Risk assessment and escalation of temperature or humidity variation in perioperative and sterile stock environments

Introduction

The maintenance of recommended temperature and humidity in healthcare environments is necessary to ensure patient and health worker safety and comfort. This is particularly important in specialised areas, such as the operating theatre, perioperative environment, and sterile stock areas where reusable medical devices (RMDs) are stored in bulk. Where heating, ventilation and air conditioning (HVAC) systems are unable to maintain the recommended temperature and relative humidity, facilities are to have a local risk assessment and escalation process in place to ensure minimal impact to service provision.

Temperature and humidity variations that persist for extended periods in perioperative areas – including areas where RMDs are stored in bulk – can increase the risk to patient safety through:

- impaired sterility of stock
- operating or service list disruption
- discomfort to health workers, patients and visitors/carers
- environmental contamination
- damage to clinical equipment
- potential increased infection risk to patients
- financial implications
- workforce impact.

Optimising ventilation to reduce respiratory particle transmission and airflows for transmission-based precautions are equally important. Activities in support of those precautions are not covered in this document (refer to Infection Prevention and Control in Healthcare Settings PD2023_025).

Background

Published data on the impact of relative humidity on bacterial and fungal growth in healthcare is limited. The majority of publications appear to be either related to the food industry or buildings, particularly for fungi. Many bacterial pathogens have longer survival times with higher relative humidity, and fungal growth is increased.

When it comes to healthcare environments, ideally, the temperature range within the operating environment will vary in different locations (refer to Table 1). Individual operating rooms should have a temperature range of between 20°C and 22°C; this temperature range inhibits bacterial growth and is tolerated well by patients and health workers. However, the temperature may require adjusting to accommodate some types of surgery or the condition of individual patients. For example, a higher ambient temperature may be required for burns or paediatric patients, as these patients are highly susceptible to hypothermia. Lower ambient temperatures may be required for some types of neurosurgical procedures.

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Relative humidity (RH) is the amount of water vapor present in air expressed as a percentage of the amount needed for saturation at the same temperature. RH depends on the temperature and pressure of the system of interest. To acutely decrease the RH level of an operating room, either remove water vapor or increase temperature (it is unlikely that one would increase the atmospheric pressure). Cold operating rooms have a higher RH than warm operating rooms with the same absolute humidity.

The RH in the operating room should be maintained at between 50% and 60% to both inhibit microorganism growth (such as fungi and bacteria) and decrease risks associated with static electricity. The RH requirements in other perioperative areas, such as the sterile stock room, is between 35% and 70% and perioperative environment is between 40% and 60% (refer to Table 1).

The rationale for the current 30% lower limit is that Low RH:

- decreases the shelf-life of certain supplies, such as biological indicators and chemical indicators, used for sterilisation monitoring and electrocardiogram electrodes
- increases the chance of electrostatic discharge that could harm or interfere with electromedical equipment[5], and potentially spark a fire (this is less of a recent issue because the risk of electrostatic discharge is less with non-flammable anaesthetics and antistatic surgical gowns).

The rationale for the current 60% upper limit is that High RH:

- increases the chance of surface mould and mildew growth
- may increase the risk of wound infections
- is less comfortable for operating room personnel.

It should be noted that there is sparse experimental evidence documenting the exact levels where these risks increase.

Risk management

The clinical significance of variations in temperature and humidity can depend on many factors, including the duration of the event, the rapidity of the parameter changes, and the activities that occur in the affected locations.

The operational or functional capacity to fully control variations of inside temperature and humidity ranges may also depend upon HVAC system capacity load and response capability to external weather variations. Decreasing inside temperatures may impact and increase the RH.

In the case of perioperative environmental areas and any locations where bulk RMDs are stored, facility staff need to consider undertaking a risk assessment and develop a local response or trigger plan for activation in the event of variances outside the recommendations.

A risk assessment may be used as evidence that the operational breech had no negative safety consequence and may also be used as a basis for future performance evaluations.

