



Pushing the boundaries
of biodecontamination





A complete line for environmental
and surface biodecontamination with
innovative HPE technology.

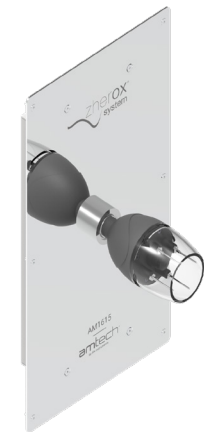
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Zherox®



Zherox® b-pack



Zherox® Fixed System



Zherox® Light

amtech®
by AM Instruments

HPE TECHNOLOGY

A <8% hydrogen peroxide solution is diffused through a nozzle, creating a mist of micro-droplets which are ionised when they pass through a high-voltage electromagnetic field.

The resulting solution has a high concentration of hydroxyl radicals and ROS (reactive oxygen species) which are able to cause damage to microorganisms by the oxidation of proteins, carbohydrates and fats.

The electromagnetic field generates an electrostatic charge in the mist which thereby acts as a gas due to the mutually repulsive action of positive charges.

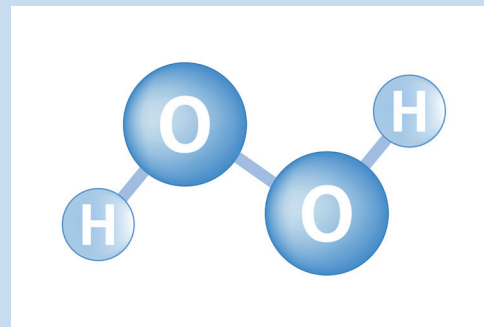
The result is a high rate of solution dispersal able to cover 100% of the area to be treated.

The resulting products, oxygen and water, leave no residue on surfaces.

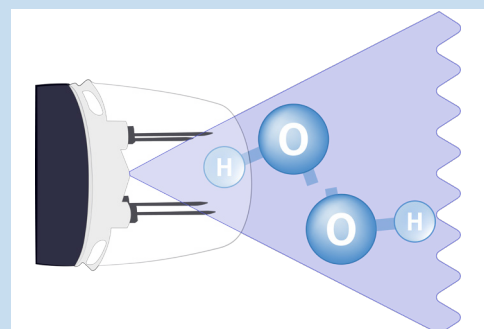
APPLICATIONS

The different systems can be used in the following applications:

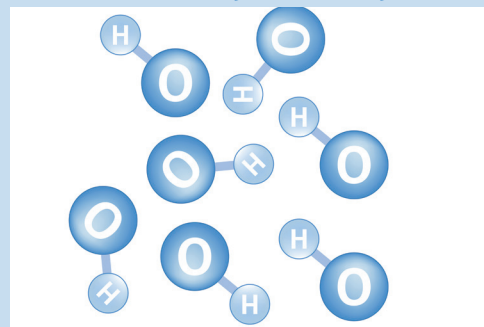
- pharmaceutical industry
- research and laboratories
- biotech
- hospitals and healthcare
- offices
- transport



Hydrogen peroxide < 8%



Ionisation and diffusion thanks to a high voltage electromagnetic field



Mist of micro-droplets of hydroxyl radicals

ZHEROX[®]

Zherox[®] is the new environmental decontamination mobile system designed and built to fully comply with GMP requirements.

proven EFFICACY

unparalleled COMPATIBILITY

innovative TECHNOLOGY

shorter CYCLE TIMES

maximum AUTOMATION

data INTEGRITY



amtech[®]
by AM Instruments

A NEW CONCEPT OF BIODECONTAMINATION

- electromagnetic hydrogen peroxide ionisation technology
- solution based on H_2O_2 <8%
- optimised diffusion
- shorter cycle times
- remote control
- no ventilation necessary for optimum diffusion
- maximum material compatibility
- settings memory and combination
- fully ergonomic
- user-friendly touch screen
- predictive maintenance
- time synchronisation with NTP (network time protocol) technology
- full traceability
- cloud-based data available anywhere, any time
- immediate GMP report generation
- compliance with directive CFR21 part 11



AM CLOUD

With AM Cloud, Zherox® is available anywhere, any time. Take out the plan which best meets your requirements to access all the data on the biodecontamination equipment and operations.

