Deprox™

# Risk Analysis and Hazard Reduction Report

V1.0

Hygiene Solutions
Integrated infection control

# Contents



# 1. Definitions and Risk Classification:

**This document follows a standard risk evaluation and preventative action processes to understand and minimise risk and hazard to operators and process efficiency.**

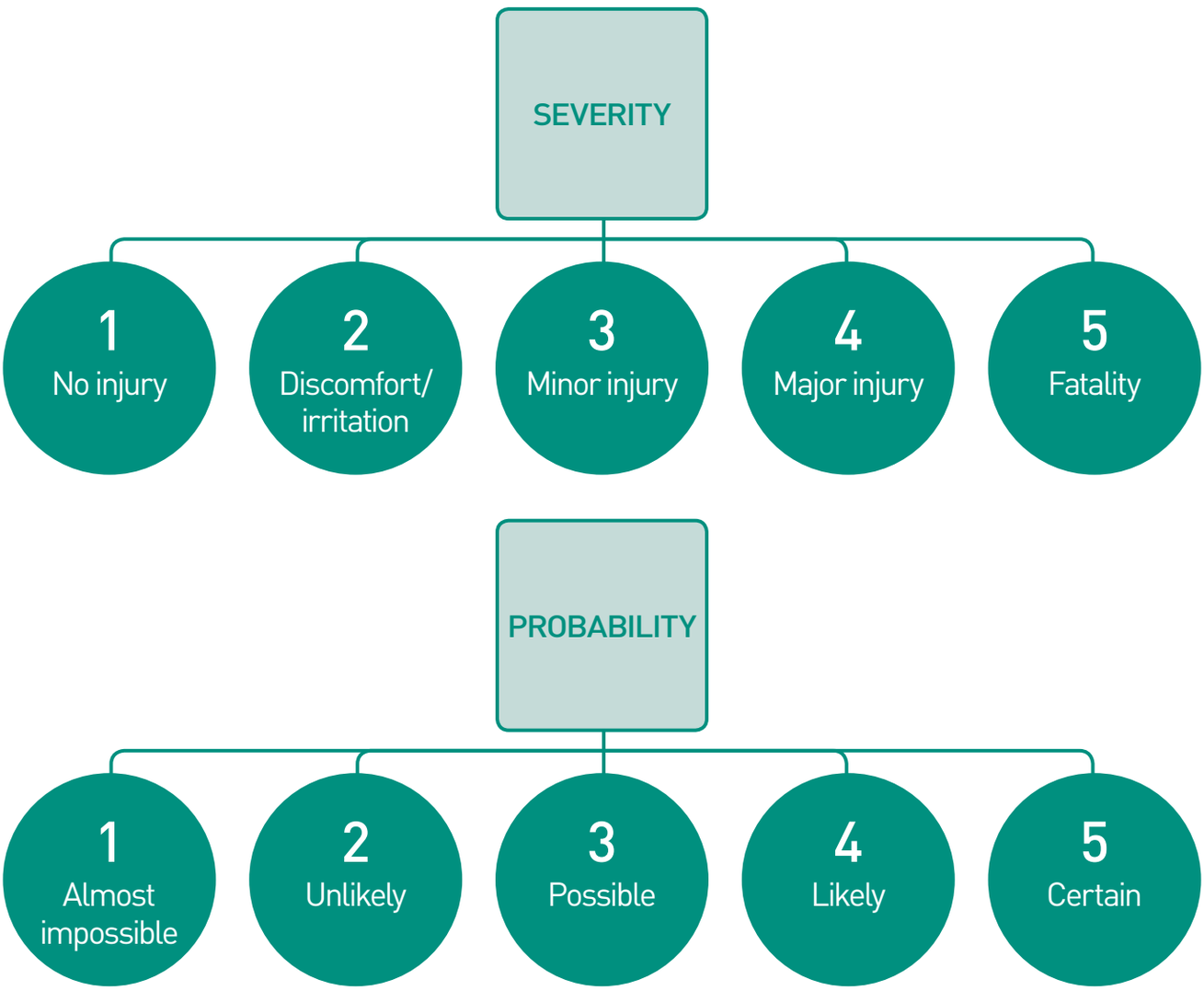
Through a process of implementation and audit of standard operating procedures, risks associated with the Deprox™ Decontamination Process can be minimised independent of operator ability, ensuring safe operation of the Deprox™ System within the healthcare setting.

