



Healthcare Human Factors

University Health Network

In-Room HEPA Cleaners: Guidance Document

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Abbreviations

All	airborne infection isolation
ACH	air changes per hour
ASHRAE	The American Society of Heating, Refrigerating, and Air-Conditioning Engineers
CDC	US Center for Disease Control
CSA	Canadian Standards Association
DOP	dioctyl phthalate
eACH	equivalent air changes per hour
ECRI	Emergency Care Research Institute, now known as ECRI Institute
FDA	US Food and Drug Administration
HEPA	high efficiency particulate air
HHFG	Healthcare Human Factors Group
HVAC	heating, ventilation and air-conditioning
ICEP	Infection Control Expert Panel
MAS	Medical Advisory Secretariat
MDT	multi-disciplinary team
MoHLTC	Ministry of Health and Long-Term Care
OHTAC	Ontario Health Technology Advisory Committee
PE	protective environment
PHAC	Public Health Agency of Canada
PPE	personal protective equipment
RFP	request for proposal
SARS	severe acute respiratory syndrome
TB	tuberculosis
US	United States
USACHPPM	US Army Center for Health Promotion and Preventive Medicine
UVGI	ultraviolet germicidal irradiation

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1 Introduction

In November 2005, the Ontario Health Technology Advisory Committee (OHTAC) reviewed the available evidence on air cleaning technologies compiled by the Medical Advisory Secretariat (MAS) of the Ministry of Health and Long-Term Care (MoHLTC). OHTAC recommended that with appropriate consultation, in-room high-efficiency particulate air (HEPA) cleaners¹ may be used to meet the ventilation requirements in standards² when it is not practical to do so using the heating, ventilation, and air conditioning (HVAC) system (OHTAC's complete recommendations can be found in Appendix 4.1). An additional recommendation was that the University Health Network (UHN) Healthcare Human Factors Group (HHFG) evaluate the current use of in-room HEPA cleaners in Ontario hospitals (24).

The complete findings and recommendations from HHFG's evaluation can be found in the following report: In-room HEPA Cleaners: Current and Recommended Practice (2007) (http://www.ehealthinnovation.org/MOH_Publications). Overall, the evaluation determined that there are a wide variety of options associated with this technology and that there was a need for guidance regarding its safe and effective use. This guidance document provides a summary of the complete report and is divided into three sections:

- Background: provides information on the ventilation controls required to effectively isolate patients on airborne precautions
- Key recommendations: summarizes the main recommendations to help health care facilities appropriately plan, acquire, install, configure, commission, operate, and support in-room HEPA air cleaners
- Appendix: includes additional information to supplement the recommendations and is linked to the main body of this guidance document through cross-references

The recommendations presented in this guidance document are based on national and international standards and guidelines, but in addition, an Infection Control Expert Panel (ICEP) was convened for their advice. The ICEP included:

- Dr. Michael Gardam, Director, Infection Prevention and Control, Medical Director, Tuberculosis Clinic, University Health Network;
- Dr. Allison McGeer, Director of Infection Control, Mount Sinai Hospital; and
- Dr. Mary Vearncombe, Medical Director, Infection Prevention and Control, Sunnybrook Health Sciences Centre.

¹ In this report, the term "unit" and "device" will at times be used to refer to an in-room HEPA cleaner.

² Various standards and guidelines have been published by national bodies regarding environmental controls in health care facilities, including, but not limited to, the Canadian Standards Association (1), Health Canada (2,3,4), The Lung Association (4), the US Center for Disease Control (CDC) (5,6,15,18), ECRI Institute (7,16), American Institute of Architects (AIA) (9), The American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) (10,11), and The US Army Center for Health Promotion and Preventive Medicine (USACHPPM)(8).

2 Background

The US Center for Disease Control (CDC) defines airborne transmission as occurring by the “dissemination of either airborne droplet nuclei or small particles in the respirable size range containing infectious agents that remain infective over time and distance” (18). The diseases known to be transmitted by the airborne route are varicella (chicken pox), tuberculosis (TB), measles (rubeola), and to some extent smallpox (18).

The management of airborne infectious diseases is achieved using the following hierarchy of controls: administrative (work practice) controls, environmental controls, and personal protective equipment (PPE) (6). The first and most important control, administrative controls, includes various managerial measures to reduce the risk of exposure to airborne pathogens by uninfected persons, including the prompt detection, isolation, and treatment of suspected or confirmed airborne infectious patients. However, the main interest for this report is the second level of controls, environmental controls. In-room HEPA cleaners have the potential to help facilities improve their environmental controls in order to meet the ventilation recommendations in standards.

The following section provides an overview of the following:

- Ventilation factors for effective management of airborne diseases
- Ventilation requirements for airborne infection isolation (AII) rooms
- In-room HEPA cleaners

2.1 Ventilation Controls

The precise effectiveness of ventilation in reducing the risk of airborne transmission is unknown (4,21). However, two key ventilation-related factors required for effective airborne infection isolation include: the direction of airflow between rooms and their surroundings (negative pressure), and dilution ventilation and filtration within a room (air dilution) (7,10). These two factors are examined below.

Negative Pressure

Effectively controlling the directional airflow between rooms can potentially contain contaminated air and limit its spread throughout the facility. Negative pressure can be used to control airflow into a potentially contaminated space. To achieve negative pressure in a room, more air needs to be removed from the room (air exhausted) than brought into the room (air supplied). The Canadian Standards Association (CSA) recommends a pressure differential between the inside and outside of the room greater than 0.762mm of water gauge (1).

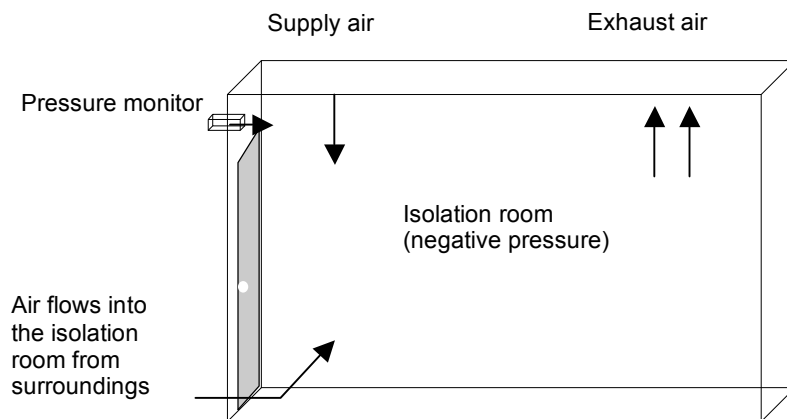


Figure 1: Under negative pressure, air flows from surrounding areas into an isolation room, thus containing potentially contaminated air.

Air Dilution

Within the contained areas, dilution of the room air occurs by continually exchanging contaminated air with air that has a lower concentration of contaminants. The amount of air moving through a room from the ventilation system (i.e., air supplied or exhausted) compared to the room volume determines the room air changes per hour (ACH). Increasing the ACH of a room decreases the room concentration of air contaminants (22).

There is insufficient data to support a precise minimum ACH to absolutely prevent the spread of airborne infectious diseases (10). However, current ventilation standards for specific areas within a hospital have been developed, supported by theoretical rationale to manage asepsis as well as occupant comfort and room odours. Table 1 highlights the ACH for selected areas recommended by CSA, but a more comprehensive list can be found in standard CSA Z317.2-01 (1).