Risk assessment steps

If the relative humidity is below or above 5% or the temperature below or above +/-1.5^{0}C for the specified period within the operating theatre, sterile stock area where bulk RMDs are stored or perioperative environment on the risk assessment, the responsible monitoring individual must notify relevant authorities. Escalation and review should occur at the earliest sign of variation ([1,7]).

The facility must conduct a risk assessment and initiate immediate action plans as per local response and recover plan in consultation with local engineers, sterilisation services, clinical professionals, management and infection prevention and control staff.

If unsuccessful in maintaining the recommended parameters in any of these areas continuously for more than 8 hours within any 24-hour period, the incident must be escalated to the highest authority within the facility to define necessary actions.

Table 1: Humidity and temperature thresholds

Area	Relative humidity (%)	Temperature ^{0}C	Time	Corrective actions
Operating theatre	Upper limit >60 Lower limit <35	Upper limit >22 Lower limit <18	2 hours	Inform facility engineers
Sterile stock area	Upper limit >70 Lower limit <35	Upper limit >25 Lower limit <18	8 hours	Conduct a risk assessment
Perioperative environment *	Upper limit >60 Lower limit <40	Upper limit >25 Lower limit <18	24 hours	Notify hospital management

* Recovery and other supporting spaces.

Suggested process or triggers for establishing appropriate humidity and temperature level in the perioperative area

Step 1

Evaluate the history of relative humidity and temperature in the area, where possible. Local facilities in consultation with subject matter experts (such as HVAC engineers, infection prevention and control, infectious diseases or microbiologists) to agree on the timeframe of the measurements (for example, between 30 and 60 minutes) and the length of time the facility wants to measure.

Step 2

Determine the relative humidity and temperature recommended for the clinical environment.

Step 3

Determine if conflicts exist between history, current parameters and product requirements.

Step 4

Assess the risk to sterile stock and patient care if the parameter variation continues. The following considerations should be given when conducting a risk assessment:

- identification or likely cause of the variation
- the duration of the expected outage and any likely reoccurrence risk (for example, predicted weather patterns and power access)
- the duration and magnitude of the variation in temperature and humidity, if any
- evidence of condensation, dampness, water splashes or water damage
- concern for compromise of equipment function or supply sterility
- the risks profile of the potentially affected supplies
- the manufacturers instruction for use (IFU) regarding supply or medication storage
- the level of gross contamination (for example, for water intrusion, if any)
- the presence or possibility of visible environmental fungi or microorganisms
- the effect on functionality of fixed and mobile equipment.

Step 5

Establish appropriate temperature and humidity level based on risk to sterile stock and patient care.

Additional timeframe considerations

Any humidity and temperature variation outside of the recommended parameters (refer to Table 1) should be escalated within a timeframe of between 2 and 8 hours. In the event an immediate rectification is not available, and remains persistent, the following steps should be considered.

In event of high humidity (>60%) for more than 18 consecutive hours

Where there has been a variation and humidity has been determined to be in the upper limit for more than 18 hours:

- Promptly assess all surfaces in the room, including walls, floors, furnishings, equipment, and sterile stock, for evidence of visible or tactile dampness.
    - If all visible surfaces are dry, locate items most likely to be affected (for example, RMDs and implantable devices)
    - Relocate supplies if there are concerns for storage at high humidity levels.

    - If any visible dampness is found, do not start any new operative or other invasive procedures until the humidity level no longer causes condensation. An exception may be made to proceed with emergency surgery ideally using surgical supplies from an area unaffected by the humidity event.
- All RMDs with evidence of moisture in or on the packaging are to be considered contaminated and should be reprocessed again.
- Consult with the local infection prevention and control team for additional assessments in conjunction with the perioperative team, and equipment and RMD manufacturers, if relevant.
- If condensation is observed during the intraoperative period, notify the surgeon of the potential risk to patient and failure in electrical equipment.
- Report any patient care that occurred in an area with visible dampness or mould growth as an event in the local incident reporting system.
- Discard any damaged supplies that cannot be reprocessed and determine if surgical procedure can continue safely.
- Report any visible dampness and/or mould growth as the event in the incident reporting system.