For the purpose of traceability this document uses the Risk Calculation and Classification Methodology to evaluate levels of risk. The following classification categories are used to rate the severity and probability of each individual risk.

## Multiplied Risk Score Categories:

| | | |
|---|---|---|
| 1 - 4 = | Low Risk | LR |
| 5 - 7 = | Medium Risk | MR |
| 8 - 10 = | High Risk | HR |
| 11 - 14 = | Very High Risk | VHR |

In the interests of corporate responsibility, Hygiene Solutions will not participate in activities that are categorised as Very High Risk.



# 2. Risk and Hazard reduction associated with Personnel:

| IDENTIFIED RISK | SEVERITY | PROBABILITY | RISK SCORE | COMMENT | PREVENTATIVE ACTION |
|---|---|---|---|---|---|
| What unusual risks are the operators potentially exposed to when replenishing the Deprox™ System with Deproxin chemical? | 1 | 2 | 2 LR | The Deproxin™ chemical is contained within a bespoke PPE plastic container with vented cap. If dropped from above 1.5m, squashed or impacted severely there is risk of spillage. | Operator to follow procedure as covered in the section 4.7 of the Training and Operator Manual. The refill loading port on the Deprox™ System is easy to access and is a closed loop system requiring no direct operator contact. |
| Can the operator be exposed to Deproxin/Hydrogen Peroxide solution when setting up, dissembling or transporting the Deprox™ equipment? | 1 | 3 | 3 LR | On removal of an empty Deproxin™/Hydrogen Peroxide container, there is risk of residual fluid remaining in bottle which could spill. | Operator to follow procedure as covered in the sections 4.7 and 4.8 of the Training and Operator Manual and invert bottle on removal of empty container from refill port and the use of PPE – disposable gloves and apron. |
| Are the Deproxin chemical refills stored safely during transport and whilst on site? | 1 | 1 | 1 LR | The Deproxin™ fluid is a 4.9% Hydrogen Peroxide solution, therefore not classified as 'Hazardous' and requires no special handling or storage arrangements.<br>Mishandling of packaged Deproxin refills could result in spillage. | The Deproxin™ chemical refills are stored upright in sealed cartons until required for use. For more information see section 1.3 of the Training and Operator manual. |
| Is there a Spillage Action Procedure in place in the event of a spillage incident? | 3 | 1 | 3 LR | The Deproxin™ fluid is a 4.9% Hydrogen Peroxide solution and not classified as 'Hazardous'. | By design all Deproxin™ refill are handled and inserted as sealed containers. In the unlikely case of spillage operator to follow procedure as covered in section 4.8 of the Training and Operator manual. |
| Does the Deproxin™ refill chemical carry the appropriate warning and disposal labels and signs? | 1 | 1 | 1 LR | All Deproxin refills should carry the appropriate labelling before leaving the manufacturing plant. | All Deproxin™ refills are batch controlled following production to ensure appropriate labelling. Each carton of Deproxin™ refill chemical contains a full Safety Data Sheet. |
| Is appropriate PPE available to the operator in the event of spillage or leakage? | 3 | 2 | 6 MR | General PPE should be available to the operator including gloves, goggles, apron and disposal container | All On-Call Decontamination Service technicians carry Emergency Spill kits on the vehicle. |
| Is there risk of strain or injury to the operator as a result of moving and handling of the Deprox™ equipment? | 2 | 3 | 6 MR | The Deprox™ equipment weighs around 70kg when loaded to full capacity. The whole unit is mounted on substantial wheeled casters for easy manoeuvring. | Operator to follow procedure as covered in the section 3.1 of the Training and Operator Manual and not attempt to lift the Deprox™ equipment unaided. |
| Is there risk of strain or injury to the operator as a result of setting up and dissembling the Deprox™ equipment before and after the decontamination process? | 2 | 3 | 6 MR | There is potential risk for finger trapping from inappropriate handling of monitor stands.<br>There is potential risk of strain from bending to unpack and pack accessories into integral compartment. | Operator to follow procedure as covered in the sections 3.3 and 4.2 of the Training and Operator Manual and observe lifting and handling recommendations. |
| Is the operator exposed to moving parts, heavy loads or unusual risks when using the Deprox™ equipment? | 1 | 1 | 1 LR | By design the Deprox™ is a sealed system and does not require any mechanical intervention by the operator | No additional action required. |
| Is there risk to the operator being exposed to electrical high voltage? | 5 | 1 | 5 MR | The Deprox™ System is a mains powered device and if used inappropriately could present a risk. Communication cables for the Process Monitor and Process Analyser are low voltage. | Operator to follow procedure as covered in the section 3.1 of the Instruction Manual and carry out checks before using equipment. All Deprox™ equipment is periodically serviced and electrically checked in accordance with Electrical Safety Regulations. |

