

Frequently Asked Questions: Ati Swachh Heat Sensitive Medical Device Disinfection Unit

What is Ati Swachh- Heat Sensitive Medical Device Disinfection Technology?

Ati Swachh Heat Sensitive Medical Device Disinfection Unit (HSMD²U) is an advance oxidative process based disinfection/sterilisation unit comprising of multiple barrier disruption approach. It works using ozonated space, aqua-ozonated space and tri-netra technology. It provides superior alternative mode of operation to sterilize medical devices/equipments comprising wide range of material (including heat sensitive material) and fabric compared to hydrogen peroxide, EtO, heat based sterilization and microwave etc.

What do you mean by 50 seconds effective treatment time?

HSMD²U is developed by Institute of Nuclear Medicine and Allied Sciences, Defence Research and Development Organization in association with the undersigned. The unit works on the principle of Tri-Netra Technology, a triple fusion technology in which radical dispenser generates a mist of aqueous ozone as microbial neutralizer while UV transforms ozone back to oxygen and water. The process supports Extreme Oxidation Process (EOP) tested and validated using standard biological indicators having bacterial spores. Bacterial spores of volcanic origin are one of the most resistant species among micro-flora and used world-wide to obtain Sterility Assurance. The process kills these spores instantaneously within effective contact time of 50 seconds. This ascertains its utility in present COVID era as Corona virus is a fragile RNA virus easily gets disrupted by such process.

Where Ati Swachh HSMD²U Unit gets Manufactured?

It is manufactured by DRDO Technology Partner with WHO GMP certified, ISO 9001: 2015; ISO 13485: 2016; and QCI Approved unit.

What is the Input Cost of Power and Maintenance?

Regarding running cost, we have two models : (a) Base Model (with Aqua-Ozonated Space Technology) has no recurring cost other than operational electric cost at 220 V, 50 Hz. On the other hand, (b) Advance Model (Tri-Netra Multi-Product Disinfection Unit) is supported by Extreme Oxidative Process is provided with multiple dispensing solutions for targeted product under disinfection. This is an optional accessory for the client with minimum cost imperatives. Regarding maintenance, it is robust machine however comes up with One Year ON-SITE Warranty and Maintenance Support.

What is Shadow Suppressor Technology in this product?

The shadow suppressor technology refers to 360 degree exposure maximum surface area coverage of Ultra Violet- C [SPACE] such that dead spots limits to least possibility.

Do similar products available in India or anywhere in the world?

Presently, single sterilents technologies do exist like Hydrogen peroxide vaporized sterilization solution; Ethylene Oxide EtO or Steam based systems. However, each one of the solution has few problems: (a) Continuous Recurring Cost is higher; (b) Environment Friendliness is questionable; (c) Non-compatibility with range of fabrics, heat sensitive medical devices however still comparative research is required at different levels; (d) Lesser oxidative potential of single sterilents technology with respect such dual / tri-technological combinations and; eventually mostly are standardized and developed outside the country and generally imported. All these methods are highly specialized, dedicated facilities require special trainings and operational instructions to operators due

to their associated hazard. Thus, the present solution is developed with respect to advent of COVID-19 spread and as technological solution towards “self reliant Indian mission”.

What is current method of disinfection in medical setup and what are all medical devices/equipments can be disinfected

The practice of disinfection is already in place at hospitals, they generally follow conservative and conventional methods (autoclave) of disinfection which may not be sufficient and suitable to the many of the heat sensitive medical devices such as plastic applicators, lumens, endoscopes, brachytherapy applicators, surgical implants, hydrogel based systems etc. Also, the current demand of medical device disinfection has been escalated many folds which require quick, sterilization-in-place (SIP) approach of medical device disinfection. Keeping this in mind, Ati Swachh Tri-Netra / Ozonated Space technology based Heat Sensitive Medical Device Disinfection Unit was designed and developed.

Can this unit be also used for disinfection of other than medical devices/equipments ?

