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CleanSpace® RESPIRATORS

Study of Protection Factors for Workers with Facial Hair using a Breath-Responsive PAPR -United Kingdom 2022

Abstract

The protection provided by a CleanSpace breath-responsive Powered Air Purifying Respirator (PAPR) to workers with and without facial hair was studied. Using a particle counter mounted in a backpack, twentytwo workers across five workplaces had their protection factors measured once per minute while they performed their normal tasks in their usual workplace. A high level of protection was found, consistent with results from an earlier study in Australia. Analysis of the results also suggested that, for a breath-responsive PAPR, protection provided in the workplace is at a similar level to that found in power-on "fit" tests.

Workplaces and Workers Studied

Studies were conducted at five sites in the United Kingdom (UK): a cement plant, a quarry, a flour mill, an above-ground gypsum plant and a below-ground gypsum plant. Workers performed their usual activities, which included cleaning (with broom, brush, compressed air), inspecting, operating underground mining equipment, driving (cart and SUV), communicating with other workers and machine maintenance.

Of the twenty-two workers studied, twenty had facial hair, ranging from light stubble to beards.



Respirators and Measurement Equipment

Study participants used CleanSpace HALO breath-responsive PAPRs. The CleanSpace HALO is a smaller respirator mostly used in the healthcare sector. It uses the same motor, battery and control circuitry, and the same control algorithm as CleanSpace2, CleanSpace ULTRA and CleanSpace EX industrial respirators. CleanSpace HALO was used because its Bluetooth capability facilitates the gathering of data.

CleanSpace breath-responsive PAPRs use silicone masks that fit snuggly against the face, but they are not tight-fitting in the sense of relying on a good seal to provide protection. The protective mechanism is the same as for a loose-fitting PAPR, in that the mask receives a greater amount of air (at any given moment) than what the wearer is inhaling. Mask pressure is monitored and the fan speed is automatically adjusted to maintain positive mask pressure. This process happens at 100 Hz (i.e., 100 mask pressure measurements and fan speed adjustments per second). With a clean particulate filter and a fully-charged battery, the CleanSpace HALO respirator will maintain positive pressure in the mask to approximately 220 litre/min. With a blocked filter (filter is due for replacement) and minimum battery level, positive pressure is guaranteed (by certification) to 120 litre/min. However, in practice, the mask pressure will remain positive at flows above 157 litre/min or higher¹.

Both ambient and in-mask dust concentrations were measured using a TSI PortaCount 8048. To enable workers to move around and perform their normal tasks, the PortaCount was mounted in a small backpack, together with a custom power-supply and a Windows Tablet². The 8048 streams data to the Tablet via TSI software. Custom (CleanSpace) software captures and stores this data stream from the Tablet screen.

The system performs a series of one-minute tests. In each minute, the PortaCount measures the ambient dust concentration, purges the sensing tubes, measures the mask dust concentration and then calculates and displays the protection factor for the minute. It then purges the sampling tubes and begins the next minute of measurement.

Protection Factor is the ratio of the concentration of particles in the outside air to that inside the mask.

Protection Factor = Concentration of particles in the outside air Concentration of particles inside the mask

For instance, if the concentration of particles on a job site is 100,000 [particles per cubic centimetre of air] and the concentration inside the mask is 100, then the protection is

$$\frac{Protection Factor}{100} = \frac{100,000}{100} = 1,000$$

¹All CleanSpace respirators retain a mask pressure above zero during the EN 12942 test 7.6.2 Inhalation Resistance after blocking, where the breathing wave form is 25 cycles per minute, 2.0 litre stroke (and thus a peak flow of 157 litre/min).

²The PortaCount is sensitive to orientation, because the "wick" must be kept immersed in iso-propanol at all times. Orienting the PortaCount with the sensing tubes exiting vertically upwards results in inconsistent measurements. However, if the machine is installed in the backpack with the tubes rotated in a left horizontal orientation, the measurement consistency is excellent. The backpack used for this study was fitted with custom inserts to ensure the PortaCount was maintained in the correct orientation and to also protect cable and tube connections from impact.

Protection factor is related mathematically to "filtering efficiency" (of a filter). The 99.95% filtering efficiency of a P3 filter is equivalent to a protection factor of 2,000. A protection factor of 10,000 means that the total filtering efficiency of the system is 99.99%.