| IDENTIFIED RISK | SEVERITY | PROBABILITY | RISK SCORE | COMMENT | PREVENTATIVE ACTION |
|---|---|---|---|---|---|
| Are operators exposed to excessive heat or cold as a result of the Deprox™ decontamination process? | 1 | 1 | 1 LR | The Deprox™ uses high frequency ultrasonics to vaporise the Deproxin /Hydrogen Peroxide chemical and does not use traditional 'flash heat' vaporisation methods. | No additional action required. |
| Is there risk of leakage from the space during the treatment cycle to adjoining areas? | 3 | 2 | 6 MR | The Deprox™ standard treatment cycle reaches 87ppm of H2O2 in the environment being treated at its process peak. There is risk of leakage from areas being treated if inadequate pre-process sealing has not taken place. This risk may be increased when treating areas of pressure differentiation. Risk of H2O2 concentration rising to above the EWEL of >1ppm. | Operator to follow procedure as covered in the section 3.3 of the Training and Operator Manual and ensure areas are adequately sealed before commencing process. The Deprox™ system has inbuilt leak detection capabilities and will terminate the cycle if it detects this. In areas of significant leakage risk the operator should remain in supervision of the Deprox™ process. In event of a leak the Deprox™ will terminate the cycle, but not immediately as it can take up to 59 minutes. See section 5.10 vaporising error. |
| Is there risk of personnel inadvertently entering the area being treated, during the process and being exposed to high levels of H2O2 vapour? | 3 | 3 | 9 HR | The Deprox™ standard treatment cycle reaches 87ppm of H2O2 in the environment being treated. This is significantly lower than traditional HPV 'gassing' processes. Personnel could enter the area and be exposed to this level of H2O2 vapour. | The room should be sealed to prevent entry, as covered in the section 3.3 of the Training and Operator Manual. If breached the Deprox™ will continue to fog until it either failed its process 5.10 vaporisng error or someone pressed the emergency stop triggering the deactivation cycle 45 minutes. |
| Is there risk to the operator in the event of system failure or emergency? | 3 | 2 | 6 MR | In the event of system failure, the Deprox™ automatically goes into deactivation. There is no reason to enter room. If needed to then the proper PPE would be required due to high levels of H2O2. | The Deprox™ reacts to system failures by entering deactivation 45 minutes automatically. Operator to follow procedure as covered in the Training and Operator Manual . |