In addition to medical devices, multiple products including instruments, hard plastic tools, general house hold items, electronic items, papers, files etc can also be disinfected in this unit. Those which are hard surfaces or electronic requiring surface sterilization only like radios, mobile phones, blue tooth, wrist bands, watches etc, can be disinfected directly by using SPACE (UV-C) cycle alone. Medical equipments require comprehensive sterilization can be disinfected either by Ozonated Space (if require dry cycle) and Tri-Netra (if require aqua Ozonated space cycle). Thus, the triple fusion technology- TriNetra Multiproduct variant of Ati Swachh HSMD Disinfection Unit provides all optional modes of disinfection cycle.

However, the manufacturer don't recommend perishable or food items to be disinfected in these chambers.

What happens to ozone if it enters into environment, does it get diluted and then dissipated?

Ozone with its occupational safety limits of 0.1 ppm X 8 hrs exposure, if enters into the atmosphere, it starts diluting immediately being gas and slowly transforms back to oxygen. The natural half life under ambient conditions of ozone is half an hour thus, with time it turns back to oxygen. Eventually it gets dissipated. In Ultra Swachh devices, in addition to UV-C aided fast transformation of ozone to oxygen, catalytic convertor is provided in exhaust assembly absorbed residual ozone leaving no traces of ozone in the emissions.

Is there any difference between sterilize, sanitize and disinfection? How it can be interpreted in terms of Ati Swachh HSMD Disinfection Unit?

Sanitization refers to procedures adopted to reduce the overall pathogenic microbes on surface, thereby reduces the chances of getting sick. Sterilization is process of decontamination by using combination of chemical application, ozone, UV-C, heat, and / or pressure to eliminate any and all pathogenic surfaces on microbes. Disinfection refers to procedure to use “specific sanitizers” for a particular targeted agent such that they are effective on inanimate surfaces, but can often be weakened if contacted by organic matter. Disinfectants always require “dwell time” to be effective. Ultra Swachh - technology provide options for mild sanitization cycle, effective sterilization cycle and comprehensive disinfection cycle based on use of combination of ‘treatment’ as well as ‘contact time’ to achieve desired outcome.

What do you mean by virucidal activity?

The process, procedure or agent with specific treatment having capacity to or tending to destroy or inactivate viruses referred as virucidal activity.

What do you mean by Advance Oxidative Process?

Advanced Oxidation Processes (AOPs) are oxidative methods based on generation of intermediate radicals, mainly hydroxyl radicals (OH^{*}), that have been successfully applied in disinfection of PPE units and other material.

What is multiple barrier disruption approach?

The multiple barrier disruption approach refers to ozone & UV combo induced disruption of membrane of microbes as well as oxidation of biomolecules beneath these barrier membranes.

What are heat sensitive medical devices?

Heat sensitive medical devices are those devices which are used in health care set up for management of patients (including infected ones) but cannot be re-utilized as they cannot be autoclaved or used in heat -induced sterilization cycle, example, endoscopes. Thus, in such cases "Heat Sensitive Medical Device Disinfection Unit" is an appropriate choice of sterilization technology.

What do you mean by curing treatment while developing the product at manufacturing facility?

"Curing treatment" refers to (a) filling up of gaps while adjoining two surfaces of Stainless Steel internal cabinet development ensuring entrapping of ozone gas; (b) treatment of SS with specific patented process while affixing ozone gel sealant in the walls of internal door of the cabinet / other sites (as required by design). This process ensure complete entrapping / containment of ozone gas as required for such Disinfection Unit.

What do you mean by Short Degasing Cycle?

The half life of ozone in presence of UV-C is extremely less thus during UV-C (SPACE) cycle, ozone gets transformed back to oxygen at a rapid rate. This led to extremely short debasing removing residual left over via catalytic convertor. In comparison to hydrogen peroxide in which debasing cycle could be hours, it is only few minutes.

How does Ati Swachh Ozonated Space technology is better than EtO and UV based Sanitizing System?

EtO is environmental toxicant while our technology has no environmental emission hazards. Ozone is best sterling being higher oxidation potential than EtO. Ozone is GRAS (Generally Recognized as Safe) agent while EtO belongs to toxicant category. In comparison to UV which is restricted to surface sterilization alone being non-penetrating radiation, Ozonated SPACE provide comprehensive sterilization of equipment even inside small lumen as well as machine is designed to provide UV conditioning and sanitization too.