Zherox® is a cloud-based system: each unit requires the creation of remote server space. The client is provided with an advanced maintenance system and regular updates.

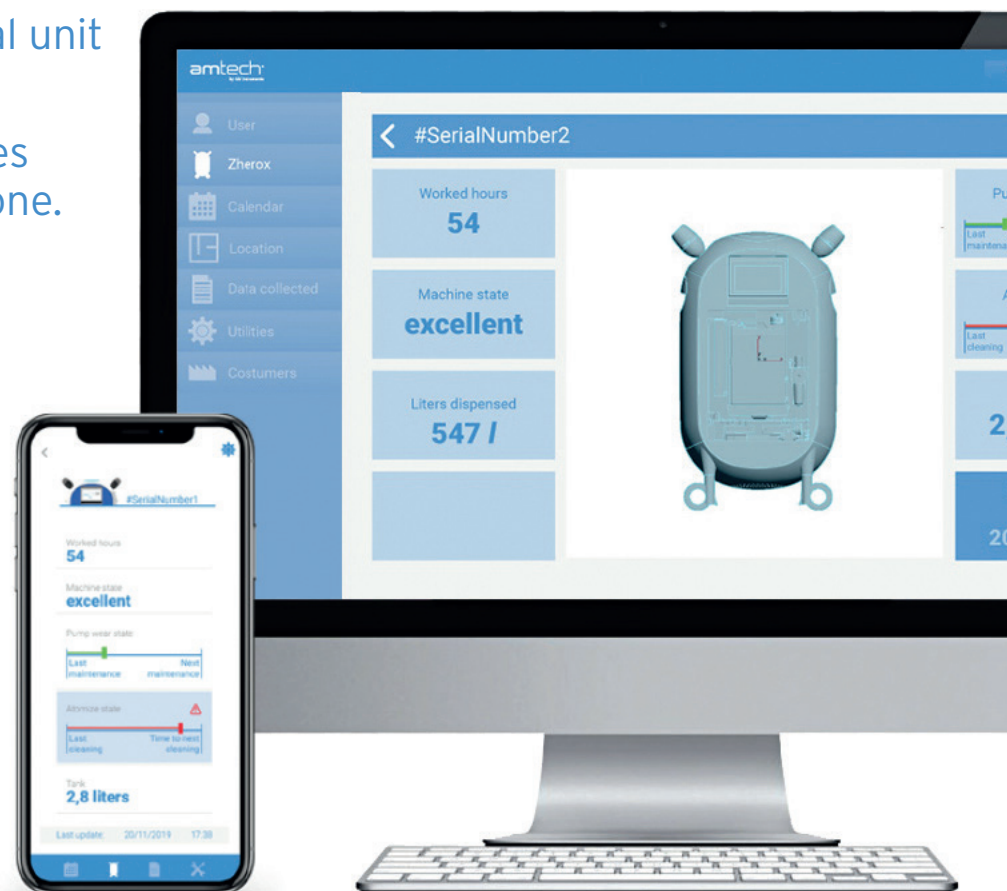
ADVANCED MAINTENANCE

With AM Cloud, you can monitor the state of each individual unit and be notified in real time of pending maintenance.

In addition, the new integrated diagnostics system facilitates rapid intervention and convenient alerts on your smart phone.

With AM Cloud, an advanced predictive system which drastically reduces interventions and enables programmable maintenance, Zherox® reduces maintenance times and the unpredictability of maintenance interventions.

Maintenance plans are available in line with the customer's requirements, as set out in the dedicated server rental contract.





EFFECTIVENESS

The biodecontamination effectiveness of the solution and its improved distribution are guaranteed by the action of a source of ionising energy consisting of an electromagnetic field able to increase the oxidising efficiency of the solution by 50%.