# 3. Risk and Hazard reduction associated with Process:

| IDENTIFIED RISK | SEVERITY | PROBABILITY | RISK SCORE | COMMENT | PREVENTATIVE ACTION |
|---|---|---|---|---|---|
| Is there risk of spontaneous combustion as a result of the Deprox™ process? | 1 | 1 | 1 LR | The peak H2O2 vapour concentration in the environment during the treatment cycle does not present the risk of auto-ignition | The Deprox™ has on board process calibration to ensure the H2O2 levels in the environment are closely monitored throughout the treatment process. |
| Are there trip hazards associated with the set up and use of the Deprox™ equipment? | 4 | 2 | 8 HR | There are potential trip hazards from the cables used between the mains power input the Process Monitor and Process Analyser. | The operator to follow procedure as covered in the sections 3.3 and 4.2 of the Training and Operator Manual. If significant risk is present, operator to use suitable cable covers. |
| Is there risk of electrical components within the Deprox™ becoming wet? | 5 | 1 | 5 MR | If the Deprox™ equipment is subjected to excessive impact, inversion or liquid exposure there is potential risk. | The electrical components of the Deprox™ are contained within a IP45 rated box. The Deprox™ is designed with industry standard electrical safety features. |
| In the event of power failure will the Deprox™ equipment abort the treatment cycle? | 3 | 1 | 3 LR | In the event of power failure or interruption the Deprox™ Process Monitor will display no visual light. When the power is reinstated the Deprox™ System will automatically switch into deactivation cycle as a preventative measure. | The operator to follow procedure as covered in the section 4.5 of the Training and Operator Manual. If no lights display on the Process Monitor, Qualified Operator only should re-enter the area with suitable PPE including breathing apparatus. |
| Is there risk of ineffective process delivery as a result of system failure? | 2 | 1 | 2 LR | If the Deprox™ system fails to emit sufficient H2O2 vapour into the area being treated the system will abort process and fail safe. | The operator to follow procedure as covered in the section 5 of the Training and Operator Manual and ensure failed processes are rectified and reinstated. |
| Is there risk of ineffective process delivery as a result of restricted air dynamics within the treated space? | 3 | 1 | 3 LR | If the contents of the room are not prepared appropriately the vapour generated will not penetrate the whole environment and spacial differentiation may occur resulting in reduced efficacy on surfaces. | The operator to follow procedure as covered in the section 3.3 of the Training and Operator Manual and prepare room contents to maximise exposed surfaces and treatment efficacy. |
| Is there risk of residual H2O2 vapour being present at the end of the treatment cycle? | 2 | 2 | 4 LR | If the room contains excessive quantities of absorbent material, the deactivation cycle of the Deprox™ process may be extended. | The operator to follow procedure as covered in the section 3.3 of the Training and Operator Manual and remove as much absorbent material as possible from the environment before commencement of the Deprox™ process. Section 4.121 of the instruction manual recommends the use of a H2O2 gas monitor to determine level of residual H2O2 vapor. |
| What is the risk as a result of damage or loss of communication to the Process Monitor and Process Analyser? | 1 | 2 | 2 LR | In the event of loosing communication with the Process Monitor or Analyser the Deprox™ will automatically go into deactivation cycle and fail safe. | By design the Deprox™ will test connectivity integrity with the Process Monitor and Analyser before starting the treatment process. If damage is detected, the Deprox™ will abort the Pre-Process check and fail safe as covered in the sections 5.2 and 5.3 of the Training Operator Manual. |
| What is the risk of inadequate supply of Deproxin™/Hydrogen Peroxide solution during the treatment cycle? | 1 | 1 | 1 LR | By design the Deprox™ will fail to start the decontamination process with insufficient Deproxin/Hydrogen Peroxide solution to effectively finish the cycle. | No additional action required. |


Deprox™
WARNING
Read instruction manual before use.
Do not tilt unit from vertical.
Fully extend mains cable before use.
Use only approved fluids.
Do not remove refill bottle until instructed to do so.
www.hygiene-solutions.co.uk Made in the U.K.
Deprox™

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Contact us now for more information about what Hygiene Solutions can do for you:

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