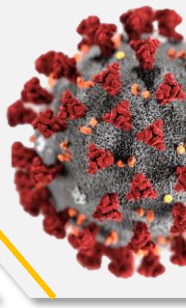
GENANO® 5250 MEDICAL GRADE AIR DECONTAMINATION UNIT



PURPOSE

To provide scientific evidence on the effectiveness and safety of Genano® 5250 air decontamination unit in improving indoor air quality, especially in hospital settings.

This brief was conducted based on a request from the Disease Control Division, Ministry of Health (MOH) Malaysia following an email from a local distributor advocating the use of this device in MOH facilities.

BACKGROUND

Ventilation plays a crucial role in maintaining a clean indoor environment. However, ventilation systems can also be major sources of airborne pollutants as a result of inadequate system design, distribution, cross-contamination, etc. Thus, air filtration technology plays a key role in protecting human health by removing indoor air pollutions, while also providing an alternative solution for reducing energy usage, operating costs and thus delivering a way to achieve sustainability. The main pollutants in the air can be divided into three categories: suspended particles, volatile organic pollutants and microorganisms. In terms of suspended particles, the main purification technologies are filtration, water washing purification, electrostatic precipitation and anion technology. Filtration is currently the most widely used purification technique of particulate matters. The most effective and commonly used purification method for harmful gases is adsorption. Because of its simplicity, effectiveness and low cost, activated carbon is a widely used adsorption material. In addition, photocatalytic and plasma cleaning technologies are also effective for the purification of volatile organic pollutants. For the elimination of microorganisms, the most efficient method is ultraviolet (UV) light, followed by photocatalytic and plasma purification. Filters are more effective in the case of bacteria with larger diameter, while they are not suitable for eliminating virus.[1]

The following tables (Table 1 and Table 2) briefly describe examples of the effect of purification technologies on main types of pollutants, as well as advantages and disadvantages of some of these technologies

Table 1: Effect of single purification technology to main types of pollutants[1]

Purification Technique	Pollutants			
	Suspended particles	Volatile organic contaminants	Microorganism	
	Dust, pollen, secondary pollutants, lampblack, etc.	Formaldehyde, benzene, ammonia, etc.	Bacteria	Virus
	Diameter 0.01-100 μm	Diameter 0.0001-0.001 μm	Diameter 0.2-10 μm	Diameter 0.01-0.3 μm
Filtration	Effective	Noneffective	Effective	Noneffective
Adsorption	Partially effective	High-efficiency	Partially effective	Noneffective
Water washing purification	Effective	Partially effective	Noneffective	Noneffective
Electrostatic precipitation	Effective	Not obvious	Partially effective	Noneffective
Anion technology	Effective	Not obvious	Partially effective	Noneffective
Photocatalysis purifying technology	Not obvious	Effective	Effective	Effective
Plasma cleaning technology	Not obvious	Effective	Effective	Effective
Ultraviolet radiation	Noneffective	Noneffective	High-efficiency	High-efficiency

Table 2: Characteristics of different purification technologies in building environment[1]

Technologies	Target	Advantages	Disadvantages	Efficiency
Fibre filtration	Particles, microorganism	Low cost, convenient installation	Resistance related to the purification efficiency, mid and high efficiency filters of high resistance	Can achieve 99.99999%
Electrostatic dust removal	Particles, microorganism	High efficiency and wild range of particle size, small pressure loss	High investment, efficiency decline after dust discharge, electric field easy to breakdown	50% (some only 20%)

Ultraviolet sterilization	Microorganism	High efficiency, safe and convenient, no residual toxicity, no pollution, small resistance	Poor dynamic sterilization effect	82.90%
Activated carbon adsorption	All the pollutants except biological pollutants	Wild sources, bigger pollutant purifying range, not easy to cause the secondary pollution	Saturated regeneration problems, resistance is bigger, mineral processing is not good	NA
Plasma	All indoor pollutants	Big range of pollutants	Cannot completely degrade pollutants and produce by-products	66.70%
Negative ions	Particles, microorganism	Accelerate metabolism, strengthen cell function, effective to some disease	Produce ozone, cause second pollution, deposition of dust damage the wall	73.40%
Photocatalysis	TVOC, microorganisms and other inorganic gaseous pollutants	Wide range of purification, mild reaction conditions, no adsorption saturation phenomenon, long service life	Compared to the activated adsorption technology, slower purification process, easy to cause the secondary pollution if response is not completed	75% (some may only 30% or even negative)

