Work Method Statement

Prepared for:
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Contents:

1. The Deprox HPRD system:

From the outset DEPROX bio-decontamination system was designed to be used by hospitals in their efforts to reduce environmental contamination and associated patient infection. The DEPROX is, by design, simple to use with risk of operator error or hazard, minimized where ever possible. From using self calculating software to low concentration chemical formulations the risks associated with using the DEPROX are significantly reduced from that of traditional vaporising decontamination processes.

The DEPROX is a calibrated vapour generating device which combines the use of high frequency ultrasonic and chemical indicators. The DEPROX will ensure a homogenous diffusion of vaporized Hydrogen Peroxide vapour around an enclosed space. The Hydrogen Peroxide solution used in this process is Deproxin, a 4.9% Hydrogen Peroxide solution containing, 0.001% silver nitrate solution (See Deproxin Safety Data Sheet).

This process is validated to deliver a 6 log reduction across a broad spectrum of organisms. Site specific validation is agreed with suitable qualified persons within the procuring organization before commencement of the process.

This technology is used by hospitals around the world and the routine use of it has been proven to reduce infection acquisition by patients. The DEPROX is now recognised by leading hospitals around the world to this end.

2. Treatment Parameters:

In order to carry out an effective decontamination cycle the DEPROX requires certain operating parameters:

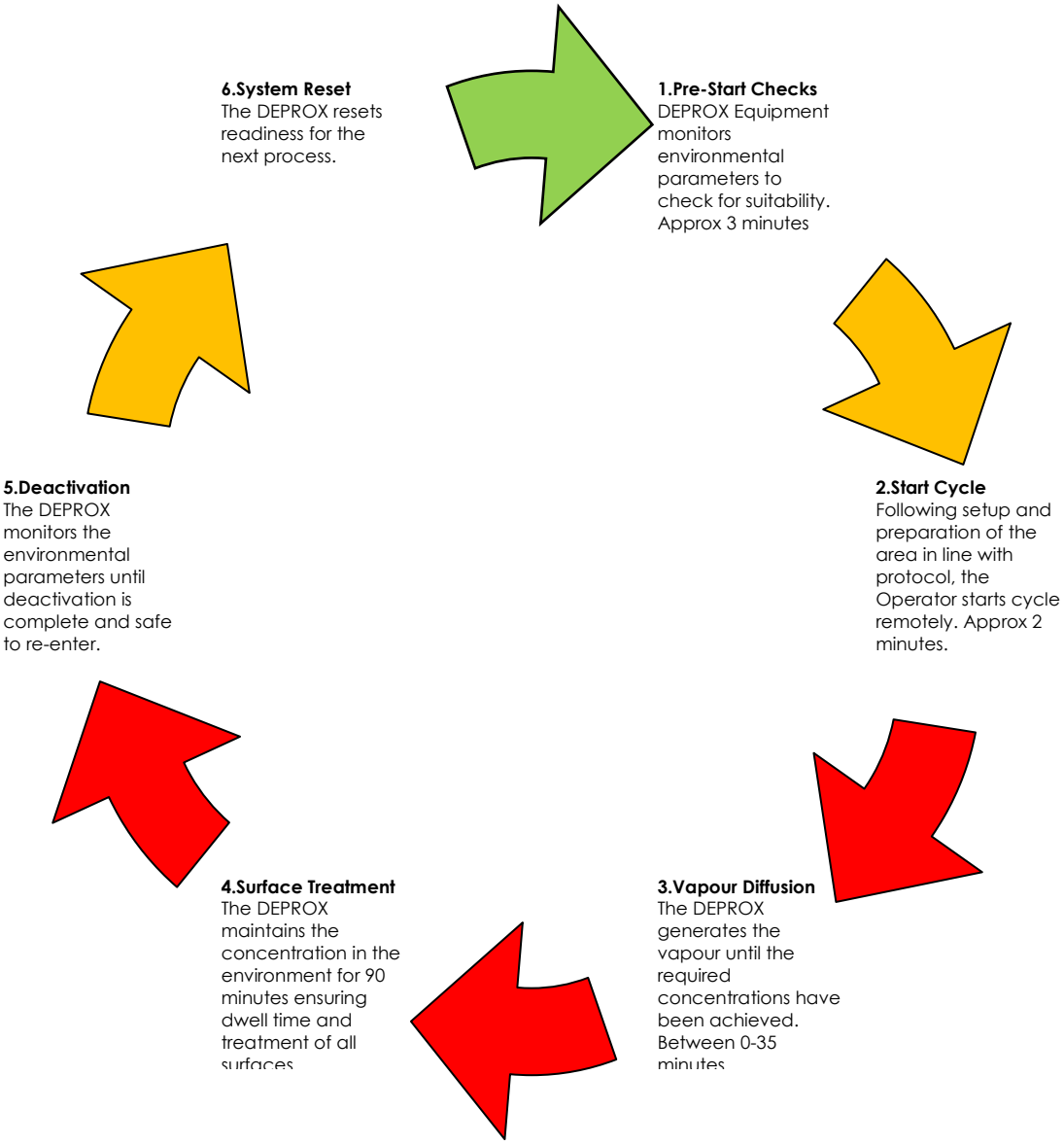
- Minimized absorbent materials within the space – although everything has a natural absorbency level irrespective of its construction, it is beneficial to remove highly absorbent materials such as textiles, paper and other porous materials. Although the presence of these will not compromise the efficacy to other surfaces, they will increase the treatment and deactivation times.
- Exposed surfaces – the DEPROX is a vaporizing process and relies on the movement of vapour and gaseous hydrogen peroxide around a space to treat the surfaces within it. Directly adjacent surfaces, i.e. two flat surfaces touching, will not be easily penetrated by the process and could remain untreated.
- Ambient and surface temperatures of between 10 °C and 35 °C – to ensure capacity for the vapour in the enclosed air volume to reach the required concentration, without reaching saturation or 'dew point'.
- Ambient humidity of between 15% and 70% - to ensure capacity for the vapour in the enclosed air volume to reach the required concentration, without reaching saturation or 'dew point'.
- Contained air volume – to effectively treat the surfaces contained within the space, the DEPROX requires a contained air volume. This involves sealing ventilation and potential leak points to ensure the air volume remains the same throughout the process.

