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Defend 400, prototype P4 US Medical – Max Speed

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REVISION	DATE	DESCRIPTION
1	04/12/2020	Defend 400 US Medical prototype performance testing at maximum fan Speed

1 INTRODUCTION

This in vitro study was conducted to determine the performance of the Defend 400 prototype P4 at the maximum speed setting against aerosolized *Staphylococcus epidermidis*.

The Defend 400 is an air purification system intended for use in large room settings to reduce the bioburden within the environment. It has variable speed settings ranging from 60 m^3/h at the minimum setting to 364 m^3/h at the maximum setting. The prototype device used for testing was set to the maximum speed of 364 m^3/h for each test run outlined in this report. The prototype device is identified as “P4 US Medical” and is based on the NOVAERUS air purification device platform NV340.

The Defend 400 device is a standalone air purification system containing high efficiency plasma technology located within the core region of the device. This technology is complimented further with the addition of HEPA grade filtration. This P4 US Medical prototype contained an M5 Camfil prefilter, a HEPA H13 Camfil filter, and a carbon Camfil filter. The prototype device also includes EBM Papst fan, US voltage, model R3G250-RE21-08.

This device (serial no. *Prototype 4 US Medical*) was challenged against an aerosolized culture of *S. epidermidis* within a 30m^3 closed environmental test chamber to determine the microbial airborne load reduction rate of the Defend 400 device at the maximum speed setting. Figure 1 below shows the device set up within the test environment.

Figure 1: NV340 P4 US Medical device in Test Chamber

2 TEST SET UP

The study aims to replicate a high level of bio-aerosol contamination within a room setting using an aerosolised culture of *S. epidermidis.* The outcome is to determine the ability of the Defend 400 air purification device at removing high levels of contamination over time. This is achieved by sampling the air at regular intervals to determine the bio-aerosol reduction over time compared to a Control test environment where no air purification device is present.

The environmental chamber used for this study is 30m^3 in size and is designed to replicate a room setting. All surfaces inside the chamber are constructed of stainless steel. The chamber is equipped with a large mixing fan and a smaller stratification fan contained inside to ensure homogenous mixing of the bio-aerosol generated. The chamber contains temperature and humidity controls to optimise the test conditions. An intake and exhaust ventilation system equipped with HEPA and Carbon filters is inbuilt to re-circulate fresh air to the chamber. Bespoke ports are located on either side of the chamber to enable connection of nebulizers and bio-samplers for testing. Figure 2 shows the environmental test chamber exterior.

Figure 2: Test Chamber Exterior

The bio-aerosol was generated using a 24-jet Collison nebuliser operated with a purified filtered air supply.

The bio-aerosol samples were collected at 15-minute intervals in sterile SKC BioSampler impingers to determine the chamber concentration.

The *S. epidermidis* (ATCC 12228) culture was selected based on its Biological safety level 1 category and the ability to easily survive the harsh conditions of nebulisation. *S. epidermidis* can be considered a surrogate for *Staphylococcus aureus*, MRSA and *Micrococcus luteus*.

Control testing was previously performed to calculate the natural reduction of the bio-aerosol that occurs within the chamber over time. This reduction is used to accurately calculate the LOG reduction and the clean air delivery rate (CADR) achieved by the Defend 400 prototype device.

A detailed description of the protocol that was followed is documented in the procedure *"SOP093.03 – Bacterial Test Procedure – LED chamber".*

3 RESULTS

The table below in Table 1 outlines the raw data counts for the Defend 400 prototype device at maximum speed.

Table 1: Test data counts for Defend 400, P4 US Medical

Test	T1	T2	T3	T4	T5	T6	T7	T8	T9
Date (D/M)	10/11	11/11	12/11	13/11	17/11	24/11	25/11	26/11	27/11
Sample 1	T0	T0	T0	T0	T0	T0	T0	T0	T0

