Guide to Operation Theatre HVAC Validation

First Edition

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Indian Society of Heating, Refrigerating and Air Conditioning Engineers

COVER 2

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Authors: **B. Gautham Baliga**

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1103-1104, 11th Floor, Chiranjiv Tower,
43, Nehru Place, New Delhi – 110019, India.
Phone: +91-22-4163 5655
Email: info@ishraehq.in
Website: www.ishrae.in

Design, layout and artwork by:
Fezisons Quality Printers
Rahimtoola House, 7 Homji Street,
Fort, Mumbai - 400 001, India.

Foreword

This guide has been developed to meet a long-standing need within healthcare facilities for a **standardised and technically sound framework for the testing and certification of Operation Theatre (OT) HVAC systems.** Given the critical role of OTs in maintaining sterility, preventing surgical site infections, and safeguarding patient outcomes, HVAC system performance must be verified consistently and accurately.

While NABH guidelines clearly define the required performance criteria and target values for OT environments, there remains a practical need for **clear guidance on testing methodologies, measurement procedures, and instrumentation requirements.** This guide seeks to bridge that gap by providing **structured, step-by-step procedures** aligned with regulatory expectations and industry best practices.

Personnel involved in OT HVAC testing and certification must have a sound understanding of OT HVAC system behaviour, including airflow patterns, pressure control, and environmental stability required to achieve compliant OT conditions. Equally important is adherence to appropriate **behavioural discipline and safety protocols** within the OT, ensuring that testing activities do not compromise sterility or disrupt hospital operations. This guide addresses these aspects and also provides **basic diagnostic guidance** to help identify potential causes and corrective actions when measured values do not meet specified requirements.

This guide is intended to serve as a **training and certification reference for engineers and technicians** responsible for testing and certifying OT HVAC systems, to bring **uniformity, reliability, and technical rigour** to certification practices across healthcare institutions.

Ultimately, this publication aims to support hospitals, consultants, and validation professionals in achieving and sustaining high standards of environmental control in Operation Theatres, thereby contributing to **enhanced patient safety and clinical excellence.**

B Gautham Baliga
Chair, ISHRAE Healthcare Technical Group

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ISHRAE Technical Group (TG) H101 Healthcare

Contributors

Bipin Patil
Aerience Air Science & Contamination Control Pvt. Ltd.
(Entire 1st Draft of the Guide Book)

Shankar Rajasekaran
Impec Filters Pvt Ltd
(Chapters 1,2 & 3)

Dr. Roshini T Easow
PhD (IIT, Bombay)
(Chapter 4)

B Gautham Baliga, Chair TG H101 Healthcare
Opal HVAC Engineers Pvt. Ltd.
(Chapter 5)

Ravindra S Kulkarni
RS Kulkarni HVACR Consultants
Chapter 6

Prashant Desai
Elm Enterprises Private Limited
(Chapter 7)

Sant Advani
Guidance for the guidebook

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Chapter 1

Introduction to HVAC Systems for Surgical OTs

Heating, Ventilation, and Air Conditioning (HVAC) systems in surgical operating theatres (OTs) are critical components of hospital infrastructure. They function as essential guardians of the sterile field, directly influencing patient safety, surgical outcomes, and occupational health and safety concerns for medical personnel. Hence, the HVAC system of a surgical OT is recognised as a fundamental infrastructural element concerning a surgical procedure.

The design, installation, operation and maintenance of these systems demand interdisciplinary knowledge of engineering, infection control, medical, and regulatory requirements. Professionals in this field are required to stay up to date with the latest regulations and technological advancements.

As the future of surgical care becomes increasingly complex, the importance of robust, reliable, and meticulously maintained HVAC systems will continue to grow.

1.1 Purpose of HVAC in Surgical OTs

In a surgical OT, the HVAC system does more than keep staff comfortable. It supplies clean air over the surgical table and the surrounding areas, removes particles and exhaust gases, controls temperature and humidity, provides sufficient outdoor air, and maintains the desired room pressure gradients. This results in low microbial counts in the OT environment, thereby limiting the occurrence of surgical site infections (SSIs). Furthermore, it provides protection and comfort to the surgical staff.

1.2 Impact on Patient Safety & Surgical Outcomes

The influence of HVAC systems on patient safety and surgical outcomes is profound. Several studies conducted worldwide have established that a well-designed HVAC system directly minimizes the risk of surgical site infections (SSIs) by controlling the number and movement of airborne contaminants. Through precise design of air velocity, air exchanges, filtration, and airflow patterns, these systems create a protective envelope around the surgical field, thereby preventing microorganisms from settling directly or indirectly on the surgical wound. In line with this, national and international standards specify the use of a low-turbulence, downward-flow ventilation system, commonly referred to as an “OT laminar airflow system”, for surgical OTs. This airflow system helps transport particles and microorganisms away from both the patient and the surgical team, and lowers microbial counts throughout the OT. Thus, the system limits particles and microorganisms from settling on instruments, surgical wounds, or other critical surfaces.

Control over temperature and relative humidity has four functions. Firstly, maintaining optimal temperature and humidity in the OT inhibits the growth of microorganisms and prevents the buildup of pathogenic reservoirs. Secondly, for certain surgical procedures,

a specific temperature is required, as in orthopaedic implant surgeries. The third reason is from a safety angle. A low RH environment can pose the risk of static electricity buildup. Due to the presence of flammable gases in the OT environment, a spark from an accidental discharge of static electricity could pose a fire risk. Hence, maintaining RH is vital from a fire risk angle. It is also important to note that very low RH environments can affect sensitive electronic equipment due to interference from static electricity. Last, but not least, is the comfort of the surgical team members, who could be wearing several layers of protective clothing. Thus, controlling temperature and humidity is crucial in an OT environment.

Furthermore, maintaining positive or negative pressure gradients between adjoining rooms ensures that air flows from cleaner to less clean areas, thereby confining airborne pathogens and reducing contamination. For example, higher pressure in the operating theatre compared to adjacent spaces minimises the intrusion of contaminated air.

An effective HVAC system seamlessly integrates engineering and clinical requirements, creating a barrier against infection that supports optimal healing and safeguards both patients and surgical team members. Its role is not just supportive but essential. It is a key part of delivering high-quality surgical care.

1.3 Regulatory & Guideline Overview

A robust regulatory and guideline framework underpins the design and operation of HVAC systems in surgical operating theatres, ensuring that best practices are consistently implemented to protect patient and staff safety. This framework draws from a combination of national and international standards, each offering detailed recommendations tailored to the specific demands of healthcare environments.

NABH (National Accreditation Board for Hospitals & Healthcare Providers) is a body in India that accredits healthcare providers. NABH has published its Guidelines for Air Conditioning in Operating Theatres. This document outlines the minimum requirements for air quality, airflow, air exchanges, pressure differentials, temperature, and humidity control in OTs. It also specifies points related to selecting air conditioning equipment and to the maintenance and periodic testing of OT environments. Adherence to these guidelines is necessary for hospital accreditation, thereby bringing uniformity in healthcare infrastructure and the quality of patient care across the country.

ASHRAE, the American Society of Heating, Refrigerating and Air-Conditioning Engineers, is a globally recognised professional body that has published several standards and guidelines. The ASHRAE Standard 170, Ventilation of Healthcare Facilities, is a frequently referred standard due to its comprehensive approach to ventilation in healthcare facilities. ASHRAE 170 outlines minimum requirements for airflow rates, temperature, RH, filtration levels, and pressure relationships for several areas, including OTs, establishing clear benchmarks for both new construction and retrofit projects. Its specifications serve as a reference not only in the United States but also influence global practices.

ISHRAE, the Indian Society of Heating, Refrigerating and Air Conditioning Engineers, is a professional society that publishes several handbooks, guides and standards in India. ISHRAE guides and standards take into consideration the unique climatic and infrastructural challenges present in India. ISHRAE standards often align with, but also expand upon, global best practices to account for local realities. ISHRAE has published a guidebook for Healthcare facilities that covers HVAC, Fire and Life Safety, and HVAC systems used in OTs.

WHO, the World Health Organisation, offers global guidance rooted in evidence-based infection control and prevention strategies. The WHO publication, Global guidelines for prevention of SSIs, is an important document that emphasises the need for a clean environment in OTs. The document covers ventilation and environmental controls and serves as a global reference for reducing healthcare-associated infections.

HTM 03-01, a Health Technical Memorandum published by the UK National Health Service, applies to facilities that adhere to the United Kingdom's healthcare standards. The

document provides detailed information on the design, installation, and testing of specialised ventilation systems in healthcare premises. The document provides a detailed description of the testing procedure for certifying the HVAC system's performance in OTs. It also offers different standard layout plans for OT. These recommendations ensure that OTs in UK healthcare facilities consistently meet rigorous environmental and safety benchmarks.

DIN 1946 is a German standard for evaluating the performance of ventilation and air conditioning systems used in healthcare buildings. The unique feature of this standard is the measurement of turbulence intensity and the Degree of protection. Turbulence Intensity measurement provides information about the unidirectionality (laminarity) of the air flow. The degree of protection measurement provides information about the quantity of particles that could enter the operating field from background areas.

Together, these regulatory frameworks and guidelines provide a comprehensive reference point for the design and operation of surgical OT HVAC systems. Their intersection ensures that patient safety remains the utmost priority and also promotes consistency, accountability, and continual improvement in healthcare environments.

1.4 Overview of Cleanroom Technology and Classification

Modern healthcare environments, particularly surgical operating theatres, aim to achieve low concentrations of airborne particles. In other words, the surgical OTs fall within the definition of a cleanroom. According to the ISO 14644 standard, a cleanroom is an indoor environment where the concentration of airborne particles is controlled and which is designed, constructed, and operated to control the introduction, generation, and retention of particles. Thus, all contamination controls applicable to a cleanroom are also applicable to an OT. The ISO 14644-1 standard, established by the International Organisation for Standardisation, provides a systematic method for classifying the cleanliness of air in cleanrooms and controlled environments based on the concentration of airborne particulate matter. Airborne particle matter refers to all the particles that are suspended in the air, including both viable and non-viable particles. Thus, each room in the OT suite, including the change rooms, sterile corridors, dirty corridors, service areas, scrub rooms, ancillary sterile areas, recovery rooms, and theatres, can be considered a cleanroom with varying cleanliness classes and differential pressure requirements, depending on its intended use.

ISO 14644-1 defines cleanroom classes, ranging from ISO Class 1 (the cleanest cleanroom) to ISO Class 9 (the dirtiest cleanroom), which specify the maximum allowable concentrations of particles of specified sizes per cubic meter of air. This hierarchical classification enables facilities to tailor their environmental controls to the varying needs of healthcare, pharmaceutical, electronics and other applications. For instance, critical zones such as operating theatres or compounding pharmacies may target ISO Class 5 or 6 classes, whereas ancillary spaces may comply with lower cleanliness classes. NABH guidelines refer to ISO 14644 for specifying requirements for airborne particle concentration in OTs. A portion of the ISO 14644 Cleanroom Classification table, specifically relevant to healthcare applications, is provided below.

Cleanroom classification can be specified in "as built", "at rest" and "in operation" conditions. For the purpose of conducting performance testing in a surgical OT, only the "at rest" condition is considered. The selected cleanliness class for an environment influences the selection of air filters, the air velocity at the supply air outlet, the type of supply air diffuser, and the air exchange rate. For surgical OTs, NABH specifies that the air particle concentration at the supply air diffuser should meet ISO Class 5, based on measurements at the 0.5 µm particle size in "at rest" conditions.

By aligning their environments with the requirements of ISO 14644-1, healthcare facilities establish a measurable and internationally comparable benchmark for controlling airborne contamination, thereby reinforcing their commitment to patient safety and quality.

Chapter 2

Basics of Infection Control in OTs

Infection control within operating theatres (OTs) is a critical component of surgical practice, essential for optimizing patient safety and maintaining clinical standards. The primary objective in these environments is to reduce the risk of healthcare-associated infections (HAIs), particularly surgical site infections. SSI can occur when microorganisms are introduced into the surgical site in sufficient numbers and/or virulence to overcome the patient's local and systemic defense mechanisms, leading to infection. The pathway for these microorganisms reaching the surgical site can be through the airborne route or through the direct/indirect contact transfer route.

An effective infection control strategy requires a comprehensive and systematic approach that integrates engineering controls with rigorous protocols for maintaining aseptic environment and personnel compliance with established SOPs. Environmental control forms the basis of this strategy, with advanced HVAC systems controlling key parameters such as air quality, temperature, relative humidity, differential pressure, and airflow to minimise microbial load within the operative field and prevent the ingress of contaminated air from adjacent spaces.

Beyond mechanical systems, infection control protocols include a well-thought-out OT suite layout, rigorous cleaning and disinfection routines, the use of sterile consumables, and strict adherence to aseptic techniques by surgical staff. Additionally, to reduce opportunities for contamination ingress, infection control protocols include access controls to the OT area, gowning guidelines, and hand hygiene.

Monitoring of environmental parameters is done at regular intervals. Airborne and surface microbial loads are regularly assessed, and any deviation from established thresholds prompts immediate corrective action.

2.1 Nosocomial Infections & Surgical Site Infections

Nosocomial infections, also known as hospital-acquired infections, pose a persistent challenge within healthcare institutions. Their consequences are particularly acute in the context of surgery. Surgical Site Infection (SSI) is a common type of nosocomial infection that involves the surgical incision site and any other areas manipulated during surgery. These infections can range from superficial involvement of the skin to deep-seated infections affecting tissues, organs, or implanted materials. According to the CDC SSI protocol 2024, these infections develop within 30 days or 90 days of surgery, depending on the type of surgery. The reasons for the onset of an SSI are multifactorial, often representing a convergence of environmental contamination, procedural lapses, and individual patient risk factors. The pathogenesis of an SSI typically involves the introduction of microorganisms into the surgical site through the transport routes mentioned earlier during a surgical procedure.