The DEPROX bio-decontamination system is not a cleaning process. On this basis all areas treated with the DEPROX must be 'cleaned', prior to the decontamination cycle. In this context cleaning would require:

- The removal of organic matter
- The removal of adhesive residues and films
- The removal of dust and visible dirt
- Free from waste material
- Free from loose or compromised surfaces

3. Process Characteristics:

The DEPROX bio-decontamination system is designed to deliver a log 6 reduction to all surfaces in the affected area through a method of calibrated vapour generation and environmental monitoring. The treatment cycle is a standardised to ensure a consistent efficacy in all environments. This cycle, which is controlled and monitored computationally onboard the DEPROX system, follows the below steps:



Process Characteristics (cont'd):

During the DEPROX decontamination process, the Process Monitor placed outside the room will provide visual indication to the operator and any personnel in adjacent areas as to the current status of the process.

- Pre-Start – Process Monitor will show a 'solid' GREEN light
- Start Cycle – Process Monitor will show a 'solid' GREEN light and 'flashing' RED light
- Vapour Diffusion – Process Monitor will show a 'solid' RED light
- Surface Treatment – Process Monitor will show a 'solid' RED light
- Deactivation – Process Monitor will show a 'solid' RED light and 'flashing' GREEN light
- Reset System – the Process Monitor will show a 'solid' GREEN light

Precautions the DEPROX bio-decontamination system will take before, during and after the process to ensure safe and effective treatment of the environment, include:

- Temperature fluctuations – above 35 °C or below 10 °C
- Humidity fluctuations – above 15% or below 70%
- H2O2 level – increase or decrease from computational model