1.00+04	104	30	28	28	13	21	23	15	21
1.00+04	90	40	30	38	14	18	32	20	23
1.00+05	11	5	4	2	1	2	3	1	2
1.00+05	8	4	3	3	1	2	2	1	2
Sample 2	T15	T15	T15	T15	T15	T15	T15	T15	T15
1.00+01	TNTC	TNTC	TNTC	TNTC	TNTC	TNTC	TNTC	TNTC	TNTC
1.00+01	TNTC	TNTC	TNTC	TNTC	TNTC	TNTC	TNTC	TNTC	TNTC
1.00+02	82	69	88	61	32	27	55	40	38
1.00+02	91	70	74	64	35	31	66	49	42
Sample 3	T30	T30	T30	T30	T30	T30	T30	T30	T30
1.00+00	83	50	59	65	40	27	68	18	26
1.00+00	84	49	61	67	36	27	72	21	27
1.00+01	8	5	5	6	4	2	7	1	2
1.00+01	9	3	7	6	4	3	8	2	2
Sample 4	T45	T45	T45	T45	T45	T45	T45	T45	T45
1.00+00	4	3	1	3	4	1	3	2	2
1.00+00	3	4	1	2	2	1	4	1	1
1.00+01	0	0	0	0	0	0	0	0	0
1.00+01	0	0	0	0	0	0	0	0	0
Sample 5	T60	T60	T60	T60	T60	T60	T60	T60	T60
1.00+00	0	0	0	0	0	0	0	0	0
1.00+00	0	0	0	0	0	0	0	0	0
1.00+01	0	0	0	0	0	0	0	0	0
1.00+01	0	0	0	0	0	0	0	0	0

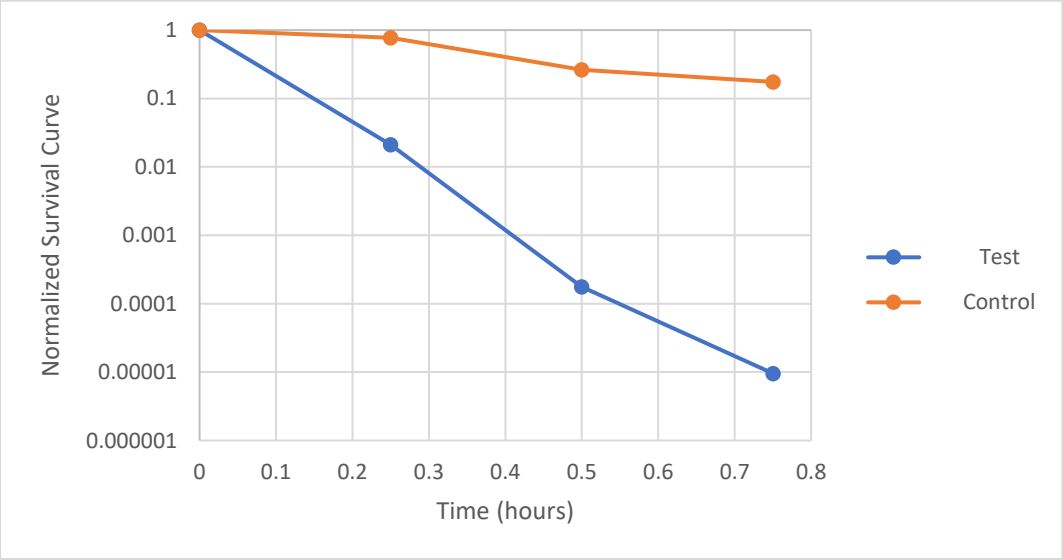


Figure 3: Average of normalized survival curves of test and control runs.

Table 2: Test and control data table: average of normalized survival data of test and control runs. These data are displayed in Figure 3.

========== Test and Control Total Average Data ==========

Time(h),	Test,	Control,
0,	1,	1,
0.25,	0.0212114,	0.770487,
0.5,	0.000176202,	0.263026,
0.75,	9.56911e-06,	0.174848,

Table 3: Average reduction in microbial sample counts in percentage units (top), and in log 10 scale (bottom).

========== Reductions ==========

Percentage Reductions

Time(h)	Average
0	0
0.25	97.247
0.5	99.933
0.75	99.9945

Log Reductions

Time(h)	Average
0	-0
0.25	1.5602
0.5	3.17402
0.75	4.26199

4 CONCLUSION

Greater than log-4 reduction (>99.99%) was achieved after 45minutes of exposure to the Defend 400 Prototype 4 US Medical at maximum speed.

The estimated clean air delivery rate (CADR) from the test and control data is 387m^3/h.

5 REFERENCES

[1] Standard Operating Procedure: SOP093.03 Bacterial Test Procedure – LED Chamber

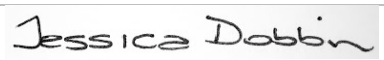
[2] Report – R-1666. NV340 US Medical Max Speed 10-11-2020

[3] Report – R-1670. NV340 US Medical Max Speed 17-11-2020

[4] Report – R-1672. NV340 US Medical Max Speed 24/11/2020

6 APPENDIX

7 APPROVALS

AUTHOR(S) PRINT NAME	SIGNATURE	DATE
Jessica Dobbin		04/12/2020

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