The air dilution within an area is also influenced by the following factors:

- Filtration of supplied air, which prevents the accumulation of particles in the air.
- Good room air mixing, which ensures there are no dead spaces in the room (air stagnation).
- Good room airflow patterns, which ensures clean air is first supplied to parts of the room where workers or visitors are likely to be present. Air should then flow across the infection source (i.e., patient area) and finally to the exhaust for removal (1,2,6,7,8,11).

Standards also recommend that rooms be supplied with fresh outdoor air to ensure patient comfort. While some ventilation systems may supply rooms with 100% air from the outdoors, others mix in recirculated air. The outdoor ACH values in Table 1 represent the minimum proportions of the total room ACH that should be fresh outdoor air.

Table 1: Extracted data points for some of the rooms in which surveyed sites reported using in-room HEPA cleaners³

Area	Area Class ⁴	Relative Pressure	Min total ACH	Minimum outdoor ACH
Patient rooms: Class A ⁵	2	Equal	6	2
Patient rooms: Class B	2	Equal	4	2
Emergency Unit				
• General	2	Negative	12	4
• Exam/treatment	2	Negative	12	4
Airborne infection isolation (All) room – new	1	Negative	12	3
Ante room for All room	1	Negative to corridor and positive to All room	9	3
Surgery:				
• Endoscopy	1	Negative ⁶	20	6
• Bronchoscopy	1	Negative	20	6
• OR	1	Positive	20	6
Examination/treatment	2	Equal	6	2
Waiting rooms	3	Negative	9	3

³ CSA Z317.2-01 contains the complete table for most hospital areas (1). Not all footnotes or areas are reproduced in the table above. With the permission of Canadian Standards Association, material is reproduced from CSA Standard, CAN/CSA-Z317.2-01 (R2006), Special Requirements for Heating, Ventilation, and Air Conditioning (HVAC) Systems in Health Care Facilities, which is copyrighted by Canadian Standards Association, 5060 Spectrum Way, Mississauga, Ontario, L4W 5N6. While use of this material has been authorized, CSA shall not be responsible for the manner in which the information is presented, nor for any interpretations thereof. For more information on CSA or to purchase standards, please visit CSA's website at <http://www.shopcsa.ca> or call 1-800-463-6727.

⁴ CSA classifies areas into three levels, with class 1 requiring the most stringent HVAC and environment parameters

⁵ Class A rooms are in Class A healthcare facilities (in-patients stay based on medical need, e.g., acute care). Class B rooms are in Class B health care facilities (e.g., long-term care, chronic care, group homes).

⁶ The standard indicates the relative pressure should be positive, but this is an error in the publication (confirmed by a CSA Z317.2-01 committee member).

2.2 Airborne Infection Isolation (All) Rooms

Airborne infection isolation rooms are used to isolate patients with suspected or confirmed airborne disease. While these patients may be transported to other areas in a health care facility during their stay (e.g., procedure rooms), the focus of this report is on the ventilation requirements in All rooms as this is where these patients primarily reside. CSA outlines that the ventilation in All rooms should have (1):

- *“Inward directional airflow from adjacent spaces to the room⁷;*
- *Directional airflow within the room such that clean supply air flows first to parts of the room where workers or visitors are likely to be present, and then flows across the infection source (i.e., patient area) to the exhaust;*
- *Non-aspirating diffusers;*
- *Low-level exhaust near the head of the patient bed;*
- *All air exhausted to the outdoors;*
- *HEPA filtration of exhaust in cases where exhaust air is not discharged clear of building openings or where a risk of recirculation exists;*
- *Monitoring and alarm of room pressure⁸;*
- *Monitoring of supply and exhaust system function; and*
- *An exhaust fan supplied by emergency power.”*

In addition, some of the other related CSA recommendations for All rooms include (1)⁹:

- Rooms with reversible airflow are not acceptable (switching from a positive to negative pressure room e.g., protective environment (PE) room to All room)
- Airflow rate of 6 ACH for existing facilities and 12 ACH for new constructions or renovations (with a minimum of 3 ACH of fresh outdoor air)
- Air supplied from the ceiling
- Recirculation of air within a specific room is permitted if a HEPA filter is used

2.3 In-room HEPA Cleaners

In-room HEPA cleaners are devices that can provide secondary ventilation to a room by pulling particle-laden air into the unit, passing it through a series of filters to remove airborne particles and then exhausting the air out of the unit. In-room HEPA cleaners are supplied in numerous configurations, but generally they include the following (7):

- An air-intake, through which air is pulled into the unit
- One or more prefilters, which are used to remove large particles from the drawn air before it reaches the HEPA filter, to extend its life
- A HEPA filter, which is defined as being at least 99.97% effective at removing particles 0.3µm in size
- A motor/blower assembly, which provides the required suction to draw air into the unit
- An exhaust duct, through which the filtered air leaves the unit
- A control panel, which may include an on/off switch, an airflow speed control, and filter status indicators (e.g., hour meter, differential pressure gauge, and filter change indicator)

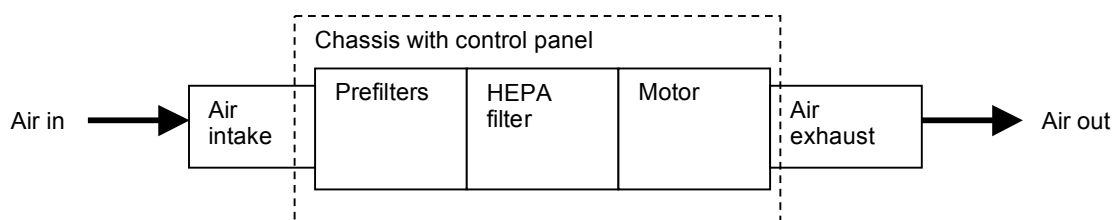


Figure 2: General design components of an in-room HEPA cleaner

⁷ “The pressure differential between areas shall be greater than 0.762mm of water pressure” (1)

⁸ Pressure alarms “shall be provided outside the room and at the nurse’s station or point of supervision” (1)

⁹ See CSA Z317.2-01 for the complete requirements: <http://www.shopcsa.ca>

Two key design components of these units are:

1. The motor: determines the airflow of the unit. This in turn affects the following room ventilation characteristics:
 - a. Negative pressure, *only* if the filtered air is exhausted outside the room
 - b. ACH or equivalent ACH (eACH)¹⁰
2. HEPA filter: removes pathogens from the air and is essential if the filtered air is returned to the room. If the air is exhausted outdoors, standards suggest that HEPA filters are not required providing the exhausted air cannot re-enter the facility (e.g., air intakes and windows) and is away from populated areas (1,6).