OPTIMISED DIFFUSION

Optimised distribution of the solution in the space. The positively charged micro-droplets repel one another, dispersing the solution as if it were a gas. It is not necessary to use ventilators to optimise diffusion.

SPEED

The system is capable of sanitising up to 300 cubic metres with a single unit. In larger areas it is possible to use several units at the same time, interconnected by Wi-Fi and managed as a single system, permitting optimised dispersal of the mist and reducing cycle times. No ambient conditioning of the premises is necessary.

MATERIAL COMPATIBILITY AND SAFETY

Maximum material compatibility: the solution used has a concentration 4 times lower (<8%) than VHP systems (35%) and has no hazard rating, is not explosive and is not flammable or corrosive.

MAXIMUM AUTOMATION

The biodecontamination cycle settings can be stored in memory and retrieved. The cycle can be started from the integrated touch screen or by connecting to the Zherox® Wi-Fi network, via any mobile or fixed device, thanks to the presence of a web server on the machine. The coverage of the Zherox® Wi-Fi network can be expanded through the Wi-Fi extender kit. Maximum automation of activities.

GMP REPORT

The system ensures that biodecontamination operations are fully traceable: insertion or modification of operating parameters, configuration, maintenance, users, data on the sanitiser used.

All operations are stored in memory and are available to consult or for report generation. All data is present and accessible on the cloud for consulting and reporting purposes.

SANITISER MONITORING

Zherox® can be fitted with a 5 L tank of sanitiser with full data monitoring at all times.

REAL-TIME CONTROL

The machine senses the solution parameters, making them remotely available in real time. The quantity of liquid delivered is controlled at all times during biodecontamination operations. It is possible to continuously monitor relative humidity, temperature and the peroxide concentration.

DATA INTEGRITY

The machine ensures data integrity in accordance with ALCOA principles. All data is attributable, legible, contemporary, original and accurate.

EASY TO USE

Zherox® introduces a new biodecontamination concept, simplifying the process from initial set-up to the drafting of the final report.

The easy-to-use interface guides the user clearly during the key steps of the biodecontamination activity.

NO NEED FOR ROOM CONDITIONING.

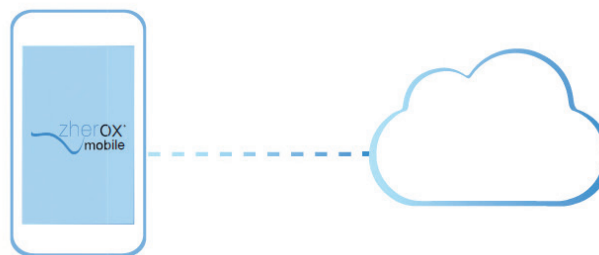


REAL-TIME CONNECTION

Zherox® “pocket-sized”: you can connect to the Zherox® system straight from your Android or iOS smart phone. Logging in from your device gives you access to the Zherox® environment including machine status, reports and operating history, all in accordance with data integrity principles.

Zherox®’s key strength is its connectivity: communication with the cloud-based servers is through the operator’s smartphone. The smartphone is a key component in the system: being connected at all times, it provides a bridge between units and servers, ensuring reliable and consistent synchronisation and improving user experience.

It is necessary to use a smartphone or tablet equipped with a SIM card to ensure connectivity to the Internet.



TEAM ZHEROX® IN ACTION

For the biodecontamination of large areas, it is possible to further boost the effectiveness and efficiency of the process by using several interconnected machines. Increasing the diffusion points reduces cycle times and improves the dispersal of sanitiser in the premises.

To ensure data completeness and simplicity of use and to minimise the possibility of operator error in the management of more than one unit, the devices connect by Wi-Fi, automatically synchronising with one another.

Once the cycle permitting the use of more than one unit has been set up, the machines will start up together to complete the programmed cycle.

All information as well as the list of machines and the solution batches used will be delivered in the final report.



