User Manual: Assessing Fit Factor and Breathability of Pediatric Facemasks

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User Manual

Assessing Fit Factor and Breathability of Pediatric Facemasks

The User Manual provided below describes how to measure the fit-factor and breathability of pediatric facemasks using pediatric manikin headforms.

To use the tool the following instruments will be necessary –

1. Pediatric manikins of various age groups[1,2] printed using a 3D printer.
2. A Fit Testing Instrument[3]
3. A computer for using the Software that can be used to record the manikin fit for the pediatric manikin being tested[4]. This Software will need to be compatible with the Fit Testing Instrument used.
4. An aerosol generator that can generate sodium chloride aerosols[5]. These aerosols will be used to assess fit of the pediatric manikin being tested.
5. Instrument for punching a sampling port into the pediatric mask being tested[6].
6. Mass flow controller that can measure vacuum flow rate up to 45 Liters/minute.
7. Pressure transducers for measuring breathability of the pediatric facemasks.[7]

3D printing files and Workflow for creating Pediatric Headforms

The headforms and their related parts were printed on an EOS P 396 LPBF printer (EOS GmbH, Krailling, Germany) using polyamide 12 powder with a virgin/used mixture ratio of 50:50, slicing thickness of 0.12 mm per layer, and printing parameters recommended by EOS.

To create a pediatric headform for fit-testing and breathing resistance measurements, the following steps were followed:

1. There are two ways to obtain the headforms file for printing: either freely from the FDA Virtual Family Project[8] and or by paying to Foundation for Research on Information Technologies in Society (IT'IS)[9]. In this user manual, Dizzy (8-year-old male) and Billie (11-year-old female) headform are being made available for use. The IT'IS headforms are licensed and, therefore, cannot be shared, and thus, are not provided.
2. The downloaded geometries were modified through several complex operations using the software Magics (Materialise). The resulting geometries are provided below (Table 1).

Table 1. Stereolithography (STL) files for different parts of the 8-year-old Dizzy and 11-year-old Billie.

Part	Purpose	STL file attachments	
		Dizzy	Billie
a) Headform with Ports on Base	Headform (Fig 1a)	Refer to STL file: Dizzy final headform (reduced file size).[10]	Refer to STL file: Billie final headform (reduced file size).[10]
b) Right Ear	Right ear of the headform (Fig 1b)	Refer to STL file: Dizzy R ear 1mm reduced (reduced file size).[10]	Refer to STL file: Billie R ear 1mm reduced (reduced file size).[10]
c) Left Ear	Left ear of the headform (Fig 1c)	Refer to STL file: Dizzy L ear 1mm reduced (reduced file size).[10]	Refer to STL file: Billie L ear 1mm reduced (reduced file size).[10]
d) Sample Port Adapter 0.5 in OD Acrylic Tubing	Needed for counting the inhaled aerosols (C_{out}) and to create suction flow rate (Fig 1d)	Refer to STL file: Sample Port Adapter 0.5inOD Acrylic Tubing.[10]	
e) Metal Sample Tube Support	To enable isokinetic sampling of the inhaled aerosols (Fig 1e)	Refer to STL file: Metal Sample Tube Support.[10]	
f) Full Face 5 mm Skin Hollow with Aligner and Handle	To create the outer contour mold, face (Fig 2a)	Refer to STL file: Dizzy larger face (reduced file size).[10]	Refer to STL file: Billy larger face (reduced file size).[10]
g) Inner Face 5 mm Skin Solid with Aligner and Handle	To create the inner contour, face (Fig 2b)	Refer to STL file: Dizzy smaller face (reduced file size).[10]	Refer to STL file: Billy smaller face (reduced file size).[10]

3. A separate geometry was created by subtracting a uniform 5 mm thickness around the face (Table 1). Since the straps of the pediatric facemasks go over the ears, not the back of the

head, making skin for the back of the head was unnecessary and can be skipped to conserve material and time.

4. To create distinct components of the headform, the ears were printed separately with a 1 mm subtraction (Fig 1b and 1c). A 1 mm thick layer of skin-mimicking silicone was then added around the ears, where the straps of the pediatric facemask loop around. Acrylic tubing (for vacuum and pressure drop measurements) and Aluminum sampling tubing with support (Fig 1e) were inserted through the holes in the mouth of the headform (The mouth sample ports may need modification before use; due to variation with 3D printing, holes in the STL files may need to be edited to reflect the specific clearance desired or machined after printing). Additionally, the sample port adaptor was 3D printed and affixed to the headform. Hose barb fittings were securely attached to the rear adapter using RTV silicone to facilitate the connection of vacuum and sampling hoses.

