



## **Guidance on Critical Ventilation System Risk Assessment Process and Factors**

This guidance document has been produced to provide assistance to healthcare professional with responsibilities for the management, maintenance and use of critical ventilation systems.

It aims to outline factors to consider when assessing any critical ventilation system to ensure that unplanned unavailability issues are as far as reasonably practical minimised and identify control measures or mitigation in managing the identified risks.

## **Acknowledgments**

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All members of the Specialist Ventilation for Healthcare Society

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## **Introduction**

Following concerns and incidents of ventilation system catastrophic failures during use, primarily around operating theatre plant and the potential impact on patient safety this risk assessment, guidance has been produced to outline the areas for consideration when undertaking an assessment of risk and impact for healthcare premises which may have high risk, vulnerable or ageing ventilation plant or systems and need additional consideration / monitoring to minimise the risk of catastrophic failure in use.

Critical ventilation systems in healthcare are often necessary to dilute airborne micro-organisms and protect or separate potential sources of contamination from patients, users, or staff. As such the ventilation systems can be considered as control measures to control substances which can be hazardous to health. Whilst clinical assessment is used to identify and control known risks the ventilation system should be assessed to ensure as far as reasonably practicable the systems continue to function reliably and unplanned interruptions are minimised.

Full and detailed risk assessments with emergency actions and contingency plans should be provided for all critical ventilation systems.

The use of a standard 5x5 impact and likelihood scoring system should enable healthcare staff to identify and prioritise those systems at greatest risk, although it is strongly recommended that the assessment is undertaken by a multi-disciplinary team involving Estates, Infection Prevention Control and Clinical team members to ensure a comprehensive review.

## **Factors to be considered**

Below is a list of elements that may need to be considered and assessed when completing a critical ventilation system risk assessment process. A template for recording and scoring is appended. This list may not be comprehensive and it is recommended that this be used as a basis for discussion to develop a site specific range of factors to assess.

### **Age of system / Unit**

In general terms an air handling unit once properly installed, commissioned and validated will have an anticipated working life of between 15 to 25 years. As a unit ages it will tend to follow a recognised 'bath-tub' curve of reliability. Once through any initial teething issues a unit and system will normally operate with a relatively low risk of failure for the first three quarters of its anticipated life (say from year 1 to year 12-15) and be considered as low risk. Once into the final quarter of its estimated lifespan the risk would normally increase to a medium risk rating. Any unit or system which continues beyond its anticipated working life should be considered and assessed as high risk. This is not only based upon age and normal wear and tear but is also informed by the availability of spares and replacement components.

### **Hours of Operation / intensity of use**

Systems which operate 24/7 such as ITU's, critical care units, infectious disease isolation units, or aseptic pharmacies must be considered as a high risk. Systems which operate daily for long periods such as operating theatres, CSSD's, or endoscopy suites would normally be considered as medium risk with occasionally used systems such as LEV's or treatment rooms being low risk. However any assessment must take full account of specific site circumstances, with input from all stakeholders.

### **Complexity of system**

Any critical ventilation system should have a dedicated unit serving a single defined clinical area, however many of the systems present in a healthcare setting can be very complex, both in terms of layout and system control and configuration. Putting it simply the more complex and intricate the system the more elements there are which could fail and if due to original design constraints or subsequent system modifications the system is complex then an assessment of risk needs to be made to quantify the relative risk of each system.

### **Location of AHU**

If air handling units are located externally or on roofs they are likely to have a significantly reduced working life expectancy and be more vulnerable to breakdowns or environmental issues, however this can be further exacerbated by access issues for replacement components and parts (craning / lifting issues). Therefore external units / systems are likely to be considered as high risk within this factor. Units mounted internally but within ceiling voids or very congested plantrooms whilst being protected from external environments can also have considerable access issues and as such would be considered as medium or high risk depending upon the severity of access issues. Units located in plantrooms with good or adequate all round access to components and located at ground level with minimal obstructions would be considered as low risk within this factor.

### **Identified elements with single point of failure risk**

Almost all ventilation systems will have elements which incorporate potential single points of failure. Typically and in accordance with HM 03-01 fans should have dual motors, although this is becoming increasingly replaced by the use of plug fan units which are intended to enable ease of replacement or change in the event of a problem. That said most systems have single air intakes, heating or cooling coils, humidifiers, and fan units or shafts where a single bearing failure can leave the unit in-operable. Some measures can be taken to minimise these risks provided an assessment is made prior to operation of what and how to manage these single points of failure. In some cases systems may be able to be operated with some elements temporarily by-passed to maintain basic operation, such as isolation of heat recovery batteries or isolation of humidification, provided it is clinically acceptable. Other options could include standardisation of fan and motors with specific fan design performances achieved through VSD controls. This would enable a limited number of replacement units to be held 'in stock' to facilitate repairs to be undertaken quickly. Another area of potential standardisation is for heater or cooling batteries where if a standard size can be set replacement units could be held which would fit a number of units on site. This approach to resilience planning is likely to be a long term goal and would take years to be adopted across an entire site, however if started could reduce potential risk of unavailability or at least minimise disruption when and if failure occur.

### **Anticipated likely timescale for repair / replacement**

The time taken from a failure or fault being identified and its subsequent repair can vary wildly depending upon the nature and extent of an issue. Changing a broken drive belt or switching a fan motor (if not automatic) can take only a few minutes, although the issue of practically raising an issue, getting 'on site' to investigate and instigating even a simple reset or repair is likely to take between 30 to 60 minutes. If the issue requires a full system shutdown, replacement of AHU components and re-validation to confirm correct operation the disruption to clinical services is likely to be measured in terms of days or even weeks. This can be further extended if spare or replacement parts need to be designed and manufactured.