The impact of nosocomial and surgical site infections extends far beyond immediate clinical concerns. Patients may experience prolonged hospital stays, delayed wound healing, require additional medical and/or surgical interventions, and face an increased risk of mortality. These infections place a significant burden on healthcare resources and a financial burden on the patients.

Effective prevention of SSI relies on a combined approach: rigorous adherence to sterilisation protocols, meticulous surgical practices, robust environmental cleaning, and effective engineering controls. In addition, continuous surveillance, staff education, and prompt response to outbreaks are essential aspects in controlling nosocomial infections.

2.2 Sources and transport routes of Infection

Understanding the diverse sources and transport routes of microorganisms that lead to contamination within operating theatres is essential for developing comprehensive control strategies. In these complex environments, microorganisms can originate from five primary sources and get transported to the surgical wound through two routes.

The five primary sources of contaminants are

External non-aseptic environments

Supply air outlets of the air conditioning system

Surgical team members

Internal surfaces of the OT

Surgical procedure

Contaminants from non-aseptic areas adjacent to the OT, such as a corridor, can gain ingress through door gaps even when the doors are closed. This ingress is minimised by maintaining a positive differential pressure in the OT relative to the adjoining area. When the door is opened, this pressure differential is lost, and the contaminants could enter the OT during door openings. To avoid this, it is advisable to design OTs with an anteroom that maintains the same air quality as the OT and is located between the OT and the corridor.

Supply air outlets of the air conditioning systems in the OT could introduce contaminants. To avoid this, HEPA filters are installed in the supply air outlets. Furthermore, the supply air diffuser must be regularly cleaned and disinfected to prevent the buildup of bioburden at the supply air outlets.

Surgical team members inside the OT are a significant source of contaminants. By nature, humans shed large quantities of particles, many of which may carry microorganisms. To prevent these particles from being released into the OT environment and causing infections in patients, surgical-grade aseptic gowning and gloving protocols are enforced. Strict adherence to personal behaviour protocols during entry and while inside the OT plays a significant role in limiting this problem.

The internal surfaces of the OT, especially the crevices and corners of the OT, could be a source of microorganisms. To minimize the buildup of sources, OT interiors are engineered with materials that inhibit the growth of microorganisms and are constructed to avoid sharp corners and crevices. Furthermore, regular deep cleaning and disinfection of all interior surfaces is carried out in accordance with established SOPs. Swabs from different surfaces are microbiologically analyzed to ascertain sterility.

During surgical procedures involving cutting or drilling into bones, such as in orthopaedic, cardio-thoracic, and neurosurgery, microscopic particles are generated, which remain airborne and settle on OT surfaces, creating a breeding ground for microorganisms. Furthermore, surgical smoke generated by cauterisation during surgery consists of ultrafine particles formed by vapour condensation. Similarly, surgical procedures can generate bioaerosols that may remain airborne in the OT environment. Especially during long-duration surgeries, the accumulation of anaesthetising gases in the OT can pose a health hazard to the surgical team. Regular cleaning of OT surfaces, proper ventilation, and effective air exchanges in the HVAC design help control the buildup of these contaminants.

The two transport routes of contaminants are

Airborne route

Contact transmission

Contaminants, such as microdroplets and particles generated from the sources mentioned above, can remain airborne for extended periods and be transported directly to the surgical site through air currents or diffusion. This is direct airborne transmission. Alternatively, these airborne contaminants may also settle on sterile supplies, such as surgical instruments and consumables, and then be indirectly transported to the surgical site. In such cases, these intermediate surfaces (such as sterile instruments and consumables) could become secondary sources. This is indirect airborne transmission. These contaminants could harbour disease-causing pathogens, thereby causing infections in patients, typically SSIs.

A contaminant can be transported from the source to the surgical site through direct or indirect contact transmission. Direct contact transmission occurs when a person or a sterile supply physically comes into contact with a primary source and then transfers the contaminant to the surgical site during a surgical procedure. Indirect contact transmission refers to the transfer of the contaminant from the source to an intermediate surface secondary source) and then transferred from the secondary source to the surgical site by the same person or another. Avoiding contact transmission is a primary responsibility of the surgical team and is guided by WHO-recognised best practices for surgery.

A properly designed, installed, tested, and maintained HVAC system, coupled with stringent OT protocols, helps reduce the source strengths and reduces the possibility of contaminant transmission from the source to the surgical site, thereby reducing infection risks.

2.3 Role of HVAC in Airborne Contamination Control

HVAC systems play a vital role in preventing infections by controlling airborne viable contaminants in an OT. These systems regulate the temperature, relative humidity, and airflow inside the OT, and also filter out particles in the air supplied to the OT. Thus, an HVAC system rapidly removes the contaminants generated internally and also prevents their infiltration from adjoining areas. By this action, the concentration of viable microbial contaminants in the OT is controlled, thereby reducing the risk of patient infection.

The growth of microbial colonies is temperature-dependent: most organisms, especially bacteria and fungi, multiply faster at higher temperatures, with 37°C being the most favourable. Lower temperatures reduce microorganisms' ability to multiply, thereby limiting bioburden in the OT environment. Hence, HVAC systems are designed to maintain the environmental temperature at a level that is sub-optimal for microbial growth, typically around 20°C.

Environmental relative humidity influences microbial growth, with both high and low humidity supporting the growth. While fungi and some bacteria find higher relative humidities favourable, some bacteria and viruses find lower humidity environments favourable for growth. A moderate level of relative humidity, between 40 and 60%, is found to be the least favourable for microbial growth. Hence, HVAC systems are designed to control indoor relative humidity within this range, regardless of external conditions.

Air movement in the OT is responsible for transporting airborne contaminants away from the OT and preventing contaminants in adjoining areas from infiltrating the OT environment. By suitably sizing and positioning the supply air outlets and return air inlets in the OT, the HVAC system establishes an airflow pattern that facilitates particle removal and prevents particle infiltration from adjacent areas. The unidirectional flow system ensures that the air from the supply air outlet moves downward, reaches the surgical table, and then moves outward towards the peripheral areas of the OT, finally entering the return air inlets. This creates a sweeping action that transports particles away from the sterile field and prevents

contaminants in the OT from moving towards the surgical table. The velocity of the supply air outlet is designed to reduce turbulence in the OT and improve the system's contaminant removal effectiveness. The HVAC system's air exchange rate directly affects the dilution rate; therefore, higher air exchange rates result in greater particle removal, thereby controlling airborne contaminants in the OT.

Multi-stage air filtration is an essential feature of the OT HVAC system. A minimum of three filtration stages with progressively increasing levels of filtration efficiency are typically used in the system. The final filter, a HEPA filter, is installed in the supply air outlet directly above the surgical table. HEPA filters are known to filter out sub-micron particles and bioaerosols with an efficiency greater than 99.95% (commonly referred to as 99.99% efficient for 0.3 micron particles). Thus, it helps supply contaminant-free air into the OT, which is necessary for dilution to reduce indoor airborne contaminants.

2.4 Concept of Zoning and OT layout

The infection control program for an OT begins at the project design stage, when the plan/layout of the OT suite is determined. An adequately designed layout, taking into account the space required for engineering services, is critical to reducing infection risks. At this design stage, it would be prudent to consider that the rooms directly connected to the OTs are also controlled and classified for airborne particle cleanliness and pressure differentials. This will reduce contamination ingress during the numerous door openings that occur during the course of the surgery.

The entire OT suite, which may comprise multiple OTs, is divided into several zones, each serving a specific purpose and having unique environmental requirements and protocols. The first zone is where the other common hospital areas are separated from the OT suite, where street footwear and personal belongings are removed and stored. The second zone is where the washrooms and change rooms are located. The third zone is where the pre-anaesthesia area and the recovery rooms are located. The fourth zone is the sterile corridor linking all the OTs. The scrub area, sterile stores area, and equipment rooms are all connected to the sterile corridor. Finally, the fifth zone is the OT itself. Some hospitals have a separate zone, called the dirty corridor, to transport biomedical waste from the OT after surgery. The doors between the zones may be interlocked, so that two doors in the same zone cannot be opened simultaneously. Zoning helps limit the migration of contaminants from other areas of the hospital to the OTs. Furthermore, it facilitates the regulation of personnel movement and establishes procedural protocols related to entry into OTs.

Inside the OT, there are three zones: the surgical zone, the protected zone, and the peripheral zone, listed in order of criticality for air quality. The surgical zone is where the surgical table is positioned, usually at the centre of the OT and directly below the unidirectional airflow supply air outlet. The protected zone, also covered by unidirectional airflow, is the area immediately surrounding the surgical table and houses all sterile surgical tools, instruments, and consumables. The surgeons and the scrub nurses are also in this zone. Finally, the peripheral zone is the area within the OT that surrounds the protected zone. All the equipment and consumables received from the sterile stores are stored in this area. The anaesthetist, rotating nurses and other OT technicians are in this area. The airflow pattern in the OT should be such that it flows from the clean to the dirty zones, i.e., from the surgical to the peripheral zone. This ensures that contaminants generated in the peripheral zones will not travel towards the surgical zone.

2.5 Pressure cascading

Even when the door between two rooms is kept closed, contaminants can still migrate through gaps around the door. To protect the OTs from contaminant infiltration when the doors are kept closed, the pressure cascading concept is employed. Pressure cascading refers to the creation of controlled air pressure differences between two adjacent rooms. The more critical of the two rooms is maintained

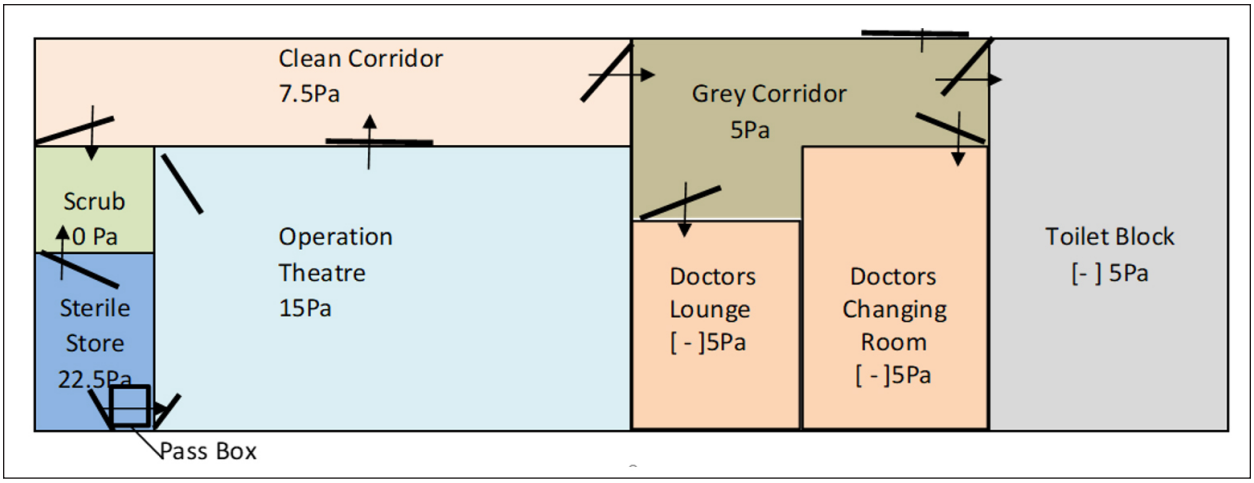


Figure 1: Pressure Cascading for Operation Theatre

at a positive differential pressure with respect to the less critical room, thereby reducing the migration of contaminants into the more critical room. This concept is applied to each of the five zones mentioned above. Considering the differential pressure relative to atmospheric pressure, zone 1, the least critical or dirtiest room in the OT suite, will be maintained at the lowest differential pressure. The OT, which is the most vital and cleanest zone, will be kept at the highest differential pressure relative to the atmosphere. However, the pressure difference is lost when the door is opened, and the protective barrier is breached. To avoid this risk, interlocking of doors and/or the use of anterooms are recommended, wherever possible.

Pressure cascading is done by a process called “pressure balancing”, in which the supply and return air flow rates in the different rooms of the OT suite are carefully adjusted. Each OT is provided with a manometer to measure the differential pressure between the OT and the adjoining room. The concepts of zoning and pressure cascading ensure that contamination of the OT resulting from infiltration is minimised.

2.6 Testing for microbiological contamination in OTs

Although microbiological contamination testing in OTs is outside the scope of the engineering team, it is an important and closely related test method. Microbiological testing is performed to assess the effectiveness of environmental controls such as ventilation, cleaning, and operational discipline. Environmental microbiological monitoring is primarily a quality assurance function, helping identify deviations in ventilation performance, cleaning effectiveness, operational discipline and potential lapses in infection prevention practices within the operating theatre.

Microbial contamination testing in OTs is conducted using a combination of air and surface sampling methods. Airborne contamination is evaluated through active air sampling, which quantifies viable microorganisms per unit volume of air, and passive air sampling using settle plates, which estimates the rate of microbial fallout onto critical surfaces over time. Surface contamination is assessed using contact plates or swab sampling on selected high-risk areas such as operating tables, instrument trolleys, lights, and walls.

The samples collected from the OT are inoculated onto appropriate sterile nutrient culture media that support the growth of viable microorganisms and are aseptically transported to the microbiology laboratory. The samples are then incubated under specified temperature and time conditions appropriate for detecting microorganisms. Colony-forming units are counted, recorded, and expressed in standardised units, such as CFU/m^3 for air or CFU/plate for surfaces. The results are interpreted against applicable reference values and historical trends, with deviations triggering investigation and corrective actions.

Chapter 3

HVAC system Components for Infection Control in OTs

The air side of the HVAC system comprises two major sub-components/systems: the Air handling unit (AHU) and the Air distribution system. When precisely designed, installed, and maintained, the HVAC system supports the hospital's infection control plans, especially in preventing SSIs, and thus becomes a vital infrastructure for OTs.

