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TATA CONSULTING ENGINEERS LIMITED

ENGINEERING A BETTER TOMORROW SINCE 1962

Sterilisation and Decontamination

An Overview

Executive Summary

The world is currently reeling under one of the worst pandemic ever known to humankind, COVID19. This deadly virus has infected millions of people, and several hundred thousand people have lost their lives to this outbreak. Countries across the globe have announced lock downs and social distancing.

Citizens are mandated to practise personal hygiene and use personal protective equipment (PPE) like face masks, hand gloves and hazmat suits to fight against the spread of the outbreak. The pandemic is also posing severe challenges in terms of sterilisation and disinfection of medical devices, surgical equipment, lab instruments, utensils, packages, surfaces, personal belongings and sanitisation of people entering malls, hospitals, restaurants etc. to avoid direct or indirect transmission.

Various new technologies have been developed and existing technologies modified to achieve sterilisation and decontamination of items that are used in daily life and to control the spread of such contactable disease-causing micro-organisms. Some of the sterilisation and decontaminations techniques are:

1. Sanitisation chambers/tunnel - spraying sanitisation solution on people passing through.
2. Ultraviolet hand-held device/box/chamber/ room - using UV-C lights for sterilising personal belongings, PPEs, surfaces, packages, rooms, dental implants etc.
3. Hydrogen Peroxide and Vaporised Hydrogen Peroxide chambers and tunnels – Suitable for packages, utensils, medical instruments, personal decontamination etc.
4. Irradiation process - utilised for food, vegetables and medical products.
5. Autoclave, Steam chambers - utilised to sterilise implants, medical instruments etc.
6. Biomedical waste incinerators - employed to burn medical and biomedical waste.

Few technologies are discussed in the following paragraphs:

Sanitisation Chambers

Price Range: INR 25000 to 1.5 lakhs

Sanitisation chamber is one of the essential technologies being used to disinfect the personnel from the deadly microbes. Sanitisation chamber is equipped with sodium hypochlorite sanitiser containers, and when triggered through sensors, a mist of sodium hypochlorite is created to disinfect the persons passing through it. The prescribed quantity of the Sodium hypochlorite solution is mixed with water through the metering pump, and this solution can be sprayed for 20 seconds minimum in order to achieve satisfactory sanitation. The chamber can also be fitted with air curtains so that the stream of high-pressure air can dislodge the microbes from the cloth.

Chamber can be provided with the sliding glass doors operating based on proximity sensors for touch-free operation. A separate cabin for the operator can be provided for monitoring purposes. Adequate lighting arrangements can be provided inside the chamber for functioning at night. These sanitisation chambers are placed at the entrance of sensitive places including hospitals, malls, railway stations, airports, banks, housing complexes, office buildings etc. to disinfect the personnel and avoid the spread of contagious diseases.

Ultraviolet Light Sterilisation

Price Range: INR 10000 to 1.5 lakhs
The price depends on the specifications and size of the chamber

Ultraviolet spectrum with a wavelength of around 252 to 254 nanometres (UV-C) has excellent germicidal capabilities. In many industries, surface disinfection is carried out without the use of chemicals, and this critical disinfection is achieved through UV light sterilisation, which provides a safe, effective solution. In the food industry, UV lamps are used for irradiation. Ultraviolet light (UV-C) sterilisation neutralises viruses, bacteria, yeast and fungi within seconds by damaging the DNA of the micro-organisms.

UV light sterilisation effectively sterilises the space without using any of the harmful chemicals. UV technology is used for disinfecting the areas from fungi, bacteria, viruses, dust mites and spores from transmitting as these micro-organisms are inactivated. UV technology is proving its importance in hospitals and other setups, where it is integrated into air conditioning systems to sterilise micro-organisms that spread disease and contaminants which cause severe respiratory issues. UV lamps to eliminate hazardous or toxic chemicals that are produced in some of the food/ pharma industries and eliminate Volatile Organic Chemicals.

Applications include baggage in airports, packaging materials at warehouses and malls, conveying equipment like belts in airports, roller conveyors in stations, shipper boxes, packages and containers, surfaces, countertops to destroy mould and bacteria.