Options offered by some manufacturers' of in-room HEPA cleaners include:

- Ultraviolet germicidal irradiation (UVGI) lamps¹¹
- Charcoal filters to remove odours
- Various exhaust configurations, including recirculating the filtered air back into the room, exhausting it outdoors, or a combination of both (Figure 3)
- Various installation configurations, including permanently mounting the unit to a wall, ceiling or floor

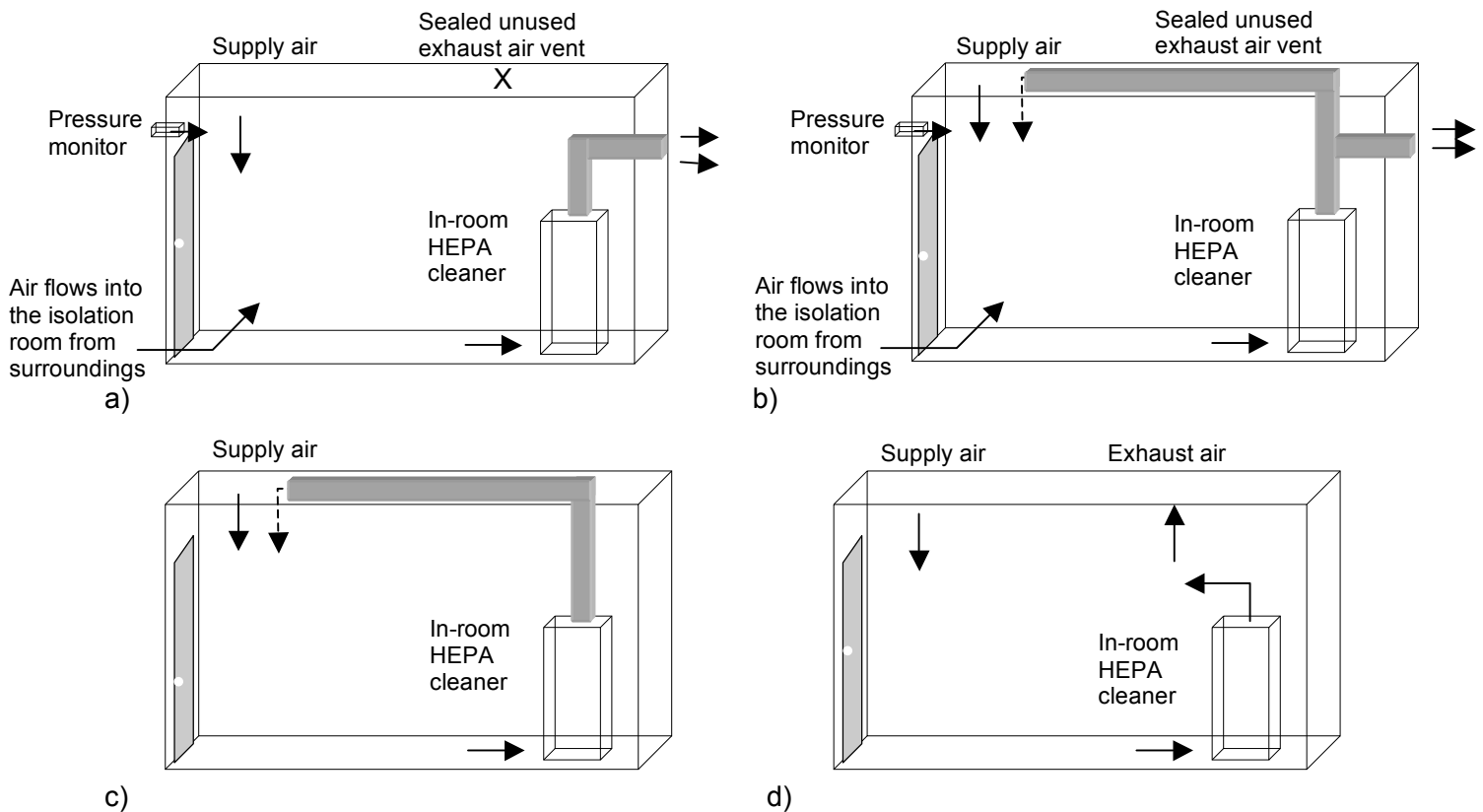


Figure 3: Some exhaust configurations promoted by vendors for in-room HEPA cleaners: a) ducted to outdoors (out window or via exhaust air system); b) ducted to outdoors with partial recirculation; c) recirculation within room (ducted); or d) recirculation within room (non-ducted). Note when used only to recirculate air, this may not meet the requirements in standards. See section 3.3 for recommendations regarding the appropriate and preferred unit configurations. The above diagrams are not meant to guide installations.

¹⁰ When used to recirculate room air, the affect of the unit's airflow is expressed in equivalent air changes per hour (eACH). The eACH is determined by calculating the ratio of the airflow rate of the unit to the room volume (22).

¹¹ UVGI uses ultraviolet light to disinfect air. UVGI alone has been found to be effective in experimental conditions at reducing airborne infectious particles in the air (22). However, its effectiveness depends on the intensity of light, duration of exposure of the airborne particle (airflow) and the relative humidity (6). CDC highlights that UVGI is not a substitute for HEPA filtration and recirculating air(6). OHTAC advises that there is insufficient evidence regarding the benefits of combining HEPA and UVGI units over those with HEPA filtration only (24).

The effectiveness of this technology has been found to vary, but overall when properly used and supported it is effective at removing aerosolized particles from the air (6,7,22). The effectiveness is dependent on the following:

- Unit airflow rate (6,7)
- Unit filter efficiency
- Room airflow patterns, which will be affected by the unit's placement with respect to the furniture, staff, patient, and air supply and exhaust registers (6,7)
- Routine maintenance (6,7)
- Knowledgeable use (6,7)

Overall, standards and guidelines have acknowledged in-room HEPA cleaners as an alternative when the HVAC system cannot provide the required performance (6,7,9,11). However, guidelines regarding the application of this technology are vague and typically only focus on their application in recirculating air within a room (e.g., mobile units) and not in creating directional airflow (negative pressure).

When mobile in-room HEPA cleaners are used only to recirculate air within a room (Figure 3c and 3d), there are two major concerns:

1. No effect on directional airflow (negative pressure)

In-room HEPA cleaners that are not exhausted outdoors, cannot control the directional airflow between rooms to contain potentially contaminated air (i.e., negative pressure). They can only remove pathogens by recirculating filtered air back into the room, increasing the eACH. When used in this manner, air concentration within the room is diluted, thus creating a potentially safer environment, but this does not meet the requirements to adequately support a patient requiring airborne precautions as outlined in section 2.2; negative pressure must also be achieved, and fresh outdoor air supplied (1).

2. Encourages inadequate planning and placement

By virtue of being mobile, the precise placement of mobile in-room HEPA units in a room is difficult to manage and is often done without adequate consultation and performance verification. Some potential issues may include:

- short-circuiting of air between the unit exhaust and intake, resulting in poor room air mixing and dead spaces in the room
- undesirable room airflow patterns, resulting in contaminated air being pushed towards the door and health care workers
- entraining contaminated air into the hospital ventilation system if placed in a room with a recirculating HVAC exhaust duct that supplies air to other areas within the facility¹² (8)
- pulling air from the exhaust vents

The subsequent section provides recommendations to help avoid these, and other, issues, to ensure in-room HEPA air cleaners are deployed and supported safely and effectively.

¹² This potential issue can be avoided if the room exhaust duct leads directly outdoors or is configured with an in-line HEPA filter. Note: The exhaust vents should not be sealed in rooms with mobile units to not disrupt existing pressure relationship (e.g., inadvertently create a positive environment).

3 Key Recommendations

The following section presents a sequential series of recommendations based on standards and guidelines as well as advice from our ICEP. The recommendations are in keeping with OHTAC's initial recommendations (Nov 2005), but provide further details. The recommendations are presented as checklists so they may be used by those facilities looking to purchase in-room HEPA cleaners, and also by those who currently use this technology, to verify their current practices. The checklists are not meant to be exhaustive, but rather address some of the key issues discovered as part of the Ontario practice survey (further details are presented in the Appendix and the following report: "In-Room Cleaners: Current and Recommended Practices" http://www.ehealthinnovation.org/MOH_Publications). The following figure illustrates a roadmap to support the safe and effective use of this technology from the decision to use the technology through to its ongoing operation and support; each phase is examined further in subsequent sections.