In event of low humidity (<30%) for more than 18 consecutive hours

Conduct a careful fire prevention risk assessment to identify if there are potential fire ignition hazards including any fuel, ignition, and heat or oxidizer sources. Take appropriate measures to prevent surgical fires, including:

- ensuring alcohol-based skin preparations do not pool and are fully dry before draping
- removing drapes soaked with antiseptic before using potential ignition sources
- seek specialist advice from engineering and fire safety experts in your service.

For high temperature for more than 18 consecutive hours

- Physically inspect all surfaces in the room for humidity and evidence of visible or tactile dampness.
- Assess supplies and review the manufacturer's IFU to ensure supply performance is not affected by high temperatures for the duration of the event.
- Relocate stored items likely to be affected by high temperatures.
- Discard any damaged supplies and conduct risk assessment to determine if operations can continue safely.
- Report the event in the incident reporting system.

For low temperature for more than 18 consecutive hours

- Review patient status especially those who are vulnerable to unintentional perioperative hypothermia, and reschedule if appropriate.
- Ensure the patient's temperature is monitored upon arrival to the postanesthetic care unit and until normothermia is reestablished.
- Promptly assess all surfaces in the room, including walls, floors, furnishings, equipment, and sterile stock, for evidence of visible or tactile dampness.
- Relocate items most likely to be affected by storage at low temperatures.
- Report the event in the incident reporting system.

Suggested mitigation steps

- The local maintenance team to check and re-set chiller settings, if needed, to accommodate increasing outside temperature.
- Engage appropriate experts (such as engineers) to analyse the role of energy efficiency strategies that may potentially contributing to increases in temperature +/- humidity.
- Check ventilation systems in adjacent parts of the hospital to make sure they are not having an impact that the operating theatre ventilation system is trying to compensate for (for example, energy efficiency measures, such as increasing ambient temperatures or decreased the function of air conditioning systems afterhours).
- Check air handling system capacity and, where able, increase.
- Outside air intake is key to ensure sufficient fresh air is available within the theatre. Steps should be taken to condition the outside air entering the operating suite.
- Consider dehumidification to reduce the humidity. However, these portable items can pose work health and safety issues. Location, placement, and type of dehumidifier are crucial due to potential changes to air flow and impact on sterile field. (Note: portable dehumidification devices can pose additional infection risk in the perioperative environment; if used, they must be cleaned, and water trap emptied).
- Implement an automatic monitoring system with active alerts when the temperature or humidity thresholds are exceeded, where possible or available. These devices require calibration and maintenance. Consider incorporating signs of condensation into the monthly checklist, particularly in low-risk areas.
- Establish a built-in process for facilities engineering services staff to perform early investigation and corrective action to restore temperature and humidity to normal parameters.
- Implement an active internal escalation, notification and response process to relevant stakeholders when out-of-range temperatures or humidity occur and are expected to be prolonged.

- Implement early decision-making by authorised team to relocate supplies and, when needed, stop procedures in consultation with infection prevention and control, infectious diseases/microbiologist and facilities engineering services.

Table 2: Recommended temperature and relative humidity as per various standards

Standard/ Guide	Area	Relative humidity range (%)	Temperature range (^{0}C) *
Health Engineering Services Guide:2022	Operating theatres	35–60	18–27
	Bronchoscopy Endoscopy Procedural room	35–60	20–23
	Sterile stock store operating theatres	35–60	20–23
AusHFG Part B 0190	Sterile stock store for RMDs	35–70**	Not exceed 25
ACORN	Operating theatres	50–60	20–22
	Sterile stock store	35–68	18–22
	Perioperative environment	40–60	18–24
AS 5369:2023	Sterile stock store	35–70	18–25
ASHRAE (US Guideline)	Operating theatres	20–60	20–24
HTM-03 (UK Guideline)	Operating theatres	Floating with max 60%	18–25

* Local adjustable +/1^{0}C from setpoint.

** Many commercial RMDs require <60.

References

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