User Manual: Modified Adult Manikin Fit (MAMF) Test Method for Assessing Re-used and/or Decontaminated N95 Respirators

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Modified Adult Manikin Fit (MAMF) Test Method for Assessing Re-used and/or Decontaminated N95 Respirators

The User Manual provided below describes how to measure the individual fit-factors at 10 Liters/minute (LPM) and 85 LPM for re-used/decontaminated N95 respirators.

To use the tool the following instruments would be required –

1. An adult manikin printed using a 3D printer.
2. A Fit Testing Instrument[1]
3. A computer for using the Software that can be used to record the manikin fit for the N95 respirator being tested[2] . This Software will need to be compatible with the Fit Testing Instrument used.
4. An aerosol generator that can generate sodium chloride aerosols[3] . These aerosols will be used to assess fit of the N95 respirator being tested.
5. Instrument for punching a sampling port into the N95 respirator being tested[4]
6. Mass flow controller that can measure vacuum flow rate up to 85 Liters/minute.

3D printing files and Workflow for creating Adult Manikin

1. To create a NIOSH manikin headform for fit-testing, the following steps should be followed:

NIOSH Medium headform was downloaded from (5).

2. The downloaded geometry was modified through several complex operations using software Magics (Materialise). The resulting geometries are provided below (Table S1) so an user does not have to undertake these operations themselves.

Table S1. STL files for different parts of the NIOSH headform. The STL files can be accessed in the following link - doi.org/10.6084/m9.figshare.25330738

Part	Purpose	STL file attachents
a) NIOSH Medium Inner Head Bottom with Ports on Base	Main part of the headform (Figure S1 a)	Refer file name "File-a"
b) NIOSH Medium Inner Head with Ports Scalp Hollowed	Top of the headform (Figure S1 b)	Refer file name "File-b"
c) NIOSH Medium Right Ear	Right ear of the headform (Figure S1 c)	Refer file name "File-c"
d) NIOSH Medium Left Ear	Left ear of the headform (Figure S1 d)	Refer file name "File-d"
e) Sample Port Adapter 0.5 in OD Acrylic Tubing	Needed for counting the inhaled aerosols (C_{out}) and to create suction flow rate (Figure S1)	Refer file name "File-e"
f) Metal Sample Tube Support	To enable isokinetic sampling of the inhaled aerosols (Figure S1)	Refer file name "File-f"
g) NIOSH Medium Full Back 5 mm Skin Hollow with Aligner	To create the outer contour mold, back (Figure S2a-2c)	Refer file name "File-g"
h) NIOSH Medium Full Face 5 mm Skin Hollow with Aligner	To create the outer contour mold, face (Figure S2a-2c)	Refer file name "File-h"
i) NIOSH Medium Inner Back 5 mm Skin Solid with Aligner and Handle[6]	To create the inner contour, back (Figure S2e)	Refer file name "File-i"
j) NIOSH Medium Inner Face 5 mm Skin Solid with Aligner and Handle[6]	To create the inner contour, face (Figure S2e)	Refer file name "File-j"

3. A separate geometry was created also by subtracting a uniform 5 mm thickness around the face and the head (refer to Table S1 i and j files).

4. Fabricate the different parts of the headform (Figure S1):

Each of these parts were printed separately instead of a consolidated head for various reasons. The 5 mm subtraction of the NIOSH headform would significantly deform the ear and therefore the subtraction operation was not performed on the ear. Instead, the ears were printed as separate parts (Figure S1-c and d). The scalp (Figure S1-b) was printed separately so the inside of the head base (a above) could be accessed, and residual manufacturing debris could be removed. Then, Acrylic tubing (for vacuum and pressure drop measurements) and Aluminum sampling tubing with support (Figure S1-f) can be inserted through the holes in the mouth of the headform. Additionally, the sample port adaptor (Figure S1-e) can also be printed and attached to the headform. Hose barb fittings were glued into the rear adapter using RTV silicone to connect vacuum and sampling hoses.

5. To fabricate all the parts listed in the table S1, the NIOSH Medium Inner Back and Face with Aligner and Handle[6] were printed. Then the printed parts were coated with mold release. This printed part was then used to create a mold (Figure S2-a). Making the mold requires the OUTER layer (the bigger pieces) to maintain the outer contours of the face.

6. For the mold, a box was created with an aligner and the silicone (Mold Star 15 SLOW) was poured into the box. Then, OUTER sized face and back of head into the box of silicone were set and cured (Figure S2-b and c). During curing an additional step of vacuuming can be implemented to reduce bubbles within the mold.

