# Evaluation and Response to Incidents of Temperature and Humidity Extremes in the Medical Device Reprocessing Area, Sterile Storage Area, and Decontamination Area

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## OBJECTIVE

To provide direction about:

- Daily monitoring and documentation of the temperature and relative humidity in medical device reprocessing area (MDRA) and sterile supply areas located in the MDRA.
- Actions to be taken if the recommended humidity is exceeded.

## APPLICABILITY

Compliance with this document is required by all Alberta Health Services employees, members of the medical and midwifery staff, students, volunteers, and other persons acting on behalf of Alberta Health Services (including contracted service providers as necessary) working within MDRAs.

See also *Evaluation and Response to Incidents of Temperature and Humidity Extremes in the Surgical Suite* for guidance about the surgical suite and any sterile supply areas outside MDRA.

## ELEMENTS

1. The facility shall monitor and document relative humidity (RH) levels and temperature at least daily.
   Current guidelines recommend the following:
   - RH levels of 30 to 60%.
     AND
   - Temperature between 18°C to 23°C within MDRAs and between 22°C to 24°C for storage areas within the MDRAs

   RH measures water vapour but is relative to the temperature of the air. It is expressed as



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the amount of water vapour in the air as a percentage of the total amount that could be held at its current temperature.

2. The table below outlines recommended actions based on RH and temperature.
    - The time interval of concern depends on the circumstances of a particular event.
    - Also take into account the larger picture beyond RH, temperature and time parameters when deciding next steps (e.g. staff/physician discomfort, wet packs, visible condensation, etc.).
    - Once RH exceeds 60% and temperature exceeds 24°C, recommended actions in the table below should be followed as a **proactive** measure.
    - RH exceeding 70% should be treated as an event that needs an **immediate** response. If packages are exposed to these conditions for prolonged periods, sterility might be compromised.

3. A multidisciplinary team (MDT) should be assembled to coordinate further notifications and to evaluate corrective actions. The MDT may include (but is not limited to):
    - Site MDRA Executive Director or designate
    - Facilities Maintenance and Engineering (FM&E)
    - Surgery Program Unit Manager and/or Patient Care Manager
    - Surgery Program Executive Director
    - Surgery Program Chief or designate
    - Infection Prevention and Control (IPC)
    - IPC Physician
    - Workplace Health and Safety (WHS)
    - Site Administration/Senior Leadership
    - Site Medical Director
    - Other program representatives as appropriate

4. Occasional incidents during which the relative humidity rises to between 60% and 70% are generally not considered cause for concern for the safety of medical devices. However, frequent incidents of this nature indicate that HVAC systems may need to be adjusted or improved.

5. This document has a focus on higher than acceptable RH. In some instances, RH may be lower than acceptable (i.e. less than 30%).
    - Follow a similar process; also consider RH level, timelines, and other specific circumstances.
    - Assemble an MDT to coordinate further notifications and to evaluate possible corrective actions.



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## TABLE 1: LEVEL OF CONCERN and ASSOCIATED ACTIONS

