Supplementary information

for

Modifying NIOSH's Manikin Fit Evaluation Method to Match Fit Testing with Human Subjects

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3D printing files and Workflow for creating Adult Manikin

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

NIOSH Medium headform information was downloaded from [1].

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

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 was 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 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.

Table S1. STL files for different parts of the NIOSH headform.

Part	Purpose	STL file attachments
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_{in}) and to create suction flow rate (Figure S1 e). Used for downstream sampling.	Refer file name "File-e"
f) Metal Sample Tube Support	To enable isokinetic sampling of the inhaled aerosols (Figure S1 f)	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	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	To create the inner contour, face (Figure S2e)	Refer file name "File-j"

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).

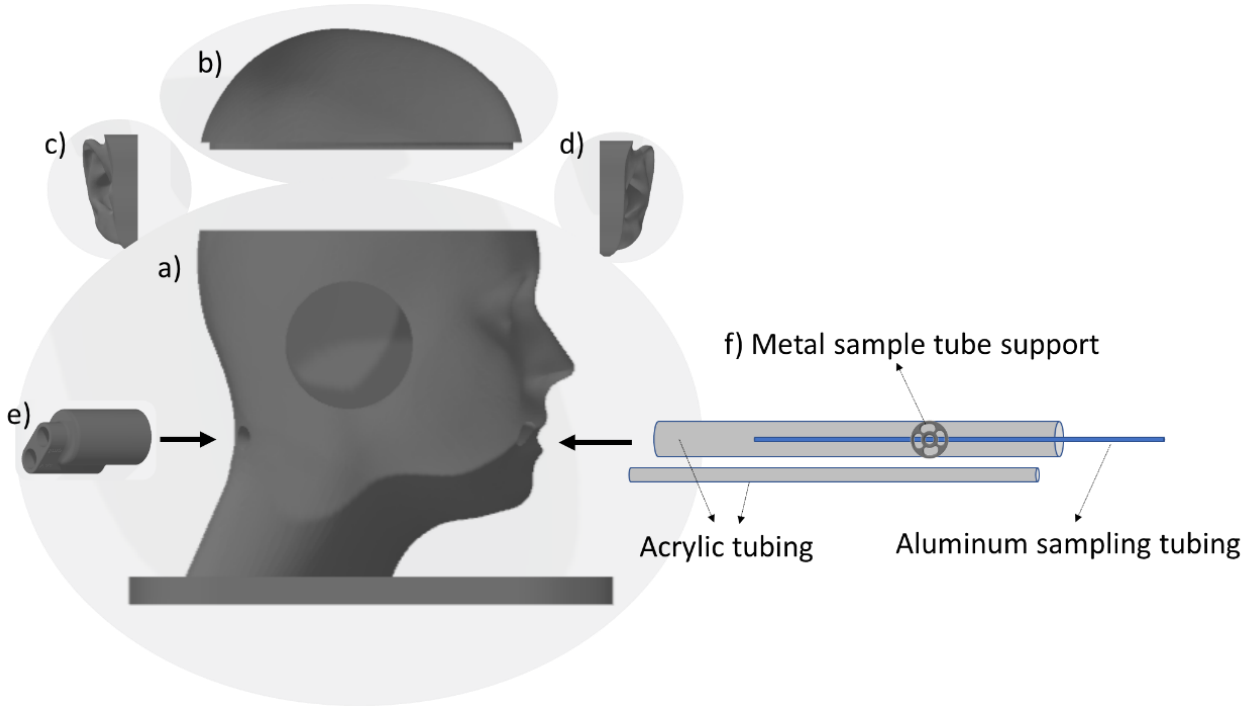

Figure S1. Different parts of the headform with 5 mm reduced thickness. This thickness is then replenished using human skin mimicking material (Figure S2). The acrylic tube with the smaller diameter is an accessory that can be used as a probe for measuring pressure drop across the respirators by connecting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