DISPLAY & REPORT

DISPLAY

The 7" touch screen has a user-friendly graphic interface permitting the following actions:

- initial configuration/retrieval of existing programme settings
- maintenance and diagnostic processes
- local user input
- monitoring of operating parameters
- consulting of data

All the operations mentioned can also be managed remotely, within the Zherox® Wi-Fi coverage.

REPORTS

The report contains the following:

- company name and logo
- data and time
- credentials of the operator executing the cycle
- batch and expiry date of the sanitiser used
- cycle parameters: name of premises and cubic meterage/mL delivered/delivery time/contact time
- sanitisation result (presence or absence of anomalies)
- value in ppm peroxide+T+RH% read from the sensor (optional) at the end of gassing
- printout date and time
- credentials of the person making the printout
- approval signature field

At the end of the operation, it is possible to activate a flag on the machine to automatically generate the report on the decontamination just completed.

DATA INTEGRITY

ACCESS

Registration of operators:

- username as the unique ID
- name
- surname
- alphanumeric password
- role

Depending on the hierarchical role, specific functionalities may be available

ALCOA

The machine guarantees data integrity in accordance with the ALCOA principle.

The data provided by Zherox® are in fact:

- A/Attributable: each data is associated with the person and/or activity that generated it. The cycles, as well as the ordinary and extraordinary maintenance operations and the loading of the consumable product into the machine, are recorded and attributed to the operator responsible
- L/Legible: the data is legible and permanent. No data is encrypted or coded in order to allow the clearest usability
- C/Contemporary: the recording of the data is contextual to the event that generates it through a unique "time stamp", and is immediately verifiable
- O/Original: the data is original and validated, without any possibility of modification
- A/Accurate: the data adheres strictly to the activities and actions carried out.

ZHEROX® LIGHT

Zherox® Light is a stand alone machine capable of biodecontaminating areas up to 300 m³. Through the touch display it is possible to manage biodecontamination operations and routine and extraordinary maintenance. The AM GMPREP app allows you to generate GMP reports.



FUNCTIONALITY

- generation of a known volume of sanitising solution
- verification of the presence of the tank and the minimum quantity necessary to perform the activity
- real-time monitoring of the parameters necessary for proper nebulisation, functional to the activity in progress (liquid flow and air pressure)
- status communication through visual signals (display, LED ring)
- GMP report generation via AM GMPREP app

CYCLE

The execution of a cycle must start from one of the following inputs:

- insertion of the dimensional data of the room to be treated and automatic calculation of the quantity of solution to be generated
- direct entry of the quantity of solution to be generated
- the management of biodecontamination operations, operational/functional parameters as well as ordinary and extraordinary maintenance of the machine can be performed using the 7" touch display on board

REPORT

- each machine is independent and able to generate GMP reports through the dedicated AM GMPREP app
- the reports are recorded on the internal memory of the machine with the possibility of downloading the documentation on a USB key



ZHEROX® FIXED SYSTEM

The fixed biodecontamination systems use innovative Zherox® technology and TLP diffusers. The diffusers with their supports, which are suitable for wall or ceiling mounting, are designed to minimise impact on the existing structure and to be fully compatible with contamination-controlled and/or sterile areas.

The system is managed using a control panel positioned in a non-classified zone. A proprietary application compliant with Directive CFR 21 Part 11 monitors and manages all the functions of the biodecontamination system; the graphic interface is designed to facilitate use for operators at every access level.