TVOC: total volatile organic compounds; NA: not available

Genano® 5250 is a portable, stand-alone air decontamination unit developed by the Finnish hi-tech company Genano Ltd. This electric filterless equipment allows for easy plug & play installation in desired indoor areas that require continuous nanoscale decontamination of the room air such as laboratories, cleanrooms, isolation wards and operating theatres. All Genano portable units are electrostatic precipitators with molecular filtration that work by employing patented non-thermal (cold) plasma technology with cleaning efficiency rate of 99.5% down to three nanometre (nm) particle size. A powerful corona discharge produced by one of the two electrodes inside the equipment would negatively charge particles of the contaminated air. These ionised particles would later get attracted to the other positively charged electrode, that is the collection chamber. It is claimed that it kills organic microbes such as viruses, bacteria and mould with electronical shocks. Furthermore, it has a special 3-layer active carbon collector that removes dangerous volatile organic compounds (VOCs) and odours from the air flow at the last stage of the decontamination process. The unit is also equipped with an automatic once a week cleaning function that removes all collected particles and impurities from the surface of the collection chamber and this function may be switched off in critical areas.[2,4,6] Figure 1 briefly explains the basic working mechanism for all Genano portable air decontamination unit, while Table 3 presents the specification of the 5250 model.

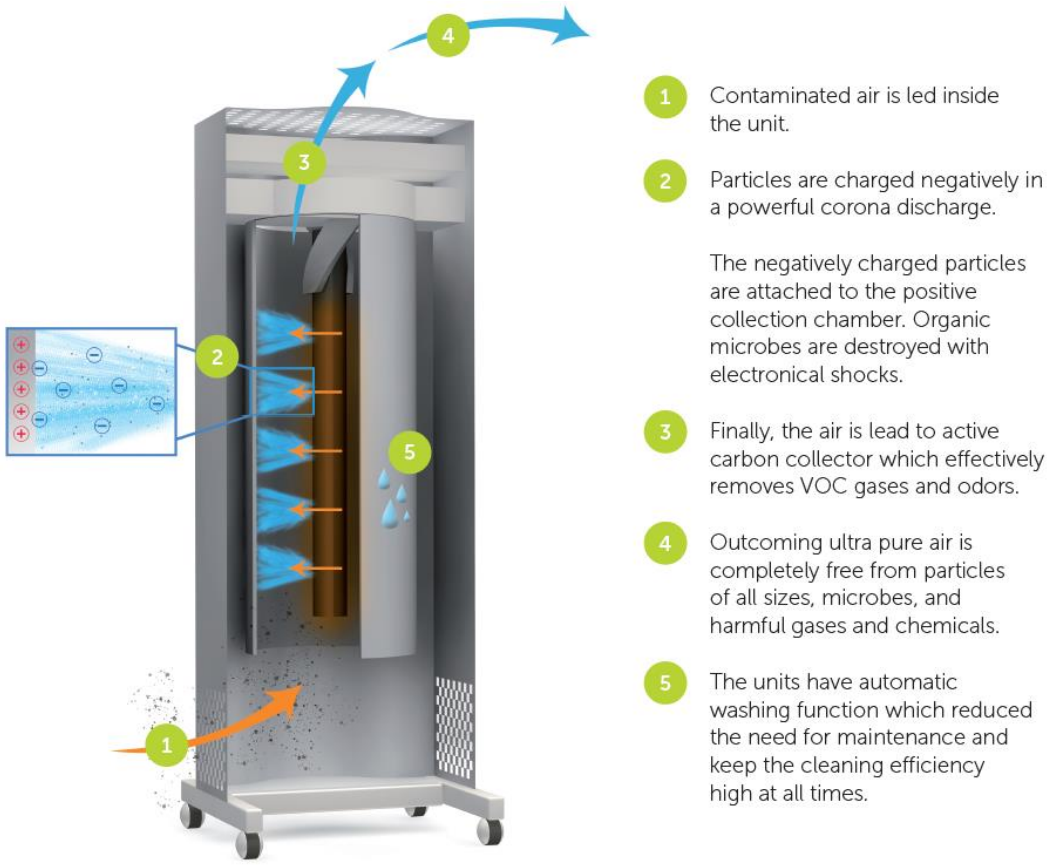


Figure 1: Basic working mechanism in Genano portable air decontamination units[2]

Table 3: Genano® 5250 technical specification[2]

Technical information	Genano® 5250M/A
Cleaning capacity	max. 500 m^3/h
Particle size arrestance	> 0,003 µm
Cleaning efficiency	99,5 %
Gas removal	Included 800 g activated carbon, 60 mm
Dimensions (W x H x D)	600 x 1680 x 600 mm
Weight	91 kg
Chassis	Painted steel
Installation	Mobile
Fan speed	M: 3 speed options (200, 350 and 500 m^3) A: Stepless adjustment (200-500m^3/h)
Power consumption	M: 50–150 W A: 60–130 W
Sound level	25–42 dBa
Operating voltage	198–264 V, 50/60 Hz
Usage temperature	+5...+60 °C

