BRITISH ALLERGY FOUNDATION

and

SHARP ELECTRONICS (UK) LTD

Sharp Plasmacluster Air Cleaner
Model No: FU 40SE

SEAL OF APPROVAL
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REPORT FOR SEAL OF APPROVAL APPLICATION NO 200207

SHARP PLASMA CLUSTER AIR PURIFIER MODEL FU 40SE

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SUMMARY

The Sharp Plasma cluster air purifier Model FU40SE was tested to determine whether it should be awarded the seal of approval. The tests were done according to a protocol supplied by Dr Devalia but with agreed modifications and additions. The Casella air filters collected only small amounts of allergen in the 15min runs but the ELISA results indicated that the Sharpfilter unit was having an impact on the allergen load of the air. Air samples were taken through the tests runs and were analysed by Image analysis for numbers of particles in size classes. These results showed notable differences between the test runs with and without the Sharp filter unit. Pollen removal was not tested. Allergenic pollen is in the size range 10 to 130 microns. These particles would be removed together with other particles from the airflow as shown by the image analysis results. Based on the combination of ELISA results and image analysis evidence the Sharp Plasmacluster air purifier Model FU40SE can be recommended for the award of the seal of approval.

1. INTRODUCTION

The National Pollen Research Unit (NPRU) was asked to test the Sharp Plasma cluster purifier Model FU 40SE in order to determine whether it should be recommended for the award of Seal of Approval by Allergy Research Ltd. A protocol for testing air filters had already been written by the scientific consultant of Allergy Research Ltd. Some modifications were made to this protocol with the approval of Allergy Research Ltd and some additional tests were conducted in order to gain more information.

2. PROTOCOL AND METHODS

The Sharp Plasma cluster purifier Model FU 40SE was tested for the removal of house dust mite allergen and cat allergen from the air according to the protocol prepared by Dr JL Devalia (attached) but with the following modifications which had been agreed with Allergy Research Ltd.

1 The air sample tests with the Casella Portable samplers were run for 15mins each as previous experience at NPRU had found that a sampling duration of 5 mins was insufficient to get enough allergen from airborne stock house hold dust for the ELISA. The samples were taken from 0-15mins, 15 to 30 mins, 30 to 45 mins, 45 to 60 mins and at 120 to 135 mins for each test run.

2. The sample at 240 mins was not taken. It was thought that the impact of the filter should be apparent on the airborne allergen content of the room by two hours.

3. Three repeats of each test were done . These were numbered 1 , 2 and 3 for the measurement of air samples without the filter running; 4,5 and 6 for the tests with the filter unit running and 7, 8 and 9 for the tests done after the filter had been aged.

4. The filters in the unit were weighed before and after every test run. No new filters were supplied so the unit was run without changing the filters in it.

5. In addition to the Casella air samplers, the particle content of the air was sampled continuously with a Burkard indoor volumetric air sampler. This samples at 10 l /min through a critical orifice onto an adhesive tape to give a continuous record of the particle concentration in the air. This was done to provide further evidence in case the results from the ELISA samplers were inconclusive. The particle samples were examined by image analysis. In this method microscope images of each particle are measured and the numbers in different size classes are counted automatically by computer. The analysis of the samples on the tapes were taken to coincide with the Casella sampling periods.

The removal of pollen from the air was not tested specifically. Allergenic pollen is in the size range of approximately 10 microns to 130 microns. If the filter unit removes particles from the air of these dimensions and has a significant impact on the airborne concentrations of particles with house dust mite allergen and with cat allergen it is reasonable to conclude that it will also be effective in removing pollen.

The tests were done in an empty test room 3.5 m wide by 3.9 m long and 2.9 m high, giving a volume of 36.5 m^3

The filter unit was placed in the centre of the room on the floor. The Burkard indoor air sampler was placed 0.5m from the filter unit in front of it. The Casella personal air samplers were used 0.5 m from the unit and at 1.6m above the floor.

For each test 20g of fine dust was introduced to the air of the room. This was considered to be sufficient for the size of the room in order to mimic a very dusty and contaminated environment.

The tests and analysis were done by Prof Jean Emberlin assisted by staff at NPRU

3. RESULTS

3.1 Stock dust

Table 1

Allergen content of stock dust

Stock dust was prepared from a mixture of dust from homes with cats

Allergen	Content in µg/g
Der p 1	6.25
Fel d 1	29.7

Both of these concentrations are well above threshold levels for responses in atopic people.

