Evaluation of the Antimicrobial and Odor-removing Efficacy of Bio Oxygen Device for Air Decontamination

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Background

Maintaining a clean air in the contemporary environment laden with pollution from several factors has continued to be a challenge. Modern technological advancement has continued to make several attempts at ameliorating environmental pollutions and make the air humanly safe. One of such technological attempts is the Bio-Oxygen which is a type of air purifier that, as the manufacturer claims, produces oxygen clusters, and as a result, thereby purify air of pathogens, and remove unpleasant odour from the environmental air.

1. **Antimicrobial Activity:** The manufacturing company claimed that the oxygen clusters could aggregate and destroy viruses, bacteria, fungus, yeast, mould, mildew spores, protozoa and other pathogens. The manufacturer presented some results from in vitro experiments showing significant log reduction in bacterial growth in agar plate, Bio Test strips and air sample. However, there is, so far, no test done on other pathogens like viruses, fungi, yeasts, spores etc.
2. **Odour Removal:** The bio –oxygen process also claims to be capable of removing odours, gases, chemical fumes and vapours including those arising from urine, faeces, vomit, body odour, toilets, garbage, sewage, fertilizers, cooking, fermentation, spoilage and rotting etc. as well as from chemicals such as from paints, varnishes, thinners, adhesives, glues, plastics , waxes, carpets, disinfectants, deodorants and perfumes etc. Some laboratory test findings have shown that Bio-Oxygen could reduce odour by up to 91%. The company showed several testimonials from some of its customers that installed the machine on exhaust ducts to reduce obnoxious smells emanating from their industries, e.g., in poultry, piggeries and waste management settings. There are, also the claim of successful use in smoking rooms, and in clubs to curtail smells coming from the nearby railway station.[1]

OBJECTIVE:

To assess the safety and effectiveness of BIO-OXYGEN in odor control (odor removal) and air purification (antimicrobial claim).

Methods:

The Infection Control Department of King Khalid University Hospital Riyadh evaluated the machine for both its antimicrobial claims and odor removing claims. King Khalid University Hospital is a tertiary teaching hospital, and the headquarters of King Saud University Medical City, Riyadh.

After obtaining the necessary approval, evaluated the Bio-Oxygen machine in an air supply duct supplied by an isolated air handling unit that supplies the waste collection rooms and part of the laundry department on the ground floor of the West Building. The evaluation process includes the following phases:

1. **Pre-Installation Phase**

During the pre-installation phase, the infection control environmental team, the engineering team from the company and that of the Medical City met and discussed the mode of operation of the machine, including its installation requirements (electrical), the positioning of the machine in the air duct, and whether it would be placed on air intake or exhaust as well as its influence on the existing ventilation settings of the HVAC system presently operating.

The Infection control team used the opportunity to ask for any certification on its safety to humans, and the company assured the infection control team of its safety to humans, and pledged to provide one.

The teams inspected and selected the air handling unit supplying the waste room and laundry department for the trial. The engineering team tested the machine in an office in Engineering Department before eventually installing it in the pre-selected air handling unit as stated above.

The team visited the Wastes collection room, and the laundry department, and fully explained the full details of the evaluation process and their role in providing feedback to the team. All members of the housekeeping, and Laundry departments had shown that they have fully understood the process, and were willing to fully cooperate and participate in the process.

Just before the installation and operation of the machine, the infection control team took baseline samples of air particle count, air samples for microbial growth and odor level (See Table). We used following instruments to test the odor, air particle counts and air sampling for microbial growth:

1. BioMérieux's AES Samplair Pro® to conduct air sampling with a Sabouraud (fungal) and agar (bacterial) plate
2. IQair® Particle Scan Airborne Particle Counter to do the air particle counts.
3. Kanomax's® OMX –SRM Odor Meter to measure the odor levels during the evaluation process.

Air Sampling

The International Standard Organization (ISO), in its official documents for bio-contamination control, do not provide precise recommendations with regard to the sampling protocol (precise air volume to be sampled, length of sampling time etc.)[2] However, as per the Manufacturer's instructions for use, we used the AES Samplair Pro to take air samples for microbial growth.