Participants wore commercial wrist-mounted heart-rate monitors (Fitbit). Work rates were calculated from the heart-rate data, using the equations in ISO 8996.

Method

Each worker followed the same sequence of steps, as shown in the flow chart. Most (but not all) workers had previous experience with CleanSpace respirators. After an introduction to the process and the measurement equipment (backpack and tubes) each worker donned their respirator, underwent a power-off fit test, then a power-on fit test and then entered the contaminated area and performed approximately twenty-five (25) minutes of work. At the end of their first work session, they left the contaminated zone, doffed the respirator and had a short rest. Then they re-donned the respirator, entered the contaminated zone and performed about another twenty-five (25) minutes of work. At the end of their first of work. At the end of the respirator, entered the contaminated zone and performed about another twenty-five (25) minutes of work. At the end of the study, they left the contaminated zone and performed about another power-off fit test.

All fit tests were performed to the OSHA protocol (29 CFR 1910.134) and using the same PortaCount (in the backpack) used for the workplace measurements.



Checking Data Validity

The pilot Work Place Factor (WPF) study in Australia (discussed further below) revealed several factors that can invalidate the protection factor data. These include:

- Ambient dust level too low, or fluctuating too rapidly;
- Worker (particularly a smoker) coughs into the mask;
- PortaCount sampling tube pulled out of the mask (hooked up on a valve handle);
- Respirator stops communicating and is turned off and on to restart.

These issues were not encountered in the UK study. In particular, the ambient dust levels were high to very high at all five work sites.

Average ambient dust concentrations are shown below.

Average Ambient Dust Concentrations by Site – UK WPF – Oct 2022								
Cement Plant	2,651							
Quarry	21,613							
Flour Mill	17,060							
Gypsum Plant - Underground	60,808							
Gypsum Plant - Above ground	28,353							

However, the high ambient dust levels, while generally providing excellent measurement accuracy, occasionally caused the PortaCount sampling system to briefly block up, causing it to read zero on whichever environment it was sampling at the time. If this happens in the mask (where a reading of <1 particle per cc is not unusual), it can be identified as an unusually long period of zero readings (more than ~10 seconds). When the machine is sensing the ambient dust level, any drop to zero is questionable (and obvious). The problem was usually self-correcting and would disappear after 1 – 2 minutes. The PortaCount machines were cleaned and filters replaced at the end of each day. On two runs, the problem persisted and the data from the work session (total 36 minutes)³ had to be abandoned.

In all, two full sessions and 16 other individual minutes of data had to be abandoned due to blocking. The total number of minutes of data collected was 1173, so this loss (52 minutes) was less than 5% of the total. In future studies where dust levels are very high, a lunch-time cleaning session for the PortaCount machines will be proposed.

Protection Factor Results

The average protection factor for the two clean-shaven participants was 13,190 with a 5th percentile result of 1,752.

For the twenty workers with facial hair, the average protection factor was 9,505 with a 5th percentile of 1,285. The lowest 1-minute protection factor recorded in the study was 262 (i.e., the dust concentration in the mask was 262 times lower than in the surrounding air for that minute).

The activities conducted by the workers were physically demanding. ISO 8996 classified the readings captured from their recorded heart rates as follows - two workers recorded "moderate" work rates, three "high" and the remaining workers all experienced at least one period of "very high" work rate.

Average heart rates were as shown below. Peak heart rate data was not captured in this study and will be considered for future studies.



AVERAGE HEART RATES [BPM] BY WORKER AND WORK SESSION – UK WPF – OCT 2022									
Worker #	Worker Session 1	Worker Session 2							
10-1A	107	106							
10-1B	115	108							
12-1A	131	101							
12-1B	97	94							
12-2A	100	101							
12-2B	88	92							
13-1A	118	123							
13-1B	107	108							
13-2A	121	117							
13-3A	128	126							
13-3B	117	128							
17-1A	107	117							
17-1B	122	125							
17-2A	126	123							
17-2B	119	101							
18-1B	117	117							
18-2A	113	128							
18-2B	105	104							
19-1A	113	112							
19-1B	120	118							

³ By chance, these two work sessions were shorter than usual and only totalled 36 minutes, not ~50 minutes as would have been expected.