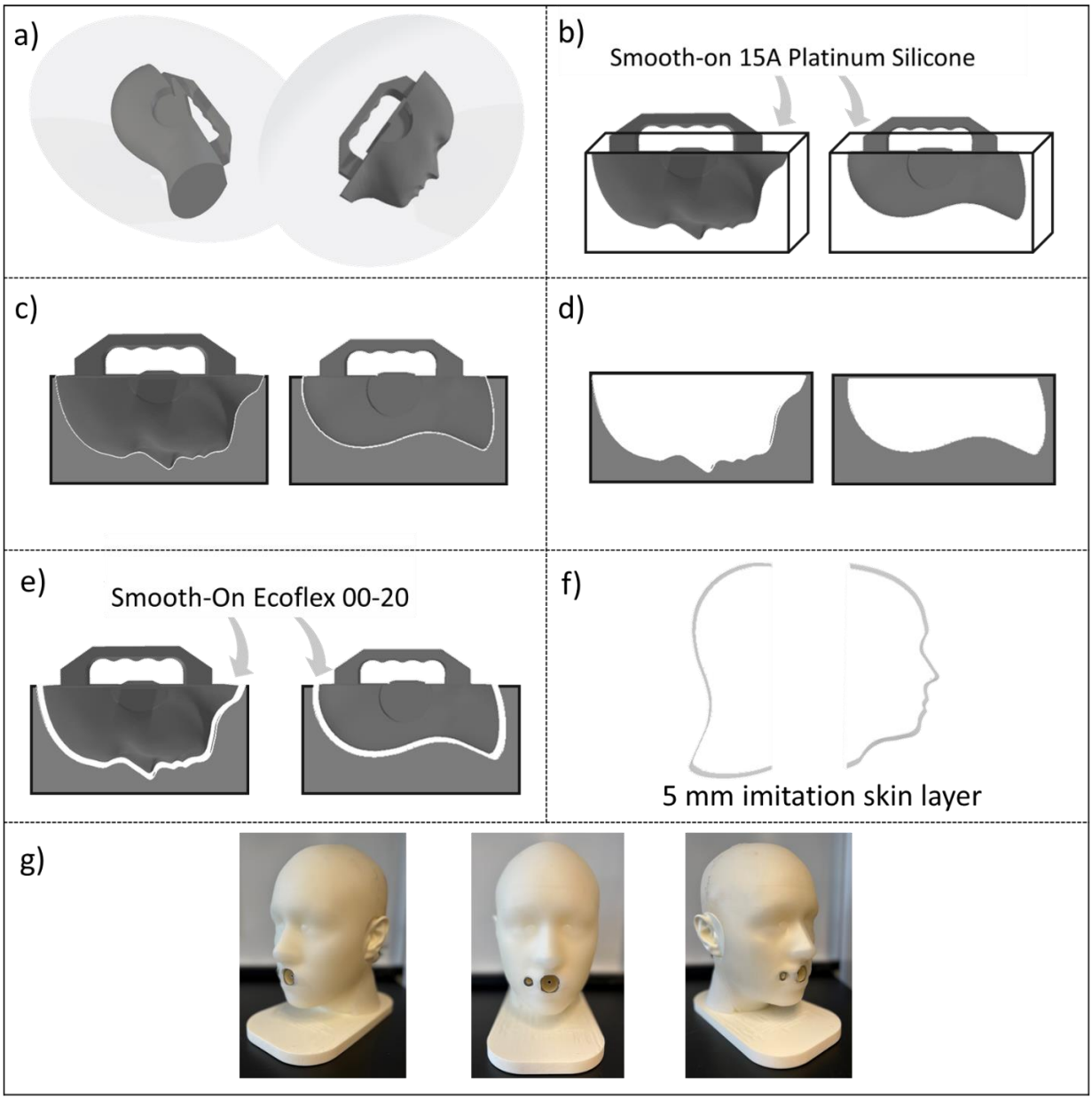

Figure S2. Steps to create the skin layer for the NIOSH manikin headform. The handles shown in figures a-c and e, above are for schematic purposes only, and although included in the STL files are not intended for printing. A user can directly purchase the handles elsewhere [2].

