TABLE II

TFE OF THE TESTED COMMUNITY AND SMS, AND TOTAL UNCERTAINTY (u_{tot}) CALCULATED ACCORDING TO (10), WITH ITS COMPONENTS (u_{A}, u_{B}) IN DETAIL. DATA ARE REPORTED FOR LOW (30 L/MIN), MEDIUM (90 L/MIN), AND HIGH (160 L/MIN) FLOW RATES

ID mask	TFE (%)											
	@ 30 L/min				@ 90 L/min				@ 160 L/min			
	Mean	u_{tot}	u_A	u_B	Mean	u_{tot}	u_A	u_B	Mean	u_{tot}	u_A	u_B
CM01	33.4	5.1	0.8	5.0	50.7	3.9	0.8	3.9	59.1	3.8	0.4	3.8
CM02	13.0	3.5	0.2	3.5	24.5	2.1	0.4	2.1	31.2	2.2	0.3	2.1
CM03	53.2	19.7	1.8	19.6	77.0	10.0	2.5	9.7	84.1	8.3	2.5	7.9
CM04	17.8	6.3	0.4	6.3	26.6	3.1	0.8	2.9	35.5	3.0	0.9	2.8
CM05	17.3	6.2	0.5	6.1	35.1	3.5	1.0	3.4	45.5	3.5	1.1	3.3
CM06	21.2	21.6	0.6	21.6	47.1	9.4	1.4	9.3	61.4	7.7	1.1	7.6
CM07	23.9	24.9	0.8	24.9	51.1	10.3	1.2	10.3	64.2	8.2	1.1	8.2
CM08	26.5	9.4	0.4	9.4	45.9	4.9	0.5	4.9	55.8	4.6	0.5	4.6
CM09	28.3	13.6	2.6	13.4	53.4	6.8	0.6	6.7	63.5	6.1	0.8	6.1
CM10	22.8	6.2	0.3	6.2	35.4	3.5	0.6	3.4	47.2	3.5	0.5	3.5
CM11	4.8	2.5	0.1	2.5	9.7	2.3	0.1	2.3	14.5	1.1	0.1	1.1
CM12	29.2	15.3	0.5	15.3	46.3	6.9	0.6	6.9	60.9	6.3	0.9	6.2
CM13	17.2	17.5	0.5	17.4	38.5	7.4	1.3	7.2	50.5	5.8	1.2	5.7
CM14	28.4	10.2	0.5	10.1	45.2	5.1	0.6	5.1	57.8	4.9	0.7	4.8
CM15	18.4	10.8	2.0	10.6	26.4	4.2	0.3	4.2	35.5	3.5	0.5	3.5
CM16	11.6	3.2	0.1	3.2	20.7	1.9	0.4	1.9	27.5	1.9	0.2	1.9
CM17	14.0	3.8	0.1	3.8	23.2	2.1	0.2	2.1	32.3	2.2	0.2	2.2
CM18	12.9	2.7	0.6	2.7	24.1	1.9	0.3	1.8	31.5	2.1	0.3	2.0
CM19	11.3	3.1	0.1	3.1	20.7	1.8	0.3	1.8	27.1	1.8	0.2	1.8
CM20	10.7	3.3	0.7	3.2	20.7	1.8	0.3	1.8	29.5	2.0	0.4	2.0
CM21	13.6	4.6	1.2	4.5	24.5	2.8	1.4	2.4	32.5	3.1	1.9	2.5