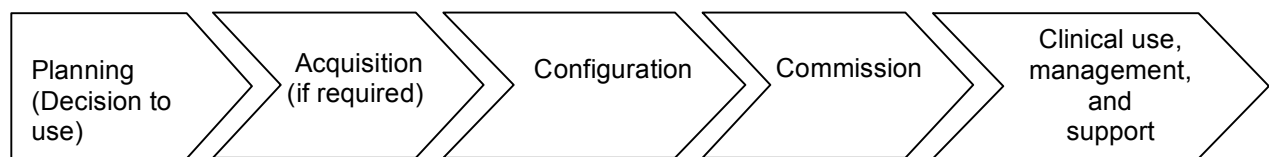


Figure 4: Road map to the effective and safe use of in-room HEPA cleaners

3.1 Planning (Decision to use)

The first major step in the road map is for health care facilities to review when and where it is appropriate to use in-room HEPA air cleaners. Figure 5 summarizes the recommended decision process on when and how these units should be used by health care facilities, with consideration for the following:

- Health care facilities should periodically conduct an assessment of the risk of transmission of airborne diseases to establish the required environmental controls to support their patient population appropriately at all stages of care in their facility (i.e., number and location of All and procedure rooms to accommodate patients on airborne precautions). A multidisciplinary team that includes expertise in infection prevention and control, risk management, facility design, ventilation, construction, occupational health and safety, and epidemiology should complete this assessment.
- Health care facilities should confirm whether existing ventilation controls are sufficient and verify that they are performing to standard.
- If improved ventilation controls are required (i.e., need more controls or existing controls not performing to specification), an engineering assessment should be conducted to establish and document the gap between current ventilation performance in the room(s) of interest and the requirements outlined in standards.
- Health care facilities should verify whether it is feasible to use, modify, upgrade or replace the central HVAC system to meet ventilation guidelines through an engineering assessment. In addition, facilities should develop a business case to review the sustainability and long-term costs of using or modifying the central HVAC system compared to in-room HEPA cleaners. Note: for new constructions and major renovations, the performance requirements of the HVAC systems should be specified to meet standards at the outset so that in-room HEPA cleaners are not needed.
- In-room HEPA cleaners should be purchased and installed only when the ventilation recommendations outlined in standards cannot be met by using or modifying the HVAC system, i.e., to supplement the room ACH and/or create negative pressure to meet standards. Units should not be used simply to augment the room ACH *unless* required to

meet standards *and* the room already meets the fresh air and directional airflow requirements.

- ❑ Health care facilities should review the following recommendations from our ICEP regarding the application of in-room HEPA cleaners in the following situations:
 1. **Suspect a room does not meet ACH requirements in standards:** It is recommended that a comprehensive engineering assessment of the room's environmental controls be made (i.e., confirm the room ACH as well as the directional airflow) and only consider using in-room HEPA cleaners to augment the room ventilation as outlined in Figure 5.
 2. **Desire to increase ACH above those specified in standards:** While rooms should be verified to ensure they meet the requirements outlined in the guidelines, it is not recommended that in-room HEPA units be used simply to augment the room ACH above those requirements (no clinical evidence to support this practice).
 3. **Desire to periodically augment the room ACH:** It is not recommended to periodically transport a mobile in-room HEPA cleaner into a room to augment its ACH in order to accommodate procedures on patients on airborne precautions or if more All rooms are required. While augmenting the room ACH does dilute the room air, it may provide a false sense of security because the room might not meet the requirements to adequately support a patient on airborne precautions; negative pressure must also be achieved to control the directional airflow between rooms. If procedures on patients with suspected or confirmed airborne infections are to be performed, or if more All rooms are required, this information should be included in the facility infection control risk assessment plan (Figure 5).
 4. **Pandemic planning:** It is not necessary for health care organizations to preemptively purchase in-room HEPA cleaners as part of their pandemic plan since our ICEP predicts that a pandemic is most likely to be influenza-based, and therefore airborne transmission is unlikely.
 5. **Use in non acute health care facilities:** When risk analysis at any health care facility (e.g., long-term care and ambulatory care) reveals an enhanced potential for undiagnosed or confirmed airborne infectious patients, a comprehensive infection prevention and control program should be designed and implemented to manage and support this patient population. This program should not only ensure access to the required clinical expertise to support this population (including infection control practitioners), but should also ensure that adequate administrative, personal protection, and environmental controls are implemented and are aligned with relevant standards. Non-acute care health facilities should follow the recommended approach in Figure 5 when deciding whether to acquire in-room HEPA cleaners.