3.1 Air Handling Unit

An AHU's purpose is to provide the necessary air movement to remove airborne contaminants from the OT while maintaining the temperature and humidity as required in the OT environment with minimal noise and vibration. The AHU draws air from the OT, adds outdoor air, corrects the temperature and humidity, removes contaminants and supplies the air back to the OT. In some cases, the AHU is also used to exhaust a part of the air from the HVAC system.

The AHU is a thermally insulated micro-environment that houses,

A cabinet or housing
A blower
A mixing chamber
Air filters
Thermal conditioning equipment
Condensate drain

3.1.1: Cabinet

The AHU cabinet, which houses all internal components of the AHU, is made using double-skinned sandwiched panels and a skeleton made of thermal-break aluminium profiles. The AHU cabinet should be free of air leaks and have sufficient thermal insulation to prevent condensation on its exterior, even in high outdoor humidity. The cabinet should be structurally strong enough to withstand the pressure of the HVAC system. The AHU interiors should be suitable for "hygiene" applications.

3.1.2: Blower

The blower, usually a centrifugal one, is

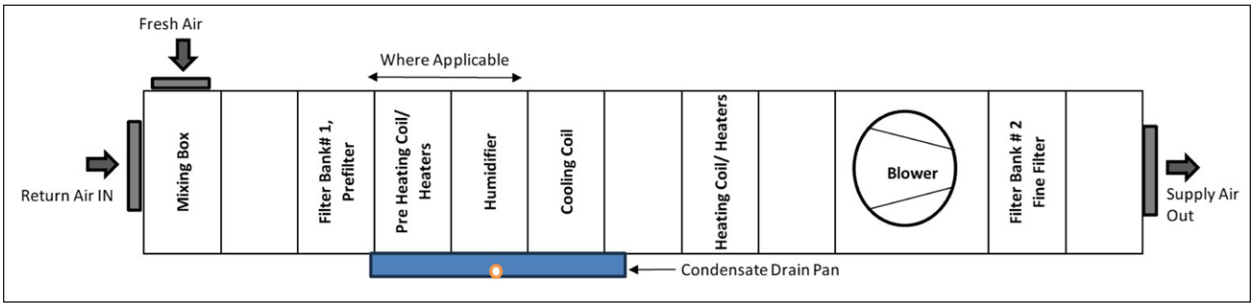


Figure: 2 Typical AHU Schematic Drawing for Operation Theatre

the prime mover of air for the entire system. It is responsible for sucking the return air (RA) from the OT and the outdoor air (OA) and delivering the conditioned air back into the OT. In an OT HVAC system, several stages of air filters, including a HEPA stage, are used. This increases the system's resistance to airflow. The blower is therefore designed for high static pressure, capable of delivering the required air quantity even under high-resistance conditions. The blower airflow rate is so selected that it can provide the design airflow at the highest resistance condition the system is expected to encounter. Since OT HVAC systems must run continuously, the AHU blower is expected to operate 24/7; hence, it should be energy-efficient.

3.1.3: Mixing Chamber

It is necessary to take in outdoor air (OA) into the system for three reasons. (1) To dilute the gaseous contaminants that are generated inside the OT during surgical procedures. (2) As a make-up air to compensate for the bleed air that is lost from the OT due to the positive differential pressure in the OT. (3) To keep the CO2 concentrations inside the OT at an acceptable level. The mixing chamber of the AHU has ports for sucking the OA and the return air from the OT (RA). The RA and OA suction ports are positioned so that the OA and RA mix uniformly before reaching the thermal conditioning equipment. It is necessary to control the proportions of OA and RA as specified in the design. To facilitate this, separate air-volume-control dampers (VCDs) are provided for RA and OA suction ports in the AHU's mixing chamber.

3.1.4: Air filters

There will be a minimum of two air filtration stages (sometimes three stages) in an AHU. The first and the second-stage air filters in the AHU are the coarse filter (typically MERV 8; ASHRAE 52.2) and the fine filter (typically MERV 11 or MERV 13; ASHRAE 52.2), respectively. They are installed in the AHU upstream of the thermal conditioning equipment. These filters remove a significant portion of coarse and fine particles, ensuring the thermal conditioning equipment remains clean and achieving optimal heat transfer efficiency. They are also responsible for prolonging the life of the filters in the downstream sections. Air filters are also installed at the outdoor air intake opening of the AHU to filter out ambient dust particles before the outdoor air is introduced into the AHU. This filter would typically be a MERV 8; ASHRAE 52.2 filter; however, an additional MERV 11; ASHRAE 52.2 filter would also be beneficial. In some cases, an additional fine filter (typically MERV 15; ASHRAE 52.2) is installed at the AHU, downstream of the thermal conditioning equipment and the blower. When installed, this filter helps keep the supply ducts clean and prolongs the life of the terminal HEPA filters. NABH suggests that a minimum of two filtration stages are required in the AHU: a "10 micron" and a "5 micron", "washable" air filters.

3.1.5: Psychrometric Conditioning Equipment

The psychrometric conditioning equipment adjusts the temperature and the humidity of the air that is entering the AHU before being discharged into the OT. The conditioning equipment typically consists of a cooling coil, which can be either a direct-expansion or a chilled-water coil. Additionally, a reheat facility (such as a steam coil, hot-water coil, or electric heaters) and/or humidifiers may be used to control humidity. Together with the temperature and humidity controllers, they ensure that the air discharged from the AHU is at a condition necessary to maintain the temperature and relative humidity in the OT within a particular set range. It is recommended to install UV-C irradiation lamps on the exit side of the cooling coil to prevent biofilm buildup on its surface. This helps prevent the deterioration of the cooling coil's heat transfer efficiency over time.

3.1.6: Condensate Drain

Since the surface of the cooling coil is at a temperature that is much lower than the dew point of the incoming air, the moisture in the air will condense to form water. This condensate must be collected and drained away to prevent

water accumulation inside the AHU. The drain piping should have “U” traps and a suitable gradient to allow condensate to drain even when the AHU fan is running.

3.2 Air Distribution System:

The purpose of the air distribution system is to provide an optimal pathway for the transport of air from the AHU to the OT and back to the AHU, while accounting for frictional losses, noise, and vibration. The air distribution of an OT HVAC system comprises

HVAC Ducting
Volume control dampers
Supply air outlet
Return air inlets

3.2.1: HVAC Ducting

In an OT, there are two types of HVAC ducts: Supply Air Ducts (SAD) and Return Air Ducts (RAD). SAD is used to transport air from the AHU to the supply air outlet in the OT, while the RAD is used to transport air from the OT back to the AHU. For this reason, the SADs are under positive pressure while the RADs are under negative pressure with respect to the atmosphere. The HVAC ducting is usually made of aluminium or galvanised sheet steel and is adequately thermally insulated on the exterior side to prevent condensation and energy loss. It is designed to minimise frictional pressure losses. Adequate thermal insulation is crucial to minimise energy losses, as the SAD will carry air at a temperature of around 11 to 13°C. Ducts are constructed to ensure that the seams are leak-free and the duct joints are suitably gasketed to prevent air leaks. Duct leaks are a significant problem in OT supply air ducts. Due to the presence of HEPA Filters in the supply air outlet of the OT, the supply air ducts remain pressurised, and this results in significant air losses due to leaky ducts. Leaky return-air ducts allow uncontrolled outdoor air and contaminants to enter the system. The introduction of uncontrolled outdoor air hampers control of relative humidity in the OT. Introduction of contaminants into the system leads to unnecessary dirt buildup and an increased microbial burden. Furthermore, a leaky duct leads to significant energy loss. To avoid duct leaks, it is recommended to conduct duct pressure testing during erection and to ensure that duct leaks are kept to a minimum. Both inadequate insulation and duct leaks lead to condensation on surfaces. This facilitates microbial growth on surfaces, posing an infection risk in hospital buildings.

3.2.2: Volume Control Dampers

Volume control dampers (VCD) are provided at the air entry and air exit points of the AHU, called the Return air damper (RAD) and the Supply air damper (SAD), respectively. During pressure balancing of the OT, the RAD is adjusted to achieve the required positive pressure. The SAD is used to control the volume of airflow delivered by the AHU. Additionally, a VCD is installed in the outdoor air intake opening of the AHU to regulate the amount of outdoor air introduced into the system.

3.2.3: Supply Air Outlet

The supply air outlet (SAO) discharges air at a low and uniform velocity, with minimal turbulence, into the OT, directing the airflow downwards towards the surgical table. In this way, the airflow from the SAO prevents contaminants in the OT from moving towards the surgical table; instead, they are pushed towards the return air inlets. The SAD connects the AHU and the SAO, transporting the conditioned air from the AHU to the SAO. The SAO comprises a plenum that houses the terminal HEPA filters (final-stage air filter, rated for a minimum H13, EN1822-1) and the unidirectional airflow diffuser. It is positioned in the centre of the OT, directly above the surgical table, and delivers air into the OT. The SAO should be sized to cover the surgical team members, the surgical table, and all critical sterile instruments and consumables surrounding the surgical table. NABH recommends the use of unidirectional airflow diffusers for all types of OTs. In some General (Type II) OTs, the terminal HEPA filter may be located at the AHU rather than at the SAO. While the NABH allows this in exceptional cases, it is generally recommended to install the HEPA filters at the SAO.

A vertical chute is located at the centre of the supply air plenum to accommodate the installation of the OT surgical light. This chute should be fully sealed at the lower boundary of the unidirectional flow plenum to prevent air exchange between the OT and the space above the false ceiling. This sealing is essential to minimise the risk of condensation and subsequent water dripping at the centre of the OT, and to prevent the ingress of airborne contaminants into the OT.

3.2.4: Return Air Inlets

The Return Air Inlets (RAI) serve as the suction port, removing air from the OT environment. The RAD is connected to the RAI and transports the OT air back to the AHU. The OT would have multiple RAIs, typically placed at a lower level, 150 to 300 mm from the floor. Although it is common practice to position the RAIs at all four corners of the OT, standards are mostly silent on this specification. On a conceptual level, RAIs are required all around the OT to reduce air stratification. The RAIs are equipped with individual volume-control dampers to balance airflow through each unit. Each RAI is also fitted with a coarse filtration stage, commonly referred to as “Fluff” or “Lint” filters (typically a MERV 5; ASHRAE 52.2 filter), to prevent coarse particles and fibres from settling in the RAD. Since the RAIs are positioned at a lower level in the OT, Return Air Risers (RAR) are used to connect the RAIs to the RAD.

In addition to the air-side of the HVAC system, chilled water pipes and refrigerant pipes are installed inside the hospital building. These pipes transport refrigerant at 7 to 10°C between the AHU and the chiller unit. Thermal insulation of these pipes is also crucial for the same reasons as for HVAC ducts.

Thus, the HVAC system helps control temperature and relative humidity rapidly in the OT environment and facilitates the quick removal of contaminants, thereby maintaining an aseptic environment.

3.3 Cleaning and Disinfection in OTs

Due to personnel and equipment movement within an OT, as well as the potential for spillage of the patient’s body fluids, the OT is likely to become contaminated. Unless these contaminants are removed, they could become breeding grounds for various microorganisms. Regular cleaning and disinfection help reduce the environmental reservoirs that could harbour pathogens inside an OT.

Cleaning is the essential first step in the hygiene continuum, forming the base of an infection prevention strategy. It involves physically removing the visible dirt, body fluids, and organic debris from all accessible surfaces. Proper cleaning removes the substrates that support microbial growth, thereby reducing the microbial load before disinfection. Using approved cleaning agents and mechanical action, all floors, walls, furniture, and equipment surfaces are cleaned free of particulate matter through wiping, mopping, or scrubbing. Meticulous deep cleaning is a very effective defence against the spread of infection and ensures that disinfection can be most effective.

Surface disinfection targets invisible pathogens that linger beyond the reach of cleaning agents. Chemical disinfectants with proven efficacy against bacteria, viruses, and spores are applied to critical and high-touch areas, including surgical tables, surgical lights, monitors, switches, and door handles. These areas are prone to the transfer of microorganisms during and between procedures. Correct selection and rotation of disinfectants, adherence to recommended contact times, and validation of cleaning efficacy are essential for preventing the development of resistance and ensuring sustained control over microbial presence.

Space disinfection, also called environmental decontamination, targets the decontamination of air inside the OT. This process involves releasing antimicrobial fogs, vapours or gases that permeate every crevice, including those inaccessible to manual cleaning and surface disinfection. In addition, it is also effective in neutralising the airborne microbial load. It is

generally performed after major renovations, contamination incidents, or during scheduled shutdowns. The process of “Fogging”, which uses antimicrobials suspended in ultra-pure water, is standard in OTs. A fogging machine that atomises the antimicrobial agent is used for this purpose. In modern practice, these antimicrobial agents are mostly aldehyde-free and are considered safe for human exposure. However, if the situation demands the use of other forms of antimicrobial agents, it should be ensured that residual airborne antimicrobial agents are removed after the environmental decontamination process, thereby restoring air quality that is safe for human occupancy.

Cleaning and disinfection in conjunction with air filtration, unidirectional airflow and pressure gradientsserveto continuously remove airborne contaminants in an OT. Together, they form a multilayered shield against infection, ensuring that both the physical environment and the air remain aseptic.

Chapter 4

Introduction to Testing of OT HVAC Systems

This chapter introduces the principles and preparatory considerations associated with testing of HVAC systems serving Operation Theatres (OTs). It is intended as a training-oriented chapter for engineers, technicians, and validation personnel, focusing on behavioural discipline, system readiness, and preparatory checks that directly influence the reliability and repeatability of OT HVAC testing outcomes.

Unlike Chapter 5, which defines formal validation methodology, acceptance criteria, and certification requirements, this chapter deliberately avoids detailed test procedures, calculations, and limits. Its purpose is to establish the correct mindset, discipline, and preconditions before formal validation activities commence.