Measured protection factors were also fairly consistent across the five work sites. It is observed that the average results at the gypsum plant – Site 4 and Site 5 - were higher than the average readings at the other sites.

MEASURED PROTECTION FACTORS - WORKERS WITH FACIAL HAIR - UK OCT 2022										
	Site 1	Site 2	Site 3	Site 4	Site 5	Total Study				
Average	6,197	7,575	7,203	17,444	15,328	9,505				
5th Percentile	1,602	614	1,977	3,456	1,869	1,285				
Minimum	518	285	1,133	744	544	262				

Results of Earlier Australian Study

In 2019, CleanSpace carried out a pilot Work Place Factor (WPF) study in Australia. Nine workers with facial hair who participated in the pilot study recorded results as shown in the table below:

MEASURED PROTECTION FACTORS - WORKERS WITH FACIAL HAIR - AUSTRALIA 2019							
Average	6,480						
5th Percentile	1,309						
Minimum	186						

How do these results align with our understanding of PAPRs

Combining the results of the Australian and UK studies, it can be seen that the average level of protection received by workers with facial hair was in excess of 6,000 and the 5th percentile result was around 1,300. Understanding protective mechanisms can aid in comprehending how a breath-responsive PAPR can protect a worker with facial hair.

- In a negative pressure device, anything that compromises fit will compromise protection, because a good seal is the only thing preventing contaminated air entering the mask. Thus, any change to face shape (for instance during talking), or the presence of dirt under the seal, or facial hair, or any number of other changes, will compromise protection. This type of mask is vulnerable to quite subtle changes in face shape and anything that disturbs the smooth facial profile (for instance hair) will result in a significant loss of protection. It is likely that the protection a worker has documented at the initial fit test will be close to the highest that they will ever achieve and the average level of protection through the day will likely be much lower.
- When wearing a PAPR, the situation is different, because it is mainly the positive pressure that is preventing contaminated air entering the mask, and not the mask seal. A consistently positive mask pressure leads to higher protection levels and also to greater consistency in results. Changes in face shape, hair, dirt or other contaminants between the seal and the face have a minimal impact in the level of protection provided.

It has been recognised for some decades that a traditional constant flow PAPR does not required fit testing and will provide protection for workers of all face shapes and levels of facial hair. Despite its low-

profile and face-hugging appearance, a CleanSpace breath-responsive PAPR uses the same protective mechanism as a constant flow PAPR. It supplies more air to the mask (at any given moment) than what the user is breathing in, thus ensuring positive pressure in the mask.

For a PAPR, leaks between mask and face will only affect the level of protection achieved if the fan is unable to keep the mask pressure above ambient. Up to that level, all leaks are outwards and do not substantially affect protection. So, provided the fan is sufficiently powerful, no air-tight seal is required. In most conditions, the flow rates available from a CleanSpace PAPR are very similar to those available from a constant-flow PAPR. Therefore, considering the mechanism of breath-responsive PAPRs, it is anticipated that they provide workplace protection factors for wearers with facial hair similar to those provided by a traditional PAPR. The data presented in this paper supports that view.

Fit Tests vs. WPF Studies

It has been assumed, within the respiratory protection industry, that the protection offered by a respirator in the workplace is much lower than the protection level measured in the laboratory. The hypothesis is that fatigue, dirt, sweat and a lack of supervision will degrade the effectiveness of the respirator. As explained above, this theory is very likely accurate for negative-pressure masks.

The results of this study suggest that it may not be accurate for breath-responsive PAPRs. Examining the UK study results, it is notable that <u>every single worker scored better in their work sessions than they did in their power-on "fit" test</u>. This is a noteworthy result. As shown in the graph below, most workers enjoyed three (3) times the level of protection in their work session then what they achieved in their fit test. (In the graph, the blue line is the protection factors that would have been achieved if the work session average had been exactly equal to the fit test result. All results (orange dots) lie above that line. This means that for every worker, the average protection factor during their work session was higher than their fit test result. The orange line is a linear fit of the data, showing that, on average, the workplace results were about three (3) times the fit test results).



