

The Five Pillars Of Safety
In Healthcare

Appendix

Scientific Air Management™

Appendix

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Date: Mon, Jan 6, 2020 at 10:18 AM
Subject: S400 Update at Princeton
To: randv.nobles@samairsv.stems.com <randy.nobles@samairsystems.com>
Cc: arlynn@samairsv.stem.com <arlynn@samairsystem.com>

Hi Randy/ Arlynn,

I hope this email finds you both well and that you and your family had a great Holiday season??

As promised I wanted to circle back and give you some updates as to the Scientific Air S400 device being utilized at my account.

- As stated before to Paul Fratta we have received positive testimonial from several nurse managers, claiming that the device assist greatly in minimizing organic odors present in the patient units.
- In addttion we have successful passed several AIR testes in our Cancer Center IV room areas, where in the past have proven to be challenging for us.
- Just recently on 12-18-2019 we had air testing performed in the Cancer Center and the result came back as a PASS. I unfortunately do not have the actual results, but based on feedback from the Pharmacy Director their areas pass with no issues.

The device has been very helpful and useful and has added value to these areas where we have had the S400 device utilized.

Thank you Randy (Scientific Air) for allowing me the opportunity to utilize the device at my account. Please let me know if you require anything further from me regarding next steps?

Take care!!!!!!

Just wanted to get you the latest update on the S400 device we have been utilizing here at my Princeton medical Center account.

Lazaro (Larry) Garcia
Director of Environmental Services
Penn Medicine Princeton Medical Center
One Plainsboro Road
Plainsboro NJ 08536
1-609-853-6142 (W)
1-609-558-4936 (C)
Lagarcia@P-rincetonhcs.org





Study Title

Antibacterial Activity and Aerosol Efficacy of Scientific Air Management's Device

Test Method

Custom Aerosol Study

Study Identification Number

NG6997

Study Sponsor

Dr. Gary Russotti
Scientific Air Management LLC
1303 West Copans Road Suite C6
Pompano Beach Florida 33060

(585) 797-4259

letitbemd@comcast.net

Test Facility

Microchem Laboratory
1304 W. Industrial Blvd
Round Rock, TX78681
(512) 310-8378

Test Device Information

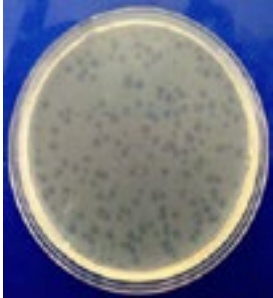
The test device was received on 10 MAR 2016 .



(note: photos depict the test device analyzed in this study)
Test device received: Scientific Air Management S400

Test Microorganism Information

The following test microorganisms were selected for this test:



MS2 Bacteriophage (MS2), 15597-B1

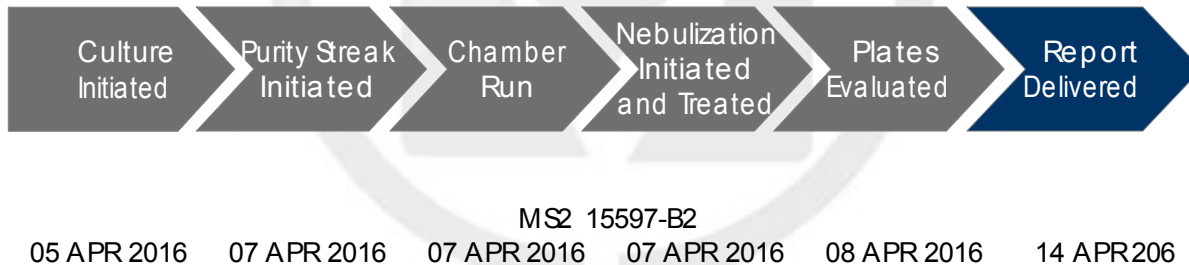
This virus is a non-enveloped positive-stranded RNA virus of the bacteriophage family Leviviridae. Bacterial cells are the hosts for bacteriophages, and *E. coli* 15597 serves this purpose for MS2 bacteriophage. Its small size, icosahedral structure, and environmental resistance has made MS2 ideal for use as a surrogate virus (particularly in place of picorna viruses such as poliovirus and human norovirus) in water quality and disinfectant studies.

Permissive Host Cell System for MS2: *Escherichia coli*, 15597

Summary of the Procedure

- Bacterial cultures, fungal culture, and a virus stock are pooled to target concentrations as appropriate.
- The test inoculum is split into two equal parts and added to two nebulizers. Liquid culture should not exceed 18ml per nebulizer.
- The chamber is set up and the safety checklist is completed prior to test initiation.
- The nebulizers are activated for 60 minutes to ensure target microbial concentrations are achieved prior to activation of the device.
- An SKC bio-sampler is used to take a time zero sample to determine starting chamber concentration for baseline comparison.
- Device is activated for the study sponsor determined contact time. After each contact time, the SKC bio-samplers are activated for 10 minutes to determine microbial concentrations.
- Samples are enumerated using standard dilution and plating techniques.
- Microbial concentrations are determined after 24-48 hours of incubation for bacteria and viruses. Fungal plates are incubated at room temperature for 5-7 days.
- Reduction of microorganisms are calculated relative to concentration at Time Zero.

Study Timeline



MS2 15597-B2

05 APR 2016

07 APR 2016

07 APR 2016

07 APR 2016

08 APR 2016

14 APR 2016

Amended report delivered 31 AUG 2016

Criteria for Scientific Defensibility of a Custom Device Study

For Microchem Laboratory to consider a Device Study to be scientifically defensible, the following criteria must be met:

1. The average number of viable bacteria recovered from the time zero samples must be approximately 1×10^5 cells/m³ or greater.
2. Positive/Growth controls must demonstrate growth of the appropriate test microorganism.
3. Negative/Purity controls must demonstrate no growth of test microorganism.

Passing Criteria

Because of the nature of the study, passing criteria may be determined by the Study Sponsor.

Testing Parameters used in this Study

Volume of Inoculum added to Nebulizer	15 ml per nebulizer (30 ml total)
SKC Biosampler Media (Vol.)	Phosphate Buffered Saline (20 ml)
Nebulization Time	60 minutes
SKC Biosampler Time	10 minutes
Sampling Time Points	Time zero, 5 minutes 15 minutes, 30 minutes
SKC Biosampler Sampling Rate	12.5 L/minute
SKC Biosampler Liters Sampled	125 L sampled per sampling time point

Test Microorganism	MS2 Bacteriophage
Culture Growth Media	N/A Stock Solution
Culture Growth Time	N/A Stock Solution
Culture Dilution Media	Phosphate buffered saline
Target Concentration	$\geq 1.0 \times 10^6$ CFU/m ³
Enumeration Media	50% Tryptic Soy Agar
Enumeration Type	Poured with <i>E. coli</i> 15597
Enumeration Incubation Time	18-24 hours

Study Notes

No additional observations or notations were made for this study.

Study Photographs



Photographs are the device received by the laboratory on 10 MAR 2016. The device is photographed operating within the chamber and the SKC bio-sampler in the foreground.



OBSERVATIONS

Control Results

Neutralization Method: Not applicable
 Growth Confirmation: Confirmed

Media Sterility: Sterile

Calculations

$$\text{Percent Reduction} = \left(\frac{B - A}{B} \right) \times 100$$

Where:

B = Number of viable test microorganism on the control carriers immediately after inoculation

A = Number of viable test microorganism on the test carriers after the contact time

$$\text{Log}_{10} \text{Reduction} = \text{Log} \left(\frac{B}{A} \right)$$

Where:

B = Number of viable test microorganism on the control carriers immediately after inoculation

A = Number of viable test microorganism on the test carriers after the contact time

$$\text{CFU}/\text{m}^3 = 1000 \times \left(\frac{\frac{\text{CFU}}{\text{ml}} \times (V_s)}{T_s (12.5)} \right)$$

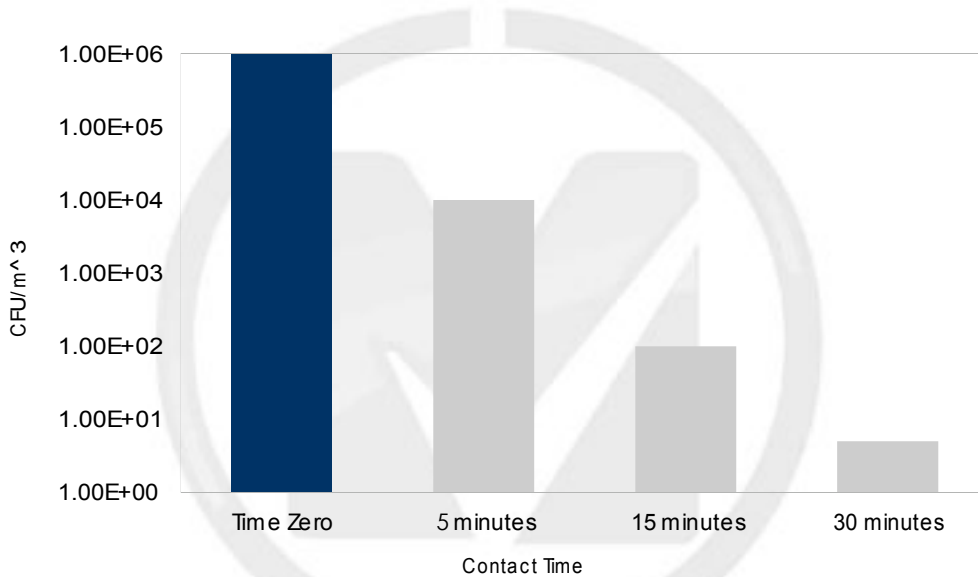
Where:

V_s = Bio-sampler volume (ml)

T_s = Time sampled (min)

Result of the Study

Test Device	Microorganism	Inoculum Concentration (CFU/ml)	Treatment Time Point	Recovery (CFU/m ³)	Percent Reduction vs. Time Zero	Log ₁₀ Reduction vs. Time Zero
Scientific Air Management S400	MS2 Bacteriophage ATCC 15597-B1	1.00E+07	Time Zero	1.00E+06	N/A	
			5 minutes	1.00E+04	99.0%	2.00
			15 minutes	1.00E+02	99.990%	4.00
			30 minutes	5.00E+00	99.9995%	5.30



The results of this study apply to the tested substances(s) only. Extrapolation of findings to related materials is the responsibility of the Sponsor.