Sterilisation by Hydrogen Peroxide

Price Range: INR 25000 to 2 lakhs

Sterilisation of surfaces can be achieved by hydrogen peroxide (H2O2) cloud or low-temperature plasma which is produced by a strong electrical field. Hydrogen peroxide plasma is formed directly in the sterilisation chamber. During hydrogen peroxide gas plasma sterilisation process, the air from the chamber is removed by applying vacuum after placing the surfaces to be sterilised like medical devices and surgical instruments. Before starting each sterilisation cycle, the operator inserts the self-contained cassette of the solution of 58% of hydrogen peroxide and water, and this solution is injected into an outer chamber. The solution is then vaporised and allowed to diffuse throughout the sterilisation chamber, enveloping the items required to be sterilised. An electromagnetic field is created by applying radiofrequency energy initiates the generation of gas cloud or plasma. At the end of the sterilisation cycle, the electromagnetic field is turned off, and the reactive hydrogen peroxide is converted into water vapour and oxygen. The sterilisation chamber is re-pressurised, and the air passed through an activated charcoal filter to remove any residual hydrogen peroxide.

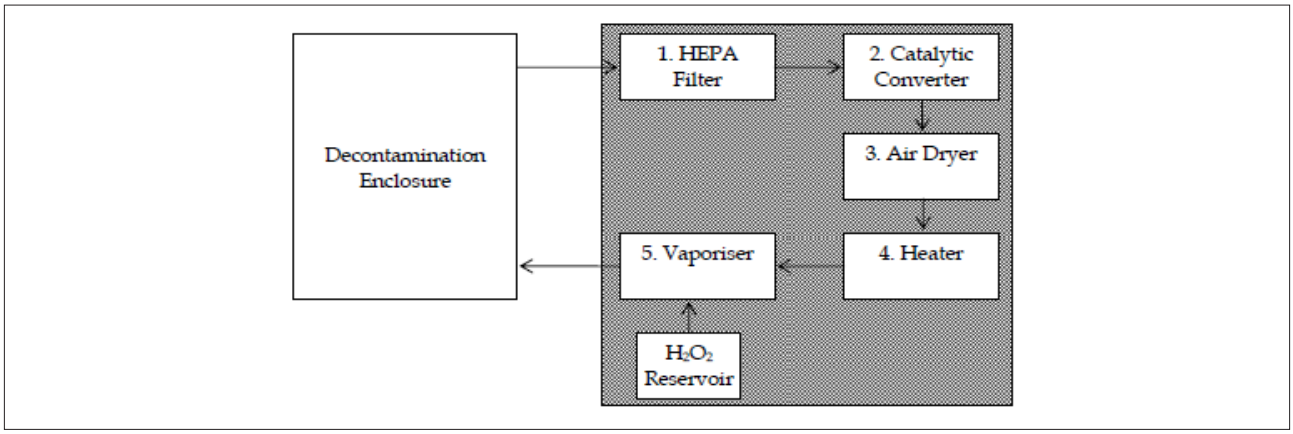
Advantages of low-temperature hydrogen peroxide gas plasma system are:

- Low-temperature hydrogen peroxide gas plasma sterilisation process offers lesser risk to the users and the environment as compared to other chemical sterilisation processes.
- As per OSHA regulations, exposure to hydrogen peroxide has been limited to one (1) ppm in eight (8) hours.
- Destroys a broad spectrum of micro-organisms, including vegetative bacteria, mycobacterium, yeast, fungi, and viruses, as well as highly resistant aerobic and anaerobic bacterial spores.
- No release of toxic residues as Hydrogen peroxide is broken down into water and oxygen.
- Inventory of expensive surgical instruments can be minimised as the process has a shorter sterilisation cycle time (about one hour) and ensures all patients will receive a germ-free device each time.
- Wide range of medical and surgical instruments can be sterilised by this technique and has significantly lower harmful effects on metal surfaces as compared to steam sterilisation. Increases the longevity of the surgical instruments and reduces replacement costs of these instruments.
- Hydrogen Peroxide sterilisation process does not require any special installations. Only a power socket is required, and the system is ready to be installed. The operation theatres can also be fitted with H2O2 sterilisation system in order to facilitate quicker sterilisation of instruments required for the procedures.
- The process is easy to follow, and hence training on preparation of items for sterilisation process such as instrument pre-cleaning, loading, unloading, assembling, and packaging can be cost-effective.
- Self-contained ampoules of hydrogen peroxide are used that eliminates exposure to the chemical.

Major disadvantages of this technology include:

- Inability in the sterilisation of linens and other cellulose-containing materials, as the hydrogen peroxide, reacts with the organic material found in these items.
- As this technology relies upon diffusion, materials such as powders and liquids cannot be sterilised.