4.1 Importance of Behavioural Discipline During OT HVAC Testing

An Operation Theatre is a highly controlled environment designed to maintain sterility and stable environmental conditions. During HVAC testing activities, personnel behaviour has a direct and measurable impact on airflow patterns, particle generation, pressure stability, and test integrity.

All personnel entering the OT for testing purposes shall observe the following principles:

- Movements inside the OT shall be calm, deliberate, and purposeful. Sudden movement, crowding, or unnecessary activity can disturb airflow patterns and artificially elevate particle levels.
- Contact with walls, ceilings, surgical lights, air diffusers, return grilles, and medical equipment shall be avoided unless explicitly required for the test being performed.
- Strict adherence to OT dress codes and personal hygiene protocols is mandatory, including approved scrubs, caps, masks, footwear, gloves and hand hygiene.

Figure 3: Maintaining Hand Hygiene

- Door openings shall be minimised and coordinated. Simultaneous opening of multiple doors must be avoided to preserve pressure differentials.

- Supply air diffusers and return air grilles shall remain unobstructed. Test instruments shall be positioned so as not to block airflow paths or influence test conditions.

Behavioural discipline within the OT is as critical as technical competence. Inadequate discipline can invalidate test results and lead to incorrect conclusions regarding HVAC system performance.

4.2 Awareness of Cross-Contamination Pathways

Personnel involved in OT HVAC testing must understand basic cross-contamination mechanisms. Disturbance of airflow, improper movement between clean and less-clean zones, touching of surfaces, and uncontrolled door operation can introduce contaminants into critical areas.

All testing activities shall therefore be conducted in alignment with established infection control guidelines and OT operational protocols. HVAC testing must support, and never compromise, the sterile environment.

4.3 Cleanliness Classification Awareness

Operating theatres are designed to meet defined airborne cleanliness targets, commonly referenced to ISO 14644 cleanroom classifications or applicable national healthcare guidelines.

Testing personnel must be aware that:

- Cleanliness targets define permissible airborne particle concentrations
- These targets influence test conditions and interpretation
- OT HVAC testing is typically conducted in the “at-rest” condition

A basic understanding of cleanliness classification helps reinforce the importance of controlled preparation and disciplined behaviour during testing.

4.4 Design Review & As-Built Verification (Pre-Test Readiness)

Before commencing OT HVAC testing, personnel shall confirm that the installed HVAC system and OT configuration reflect the approved design intent. This includes verification of airflow concepts, zoning philosophy, pressure hierarchy, filter locations, and terminal device placement.

Testing a system that deviates from approved design—due to undocumented site changes, incomplete installation, or incorrect configuration—can result in misleading outcomes and repeated non-conformances. At this stage, the objective is not performance validation, but confirmation that the system is fundamentally suitable for testing.

4.5 Maintenance History & Filter Change Record Review

OT HVAC testing assumes that the system is in a maintained and serviceable condition. Prior to testing, maintenance logs and filter replacement records should be reviewed to confirm that routine servicing has been performed and that filters are within their recommended service life.

Unresolved maintenance issues—such as overdue filter replacement, incomplete servicing, or previously reported unresolved faults—can significantly influence test outcomes and should be addressed before formal validation activities commence.

4.6 Pre-Test Readiness and Environmental Stability

Before formal validation testing begins, the following readiness checks shall be completed:

- Review of relevant SOPs, work instructions, and user protocols
- Confirmation that HVAC systems are operating in normal control mode
- Verification that temperature, relative humidity, airflow, and pressure conditions are stable
- Allowing sufficient system run time to achieve steady-state conditions

Completion of these steps establishes a stable baseline and prevents misinterpretation of test results due to transient or unresolved system issues.

4.7 Position of This Chapter Within the Validation Framework

This chapter serves as a preparatory and

training-focused introduction to OT HVAC testing. It provides behavioural guidance, system readiness awareness, and pre-test discipline that support the formal validation procedures detailed in Chapter 5.

Chapter 5 shall be referenced for:

- Test methods
- Acceptance criteria
- Compliance requirements
- Reporting and certification procedures

Together, Chapters 4 and 5 ensure that OT HVAC testing is conducted with both technical rigour and appropriate operational discipline.

This chapter introduces the principles and preparatory considerations associated with testing of HVAC systems serving Operation Theatres (OTs). It is intended as a training-oriented chapter for engineers, technicians, and validation personnel, focusing on behavioural discipline, system readiness, and preparatory checks that directly influence the reliability and repeatability of OT HVAC testing outcomes.

Unlike Chapter 5, which defines formal validation methodology, acceptance criteria, and certification requirements, this chapter deliberately avoids detailed test procedures, calculations, and limits. Its purpose is to establish the correct mindset, discipline, and preconditions before formal validation activities commence.

Chapter 5

Operation Theatre HVAC Validation

5.1 Introduction, Scope & Compliance Principles

5.1.1 Introduction

Operation Theatres (OTs) function as controlled environments that require stable, hygienic conditions to minimise airborne contamination and support patient safety. The HVAC system is central to infection control and must be verified through standardised, repeatable test methods.

This manual establishes a structured methodology for validating OT HVAC performance. It aligns procedures, terminology, and reporting formats with relevant international cleanroom principles, particularly ISO 14644-3, which defines cleanroom test methods.

The document provides a practical reference for engineering, clinical, and quality professionals engaged in commissioning, auditing, and certifying surgical environments.

5.1.2 Purpose

The objectives of this manual are to:

- Standardise HVAC performance testing across all OTs
- Ensure ventilation systems consistently meet design intent
- Support infection control and patient safety
- Enable traceable audit and certification practices

This Manual converts field practices and existing SOPs into a structured validation framework suitable for training and regulatory compliance.

5.1.3 Scope

This manual applies to:

- Unidirectional airflow and Mixing / Turbulent airflow OTs.
- Commissioning, annual validation, post-maintenance revalidation, and corrective verification

Covered procedures address airflow pattern, differential pressure, installed HEPA filter system leakage, airborne particle concentration, air change rate, temperature, and relative humidity as outlined in ISO 14644-3 Annex B.

Exclusions:

- Microbial monitoring (ISO 14698)

5.1.4 Compliance & Test Philosophy

Testing demonstrates compliance with design intent, safety expectations, and relevant standards. ISO 14644-3 emphasizes the application of test methods suited to the validated process and occupancy conditions.

Accordingly, tests must be:

- Repeatable and instrument-traceable
- Conducted with calibrated equipment

- Sequenced to avoid interference
- Documented for reliability and audit purposes

Where multiple acceptable methods exist, the customer and testing specialist shall agree on the preferred method, consistent with ISO guidance.

5.1.5 Roles & Responsibilities

User

- Defines performance targets
- Reviews results
- Approves compliance status

Facility/HVAC Engineering

- Executes testing
- Ensures instrument calibration

Quality & Compliance Oversight

- Reviews reports
- Ensures alignment with standards and accreditation criteria

Infection Control Team

- Observes critical tests
- Supports interpretation relative to clinical risk

Responsibility assignment mirrors existing organisational practices in your SOPs .

5.1.6 Referenced Standards

Primary reference:

- ISO 14644-3 — Test Methods for Cleanrooms and Controlled Environments

Supporting references include:

- ISO 14644-1 (classification by airborne particle concentration)
- ASHRAE 170 (ventilation of healthcare facilities)
- NABH/ISHRAE Healthcare HVAC guidelines

These references inform test definitions, methodology boundaries, and reporting expectations.

5.1.7 Documentation Requirements

Per ISO 14644-3 Clause 5, each test record must include at minimum:

- Facility name and test date
- Reference to this manual and the relevant ISO standard
- Occupancy condition
- Instrument model and calibration status
- Measured values vs acceptance criteria
- Result statement (Pass/Fail or Conform/ Not Conform)

- Tester and verifier signatures

Records support traceability, trending, and audit assurance.

5.1.8 Validation Frequency & Test Condition

Validation shall be conducted:

- At initial commissioning
- Following maintenance or modification
- Annually or at defined intervals
- When monitored conditions deviate from defined targets

All tests will be conducted in the as-built/at-rest states. These conditions are defined below in line with ISO 14644.

5.2 Test Matrix & Performance Criteria

ISO 14644-1 Particle Classification Table (≥0.5 µm)

ISO Class	Maximum particles/m^3 ≥0.5 µm
ISO 5	3,520
ISO 6	35,200
ISO 7	352,000
ISO8	3,520,000

5.2.1 Key Definitions

The following terms are used throughout this manual and testing documentation:

Cleanroom / Clean Zone

A controlled area where airborne particulate concentration is managed and classified, and supporting physical conditions (temperature, humidity, pressure) are maintained to meet specified cleanliness levels.

At-rest State

Condition where the OT is complete, equipment installed and operating, HVAC

systems stabilised, and **no personnel are present** — the designated state for OT HVAC testing in this facility.

As-built State

Condition in which the facility structure and base building services are complete and constructed in accordance with the approved design, before installation of OT equipment — the designated reference state for as-built documentation and verification.

Air Change Rate

The number of times per hour the room air volume is replaced by supply airflow.

Installed Filter Integrity

Confirmation that HEPA filters and housings are installed without leakage and meet required aerosol penetration limits.

Particle Concentration

Number of airborne particles per cubic metre at a given particle-size threshold.

Definitions align with Section 3 terminology within ISO 14644-3 pages 3–6 .

5.2.2 OT Validation Test Matrix

The following performance checks are required for certification of surgical OTs and associated zones. This test matrix follows the supporting test structure of ISO 14644-3 Annex A and B.

Test	Purpose
Airflow Velocity & Uniformity	Confirm unidirectional flow over the sterile field
Air Volume Flow / ACH	Verify dilution
Airflow Direction	Confirm directional sterile bias.
Pressure Differential	Validate positive pressure cascade
Installed HEPA Filter Leakage Test	Verify filter integrity and sealing
Particle Count Test	Verify ambient particulate cleanliness
Temperature Test	Confirm thermal comfort/ stability
Humidity Test	Verify moisture control for infection risk
Noise Test	Check ergonomic/occupational standards

These correspond to ISO Annex B supporting test categories (airflow, direction, installed filter leakage, temperature, humidity, etc.).

5.2.3 Performance Requirements

Performance limits shall reflect:

- ISO test methodology (procedural compliance)
- NABH / healthcare environment expectations
- Design specifications for the OT installation

Typical ranges applied in this facility:

Parameter	Acceptable Range
Air velocity over the sterile zone	25 to 35 fpm (0.127 to 0.177 m/s)
Total Air changes per hour (TACH) & Fresh Air changes per hour (FACH)	TACPH > 20 per hour and FACH >4 per hour
Temperature	21–24 °C or as agreed
Relative humidity	40–60%
Pressure differential	≥ 5 Pa between zones
Particle concentration targets	ISO 5–6 at rest, depending on design
HEPA leakage limit	≤ 0.01% of upstream challenge

These values are aligned with ISO/NABH norms.

5.2.4 Acceptance Principles

A test is considered compliant when:

- Measured values meet or exceed design intent
- Readings conform to defined ranges
- Test equipment calibration is current
- Measurement integrity is verified by repetition where required
- Deviations (if any) are documented, explained, and accepted after corrective action

ISO 14644-3 emphasizes that test method selection and acceptance must be agreed between customer and supplier, and evidence must be recorded in test reports.

5.2.5 Failure & Escalation Criteria

A test shall be declared non-compliant when one or more of the following occur:

- Readings fall outside accepted tolerance limits
- Filter integrity testing reveals leakage > 0.01%
- Pressure cascade reverses or is below 2.5 Pa
- Airflow patterns do not demonstrate sterile bias
- Particle counts exceed the target ISO class threshold

Corrective action may include:

- Filter reseating or replacement
- Rebalancing of air handling units
- Obstruction removal
- Design or control logic adjustments
- Replacement of any defective equipment

All failures must be recorded and re-verified before certification release.

5.2.6 Test Sequencing Logic

To prevent result interference, testing shall follow this sequence:

1 Pre-inspection and instrument calibration
2 Airflow measurements (velocity & volume)
3 Pressure differential verification
4 Airflow direction (visualisation)
5 Installed HEPA filter leakage testing
6 Particle counting
7 Thermal and humidity measurements
8 Noise checks
9 Compliance review and reporting

This sequence is consistent with ISO Annex A guidance on order selection to avoid adverse test interaction.

5.2.7 Document Control

This manual forms part of the OT Certification Quality System.

Revision control, procedure numbering, issuing authority, and retention duration are governed under the facility's documentation policy.

5.3 Test Apparatus, Calibration & Traceability Requirements

5.3.1 Purpose

This section defines the measurement instruments required for OT validation testing, along with calibration, certification, and traceability expectations.

It aligns with ISO 14644-3 guidance on test apparatus reliability and documentary control of instrument performance.

5.3.2 Instrumentation Requirements Overview

All instruments used for HVAC performance testing must be:

- Fit for the intended measurement range
- Calibrated
- Traceable to an accredited laboratory or national standard
- Operated according to manufacturer's instructions

This approach aligns with ISO 14644-3 test apparatus descriptions and reporting requirements.

5.3.3 Test Equipment List

The following minimum equipment set is required for OT certification activities:

This list corresponds with the equipment described in ISO 14644-3 Annex C and instruments referenced in your existing SOPs.