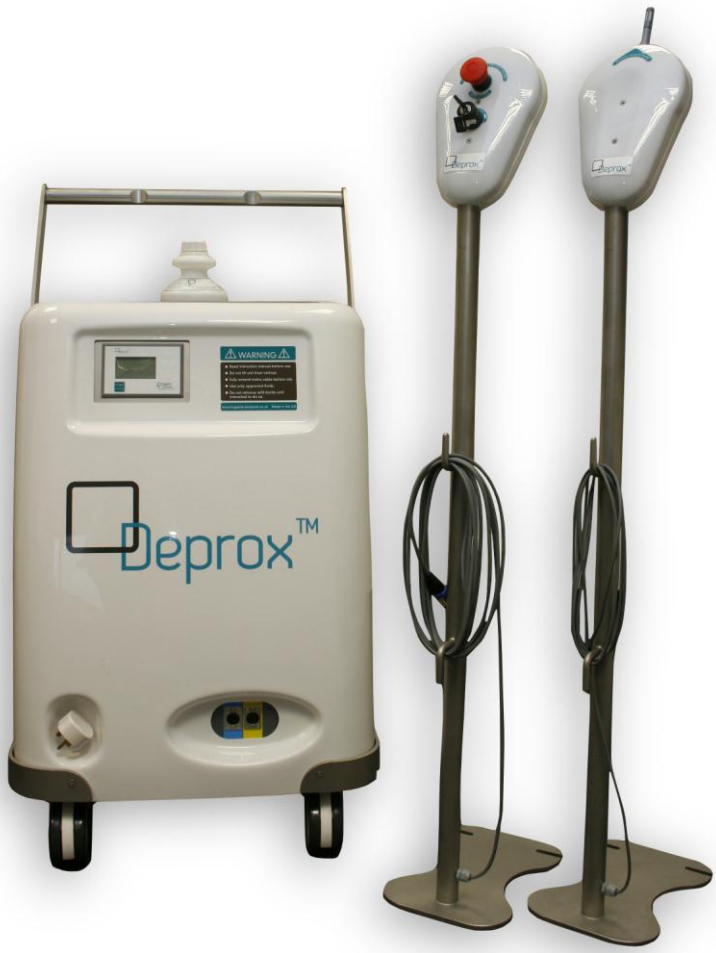
In the event of any of the above parameters being breached, the DEPROX will register 'fault mode' and move into a deactivation cycle.

4. Validation

The DEPROX bio-decontamination system vaporizes the Hydrogen Peroxide solution using high frequency ultrasonic's. The benefit of this method is the efficient generation of vapour of a selected size to effectively defuse throughout the space and decontaminate the surfaces in the affected environment. Hygiene Solutions will agree with suitably qualified persons before commencing the process the preferred method of validation. Recommended methods include:

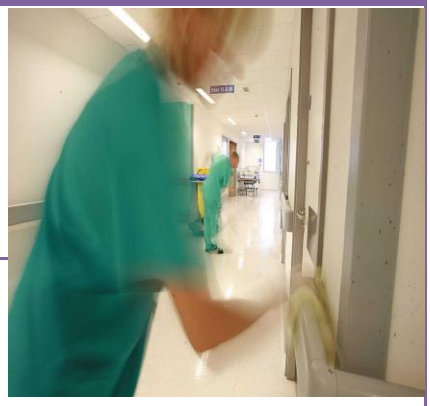
- Surface sampling before and after for specific organisms – subject to prior agreement with suitably qualified persons regarding surfaces, location, organisms and laboratory protocol. Details will be recorded onto the Validation Record and corresponding Floor Plan for future reference and audit.
- Surface seeding with sampling before and afterwards for specific organisms – subject to prior agreement with suitably qualified persons regarding surface seeding, location, organisms and laboratory protocol. Details will be recorded onto the Validation Record and corresponding Floor Plan for future reference and audit.
- Biological indicators of surrogate organisms inoculated onto test surfaces – subject to prior agreement with suitably qualified persons regarding location, organisms and laboratory protocol. Details will be recorded onto the Validation Record and corresponding Floor Plan for future reference and audit.
- Chemical indicators to indicate vapour movement and space penetration - subject to prior agreement with suitably qualified persons regarding location. Details will be recorded onto the Validation Record and corresponding Floor Plan for future reference and audit.