1. Put on the machine, and set the volume of air sample at 1000ml or 10 minutes at 100ml/minute.
2. Perform hand hygiene according to the WHO's six steps.
3. Placed a new Sabouraud plate on the mounting in the air sampler
4. Cover with a newly sterilized perforated cover
5. Start the machine and place it just under the air supply vent.
6. Active sampling was carried out over the period of 10 minutes when the plates were exposed, drawing 100 L of air per minute for a total volume of 1000 L at each site selected.
7. After the session, aseptically replace the Sabouraud plate cover and seal the edges with a paraffin film to prevent contamination.
8. Label the specimen appropriately, and send to the KKUH mycology lab as soon as possible.
9. Air samples were taken before the installation and a day following the installation, and daily for 7 days.

Air Particles Count

Determining Key Factors for Particles Count:

1. Size of the Particles to be counted: The Particle Scan Lite® can count particles of 0.3/0.5/5.0 µm sizes. Based on ISO 14644-1 Cleanroom Standards, we selected for a room air settings (ISO 9) for the site (waste Room). Although the sizes of air particles could vary, since we are focusing particularly on fungal growth in the air sample, we used our standard size selection of 0.3 µm particle that may escape through standard filters that may have been installed in the air handling units.[3] This is determined by the ISO class of your cleanroom. Make sure the particle counters you are looking at can measure all the particle sizes that you need to monitor. For example a particle counter can have a size range of 0.3/0.5/5.0 µm. According to ISO 14644-1 Cleanroom Standard, the acceptable level of particles count in room air (ISO 9) for particle size of 0.3 µm is 1.02×10^8.[4]
2. The second factor is the flow rate capacity of the particle counter. To do this you will need this formula: Vs = 20/Cnm) x 1000. Vs is the minimum single sample volume per location. Cnm is the class limit for the largest considered particle size specified for the class of your cleanroom. 20 is the defined number of particles that could be counted for class of the cleanroom. This calculates the number of liters of air that need to be sampled in a cleanroom.

The team complied with the air sampling procedure as advised by the Manufacturer of the Particle Scan Lite® as follows:[5]

1. Selected the site of the particle count (see sites in Table 2)
2. Take the Particle Scan Lite®out of the carrying case and remove the protective red rubber cap from the air intake nozzle located at the top of the ParticleScan Lite.
3. Connect the supplied isokinetic probe to the air intake nozzle with the attached plastic tube. The ParticleScan Lite is now ready for sampling.
4. Turn ParticleScan Lite on with the ON/OFF switch located on the right side of the device. A humming sound indicates that the pump is drawing in air for sampling.
5. Immediately after it is switched on, the instrument starts a short countdown until its first particle reading. The particle reading is updated every 2 seconds thereafter.
6. The particle reading appearing in the display represents the concentration of particles (0.3 µm or larger) per cubic foot of air.
7. The results of the air particles counts are as stated in **Table 1**.

Measuring the Odor Level

As stated above, we used Kanomax's® OMX –SRM Odor Meter to measure the odor levels during the evaluation process. We measured the odor level at the supply vent, and close to the wide opening of the large trailer full of healthcare risk wastes already collected from various units. All the readings were taken with all doors closed, and with no human traffic except for the team. The same procedure was followed for all tests (for both pre- and post-instalment tests). Further reading was also done within some specific areas of the laundry department, before and daily, after the installations for the succeeding 7 days. The results are as recorded in Table 1.

Installation Phase

After conducting the pre-installation tests for baseline information, the Engineering team installed and operated a unit of Bio-Oxygen MODEL 7000 with 10 bulbs in the air handling unit supplying the Laundry and Waste Room on the ground floor of the West building.

Post installation Phase

The day after the installation of Bio-Oxygen 7000, the infection Control team took samples of air for particle count and for microbial growth, and odor to compare with the baseline data. The results of the tests are as stated in Table 1.

Additionally, as a follow up to the tests, the infection control team distributed a questionnaire to Laundry and Housekeeping department to provide us with feedback on their experience after the installation of BIO-Oxygen 7000.