3.2 Filter Weights

Table 2. Weights of air filters from Casella personal air samplers

NB Weights are in g to four decimal places. If second weight shows no increase over first weight it is assumed that there is a trace of dust present (< 0.0001g). All measurements were done at the same temperature and RH.

Weight of Filters from Casella

Filter Number	Weight before	Weight after	Difference
Test one 1	0.0578	0.0579	0.0001
2	0.0576	0.0577	0.0001
3	0.0573	0.0573	0
4	0.0571	0.0574	0.0003
5	0.0570	0.0570	0
Test two 6	0.0575	0.0580	0.0005
7	0.0571	0.0570	0
8	0.0564	0.0563	0
9	0.0567	0.0570	0.0003
10	0.0570	0.0570	0
Test three 11	0.0564	0.0570	0.0006
12	0.0561	0.0562	0.0001
13	0.0567	0.0570	0.0003
14	0.0570	0.0570	0
15	0.0566	0.0570	0.0004
Test four 16	0.0564	0.0566	0.0002
17	0.0568	0.0570	0.0002
18	0.0561	0.0561	0
19	0.0564	0.0565	0.0001
20	0.0561	0.0565	0.0004
Test five 21	0.0564	0.0567	0.0003
22	0.0554	0.0559	0.0005
23	0.0551	0.0553	0.0002
24	0.0565	0.0565	0
25	0.0564	0.0565	0.0001
Test six 26	0.0556	0.0562	0.0006
27	0.0568	0.0570	0.0002
28	0.0573	0.0573	0
29	0.0567	0.0567	0
30	0.0564	0.0573	0.0009
Test seven 31	0.0565	0.0568	0.0009
32	0.0563	0.0567	0.0004
33	0.0570	0.0577	0.0007
34	0.0563	0.0568	0.0005

After test 9:	Carbon= 377.58g HEPA= 369.38g	zero- 0.04g

The weights for the carbon filter after tests 8 and 9 were checked as there was a slight decrease but no increase.

3.3 ELISA RESULTS for the assessment of Der p1 on Casella filter samples

The individual samples were analysed in tripiclate and read at 1:10 dilutions. The averages of the three repeats were taken for the result. A standard procedure was applied using Monoclonal antibody 5H8 and Biotinylated monoclonal antibody 4CL (Indoor Biotechnologies).

All the results are within the lower third zone of the standard curve. This means that only small amounts of the allergen were present on the filters and that the results may not be reliable because they are near the lower limit of sensitivity of the method.

Table 3a

Tests without filter running

Results are Der p 1 as ng/ml

Time	Test one		Test two		Test three		mean	
	Filter		Filter		Filter			
0-15mins	1	8.25.	6	6.79	11	7.80		7.60
15-30mins	2	9.45	7	9.30	12	9.80		9.52
30-45mins	3	8.50	8	9.80	13	8.90		9.07
45-60 mins	4	6.40	9	8.60	14	7.80		7.60
120-135 mins	5	6.00	10	6.80	15	7.00		6.60
Decrease max to last		3.45		3.00		2.80	3.08	2.92

Tabel 3b

Tests with filter unit running

Results are as Der p 1 ng/ml

Time	Test four		Test five		Test six		mean	
	Filter		Filter		Filter			
0-15mins	16	7.50	21	9.50	26	4.60		7.20
15-30mins	17	8.50	22	5.60	27	9.80		7.96
30-45mins	18	7.00	23	4.50	28	7.50		6.33
45-60 mins	19	7.00	24	5.00	29	6.75		6.25
120-135 mins	20	6.00	25	4.00	30	5.50		5.17
Decrease max to last		2.50		5.50	4.30		4.1	2.79

Table 3c

Tests with aged filter
Results are as Der p 1 ng/ml

Time	Test seven		Test eight		Test nine		mean	
	Filter		Filter		Filter			
0-15mins	31	9.45	36	5.75	41	9.60		8.26
15-30mins	32	7.50	37	8.50	42	12.40		9.46
30-45mins	33	7.30	38	7.45	43	8.55		7.76
45-60 mins	34	6.80	39	8.55	44	7.50		7.62
120-135 mins	35	6.50	40	4.50	45	5.55		5.51
Decrease max to last	2.95		4.05		6.85		4.61	3.95

3.4 ELISA RESULTS for the assessment of Fel d1 on Casella filter samples

A standard ELISA procedure was used with Monoclonal antibody 6F9 and Biotinylated monoclonal antibody 3E4 (indoor Biotechnologies). All samples were analysed in triplicate and assessed at 1:10 dilutions. The average of the three readings was taken.

