 76.07			Maximum Filter Efficiency: 97.68		

MTT-2021-18



SAFE+MASK®

N95 Particulate Respirator

Respirateur N95 contre les particules

Respirador para partículas N95

QTY: 20 Respirators
Respirateurs
Respiradores



National Institute for
Occupational Safety and Health
NIOSH

GIKO 1200

**White
Blanc
Blanco**



REF: 2321

SAFE+MASK® N95 BENEFITS

- Meets NIOSH 42 CFR84 N95 classification.
- 95% filtering efficiency aerosol particles free of oil.
- 95% Particulate Filtration Efficiency (PFE), not resistant to oil.
- Disposable, lightweight & comfortable fit with dual head strap.

SAFE+MASK® N95 BÉNÉFICES

- Rencontre les normes NIOSH 42 CFR84 N95.
- Efficacité de filtration jusqu'à 95% de particules aérosol sans huiles.
- 95% d'efficacité de filtration de particules, non résistante à l'huile.
- Légers et confortables comportant bandes élastiques d'ajustement.

SAFE+MASK® N95 VENTAJAS

- Encuentra las clasificaciones NIOSH 42 CFR84 N95.
- Eficacidad de filtración hasta 95% de partículas de aerosol sin aceite.
- Filtración de Partículas Eficiente (PFE) a 95%, no resistente al aceite.
- Ligeras y cómodas con bandas elásticas de ajuste.



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Question or comments?/Questions ou commentaires?

☎ : 1 (800) 361-2862

✉ : sales@medicom.com

LOT

112631



Made in China / Fabriqué en Chine / Hecho en China

REF: 2321

Manufactured for and distributed by:
Fabriqué pour et distribué par:
Hecho para y distribuido por:

A.R. MEDICOM INC.

A.R. Medicom Inc.
1200 55th Ave.
Montréal, Québec
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Medicom USA
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Medicom Healthcare B.V.
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The Netherlands

Medicom (Asia) Inc.
Rm. 1511-B, Kailley Industrial Centre
12 Fung Yip Street
Chai Wan, Hong Kong

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Fitting Instructions

1. Cup the respirator in your hand, with the metal nosepiece on your fingertips.
2. Position the respirator under your chin with the nosepiece resting above your nose. Pull the bottom strap over the back of your head and position it below your ears. Pull the top strap over your head and position it high above the back of your head.
3. Using two hands, place your fingertips on top of the metal nosepiece. Shape the metal piece to the shape of your nose, while moving your fingertips down the sides of the nosepiece.
4. A seal check is recommended by the user. Place both hands over the respirator and inhale. If air leaks around nose, readjust the nosepiece as described in step 3. If air leaks at the respirator edges, readjust the straps along the sides of your head.

Instructions

1. Tenir le masque dans le creux de votre main avec la pièce métallique vers les doigts.
2. Placer le respirateur sous le menton tout en tenant le contour moulé en métal vers le haut du nez. Tirer et placer la courroie inférieure jusqu'à la nuque, en dessous des oreilles. Ensuite, tirer la deuxième courroie vers l'arrière jusqu'au haut de la tête.
3. Avec vos mains, placer vos doigts sur le dessus du contour moulé en métal. Appuyer des deux côtés jusqu'à que la pièce de métal s'ajuste au contour de votre nez.
4. Pour vérifier l'étanchéité. Placer vos deux mains au devant du respirateur et respirez profondément. Si de l'air s'échappe alentour du nez, réajuster le contour moulé tel que décrit à l'étape 3. Si de l'air s'échappe par les côtés, réajuster les courroies.

Instrucciones de uso

1. Sostenga el respirador en su mano manteniendo la pieza metálica en sus dedos.
2. Coloque el respirador debajo de la mentón con la pieza de metal hacia la nariz. Estire la banda elástica inferior sobre la cabeza y coloque alrededor del cuello, debajo de las orejas. Estire la banda superior sobre la cabeza y coloque en la parte superior de la cabeza.
3. Con ambas manos moldeé la zona de la nariz, con sus dedos apreté la pieza metálica de ambos lados a la vez.
4. Examiné el sello. Cubra completamente la máscara con ambas manos y respire profundamente. Si siente aire alrededor de la nariz, reajuste la pieza de metal. Si siente aire circular por los bordes, reajuste las bandas.

Warning :

Follow all instructions and warnings on the use of this mask. Failure to do so will reduce mask effectiveness and wearer protection, which may result in sickness and/or death. This respirator helps protect against certain particles.

Limitations:

If respirator becomes damaged soiled or if breathing becomes difficult leave area and dispose of respirator

Do not use for:

Gases, vapors, including paint spraying, oil aerosol use, asbestos or sandblasting. This respirator does not supply oxygen.

Mise en garde :

Veillez suivre toutes les instructions et les mises en garde à propos de l'utilisation de ce masque. Omettre de suivre les instructions, réduit l'efficacité de filtration et de protection du respirateur ce qui pourrait provoquer de graves problèmes de santé et/ou entraîner la mort

Limitations :

Si le respirateur est endommagé, sali ou si la respiration devient difficile, quitter la région affectée et jeter respirateur.

Ne protège pas contre :

Les particules de peinture en aérosol, les aérosols contenant des huiles, les gaz, les vapeurs, l'amiante et la poussière de décapage au jet de sable. Ce respirateur ne fournit pas d'oxygène.

Aviso :

Siga todas las instrucciones y avisos al utilizar el respirador, la eficacia del mismo disminuirá y podrá resultar en enfermedad o muerte.

Limitaciones :

Si el respirador se encuentra dañado, sucio o si respira con dificultad, salga de la área y deseche el respirador. Estos respiradores no proveen oxígeno.

No usar para :

Pintura en spray, aerosoles con aceite, gases, vapores, asbesto o polvos creados por lavado con chorro de arena. Este respirador no suministra oxígeno.

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