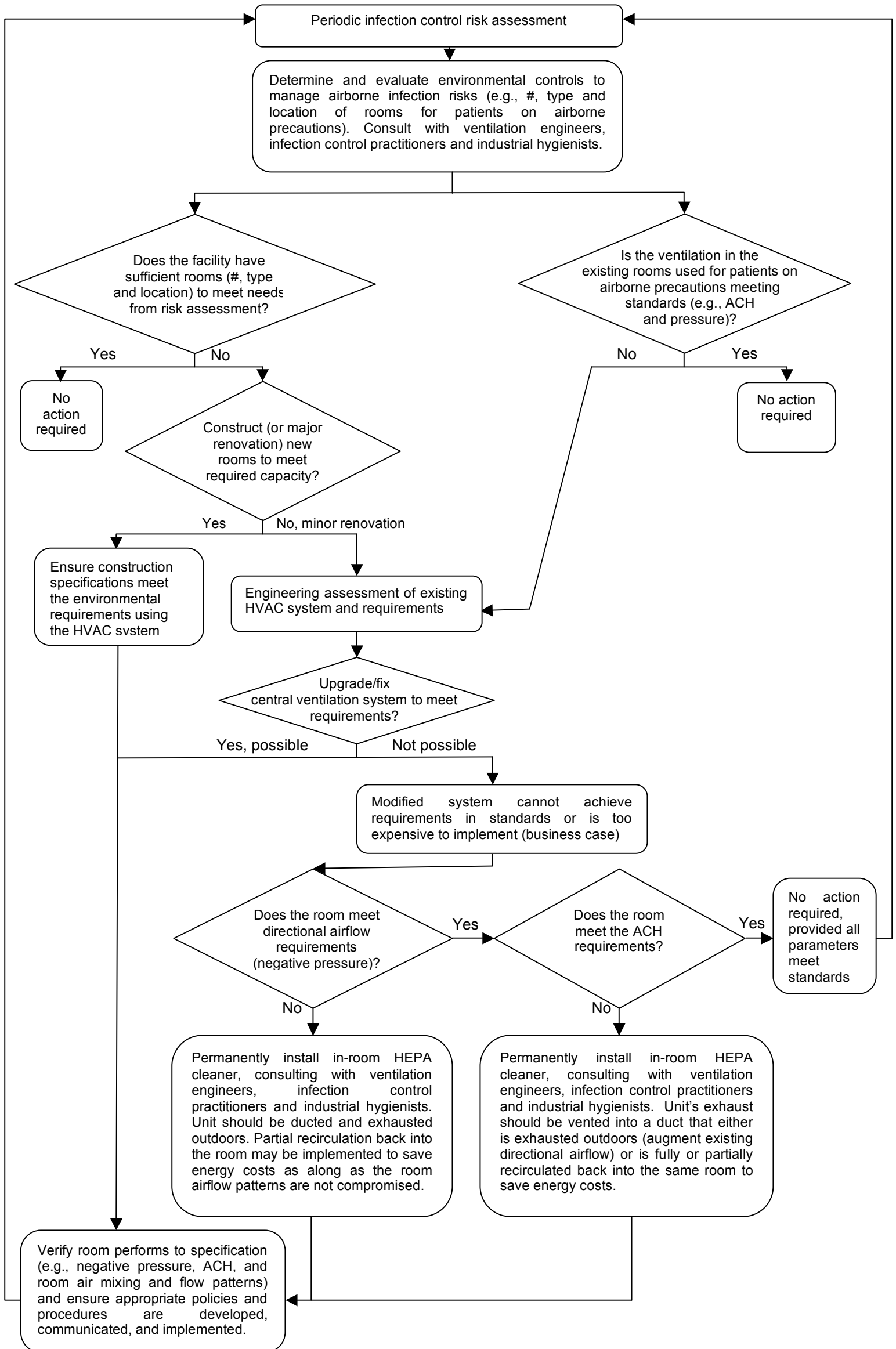


Figure 5: Process flow diagram for deciding when to use in-room HEPA cleaners to help minimize nosocomial airborne infections

3.2 Acquisition

The following steps should be considered when acquiring in-room HEPA cleaners:

- Establish a multidisciplinary team (MDT) of key stakeholders (e.g., Facilities Engineering, Infection Prevention and Control, clinical areas, and Purchasing) to participate in the technology acquisition and consequential planning and management of the units.
- Consider issuing a request for proposal (RFP) to vendors to ensure that purchase requirements and performance specifications are submitted in writing.
- Consider grouping purchases with related technology, such as room pressure monitors.
- Gather information by conducting a thorough market scan, reviewing vendor materials (and response to RFP), checking vendor references, reviewing published material (e.g., previous alerts and published product comparisons), and organizing vendor demonstrations.
- Evaluate the unit performance¹³ (including potential human factors issues), unit configuration, total cost of ownership, service requirements, vendor support, warranties and guarantees, and conformance with government regulations (i.e., units are certified by a testing organization accredited by the Standards Council of Canada) (14).
- Acquisition decisions should be made by the MDT to ensure the inclusion of all key stakeholders.
- Make acquisitions conditional on the units meeting performance criteria post-implementation, e.g., room ventilation meets standards and unit passes a HEPA filter seal test (see Appendix 4.4).

3.3 Configuration

In order to ensure units are configured and installed to promote effective and safe use, the following should be reviewed:

- Consult with the vendor and review manufacturer's configuration recommendations.
- Permanently install units in a room, regardless of how the unit's exhaust will be configured (e.g., 100% exhausted outdoors, 100% recirculated or a combination of both).
- Determine how filtered air will be exhausted from the unit to ensure the room's resulting ventilation meets the required specifications from the situation assessment (see Table 2).
- Evaluate and determine how best to position and install the unit based on the design of the technology, the client population served, and the room design and workflow. Options may include mounting the unit to the ceiling or wall or having the unit sit on the floor. Items to consider include ensuring good air mixing, room airflow patterns, unobstructed airflow, and accessibility for filter change and preventive maintenance.
- Have the unit installed by qualified personnel familiar with health care facility standards to ensure installation meets the required performance specifications and is installed using appropriate materials and design. Some important installation considerations for units that are exhausted outdoors include:
 - o Ensure that the unit is compatible with the existing primary ventilation system.
 - o Air should be exhausted outdoors, clear of facility air intakes and pedestrian traffic (8).
 - o Seal room return/exhaust grills to prevent entraining air into the facility ventilation system and/or pulling air from the exhaust (¹⁴).
 - o Minimize room air leakage (6,9,10). However, do not completely seal door openings, as air must flow into the room to ensure directional airflow.
 - o Provide emergency backup power to the unit in case of a power failure (1,5,9).
 - o Consider human factors issues that may interfere with the unit's ease of use, safety, and support (e.g., millwork around the unit may limit service access).
 - o Dampers should not limit exhaust airflow.

¹³ Some guidelines suggest units should be purchased to exceed the minimum airflow required to meet ventilation standards to account for imperfect air mixing, airflow losses post installation, power fluctuations, and unit inefficiency from filter loading; recommended safety factors range from 1.25 – 1.5 (13,7).

¹⁴ Exhaust vents should not be sealed in rooms with mobile units.

- ❑ Only use non-ducted mobile units in occasional emergency situations after consultation with Facility Engineering and Infection Prevention and Control staff, recognizing the limitations and risks of this use (see section 2.3). They should not be used as a long-term solution. In these emergency situations, preference is to focus on implementing proper administrative controls, PPE, and transferring the patient to a facility that can provide the recommended environmental controls.

Table 2: Hierarchy of ventilation controls and configuration options of in-room HEPA cleaners

Ventilation control	Potential to improve:		Notes
	ACH?	Negative Pressure?	
1. Facility HVAC system	Y	Y	Preferred control.
2. Installed (exhaust ducted) in-room HEPA cleaner with all air exhausted outdoors	Y	Y	Acceptable. Common configurations include ducting the exhaust out through a window, wall or dedicated duct.
3. Installed (exhaust ducted) in-room HEPA cleaner with partial recirculation of exhausted air back into room	Y	Y	Acceptable. Adjust the ratio of exhausted to recirculated air to ensure sufficient air is exhausted to maintain negative pressure, if required.
4. Installed (exhaust ducted) in-room HEPA cleaner with all air recirculated back into room	Y	N	Acceptable, provided the room already meets directional airflow (negative pressure) requirements outlined in standards.
5. Mobile (not ducted) in-room HEPA cleaner fixed in a dedicated room with all air recirculated back into room	Y	N	Only consider use in rare temporary emergent situations, recognizing risks and limitations. Use only in consultation with a ventilation and infection control expert.
6. Mobile (not ducted) in-room HEPA cleaner with all air recirculated back into room	Y	N	Only consider use in rare temporary emergent situations, recognizing risks and limitations. Use only in consultation with a ventilation and infection control expert.
7. Nothing	N	N	

3.4 Commission

Before first clinical use and final payments made to vendors, the following should be completed to ensure in-room HEPA cleaners will operate safely and effectively:

- ❑ Verify that each unit meets performance, safety, and quality criteria by inspecting and testing conformance to specification (e.g., verify alarm functions, quality of construction, and electrical safety). Consider having the unit's HEPA filter seal tested (see Appendix 4.4).
- ❑ Verify the room ventilation meets standards once the unit has been installed (e.g., negative pressure, ACH, air mixing, and airflow patterns). Record the resulting room ACH (total and fresh outdoor air) and directional airflow.
- ❑ Confirm that the installation of the unit does not adversely affect ventilation in the surrounding areas.
- ❑ For units with variable fan/blower speeds, record the setting that produces the required airflow to meet ventilation standards. Clearly mark this requirement on the unit.
- ❑ Ensure users and support staff receive appropriate training to understand the technology purpose, appropriate operation, support and cleaning requirements, and associated policies and procedures.