EVIDENCE/ INFORMATION SUMMARIES

A search using specific keyword “Genano” was conducted on Ovid Medline electronic scientific database, EBM Reviews of Cochrane Database of Systematic Reviews, Database of Abstracts of Reviews of Effects, Health Technology Assessment database, NHS Economic Evaluation database and PubMed in March 2020. Only one English abstract (full text is in Polish) was retrieved. However, there was insufficient information to be extracted from the available abstract. On the other hand, a search using the same keyword on Google Scholar returned 354 titles (latest run on 22nd March 2020), of which 16 potentially relevant English titles were identified and screened for full text. Two full-text research articles[5,7] were relevant and included in this review. In addition, one full-text article[3] and one test report[8] on Genano air decontamination solutions obtained from Genano website (www.genano.com) were also included.

Effectiveness

Mossad IM et al. (2018) reported the performance of Genano® 4500 air decontamination unit employed in one operating room of a paediatric surgery department. Air samples were taken between April 2017 and April 2018. Prior to installation of the equipment, the operation room studied was classified as ISO Class 8, following the ISO 14644 standardization. Particle sizes of 0.3 µm, 0.5 µm, 1.0 µm, 2.5 µm, 5.0 µm and 10.0 µm were measured using a portable dust monitor at only one sampling point located nearly 1 meter away from the surgical table. Air samplings were done early in the morning when the room is resting (not operating), during which, indoor air was conditioned but not heated. The operating room area was supplied with a ceiling-mounted high efficiency particulate air (HEPA) – filtered laminar air flow with 15 air changes per hour (only sixty percent of the recommended value, i.e. 25 times). The operation room indoor air quality has improved to ISO Class 6 after the installation of Genano® 4500 unit. Mean particle size of 0.5 µm and larger were reduced from 72,715 to 32,725 (p=0.000). With the exception for particle size of 2.5 µm, the researchers found a statistically significant improvement in the means of the particle counts measured for other particle sizes after the equipment was run. There were about 54 per cent reduction in the mean particle counts for particle size of 2.5 µm after the equipment, though this was not statistically significant (p=0.226). Furthermore, they also evaluated microbial contamination through active and passive air sampling methods. Through the passive sampling, Colony Forming Unit (CFU) count in the operating room was found to exceed the maximum limit value of <5 CFU/ 9 cm diameter plate/hour. There was no statistically significant difference between the CFU counts before and after the installation of Genano® 4500 for passive bacterial sampling (p=0.919). However, passive fungal sampling showed a significant reduction in the CFU counts (p=0.013). In comparison, both active sampling for bacterial and fungal has indicated a significant drop in the CFU after applying the electronic filtration device (p=0.043 and p=0.010, respectively). Post installation of the equipment, *Micrococci* species, *Bacillus* species and *Diphtheroids* which were present earlier in 100% of samples, have decreased markedly, while harmful species like *Klebsiella* species, *Pseudomonas aeruginosa* and *Escherichia coli* disappeared completely. Besides, all sampling plates showed no growth of fungi, where *Aspergillus* species, *Penicillium* and *Candida albicans* were present before.[3] Table 4 shows the technical specification for Genano® 4500.

Table 4: Technical specification for Genano® 4500[4]

Technical Information	Genano® 4500
4500 MOB dimensions (WxDxH)	570 x 440 x 1517
Weight	65 kg
Chassis	Full steel
Decontamination efficiency	up to 99.5%
Air volume flow capacity	200 - 450 m^3/h
Applicable air volume	up to 200 m^2
Power	200 -240V 50Hz/110 - 120V 50/60 Hz
Energy consumption	90 - 140 W
Operating temperature range	0 - 60° C
Relative humidity (RH)	0 - 95%
Sound level	35 - 45 dB (A)
Medical device certification	MDD Class 1

Similarly, Sezdi M (2014) assessed the performance of a Genano® 310 air decontamination unit in reducing the number of counting particles in a patient room in bone marrow transplantation unit (BMTU) that had an area of 42 m^2 (7.2 m x 5.8 m). The room was not installed with any HEPA filter. The equipment was placed in three different locations in the room, repeated on different days: 1) opposite corner of the bed, 2) in the adjacent wall, and 3) near the bed's headboard. Particle sizes of 0.3 µm, 0.5 µm, 1.0 µm, 2.5 µm, 5.0 µm and 10.0 µm were counted at each 1 minute in total 15 minutes using a specific particle counter and the measurement results were compared by considering the decontamination time. The classes of the patient room for the three different positions of the air purifier were determined in accordance to the ISO 14644 standardization, i.e. it should be ISO Class 6 for 0.5 µm or larger particle size. Initially, the room was in ISO Class 9 for all positions because the number of particles were counted higher than 3,520,000. The Genano® 310 air purifier was found to decrease the class room to an acceptable ISO class 6 by bringing down the particles measurement to lower than 35,200 in 12 minutes when placed in position 2 and 3, and 13 minutes in position 1.[5] Table 5 shows specification for Genano® 310, which is smaller in size, has much lesser cleaning capacity and smaller size of carbon collector when compared to that of 5250 model.