7. Once the mold was prepared (Figure S2-d), it was placed in a 5 mm smaller-sized back and face part of the headform.

8. Smooth-On Ecoflex 00-20 was used to create the skin layer. The Ecoflex 00-20 was poured into the mold, filling the 5mm gap between the mold and the smaller back or face part (Figure S2-e). Since the gap is relatively small, and the silicone can be viscous, some mold was poured into the bottom of the mold first, and then the manikin head was placed in and then pouring would continue from the sides. Note that it is relatively easier to trim off excess or overflow than to try to assess if the whole cavity is adequately filled.

9. Finally, each half of the skin layer were carefully separated from the mold (Figure S2-f), placed carefully without being stretched, and glued onto the full 5 mm reduced headform, completing the assembly of the NIOSH manikin headform for fit-testing (Figure S2-g).

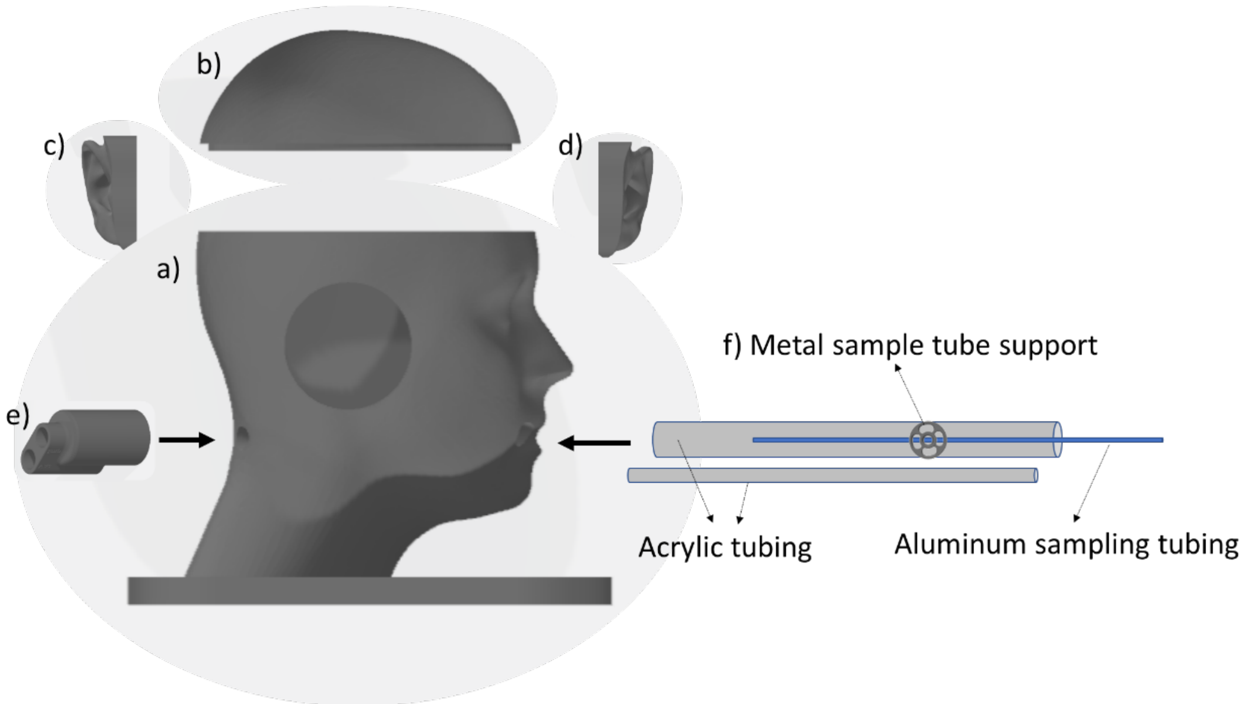

Figure S1. Different parts of the headform with 5 mm reduced thickness. This thickness is then replenished using human skin mimicking material (Figure S2). The acrylic tube with the smaller diameter is an accessory that can be used as a probe for measuring pressure drop across the respirators by connecting the tubing to a pressure gauge or transducer. Data obtained using the smaller acrylic tube has not been shown in the manuscript as its outside its scope.