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RESULTS



CHARLES SOLANA & SONS

80 Modular Avenue, Commack, NY 11725 • Phone: (631) 864-6483 Fax: (631) 864-6488
 Regional Office of: **Independent Certification Services, Inc.**

Raritan Bay Medical Center
 1 Hospital Plaza
 Old Bridge, NJ 08857

Attention: Jim Barna / Maria Polczyk - Pharmacy Department
 E-Mail: maria.polczyk@hackensackmeridian.org & fedorka41@gmail.com

ENVIRONMENTAL VIABLE PARTICLE TEST USP797

SAMPLES TAKEN 10/18/18 BY TECHNICIAN: Robert Fedorka

LAB RESULTS BY: EM LAB P&K

REPORT NO: 188094

1	<u>P_3 Ante Rm</u>		
	RESULTS: A	TSA PLATE, 1000 LITERS BACTERIA PLATE COUNT (CFU)	<u><1</u>
	RESULTS: B	MEA PLATE, 1000 LITERS FUNGI PLATE COUNT (CFU)	<u><1</u>
	RESULTS: A	TSA SWAB, BACTERIA SURFACE SWAB PLATE COUNT (CFU)	<u><1</u>
	RESULTS: B	MEA SWAB, FUNGI SURFACE SWAB PLATE COUNT (CFU)	<u><1</u>
2	<u>P_3 Non Hazardous Rm</u>		
	RESULTS: C	TSA PLATE, 1000 LITERS BACTERIA PLATE COUNT (CFU)	<u><1</u>
	RESULTS: D	MEA PLATE, 1000 LITERS FUNGI PLATE COUNT (CFU)	<u><1</u>
	RESULTS: C	TSA SWAB, BACTERIA SURFACE SWAB PLATE COUNT (CFU)	<u><1</u>
	RESULTS: D	MEA SWAB, FUNGI SURFACE SWAB PLATE COUNT (CFU)	<u><1</u>
3	<u>P_3 Hazardous Rm</u>		
	RESULTS: E	TSA PLATE, 1000 LITERS BACTERIA PLATE COUNT (CFU)	<u><1</u>
	RESULTS: F	MEA PLATE, 1000 LITERS FUNGI PLATE COUNT (CFU)	<u><1</u>
	RESULTS: E	TSA SWAB, BACTERIA SURFACE SWAB PLATE COUNT (CFU)	<u><1</u>
	RESULTS: F	MEA SWAB, FUNGI SURFACE SWAB PLATE COUNT (CFU)	<u><1</u>



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Page 2

CONTROL PLATE TSA - NO COLONIES DETECTED
CONTROL PLATE MEA - NO COLONIES DETECTED
CONTROL SWAB TSA - NO COLONIES DETECTED
CONTROL SWAB MEA - NO COLONIES DETECTED

COMMENTS: Counts are all under recommended action levels.

ISO CLASS	Recommended action levels	
	MAX. CFU -USP 797 AIR	MAX. CFU SURFACE
5	>1	>3
7	>10	>5
8	>100	>100

EMLab P&K3000 Lincoln Drive East, Suite A, Marlton, NJ 08053
(866) 871-1984 Fax (856) 334-1040 www.emlab.com

Client: Charles Solana and Sons, Inc.

C/O: Mr. Michael Young

Re: 188094; Raritan Bay Medical Center - Old Bridge

Date of Receipt: 10-19-2018

Date of Report: 10-25-2018

USP 797 - Summary of Sample Analysis Results

Location	Media	Type	Total CFU†	Colony Identification	ISO Class
188094 - P3 Ante Rm. A:Raritan Bay Medical Center - Old Bridge	TSA	Air	< 1	No colonies detected	7
188094 - P3 Ante Rm. B:Raritan Bay Medical Center - Old Bridge	MEA	Air	< 1	No colonies detected	7
188094 - P3 Non-Haz. Rm. C:Raritan Bay Medical Center - Old Bridge	TSA	Air	< 1	No colonies detected	7
188094 - P3 Non-Haz. Rm. D:Raritan Bay Medical Center - Old Bridge	MEA	Air	< 1	No colonies detected	7
188094 - P3 Hazardous Rm. E:Raritan Bay Medical Center - Old Bridge	TSA	Air	< 1	No colonies detected	7
188094 - P3 Hazardous Rm. F:Raritan Bay Medical Center - Old Bridge	MEA	Air	< 1	No colonies detected	7
188094 - TSA Control Plate:Raritan Bay Medical Center - Old Bridge	TSA	Air	N/A	No colonies detected	None
188094 - MEA Control Plate:Raritan Bay Medical Center - Old Bridge	MEA	Air	N/A	No colonies detected	None
188094 - P3 Ante Rm. Swab A:Raritan Bay Medical Center - Old Bridge	TSA w/ Lecithin & Tween	Surface	ND	No colonies detected	7
188094 - P3 Ante Rm. Swab B:Raritan Bay Medical Center - Old Bridge	MEA	Surface	ND	No colonies detected	7
188094 - P3 Non-Haz. Rm. Swab C:Raritan Bay Medical Center - Old Bridge	TSA w/ Lecithin & Tween	Surface	ND	No colonies detected	7

† The Total CFU value reported in this column is the Total CFU/unit value for the entire sample. For details, refer to the detailed results page of each sample in this report. In order to calculate Total CFU/unit values for air sample types, an air volume must be provided. Air samples without air volumes provided are reported as N/A (Not Applicable). A reported value of ND indicates none detected.

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188094 - P3 Non-Haz. Rm. Swab D:Raritan Bay Medical Center - Old Bridge	MEA	Surface	ND	No colonies detected	7
188094 - P3 Hazardous Rm. Swab E:Raritan Bay Medical Center - Old Bridge	TSA w/ Lecithin & Tween	Surface	ND	No colonies detected	7
188094 - P3 Hazardous Rm. Swab F:Raritan Bay Medical Center - Old Bridge	MEA	Surface	ND	No colonies detected	7
188094 - TSA Control Swab:Raritan Bay Medical Center - Old Bridge	TSA w/ Lecithin & Tween	Surface	ND	No colonies detected	None
188094 - MEA Control Swab:Raritan Bay Medical Center - Old Bridge	MEA	Surface	ND	No colonies detected	None

† The Total CFU value reported in this column is the Total CFU/unit value for the entire sample. For details, refer to the detailed results page of each sample in this report. In order to calculate Total CFU/unit values for air sample types, an air volume must be provided. Air samples without air volumes provided are reported as N/A (Not Applicable). A reported value of ND indicates none detected.

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USP 797 - Detail Sample Analysis Results

Location:	188094 - P3 Ante Rm. A:Raritan Bay Medical Center - Old Bridge	188094 - P3 Ante Rm. B:Raritan Bay Medical Center - Old Bridge	188094 - P3 Non-Haz. Rm. C: Raritan Bay Medical Center - Old Bridge	188094 - P3 Non-Haz. Rm. D: Raritan Bay Medical Center - Old Bridge
Comments (see below)	None	None	None	None
Area Designation	ISO Class 7	ISO Class 7	ISO Class 7	ISO Class 7
Sample type	SAS sample	SAS sample	SAS sample	SAS sample
Media used	TSA	MEA	TSA	MEA
Lot#/Expiration date	1824100/12-19-2018	1820612/11-14-2018	1824100/12-19-2018	1820612/11-14-2018
Lab ID-Version [‡] :	9558688-1	9558689-1	9558690-1	9558691-1
Analysis Date	10-22-2018	10-24-2018	10-22-2018	10-24-2018
Incubation	30° - 35°C for 2-3 days	26° - 30°C for 5-7 days	30° - 35°C for 2-3 days	26° - 30°C for 5-7 days
	raw ct. cfu*/m3	raw ct. cfu*/m3	raw ct. cfu*/m3	raw ct. cfu*/m3
§Total	ND < 1	ND < 1	ND < 1	ND < 1
Sample size	1000 liter	1000 liter	1000 liter	1000 liter
Positive Hole	380	380	380	380

*cfu = colony forming units Positive hole correction chart used for all calculations ND = none detected

Comments:

Identifiers listed without a count or data entry were not detected during the course of the analysis for the respective sample.

Note: Interpretation is left to the company and/or persons who conducted the field work. Some rare strains of Staphylococcus produce free (unbound) coagulase exclusively. The applied coagulase test only measures bound coagulase.