SM01	15.5	5.5	0.3	5.5	33.9	3.1	0.9	3.0	47.9	3.4	0.4	3.4
SM02	23.7	5.1	1.1	4.9	43.3	3.6	0.9	3.4	53.5	3.8	1.1	3.6
SM03	33.4	11.4	2.2	11.2	63.1	6.5	1.2	6.4	73.3	5.8	1.2	5.7
SM04	15.2	7.9	0.2	7.9	29.8	3.6	0.4	3.6	42.7	3.5	0.4	3.5
SM05	39.3	9.7	2.1	9.5	59.3	5.6	0.4	5.6	69.6	5.2	0.3	5.2
SM06	14.4	5.1	0.3	5.1	22.0	2.4	0.5	2.4	31.4	2.4	0.5	2.3
SM07	6.0	4.6	1.1	4.5	12.4	1.8	0.4	1.8	18.9	1.6	0.3	1.6
SM08	18.5	6.6	0.4	6.6	28.3	3.2	0.6	3.1	41.2	3.2	0.4	3.2
SM09	4.7	4.8	0.1	4.8	10.9	1.8	0.1	1.8	15.6	1.4	0.3	1.4
SM10	16.1	6.2	1.2	6.1	27.9	2.9	0.5	2.8	39.6	3.0	0.4	3.0
SM11	13.1	8.5	2.0	8.3	26.7	3.6	0.3	3.6	40.5	3.4	0.3	3.4
SM12	20.6	4.1	0.7	4.0	37.8	2.9	0.3	2.9	47.1	3.1	0.3	3.1
SM13	19.0	4.3	0.2	4.3	32.4	2.7	0.5	2.7	41.6	2.8	0.3	2.8
SM14	14.4	7.5	0.2	7.5	26.8	5.0	0.6	5.0	38.5	3.2	0.4	3.2
SM15	24.2	24.6	0.6	24.6	50.3	9.9	1.7	9.7	59.1	7.8	1.1	7.8
SM16	29.9	5.3	0.9	5.3	46.2	4.1	1.5	3.8	50.9	3.4	0.4	3.4
SM17	8.8	6.6	0.1	6.6	22.0	3.9	0.2	3.9	31.4	4.6	0.3	4.6
SM18	13.8	7.1	0.2	7.1	25.1	3.1	0.3	3.1	36.9	3.1	0.4	3.1
SM19	13.9	5.7	1.3	5.5	31.6	3.0	0.8	2.9	43.1	3.1	0.4	3.1
SM20	23.6	5.3	0.3	5.3	41.5	3.7	0.9	3.5	47.9	3.3	0.4	3.3
SM21	14.1	5.5	0.2	5.5	29.3	5.2	0.6	5.2	39.9	6.6	0.5	6.6
SM22	15.4	4.9	1.1	4.8	28.0	2.7	0.5	2.6	39.3	2.8	0.3	2.8
SM23	18.4	6.4	1.2	6.3	33.5	3.4	0.8	3.4	45.2	3.3	0.3	3.3
SM24	14.2	4.6	1.0	4.4	27.8	2.5	0.4	2.5	37.6	2.6	0.3	2.6
SM25	6.6	6.7	0.1	6.7	21.6	2.9	0.4	2.8	29.4	2.5	0.4	2.5
SM26	19.5	5.3	0.2	5.3	31.0	2.9	0.4	2.8	40.3	2.9	0.3	2.9
SM27	19.3	5.3	0.2	5.3	31.4	2.8	0.4	2.8	43.3	3.1	0.2	3.1
SM28	11.4	5.9	0.1	5.9	25.7	2.9	0.5	2.8	39.4	3.0	0.3	3.0
SM29	25.4	5.8	0.3	5.7	40.0	3.5	0.5	3.5	50.2	3.5	0.3	3.5