### **Level of monitoring / maintenance**

If a critical ventilation system is subject to the minimum levels of quarterly inspection (as required by HTM 03-01) then the system is compliant, however this level and extent of inspection and maintenance provides limited assurance of preventative maintenance. If a system is critical to clinical service by extending the remit of the maintenance activities, increasing the frequency, or/and undertaking trend analysis of both breakdowns and operational parameters the risk of unforeseen 'in use' failures can be significantly reduced.

### **Number of critical areas served and alternative location availability**

As previously stated above any critical ventilation system should have a dedicated unit serving a single defined clinical area, however many of the systems present in a healthcare settings have historic issues which have resulted in single units serving two or more theatres or clinical areas. This approach whilst potentially reducing initial capital cost can have a significant impact to clinical disruption in the event of a failure event. Healthcare organisations are also increasingly driven to maximise occupation and usage rates for critical areas such as theatres and whilst this maximises clinical throughput it can lead to situations where in the event of a failure there are no suitable alternative areas where care or treatment can be continued. An example would be a suite of theatres where all theatres are in use, if one theatre becomes unusable in the middle of a complex or lengthy operation where else could the patient be moved which is safe to continue the operation.

### **Criticality of patient risk**

Finally the issue of patient vulnerability needs to be assessed. This can be a very difficult issue to quantify as it can change constantly due to patient profiles and conditions, however an assessment should be made for both routine and exceptional patient types to establish and try to quantify the appropriate level of risk in any given critical ventilation system failure event. Highly infectious or highly vulnerable patients will always be considered as a high risk. Those undergoing invasive procedures will similarly be high risk, however some less or minimally invasive procedures or more general patient categories are likely to have medium or even low risk characteristics. Some systems could exclude this assessment completely such as LEV's as the system should not be used if not working correctly, however the impact to patient care still needs to be acknowledged and addressed if appropriate.



## Risk Rating Definitions

### Impact

**Catastrophic (5)** A rating of catastrophic should be interpreted as incurring an extreme / critical risk in the event of failure. This would be a death, or multiples, legal prosecution, or significant/ permanent loss of service / business capacity. It also is connected with the overall cost implications.

**Major (4)** A rating of major should be interpreted as incurring a major / critical risk in the event of failure. This could be a major injury or dangerous occurrence, HSE prohibition, legal prosecution, or significant loss of service / business capacity. It also is connected with the overall cost implications.

**Moderate (3)** A rating of moderate should be interpreted as incurring a significant risk in the event of a failure. This could include time loss injury, HSE improvement notices or investigation, or a loss of service / business capacity. It also is connected with the overall cost implications.

**Minor (2)** A rating of minor should be interpreted as incurring a manageable risk in the event of a failure. This could include minor injury, near misses with potential HSE investigations / reports, or a minor loss / interruption of service / business capacity. It also is connected with the overall cost implications.

**Insignificant (1)** A rating of insignificant should be interpreted as incurring a minimal risk in the event of a failure. This could include a near miss with no potential of injury, or a minor interruption of service / business capacity. It also is connected with the overall cost implications.

**Likelihood** - The likelihood of any occurrence is also scored against a 5 category probability system of:  
- Rare (1), Unlikely (2), Possible (3), Likely (4), & Almost Certain / Certain (5).

### Overall Risk Rating

These two scoring systems are then multiplied to ascertain an overall risk rating for any given issue.

**High** A rating of high should be interpreted as incurring a major / critical risk in the event of failure. This could be a death, legal prosecution, or significant loss of service / business capacity. It also is connected with the overall cost implications and likelihood of occurrence.

**Medium** A rating of medium should be interpreted as incurring a significant risk in the event of a failure. This could include serious injury, HSE prohibition notices, or a minor loss of service / business capacity. It also is connected with the overall cost implications and likelihood of occurrence.

**Low** A rating of low should be interpreted as incurring a minimal risk in the event of a failure. This could include minor injury, HSE investigation, or a minor loss of service / business capacity. It also is connected with the overall cost implications and likelihood of occurrence.



**Critical Ventilation System – Risk Assessment**

System reference / area served \_\_\_\_\_

Elemental Factor	Impact	Likelihood	Risk Rating	Mitigation	Revised Impact	Revised Likelihood	Controlled Risk Rating	Comments
Age of system / Unit								
Hours of Operation / intensity of use								
Complexity of system								
Location of AHU								
Identified elements with single point of failure risk								
Anticipated likely timescale for repair / replacement								
Level of monitoring / maintenance								
Number of critical areas served and alternative location availability								
Criticality of patient risk								
Other Identified areas of risk assessment								

**All risk ratings are based on a range of 1 to 5 (1 being very low or minimal to 5 being very high or critical)**



## **Conclusions / Recommendations**

It is recommended that a risk assessment is undertaken by a multi-disciplinary team involving Estates, Infection Prevention Control and Clinical team members to ensure a comprehensive review.

This assessment should include and consider all factors which may affect the management of the clinical area, the ventilation system and the mitigation which could be developed or adopted to minimise the risk of unplanned unavailability.

## **References**

HTM03-01 Specialised ventilation for healthcare premises. Part A Design and installation

HTM03-01 Specialised ventilation for healthcare premises. Part B Operational management and performance verification

Health Technical Memorandum 00 - Policies and principles of healthcare engineering 2014 edition

Health Building Note 00-07 - Planning for a resilient healthcare estate 2014 edition

CIBSE Guide B: 2002 Heating, ventilating, air conditioning and refrigeration

CIBSE Guide M: 2014 Maintenance engineering and management

National Health Service Model Engineering Specification C04 – Mechanical Ventilation & Air Conditioning Systems (Revision 3: 1997)

HVCA SFG 20 – Standard Maintenance Specification for Services in Buildings