3.5 Clinical Practice and Use

Health care facilities should consider the following regarding the clinical use of in-room HEPA cleaners:

- ❑ Care for patients with suspected or known airborne infectious diseases (varicella, tuberculosis, measles, and to a small extent smallpox) in a room that meets airborne infection isolation standards. If a facility does not have an effective isolation room or a comprehensive infection prevention and control program to manage and support this patient population (including trained staff), patients should be transferred to a properly equipped facility.
- ❑ As initially recommended by OHTAC, “in-room HEPA cleaners are unlikely to be of any benefit in the containment of non-airborne transmitted infections diseases, such as influenza and SARS, as these diseases are primarily transmitted by direct and indirect contact” (24).
- ❑ Before using in-room HEPA cleaners intermittently, consult with a ventilation engineer to ensure appropriate ventilation in the room and surrounding areas when the unit is on and off.
- ❑ Ensure adequate time has passed between patients before turning units off to ensure the room is clear of droplet nuclei (1,3,6)¹⁵. Until adequate time has passed, health care workers (e.g., Housekeeping staff) should continue to use appropriate precautions when entering the room. The time required depends on the unique installation and in particular, the ACH measured during the commissioning process. In turn, this ACH should be used to extrapolate the time required from Figure 6 (graphed data assumes perfect air mixing so an added safety measure may be required depending on the room configuration). In practical terms, adequate time will likely have passed by the time the room is turned over and ready for occupation by a new patient, assuming the room meets the ACH requirements outlined in the CSA standard (~60min).

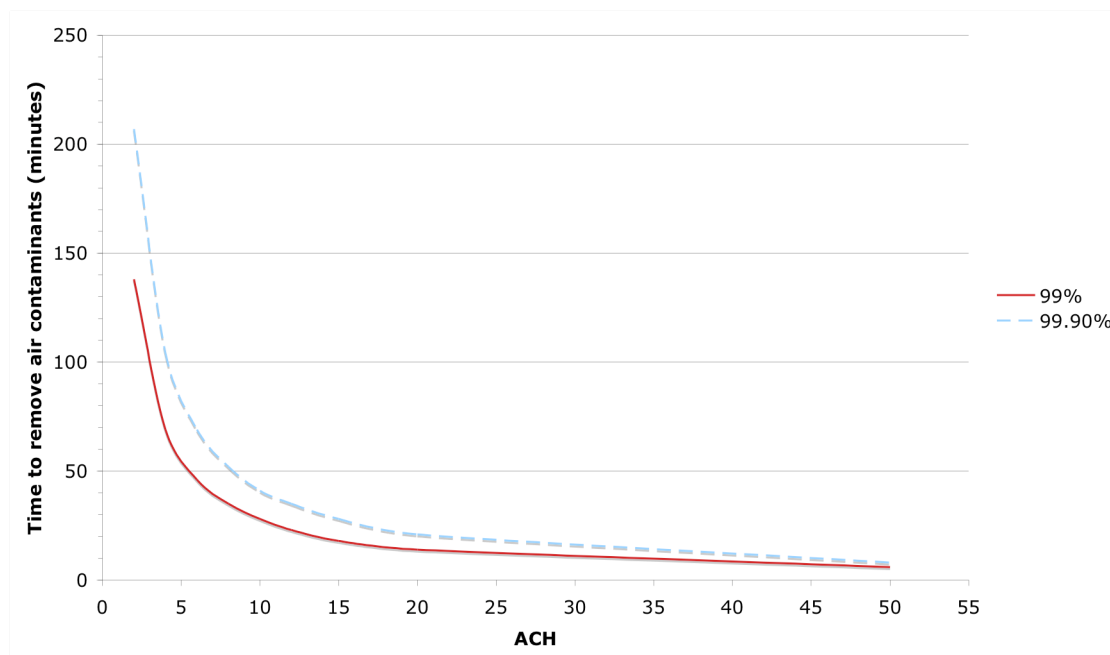


Figure 6: Air changes per hour and time required to remove 99% or 99.9% of airborne particles from room air after the patient leaves the area or when aerosol-producing procedures are complete. Assumes perfect air mixing. (6)

¹⁵ Although the risk of airborne transmission is higher for varicella and measles than with TB, procedures should be developed to ensure adequate time has passed once any patient on airborne precautions leaves the area or aerosol-producing procedures are complete.

3.6 Management and Support

Before using in-room HEPA cleaners, health care facilities should consider the following regarding their management and support:

- ❑ Develop and implement policies and procedures regarding the use and support of in-room HEPA cleaners, assigning clear roles and accountabilities. These policies and procedures should be developed in consultation with the affected departments and should be aligned and linked with other related policies and procedures (e.g., monitoring isolation room performance, cleaning air supply grills, and initiating appropriate work practices for managing patients on airborne precautions).
- ❑ One department should be responsible for the overall management of the units and delegate specific functions as required. Facilities Engineering is the preferred department to service and support in-room HEPA cleaners given that they are a secondary ventilation system.

Device Operation

- ❑ Ensure that protocols are developed related to the device and room setup (e.g., test room pressure, ensure air intake and exhaust are free from obstruction, and select appropriate blower speed), device operation (e.g., cleaning) and device discontinuation (e.g., ensure adequate time between patients).
- ❑ Typically, filters do not need to be changed after use in a room with a confirmed airborne infectious patient (confirm requirements with vendor).

Device and Room Maintenance and Service

- ❑ Develop a comprehensive inspection and preventive maintenance procedure to ensure the safety and performance of the device. As the filters load, the resistance to airflow increases, compromising the unit's ability to effectively deliver the required environmental controls (15,16). Facilities should establish how filter condition will be monitored and when the prefilters and HEPA filter will be replaced (see Appendix 4.3). The prefilters may need to be replaced as frequent as every 1-3 months and the HEPA filter every 1-3 years, but will depend on manufacturer's recommendations, unit design, environmental conditions, and the duration of use. Facilities should also evaluate the need for a HEPA filter seal test based on how the unit is used, manufacturer-specific recommendations, and the unit condition (see Appendix 4.4).
- ❑ Establish routine protocols for monitoring ventilation in rooms using in-room HEPA cleaners (e.g., test room pressure and ACH, procedure should the device fail). See Appendix 4.2.
- ❑ Review the following recommendations from our ICEP regarding service on in-room HEPA cleaners:
 - Service on in-room HEPA cleaners does not need to be performed in a room with special environmental controls as re-aerosolization and transmission of viable pathogens from filter material is not probable. Furthermore, units do not need to be decontaminated prior to servicing or filters disinfected before disposal.
 - As an added precaution, staff should use gloves and an N95 respirator during service. Internal components in the airflow channel up to and including the HEPA filter should be disposed of as biohazardous waste.

Documentation and Communication

- ❑ Given that multiple departments may be involved in the management, use, and support of these units, clearly document and communicate protocols and performance test results (e.g., filter condition, room ACH, and room pressure) to staff to ensure continued compliance with standards. The following are some suggestions:
 - Outside room: Post information regarding the room ventilation performance and associated protocols (e.g., ventilation test results, time required to clean air between patient, PPE, and keep doors closed).