Table 5: Genano® 310 technical specification[6]

Technical information	Genano® 310
Cleaning capacity	max. 170 m^3/h
Particle size arrestance	> 0,003 µm
Cleaning efficiency	99,5 %
Gas removal	Included: 400 g activated carbon, 60 mm
Dimensions (W x H x D)	460 x 1470 x 400 mm
Weight	55 kg
Chassis	Painted galvanized steel
Installation	Stand-alone
Fan speed	3 speeds
Power consumption	60–120 W
Sound level	31–44 dBa
Operating voltage	198–264 V, 50/60 Hz
Usage temperature	+5...+60 °C

In another study, Nawrot U et al. (2010) investigated the fungal air contamination in 11 patient rooms of the haematology ward (HAEMU) and three patient rooms of the BMTU. The HAEMU rooms were naturally ventilated, and a Genano® 310 Medical Air Cleaning System (Genano Ltd., Finland) was later added into each room in September 2007, while the BMTU rooms were equipped with a HEPA filtration system with laminar flow and no opened windows. In addition, there were two operating rooms in the HAEMU, which were naturally ventilated and disinfected daily with ultraviolet (UV) irradiation between two to five hours. Air samples from all the rooms were taken eight times between November 2006 and June 2009. The researchers observed a significant reduction in the fungal contamination of the air in the HAEMU rooms in November 2007 (after the rooms were disinfected and Genano units were installed in September 2007), ranged from zero to 80 CFU/m^3 total fungi versus that in August 2007, ranged from zero to 383 CFU/m^3 total fungi ($p<0.005$). In addition, the potentially pathogenic species of *Aspergillus* isolated from the air samples in August 2007, ranged up to 200 CFU/m^3 was reduced to a range of up to 35 CFU/m^3 in November 2007. Nevertheless, compared to the BMTU rooms equipped with the HEPA filter system, the fungal contamination of the air ranged from zero to 75 CFU/m^3 total fungi (ranged up to 60 CFU/m^3 *Aspergillus* – i.e. prior to exchange of HEPA filter) and was significantly lower than in the HAEMU ($p<0.0005$). Meanwhile, the concentration of fungal aerosol in the operating rooms ranged from 15 to 195 CFU/m^3. While the researchers agreed that the Genano® 310 air decontamination equipment did reduce the concentration of fungi in the HAEMU rooms, it was found that it might not work effectively in naturally ventilated rooms. This was shown from the increase in fungal contamination of the air in June, August and October of 2008, plus June 2009, ranged from zero to 440 CFU/m^3. They suggested the peak in the number of fungi may be attributed to the lack of a professional air-conditioning system in the department along with the seasonal increase in fungal aerosol outdoors.[7]

Safety

There was no retrievable evidence on ozone emission by Genano portable air decontamination units neither from scientific databases mentioned above nor Google Scholar. A test report obtained from Genano website (www.genano.com) has stated that the ozone emission was 17.5 parts per billion (ppb; +/- 1 ppb) for Genano® 310 when measured at the clean air outlet, during which the background concentration at the test room was less than 1 ppb.[8] This value is much lower than 0.05 parts per million (ppm) which is the acceptable limit for indoor ozone concentration recommended by Department of Occupational Safety and Health (DOSH), Malaysia.[9] There was no retrievable evidence on United States Food and Drug Administration (U.S. FDA) and adverse events related to Genano from the included articles.

CONCLUSION

There was no evidence retrieved on the effectiveness of Genano® 5250 in improving indoor air quality. However, there was very limited evidence retrieved for other Genano portable models which principally, utilize the same technology though their cleaning capacities vary. Based on the limited evidence, Genano air decontamination unit was found to be effective in reducing indoor particulate matter, bacteria and fungi. However, more high-quality evidence is needed.

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Based on available evidence up to 1 April 2020

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Disclaimer: This rapid assessment was prepared to provide urgent evidence-based input during COVID-19 pandemic. The report is prepared based on information available at the time of research and a limited literature. It is not a definitive statement on the safety, effectiveness or cost effectiveness of the health technology covered. Additionally, other relevant scientific findings may have been reported since completion of this report.

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