As in the case of the Der p 1 measurements , all the results are within the lower third zone of the standard curve. This means that only small amounts of the allergen were present on the filters and that the results may not be reliable because they are near the lower limit of sensitivity of the method.

Table 5a

Tests without filter unit running

Results are as Fel d1 mU/ml

Time	Test one	Test two	Test three	Mean
	Filter	Filter	Filter	
0-15mins	1 4.20	6 2.50	11 4.75	3.82
15-30mins	2 4.75	7 4.95	12 4.95	4.88
30-45mins	3 4.90	8 2.30	13 3.85	3.60
45-60 mins	4 2.60	9 0.75	14 2.75	2.03
120-135 mins	5 2.90	10 0.85	15 1.75	1.83
Decrease max to last	2.0	4.1	3.2	3.1 / 3.05

Table 5b

Tests with filter unit running
Results are as Fel d1 mU/ml

Time	Test one	Test two	Test three	Mean
	Filter	Filter	Filter	
0-15mins	16 4.60	21 5.75	26 4.75	5.03
15-30mins	17 4.50	22 5.85	27 5.65	5.33
30-45mins	18 3.75	23 4.25	28 3.75	3.92
45-60 mins	19 2.50	24 2.50	29 3.25	2.75
120-135 mins	20 0.80	25 1.25	30 1.25	1.10
Decrease max to last	3.8	4.6	4.4	4.26 / 4.23

Table 5c

Tests with aged filter

Results are as Fel d1 mU/ml

Time	Test one		Test two		Test three		Mean
	Filter		Filter		Filter		
0-15mins	31	4.50	36	4.80	41	5.25	4.85
15-30mins	32	4.75	37	5.25	42	6.50	5.5
30-45mins	33	3.75	38	4.25	43	4.75	4.25
45-60 mins	34	3.50	39	3.75	44	4.25	3.80
120-135 mins	35	1.25	40	0.85	45	1.75	1.28
Decrease max to last		3.50		4.45		4.75	4.23 / 4.22

3.5 RESULTS OF IMAGE ANALYSIS OF PARTICLE COUNTS FROM BURKARD INDOOR AIR SAMPLER

Table 6a

Tests without filter running. Average values for tests.

Numbers are particles per cubic metre of air sampled

	Size range in microns								
Position on slide	Time in mins		Above 20		20.0 to 10.0		10.0 to 2.5		Below 2.5
0.5mm	0-15		48,378		108,484		416,344		2,458,482
1mm	15-30		63,038		68,902		494,042		1,102,432
1.5mm	30-45		55,708		118,746		652,370		2,442,356
2mm	45-60		51,310		120,212		584,934		1,130,286
4mm	120-135		13,194		26,388		124,610		494,042
TOTAL			**231,628**		**442,732**		**6,969,364**		**762,598**
% decrease max to 2mm			19		none		11		54
% decrease max to 4mm			79		78		81		80

Table 6b

Tests with filter unit running. Average values for tests

Numbers are particles per cubic metre of air sampled

	Size range in microns								
Position on slide	Time in mins	Above 20		20.0 to 10.0		10.0 to 2.5		Below 2.5	
0.5mm	0-15		46,912		96,756		571,740		1,234,372
1mm	15-30		48,378		77,698		637,710		1,369,244
1.5mm	30-45		20,524		73,300		397,286		986,618
2mm	45-60		41,048		77,600		474,984		1,122,956
4mm	120-135		16,126		2,932		35,184		159,794
Totals			**172,988**		**328,286**		**2,116,904**		**4,872,984**
% decrease max to 2mm			16		1		25		18
% decrease max to 4mm			66		97		94		88

Table 6c

Test with aged filter. Average values for tests.

Numbers are particles per cubic metre of air sampled

		Size range in microns			
Position on slide	Time in mins	Above 20	20.0 to 10.0	10.0 to 2.5	Below 2.5
0.5mm	0-15	65,970	98,222	536,556	1,131,752
1mm	15-30	52,776	120,212	774,048	1, 373,642
1.5mm	30-45	99,688	58,640	460,324	1,073,112
2mm	45-60	45,446	102,620	527,760	889,862
4mm	120-135	10,262	20,524	57,174	228,696
Totals		**274,142**	**400,218**	**2,355,862**	**4,697,064**
% decrease max to 2mm		54	15	32	35
% decrease max to 4mm		90	83	93	83

4. DISCUSSION

4.1 Stock dust.

The Der p 1 and Fel d 1 allergen content of the stock dust was well above the accepted thresholds of response in atopic people. The amount of stock dust used per test (20 g introduced over one minute) produced a contaminated atmosphere in the test room with concentrations well above those which would normally be encountered in most domestic environments.