Vapourised Hydrogen Peroxide (HPV or VHP



Schematic of VHP Process
Source: Establishment of a Vaporous Hydrogen-Peroxide Bio-Decontamination Capability by Andrew M. Mcanoy, Michelle Sait and Sue Pantelidiis

Hydrogen peroxide solutions are being used as a chemical sterilant for many years. One of the methods of generating VHP is, hydrogen peroxide of 30%–35% concentration from a disposable cartridge is passed through a heated vaporiser and then is pulled through a vacuum system into a sterilisation chamber. In a second, a flow-through approach, where VHP is carried into the sterilisation chamber or space by a carrier gas (air) either in a slightly negative pressure (vacuum) or slightly positive pressure.

Applications of VHP technology include vacuum systems for industrial sterilisation of medical devices and atmospheric systems for decontaminating large and small areas, such as laboratory workstations, isolation and pass-through rooms, and even aircraft interiors. VHP offers several appealing features that include lower cycle time for decontamination of 30–45 minutes, low temperature, environmentally safe by-products (water, oxygen), better compatibility with materials, easier operation, installation and monitoring. VHP has serious limitations as it cannot process cellulose, on the exposure of VHP makes nylon brittle, and VHP penetration capabilities are lesser compared to that of Ethylene Oxide.

The VHP process cycle consists of three distinctive phases:

- Preconditioning
- Decontamination
- Post-Conditioning

In the preconditioning phase, the chamber is dehumidified to ensure a successful process. In addition, this phase lowers the number of particulates on the package or surface to be decontaminated.

Post–Conditioning VHP gas from a chamber is removed by an efficient catalyst breaking VHP gas into water and oxygen. The door can be opened when VHP concentration within acceptable/safe level inside the chamber.

The unit is controlled by Programmable Logic Controller (PLC) and Human Machine Interface (HMI). PLC has capabilities of configuring various parameters to accommodate different loads. Following are salient features of VHP:

- It is a unique process for reducing particulates on various packages
- Has shorter cycle time with satisfactory decontamination throughout the chamber.
- It is an independent system, easy to install and validate.
- Consumes very low hydrogen peroxide
- Extensive risk analysis is carried out to ensure operator safety

Radiation Processing of Food & Medical Products

Gamma radiation processing as compared to other sterilisation methods like sterilisation of health care products using either Ethylene Oxide or wet steam as a sterilant has many advantages. Some of the advantages include:

- As gamma rays are powerful and penetrate right through the package and products, products of any shape can be sterilised.
- Plastic medical devices that are sensitive to heat and other pharmaceutical equipment/ products can be sterilised without causing damage as it is a cold process.
- Offers better packaging flexibility since the packages can be filled or packed individually in sealed bags and then the package is sterilised.
- As the sterilisation process is carried out after final packaging, the product's sterility is retained until the package is damaged.
- It is a continuous, fully automated process with a single parameter to be controlled, the time of exposure. Steam sterilisation and Ethylene Oxide apart from being batch processes; require more than one parameter to be controlled.
- The treated product can be used immediately.
- A very precise and reproducible treatment process.

Radiation sterilisation using gamma rays is an efficient and convenient technique in achieving high levels of sterility in medical supplies. Sealed food and medical products in cardboard cartons, steel or aluminium boxes can be exposed to a dosage of 25 kiloGray as a minimum in order to achieve better results. Exposure of products manufactured as per Good Manufacturing Practices (GMP), to a minimum radiation dose of 25 kGy ensures sterility assurance level (SAL) of around 10-6. This dose provides higher safety factor, and when the product has a low initial microbial count (<103 CFU per unit), the probability of microbial survival rate of less than one in one million can be ensured.

Gamma radiation has proved its effectiveness in the inactivation of micro-organisms. Finished products must be handled as less as practicably possible during manufacturing in order to reduce the count of micro-organisms to the lowest possible. Premises, where gamma radiation is used, shall be clean and dry, properly ventilated with cleaner air, and the materials selected are suitable to withstand regular and thorough cleaning.

Autoclaves

Price Range: INR 1 lakhs to 10 lakhs

Autoclaves are used in sterilising the equipment, instruments or packages that can withstand the temperature range. Air is removed from the chamber by means of vacuum pumps to create a low-pressure. Moist heat, in the form of pure steam, has better heat transfer capabilities and is more effective in destroying micro-organisms and spores as compared to dry heat. That is the reason for removing trapped air so that the steam is not diluted by air.

Moist heat at a lower temperature can destroy contaminants as effectively as much higher temperatures of dry heat, allowing fragile materials such as clothing to be sterilised.