The limit of detection is a raw count of 1. The analytical sensitivity for air samples is equal to 1 raw count divided by sample size and multiplied by the positive hole correction factor. The analytical sensitivity for surface samples is equal to 1 raw count divided by a sample size of 1 plate.

‡ A "Version" indicated by "-x" after the Lab ID# with a value greater than 1 indicates a sample with amended data. The revision number is reflected by the value of "x".

§ Total cfu/unit has been rounded to two significant figures to reflect analytical precision.

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USP 797 - Detail Sample Analysis Results

Location:	188094 - P3 Hazardous Rm. E: Raritan Bay Medical Center - Old Bridge	188094 - P3 Hazardous Rm. F: Raritan Bay Medical Center - Old Bridge	188094 - TSA Control Plate: Raritan Bay Medical Center - Old Bridge	188094 - MEA Control Plate: Raritan Bay Medical Center - Old Bridge
Comments (see below)	None	None	None	None
Area Designation	ISO Class 7	ISO Class 7	None	None
Sample type	SAS sample	SAS sample	SAS sample	SAS sample
Media used	TSA	MEA	TSA	MEA
Lot#/Expiration date	1824100/12-19-2018	1820612/11-14-2018	1824100/12-19-2018	1820612/11-14-2018
Lab ID-Version‡:	9558692-1	9558693-1	9558694-1	9558695-1
Analysis Date	10-22-2018	10-24-2018	10-22-2018	10-24-2018
Incubation	30° - 35°C for 2-3 days	26° - 30°C for 5-7 days	30° - 35°C for 2-3 days	26° - 30°C for 5-7 days
	raw ct. cfu*/m3	raw ct. cfu*/m3	raw ct. cfu*/m3	raw ct. cfu*/m3
§Total	ND < 1	ND < 1	ND N/A	ND N/A
Sample size	1000 liter	1000 liter	0 liter	0 liter
Positive Hole	380	380	0	0

*cfu = colony forming units

Positive hole correction chart used for all calculations

ND = none detected

Comments:

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USP 797 - Detail Sample Analysis Results

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Comments (see below)	None	None	None	None
Area Designation	ISO Class 7	ISO Class 7	ISO Class 7	ISO Class 7
Sample type	Swab sample	Swab sample	Swab sample	Swab sample
Media used	TSA w/ Lecithin & Tween	MEA	TSA w/ Lecithin & Tween	MEA
Lot#/Expiration date	119560/11-27-2018	1824102/12-19-0018	119560/11-27-2018	1824102/12-19-0018
Lab ID-Version‡:	9558680-1	9558681-1	9558682-1	9558683-1
Analysis Date	10-22-2018	10-24-2018	10-22-2018	10-24-2018
Incubation	30° - 35°C for 2-3 days	26° - 30°C for 5-7 days	30° - 35°C for 2-3 days	26° - 30°C for 5-7 days
	raw ct. cfu*/plate	raw ct. cfu*/plate	raw ct. cfu*/plate	raw ct. cfu*/plate
§Total	ND ND	ND ND	ND ND	ND ND

*cfu = colony forming units

ND = none detected

Comments:

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Comments (see below)	None	None	None	None
Area Designation	ISO Class 7	ISO Class 7	None	None
Sample type	Swab sample	Swab sample	Swab sample	Swab sample
Media used	TSA w/ Lecithin & Tween	MEA	TSA w/ Lecithin & Tween	MEA
Lot#/Expiration date	119560/11-27-2018	1824102/12-19-0018	119560/11-27-2018	1824102/12-19-0018
Lab ID-Version‡:	9558684-1	9558685-1	9558686-1	9558687-1
Analysis Date	10-22-2018	10-24-2018	10-22-2018	10-24-2018
Incubation	30° - 35°C for 2-3 days	26° - 30°C for 5-7 days	30° - 35°C for 2-3 days	26° - 30°C for 5-7 days
	raw ct. cfu*/plate	raw ct. cfu*/plate	raw ct. cfu*/plate	raw ct. cfu*/plate
§Total	ND ND	ND ND	ND ND	ND ND

*cfu = colony forming units

ND = none detected

Comments:


Identifiers listed without a count or data entry were not detected during the course of the analysis for the respective sample.

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 ScientificAir

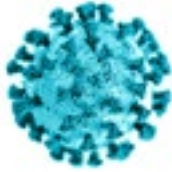
Engineering Air for a Cleaner Environment

 **ScientificAir**

800.923.9309

www.ScientificAirManagement.com

Scientific Air's S400 goes beyond filtration -- capturing airborne pathogens with a UVC dosage close and long enough for up to a **99.9995%** virus kill rate, eliminating bacteria, mold, odor, and VOC's.



Virus



Bacteria



Mold



Odor VOC's



DISINFECT AIR -- FAST!

The S400 uses patented **UVC technology**, bio-aerosol full room size laboratory validated, to kill pathogens, reduce particulates, removes mold, odor, and VOC's in a standard 800 cubic-foot room **in minutes**.

Helps reduce airborne HAI's with up to a 99.9995% UVC pathogen killing rate.

Reduces airborne particulates by as much as 99.97%.

Quiet 24/7 UVC air scrubbing, entirely safe for patients and staff.

Hospital proven in facilities like:

- NYU Medical Center
- University of Rochester
- Federal VA Hospitals
- NY Health+Hospitals
- Baptist Health Systems

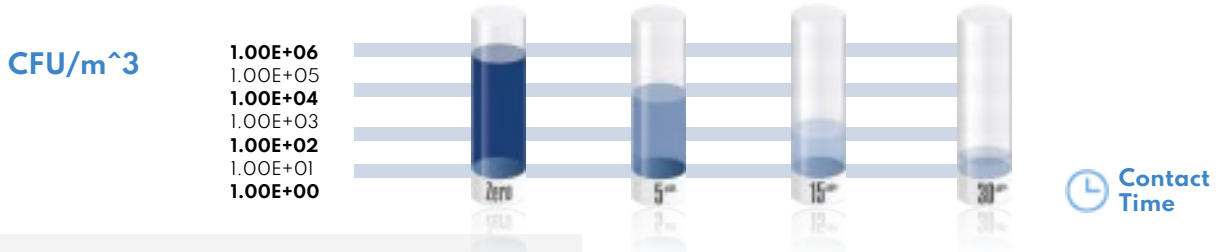
Powerful air management **24/7 in occupied spaces** like emergency rooms, intensive care units, operating rooms, patient rooms, compounding pharmacies laboratories, food-service, waiting areas, and more.

Room size bio-aerosol laboratory tested

The S400 conducted two separate efficacy analysis at independent nationally recognized facilities; Microchem Laboratories and Environmental Diagnostics Laboratories. Tests were conducted in a 10'x10'8" bio-aerosol guideline aerosolized chambers.



Test Device	Microorganism	Inoculum Concentration (CFU/ml)	Treatment Time Point	Recovery (CFU/m ³)	Percent Reduction Vs. Time Zero	Log ₁₀ Reduction Vs. Time Zero
Scientific Air Management S400	MS2 Bacteriophage ATCC 15597-B1	1.00E+07	Time Zero	1.00E+06	99.0% 99.990% 99.9995%	N/A
			5 minutes	1.00E+04		2.00
			15 minutes	1.00E+02		4.00
			30 minutes	5.00E+00		5.30



S400 Features

- High volume 400 cubic feet per minute fan operation for complete air change within 2 -5 minutes in a typical room of 800 cubic feet.
- Powerful yet quiet brush-less high-speed motor disinfects 400 CFM of air volume (42 - 46 decibels at average operating speeds).
- High capacity HEPA pre-filter cartridge captures particulates down to 0.3 microns.
- Large volume UVC induction chamber for full process of pathogen-laden air, lab tested for up to 99.9995% efficacy.
- 360-degree total air intake system creates a quiet undetectable air induction vortex.
- Patented carbon substrate for complete odor and VOC removal.
- No airflow disturbance, no temperature or humidity variations, and no negative or positive air pressure interference.
- Zero ozone production.
- 110-120 voltage standard outlet --same power requirements as a typical residential ceiling fan.
- On-Board Digital screen reporting
- HEPA Filter/Air Flow integrity metering
- UC-V Light integrity/intensity metering

- Carbon Final Filtration metering
- Pathogen and Particulate process metering
- Premium hospital wheels for effortless mobility on all surfaces with toe touch locking wheels.
- Filter replacements available with simple economical annual self service.

Eliminates up to **99.9995%** of airborne viruses in minutes!

37" tall
22" wide
62 lbs.



S400 Specification sheet

The S400 uses patented UVC technology, laboratory tested in bio-aerosol test chambers, to eliminate up to 99.9995% of viruses, eradicate bacteria and mold, removing up to 97% of non-viable particulates, destroying odor, and removing VOC's in a standard room in minutes!

The S400 is facility proven. Nationally recognized by hospitals like NYU Medical Center, University of Rochester, Federal VA Hospitals, NY Health+Hospitals, and Baptist Health Systems. The S400 is effective in Intensive Care Units, Operating Rooms, Patient Rooms, Compounding Pharmacies, Laboratories, Isolation Rooms, Food-Service, ER's, Waiting Rooms, and more.