The DEPROX carries on board chemical indication for the purpose of the treatment cycle and designed safety features. When in routine use within the general hospital setting, as part of an enhanced cleaning programme, this would become the usual validation method unless under exceptional circumstances.

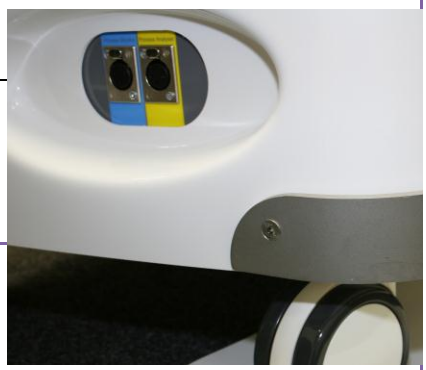


Work Method Statement:

This is a Method Statement specific to the Deprox HPRD system within an NHS Acute Trust:

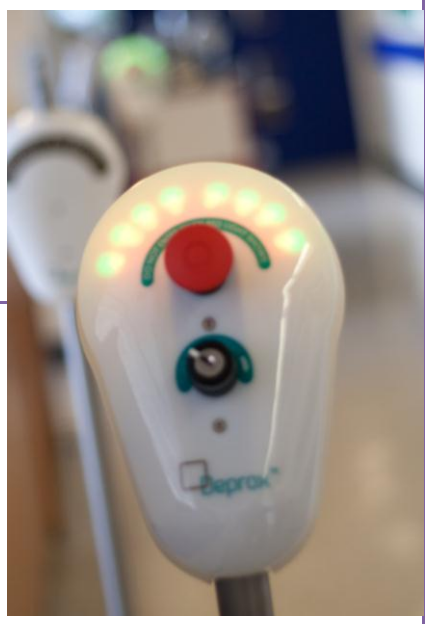
Action	Description	
1	Remove absorbent materials within the space such as linen, paper towels, tissues, curtains, gowns and any other porous materials. Ensure hospital protocol is followed	
2	Ensure the room has been manually cleaned to remove gross soiling, dust and dirt and ensure all surfaces within the room are dry. Ensure hospital protocol is followed.	
3	Remove all items that may have been used in patients ie: catheters, thermometers etc	
4	Remove any waste from the bins.	
5	Remove any food items, drinks water jugs etc.	
6	Turn any mattresses in the area on to their side.	

Action	Description	
7	Ensure bins and dispensers are opened.	
8	Turn chair cushions on to their side.	
9	Hold bathroom door open with a stool/chair/doorstop etc.	
10	Ensure cabinet drawers, bedside cabinets and cupboards are open.	
11	Close all windows.	
12	Seal the ventilation in the area to be treated using the Ventilation Restriction Kit.	

Action	Description	
13	Seal the fire alarm sensors in the area to be treated using the Fire Detector Cap Kit	
14	Place "Decontamination in progress" sign on all entrances into the area that you are going to run the process in. Ensure that these are put in a visible place to any persons that may approach the entrances.	
15	Operator informs senior person in surrounding area i.e. Senior Nurse of the proposed process and potential hazards: a. Process description b. Process cycle times and affected areas c. Hazards and risk reduction d. Protocol in the event of i. Fire alarm ii. Process termination iii. Vapour leakage	
16	Ensure ward staff are informed of the process taking place, who they should call in the event of a suspected issue and when the process is likely to finish	
17	Operator places the Deprox HPRD system in the centre of the room to be treated and secure wheels using the brakes.	
18	Operator unhooks the process analyser from the rear of the machine and plugs the cable into the yellow socket on the front of the machine.	

Action	Description	
19	Operator positions the process analyser away from the Deprox System.	
20	Operator unhooks the process monitor from the rear of the machine and plugs the cable into the blue socket on the front of the machine.	
21	Operator plugs the mains plug into a convenient socket.	
22	Operator presses the start cycle button the the control panel, both the red and green lights should be Illuminated on the process monitor.	