5. To fabricate all the parts listed in Table 1, the Full Face 5 mm Skin Hollow with Aligner and Handle was printed. Then, the printed parts were coated with mold release. This printed part was then used to create a mold (Fig 2a). Making the mold requires the outer layer (the bigger pieces) to maintain the outer contours of the face.

6. For the mold, a box with an aligner was created, and the silicone (Mold Star 15 SLOW) was poured into the box. The outer sized face of the head was set into the box of silicone and cured (Fig 2c and 2d). An additional step of vacuuming could be implemented during curing to reduce bubbles within the mold.

7. Once the mold was prepared (Fig 2e), it was placed on a 5 mm smaller-sized 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 5 mm gap between the mold and the smaller face part (Fig 2f). Since the gap is relatively small, and the silicone can be viscous, a small amount of mold was poured into the bottom of the mold first. Then, the manikin head was placed in, and pouring would continue from the sides. Excess silicone can be trimmed after curing; underfilling the cavity is more difficult to correct.

9. Finally, the skin layer was carefully separated from the mold (Fig 2g), placed without being stretched, and glued onto the full 5 mm reduced headform, completing the assembly of the pediatric headform for fit-testing and breathing resistance measurements (Fig 2h).

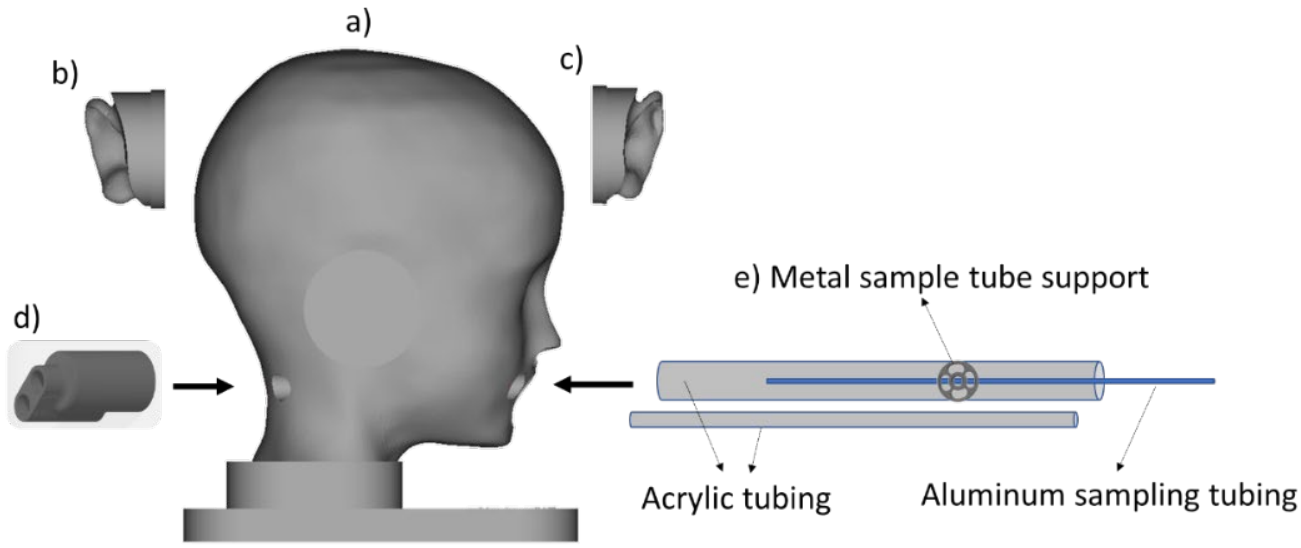

Figure 1. *Different parts of the headform with 5 mm reduced thickness. This thickness is then replenished using human skin mimicking material (Figure 2). The acrylic tube with the smaller diameter was used as a probe for measuring breathing resistance across the facemask by connecting the tubing to a pressure gauge or transducer.*