There is other evidence to support the view that, for a CleanSpace breath-responsive PAPR, a poweron fit test is a good (conservative) estimate of the protection that will be delivered in the workplace. These tests conducted by most companies before a worker is issued with a respirator, and periodically thereafter. CleanSpace has a record of de-identified "fit" testing results that were conducted on its devices in industry, performed by either CleanSpace staff or by 3rd party testers.

To date (April 2023) the results are as followed:

PROTECTION FACTOR (POWER-ON "FIT") TESTS - CLEANSPACE PAPRS ON WORKERS WITH FACIAL HAIR - TO APRIL 2023								
Number of Tests	371							
Average	8,194							
5th Percentile	1,337							
Minimum	105							

Comparing the results from the two WPF studies with our database of "fit" test results, it is evident that <u>there is not the predicted drop in performance when moving from the laboratory to the work site</u>. Instead, the level of protection remains steady.

MEASURED PROTECTION FACTORS - WORKERS WITH FACIAL HAIR - ALL SOURCES TO APRIL 2023								
	WPF Study Australia 2019	WPF Study UK 2022	"Fit" Testing in Industry					
Average	6,480	9,505	8,194					
5th Percentile	1,309	1,285	1,337					
Minimum	186	262	105					

The 5th percentile results are particularly stable. All three studies (a total of more than 2000 one-minute or full protection factor tests) show a 5th percentile within +/-50 of 1,300.

From this analysis it appears likely that the level of protection a worker receives in their workplace will be similar to (and most probably higher than) their score in a power-on fit test.



Conclusions: Understanding Breath-Responsive PAPRs

Two finding emerge from this study:

- 1. A CleanSpace breath-responsive PAPR can provide effective protection for workers with facial hair; and
- 2. The level of protection received in the workplace will usually be similar to (and often higher than) the level at initial power-on fit test.

Both results are explainable in terms of the protective mechanism of a CleanSpace breath-responsive PAPR, which monitors mask pressure at 100Hz and adjusts fan speed to maintain positive pressure in the mask up to very high flow rates. This is a robust protective mechanism which does not rely on maintaining a good mask seal. It will provide high (and consistent) results when faced with challenges such as a non-optimal fit, facial hair, talking, accumulation of dirt or sweat.