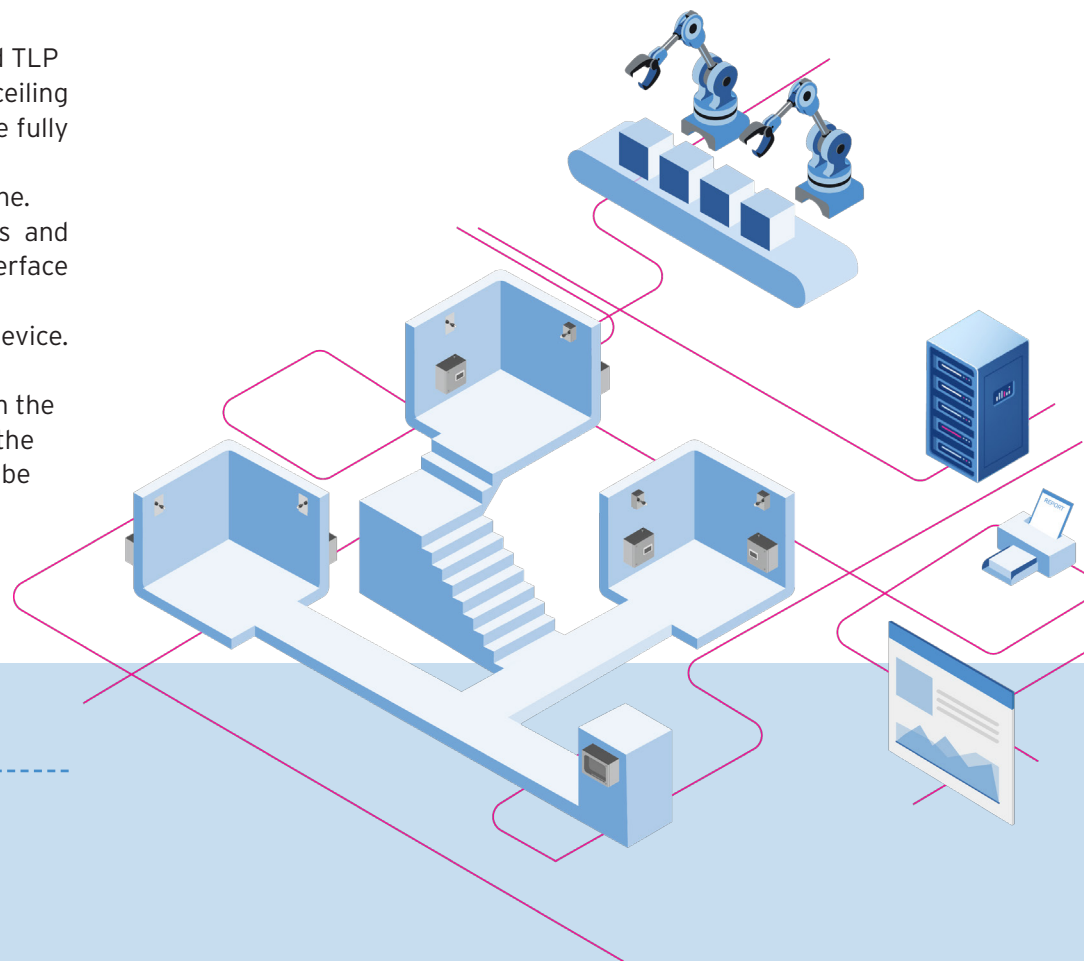
System access is possible both from the control panel and from a PC or mobile device. Data integrity is guaranteed by the application of the ALCOA principles.

Our biodecontamination system communicates with and can be managed from the main monitoring systems used by the client. Every system is customisable on the basis of requirements, and the characteristics of the premises in which it is to be installed.

The systems are equipped with IQ, OQ and, on demand, PQ protocol.