Whether Ati Swachh includes UV based Sterilization too?

Yes, it covers UV based sterilization too. The sterilization cycle begins with Ozone that has extremely high oxidation potential followed by UV-C exposure such it performs two functions (a) conditioning / sterilization of surfaces and; (b) Re-transformation of ozone

back to oxygen (while doing this, it supports Advance Oxidative Process le sterilization). In brief, UV-C alone is “energy based surface sterilization” while Ozonated Space is “ozone mixed UV-C led Advance Oxidative Process based comprehensive sterilization”. The latter is extremely superior sterilization technology.

How Ati Swachh Ozonated Space/TriNetra technology is different from microwave sterilization ?

Microwave sterilization technology works on the principle of internal heat induced sterilization while Ati Swachh - trinetra&ozonated space sterilization has no internal or external heat involvement. Thus Tri-netra sterilization is extremely useful for heat sensitive medical devices. Microwave technology is not compatible with metallic objects while ultra swachh product series don't have any such limitation. Literature reports indicated melting of inner foam, face shield or masks and may cause damage to PPE material. Ozone is GRAS (Generally Recognized as Safe) agent with comprehensive sterilization coupled with UV and radical dispenser are ideal for PPE sterilization. Microwave treatment reduces filtration capacity of equipment leading to functional loss which is not present in Ultra Swachh counterparts.

Whether the present product's output can be linked up with any USB or computer for data recording / observations?

No in the present model, these features are not included, however, such provisions will be added in future models.

What is Ozone and what are the benefits of this technology? How advanced is this Ozone based technology and what is international benchmark?

Ozone is the most powerful oxidative agent that occurs naturally. With its extra free radical oxygen molecule, ozone is able to destroy germs, viruses, and microbes that may cause surface or air contaminations. Furthermore, ozone leaves no chemical residue typical of alternative detergent or synthetic cleaners, and if handled properly – by converting ozone back to oxygen molecules - it can be one of the most effective sterilizing tools. The ozone generation has no recurring cost unlike chemical disinfectants thus considered as “poor man sterilization technology” however, it's oxidation potential is highest than it's counterparts hence referred as “advance oxidation potential”. Combining these two norms, the usage of ozone sterilization in water treatment, waste management, PPE disinfection, PPE conditioning, air sanitization has already been added into global benchmarks (see questions below how regulations have evolved with ozone's importance in sterilization sector). With advent of COVID-19 and countries to develop “cost effective” less dependent and environmental friendly technologies for sterilization industry, Ozone technology is in front line. We are using it as primary sterilant as in combination with one or two other sterilant, it can even support Extreme Oxidative Process, a need of the hour.

How it comply with requirements of US FDA-21 or GRAS?

Ozone is generated and calibrated / contained in the sterilization chamber for sterilizing PPEs. Ozone is considered as GRAS- Generally Recognized as Safe grade III sterilient as per US FDA-21CFR 178.1010 (b) - 16/3/1977. As per QC verification for products under supply (as recommended by DRDO), ozone levels are checked and verified by the manufacturing unit certifying this claim.

How it is related to USDA National Organic Program 205.605 (b) (20) Page 437?

The product primary sterilient is “Ozone” thus this machine automatically fits to this criterion. As per above criterion, despite that ozone is chemical or gas, it is considered as “organic” especially for its acceptance in Food Industry.

How this product complies with CT Values as per EPA Guidance AWWA 1991?

As per EPA Guidance AWWA 1991, these are CT value for deactivation of viruses by various disinfectants:

Disinfectant	Units	Inactivation		
		2-log	3-log	4-log
Chlorine	mg.min/L	3	4	6
Chloramine	mg.min/L	643	1,067	1,491
Chlorine Dioxide	mg.min/L	4.2	12.8	25.1
Ozone	mg.min/L	0.5	0.8	1.0
UVC	mW.s/cm ²	21	36	-

The machine is optimized by DRDO for its default settings using above-mentioned Contact Values for Ozone and UVC as Ozonated Space. The complete cycle of sterilization is standardized fulfilling this requirement.