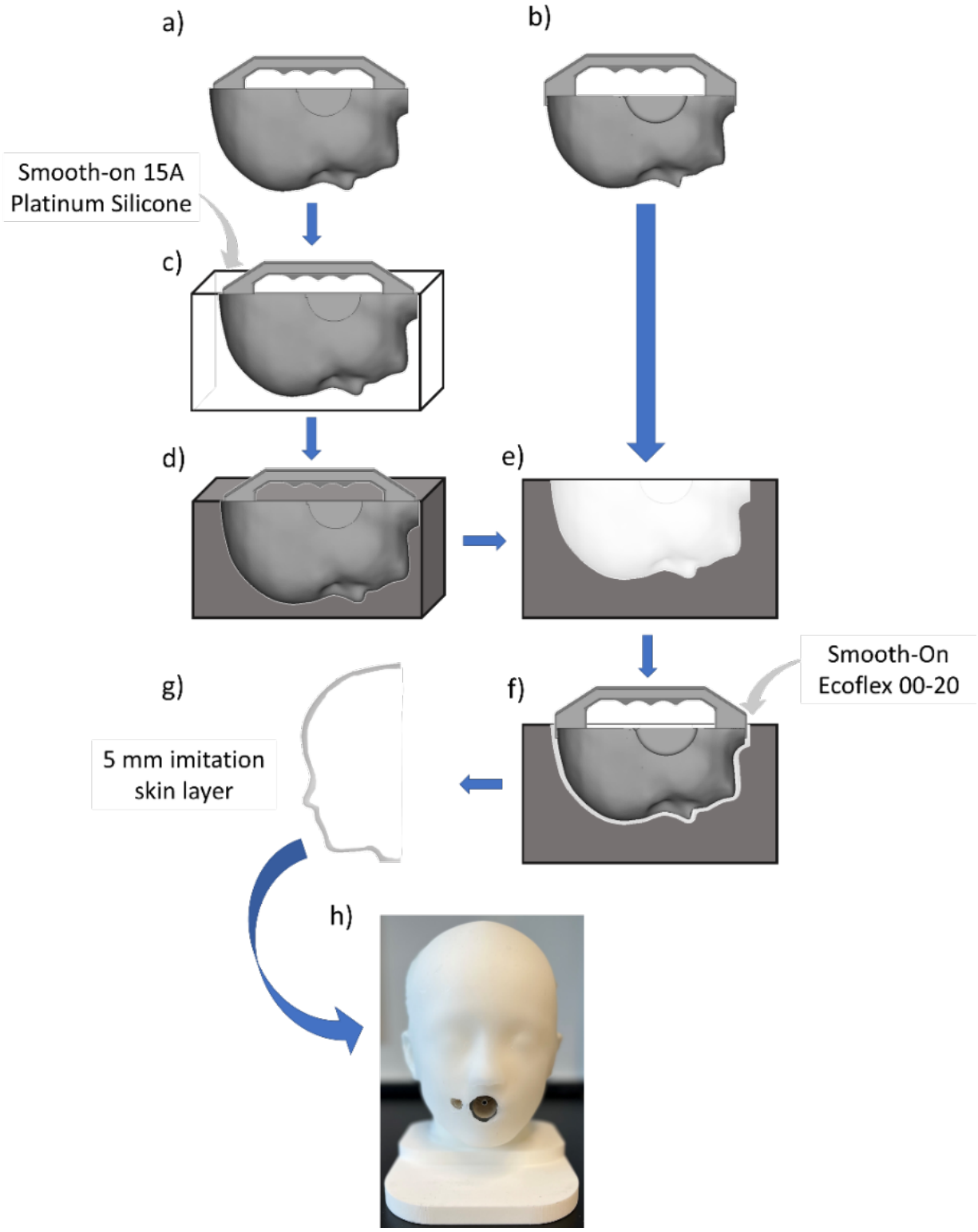

Figure 2. *Steps to create the skin layer for the pediatric manikin headform. The handles shown in figures a-b are for schematic purposes only, and although included in the STL files are not intended for printing. A user can directly purchase the handles elsewhere*[10].

Verification of the Printing Process

Once a headform for a specific age group has been printed and assembled, specific dimensions can be measured to verify the printing process and then compared against the average human subject data for that age group. The average human subject data is reported elsewhere[1]. The difference between the printed headforms and the average human subject data is reported in Table 2 below.