Large Appendix Data Part 1

	F	PROT	ECTI	ON F	ACT	ORS N	MEAS	URE	D DU	RING	WO	RK SI	ESSIO	NS –	UK V	VPF -	- 0C1	202	3	
Worker ID & Session #																				
Time (Min)	10-1A -S1	10-1A -S2	10-1B -S1	10-1B -S2	12-1A -S1	12-1A -S2	12-1B -S1	12-1B -S2	12-2A -S1	12-2A -S2	12-2B -S1	12-2B -S2	13-1A -S1	13-1A -S2	13-1B -S1	13-1B -S2	13-2A -S1	13-2A -S2	13-3A -S1	13-3A -S2
1	2306	3876	7057	1860	18860	4929	1413	597	6697	5541	2471	2502	1986	22448	2177	2896	36323	5563	3223	14025
2	4797	5201	5898	1273	4698	5231	557	1909	6686	6411	1946	1788	3964	6847	1677	6389	3528	7851	7127	9938
3	6567	4952	7612	1646	4568	5546	1278	368	6061	8463	928	1055	8027		1133	1910	7848	7325	5938	4000
4	3748	4073	9026	3045	7751	4466	2080	584	2563	24012	1092	1182	5128	8143	1956	3114	1317	11394	3121	5317
5	5054	10782	9934	2499	6546	1910	1875	602	5120	14411	8017	3305	1318	7085	3614	5622	8017	4353	2654	4852
6	6544	5994	14360	2208	4505	2632	1900	889	4104	9728	21833	8285	3042	8193	3227	8093	4207	6434	2174	4242
7	3719	2688	7654	1875	8023	3481	2144	837	3866	7213	9201	5426	2888	9304	5779	9194	6719	13489	3764	3508
8	6458	3393	6267	1788	2239	4103	2122	938	3808	9529	1478	5987	10116	5814	6665	6101	6363	11981	5380	4422
9	6270	3760	7604	1638	2253	4419	2243	1198	3759	8366	3902	4097	15217	11454	8808	3514	7766	11725	2234	6286
10	8081	2725	7174	1612	5446	3854	1684	1222	11769	9834	8355	1132	3730	6124	4907	4823	5673	10948	2811	5362
11	11858	2983	7519	1401	5041	7040	5890	1688	55749	9947	16960	1910	Blocking	9576	5978	5207	6594	8664	3602	5602
12	6585	8844	7173	1559	7196	2288	5124	1421	65505	7167	10338	3191	Blocking	10137	5738	6160	7744	16125	4767	6217
13	8363	18021	7741	1719	8799	7625	3667	3380	12906	8632	4547	1882	8295	7750	3710	6154	7940	5450	5235	5002
14	5508	24900	6505	1752	5459	9525	12316	3841	87432	20121	1609	2811	Blocking	4812	5188	5116	10099	7833	4094	4685
15	5283	10494	8785	1384	4141	1994	33055	2979	4480	17007	1445	2132	Blocking	1927	3831	5416	6469	1241	5139	4964
16	4527	9795	5909	7087	3794	Blocking	2629	7394	5677	13230	20601	2489	23058	7571	4730	5668	8362	5010	6335	8880
17	6098	6119	6334	1857	3709	2589	12597	4336	4437	14439	2630	2870	45145	8812	3563	6101	7669	2400	4859	8723
18	9147	2548	8706	1587	6377	1008	17119	4898	3974	16434	2674	2526	9392	3329	4172	5199	17051	4746	4428	8514
19	4790	14435	4864	1896	6250	9189	2845	27083	2747	4745	2210	2409	11502	11689	5631	6514	9740	5405	6127	8371
20	5086	10684	4887	1880	5445	3416	3644	2296	34313	12105	2663	17754	11346	8195	3944	6006	6296	1993	6556	3895
21	6286	6249	5118	1716	7023	2412	11315	3728	27895	21735	1762	30190	6969	13623	6549	6243	18864	1410	7107	7116
22	3517	6755	3147	1542	6859	3429	285	4936	89868	8820	2503	26361	9316	15058	5861	6095	8857	1918	5851	15068
23	4097	17103	4483	1966	2636	Blocking	266305	3400	65053	16641	1285	1935	33083	9149	6640	7614	9807		5166	
24	2787	7991	5500	1859	7906	6224	2674	1814	17671	58875	10741	1102	7049	8397	5887	6512	10055		8678	
25	3519	15723	6217	2227	1453	4089	12609		84243	152529	1955	63916	5328	12542	6584	6175	4097		6749	
26	6043	4846	5268	2395	10028		6626		4746	4957	1818	39822	8541	13995	5631	7206	9904			
27	6250	15617	5622	1753	9423		1899		4861			1972	12830	5506	8148	4412	11045			
28	5285	13574	518	1921			4615		7442				Blocking	3865	2445	3672	16383			
29	2518	2751	6451	2807									6606		6715	3083	1319			
30	2115	11885	4833	1946									4130		5439	2958				
31	3804	2208	4308	1912									Blocking							
32	13177	4619	12193	3067									5189							
33	18239		17006										9237							
34	18414		18720										5070							
35	24700																			