Installing the sampling port to a respirator

The TSI PortaCount comes with a spring-loaded device for punching a port (TSI Model 8025-N95) into the respirator (Figure S3) that was used to place the probe kits into the respirators. The instructions for how to insert the probe kits into the respirators can be found elsewhere [3].

Figure S3. TSI spring-loaded device for punching a port into the respirator (3).

Mounting the respirator to the headform

To mount a respirator to the headform, first the straps were pre-stretched by pulling them back.

Then the straps were allowed to return to their original position.

Then both straps were brought to the front of the respirator and bottom strap was placed near the chin of the headform. Without allowing the respirator to move, the bottom respirator strap was 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.

Then, the upper strap was brought over the headform and settled above the ears, resting on the crown of the head.

Adjusting the donned respirator to achieve good fit

Achieving good fit is an iterative process, and multiple iterations of the steps below may be required.

The respirator was pulled up onto the bridge of the nose, with the top of the respirator near where the bottom eyelashes would be. At this point we visually made sure the respirator is stuck to the chin without any leakage. Then the same steps were repeated for the cheeks, and finally the nose. The thumb and index fingers were used to press the nosepiece onto the nose bride of the manikin.

Then the nosepiece onto the bridge of the nose was firmly squeezed. A fair amount of pressure should be allowed without damaging the tissue mimicking skin. One should avoid making a point in the nosepiece at the apex of the bridge, as this can cause a channel to form in the respirator.

Once the nose piece was adjusted, and the respirator was grabbed from the sides and pulled down gently without letting the respirator separate from the headform until the respirator rested on the cheeks. This ensure better fit of the nose-clip wedge of the respirator into the nosepiece.

Lastly, visual inspection for gaps around the nosepiece and chin was done. If any gaps were spotted, the steps 1-4 would be repeated again until no visible gaps remained.

Additional tips

For respirators with stapled straps, we also visually inspected for leaks around staples of the straps, and ensured nosepieces were not missing. If yes to any of the above, then the respirators would be discarded.

When creating the sample probe, we tried avoiding creation of the port on a seam of a respirator.

If sampling port was not achieved with one motion a new respirator would be used, and the failed respirator would be discarded..

If at the end of the testing FF 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.

We made sure the nosepiece ends were not pointed up, flattening the ends if necessary so they are flush with the headform.

Generated aerosol particles were 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.

Operation of the PortaCount

The PortaCount 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 PortaCount:

1. The isopropanol-soaked wick was inserted into the PortaCount.

2. Then background aerosol particles would be generated with the TSI 8026 particle generator using a 0.01 g/mL solution of sodium chloride.

3. Then the PortaCount Respirator Fit Tester (TSI Inc. Model 8048) was powered up and connected it to the TSI PortaCount control program.

4. Then and between uses, the background checks with the TSI program were run. The sampling hose was attached to the sampling port on a fitted respirator when determining fit.

More details on operating the TSI Inc. 8048 model and recording the data can be found elsewhere [4].

References

1. NIOSH Anthropometric Data and ISO Digital Headforms (2023). The National Institute for Occupational Safety and Health.

2. https://www.mcmaster.com/products/handles/ (Link accessed on August 1, 2023)

3. TSI Inc. Fit Test probe Kit Instructions. https://tsi.com/getmedia/1d25c231-2423-4e37-a731-f1486d6eb217/1980262-8025-N95-Fit-Test-Probe-Kit-web?ext=.pdf (Link accessed on September 4, 2023).

4. TSI Inc. PortaCount Respirator Fit Tester 8048. https://tsi.com/products/respirator-fit-testers/portacount%E2%84%A2-respirator-fit-tester-8048/ (Link accessed on September 4, 2023).