SPECIFICATIONS

Physical Dimensions

- 22 x 37 inches
- Weighs 62 pounds

Electrical Ratings

- Rated at 110 volts
- Rated at 1.6 Amps
- Green Dot Grounded

Decibel Level

- 62-64 decibels Certifications
- MET US/C UL 507

Construction

- High grade steel
- Antimicrobial powder coating
- Aluminum wheel base

Air Circulation

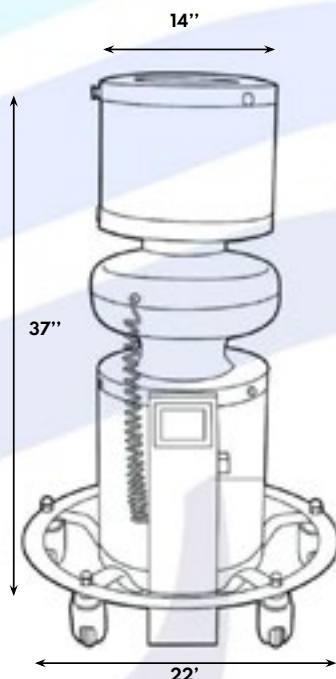
- 400 CFM
- Will not affect positive/negative pressure
- Air intake matches air exhaust
- 360 degree vortex air flow over a large surface area.
- Will not affect room air exchanges or room air flow.

Disinfection Process

- HEPA (0.3 um) pre-filter
- UV-C 253.7nm (254 nm) 36W non-ozone light array
- Treated carbon-coir substrate final filter granulated moisture resistant

Cleaning

- Wipe down entire machine with
- antibiotic cleaner



FEATURES

- Powerful 400 CFM fan performs complete air change disinfection within 2-5 minutes in a typical room of 800 cubic feet (10'x10'x8)
- High-capacity HEPA pre-filter reduces particulates down to 0.3 microns.
- Large-volume UVC kill chamber processing germ-laden air destroying virus, bacteria, Mold, odor, and VOC's.
- 360-degree total air circulation system is quiet, and undetectable with matching air induction and exhaust vortex.
- Zero airflow disturbance, no temperature or humidity variations, no negative or positive air pressure interference, NO by products, NO ozone.
- Lightweight 62 lbs. With aluminum balanced security base for superb stability and safety.
- 110-120 voltage standard outlet with the same power requirements as a typical residential ceiling fan.
- Green-Dot grounded electrical cord.
- On-Board Digital screen reporting:
 - HEPA filter/air flow integrity
 - Carbon final filtration integrity
 - UVC light intensity/integrity
 - Processed CFM air volume
- Premium hospital wheel for effortless mobility on all surfaces with touch toe locking casters.
- Consumable component "snap-in snap-out" replacements with simple and economical annual self service.
- Dimensions 22"W x 37"H 62lbs.

 **ScientificAir**

1301 West Copans Road
Pompano Beach FL 33060
PH 800.923.9309
randy.nobles@samairsystems.com

120VAC 1.2A 60Hz

EPA Est.
92896-FL-1



Field Test Conducted At A Pharmacy Compounding Facility Using the S400 Air Disinfection Unit

Report Date: 10/10/2018

Test period 08/15/2018 - 09/28/2018

Summary:

A pharmacy compounding facility at a major Florida hospital was experiencing difficulties with compliance of USP 797 and CAG-009 guidance documents in two specific rooms.

Test results indicated the airborne presence of a *Bacillus* species in one of the ante rooms and *Aspergillus flavus* in one of the chemo rooms (page 2).

Pharmacy personnel contacted the Infection Prevention department for assistance. The IP team suggested the use of the S400 Air Disinfection unit they had implemented in the ER waiting rooms and postoperative recovery rooms for the reduction of airborne influenza pathogens.

An S400 unit was employed for 12 continuous days in the two rooms (ante and chemo) that failed compliance testing. After 12 days of using the S400 units the pathogens (*bacillus* and *Aspergillus*) were eliminated in both rooms. Retesting showed compliance with ISO Clean Room Class 7, USP 797 and CAG-009 guidance documents (page 3).

This field test along with bio-aerosol chamber tests at two nationally recognized, third party labs (Microchem & EDL) fully support the pathogen efficacy claims of the S400 unit.

September 2018 - Florida Hospital Compounding Pharmacy uses S400 to PASS requirements for USP797 - CAG-009.

Testing Before S400

AeroMetric 797™ Results Summary Sheet Test Date 09/02/2019

Sample location	Class	Pass	Acpt	O.O.C	Cause
1A I.V. Room	7	Pass			
2A Passthrough #1 (Double Interlock)	7	Pass			
3A Ante Room	7	Pass			
4A Ante Room	7		Acpt		
5A Passthrough #2 (Double Interlock)	8	Pass			
6A Chemo Room	7		Acpt		
7A BVBI-6SS-RX {S#6S-15-BVBI-16574}	5	Pass			
8A BZ-655-RX (65-15-BH-16573)	5	Pass			
9A NV-425-400 (105725041106)	5	Pass			
1B I.V. Room	7	Pass			
2B Psssthrough #1 (Double Interlock)	7	Pass			
3B Ante Room	7	Pass			
4B Ante Room	7			O.O.C	Maximum cont for Class 7 exceeded
5B Passthrough #2 (Double Interlock)	8	Pass			
6B Chemo Room	7			O.O.C	Maximum cont for Class 7 exceeded
7B BVBI-6SS-RX(S#6S-15-BVBI-16574}	5	Pass			
8B Z-6SS-RX (6S-15-BH-16573)	5	Pass			
9B NV-425-400(105725041106)	5	Pass			



No growth of microorganisms. Sample in compliance with USP 797 and CAG-009. Growth of microorganisms. Sample in compliance with USP 797 and CAG-009 .
 O.O.C. - Out of Compliance. Unacceptable concentrations or presence of actionable microorganisms. Sample not in compliance wh USP 797 and CAG-009.

SAMPLE #4B Ante Room FAIL

Lab Sample #: **18021805-013**
 Sample Location : **Client Sample# 4B**
 Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2 Positive Hole Corrected Result: 2 CFU/m³
 Organism(s) Isolated : **Bacillus species Non-sporulating colony**

Raw Count	CFU/m ³	% TOTAL	MRL
1	1	50	1
1	1	50	1
2	2	~100%	

Sample was incubated for **7days at 26 °C** Bacteria colonies counted on MEA plate per client request.
 Positive Hole: 300 Air Volume: 1000 (L) MRL: 1

COMMENTS O.O.C. 2 CFU/m³

SAMPLE #6B Chemo Room FAIL

Lab Sample #: **18021805-015**
 Sample Location : **Client Sample# 6B**
 Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2 Positive Hole Corrected Result: 1 CFU/m³
 Organism(s) Isolated : **Aspergillus flavus**

Raw Count	CFU/m ³	% TOTAL	MRL
1	1	50	1
1	1	50	1
1	1	~100%	

Sample was incubated for **7days at 26 °C** Bacteria colonies counted on MEA plate per client request.
 Positive Hole: 300 Air Volume: 1000 (L) MRL: 1

COMMENTS O.O.C. 1 CFU/m³

Compounding Pharmacy places S400 in failed test locations. USP-797-CAG-009 Re-tested after SAM placement = PASS.

Testing After S400

AeroMetric 797™ Results Summary Sheet

Test Date 09/28/2019

Sample location	Class	Pass	Acpt	O.O.C	Cause
1A I.V. Room	7				
2A Passthrough #1 (Double Interlock)	7				
3A Ante Room	7				
4A Ante Room	7				
5A Passthrough #2 (Double Interlock)	8				
6A Chemo Room	7				
7A BVBI-6SS-RX {S#6S-15-BVBI-16574}	5				
8A BZ-655-RX (65-15-BH-16573)	5				
9A NV-425-400 (105725041106)	5				
1B I.V. Room	7				
2B Pssthrough #1 (Double Interlock)	7				
3B Ante Room	7				
4B Ante Room	7				No growth of microorganisms. Compliance with USP 797 and CAG-009
5B Passthrough #2 (Double Interlock)	8				
6B Chemo Room	7				No growth of microorganisms. Compliance with USP 797 and CAG-009
7B BVBI-6SS-RX(S#6S-15-BVBI-16574}	5				
8B Z-6SS-RX (6S-15-BH-16573)	5				
9B NV-425-400(105725041106)	5				



No growth of microorganisms. Sample in compliance with USP 797 and CAG-009.

SAMPLE #4B Ante Room PASS

Lab Sample #: 18026208-001 (Lot# 118206)

Sample Location : Client Sample# 4B
 Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Positive Hole Corrected Result: **NO GROWTH**
 Sample was incubated for **7days at 26 °C** Bacteria colonies counted on MEA plate per client request.

Positive Hole: 300 Air Volume: 1000 (L) MRL: 1

COMMENTS No Growth

SAMPLE #6B Chemo Room PASS

Lab Sample #: 18026208-002 (Lot# 118206)

Sample Location : Client Sample# 6B
 Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Positive Hole Corrected Result: **NO GROWTH**
 Sample was incubated for **7days at 26 °C** Bacteria colonies counted on MEA plate per client request.