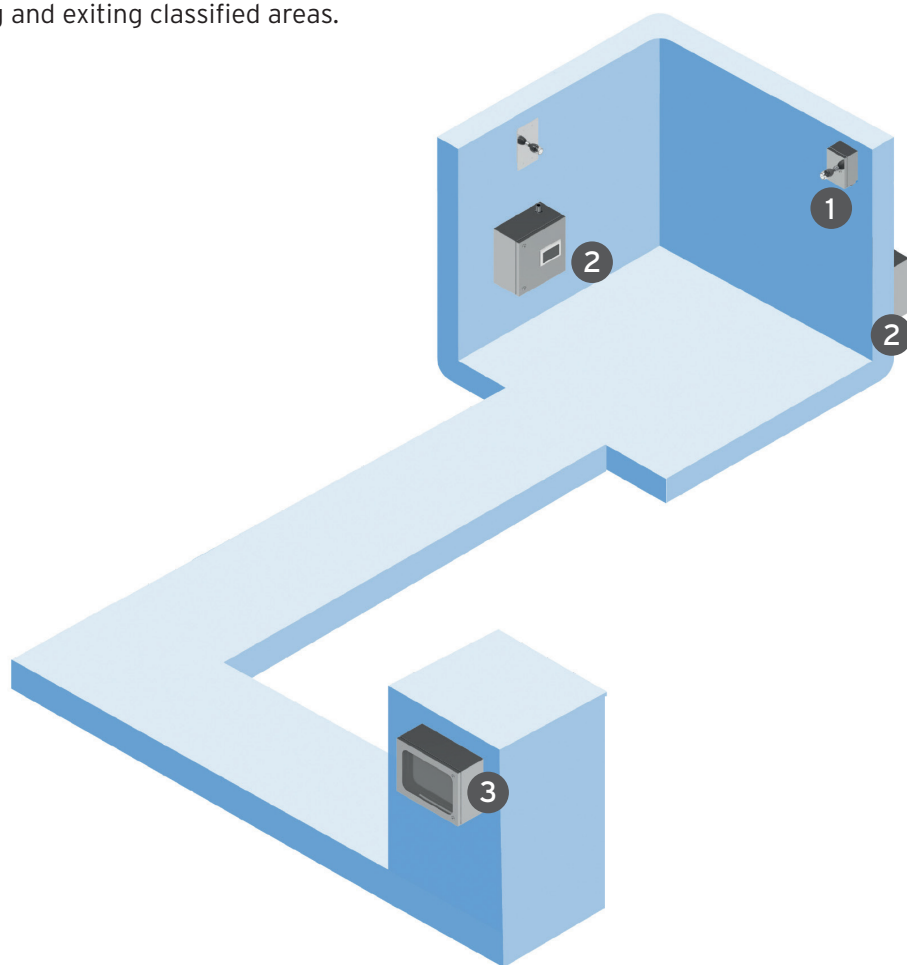
SMART INTEGRATED SYSTEM

- can be integrated with centralized management systems (SCADA)
- can be integrated with BMS systems (Building Management System)



A MODULAR SYSTEM

Zherox® Fixed System is modular and can be configured according to customer needs. It is preferable to place the control unit outside the cleanroom to minimise the movement of materials and operators entering and exiting classified areas.



COMPONENTS

1. TLP

The TLP diffuser can be installed on the wall or on the ceiling. The number of dispensing points varies according to the size and geometry of the sterile area in which it is installed.

2. TLP CONTROL UNIT

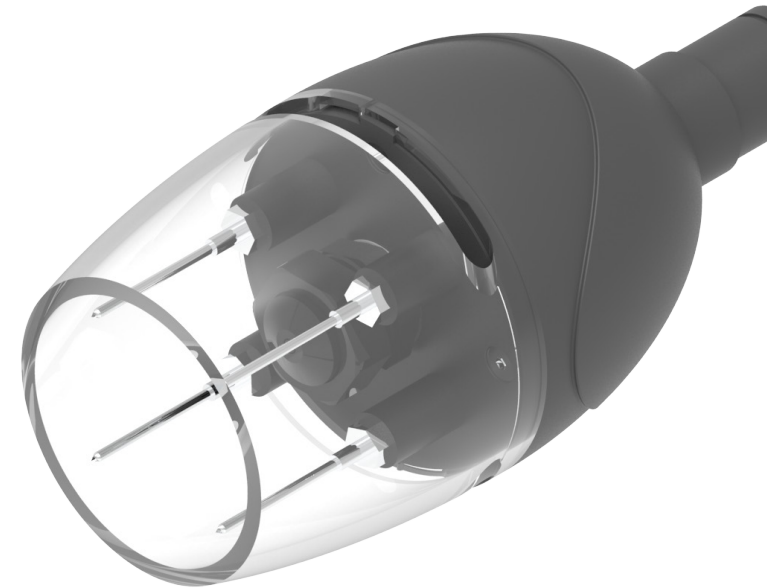
Each dispensing point is equipped with its own control unit.