The questionnaire includes the following questions bordering safety, user-friendliness and ease of use:

1. Is the product user friendly? (Specify)
2. Is there a new unpleasant smell? (Specify)
3. Did you feel any ill-health? E.g., headache, dizziness etc., (Specify)
4. Does it change ambient temperature? (Specify)
5. Has it changed the humidity of the room? (Specify)
6. Any effect on the air quality? (Specify)
7. Any changes to particle count? (Specify)
8. Any effect on air sample test results? (Specify)

9. Is the product easy to use to achieve compliance?
10. Is the product compatible with items/materials in use?
11. Is the product labour/time intensive?
12. Training and support offered?

See the attached questionnaire in Table 2.

Findings:

The findings of the three types of tests done indicates that there was a significant reduction in the levels of air particles, fungal growth and odor level in all sites tests as compared to the baseline tests done before the installation of Bio-Oxygen.

For instance, the pre-installation air particle counts for fresh air supply was 455, 224, but from a day after the installation, the particle count had dropped to 184,627 (↓ by 66.67%). The exhaust outlet had 470, 034 particle counts pre-installation as against 264, 962 ((↓ by 66.17%) while that of the fan cooling unit dropped from 345, 430 to 230, 137 (↓ by 66.66%). In all the three sites, there was a decrease of particle count by an average of about 50%.

On the other hand, the pre-installation odor level over the containers full of wastes was between 7 and 10, however, a day after the installation, the level had dropped to zero.

As regards the air sample results for total fungal growth, it has shown a significant drop in the magnitude of growth. From the fresh air supply, the initial baseline result was 51cfu dropped to 17 on the following day after installation, and subsequently. Furthermore, the exhaust out reduced from 30cfu to 14cfu, while at the site of the cooling fan unit, it reduced from 38cfu to 29cfu (See Table 1).

The common fungal elements found in the air are Filamentous fungi, *Aspergillus Niger, Flavus* and *Terreus, as well as* Mould. A review of the pre- and post-intervention counts for each fungal element shows a consistent reduction in counts for all of the identified fungi. (See Table 1.) There is up to 86% reduction in count of Aspergillus Niger, 84% in Filamentous fungi and inconsistent findings for Flavus (1005 reduction in one, and 50 increase in another).

And finally, the feedback received from the housekeeping and laundry staff was varied. About three staff complained of nausea, light-headedness, dizziness and vomiting on the first day of installation. The staff reported “burning smells” on the first day, which

virtually disappeared after the third day of the installation, although minimal "different," but not unpleasant, smell of "freshness" was reported by at least one person in the lobby of the laundry department. The overall satisfactory response was 58.4% as against the 41.6% of unsatisfactory response. (See Table 2)

Discussions:

Although this oxygen aggregation technology seems to be not as popular in air decontamination as other similar technologies like fumigation, the results of this evaluation has shown that Bio-Oxygen machine has the potential to significantly reduce odor, particle counts and microbial grown. The user friendliness evaluation response from the end-users to show slight acceptability of the device.

However, in spite of these claims antimicrobial activity, odor control and air decontamination, there has been concern regarding the safety of using a technology to "aggregates oxygen" in human settings. The literature has shown that breathing oxygen at a concentration of 40% or higher portends a high risk to health hazards including, a progressively decreasing heart rate,[6] lung alveolar damage,[7] twitches, vision loss and loss of consciousness in humans.[8]

The Malaysian Ministry of Health Technology commissioned two systemic reviews of the literature for evidence of its effectiveness as claimed.[9] Both reviews raised two fundamental concerns about uncertainty of effectiveness and safety. The reviews consistently concluded that there was insufficient evidence regarding the effectiveness of the BIO- OXYGEN device, and that there was no evidence retrieved on the safety aspect of the device.