Positive Hole: 300 Air Volume: 1000 (L) MRL: 1

COMMENTS No Growth

AeroMetric 797™ Results Summary Sheet

Sample Location	Class	Pass	Acpt	O.O.C.	Cause
1 1A I.V. Room	7	Green			
2 2A Passthrough #1 (Double Interlock)	7	Green			
3 3A Ante Room	7	Green			
4 4A Ante Room	7		Blue		
5 5A Passthrough #2 (Double Interlock)	8	Green			
6 6A Chemo Room	7		Blue		
7 7A BVBI-6SS-RX (S#6S-15-BVBI-16574)	5	Green			
8 8A BZ-6SS-RX (6S-15-BH-16573)	5	Green			
9 9A NV-425-400 (105725041106)	5	Green			
10 1B I.V. Room	7	Green			
11 2B Passthrough #1 (Double Interlock)	7	Green			
12 3B Ante Room	7	Green			
13 4B Ante Room	7			Red	Maximum count for Class 7 exceeded
14 5B Passthrough #2 (Double Interlock)	8	Green			
15 6B Chemo Room	7			Red	Maximum count for Class 7 exceeded
16 7B BVBI-6SS-RX (S#6S-15-BVBI-16574)	5	Green			
17 8B BZ-6SS-RX (6S-15-BH-16573)	5	Green			
18 9B NV-425-400 (105725041106)	5	Green			

- No growth of microorganisms. Sample in compliance with USP 797 and CAG-009 guidance documents.
- Growth of microorganisms. Sample in compliance with USP 797 and CAG-009 guidance documents.
- O.O.C. - Out of Compliance. Unacceptable concentrations or presence of actionable microorganisms.

Client Sample #: 4B
 Sample Location: 4B Ante Room
 Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Positive Hole Corrected Result: **2 CFU/m**

Lab Sample #: 18021805-013
 Positive Hole: **300**
 Air Volume: **1000 (L)**
 MRL: **1**

Organism(s) Isolated:	Raw Count	CFU/m ³	% Total	MRL
Bacillus species	1	1	50	1
Non-sporulating colony	1	1	50	1
	2	2	~100%	

Comments: **O.O.C.**
 Sample was incubated for 7 days at 26 °C. Bacteria colonies counted on MEA plate per client request.

Client Sample #: 6B
 Sample Location: 6B Chemo Room
 Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
 Positive Hole Corrected Result: **1 CFU/m**

Lab Sample #: 18021805-015
 Positive Hole: **300**
 Air Volume: **1000 (L)**
 MRL: **1**

Organism(s) Isolated:	Raw Count	CFU/m ³	% Total	MRL
Aspergillus flavus	1	1	100	1
	1	1	~100%	

Comments: **O.O.C.**
 Sample was incubated for 7 days at 26 °C

Passing USP 797 Test Results
Scientific Air Management SAM 400
implementation in previous "failed test" areas
09/12/2018

AeroMetric 797™ Results Summary Sheet

Sample Location	Class	Pass	Acpt	O.O.C.	Cause
1 4B Ante Room	7				
2 6B Chemo Room	7				



No growth of microorganisms. Sample in compliance with USP 797 and CAG-009 guidance documents.



Growth of microorganisms. Sample in compliance with USP 797 and CAG-009 guidance documents.



O.O.C. - Out of Compliance. Unacceptable concentrations or presence of actionable microorganisms.

Client Sample #: 43 (Lot#118206)

Lab Sample #: 18026208-001

Sample Location: 4B Ante Room

Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Positive Hole: **300**

Positive Hole Corrected Result: **No Growth**

Air Volume: **1000 (L)**

MRL: **1**

Comments: **Pass**

Sample was incubated for 7 days at 26 °C

Client Sample #: 6B (Lot#118206)

Lab Sample #: 18026208-002

Sample Location: 6B Chemo Room

Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2

Positive Hole: **300**

Positive Hole Corrected Result: **No Growth**

Air Volume: **1000 (L)**

MRL: **1**

Comments: **Pass**

Sample was incubated for 7 days at 26 °C

GLOSSARY

Aspergillus flavus: Aspergillus is one of the most common fungi worldwide, occurring on a very large number of substrates. There are about 280 species, some of which can grow at high temperatures. They produce unicellular, usually globose, hydrophobic spores, in unbranched chains on distinctive structures with a swollen vesicular apex. The spores are usually green-blue, greenish or grey green in mass (occasionally brown or black). They are often produced indoors, but may also enter with outdoor air. Most species are not problematic, but some cause opportunistic infections in humans, particularly in immunocompromised patients. Some species produce mycotoxins such as aflatoxins, which are carcinogenic, and some may be allergenic. The spores, when present without the diagnostic structures that produce them, are impossible to differentiate visually from those of Penicillium.

Bacillus species: Bacillus species are aerobic endospore-forming, gram-positive rods. They are widely distributed in the environment. The majority of these species are not pathogenic. Most aerobic, endospore-forming, gram-positive bacteria are in the genus Bacillus but others have been reassigned to other genera through taxonomic revision.

Coag-negative Staphylococcus species: Staphylococcus are non spore-forming, gram-positive cocci. Coagulase Negative Staphylococcus species constitute a major part of the normal microbiota of humans.

Corynebacterium-like: The majority of bacteria in this group are irregularly shaped, non spore-forming, gram-positive rods. Many species are part of the normal microbiota of the skin and mucous membranes of mammals. Some species are found in the environment. Some corynebacterium cause infection, particularly Corynebacterium diphtheriae.


Non-sporulating colony: For most microscopic identification of fungi, spores need to be present. This colony has not sporulated, therefore the analyst can not make a proper identification.

AeroMetric 797™ Results Summary Sheet

Sample Location	Class	Pass	Acpt	O.O.C.	Cause
1 1A I.V. Room	7				
2 2A Passthrough #1 (Double Interlock)	7				
3 3A Ante Room	7				
4 4A Ante Room	7				
5 5A Passthrough #2 (Double Interlock)	8				
6 6A Chemo Room	7				
7 7A BVBI-6SS-RX (S#6S-15-BVBI-16574)	5				
8 8A BZ-6SS-RX (6S-15-BH-16573)	5				
9 9A NV-425-400 (105725041106)	5				
10 1B I.V. Room	7				
11 2B Passthrough #1 (Double Interlock)	7				
12 3B Ante Room	7				
13 4B Ante Room	7				Maximum count for Class 7 exceeded
14 5B Passthrough #2 (Double Interlock)	8				
15 6B Chemo Room	7				Maximum count for Class 7 exceeded
16 7B BVBI-6SS-RX (S#6S-15-BVBI-16574)	5				
17 8B BZ-6SS-RX (6S-15-BH-16573)	5				
18 9B NV-425-400 (105725041106)	5				

 No growth of microorganisms. Sample in compliance with USP 797 and CAG-009 guidance documents.

 Growth of microorganisms. Sample in compliance with USP 797 and CAG-009 guidance documents.

 O.O.C. - Out of Compliance. Unacceptable concentrations or presence of actionable microorganisms. Sample not in compliance with USP 797 and CAG-009 guidance documents.

 Sample results not applicable to USP 797 and CAG-009 guidance documents.

Client Sample #: 9A
Sample Location: 9A NV-425-400 (105725041106)
Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 18021805-009
Positive Hole: **300**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**
Sample was incubated for 48 hours at 35 °C

Client Sample #: 1B
Sample Location: 1B I.V. Room
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 18021805-010
Positive Hole: **300**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**
Sample was incubated for 7 days at 26 °C

Client Sample #: 2B
Sample Location: 2B Passthrough #1 (Double Interlock)
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 18021805-011
Positive Hole: **300**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**
Sample was incubated for 7 days at 26 °C

Client Sample #: 3B
Sample Location: 3B Ante Room
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 18021805-012
Positive Hole: **300**
Air Volume: **1000 (L)**
MRL: **1**

Comments: **Pass**
Sample was incubated for 7 days at 26 °C

Client Sample #: 5A
 Sample Location: 5A Passthrough #2 (Double Interlock)
 Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Positive Hole Corrected Result: **No Growth**

Lab Sample #: 18021805-005
 Positive Hole: **300**
 Air Volume: **1000 (L)**
 MRL: **1**

Comments: **Pass**
 Sample was incubated for 48 hours at 35 °C

Client Sample #: 6A
 Sample Location: 6A Chemo Room
 Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Positive Hole Corrected Result: **1 CFU/m³**

Lab Sample #: 18021805-006
 Positive Hole: **300**
 Air Volume: **1000 (L)**
 MRL: **1**

Organism(s) Isolated:	Raw Count	CFU/m ³	% Total	Reservoirs
Coag-negative Staphylococcus species	1	1	100	Human
	1	1	~100%	

Comments: **Acceptable**
 Sample was incubated for 48 hours at 35 °C

Client Sample #: 7A
 Sample Location: 7A BVBI-6SS-RX (S#6S-15-BVBI-16574)
 Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Positive Hole Corrected Result: **No Growth**

Lab Sample #: 18021805-007
 Positive Hole: **300**
 Air Volume: **1000 (L)**
 MRL: **1**

Comments: **Pass**
 Sample was incubated for 48 hours at 35 °C

Client Sample #: 8A
 Sample Location: 8A BZ-6SS-RX (6S-15-BH-16573)
 Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2
 Positive Hole Corrected Result: **No Growth**

Lab Sample #: 18021805-008
 Positive Hole: **300**
 Air Volume: **1000 (L)**
 MRL: **1**

Comments: **Pass**
 Sample was incubated for 48 hours at 35 °C

Client Sample #: 1A Lab Sample #: 18021805-001
 Sample Location: 1A I.V. Room
 Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2 Positive Hole: 300
 Positive Hole Corrected Result: **No Growth** Air Volume: 1000 (L)
 MRL: 1