- On in-room HEPA cleaner: The following information posted on the unit may be beneficial, either using log sheets, labels, stickers, or other communication tools: initial pressure readings with clean filters (7), inspection due date, date of last inspection and the corresponding pressure gauge and operating hours readings, support contact information (including after hours), laminated abbreviated instructions, and a warning sign to not block air intake or exhaust (7).
- Central documentation: All documentation regarding the performance of in-room HEPA cleaners should be stored centrally and linked with other documentation for isolation rooms that use the primary HVAC system. This documentation should include the following: inventory of units, initial commissioning results of the room and unit, schedule of room and unit inspections, and documentation of all scheduled and unscheduled maintenance (e.g., inspection results, filter replacement, and room ACH and pressure).

3.7 Other Related Issues

As part of this research, it was discovered that central ventilation systems may deteriorate and fail to meet the original design specifications (2). Therefore, similar to the recommendations made for rooms using in-room HEPA cleaners, health care facilities should:

- Ensure *all* rooms used for patients on airborne precautions are routinely monitored and tested to verify that they meet ventilations recommendations outlined in standards (e.g., room ACH and pressure),

4 Appendix

4.1 OHTAC's Initial Recommendations (2005)

The following are OHTAC's recommendations based on the literature review compiled by MAS (November 2005)(24):

- *"In-room air cleaners may be used to decrease the concentration of airborne infectious pathogens in a room.*
- *In room air cleaners are unlikely to be of any benefit in the containment of non-airborne transmitted infections diseases such as influenza and SARS as these diseases are primarily transmitted by direct and indirect contact.*
- *In room air cleaners are optimally deployed as fixed and permanent devices and used when the HVAC system cannot meet building ventilation rate requirements as set out in international and national guidance documents or when after an infection control risk assessment an increase in the number of negative pressure rooms is required in the health care facility and these cannot be created by renovating the HVAC system.*
- *In room air cleaners may be used as portable devices and as a temporary solution for supplemental ventilation and or creation of negative pressure rooms in acute situations where surge capacity is needed to manage the spread of a known or suspected airborne infectious disease. This would include situations in which the mode of spread of the pathogen is not yet determined and airborne transmission cannot be ruled out.*
- *In all situations of use, in-room air cleaners should be deployed only after consultation with a ventilation engineer and an infection control practitioner.*
- *All air cleaning systems in health care facilities should have written protocols for maintenance and monitoring of these systems. Monitoring of air cleaning systems should include assessment of room air flow patterns, air flow rates provided by the HVAC system or through an in-room air cleaner and the pressure differential between the inside and outside of a room designated to be under negative pressure.*
- *There is insufficient evidence at this time regarding any additional benefit of using an in-room air cleaner with combined UVGI lights and HEPA filter air cleaning technology instead of those with HEPA filter technology only.*
- *It is recommended that The University Health Network Human Factors Laboratory undertake the evaluation of the use of in-room air cleaners in hospitals."*

4.2 Room Monitoring

As recommended in section 3.6, health care facilities should ensure that the ventilation in rooms using in-room HEPA cleaners is periodically monitored and tested, particularly the pressure and ACH.

Pressure¹⁶

Small alterations in the HVAC performance can affect the room ventilation, particularly the pressure of a room, and even cause a negative pressure room to become positive (6). Standards specify that the pressure in all isolation rooms should be monitored and tested (1,2,4,5,6,8,9,10,11). However, a survey of 763 US hospitals in 1992 revealed that only 47% of the surveyed sites routinely verify isolation rooms for negative pressure (8).

CSA recommends using continuous pressure monitors in all class I rooms¹⁷ (e.g., All rooms) and ensuring these monitors are calibrated regularly, preferably twice a year (1).

¹⁶ Rooms in which it has been deemed appropriate to use in-room HEPA cleaners intermittently should ensure this practice is compatible with the room pressure monitoring tool so that nuisance alarms are not triggered during unit deactivation or service.

The guidelines vary with regard to the frequency at which the pressure in rooms needs to be inspected and tested to ensure the required pressure differential is maintained and the optimal performance of monitoring devices (2). However, typically standards recommend that room pressure be tested before occupancy by a patient requiring airborne precautions, routinely during occupancy (daily or weekly), and less frequently when not used for patients requiring airborne precautions (monthly or every 6 months) (2,4,5,6,8,11). Testing of the room pressure (and room pressure monitor) can include simple visual indicators such as using a smoke tube, ball-in-tube or flutter strip (5).

ACH

Guidelines stipulate that the ACH of rooms should be periodically monitored, tested, and documented (1,6,8). Both the total and outdoor ACH should be determined by an engineering assessment. Current guidelines are vague on the recommended testing frequency and methods, but given that the performance of ventilation systems are known to degrade with time it should be tested sufficiently to ensure continued conformance to standards.

4.3 Filter Changes

The prefilters and HEPA filters should be monitored and changed regularly (1,5,8,15). As the filters load, the resistance to airflow increases, compromising the unit's ability to effectively deliver the required environmental controls (15,16). If not changed regularly, eventually the airflow can be completely inhibited (15). The loading of filters will depend on the unit design, environment in which they are used (e.g., dust and humidity) and the duration of use (e.g., continuous or intermittent). In addition, loading of the HEPA filter can be reduced through proper maintenance and replacement of the prefilters.

Given these variables, standards typically defer to manufacturer recommendations to guide filter replacement. ECRI Institute indicates the prefilters may need to be replaced as frequently as every 1-3 months and the HEPA filter every 1-3 years (16).

The HHFG's field study results indicate that manufacturer guidelines can be vague and confusing and suggest multiple options to determine when filters can be changed, including using the pressure differential across the filters, hours in operation, and/or fixed intervals. Health care facilities should contact their vendor for clarification on how to integrate and use the various options, but the following can also be used to help explain these different options (note: not all units have the following indicators):

1. Pressure: Monitoring the pressure differential across the filters is the preferred method of measuring filter function in guidelines; this is more accurate than the operation hours (1,5,6,7,15). Because the pressure differential across the filters is relative, the pressure at commissioning when the filters are clean should be recorded (16). Manufacturers can provide pressure drop characteristics of filters (15,16). Filters should be changed when the pressure gauge readings indicate the performance is compromised in accordance with the manufacturer guidelines. However, users should clarify with vendors whether the pressure monitor is measuring the pressure across all filters or just the HEPA filter.
2. Hours of operation: The hours of operation after which filters require changing are typically based on the manufacturer's experience to predict when the filter function will degrade. If the pressure gauge readings indicate compromised performance before the unit reaches the recommended hours of operation, the filters should be replaced.

¹⁷ CSA classifies areas into three levels, with class 1 requiring the most stringent HVAC and environment parameters.

3. Fixed intervals: Fixed intervals recommended by manufacturers are typically based on a similar premise as the hours of operation, but assume continuous use. If the unit is used intermittently, facilities may prefer to use the hours of operation to predict filter replacement.
 4. Indicator lights: Some units have an indicator that illuminates when the filters need changing, which can be triggered by multiple factors such as operating hours and pressure. However, supporting departments should clarify with vendors what triggers its illumination to ensure that it is appropriate for their environment and use, and whether the indicator is for all filters or just the HEPA filter.
- ❑ Depending on the unit and its use, health care facilities need to establish how filter condition will be monitored and when filters will be replaced (15,16). Regardless of which method is used to trigger filter replacement, filter condition should be inspected on a regular schedule. The following may serve as a guide:
- Prefilter(s): Initially inspect the filters at the manufacturer recommended interval or every 1-2 months and monitor the condition of the filters. Record the pressure differentials and operation hours; replace the filters accordingly, as recommended by the manufacturer. Adjust the inspection frequency based on professional judgment.
 - HEPA filter: HEPA filter condition should be monitored whenever the prefilters are inspected and replaced in accordance to manufacturer's recommendations. Typically the pressure gauge readings should be used to measure the filter condition, if available. However, if the operating hours reach the recommended time by the manufacturer, health care facilities should consider proactively changing the filter. In addition, while HEPA filters generally have a long life, anecdotal reports and guidelines suggest it is finite no matter how lightly they are used (5,8). Therefore, facilities should investigate this issue further with the filter manufacturer/supplier, particularly if the unit is used infrequently.
- ❑ The following are additional recommendations:
- Filters should be purchased and used for the rated pressure drop and face velocity (15).
 - Filters should be handled with special care and visually inspected for damage: check all filters before and after installation (6). Examine the filter in front of a light to help detect major tears or damage to the filter and/or its frame (15).
 - Do not attempt to clean used prefilters or HEPA filter.
 - Only HEPA filters certified as HEPA quality should be purchased (16). Facilities should ensure HEPA filters are labeled with their filter efficiency and airflow resistance (16).