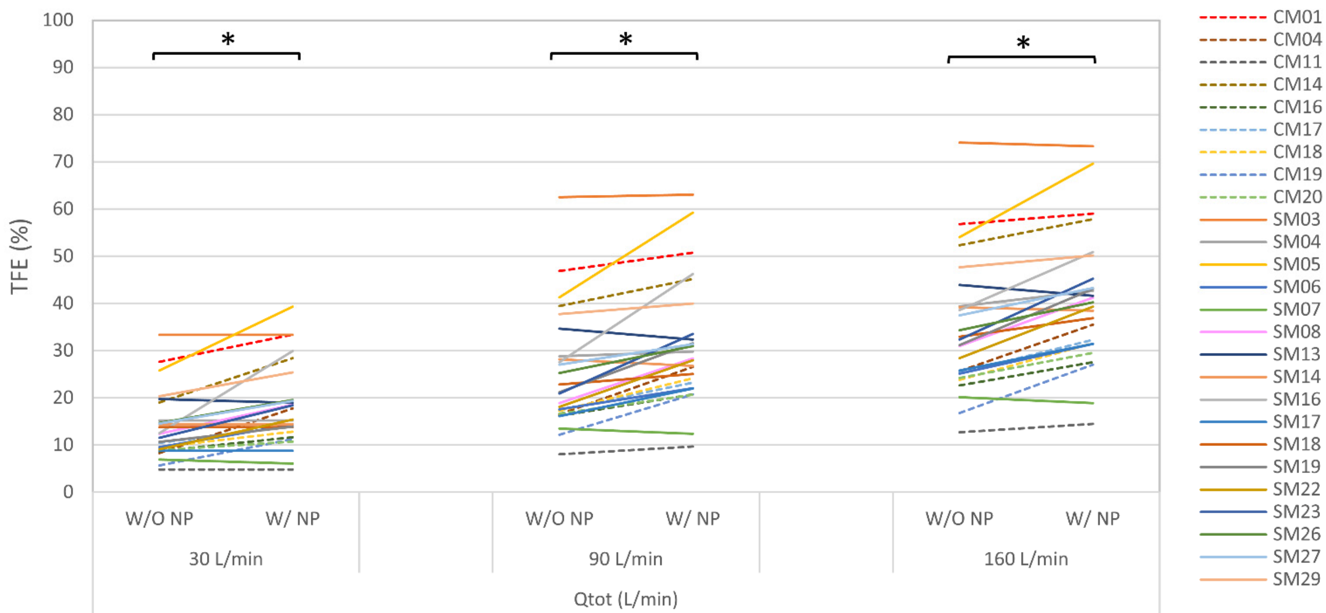

Fig. 6. TFE of face masks ($N = 26$) with (w/ NP) and without (w/o NP) nosepiece. Data are presented for three different flow rates of 30, 90, and 160 L/min. Each colored line (dashed for CMs and continuous for SMs) indicates the performance of the same mask with and without the nosepiece. $^*p < 0.05$.

However, six masks out of 26 showed no changes in TFE with or without the nosepiece when tested at 30 L/min, and 2, 3, and 4 masks out of 26 showed an increase of TFE when tested without nosepiece at 30, 90, and 160 L/min, respectively. Usually, the increase or decrease in TFE was consistent for the same mask across the three tested flow rates conditions.

To better quantify the variation of TFE with respect to the presence/absence of the nosepiece, the difference between the TFE values obtained from the same mask with and without nosepiece was calculated and identified as ΔTFE. The median values [first quartile; third quartile] of ΔTFE over the 26 tested masks were 4[0,6]%, 5[2,9]%, and 6[3,10]% at a flow rate of 30, 90, and 160 L/min, respectively, being influenced by the general increase of TFE with the increase of the outward airflow.

The ΔTFE was then analyzed distinguishing between nosepieces made of or incorporating a metal wire (MW) and those made only by a polymeric band (PO). Fig. 7 shows that ΔTFE obtained when MW nosepieces are applied is significantly higher than those obtained by applying a PO nosepiece. Differences between MW and PO subgroups were statistically significant at all the three tested flow rates. ($p < 0.05$, Mann–Whitney U test). A median ΔTFE of 5%, 6%, and 7% was associated with the use of an MW nosepiece when the outward airflow was 30, 90, and 160 L/min, respectively, with a maximum value of 19% reached by SM16 at 90 L/min.

D. Response Surface Method

The RSM could identify a model that well-fit the collected data ($R^2 = 0.87$), as shown in the actual versus predicted Fig. 8 (left). Despite small deviation from normality in the residuals distribution, as shown in Fig. 8 (right), residuals were acceptable to perform reliable predictions.