Comments: **Pass**
 Sample was incubated for 48 hours at 35 °C

Client Sample #: 2A Lab Sample #: 18021805-002
 Sample Location: 2A Passthrough #1 (Double Interlock)
 Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2 Positive Hole: 300
 Positive Hole Corrected Result: **No Growth** Air Volume: 1000 (L)
 MRL: 1

Comments: **Pass**
 Sample was incubated for 48 hours at 35 °C

Client Sample #: 3A Lab Sample #: 18021805-003
 Sample Location: 3A Ante Room
 Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2 Positive Hole: 300
 Positive Hole Corrected Result: **No Growth** Air Volume: 1000 (L)
 MRL: 1

Comments: **Pass**
 Sample was incubated for 48 hours at 35 °C

Client Sample #: 4A Lab Sample #: 18021805-004
 Sample Location: 4A Ante Room
 Test: 1107, USP 797 Culture, Air, Bacterial Counts with ID: SOP 2.2 Positive Hole: 300
 Positive Hole Corrected Result: **2 CFU/m³** Air Volume: 1000 (L)
 MRL: 1

Organism(s) Isolated:	Raw Count	CFU/m ³	% Total	Reservoirs
Coag-negative Staphylococcus species	1	1	50	Human
Corynebacterium-like	1	1	50	Human, Environment
	2	2	~100%	

Comments: **Acceptable**
 Sample was incubated for 48 hours at 35 °C

AeroMetric 797™ Results Summary Sheet

	Sample Location	Class	Pass	Acpt	O.O.C.	Cause
1	4B Ante Room	7				
2	6B Chemo Room	7				

No growth of microorganisms. Sample in compliance with USP 797 and CAG-009 guidance documents.

Growth of microorganisms. Sample in compliance with USP 797 and CAG-009 guidance documents.

O.O.C. - Out of Compliance. Unacceptable concentrations or presence of actionable microorganisms. Sample not in compliance with USP 797 and CAG-009 guidance documents.

Sample results not applicable to USP 797 and CAG-009 guidance documents.

Client Sample #: 4B Lab Sample #: 18021805-013
 Sample Location: 4B Ante Room
 Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2 Positive Hole: 300
 Positive Hole Corrected Result: **2 CFU/m³** Air Volume: 1000 (L)
 MRL: 1

Organism(s) Isolated:	Raw Count	CFU/m ³	% Total	MRL
Bacillus species	1	1	50	1
Non-sporulating colony	1	1	50	1
	2	2	~100%	

Comments: **D.O.C.**
 Sample was incubated for 7 days at 26 °C. Bacteria colonies counted on MEA plate per client request.

Client Sample #: 5B Lab Sample #: 18021805-014
 Sample Location: 5B Passthrough #2 (Double Interlock)
 Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2 Positive Hole: 300
 Positive Hole Corrected Result: **No Growth** Air Volume: 1000 (L)
 MRL: 1

Comments: **Pass**
 Sample was incubated for 7 days at 26 °C

Client Sample #: 6B Lab Sample #: 18021805-015
 Sample Location: 6B Chemo Room
 Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2 Positive Hole: 300
 Positive Hole Corrected Result: **1 CFU/m³** Air Volume: 1000 (L)
 MRL: 1

Organism(s) Isolated:	Raw Count	CFU/m ³	% Total	MRL
Aspergillus flavus	1	1	100	1
	1	1	~100%	

Comments: **D.O.C.**
 Sample was incubated for 7 days at 26 °C

Client Sample #: 7B Lab Sample #: 18021805-016
 Sample Location: 7B BVBI-6SS-RX (S#6S-15-BVBI-16574)
 Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2 Positive Hole: 300
 Positive Hole Corrected Result: **No Growth** Air Volume: 1000 (L)
 MRL: 1

Comments: **Pass**
 Sample was incubated for 7 days at 26 °C

Client Sample #: 4B (Lot#118206)
Sample Location: 4B Ante Room
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 18026208-001

Positive Hole: 300
Air Volume: 1000 (L)
MRL: 1

Comments: **Pass**
Sample was incubated for 7 days at 26 °C

Client Sample #: 6B (Lot#118206)
Sample Location: 6B Chemo Room
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 18026208-002

Positive Hole: 300
Air Volume: 1000 (L)
MRL: 1

Comments: **Pass**
Sample was incubated for 7 days at 26 °C

Client Sample #: 8B
Sample Location: 8B BZ-6SS-RX (6S-15-BH-16573)
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 18021805-017

Positive Hole: 300
Air Volume: 1000 (L)
MRL: 1

Comments: **Pass**
Sample was incubated for 7 days at 26 °C

Client Sample #: 9B
Sample Location: 9B NV-425-400 (105725041106)
Test: 1108, USP 797 Culture, Air, Fungal Counts with ID: SOP 3.2
Positive Hole Corrected Result: **No Growth**

Lab Sample #: 18021805-018

Positive Hole: 300
Air Volume: 1000 (L)
MRL: 1

Comments: **Pass**
Sample was incubated for 7 days at 26 °C

USP 797 Class and Action Levels

ISO Clean Room Classification	ISO, 0.5 μm^3 Particulate	Viable Air Sampling 400-1000 CFU/ m^3	Surface Contact CFU/plate	Gloved Fingertip CFU/plate	Gloved Fingertip CFU/plate Gown Validation
Class 5	3,520	>1	>3	>3	>0
Class 7	352,000	>10	>5	N/A	N/A
Class 8 or Worse	3,520,000	>100	>100	N/A	N/A

Source PtC/S, 2007

Footnotes and Additional Report Information

1. Regardless of the number of CFU identified, further corrective actions are required if any pathogenic organisms are identified. It is therefore suggested to identify any colonies seen on the plate to genus level to rule out pathogens such as: gram-negative rods bacteria, and coagulase positive staphylococcus spp., yeasts, and mold.
2. **Regardless of ISO Class, any fungal identification on an air or surface sample will cause the sample to be Out of Compliance.**
3. Positive-hole correction factor is a statistical tool which calculates a probable count from the total raw count, taking into account multiple particles can impact on the same hole. For this reason the sum of calculated counts may be less than the positive hole corrected total.
4. TSA (Tryptic Soy Agar) for bacteria is incubated at 30-35°C for 2 days. MEA (Malt Extract Agar) or other suitable fungal media is incubated at 26 - 30°C for 5 to 7 days.
5. MEDIA CONTROLS. An unexposed TSA plate or MEA plate from each sampling event/project should be submitted for quality control purposes. The lot number for controls should be the same as those plates being submitted for analysis.
6. Semi-annual monitoring for viable bacteria and fungi in air, surface contact plates, gloved fingertip and particulates is required for both Class 5 and Class 7 defined areas.
7. Viable cultures must be collected using an impaction style sampler for volumetric capture. A sufficient volume of air (400 to 1000 liters) should be tested at each location to obtain the sensitivity and detection limit necessary for class action levels.
8. Standard contact plates have an area of 25 cm^2 , unless otherwise noted in the sample area.
9. The results in this report are related to this project and these samples only.
10. **MRL** Units for USP 797 Cultures are as follows: AIR is CFU/ m^3 , SURFACE is CFU/25 cm^2 , and CONTROL is colony/sample.
MRL: Minimum Reporting Limit.
11. **TARGET IDENTIFICATIONS:** Any gram-negative rod, *Staphylococcus aureus*, yeast and molds
12. Non-sporulating colony is a colony of a filamentous mold on an agar plate that is not producing spores and/or conidiophores that allows the analyst to identify it further than a non - sporulating colony. Identification structure must be present for identification.
13. If the final quantitative result is corrected for contamination based on the blank, the blank correction is stated in the sample comments section of the report.

Due to rounding totals may not equal 100%.

USP 797 Class and Action Levels

ISO Clean Room Classification	ISO, 0.5 μm^3 Particulate	Viable Air Sampling 400-1000 CFU/ m^3	Surface Contact CFU/plate	Gloved Fingertip CFU/plate	Gloved Fingertip CFU/plate Gown Validation
Class 5	3,520	>1	>3	>3	>0
Class 7	352,000	>10	>5	N/A	N/A
Class 8 or Worse	3,520,000	>100	>100	N/A	N/A

Source PIC/S, 2007

Footnotes and Additional Report Information

- Regardless of the number of CFU identified, further corrective actions are required if any pathogenic organisms are identified. It is therefore suggested to identify any colonies seen on the plate to genus level to rule out pathogens such as: gram-negative rods bacteria, and coagulase positive staphylococcus spp., yeasts, and mold.
 - Regardless of ISO Class, any fungal identification on an air or surface sample will cause the sample to be Out of Compliance.**
 - Positive-hole correction factor is a statistical tool which calculates a probable count from the total raw count, taking into account multiple particles can impact on the same hole. For this reason the sum of calculated counts may be less than the positive hole corrected total.
 - TSA (Tryptic Soy Agar) for bacteria is incubated at 30-35°C for 2 days. MEA (Malt Extract Agar) or other suitable fungal media is incubated at 26 - 30°C for 5 to 7 days.
 - MEDIA CONTROLS.** An unexposed TSA plate or MEA plate from each sampling event/project should be submitted for quality control purposes. The lot number for controls should be the same as those plates being submitted for analysis.
 - Semi-annual monitoring for viable bacteria and fungi in air, surface contact plates, gloved fingertip and particulates is required for both Class 5 and Class 7 defined areas.
 - Viable cultures must be collected using an impaction style sampler for volumetric capture. A sufficient volume of air (400 to 1000 liters) should be tested at each location to obtain the sensitivity and detection limit necessary for class action levels.
 - Standard contact plates have an area of 25 cm^2 , unless otherwise noted in the sample area.
 - The results in this report are related to this project and these samples only.
 - MRL.** Units for USP 797 Cultures are as follows: AIR is CFU/ m^3 , SURFACE is CFU/25 cm^2 , and CONTROL is colony/sample.
MRL: Minimum Reporting Limit.
 - TARGET IDENTIFICATIONS:** Any gram-negative rod, *Staphylococcus aureus*, yeast and molds
 - Non-sporulating colony is a colony of a filamentous mold on an agar plate that is not producing spores and/or conidiophores that allows the analyst to identify it further than a non - sporulating colony. Identification structure must be present for identification.
 - If the final quantitative result is corrected for contamination based on the blank, the blank correction is stated in the sample comments section of the report.
- Due to rounding totals may not equal 100%.