Test	Required Apparatus	Resolution	Accuracy / Max Permissible Error
Airflow velocity	Hot-wire / vane anemometer	0.01 m/s (0.2–0.99 m/s) 0.1 m/s (≥1.0 m/s)	±0.1 m/s or ±10% of reading
Air volume	Flow capture hood / velocity grid method	0.001 m^3/s	±0.01 m^3/s or ±10% of reading
Airflow direction	Visible tracer aerosol generator	Qualitative	Not applicable
Pressure differential	Differential pressure gauge/ micromanometer	0.5 Pa (≤50 Pa) 1.0 Pa (≤250 Pa)	±2 Pa or ±5% of reading
Filter leak test	Aerosol generator + photometer	0.0001 (instrument scale)	±10% of selected range
Particle count	Laser airborne particle counter	1 count	ISO 21501-4 compliant
Temperature	Digital thermometer	≤20% of allowable tolerance band	As per ISO 7726
Humidity	Digital thermo-hygrometer	≤20% of allowable RH tolerance band	As per ISO 7726
Noise	Calibrated sound level meter	0.1 dB(A)	±1.5 dB(A)

Figure 4: Image of a Particle Counter

Figure 7: Aerosol Generator

Figure 5: HEPA filter Test Scanning with Photometer

Figure 8: Airflow Measurement with Capture Hood

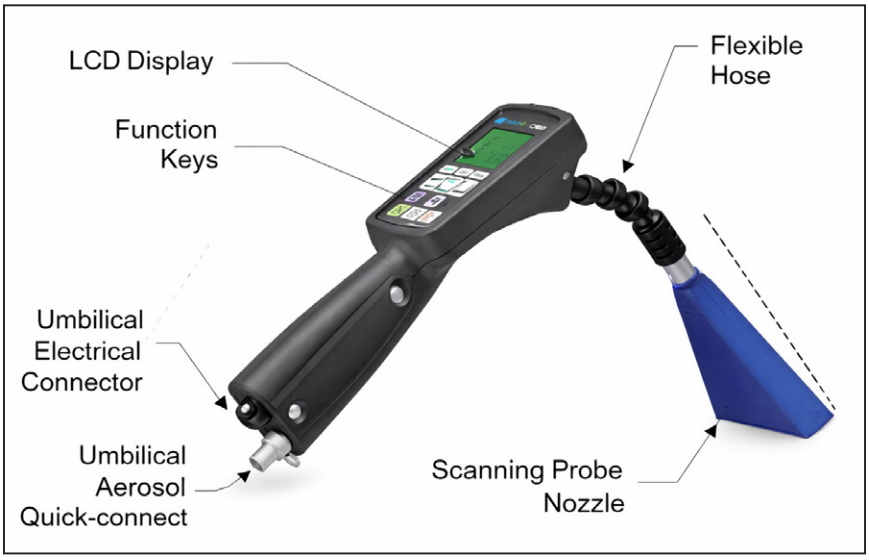


Figure 6: Scanning Probe of a Photometer

Figure 9: Air Flow Pattern Test in an Operation Theatre

5.3.4 Calibration Requirements

5.3.4.1 Calibration Cycles

All instruments shall meet the following rules:

- Calibration interval: **annual,** or as recommended by the manufacturer.
- Calibration agency: **ISO 17025 accredited or equivalent**
- Instrument must display a **valid calibration date label**

Any instrument without current calibration must be withdrawn from use.

5.3.4.2 Calibration Records

Calibration documentation must include:

- Instrument model, serial number
- Calibration date and expiry date
- Traceability reference
- Calibration certificate copy or QR-linked reference

Records shall be retained with validation files to support technical traceability and audit review.

5.3.5 Check-Before-Use Requirements

Before any test session, the operator shall verify:

- Display response / auto-zero performance (Examples given in annexure to this section)
- Sensor surface cleanliness (for probes/ anemometers)
- Battery charge or power supply stability
- Probe orientation for directional measurements
- Functionality checks (warm-up cycles, zeroing, etc.)

These are consistent with ISO 14644-3 emphasis on instrument suitability and apparent accuracy checks before use.

5.3.6 Traceability & Instrument Control

5.3.6.1 Asset Register

A master list of all instruments used for OT validation is maintained.

It includes:

- Serial number tracking
- Calibration status
- Storage location
- Assigned custodian

5.3.6.2 Instrument Identification

Each device shall display:

- Unique ID number
- Calibration label
- Status indication (active / expired / under service)

5.3.7 Environmental Considerations

Measurement accuracy can be influenced by:

- Temperature
- Humidity
- Probe angle
- Personnel movement

Operators must conduct readings under stable conditions and repeat measurements where variation is suspected.

5.3.8 Failed Instrument Handling

If an instrument is found uncalibrated or defective:

- Remove from active service
- Tag as non-conforming
- Replace with calibrated equivalent
- Record the deviation and notify quality authority

Pending tests must be rescheduled or re-performed with conforming equipment.

5.3.9 Documentation of Apparatus

In accordance with ISO 14644-3 Clause 5 (reporting requirements), each test report shall record:

- Instrument type and model
- Serial number
- Calibration due date

ANNEXURE To Section 5.3.5

Document Title: Check-Before-Use Verification of Test Instruments for Operation Theatre Certification

1. Purpose

To ensure that all instruments used for Operation Theatre certification and re-certification are verified for functional display response and acceptable zero performance prior to testing, in line with ISO 14644-3, NABH 6th Edition, and JCI 8th Edition requirements.

2. Scope

Applicable to all environmental and performance tests conducted in Operation Theatres, including airflow, pressure, particulate, thermal comfort, noise, and illumination measurements.

3. Reference Standards

- ISO 14644-3 – Cleanrooms and associated controlled environments – Test methods
- NABH 6th Edition – Facility Management & Safety (FMS)
- JCI 8th Edition – Environment of Care (EC)
- Manufacturer operating manuals for test instruments

4. Responsibility

- **Testing Engineer** / **Operator:** Perform and record check-before-use verification
- **QA** / **Engineering Supervisor:** Review records and authorize use of instruments

Check-Before-Use Instrument Verification Record

(To be completed before commencement of each OT certification test session)

Sr. No.	Test Parameter	Instrument Description	Instrument ID	Calibration Due Date	Check-Before-Use Verification (Display Response / Auto-Zero)	Acceptance Criteria	Result (Pass / Fail)	Operator Name & Signature	Date
1	Airflow velocity	Hot-wire / Vane anemometer			Display ON; zero verified in still air; response confirmed when airflow applied	Stable zero; smooth response; correct unit			
2	Air volume	Flow capture hood/velocity grid			Display initialized; zero checked with no airflow; response verified at diffuser	Zero stable; proportional response			
3	Airflow direction	Visible tracer aerosol			Visible tracer aerosol output verified; continuous and visible plume	Uniform, visible tracer aerosol suitable for visualization			
4	Pressure differential	Differential pressure gauge/micromanometer			Zero verified with ports open; positive/negative response checked	Zero ± manufacturer tolerance; correct unit			
5	Filter leak test	Aerosol generator			Aerosol generation verified visually	Adequate aerosol output			
		Photometer			Warm-up completed; auto-zero performed with HEPA filter	Zero within the manufacturer's limit			
6	Particle count	Laser airborne particle counter (≥0.5 μm & ≥5.0 μm)			Zero count performed using a certified zero filter	Zero count within the manufacturer's specification			
7	Temperature	Digital thermometer			Ambient reading stable; response verified by probe warming	Responsive display; correct unit (°C)			
8	Humidity	Digital thermo-hygrometer			RH response verified; display stable	Reasonable ambient RH; responsive			
9	Noise	Sound level meter			A-weighting selected; auto-zero/ internal check completed	Stable baseline; correct settings			

Note: Where instruments are provided with an in-built printer, printer functionality, legibility, and correct date/time stamp were verified prior to use

6. Acceptance Criteria (General)

- Instrument display shall be fully functional and legible
- Zero or baseline reading shall be within manufacturer-specified tolerance
- Instrument shall respond appropriately to applied stimulus
- Calibration validity shall be current at the time of testing

7. Operator Declaration

I confirm that the above instruments were verified prior to use and found suitable for testing in accordance with ISO 14644-3, NABH 6th Edition, and JCI 8th Edition requirements.

Name: _____

Signature: _____

Date: _____

8. Reviewer / Supervisor Verification (Mandatory for NABH / JCI)

Records reviewed and instruments authorized for use.

Name: _____

Signature: _____

Date: _____

5.4 Test Methods & Acceptance Procedures

This section describes the validated procedures used to assess OT HVAC performance. Methods described herein are aligned with ISO 14644-3 Annex B procedural structure and reflect healthcare OT practice.

Each test includes:

- Objective
- Pre-conditions
- Apparatus
- Procedure
- Acceptance criteria
- Reporting requirements

Instrument accuracy requirements are provided in the respective SOP documents, ensuring alignment with the correct measurement tolerance.

5.4.1 Airflow Velocity & Uniformity Test

Objective

To verify that the supply airflow in the Operation Theatre meets the design intent for unidirectional (laminar) airflow by confirming the average airflow velocity and the uniformity of velocity, in accordance with ISO 14644-3:2019, Annex B, Section B.2.

Applicable OT Type

Unidirectional airflow (laminar flow) Operation Theatres.

Test Condition (Pre-conditions)

- Operation Theatre in at-rest condition
- HVAC system operating and stabilised for a minimum of 30 minutes
- All doors closed
- No personnel movement during measurements

Test Apparatus

- Calibrated hot-wire, thermal, ultrasonic, or vane-type anemometer suitable for low air velocity measurement
- Tripod or positioning device to maintain probe stability and correct distance from filter face

All instruments shall have valid calibration and traceability records.

Measurement Plane and Grid Layout

- Define a measurement plane perpendicular to the supply airflow.
- Measurements shall be taken 150 mm to 300 mm below the HEPA filter face or supply outlet plane.
- The measurement plane shall be divided into equal-area grid cells.
- The minimum number of measurement points shall be determined using the ISO 14644-3 formula:

$$N = \sqrt{(10 \times A)}$$

Where:

- *N* = minimum number of measurement points (rounded up to the next whole number)
- *A* = measured filter or supply area in m^2

At least one measurement point per filter or fan-filter unit shall be included.

Measurement Procedure

- Position the airflow probe at the centre of each grid cell.
- Align the probe correctly with the airflow direction.
- Allow sufficient time at each point to obtain a stable, repeatable reading.
- Record the time-averaged airflow velocity at each measurement point.
- Repeat measurements if abnormal fluctuation is observed.

Calculation of Average Airflow Velocity

The average airflow velocity shall be calculated as:

Va = (ΣVn) / N

Where:

- *Va* = average airflow velocity (m/s)
- *Vn* = airflow velocity at each measurement point (m/s)
- *N* = total number of measurement points

Evaluation of Velocity Uniformity

Velocity uniformity shall be evaluated using the ISO 14644-3 statistical methodbased on standard deviation.

The Uniformity of Velocity (UV) is calculated as:

UV = [1 − (σ / Va)]

Where:

- *σ* = standard deviation of measured airflow velocities

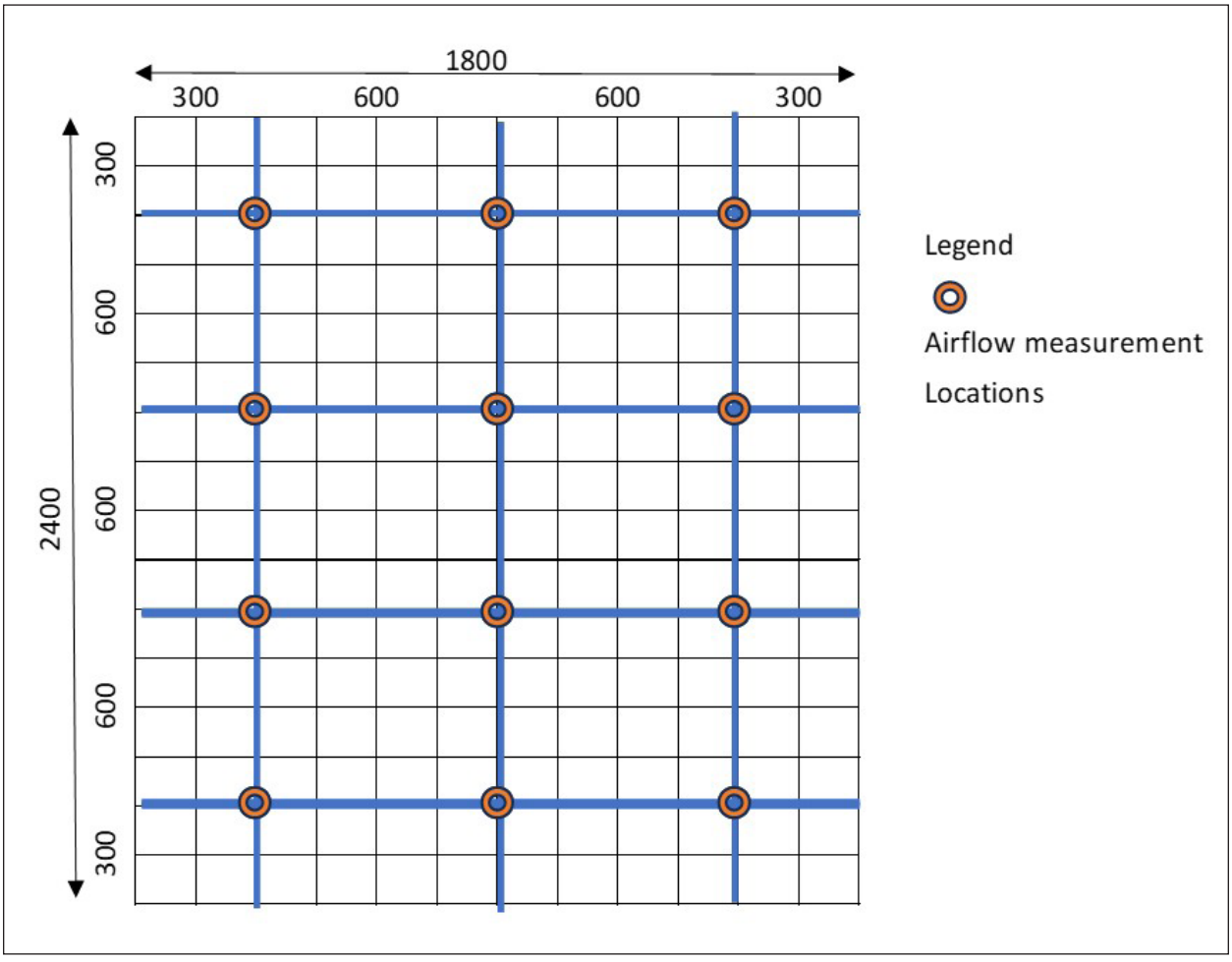


Figure 11 Recommended Grid Locations for Air Velocity Measurements for a 2400mm x 1800mm Unidirectional Airflow Unit