4.2 Filter weights

Despite running for 15 mins per sample the Casella filters captured only very small amounts of dust. This produced very small amounts of allergen for analysis.

The Filters in the air filter unit showed increases in weight during the test 4, 5 and 6. The largest amount of increase was in the first test run with the filter unit

when the carbon filter gained 15.38g and the HEPA filter gained 0.39 g. Together this weight of 15.77g of stock dust would contain 98.56 ng of Der p1 and 468.37 ng of Fel d 1.

The gains in weight after the 5th test run were 3.71 and 0.18g respectively giving a total of 3.89g . This amount of stock dust would have contained 24.31 ng Der p1 and 115.53 Fel d 1.

After the 6th test run the gains in weight were 3.64g and 0.23g, giving a total of 3.87g. this amount of stock dust would have contained 24.19 ng Der p 1 and 114.94 ng Fel d 1.

The weight gains after the filter was aged are considerably less or are zero. It is not clear why this should be.

4.3 Test for Der p1 removal from the air

The amounts of Der p 1 present on the Casella filters were all small and the results are towards the lower end of sensitivity of the ELISA technique. Some scatter in the results would be expected due to eddies in the room and the fact that particle concentrations in the air are rarely homogenous even under test conditions. In the tests without the filter running some particles will be deposited from the air or lost by impaction. The decay of airborne concentrations would be slower than a natural deposition rate because of the fans circulating the air. In all three tests there was a slight increase in allergen amounts on the filters in the second set of filters (15 – 30 mins).
If the rates of decay without the filter running and the rate of decay with removal by the filter are compared results for individual tests do not show clear patterns. However if the decreases in allergen load from the peaks to the last measurements are considered the averages show differences. In the decay without filter results the average decrease is 3.08 ng/ml whereas in the two sets of tests with the filter running it is 4.10 and 4.61 respectively.

4.4 Test for Fel d 1 removal from the air

The results for Fel d 1 quantification are also near to the lower limit of detection for the Elisa technique. In the tests the results show generally decreasing amounts of the allergen in the air with time with a few exceptions near to the start of some of the tests when amounts rise for the second period. As in the case of the Der p 1, the decreases from the maximum amounts to the last sample are greater in the tests with the filter running than without. On average the decrease without the filter running was 3.1mU, whereas in the sets of tests with the filter it was 4.26 mU and 4.23 mU respectively.

4.5 Particle size counts with Image analysis

The concentrations of particles (numbers / cubic metre of air) for four size classes are presented on Tables 6a to 6 c. The figures in the body of the tables are the averages for the tests for each stage. The sum of concentrations for each particle size are given.

In the cases of all size classes the sum of concentrations in the tests without the filter running are notably higher than in those tests with the filter unit operating. The particles below 10 microns are especially important as they are of respirable dimensions and it is known that Fel d 1 is associated with small particulate matter. In the size range below 2.5 microns the sum of the concentrations without the filter running is 37% higher than in the first set of tests with the filter, and 39% higher in the tests with the aged filter. In the size range 2.5 to 10 microns the comparable figures are 70% higher, and 64% higher.

Considering the percentage decrease from the maximum concentration to the last concentration, in the tests without the filter running the average is 79.9%, whereas in the two tests with the filter running it is an average of 86.0% and 87.25%

5. Conclusion

The evidence from the image analysis shows clear differences between the concentrations of particles in the air when the filter is running and when it is not .The decline in concentrations is apparent in both the first set of tests with the filter running and also with the aged filter. The stock dust is known to contain notable amounts of Der p1 and Fel d 1. The differences in the particle concentrations with the filter running would have produced notable differences in the allergen load of the air through the test period.
The ELISA results indicate that differences were occurring but the test runs of 15 min duration collected only small amounts of allergen and the results were towards the lower end of sensitivity of the test.
Allergenic pollen is in the size range 10 to 130 microns. This would be filtered out together with the other particles of this size range as shown by the results of the Image analysis.

Based on the combination of results of the image analysis and the ELISA tests I can recommend that the **SHARP PLASMACLUSTER AIR PURIFIER MODEL FU 40SE** be awarded the Seal of approval.

Professor J Emberlin
12.11.02