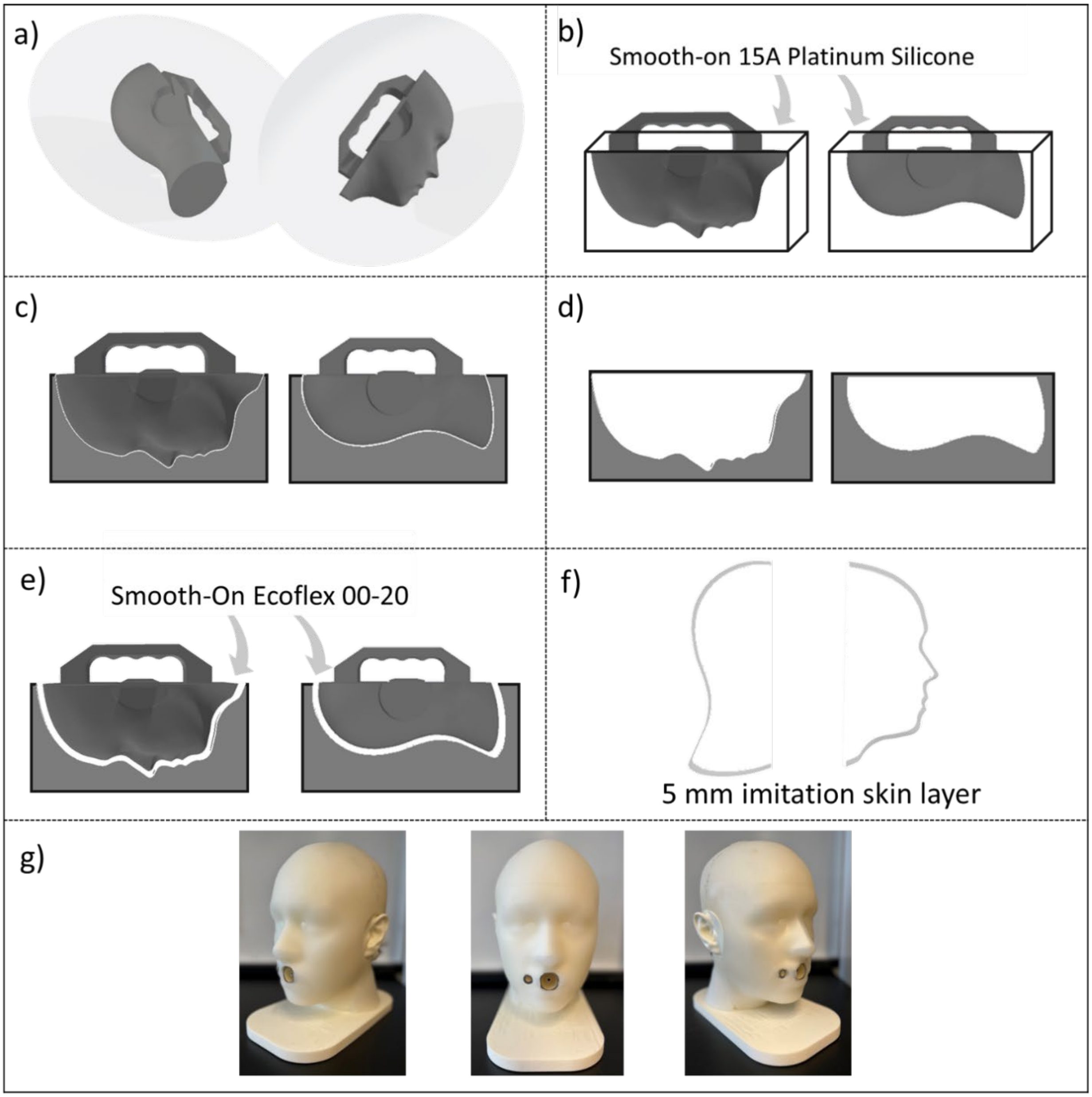

Figure S2. Steps to create the skin layer for the NIOSH manikin headform. The handles shown in figures a-c and e, above are for schematic purposes only, and although included in the STL files are not intended for printing. A user can directly purchase the handles elsewhere (2).

Verification of the Printing Process

Once the headform has been printed and assembled, specific dimensions can be measured to verify the printing process. Typical dimensions obtained by measuring the various geometric features in the adult headforms in triplicate using a caliper is provided below. Depending on the desired accuracy scales can also be used.

Geometric Features Measured	Dimensions (mm)
Interpupillary distance	64.37 ± 0.03
Jaw to Jaw distance	141.46 ± 1.10
Base of ear to bridge of nose	92.97 ± 0.08
Base of chin to nose bridge	113.80 ± 2.42
Nose bridge to back of head	209.5 ± 0.71

Preparation of the Respirator

If the sampling of the respirator is performed from the rear end of the manikin, then there is no need to place any sampling port in the front of the respirator. However, those who would like to place a sampling probe in the front can refer to the instructions provided elsewhere[7].