GLOSSARY

Aspergillus flavus: Aspergillus is one of the most common fungi worldwide, occurring on a very large number of substrates. There are about 280 species, some of which can grow at high temperatures. They produce unicellular, usually globose, hydrophobic spores, in unbranched chains on distinctive structures with a swollen vesicular apex. The spores are usually green-blue, greenish or grey green in mass (occasionally brown or black). They are often produced indoors, but may also enter with outdoor air. Most species are not problematic, but some cause opportunistic infections in humans, particularly in immunocompromised patients. Some species produce mycotoxins such as aflatoxins, which are carcinogenic, and some may be allergenic. The spores, when present without the diagnostic structures that produce them, are impossible to differentiate visually from those of Penicillium.

Bacillus species: Bacillus species are aerobic endospore-forming, gram-positive rods. They are widely distributed in the environment. The majority of these species are not pathogenic. Most aerobic, endospore-forming, gram-positive bacteria are in the genus Bacillus but others have been reassigned to other genera through taxonomic revision.

Coag-negative Staphylococcus species: Staphylococcus are non spore-forming, gram-positive cocci. Coagulase Negative Staphylococcus species constitute a major part of the normal microbiota of humans.

Corynebacterium-like: The majority of bacteria in this group are irregularly shaped, non spore-forming, gram-positive rods. Many species are part of the normal microbiota of the skin and mucous membranes of mammals. Some species are found in the environment. Some corynebacterium cause infection, particularly Corynebacterium diphtheriae.

Non-sporulating colony: For most microscopic identification of fungi, spores need to be present. This colony has not sporulated, therefore the analyst can not make a proper identification.

Airborne Particulate Management Case Study Conducted at major US Hospital.

Test were conducted in a typical occupied patient room (approximate 790 cf3) with Central Air Handler Unit with 95% filtration attachments to match particulate filtration of the SAM400 unit.

Measure Particle Concentration/Counts as stand-alone meter probe parameters. Direct-sense probes, IQ-410/610 and AS-201/202A Air Velocity probes and DP-702LH auto-zeroing Differential Pressure sensors.

- 0.3µm and higher mass concentration to limit particle size to PM10.
- Range particle counter also counted simultaneous, calculated mass concentration.
- PM0.5, PM1.0, PM2.5, PM5.0, PM10 & TSP.
- Particulate meter connected dataloggers, downloading logged data direct to data management and reporting software.
- Particle sizing chart to government and industry guidelines.
- %RH and Temperature reporting. No CO2 and TVOC reports conducted.
- Size Range 0.3 to 25µm
- Size Channels Factory calibrated at 0.3, 0.5, 1.0, 2.5, 5.0, 10.0 µm variable binning
- Flow rate 0.1 CFM (2.83 LPM)
- Concentration Limit 10,000,000 Particles/ft³ @ 10% coincidence loss

S400 shows a 99.97% efficiency in the 0.3 micron particulate range.
See measured S400 particle reduction comparison charts.

Series #1 GREEN

- Base Line is incremental from the wall mount original installation equipment Fan Coil Unit.

Series #2 RED

- S400 results.

Series #3 BLUE

- Central Air Handler with a 95% final filter attachment.

Particle count readings demonstrate a definite improvement of raw particulate counts in the rooms with a SAM400 unit. The Central Air Handler graph with a 95% final filter attachment fluctuated based on the incoming air quality due to the filter efficiency that is seen in the micron 0.3 range (blue).

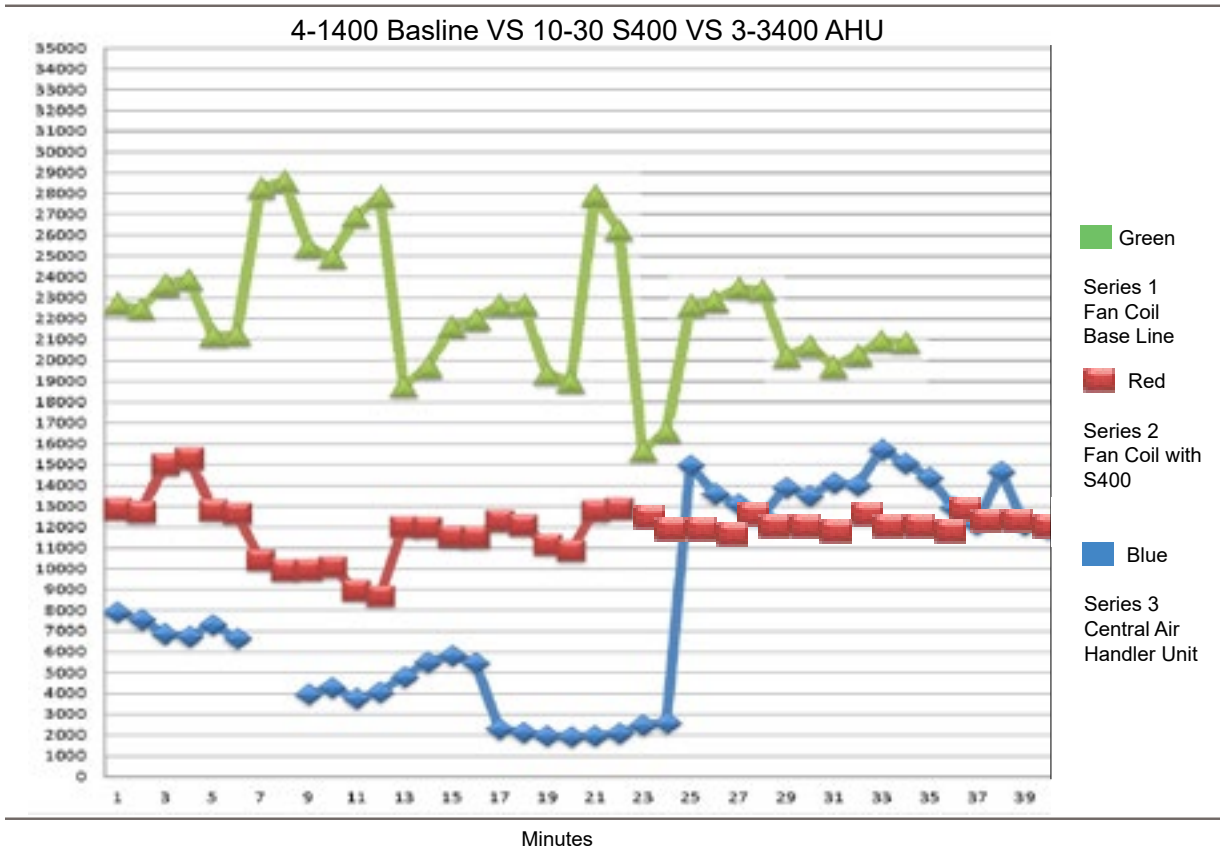
Further test indicated no temperature, humidity, or air flow variations due to S400 placement.

Director of Facilities:

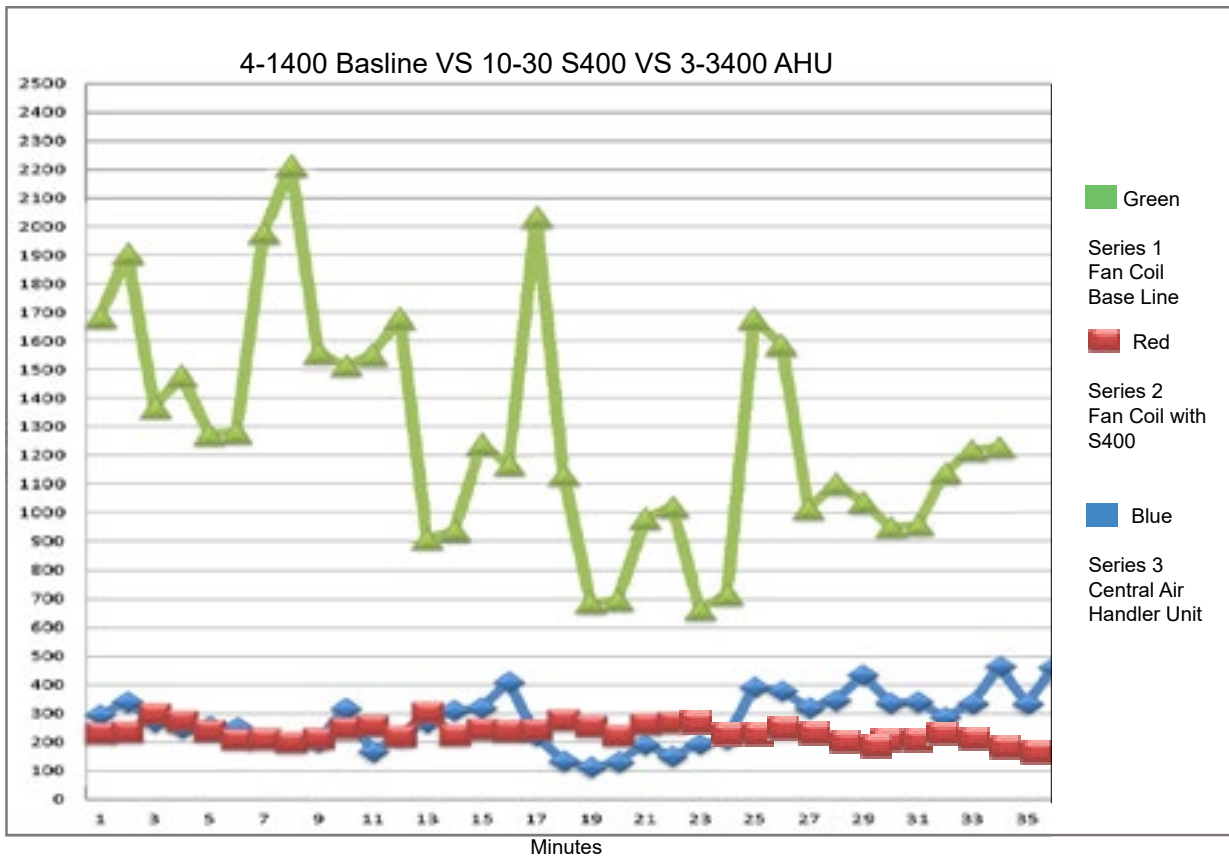
"The S400 meets or exceeds the particulate count performance of the main filter HVAC Handler Unit standards, which was our trial objective. Furthermore, the S400 provided more consistent lower level particulate counts (RED) without the deviations (BLUE) seen with the main filter HVAC handler Unit system which included a 95% efficient filter attachment. The S400 kept optimum consistent low level of particulate counts (RED) as the filtered HVAC handler fluctuated particulate movement in the room."

Size Range 0.3 to 25µm
Size Channels Factory calibrated at 0.3, 0.5, 1.0, 2.5, 5.0, 10.0 µm variable binning
Flow rate 0.1 CFM (2.83 LPM)
Concentration Limit 10,000,000 Particles/ft³ @ 10% coincidence loss

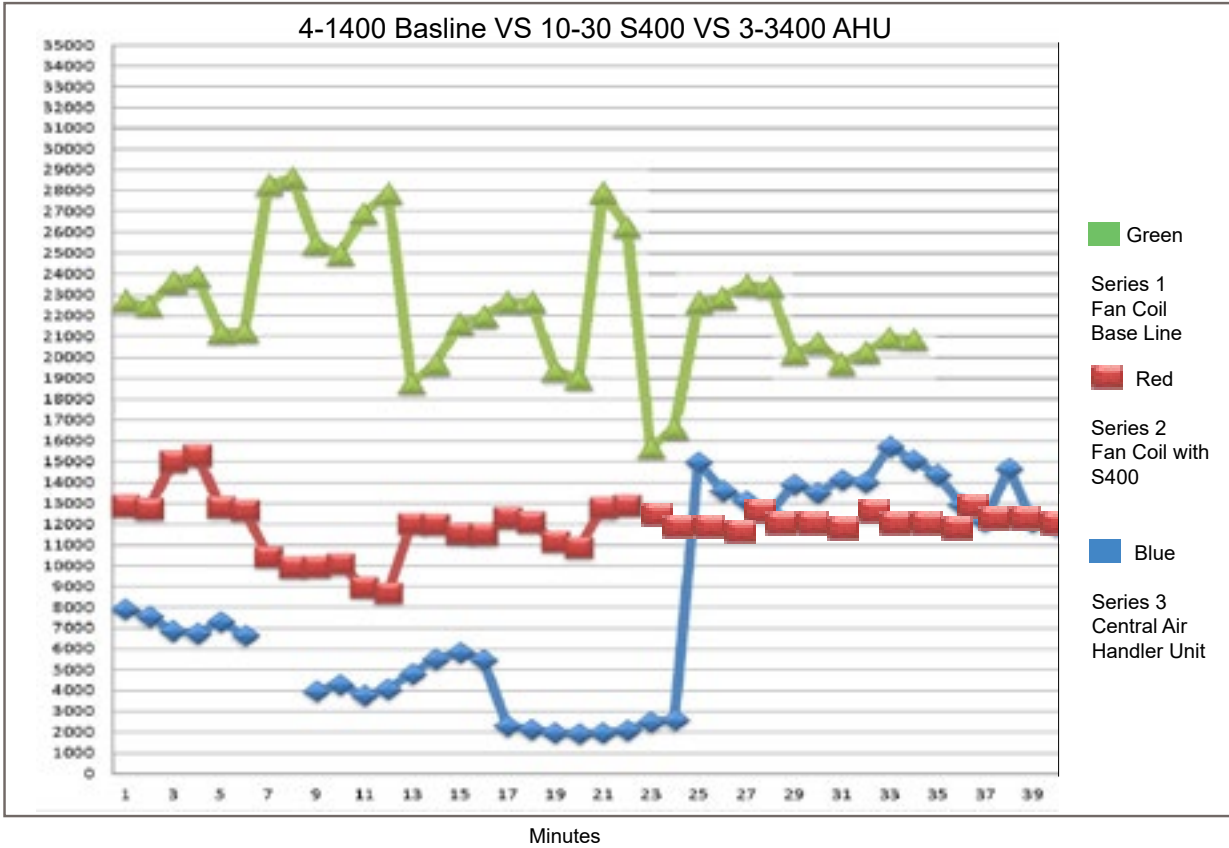
0.3 Micron



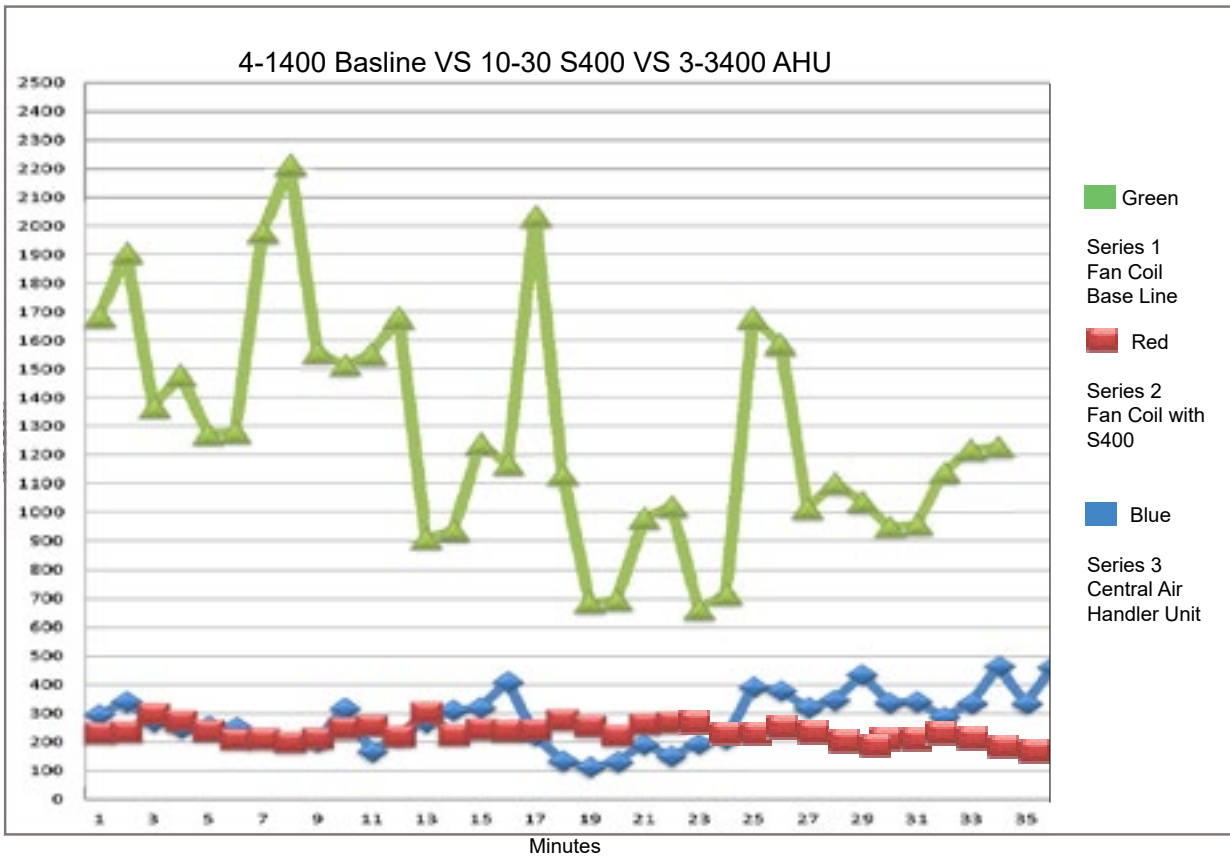
0.5 Micron



0.3 Micron



0.5 Micron



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healthcare

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