4.4 HEPA Filter Seal Test

Hospitals have had issues with filter bypass in their primary ventilation system, which occurs when air moves around the filter instead of through it, thus compromising its intended purpose (15). Bypass occurs due to filters that are not adequately sealed and/or are poorly fitted within their frame (15). Therefore the HEPA filter performance is highly dependent on its gasketing and framing.

A HEPA filter seal test, commonly known as a "DOP test", is a quantitative test recommended for all HEPA filters used in central ventilation systems by some national government bodies and organizations, such as the Public Health Agency of Canada (PHAC), the CDC, the US Army Center for Health Promotion and Preventive Medicine (USACHPPM), the National Air Filtration Association (NAFA), and ECRI Institute, (2,5,6,8,16,23). This non-destructive test challenges the HEPA filter and its seal with an aerosol of dioctyl phthalate (DOP) or equivalent and measures the unit's efficiency at removing 0.3 μm particles from the air by counting and

comparing the particles upstream and downstream; the HEPA filter unit should remove at least 99.97% of the particles. This test verifies the function and integrity of the HEPA filter itself as well as verifies that the HEPA filter is properly sealed within the unit so that air is not bypassing, or being entrained downstream of, the filter. Some manufacturers of in-room HEPA units also recommend performing these tests. It is important to note that due to health concerns regarding the use of DOP, Health Canada¹⁸ and the US Food and Drug Administration¹⁹ (FDA) have approved the use of polyalphaolefin (Emery 3004) as an acceptable replacement.

The recommended frequency at which this test should be performed varies in standards and guidelines and includes the following: periodically (ranging from 6-12 months), when the HEPA filter is initially installed²⁰, replaced or reinstalled, and/or if a leak is suspected (e.g., pressure drops) (2,6,8,16). It is important to note that in Ontario these are not legislative requirements but rather recommendations.

Resources

In order to accurately perform a HEPA filter seal test, it requires trained staff familiar with performing HEPA filter seal tests as well as expensive tools (e.g., 0.3 µm particle counter and 0.3 µm aerosol generator). Furthermore, this test can be time consuming, difficult to perform accurately, and difficult to coordinate with clinical areas.

Risks

For in-room HEPA cleaners, the potential impact of having air bypassing the filter (from a leak or puncture) or being entrained downstream is dependent on how it is being used.

(i) Unit exhausts its filtered air outdoors (i.e., negative pressure)

If the unit exhausts all or a fraction of its filtered air outdoors, there is a risk that potentially contaminated air may be exhausted outdoors if the HEPA filter is poorly sealed. However, environmental factors such as direct sunlight (UV), temperature, and pollution naturally destroy airborne microbes (17). Therefore most standards stipulate that a HEPA filter is required only if exhausted air is near air-intakes or populated areas (1,6).

(ii) Unit recirculates its filtered air

If the unit recirculates all or a fraction of its filtered air back into the same room, then a leak in the HEPA filter or seal will result in a slight reduction in filtration efficiency, thus decreasing its ability to augment the room eACH. ECRI Institute questions the need for HEPA filter seal testing in this application (16).

- ❑ Given the above resources and risks, it is up to each facility to evaluate the need for this test based on the how the in-room HEPA cleaner is being used, manufacturer specific recommendations and the condition of the unit based on their professional judgement. At a minimum, it is recommended that health care facilities should conduct a HEPA filter seal test upon initial commissioning, to validate the overall unit and filter construction and quality, but subsequently perform this test based on professional judgement.
- ❑ While the HEPA filter seal test is the only test that truly challenges the unit and filter to determine leaks to 0.3 µm particles, there are other quantitative and qualitative tools that facilities should use to help predict potential issues with the HEPA filter seal. Table 3 outlines a general practice guide to help verify the HEPA filter seal. This guide should be reviewed and modified to meet the facility and unit-specific risk management requirements.

¹⁸ Health Canada, http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/question/gmp-bpf_e.html (last accessed 20/08/07)

¹⁹ US FDA, http://www.fda.gov/cder/hdn/cnotesd6.htm#is_there_an_acceptable_DOP (last accessed 20/08/07)

²⁰ The USACHPPM indicates this test may be waived if the filter has passed an approved DOP test by the filter manufacturer (8)

Table 3: Guide to help verify the HEPA filter seal of an in-room HEPA cleaner. This Table is not a complete list of tests to verify the function of the entire unit. These tests relate to the function of the HEPA filter and seal.

When?	Action/Test	HEPA filter seal test?
At commissioning	<ul style="list-style-type: none"> • Have unit certified with a HEPA filter seal test as part of unit commissioning (include this as a purchase agreement term to be completed by vendor). • Record unit's pressure gauge readings once it has passed the HEPA filter seal test. 	Recommended
All inspections (if easily accessible and viewable) and when replace HEPA filter	<ul style="list-style-type: none"> • Monitor pressure and change filters (prefilters and/or HEPA filter) as per manufacturer recommendations. After filter(s) has been changed, ensure pressure readings return to those at commissioning. If abnormal pressure readings (e.g., readings lower than at last inspection and filters have not been changed or readings lower than the readings at commissioning after filters have been changed) then inspect the filters, chassis, and the HEPA filter seal for damage. • Inspect filter seal²¹ for quality and/or signs of age. Also inspect the chassis for damage and potential leaks. • Grease the gasket if required by manufacturer to ensure seal after filter change (16). • Ensure fasteners are tight and the HEPA filter cannot move as per manufacturer recommendations. • Record any potential concerns with the filter seal and unit construction so issues can be monitored in subsequent inspections. 	Based on professional judgement
All purchases of HEPA filters (at commissioning and when replace filter)	<ul style="list-style-type: none"> • Ensure all purchased HEPA filters have been individually certified by the manufacturer as meeting HEPA quality standards²² and are labelled with at least the filter efficiency and airflow resistance (16). • Inspect filter integrity for any potential transport damage (rips, tears or dents) 	By filter manufacturer (at plant) and based on professional judgement

²¹ Anecdotal reports indicate that the seal on some units may be fragile and age (e.g., compress, become brittle and tear). Some units may have seal issues within a year whereas other units constructed of high quality materials will have a much longer life. Monitor the condition of the HEPA filter seal.

²² Certified HEPA filters should be individually tested by manufacturer (or equivalent) to confirm they have an efficiency of at least 99.97% in removing 0.3 µm particles over the rated flows.

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