Action	Description
23	Check the Deprox HPRD system for Deproxin requirement. If a new Deproxin Cartridge is required: 1. Secure cap of remaining Deproxin cartridge 2. Remove empty Deproxin cartridge from main Deprox unit by holding the indented cartridge neck and pulling upwards from the Deprox main unit. Dispose of directly into waste bin (suitable for disposing in ordinary waste or recycling as PET). 3. Take new Deproxin cartridge by holding the indented cartridge neck and insert directly in to refill port on main Deprox unit. 4. Push down firmly to engage with extraction spears and release lid to first safety notch. The Deprox HPRD unit will now register the new cartridge and prepare for the decontamination cycle to start.
24	When the Deprox HPRD system is ready to start, double check the room and its contents are ready and move out of the room.

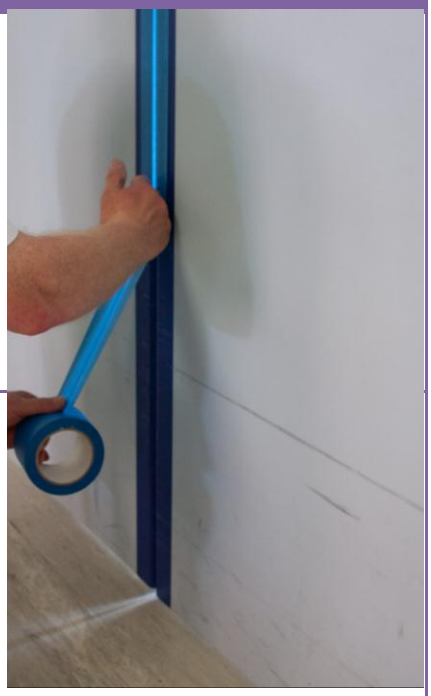
Action	Description
25	Complete the Operator checklist on the reverse of the Decontamination in progress sign to ensure that all areas have been completed appropriately. 
26	Close and seal the exit doors and secure with double door bar. Clearly mark the start time and estimated finish times on the Decontamination warning sign. 
27	Turn the key once in the process monitor outside the room. THE DEPROX HPRD SYSTEM IS NOW RUNNING DO NOT RE-ENTER THE ROOM. a. The DEPROX system starts emitting vapour into the space. The Process Analyser detects a change in the environmental parameters and monitors a rise to the required predetermined level of H2O2 vapour within the space. During this phase the Process Monitor outside the room will display a 'solid' RED light to indicate to personnel in adjacent areas of the process status and potential hazards. 

2.

a. On reaching the required level of H2O2 vapour within the space, the DEPROX with terminate the initial vaporisation cycle and maintain a consistent H2O2 vapour level within the space for the duration of the surface treatment cycle. During this phase the Process Monitor outside the room will display a 'solid' RED light to indicate to personnel in adjacent areas the process status and potential hazards.

b. On completing the surface treatment cycle the DEPROX starts the deactivation process, reducing the H2O2 vapour level back to within the EWEL (European Work Exposure Limit) of >1ppm. During this phase the Process Monitor outside the room will display a 'solid' RED light and a 'flashing' GREEN light to indicate to personnel in adjacent areas the process status and potential hazards.

c. On completion of this phase the DEPROX system automatically resets in preparation for the next cycle. At this point the Process Monitor outside the room will display a 'solid' GREEN light to indicate to personnel in adjacent areas the process status.

Action	Description	
28	When the process is finished the Process Monitor outside the room will show a 'solid' GREEN light.	
29	Unlock the door and remove signage and sealant tape.	
30	Check that the process has completed successfully on the main Deprox display unit.	
31	Operator switches off the wall socket and unplugs the Deprox System.	

Action	Description	
32	Operator unplugs the process monitor and process analyser and re-stows the monitors onto the rear of the Deprox unit.	
33	Remove the packed Deprox HPRD unit from the room and move to the dedicated store room.	
34	Open windows to ventilate room	
35	Remove Ventilation Restriction covers from all ventilation.	
36	Remove any fire detector covers.	
35	Remove sealing from doors and windows	
34	Operator Informs senior ward staff that the process is complete.	