ANOVA results (Table A of the supplementary material) showed that the quadratic model was statistically significant

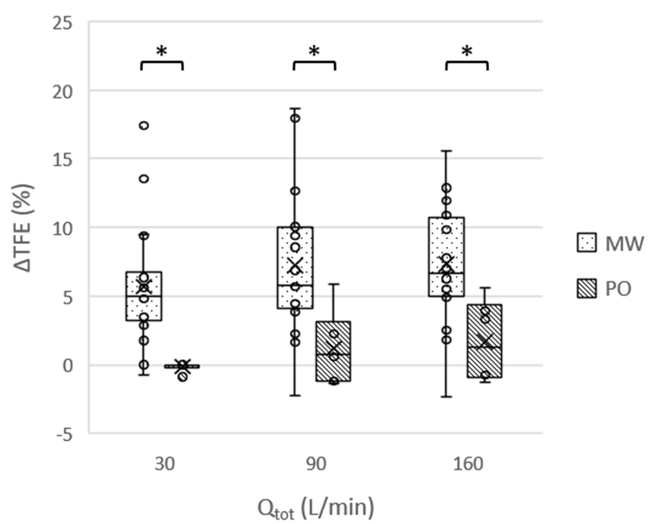

Fig. 7. ΔTFE (%) (i.e., difference of TFE values measured with and without nosepiece) according to the type of nosepiece: MW and PO. Data are presented at three different flow rates. $^*p < 0.05$.

(F-value = 110.88, p-value < 0.0001) with only a 0.01% chance that an F-value this large could have occurred due to noise. The model terms A, B, D, E, G, AD, AE, BF, BG, DF, DG, A^2, B^2, and E^2 were statistically significant, with a p-value lower than 0.05. Although not significant, the term F was included to maintain the model hierarchy, due to the presence of high-order significant terms (BF and DF). The quadratic model was the higher order model to avoid aliasing among the different terms (Table B of supplementary material) and to maximize R^2_A and R^2_P (Table C of the supplementary material). The good agreement of R^2_A and R^2_P with the calculated R^2 ensured a model without over or under fitting and with a good predictivity (Table D of supplementary material).

Estimates of the coefficients of the linear quadratic model are reported in Table III with their associated standard errors

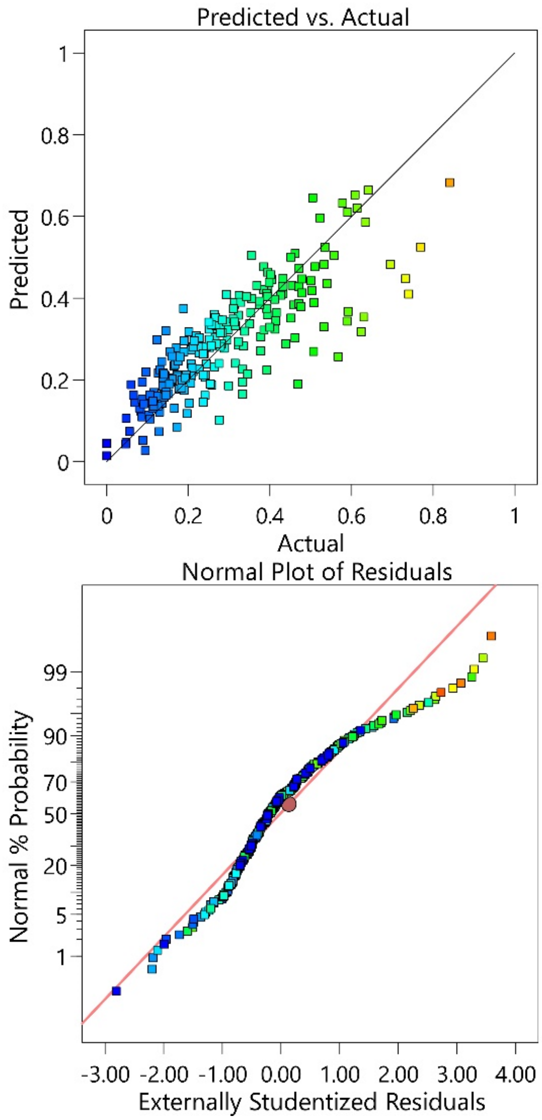

Fig. 8. Actual (experimentally collected) versus predicted (according to the model identified with the RSM) TFE values (top image). Normalized plot of residuals, showing some deviations from residual normality (bottom image), but acceptable for the validity of the model.

and 95% confidence intervals (CIs). Estimated coefficients were calculated based on the normalized model, in which each factor was normalized in the [−1, 1] range. This allows a direct evaluation of the factor's impact on TFE.