Table 2. *Headforms Details and Deviation in Facial Anthropometrics from Average Human Subject*[1]

Headform	Age (year)	Gender	Reference	Facial anthropometric deviation from the human subject norm			
				Interpupillary	Bizygomatic breadth	Lower face height	Ear-Sellion depth
Betty	2	Male	Dizzy headform reduced by 113%.	3.0 %	-1.0 %	1.2 %	-3.7 %
Roberta	5	Female	FDA Virtual Family Project	-1.9 %	-1.8 %	-3.5 %	-2.4 %
Dizzy	8	Male	FDA Virtual Family Project	2.7 %	2.5 %	1.1 %	-3.3 %
Billie	11	Female	IT'IS	-2.3 %	0.0 %	-1.0 %	-2.2 %
Louis	14	Male	FDA Virtual Family Project	0.1 %	-2.4 %	2.1 %	-3.0 %

Preparation of the Pediatric Facemasks for Fit Testing

After printing the headforms, and verifying that the printed headforms are consistent with input STL files, the next step is to prepare the pediatric facemasks for measuring fit factor.

1. To mount a pediatric facemask to a pediatric headform, first the bottom strap was pulled over the headform and settled near the neck. It was ensured that strap is not twisted and that it fits flat and flush on the headform.

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

3. The pediatric facemask was pulled up onto the bridge of the nose, with the top of the mask near where the bottom eyelashes would be.

4. At this point needs to ensure that the pediatric facemask is stuck to the chin with minimal leakage.

5. Then the same steps was 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.

6. Then the nosepiece onto the bridge of the nose was firmly squeezed. If necessary, applying moderate, controlled pressure without deforming the tissue-mimicking skin may help.

7. Lastly, visual inspection for gaps around the nosepiece and chin can be done. Any gaps are likely to imply poor fit.

Measuring Fit Factor and Breathability of the Pediatric Facemask

The fit-testing instrument used[3] is designed for use on a person, not a headform, and as such, several operations requested by the program are not applicable to the manikin testing and were therefore not performed. This protocol only used "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 was inserted into the instrument.

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

3. Then the fit testing instrument was powered up and connected to the corresponding fit testing software.

4. Then the background checks with the fit testing software was 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 was attached to the sampling port on a pediatric facemask when determining fit. More details on operating the fit testing equipment and software to be used for recording the data can be found elsewhere[1,3,4].

5. After 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, model of the mask, size and test date can be selected. Usually, fit testing software comes with multiple options of respirator brand, and size to select from but does not have saved options for pediatric facemasks. For testing fit on manikins, the person's name can be assigned using a placeholder identifier for precision.

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 the data beyond deep breathing was not collected.

8. Fit factor would need to be measured manually at each individual flow rate and recorded. Since pediatric facemasks do not offer fit factor > 100 hence the fit-testing are always going to fail and the fit-testing software does not proceed to the next step.

9. Fit-factor can be measured for each flow rate individually by measuring the concentration of sodium chloride (generated using a TSI Model 3026) before (C_{in}) or after (C_{out}) the pediatric facemasks. However, since children may engage in a variety of activities (moderate and heavy) while donning masks, an overall fit factor can be determined across three flow rates 5, 30 and 45 LPM using the following equation, where FF1, FF2 and FF3 are the fit factors at 5, 30 and 45 LPM, respectively.

$$FF_{overall} = \frac{3}{\frac{1}{FF_1} + \frac{1}{FF_2} + \frac{1}{FF_3}}$$

10. Airflow sampling can be controlled by using mass flow controller (Alicat, Model # MCR-100SLPM-D) to maintain constant suction flow. To simulate human breathing and compare fit-testing results between constant suction flow and oscillatory flow, a QuickLung® Breather breathing simulator (Ingmar Medical) can also be used.

11. For breathability measurements, we used a Raspberry Pi 4 Model B (Raspberry Pi Foundation, Cambridge, UK), an ADS1115 4-channel 16-bit ADC (Adafruit, New York, NY), and two low-range differential pressure transducers with upper ranges of 2.0 inH_2O (498 Pa) (PX165-002U, OMEGA, Norwalk, CT) and 0.25 inH_2O (62 Pa) (PX165-0.25U, OMEGA, Norwalk, CT)[7]. For one transducer, the maximum pressure drop limit was 4 × 1.59 = 6.36 mmH_2O, while for the transducer with the larger range, the limit was 4 × 12.7 = 50.8 mmH_2O.