However, the Company produced a 2006 report from the Department of Chemical Engineering of the University of Newcastle, Callaghan, UK showing that the "Oxygen Clusters that are formed by the Bio-Oxygen Process do not alter the overall concentration of the oxygen in the air and the oxygen will still only remain in the air at a concentration of up to 21%." And there is no independent evidence obtained regarding the safety of Bio-Oxygen in human environment. This review did not attempt to measure the changes, if any, of the ambient oxygen saturation in the tested rooms before, and after installation of Bio Oxygen in our facility. And in view of lack of sufficient independently verified evidence affirming that the "oxygen clusters" do not raise the saturation of oxygen, the evaluation is unable to establish with some degree of

certainty that it would not subject inhabitant of the area to the risk of a sustained oxygen toxicity in the long term.

It is worth noting that, this evaluation relied on the changes in the air particle count, reduction in fungal growth and odor level between those taken before and after the installation of Bio-Oxygen. The evaluation did not test for the effect of Bio-Oxygen on specific types of pathogens, and the susceptibility and/or potential resistance of some/any of the pathogens. Furthermore, the odometer used is only able to read the level of odor, but does not identify what king of odor, nature of gases and identification of the origin of the odor. Therefore, the test could not establish if Bio-Oxygen could eradicate all or a particular odor from the air. Unfortunately, given that the evaluation relied on the dynamics air particle counts, fungal growth and odor levels, and since its safety could not be determined by subjective nature of these responses, a scientific and verifiable well designed clinical trial would seem to be imperative to determine both its effectiveness on specific types of pathogens, and safety for humans.

Conclusions:

This evaluation may have strengthened the claim that Bio-Oxygen could potentially reduce odors, air pollution and has some antimicrobial property. However, more clinical trial would be required to determine its specific antimicrobial properties on viruses, fungi and bacterial spores. Moreover, the question of safety to humans remains unresolved, and therefore, some clinical trial should be undertaken to establish its safety to humans.

Table 1: Records of Pre- and Post-Installation Air Sampling, Particles Count and Odor levels

Location	Source	Pre Bio oxygen Treatment			Post Bio oxygen Treatment		
		Air Particle Count	Organism & CFU	Total CFU	Air Particle Count	Organism & CFU	Total CFU
Waste storage room	Fresh Air supply	455,224	Filamentous Fungi- 35cfu Aspergillus Niger- 14 cfu Aspergillus Flavus- 2 cfu	51 CFU	184,627 (↓40.43%)	Mold Filamentous Fungi- 13(↓50%) Aspergillus Niger- 4(↓62%) Aspergillus Flavus- 0 (↓100%)	17 CFU (↓66.67%)
	Exhaust Outlet	470,034	Mold Filamentous Fungi-22cfu Aspergillus Niger- 8 cfu	30 CFU	264,962 (↓56.17%)	Mold Filamentous Fungi- 9(↓60%) Aspergillus Niger - 3(↓75%) Aspergillus Flavus - 1 Aspergillus Terreus- 1	14 CFU (↓43.34%)

	Fan cooling unit	**345,430**	Filamentous Fungi- **24cfu** Aspergillus Niger- **12 cfu** Aspergillus Flavus- **2 cfu**	**38 CFU**	**230,137 (↓66.66%)**	Mold Filamentous Fungi- **22(↓8.4%)** Aspergillus Flavus- **3(↑50%)** Aspergillus Niger - **4(↓67%)**	**29 CFU (↓23.68%)**
	Blood Agar Room		No Growth			No Growth	
Laundry Store Room	**Supply Air**	**201,760**	Mold Filamentous Fungi- 25 Aspergillus Niger- 15	40 CFU	80,052 (↓60.2%)	Mold Filamentous Fungi- **4(↓84%)** Aspergillus Niger- **2(↓86.7%)**	**6 CFU (↓85%)**
	Outlet Air	**294,184**	Mold Filamentous Fungi- 7 Aspergillus Niger- 4	11 CFU	48,507 (↓83.68%)	Mold Filamentous Fungi- **3(↓57.2%)** Aspergillus Niger- **1(↓75%)**	**4 CFU (↓63.64%)**
	Manager Office	**347,846**	Mold Filamentous Fungi - 6 Aspergillus Niger -3	9 CFU	48,479 (↓86.17%)	Mold Filamentous Fungi- **2(↓66.7%)**	**2 CFU (↓77.78%)**
	Office II	**342,670**			21,776 (↓93.86%)		
	Swab-office II		No Growth			No Growth	
	Blood Agar		No Growth			No Growth	