TFE results computed according to the quadratic RSM model were plotted on bidimensional surface plots, indicating TFE as a function of mask area and filter DP. Surface plots were presented for different scenarios, according to the values assumed by the categorical variables. Only the surfaces where datapoints were present are shown in Figs. 9–12.

The negative linear coefficient of DP (factor D) dominates the RSM model, causing TFE to decrease within the range of 7–92 Pa/cm^2 at higher DP values in all scenarios, consistently with the trend of the data presented in Fig. 5. TFE is also significantly affected by the flow rate in all scenarios, showing an increase for higher flow rates in accordance with the results of Fig. 4. Minor variations in TFE appeared according to mask areas in the range 158–361 cm^2, with a maximum reached within the middle range 200–300 cm^2, a trend related to the negative coefficient of factor A^2 in the model.

TABLE III

ESTIMATION OF THE COEFFICIENTS OF THE NORMALIZED MODEL, ASSOCIATED STANDARD ERROR, AND 95% HIGH AND LOW CIs. FACTORS WERE NORMALIZED BETWEEN −1 AND 1

Factor	Coefficient Estimate	Standard Error	95 % CI Low	95 % CI High
Intercept	0.5561	0.0177	0.5213	0.5909
A-Filtering area	-0.0754	0.0332	-0.1408	-0.0100
B-n Layers	0.0639	0.0287	0.0074	0.1204
D-DP	-0.2393	0.0210	-0.2807	-0.1979
E-Flow Rate	0.1574	0.0100	0.1377	0.1772
F-Melblown	0.0100	0.0094	-0.0085	0.0286
G-Nose piece	-0.0371	0.0072	-0.0512	-0.0229
AD	-0.1257	0.0134	-0.1522	-0.0992
AE	0.0565	0.0086	0.0395	0.0734
BF	-0.0948	0.0357	-0.1650	-0.0245
BG	-0.0563	0.0199	-0.0956	-0.0171
DF	-0.0573	0.0156	-0.0881	-0.0266
DG	-0.0255	0.0121	-0.0494	-0.0017
A^2	-0.1025	0.0126	-0.1272	-0.0777
B^2	-0.1159	0.0344	-0.1837	-0.0482
E^2	-0.0332	0.0129	-0.0586	-0.0078

The highest values in TFE (above 70%), within the explored domain of DP and areas values, appeared in the scenario where a 160-L/min outward flow is exhaled against a three-layer mask equipped with the nosepiece, but no meltblown (Fig. 10). Increasing the number of layers improves TFE only when a nosepiece is in place, both with or without meltblown present (Figs. 10 and 12), indicating that only when the fitting is improved by a nosepiece, a thicker material can improve performance, since the leakage caused by the lower breathability is mitigated by the tighter fitting. In the model, the presence of a meltblown layer is associated with a slightly decrease of the TFE in the lower DP region of the surface plots (Figs. 9 and 10 versus Figs. 11 and 12), but it is worth noting that few datapoints are present there (it is challenging to obtain an effective meltblown with a low DP, and therefore, in our mask sample, there was with these characteristics), attenuating the meaning of this prediction.

Regarding the effect of the nosepiece, the predicted TFE values are higher when a nosepiece is in place, especially when a meltblown layer is present in the mask filter (Fig. 11 versus Fig. 12), and minorly when no meltblown is used (Fig. 9 versus Fig. 10). This trend indicates that when a good filtering material with a higher DP is used, the nosepiece can reduce leakage improving mask performance, but the benefit is marginal for cloth mask with a lower DP.

The standard error and the width of the 95% CI of the model coefficients quantify the impact of each factor in terms of model uncertainty. The first-order terms in decreasing order of contribution were the filtering area, the number of layers, the DP, the flow rate, the meltblown, and the nosepiece. However, the mixed term of the meltblown and the DP and the second-order term related to the number of layers had a higher contribution than the first-order terms.

IV. DISCUSSION

Experimental data showed that TFE increases at higher flow rates, coherently over all the tested masks. This behavior