Reference Values of Fit and Breathability for Comparison

Figure 3 below provides some expected reference values of quantitative fit (Figure 3a) and breathability (Figure 3b) obtained using pediatric facemasks that have already been cleared by FDA. The details discussion about the results appears elsewhere[1].

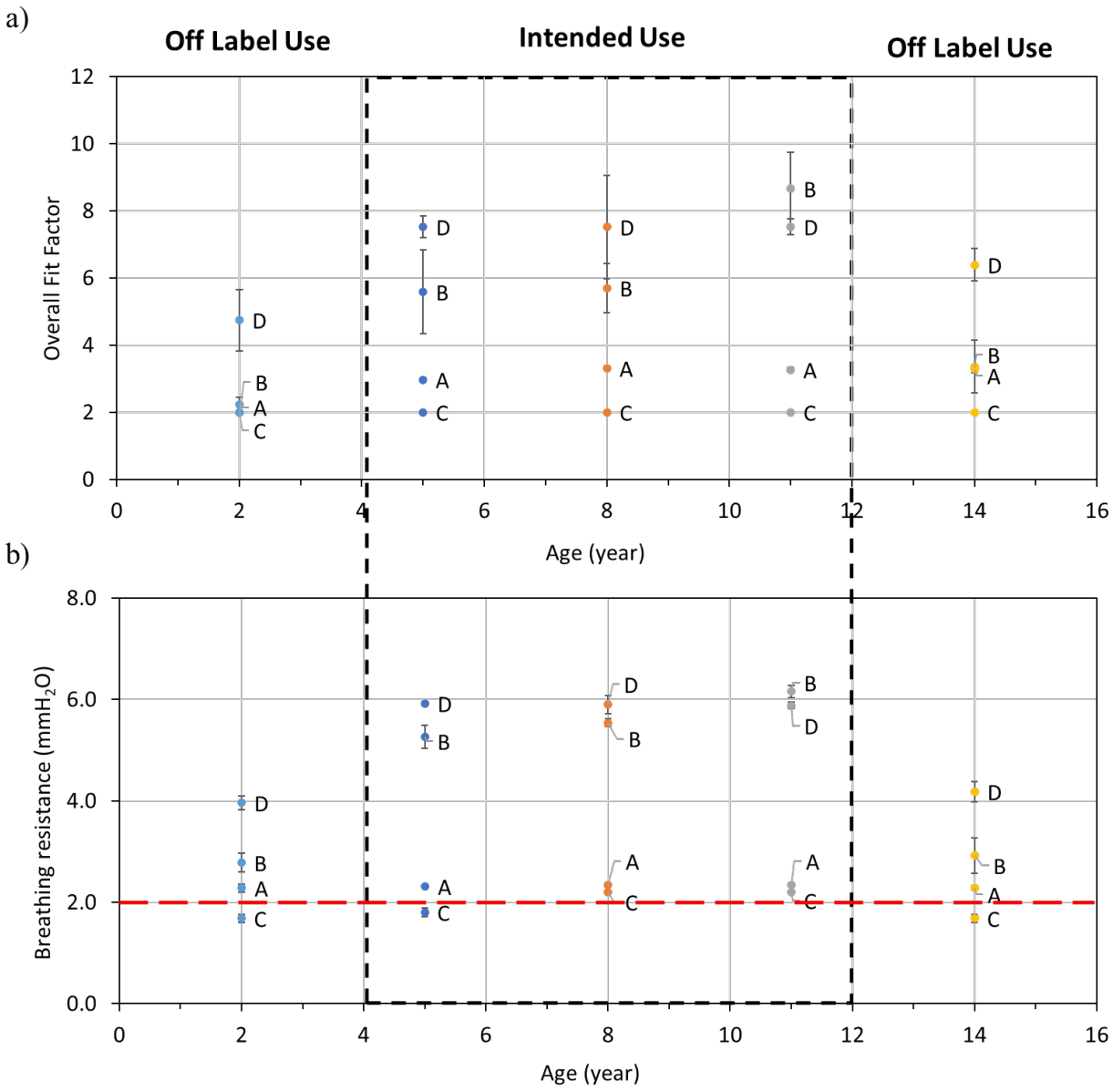

Fig 3. *a) Overall fit factor and b) breathing resistance of pediatric facemasks (brands A, B, C, and D) across all head forms. Standard deviations shown are based on measurements made in triplicates.*

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