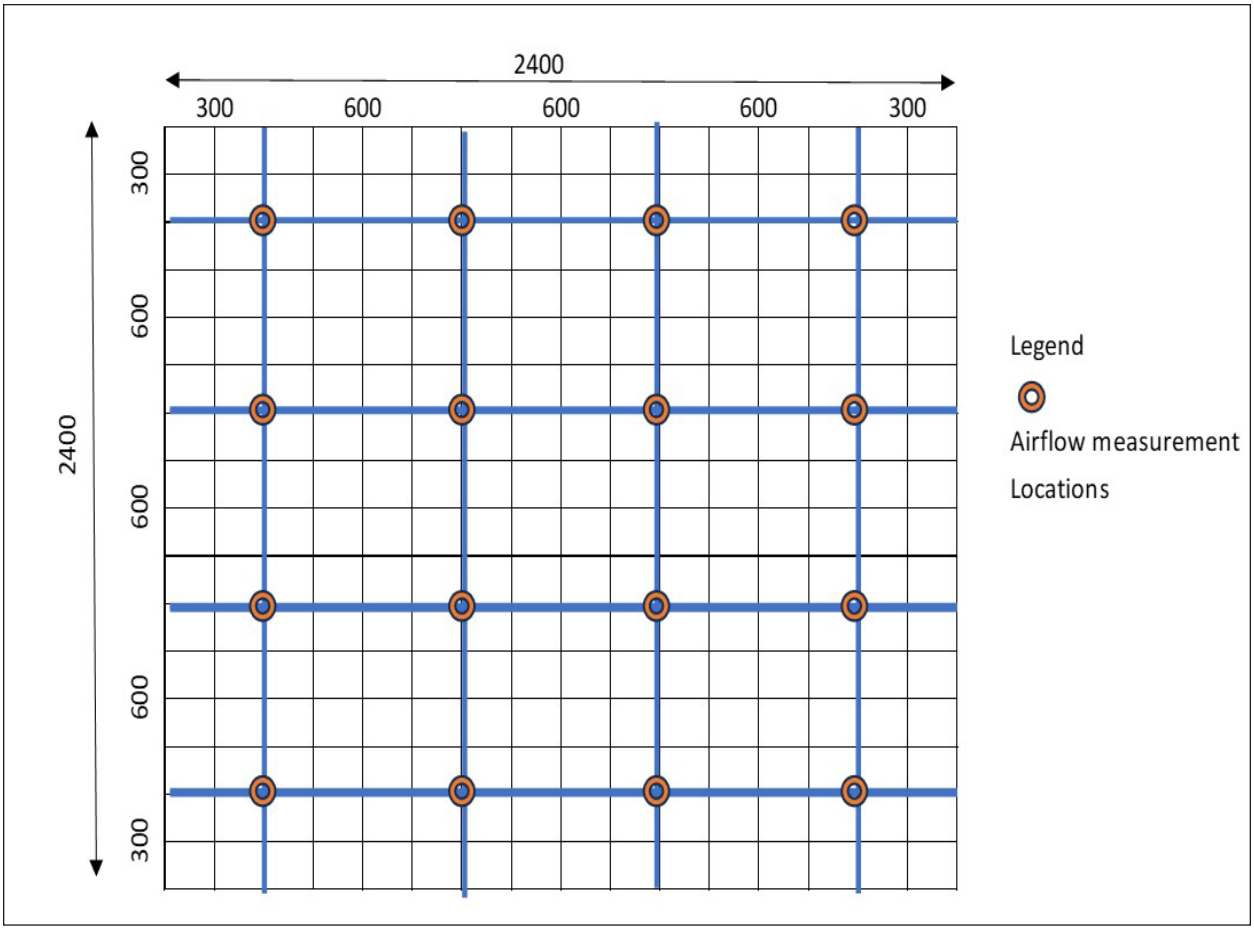


Figure 10 Recommended Grid Locations for Air Velocity Measurements for a 2400mm x 2400mm Unidirectional Airflow Unit

- *Va* = average airflow velocity

This method assesses how evenly airflow velocities are distributed across the measurement plane.

The acceptance criteria for UV value will be in line with IEST RP CC 002.3, Unidirectional Flow Clean Air Devices, and should be 0.85 or more.

Notes:

Though the number of readings to be taken, N = √(10×A) It is recommended that twice as many readings be taken. Below are the recommended points for taking the readings for the typical 2400mm x 2400mm and 2400mm x 1800mm unidirectional air flow units.

Acceptance Criteria

The following shall be demonstrated:

- Average airflow velocity meets the design-specified range for the OT installation
- Velocity distribution across the grid shows no significant localised deviation inconsistent with unidirectional airflow
- Results are consistent and repeatable

Acceptance limits shall be as defined in the approved project specifications and validation protocol.

5.4.2 Airflow Direction (Smoke Visualization Test)

Objective

To confirm that airflow within the Operation Theatre is directed away from the sterile zone toward adjacent lesser clean spaces, thereby preventing ingress of contamination.

Pre-conditions

- Same as above

Apparatus

- Visible tracer aerosol
- The visible tracer aerosol used for airflow visualization shall consist of particles small enough to faithfully follow air movement and shall not introduce thermal buoyancy or momentum effects. The tracer shall be used solely for qualitative visualization of airflow direction and turbulence, in accordance with ISO 14644-3.

Method

- Release the visible tracer aerosol at doors, floor level and return grills
- Observe movement
- Record video/images if applicable

Acceptance

- Outward movement from OT into adjoining areas
- No reverse flow

Reporting

Include visual documentation, observation summary, tester sign-off.

4.3 Air Volume Flow Rate / ACH Verification

Objective

To confirm dilution and pressurisation rate.

Pre-conditions

As-built/at-rest condition.

Apparatus

- Air capture hood or velocity grid method

Method

- Measure supply velocities & compute room air volume
- Derive ACH based on room volume

Calculation:

$$\text{Total ACH} = \frac{\text{Total Supply Air Volume (m}^3\text{/hr)}}{\text{Room Volume (m}^3\text{)}}$$

$$\text{Fresh Air ACH} = \frac{\text{Fresh Air Volume (m}^3\text{/hr)}}{\text{Room Volume (m}^3\text{)}}$$

Acceptance

Total ACH (20–25 ACH)

Fresh Air ACH (≥ 4 ACH)

Reporting

Volume readings, ACH calculation sheet, and conformance statement.

5.4.4 Pressure Differential Test

Objective

Verify pressure cascade protecting sterile spaces.

Apparatus

- Differential manometer or micromanometer

Method

- Measure between OT and scrub, prep, and corridor zones
- Take readings at steady state

Acceptance

≥ 5 Pa positive differential

Reporting

Interzone readings, trend consistency, compliance note.

5.4.5 Installed HEPA Filter Leakage Test

Objective

Confirm proper installation, sealing and absence of bypass leakage.

Pre-conditions

- HVAC stable
- Upstream injection available

Apparatus

- Aerosol generator (PAO)
- Photometer

Method

- Establish upstream concentration (1–100 mg/m³)
- Traverse filter face and perimeter with probe at ≤5 cm/s
- Document leakage points

Acceptance

- ≤ 0.01% penetration (per ISO 14644-3)

Reporting

Leak status, scanned areas, peak values, pass/fail signature.

5.4.6 Particle Count Testing

Objective

Assess airborne particulate cleanliness at ≥0.5 μm.

Apparatus

- ISO 21501-4 compliant laser particle counter

Method

- Determine the number of sampling locations using the ISO 14644-1 location formula
- At each location, sampling at 28.3 L/min is typically used.
- For ISO Class 5, perform particle concentration measurements at ≥ 0.5 μm only

Acceptance

As per the classification table inserted in Section 2:

ISO Class	Maximum particles/m³ ≥0.5 µm
ISO 5	3,520
ISO 6	35,200
ISO 7	352,000
ISO8	3,520,000

Reporting

Sampling map, readings per location, class compliance, test state confirmation.

5.4.7 Temperature & Humidity Test

Objective

Ensure acceptable thermal and moisture conditions for surgical comfort and infection control.

Apparatus

- Digital thermometer
- Thermo-hygrometer

Acceptance

- Temperature: 21–24°C or as agreed
- RH: 40–60%

4.8 Noise Level Test

Objective

Confirm ergonomic comfort and communication quality.

Apparatus

- Calibrated sound level meter

Method

- Measure at surgeon ear height under AHU running condition

Acceptance

- < 60 dB(A) typical (or as agreed in design)
- 5.4.9 Final Verification & Release

Following completion of all tests:

- Deviations recorded
- Corrective actions implemented
- Retesting documented
- Final sign-off issued

This complies with ISO 14644-3 clause requiring reporting and designation confirmation.

5.5 — Reporting, Certification & Release Criteria

5.5.1 Purpose

This section defines how test findings are documented, reviewed, approved and archived for certification of Operation Theatres.

It aligns with ISO 14644-3 reporting requirements, NABH/healthcare audit expectations, and traceability principles previously established in Section 1.

5.5.2 Reporting Structure

Each validation activity shall generate a Test Report supported by:

- Raw measurement data
- Calculations
- Instrument calibration records
- Photographic/video evidence (where applicable)
- Statement of conformity

Reports are structured to ensure:

- reproducibility
- audit transparency
- traceability

A standardised template is included in Annex Section 6.

5.5.3 Minimum Contents of a Test Report

Every report must contain:

1 Facility name and location
2 OT name/identifier
3 Test performed
4 Date/time and OT operating condition
5 Instrument details
   - Make, model, serial number
   - Calibration validity
6 Test method summary (reference to SOP section)
7 Measured data (tables / logs)
8 Calculations (if relevant — ACH, velocity average, etc.)
9 Acceptance criteria comparison
10 Result
   - Compliant / Non-compliant
11 Tester signature
12 Verifier/Approving authority signature

This mirrors ISO 14644-3 documentation expectations.

5.5.4 Conformity Statement Requirements

Every report shall end with a declaration:

"The results recorded herein represent the observed values during testing at the as-built/at-rest condition. All measurements were obtained using calibrated instruments. Based on the documented results, this test is assessed as:

☐ Conforming / ☐ Not conforming."

Where non-conformance exists, corrective actions must be logged and retesting documented.

5.5.5 Deviation & Corrective Action Recording

If a test fails:

- Identify cause
- Record deviation
- Implement corrective action
- Conduct re-test
- Capture re-measured values

Deviation logs shall include dates, responsible personnel, and closure signatures.

5.5.6 Certification & Release Criteria

An OT is considered compliant and suitable for operational clearance when:

- All tests required in Section 2 Test Matrix have been performed
- All test reports demonstrate conformance to acceptance criteria
- Deviations (if any) have been rectified and closed

Only thereafter may the signing authority issue:

Operation Theatre HVAC Validation Certificate / Clearance Note

5.5.7 Validation Certificate Format

Certification documents will include:

- OT name and code
- Test series reference / report numbers
- Validity period
- Signatures of Quality/Engineering/ Infection Control authority

A sample certificate template is included in Annex Section 6.

5.5.8 Records Control & Archiving

All test results, certificates, and reports shall be:

- Maintained under document control
- Retained for a minimum 3–5 years (or as per regulatory policy)
- Readily retrievable for audits

Electronic storage shall include version control and access restriction wherever implemented.

5.5.9 Competency & Authorisation

Certification may only be signed off by personnel with assigned accountability under Section 1.5, ensuring technical and clinical oversight.

5.6 — Annexures, Checklists & Forms

This section provides the controlled templates used for recording validation data, reporting results, and issuing certification.

All annexures and forms are issued under document control.

Copies may be customised for facility-specific use, provided core fields are retained.

Annexure A — OT HVAC Validation Checklist

This checklist shall be completed before formal testing begins.

Annexure B: OT Validation Forms:

Annexure B1 – Airflow Velocity & Uniformity

Annexure B2 – Airflow Pattern / Direction

Annexure B3 – Pressure Differential

Annexure B4 – Particle Count

Annexure B5 – HEPA Filter Integrity

Annexure B6 – Temperature & Humidity

Annexure B7 – Noise Level

ANNEXURE A – OT HVAC Validation Checklist

Sr No	Verification Item	Yes	No	Remarks
1	OT completed, equipment installed			
2	HVAC running ≥ 30 minutes			
3	Filters installed and clean			
4	Instruments available and calibrated			
5	Sampling points marked (for particle testing)			

Technician / Testing Engineer	User / Facility Representative	Date
Name & Signature:	Name & Signature:	

ANNEXURE B1 – Airflow Velocity & Uniformity Record

Grid Location	Velocity (m/s)	Remarks	
Average Velocity	Std Deviation	Uniformity (UV)	Result

Technician / Testing Engineer	User / Facility Representative	Date
Name & Signature:	Name & Signature:	

Test Sign-Off

ANNEXURE B2 – Airflow Pattern / Direction Observation

Location	Tracer Point	Observed Direction	Reverse Flow (Y/N)	Remarks

Technician / Testing Engineer	User / Facility Representative	Date
Name & Signature:	Name & Signature:	

Test Sign-Off

ANNEXURE B3 – Pressure Differential Record

From Zone	To Zone	ΔP (Pa)	Acceptance	Pass/Fail

Technician / Testing Engineer	User / Facility Representative	Date
Name & Signature:	Name & Signature:	

Test Sign-Off

ANNEXURE B4 – Particle Count Record

Sampling Location	ISO Class	≥0.5 μm	≥5.0 μm	Conformance

Technician / Testing Engineer	User / Facility Representative	Date
Name & Signature:	Name & Signature:	

Test Sign-Off

ANNEXURE B5 – HEPA Filter Integrity Scan

Filter ID	Upstream Conc.	Peak Leakage %	Leak Location	Result

Technician / Testing Engineer	User / Facility Representative	Date
Name & Signature:	Name & Signature:	

Test Sign-Off

ANNEXURE B6 – Temperature & Humidity Log

Location	Temp (°C)	Acceptance	RH %	Acceptance	Pass/Fail

Technician / Testing Engineer	User / Facility Representative	Date
Name & Signature:	Name & Signature:	

Test Sign-Off

ANNEXURE B7 – Noise Level Log

Location	Noise dB(A)	Acceptance	Pass/Fail	Remarks

Technician / Testing Engineer	User / Facility Representative	Date
Name & Signature:	Name & Signature:	

Test Sign-Off

ANNEXURE C – Validation Clearance Certificate

This certifies that the Operation Theatre has been validated as per ISHRAE OT HVAC Validation Manual.