How the product relates to Canadian License process 2002 and USFDA 2003?

This states that Canadian and US FDA has started issuing license or approval for use of ozone as safe and effective sterilization mode. Accordingly, using ozone in imported variants is available from multiple companies. This product is developed indigenously by DRDO and validated for using it in PPE disinfection.

How service support is provided by manufacturer after sales ?

In all the advance models of tri-netra technology all India on-Site installation support and service support is provided for warranty period. Beyond that, AMC standards do apply for continuous life of product.

What about supply of spares and availability of technical staff?

All the spares are standardized and list of all spares, their HSN codes and contact details to procure them is included in package provided to client. However, our National Service Support partner details are provided by Installation Engineer as well as will be mentioned on machine too.

Does the machine has any meter or indicator (audio/video) certifying whether material subjected to sterilization is really disinfected 99.99% or there was some error that it should be re-done?

First of all machine is design on "robust industrial system" with all setting sets to default level for maximum sterilization requirement. The option left to user is to use (a) SPACE alone (means surface sterilization with UV-C only); (b) Ozone + UV-C referred as Ozonated SPACE (comprehensive sterilization cycle of ozone followed by UV-C ensuring that advance oxidative process linked sterility) and; (c) Radical dispenser (of user's choice, only humidity or provided with Ultra Swachh) + Ozone + UV-C ensuring Extreme oxidative process linked sterility. Thus, the time cycles are optimized with respect to bulk usage i.e. PPE Disinfection & other materials or Waster Management. The only difference among these two processes is "time of cycle". Thus, when user is selecting an option, it is

deciding a particular sterilization mode: SURFACE STERILIZATION (SPACE); COMPREHENSIVE STERILIZATION (Ozonated Space) AND; EXTREME STERILIZATION (Tri-Netra) in successively higher sterility assurance with pre-set cycles. When user starts a particular cycle, the system automatically operates on each cycle with last part of cycle is always de-gasing phase in which user will hear an exhaust operating and then closed with all LED lights are in Off-State, if any of LED light is still ON that means due to some error the cycle is stacked in particular phase, press Emergency Override Button and it will shift to degasing phase and one can repeat the sterilization cycle accordingly.

Is there any special method to disinfect outer body or handles of Ati Swachh HSMDDU?

Consider Ati Swachh itself as a medical device that gets disinfected as part of RoomSterilization Process in which it is kept. We provide Ozonated Radical Confined Space Disinfection Unit (POORN SWACHH) too for room based sterilization. It has an extension flow pipe that can be used to disinfect "Ati Swachh HSMD Disinfection Unit" itself.

What is catalyst Convertor? How it works?

DRDO has developed multi-layered convertor to absorb residual ozone (if any) left over after completion of cycle in Ultra Swachh or similar devices. the prime purpose to ensure that even slightest ozone is not leaked into the environment.

What are certifying sterilization standards for Ati Swachh HSMDDU?

DRDO has developed and validated the process of sterilization cycle by using globally accepted biological indicator i.e. *Geobacillus stearothermophilus* (thermophile with ability to survive up to 130 deg C). It's JT2 strain showed optimal growth at 55 deg C with carbon source medium and used as validation process of sterilization technology for heat and ozone related processes respectively. It is evolved as biological indicator being tagged with fluorescent strain. Thus, purple color- decolorization test was validated and used to standardize this process. Based on this standard, whole default cycle of Ozonated Space was optimized in Ultra Swachh.

What is the guarantee that materials gets sterilized in Ati Swachh HSMDDU?

Based on standardized sterilization cycle, levels of ppm of ozone, effective contact time and energy required for secondary sterilization and re-transformation, default timings are set. Each cycle can be monitored using chemical indicators referred as "OS Sterile" strips that are white colored and once exposed, gets colored as indicator of Ozonated Space sterilization. Each PPE or other material can be pasted with these strips as direct indicator(s) that process is completed on these items.