3. SYSTEM CONTROL UNIT

The system control unit can remotely manage up to 27 dispensing points.

ZHEROX® FIXED SYSTEM: ADVANTAGES

- reduced cycle times: cycle times are optimised based on the level of microbial removal required by the customer, up to Log 6.
- remote control
- possibility to load the layout of the area in two steps
- the simplicity of installation and the immediate interface allow the customer to install the system in total autonomy
- registration and monitoring of dispensing points
- creation and saving of recipes
- status check: before starting a biodecontamination cycle, the system checks:
 - › that all the delivery points involved are connected
 - › that the quantity is sufficient to complete the intervention
 - › that the mechanical components are not worn or damaged
- continuous monitoring: during the biodecontamination cycle, all parameters under continuous surveillance:
 - › compressed air flow
 - › liquid flow
 - › high voltage presence
 - › tank level
 - › peroxide concentration
 - › timing of biodecontamination cycles
 - › temperature
 - › humidity
- advanced maintenance
 - › remote maintenance with indication of component wear
 - › local maintenance of each delivery point



Zherox® b-pack is the new portable biodecontamination system from AM Instruments.

The innovative HPE technology of Zherox® applied to a lightweight system, which allows maximum operational simplicity in full safety for the operator and with proven effectiveness.

PUSHING THE BOUNDARIES
OF BIODECONTAMINATION

EFFICACY

SAFETY

SPEED

PORTABILITY



THE DEVICE

Zherox® b-pack is a battery-powered portable device for the biodecontamination of surfaces.

b-pack contains a sanitiser tank and includes a TLP diffuser equipped with HPE ionising technology.

HPE technology provides for the ionisation of the sanitising liquid molecules, ensuring excellent diffusion while boosting the disinfectant efficacy.

Control electronics grants optimal battery management. The status LED on the diffuser indicates the charge level and the operating phase.

The aluminium alloy frame and the ABS body make the unit light and ideal for frequent use. The ergonomic diffuser allows continuous use, avoiding operator fatigue.

The 5-litre tank and the battery life of up to 3 hours duration guarantee high autonomy.



In the document: "Good Manufacturing Practice Considerations for Responding to Covid-19 Infection in Employees in Drug and Biological Products Manufacturing" (June 2020), FDA offers guidance to address the risks of Covid-19 in pharmaceutical manufacturing.

The document focuses on activities aimed at preventing both the transmission of the Covid-19 virus among employees and the contamination of drugs and materials by a virus-positive employee.

Drug companies should:

"Clean and sanitize non production areas (such as offices, elevators, break rooms, changing rooms, and restrooms) more frequently. Update existing procedures to institute more frequent cleaning, sanitization, and / or sterilization of surfaces in the production areas, particularly surfaces that are contacted frequently, such as door handles, equipment latches, bench / counter tops, and control panels. Special attention should be paid to sanitizing / sterilizing equipment and product-contact surfaces.

Consider expanding existing procedures to include using gloves, face masks, and / or gowning where such measures were not previously required.

Consider further restrictions on employee access to any manufacturing area, beyond that required by cGMP regulations and recommended by Agency guidance 18 and normal practice, to limit the possibility of contamination.

If a potential or actual viral contamination event is identified, drug manufacturers should promptly clean, disinfect, sanitize, and if necessary, sterilize affected equipment, surfaces, production areas, and facilities, before resuming manufacturing."

The Zherox® b-pack system is the ultimate solution for FDA recommended biodecontamination activities.

Zherox® b-pack is in fact ideal for more frequent sanitising of non-productive areas such as offices, changing rooms, warehouses etc., with particular attention to surfaces such as door handles, worktops, control panels.

The lightness of the instrument and its autonomy make the biodecontamination cycle as agile as ever; the micro drops of ionised hydrogen peroxide are able to reach even the most difficult to reach areas, with optimal material compatibility.





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COMPANY WITH
QUALITY SYSTEM
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