Large Appendix Data Part 2

	F	PROT	ECTI	ON F	ACT	ORS I	MEAS	URE	D DU	RING	WO	rk se	SSIC	NS -	UK V	VPF -	001	202	3	
								Wo	rker I	D&S	Sessio	on #								
Time (Min)	13-3B -S1	13-3B -S2	17-1A S1	17-1A S2	17-1B -S1	17-1B -S2	17-2A S1	17-2A S2	17-2B -S1	17-2B -S2	18-1B -S1	18-1B -S2	18-2A S-1	18-2A S2	18-2B -S1	18-2B -S2	19-1A S1	19-1A S2	19-1B -S1	19-1B -S2
1	6073	Session Data Unreliable	53893	11899	744	4492	3187	7396	43002	7343	2086	1611	15390	46835	9692	7439	Session Data Un- reliable	4579	2428	4292
2	6215	Session Data Unreliable	140342	6919	912	4934	3361	5187	6935	2252	2410	2920	10522	13654	7838	12832	Session Data Un- reliable	7551	2986	8188
3	3575	Sensor Tube Blocking	3206	9515	3403	6510	2452	14294	2688	6254	2852	3732	8488	48143	6291	1912	Sensor Tube Blocking	5183	3316	8428
4	26554		8751	9670	12033	6326	6126	3471	18848	3639	2730	3145	9616	25576	2481	2308		32339	2911	7670
5	3858		7316	7808	9595	6832	11029	8696	4965	3051	2874	2112	5108	18625	1782	2207		36481	1922	9456
6	3474		14346	9524	5639	6251	12603	490	12309	1905	2125	4183	4954	6945	1573	2362		42326	1896	8845
7	5050		50558	13157	10118	11575	15368	1430	4878	2575	4107	2018	1095	17359	2719	3977		45020	2424	9317
8	2852		7907	13302	3165	2610	5784	2469	6338	2626	2234	2908	2277	7385	1787	1995		26815	544	11580
9	4624		5542	9449	8749	23027	7682	7154	3849	3575	2109	1327	14340	23569	905	3500		23217	890	9508
10	Blocking		7871	13350	10281	54161	13507	5779	34296	6488	1135	3220	25740	28703	953	2615		34939	15825	18909
11	7669		19169	Blocking	5060	9875	13207	9110	4844	3043	486	4295	11138	651	3425	1716		32690	17439	9232
12	7034		8438	9389	4265	5578	10639	14313	7141	3882	491	2214	7443	262	2020	5218		31172	15469	15950
13	7781		7547	10217	11381	8104	9063	30451	7944	5041	509	1759	8944	7273	5119	20710		34321	9078	1835
14	14277		15570	9118	15211	4047	7221	22912	3580	3244	591	699	2336	20807	1303	46900		34279	15782	9935
15	Blocking		7337		16743	26868	8914	18234	6503	4137	604	1790	13710	4868	386	6157		53481	62961	19640
16	Blocking		30892		10888	10541	13387	14336	6096	5315	984		5234		372	5516		Blocking	5931	20334
17	5400		11689		9799	15126	8797	18578	4194	12223	4026		9416		679	3700		4728	14767	5104
18	4961		19239		5095	25331	10735	8932	8496	7534	4414		12059		776	7039		52691	12475	
19	4302		14973		16268	43334	9484	1829	8185	3503	3641		3312		1977	6115		41885	20152	
20	7678		13713		6261	31214	21338	4237	3313	1681	2638		11527		3148	4787		17003	17744	
21	6097		24708		14772	40627	13237	1855	3224	5817	20936		1070		6301	5521		4495	23183	
22	4622		17150		17394	35016	7761		7713	3767	24384		2401		6190	6783			18387	
23	21447		25629		15529	59216	10286		11729	4127	5748		1860		6871	5572			17563	
24	2053		15522		40618	60193	13498		10470	2486	2653		1256		4152	3966			10966	
25	4388		57798		3669	42211	14089		9527	3415			5069			4323			3808	
26	5132		23607		12803	15715	9877		5072	6161			938			5894			2488	
27			12513		19233	8172	16409		7818	3533			1062			4302			1729	
28			16704		27046	24512	2539			1319			953						2345	
29			9602		10919	27572	7123			4452			10018						7940	
30			17775			30563	12597			4397									4302	
31			11765			11840	11020			4585									15183	
32						27285	7289			2879									6071	
33																			12313	
34																			3090	
35																			3879	

COMPARISON OF FIT TEST RESULT WITH AVERAGE PROTECTION ACHIEVED DURING WORK SESSION – UK WPF – OCT 2022

SESSION OR MIT OCT 2022		
Worker #	Fit Test	Average for work sessions
10-1A	1585	7569
10-1B	1941	4804
12-1A	1922	5357
12-1B	1759	9709
12-2A	5030	20821
12-2B	2028	7264
13-1A	3625	9434
13-1B	2200	5158
13-2A	3841	8222
13-3A	3162	5790
13-3B	3979	7179
17-1A	4158	18509
17-1B	1927	16676
17-2A	1231	9826
17-2B	416	6614
18-1B	2037	3454
18-2A	7960	10862
18-2B	2580	5179
19-1A	4045	28260
19-1B	1584	10354