Table 2 Response to End-user Questionnaires

	Yes	No	N/A	Remarks
	1	2	0	
SAFETY PROFILE				
Is the product user friendly? (Specify)	9	4	1	After the initial discomfort of the first day, staff felt normal, and air became "fresh"
Is there a new unpleasant smell? (Specify)	11	2	0	Burning smell on the first day
Did you feel any ill-health? E.g., headache, dizziness etc. (Specify)	4	10	0	Some staff reported on the first day that they felt dizziness, nausea and headache
Sub-Total score:	25x1	16x2	1x0	
	25 (40.98%)	36 (59.01%)	0	61 (100%)
HVAC ISSUES				
Does it change ambient temperature? (Specify)….	2	3	1	Unremarkable
Has it changed the humidity of the room? (Specify)….	0	5	0	Unremarkable
Does it affect the supply air flow? (Specify)	5	0	0	Unremarkable
Any effect on the air quality? (Specify)	4	1	0	The odometer reading changed from 7 (before) to 0 (after)
Any changes to particle count? (Specify)	2	1	2	See attached report
Any effect on air sample test results? (Specify)	-	-	-	See attached report
Sub-Total Score	13x1	10x2	3x0	
	13 (39.39%)	20 (60.61%)	0	33 (100%)
EASE OF USE				
Is the product easy to use to achieve compliance?	9	0	0	"Easy plug and play device"
Is the product compatible with items/materials in use?	3	2	0	No incompatibility with HVAC system was reported
Is the product labour/time intensive?	3	1	0	"Easy plug and play device"
Training and support offered	4	0	0	Company engineer pledged to remain available for trouble shooting
Sub-Total Score	19x2	3x1	3x0	31 (100%)
	28 (90.32%)	3 (9.67%)	0	
TOTAL SCORE:	73	52	0	125

	(58.4%)	(41.6%)		(100%)

[1] Hurstville Memorial Club, July 4th, 2017

[2] Cleanrooms and associated controlled environments – Bio contamination control. Part 1: General principles and methods. UNI, Milano; 2003. 14698–1.

[3] Wen-Hai Lin, Shan Li and Chih-Shun Li, 'Size Characteristics of Fungus Allergens in the Subtropical Climate' (1996) 25 Aerosol Science and Technology 93 <https://www.tandfonline.com/action/journalInformation?journalCode=uast20> accessed 25 February 2019.

[4] ISO 14644-1 Cleanroom Classifications: https://www.gotopac.com/art-cr-iso-cleanroom-classifications Accessed 25/2/2019

[5] How to Choose the Right Cleanroom Particle Counter: https://blog.gotopac.com/2018/01/30/how-to-choose-the-right-cleanroom-particle-counter-for-your-cleanroom/ Accessed 24/2/2019

[6] Walter J Daly and Stuart Bondurant, 'EFFECTS OF OXYGEN BREATHING ON THE HEART RATE, BLOOD PRESSURE, AND CARDIAC INDEX OF NORMAL MEN-RESTING, WITH REACTIVE HYPEREMIA, AND AFTER ATROPINE *', vol 41 (1962) <https://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC289201&blobtype=pdf> accessed 5 March 2019.

[7] William J Mach and others, 'Consequences of Hyperoxia and the Toxicity of Oxygen in the Lung.' (2011) 2011 Nursing research and practice 260482 <http://www.ncbi.nlm.nih.gov/pubmed/21994818> accessed 5 March 2019.

[8] A Nagata and others, '[Effects of Breathing High Concentrations of Oxygen on Changes in Blood Indices during Bicycle Exercise].' (1990) 9 The Annals of physiological anthropology = Seiri Jinruigaku Kenkyukai kaishi 21 <http://www.ncbi.nlm.nih.gov/pubmed/2383313> accessed 5 March 2019.

[9] Technology Review Nos. 018/06 (2006) and 017/09 (2009) http://www.moh.gov.my Accessed February 20th, 2019