Result: ☐ Compliant ☐ Not Compliant

Authority	Name	Signature	Date

ANNEXURE D – Non-Conformance Report (NCR)

NCR No Date OT ID

Description of Non-Conformance:

Root Cause:

Corrective Action:

Retest Date: _____ Status: Open / Closed

ANNEXURE E – Instrument Traceability Register

Instrument ID	Type	Serial No	Calibration Date	Valid Until	Custodian

Technician / Testing Engineer	User / Facility Representative	Date
Name & Signature:	Name & Signature:	

ANNEXURE F – Glossary of Terms

Term	Definition

Chapter 6
AHU Performance Testing

This chapter is included in this guide as a training and reference module to support engineers and technicians involved in Operation Theatre (OT) HVAC validation and certification. While AHU performance testing and balancing is not, in itself, a formal part of OT HVAC validation, it is a critical prerequisite activity that must be understood and, where required, executed before OT-level validation can be meaningfully performed.

In practical field conditions, especially during new OT commissioning or when performance issues are reported in existing OTs, validation personnel are frequently required to assess whether observed non-conformances at the OT level are a result of downstream environmental issues or upstream AHU performance deficiencies. Inadequate airflow delivery, unstable temperature or humidity control, improper fan operation, or incorrect balancing at the AHU level can directly lead to OT validation failures—despite correct terminal equipment and room-level configurations.

For this reason, engineers involved in OT HVAC validation must possess a working knowledge of AHU performance verification, Testing, Adjusting, and Balancing (TAB) practices, even if these activities are executed by a separate TAB agency or maintenance team. This chapter familiarises trainees with:

- Key AHU performance parameters that influence OT environmental conditions
- Standard test formats and reporting practices used for AHU performance verification
- Common measurements and diagnostic checks carried out during AHU testing
- The logical relationship between AHU performance stability and successful OT validation

The intent of this chapter is educational and preparatory. It enables trainees to:

- Recognise when AHU-related issues may be the root cause of OT performance deviations
- Communicate effectively with TAB engineers, HVAC contractors, and maintenance teams
- Interpret AHU performance reports in the context of OT validation outcomes
- Appreciate the sequence in which HVAC systems must be tested—AHU first, OT next

Trainees should clearly note that successful AHU performance testing does not constitute OT HVAC validation or certification. Instead, it establishes the baseline system stability upon which OT environmental testing and certification can be reliably conducted.

By including this chapter, the guide ensures that certification professionals are not limited to room-level measurements alone, but are equipped with the broader system-level understanding required to carry out effective, efficient, and technically sound OT HVAC validation in real-world scenarios

6.1 Procedures

Air System Preliminary Procedures:

1. Set all volume control dampers the full open position.
2. Set outside air dampers to the Minimum position.
3. Verify correct fan rotation and speed, & record.
4. Check fan drives and adjust fans to design conditions or slightly above, on all systems.
5. Check motor amperages and voltages; make necessary adjustments.
6. Proceed with TAB work.

HVAC Air System tab Procedures:

1. All related HVAC and exhaust air systems should be operating.
2. Determine whether any other HVAC or exhaust air systems could affect the system ready to be balanced.
3. Make Pitot tube traverses on main supply and branch duct where possible to determine the air distribution.
4. Adjust balancing dampers of each major branch duct that is high on Airflow. A minimum of one branch duct balancing damper shall remain fully open.
5. Measure and record the Airflow of each terminal device in the system without adjusting any terminal outlet. Flow measuring hoods are the preferred Airflow-measuring device.
6. The main duct traverse air measurement should be within 10% of the total of all terminal outlet air measurements.
7. Check for excessive duct leakage if total terminal outlet air measurements are less than 90% of the main duct traverse air measurement.
8. Adjust the terminals that are highest on Airflow to about 10% under design Airflow.
9. Adjust each terminal outlet throughout the zone or system to design Airflow and record measurements and make any necessary branch damper adjustments.
10. An additional adjusting pass throughout the system may be necessary. Make final adjustments to the fan drive where required. Record all data.
11. Adjust terminal device vanes to minimize drafts and or proper air distribution.
12. Measure and record system static pressures and required temperatures; record plenum static pressures.
13. Measure and record coil entering and leaving air temperatures and coil pressure differentials.
14. Measure and record final fan motor full load amperages and voltages.

6.2 AHU Performance Report

Air Apparatus – Testing, Adjusting & Balancing (Tab) Report

PROJECT		**SYSTEM / UNIT**	
LOCATION		TEST DATE	
READINGS BY		PAGE	
REFERENCE	OT AHU Performance / TAB	REV	

Unit Data / Motor Data

Make / Size		**Motor Make / Frame**	
Model No. / Type		H.P. / RPM (W)	
Serial Number		Volts / Phase / Hertz	
Arrangement / Class		F.L. Amps / S.F.	
No. of Filters / Type / Size		Drive / Belt Details	
Other Details		Starter / VFD (if any)	

Test Data (Design Vs Actual)

PARAMETER	UNIT	DESIGN	ACTUAL	REMARKS
Total Airflow	CFM			
Total Static Pressure	in.w.g			
External Static Pressure	in.w.g			
Discharge Static Pressure	in.w.g			
Suction Static Pressure	in.w.g			
Fan Speed	RPM			
Motor Voltage	V			
Motor Amps (T1 / T2 / T3)	A			

REMARKS:

Apparatus Coil Test Report

PROJECT		SYSTEM / UNIT		LOCATION
COIL NOS.	COIL 1	COIL 2	COIL 3	COIL 4
COIL DATA				
System Number				
Location				
Coil Type				
No. Rows / Fins per inch				
Manufacturer				
Model Number				
Face Area (Sq.Ft / Sq.m)				
Tube Size				
Tube / Fin Material				
No. of Circuits				

TEST DATA	UNIT	COIL 1 DESIGN	COIL 1 ACTUAL	COIL 2 DESIGN	COIL 2 ACTUAL	COIL 3 DESIGN	COIL 3 ACTUAL	COIL 4 DESIGN / ACTUAL
Air. Qty.	CFM							
Air Vel.	FPM (m/s)							
Press. Drop	in.w.g (Pa)							
Out. Air DB / WB	°C							
Ret. Air DB / WB	°C							
Ent. Air DB / WB	°C							
Lvg. Air DB / WB	°C							
Air T.D.	°C							

REMARKS:

TEST DATE: _____ READINGS BY: _____

Fan Test Report

PARAMETER	FAN 1	FAN 2	FAN 3
Location			
Service			
Manufacturer			
Model Number			
Serial Number			
Arr. Type / Class			
Motor Make/Style			
Motor HP/RPM/Frame (W)			
Volts / Phase / Hertz			
F.L. Amps/S.F.			

TEST DATA	UNIT	FAN 1 DESIGN	FAN 1 ACTUAL	FAN 2 DESIGN	FAN 2 ACTUAL	FAN 3 DESIGN/ ACTUAL	REMARKS
CFM	CFM (l/s)						
Fan RPM	RPM						
S.P. In/Out	in.w.g						
Total S.P.	in.w.g						
Voltage, T1-T2, T2-T3, T3-T1	V						
Amperage, A1, A2, A3	A						

REMARKS:
TEST DATE: _____ READINGS BY: _____

Air Outlet / Terminal Device – Test Report

PROJECT		SYSTEM / UNIT	
OUTLET MANUFACTURER		TEST APPARATUS	
ROOM TEMPERATURE		ROOM RH	
ROOM PRESSURE			

AREA / DEVICE NO.	OUTLET NO./ TYPE / SIZE / AK	DESIGN VEL	DESIGN A.F.	PRELIM VEL	PRELIM A.F.	FINAL VEL	FINAL A.F.

REMARKS:

TEST DATE: _____ READINGS BY: _____

Electric Coil / Duct Heater – Test Report

PROJECT	
SYSTEM	
LOCATION	
HEATER / COIL NO.	
kW	
STAGES	
VOLTS / PHASE / HERTZ	
AMPS	

TEST DATA	UNIT	DESIGN	ACTUAL
kW	kW		
Air Velocity	m/s		
Air Flow Rate	CFM		
Entering Air Temp.	°C		
Leaving Air Temp.	°C		
Voltage (T1-T2, T2-T3, T3-T1)	V		
Amps (A1, A2, A3)	A		

REMARKS:

TEST DATE: _____ READINGS BY: _____

DUCT TRAVERSE REPORT (RECTANGULAR) Please refer to Annexure: TEST PROCEDURE for OT AHU – Supply Airflow Measurement (Duct Traverse – Equal Area Method)

PROJECT		SYSTEM / UNIT	
LOCATION		TEST DATE	
READINGS BY		PAGE	

System / Unit No.	
Location / Zone	
Traverse Air Temp.	
Duct Static Pressure	
Duct Size	
Duct Area	
Design Velocity	
Design Flow Rate	
Actual Average Velocity	
Actual Flow Rate	
Barometric Pressure	

REMARKS:

Instrument Calibration Report

LIST OF INSTRUMENTS	INSTRUMENT MAKE	SERIAL NUMBER	APPLICATION	DATES OF USE	DATE(S) OF CALIBRATION
Inclined Tube Manometer					
Combination Inclined & Vertical Tube Manometer					
Pitot Tube					
Tachometer					
Clamp on Ammeter					
Voltmeter					
Vane Type Digital Anemometer					
Digital Thermometer					
Pressure Gauges					
Sling Psychrometer					
Flow Measuring Hoods					
Micromanometer (Digital / Analogue)					
Balancing U-Tube System for Water					
Clamp on Wattmeter					
RH / AH Measurement Device					
Barometer					

REMARKS:

TEST DATE: _____ READINGS BY: _____

Component Failure Report

PROJECT	
SYSTEM / UNIT	
LOCATION	
COMPONENT	
MANUFACTURER	
SERIAL NUMBER	
MODEL NUMBER	
DATE	
ARCHITECT / ENGINEER	
CONTRACTOR	

DESCRIPTION AND PROBLEM:

FIELD TEST RESULTS:

PROBABLE CAUSE:

RECOMMENDATIONS:

REMARKS:

TEST DATE: _____ READINGS BY: _____

6.2 Makeup Air System Tab Procedures:

If direct makeup air measurements are not practical, derive the makeup air quantity based on Supply Air Temperature, Return Air Temperature, and Outside Air Temperature together with measured Supply Air Quantity.

Sr No.	Description	Readings
1	Temperature Return Air (TRA)	
2	Temperature Fresh Air (TFA)	
3	Design Return Air Quantity (CFMRA)	
4	Design Fresh Air Quantity (CFMFA)	
5	Expected Mixing Air Temperature (TEXP) = (TRA×CFMRA + TFA×CFMFA) / (CFMRA+CFMFA)	
6	Preliminary Mixing Air Temperature (TPM)	
7	Final Mixing Air Temperature after TAB	

Pre-requisites:

1. Supply air TAB done and AHU running in auto mode with constant supply air.
2. Cooling equipment and controls operational.
3. If TPM is higher than TEXP open RA damper till TEXP is achieved. If still not achieved, close FA damper till TEXP is achieved.
4. If TPM is lower than TEXP open FA damper till TEXP is achieved. If still not achieved, close RA damper till TEXP is achieved.
5. While the above procedure is the preferred procedure for ensuring adequate fresh air, possibility remains that in some cases access may not be available for measuring the fresh air quantity. In such cases, following method may be used.
   1. Measure supply air quantity in the OT (Ref section No. 5.4.1)
   2. Measure return air quantity in each riser and ceiling return grilles if any. It is recommended to use flow measurement hood for these measurements. Care must be taken to use the correct size of skirt for the flow measurement hood.
   3. The difference between the OT supply air and sum of all return air devices can provide approximate fresh air quantity.

   It may be noted that results of this procedure is impacted by the leakages in supply/return ducts as well as the leakages in the AHU casing.

Annexure: TEST PROCEDURE for OT AHU – Supply Airflow Measurement (Duct Traverse – Equal Area Method)

Reference

ANSI/ASHRAE Standard 111 – Equal Area Traverse Method

ASHRAE equal area

1. Purpose

To measure **AHU supply airflow (CFM)** for Operation Theatre systems by conducting a duct air velocity traverse using the **ASHRAE Equal Area method.**

2. Instruments Required

- Pitot tube with calibrated manometer **OR** hot-wire anemometer
- Measuring tape / ruler
- Calculator / approved worksheet

3. Preconditions

1. AHU shall be operating at **normal design condition.**
2. Supply fan running steady (no speed changes during test).
3. Filters installed and clean.
4. All access doors closed except the test opening.
5. Allow the system to stabilize for **10–15 minutes** before testing.