Steam is pushed into the autoclave chamber at 100 – 200 kPa (1-2 bar(g)), pressure and at around 121^{o}C for fifteen (15) minutes, though this may be adjusted depending on requirements. Sterilisation cycles of 134^{o}C for three (3) minutes are also common. With 100% dry steam, as the heat transfer is less efficient, the sterilisation effect is also less. For better effect Steam with 97% dryness is utilised in autoclaves to derive benefits of high temperature and pressure of dry steam, and enhanced heat transfer capability of wet steam.

Modern autoclaves are suitable for sterilising almost any object that can survive the high temperatures and pressures of the cleaning process. Some types of plastics cannot be sterilised using an autoclave. Autoclaves are available in a variety of sizes, from small tabletop instruments to large chambers.

Biomedical Waste Incinerator

Price Range: INR 2 lakhs to 22 lakhs

Biomedical waste is generated while performing procedures and treatment on patients in hospitals, diagnosis in laboratories and in R & D facilities during research activities or in the production and testing of biological and medical sources in hospital, clinic, research institute etc. It contains infectious micro-organisms, viruses etc.

Biomedical waste incineration processes in which combustion of waste in the presence of oxygen in a controlled way destroys or transforms it into less hazardous, less bulky or more controllable constituents.

Biomedical waste incineration process destroys almost all organic waste toxicity, and waste volume is reduced by 95-98%. This type of treatment uses high-temperature oxidation under controlled condition to degrade a substance into products that generally induce CO_2, H_2O vapours, SO_2, HCl and Ash. These incinerators can be diesel or gas-fired.

The incineration plant is designed for disposal of Biomedical waste and includes the site and the entire incineration lines, waste reception, storage, on-site pre-treatment facilities, waste, fuel and air supply system, treatment of exhaust gases, on-site facilities for treatment or storage of wastewater, stack, devices and system for controlling incineration operations, recording and monitoring devices.

Selection of Technology

There are various sterilisation and decontamination technologies available in the industry. One needs to employ the best-suited technology for the intended service to achieve optimum, cost-effective and safer methods of decontamination. Not many people understand the finer aspects of these technologies and install without proper due-diligence, leading to ineffective processes. The price range also greatly varies depending on the size and technical specifications.

During initial days of lock down, for personal decontamination, a lot of companies have rolled out sterilisation chambers using sodium hypochlorite and sanitiser spraying. Later, the ministry of health and family welfare came up with an advisory against the spraying of disinfectants on people. It also went on to say spraying strong chemicals on an individual may cause skin and eye irritation and may lead to a false sense of disinfection and safety.

In view of the above, it is recommended to carry out a proper study of various technologies to suit specific requirements of sterilisation, decontamination and disinfection. Tata Consulting Engineers has the experience and expertise of providing the right specifications for a particular application and support in the implementation of the best technology for a specific application.

The world is slowly limping back to normalcy in due course of time, lockdowns are partially being released, and hence it is imperative that various industries employ proper methods of sterilisation and decontamination processes. Since there are so many technologies and suppliers are available, a detailed and careful study needs to be undertaken to select the appropriate technology for ensuring the effectiveness of the process.

The Company

Established in 1962, Tata Consulting Engineers Limited (TCE) offers its customers invaluable expertise – a by-product of more than five decades of premier service as an integrated engineering service provider. To date, we have completed more than 10,000 assignments in over 55 countries.

Our specialised, in-house talent pool and the ability to provide holistic solutions under one-roof, makes us a force to be reckoned with, in the following engineering consulting sectors:

1. Infrastructure
2. Power
3. Resources - Mining & Metals
4. Resources - Hydrocarbons & Chemicals

TCE serves domestic as well as international markets and is known for several first-of-its-kind projects offering the following services:

1. Design & Engineering
2. Project Management & Safety
3. Procurement Management
4. Digital & Advanced Technologies

Tata Consulting Engineers is a renowned consulting firm offering comprehensive solutions in the food and pharmaceutical industry and has been engineering hospitals stadium, museum projects over five decades. In case of any sterilisation and decontamination requirements for hospitals, airports, malls, warehouses, railway stations etc. TCE can be approached for offering services related to product-specific sterilisation and decontamination solution.

Author

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VISION

To be an internationally respected engineering consultant offering comprehensive solutions

MISSION

Provide technically excellent and innovative solutions, for adding value for all stakeholders, and operate globally as professional consulting engineers

CORE VALUES

- Customer Satisfaction and Loyalty
- Technical excellence with professional ethics
- Responsibility to society
- Employee dignity and self-respect
- Organisational and individual growth

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June 2021