**Note:** The time interval of concern depends on the circumstances of a particular event.

| Levels of Concern [Minimum Triggers] | Actions | Sterile Supply and Packages |
|---|---|---|
| **Level 0 (Baseline)**<br>RH shall be maintained between 30% and 60% in all areas.<br><br>Temperature parameters differ by functional area:<br>• Preparation and packaging/ clean workroom temp 18°C to 23°C<br>• Decontamination/ soiled workroom temp 18°C to 20°C<br>• Sterile storage room temp 22°C to 24°C<br>• Sterilizer equipment room temp 20°C to 23°C | • No action required.<br>• Continue regular monitoring. | • No action required. |
| **Level 1 (Mild)**<br>If RH is 61% to 65% [intermittent] | • There is a temperature or humidity concern identified by either FM&E or the MDRA:<br>  ○ MDRA notifies FM&E or<br>  ○ FM&E notifies MDRA.<br>• FM&E verifies the RH and temperature.<br>• Once verified, FM&E will monitor to assess if the RH or temperature continue to rise and begin corrective actions.<br>• MDRA staff notify MDRA leadership of situation.<br>• MDRA staff monitor operating conditions within the MDRA and report any staff comfort concerns to MDRA leadership. Worker Incident Report should also be submitted.<br>• FM&E to report status updates at regular intervals to MDRA leadership and FM&E leadership until the situation is under control.<br>• MDRA leadership reports possible issue to site leadership.<br>• MDT may be assembled (recommended). | **[Applies to all levels]**<br><br>Perform a risk assessment (i.e. moisture assessment) to determine which sterile packages can be used and which should be reprocessed or discarded.<br><br>**No visible effects of moisture:**<br><br>• Use sterile packs as usual and as able.<br><br>• If humidity concerns continue, MDRA leadership may consider transfer of sterile packages to an alternate location with controlled humidity.<br><br>**Visible effects of moisture:**<br><br>• Do not use packages that are visibly wet or damaged |
| **Level 2 (Moderate)**<br>If RH is greater than 65% and less than 70% [for extended periods less than 4 hours] | • MDRA staff notifies MDRA leadership and FM&E.<br>• FM&E to take corrective actions to control RH and temperature. FM&E to advise MDRA leadership prior to increasing the room temperature to control RH. | |



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| | • FM&E to advise MDRA leadership if either RH or temperature cannot be controlled below 65% and 24°C.<br>• MDRA staff monitor if humidity is affecting either MDRA operation or staff comfort level and reports changes to MDRA Leadership. Worker Incident Report should also be submitted.<br>• MDRA leadership reports possible issue to site leadership and MDT is assembled. | (e.g., label peeling due to moisture or visible moisture on the package).<br>• MDRA staff shall notify MDRA leadership of the possible impact to sterile products.<br>• MDRA staff shall assess sterile packages to determine if packages are compromised.<br>• Repack visibly wet or damaged packages and sterilize contents.<br>• Discard any single-use medical devices. |
| **Level 3 (Severe)**<br>RH exceeds 70%<br>[for greater than 4 hours] | • FM&E notifies MDRA leadership that the RH has exceeded 70% for greater than greater 4 hours.<br>• FM&E continues to work towards lowering RH or temperature to acceptable levels.<br>• MDRA staff continue to monitor staff comfort level in MDRA and report changes to MDRA leadership. Worker Incident Report should also be submitted.<br>• Site leadership and MDT meet to discuss:<br>  ○ staff comfort concerns,<br>  ○ staff safety issue / ability to maintain sterility during surgery,<br>  ○ risk of contamination to sterile supply, and<br>  ○ appropriate actions.<br>• Site leadership or MDRA leadership advises zone leadership.<br>• If the standard methods of reducing RH are not achieving the desired effect, use of a dehumidifier may be considered. See dehumidifier usage guide. | |

## DEHUMIDIFIER USAGE GUIDE

If an MDRA is the impacted area and continued operation is required to support ongoing patient care, use of a dehumidifier may be considered to reduce humidity extremes.

The dehumidifier shall be:

- dedicated to MDRA
- strategically placed to minimize air turbulence in the sterile field area (e.g. in the hallway)
- cleaned and disinfected after each use
- stored covered in the appropriate area

To prevent organism growth, two milliliters (2mL) of bleach shall be added to the reservoir for every liter of water the reservoir can hold when:

- The dehumidifier drain cannot be directed to a utility sink (utility sinks are different from hand hygiene sinks), or
- The dehumidifier reservoir is emptied (dehumidifiers shall be checked every two hours and emptied as required).



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Using a zone standardized form, sites shall document the following information:

- date
- time
- initials of staff member who emptied the reservoir tank and changed the bleach solution

Sites determine location of forms.

## REFERENCES

- Alberta Health Services Documents
  - Environmental Public Health: Cleaning and Sanitizing Food Contact Surfaces, Equipment, Toys and Other (PUB-0698-201404)
- Non-Alberta Health Services Documents
  - *Canadian Medical Device Reprocessing*. (Canadian Standards Association) (CAN/CSA Z314:23)

## VERSION HISTORY

| Date | Action taken |
|---|---|
| November 2018 | Initial approval |
| July 2024 | Last updated |
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