4. Selection of Measurement Location

1. Select a **straight section of supply duct** downstream of the AHU.
2. Measurement plane shall be located at:
   - o Minimum **2.5 duct diameters** downstream of fan discharge for velocities ≤ 2500 fpm
   - o Add **1 duct diameter for each additional 1000 fpm** of velocity

ASHRAE equal area

3. Avoid locations near:
   - o Elbows
   - o Dampers
   - o Transitions
   - o Branch take-offs

5. Measure Duct Dimensions

Rectangular Duct

1. Measure duct **width (W) and height (H).**
2. Calculate duct area:
   - o **$A = W \times H$ (ft^2)**

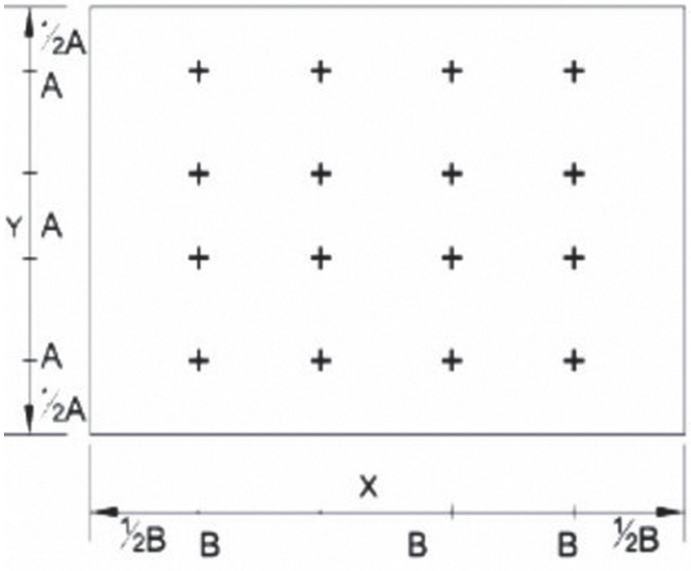
Circular Duct

1. Measure duct **inside diameter (D).**
2. Calculate duct area:
   - o $A = \pi \times D^2 / 4$ (ft^2)

Record all dimensions.

6. Determine Number of Traverse Points

1. Use the **ASHRAE Equal Area rule.**
2. Divide the duct cross-section into equal areas.



F X OR Y ARE LESS THAN OR EQUAL TO	MINIMUM NUMBER OF READINGS
4" OR LESS	2
15"	3
24"	4
35"	5
48"	6
63"	7
80"	8
99"	9
100" OR GREATER	10

Figure 12: Duct Traverse Points for Measuring Velocity

3. Minimum number of readings is based on duct size as shown in the standard
   ASHRAE equal area
   Larger ducts require more points.
4. Lay out traverse points evenly across the duct area.

7. Mark Traverse Points

1. Mark test points on the duct surface based on equal area layout.
2. Points shall be located at the **center of each equal area.**
3. Ensure points are not closer than **0.5 inches** from duct walls.

8. Velocity Measurement

1. Insert pitot tube or probe perpendicular to airflow.
2. Ensure sensing tip faces directly into airflow.
3. At each traverse point:
   - o Allow reading to stabilize.
   - o Record velocity pressure (for pitot) or air velocity (fpm).
4. Repeat until all traverse points are measured.

9. Calculate Air Velocity

If Using Pitot Tube

1. Convert velocity pressure to velocity using:
   - o **$V = 4005 \times \sqrt{(VP)}$ (fpm)**
2. Apply air density correction using measured temperature and pressure.

If Using Hot-Wire Anemometer

1. Record velocity directly in fpm.
2. Apply density correction if instrument does not auto-correct.

10. Average Velocity

1. Add all measured velocities.
2. Calculate average velocity:
   - o **$V_{avg} = (V_1 + V_2 + \ldots + V_n) / n$**

11. Calculate Supply Airflow

1. Calculate airflow:
   - o **Q = Vavg × A**
2. Record airflow as:
   - o **Supply Airflow (CFM)**

12. Acceptance Criteria

1. Compare measured airflow with design airflow for OT AHU.
2. Acceptance tolerance:
   - o Typically **±10% of design** (or as per project specification).
3. Record result as:
   - o PASS / FAIL

13. Reporting

Record the following:

- AHU tag and location
- Duct size and area
- Number of traverse points
- Average velocity (fpm)
- Calculated airflow (CFM)
- Design airflow (CFM)
- Percentage deviation
- Technician name, date, time

14. Notes / Common Issues

- Do not take readings in turbulent zones.
- Re-test if velocity profile is unstable.
- Ensure pitot tube alignment is correct.
- Seal test holes after completion.

Chapter 7

Diagnostics During OT validation

7.1 Introduction

Cleanroom validation within hospital Operation Theatres (OTs) is a critical engineering and clinical quality process that ensures that the surgical environment remains controlled, contamination-free, and compliant with national and international standards. When deviations are identified during certification activities, diagnostics play a vital role. While the trouble shooting does not for a primary responsibility of certification team, rectification of some the issues can help speed up the operation theatre uptime. In addition, the certification team can also be helpful in pointing out root causes of those deviations.

7.2 Objective

Objective of this section is to

i) List out common issues.

ii) List out probable causes of these issues.

iii) Suggest probable action plan

This however, does not relieve the responsibility of hospital maintenance team towards the troubleshooting.

7.3 Instruments required

Rotating vane anemometer

Hot wire anemometer

Differential pressure manometer

Temperature & humidity indicators or loggers **including the infrared temperature indicators.**

Aerosol photometer and generator

Hall effect clamp on meter

Continuity tester

Aerosol Tracer generator (also called smoke generator) and video camera.

All instruments must have valid calibration certificates.

7.4 Possible Issues, Causes and Remedial actions

1. Inadequate Airflow or Low ACH

Probable Causes:

- Filter clogging
- Duct blockage or leakage
- Fan motor speed underperformance
- Malfunctioning dampers

Remedial actions:

- Replace or regenerate clogged filters
- Clear ducts or repair leaks
- Adjust fan motor speeds
- Rebalance supply and return airflow

2. Pressure Differential Failure

Common Causes:

- Loose door seals or excessive door opening
- Incorrect balancing of supply/return air
- Faulty or drifting pressure sensors

Remedial actions:

- Reinforce sealing mechanisms
- Reconfigure airflow balance
- Calibrate or replace differential pressure instrumentation

3. Elevated Particle Counts an poor recovery rate post cleaning

Possible Reasons:

- Compromised HEPA filter integrity
- HEPA filter face velocities higher than the rated filter face velocity
- Damaged upstream pre-filtration devices
- Inadequate cleaning protocols
- Personnel movement or gowning errors
- Construction or maintenance activities nearby
- Reversal of OT pressure

Remedial actions:

- Perform HEPA leak test and replace defective filters
- Replace defective pre-filters
- Adjust supply air quantities and re-balance all supply and return air registers.
- Enhance facility cleaning SOPs
- Reinforce gowning discipline and traffic control
- Carry out pressure balancing again
- In case of excess particle count for sizes 5 micron and above, check for blockages of low level return grilles. It may be noted that the measurement of particle sizes of 5 μm an above is required only for the diagnostic purpose and not for validating the ISO classification of ISO-5 and better.
- Implement containment for nearby maintenance work

4. Microbial Contamination Abnormalities

Likely Causes:

- Improper aseptic handling
- Contaminated surfaces or equipment
- Unstable HVAC conditions causing stagnation
- Poor upstream filtration including terminal HEPA filters
- AHU internal cleaning not performed particularly the drain pan and U traps.

Corrective Response:

- Retrain staff on aseptic procedures
- Deep-cleaning and disinfection including fumigation
- Examine and correct HVAC operational cycles
- Check pre-filters for any damages or improper mounting. Replace the damaged filters and if the issue is of mounting, re-install the filters after replacing the gaskets.
- Check for filter integrity of the terminal filters.
- Check the AHU drain pan for any retaining of water when AHU is switched off. Correct the U trap dimensions to achieve complete draining of water from the drain pan.
- Clean the AHU internals with aqueous solution of iso-propyl alcohol.

5. Temperature and humidity Deviations

Reasons:

- Malfunctioning cooling/heating coils
- Ineffective humidifiers or dehumidifiers
- Chilled water temperatures high
- Chilled water flow low
- Outdoor units short of gas (In case of DX systems)
- Hot water/Heaters not functioning
- Incorrect BMS/HVAC setpoint configuration

Remedial Actions:

- Clean cooling and heating coils
- Check functioning of dehumidifiers
- Check humidifiers
- Check pressure drops across cooling coils/Heating coils
- Check functioning of control valves after ensuring all other valves are open
- Clean coil strainers
- Service or replace faulty components

- Validate control system accuracy
- Reset and re-optimise HVAC control sequences

6. Airflow pattern

Reasons

- Obstructions in the supply air path
- OT light obstructing the air flow
- Return air risers blocked or obstructed by ancillary and supporting equipment positions

Corrective Actions

- Reposition the OT light
- Reposition the equipment obstructing the air flow both in supply path as well as return path
- Check return air register/riser dampers. Ensure dampers are in open position.
- In extreme conditions, layout correction may be needed.

7. Clean Noise and VibraSensors tions

Reasons

- Fan imbalance
- Rotor and shaft key locking screw missing. (Normally it has two screws at 900)
- Fan spring locking bolts not released.
- Rubber mounts loosely mounted.
- The rubber bellow control rod assembly not loosed. (In case of chilled water system)

Corrective Actions

- Rebalance the fans.
- Ensure both filing screws are fully tightened.
- Loosen the spring shipping bolts so that springs are able to undulate during fan operation. Ensure star/spring washer between the fan and spring mount.
- Tighten the rubber mount bolts. Ensure star/spring washer are used in the mounting bolts.

8. Sensor and BMS display mismatch

Reasons

- Sensor out of calibration
- Loose contacts in the signal cable and field connector
- Sensor drift over the long time period
- Sensor cable resistance high (Primarily in voltage an resistance signals)

Corrective Actions

- Recalibrate the affected sensor
- Tighten all terminal connections both at sensor end as well as at the DDC panel field terminals
- Tighten the wire connections between the DDC panel field connector and the DDC.
- Measure the cable resistance after disconnecting from the sensor and the DDC panel field terminals. Replace cable if resistance found high.

9. Documentation of issues

- All deviations noticed, even if corrected during OT validation must be documented.
- Upon documentation, proper root cause analysis must be carried out, with the help of a subject matter expert if required.
- The root cause analysis needs to be succeeded by a Corrective Action & Preventive action (CAPA) document.
- This document needs to be circulated to Engineering head, Hospital administrator and any other member that needs to be made aware of the issues arisen.

COVER 3

About ISHRAE

The Indian Society of Heating, Refrigerating and Air Conditioning Engineers (ISHRAE) was founded in 1981 at New Delhi by a group of eminent HVAC&R professionals. ISHRAE has over 13,000 HVAC&R professionals as its members today along with 10,000 student members, and operates from 44 Chapters and sub-Chapters spread all over India, with its HQ in Delhi. It is led by a team of elected officers who are members of the Society working on a voluntary basis, collectively called the Board of Governors. In pursuance of its objectives, ISHRAE works in the areas of Research, Standards, Education and Training, and Publication of Technical Books and a Journal. It also organizes world-class annual exhibitions ACREX and REFCOLD, besides hosting technical seminars and conferences. ISHRAE is a responsible and socially-conscious Technical Society.

Objective

- Advancement of the Arts and Sciences of Heating, Ventilation, Air Conditioning and Refrigeration Engineering and Related Services.
- Continuing education of members and other interested persons in the said sciences through lectures, workshops, product presentations, publications and expositions.
- Rendition of career guidance and financial assistance to students of the said sciences.
- Encouragement of scientific research.

Activities

Knowledge Dissemination: ISHRAE conducts conferences, seminars, exhibitions, workshops, panel discussions and product presentations throughout the country with both national and international participants to discuss, promote and display the state-of-the-art technologies, systems, products and services.

Books and Publications: ISHRAE publications help its members and the industry to keep up with technical developments, latest trends and sunrise technologies. ISHRAE publishes Standards, books on fundamentals of various topics, HVAC&R Handbooks and the extremely popular and informative ISHRAE Journal. The latest publication is on Insulation

Exhibitions cum Conferences: ISHRAE organises ACREX India, the largest international exposition in South Asia on the Air Conditioning, Refrigeration, Ventilation and Building Services industry. Held annually, ACREX showcases the latest technologies and innovations, and provides a platform for buyer-seller meets for technical and commercial personnel in the HVAC&R field. To serve the interests of the Refrigeration and Cold-chain sector, ISHRAE organises REFCOLD annually. ISHRAE is a member and active supporter of the National Centre for Cold-chain Development (NCCD).

Education: ISHRAE is actively engaged in Education and Training, and offers several courses for technical professionals, some with post-examination certification. This helps to bring trained manpower into the HVACR industry.

Research: ISHRAE promotes research in the field of HVAC&R technologies. It offers financial support to graduate and post-graduate students to carry out innovative R&D work in technology, systems and processes. ISHRAE partners with the industry, academia and the government to carry out scientific research at Institutes of Excellence associated with ISHRAE.

Standards: ISHRAE works in the national interest with various government ministries and departments; for example, in the development of Standards and drafting of the National Building Code for the Bureau of Indian Standards, working on Energy Conservation Building Code with the Bureau of Energy Efficiency, and with the Ozone Cell of the Ministry of Environment, Forest and Climate Change on refrigerant gases. ISHRAE has also developed a pioneering Standard on Indoor Environmental Quality.

Student Activities: ISHRAE student chapters in more than 150 engineering colleges encourage students to opt for careers in the HVAC&R industry with industry exposure including factory visits. The K-12 initiative of ISHRAE reaches out to young school children to make them aware of subjects like energy conservation and environmental concerns through drawing competitions, poster designs, quizzes and more, with emphasis on STEM education to inculcate scientific fervour and help them to grow up as responsible citizens.

Global Reach: ISHRAE works in close co-operation with other similar societies and organisations, both at national and international levels, for the promotion and development of concepts like health and safety, sustainability, Green buildings, energy efficiency and environmental responsibility, often interacting with UN bodies like UNDP and UNEP.

ISHRAE is indeed looked upon as a repository of technical knowledge in the HVAC&R and Building Services Industry globally by peer organizations and the Government.

ISHRAE

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