Mounting Respirator to the Headform

1. To mount a respirator to the headform, first the straps should be pre-stretched by pulling them back.
2. Then the straps should be allowed to return to their original position.
3. Then both straps should be brought to the front of the respirator and bottom strap should be placed near the chin of the headform. Without allowing the respirator to move, the bottom respirator strap should be pulled over the headform and settled near the neck. It should be ensured that strap is not twisted and that it fits flat and flush on the headform.
4. Then, the upper strap should be brought over the headform and settled above the ears, resting on the crown of the head.
5. Achieving good fit is an iterative process, and multiple iterations of the steps below may be required.
6. The respirator should be pulled up onto the bridge of the nose, with the top of the respirator near where the bottom eyelashes would be. At this point one should make sure the respirator is stuck to the chin without any leakage. Then the same steps should be repeated for the cheeks, and finally the nose. The thumb and index fingers may be used to press the nosepiece onto the nose bride of the manikin.
7. Then the nosepiece onto the bridge of the nose should be firmly squeezed. A fair amount of pressure should be allowed without damaging the tissue mimicking skin.

8. Once the nose piece is adjusted, the respirator should be grabbed from the sides and pulled down gently without letting the respirator separate from the headform until the respirator rests on the cheeks. This is likely to ensure better fit of the nose-clip wedge of the respirator into the nosepiece.
9. Lastly, visual inspection for gaps around the nosepiece and chin should be done. If any gaps were spotted, the steps 1-4 would be repeated again until no visible gaps remained.
10. Additionally, for respirators with stapled straps, one should visually inspect for leaks around staples of the straps, and ensure nosepieces are not missing. In case any such visual leaks are found, those respirators should be discarded.

Measuring Fit Factor of the Respirator

The fit-testing instrument used[1] is designed for use on a person, not a headform, and as such, many of the operations the program requests could not be performed. For our purposes, we only looked at the “normal breathing” and “deep breathing” operations during the testing cycle with the manikin. The following self-check steps were executed for the fit testing instrument:

1. The isopropanol-soaked wick should be inserted into the instrument.

2. Then background aerosol particles should be generated with the particle generator using a 0.01 g/mL solution of sodium chloride.

3. Then the fit testing instrument can be powered up and connected it to the corresponding fit testing software.

4. Then the background checks with the fit testing software should be run. These checks typically include the particle check (ensuring that enough particles are being generated by the aerosol generator), zero check (performed with a filter ensuring that there is no leak in the set up) and the maximum fit factor that can be deduced under the expected use conditions. The sampling hose should be attached to the sampling port on a fitted respirator when determining fit. More details on operating the fit testing equipment and software to be used for recording the data can be found elsewhere[1, 2].

5. Once the maximum fit factor is obtained then one can proceed with fit-testing method and other selections.

6. Typically the next step involves selecting an assigned person. After selecting the assigned person on whom the testing is being performed, the protocol, respirator, size and test date can be selected . Usually, fit testing software comes with multiple options of respirator brand, and size to select from. For testing fit on manikins, the person name can be arbitrarily assigned.

7. Following this fit-testing can proceed. The software starts with normal breathing and provides a real time qualitative sense of the fit factor specifically for normal breathing. The test then sequentially goes through multiple exercises that are typically performed on an actual subject (e.g. head side to side movement, head up and down movement etc.). However, since this user manual only involves testing with manikins, and the manikins considered in our tool is not capable of head side to side, up and down and other movements (e.g. talking, grimace, bending over), hence there is no need to record the data beyond deep breathing.

8. If the fit-test is successful then the manikin fit-testing can be completed at the end of the normal breathing or deep breathing, and the data recorded. If the fit-testing fails, then the software does not proceed to the next step.

9. If at the end of the testing fit factor of 100 to 200+ could not achieved, then additional manipulation of respirator donning would help. Some steps in the collective experience of the authors were:

- Pulling respirator all the way up to nose-bridge, pushing strap onto nose, and then gently pulling it down created tighter seals.
- The respirator nosepiece ends should not be pointed up; if so they should flattened at the ends if necessary so they are flush with the headform.
- Generated aerosol particles should be well dispersed in the fit testing chamber. After turning on the aerosol generator, we allowed at least a few minutes to reach equilibrium in aerosol concentration.
- We made sure that the respirator was symmetrical on the headform both vertically and horizontally and never too high nor too low in relation to the eyes.
- We ensured that the metallic noseband and the sponge piece beneath were symmetrical at the respirator’s nosepiece. In some respirators, the metallic noseband were asymmetric relative to the sponge piece and were a source of the leak from the nose.
- To have a more realistic fit test using PortaCount, the ambient sampling tube must be close to the face of the manikin, not behind it.
- If these steps do not help achieve manikin fit factor of 100-200+, then starting back with a new respirator may help.

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