

# Microbiological Commissioning and Monitoring of Operating Theatre Suites

A report of a working party of the Hospital Infection Society

1. Background
2. Introduction
3. Overall principles
4. Commissioning
  - 4.1.1 Summary for conventionally-ventilated theatres
  - 4.1.2 Theatre interior
  - 4.1.3 Ventilation engineering
    - 4.1.2.1 Setback status
  - 4.1.3 Air change rates
  - 4.1.4 Pressure differentials and airflow
  - 4.1.5 Microbiological sampling
    - 4.1.5.1 Sampling media
  - 4.2 Summary for ultraclean ventilated (UCV) theatres
    - 4.2.1 Theatre interior
    - 4.2.2 Ventilation engineering
    - 4.2.3 Air change rates and velocity
      - 4.2.3.1 Air velocity and flow characteristics
      - 4.2.3.2 Contamination removal
    - 4.2.4 Microbiological sampling
5. Monitoring
  - 5.1 Conventionally-ventilated theatres
    - 5.1.1 Routine monitoring
    - 5.1.2 Sampling in a working theatre
    - 5.1.3 The air handling unit
  - 5.2 UCV theatres
    - 5.2.1 Routine monitoring
    - 5.2.2 Sampling in a working theatre
6. References
7. Additional References/Documents
- Annex A Problems and actions

External Reference

<b>Annex B</b>	<b>Airflow indicators</b>
<b>Annex C</b>	<b>Air samplers for use in operating theatres</b>
<b>Annex D</b>	<b>Model letter and certificate of compliance for conventionally-ventilated operating theatres</b>
<b>Annex E</b>	<b>Guidance for completion of certificates for conventionally-ventilated operating theatres</b>
<b>Annex F</b>	<b>Supplementary certificate of compliance for UCV theatres</b>
<b>Annex G</b>	<b>Guidance for completion of supplementary certificates for UCV theatres</b>
<b>Annex H</b>	<b>Air filters</b>

## 1. Background

Because of the need to provide clear and practicable guidelines for infection control practitioners and others in operating theatres, the Hospital Infection Society (HIS) established a Working Party (WP) on Infection Control and Operating Theatres in 1999 to examine many of these issues. The remit of this group was:

- 1 to review the scientific and other evidence for current infection control practices in theatre and following this, to make recommendations on which practices are essential, which are preferred and which are optional or are of little perceived benefit.
- 2 to produce rational, feasible and applicable guidelines for the environmental monitoring (including bacteriological air sampling) of operating theatre facilities, and specifically to address when monitoring is indicated, how it should be carried out and what action should follow if abnormal.
- 3 to consider optimal theatre facilities including when ultraclean or conventional theatre ventilation is required in the light of recent changes in surgical practice such as the increasing use of minimally invasive surgery. Work on this area is on going and the conclusions reached will be available on the HIS website in the next 12 months or so.

The WP included microbiologists/infection control doctors, an infection control nurse, an operating theatre nurse, general surgeon, orthopaedic surgeon, aerobiologist, engineer and a representative of NHS Estates. The members of the WP were: Gordon Bannister, Alan Bennett, Terie Chesworth, Chris Dobson, Ian Fraser Marjory Greig, Peter Hoffman, Hilary Humphreys (Chair), Liz Jones, Geoff Ridgway, Ed Smyth, Andrew Stacey (Honorary Secretary), Eric Taylor, John Williams and Kate Woodhead. The members of the Commissioning and Monitoring subgroup were Alan Bennett, Chris Dobson, Ian Fraser, Peter Hoffman (Lead), Geoff Ridgway, Andrew Stacey and John Williams.

The WP reviewed the literature in the relevant areas so that as far as possible the guidelines would be evidence-based. The WP also consulted with health care professionals and others as appropriate, and achieved consensus following discussion amongst the members on areas where scientific evidence was not available.

Draft documents were widely circulated to professional groups and organisations seeking comment and suggestions, and posted on the HIS website in early 2001. During the second half of 2001, the documents were revised in the light of this feedback, circulated to WP members and what follows is the result of this wide consultation exercise.

## 2. Introduction

Surgical operations and interventional procedures are performed in areas with various levels of bacteriological control of the ventilation. The following areas are recognised

- Conventionally-ventilated operating suites
- Ultraclean-ventilated (UCV) operating theatres
- Unventilated theatres
- Treatment rooms

There is no technical difference between an unventilated theatre and a treatment room. Discussion as to which procedures should be performed in which facilities form a separate section of this Working Party report. This section refers only to conventionally-ventilated and ultraclean-ventilated theatres.

Limited advice exists on conventionally-ventilated and UCV theatres in Health Technical

Memorandum (HTM) 2025<sup>1</sup>. The HTM gives limits on microbiological (bacterial and fungal) content of air in empty and working theatres, but states in a margin note "*precise guidance is inappropriate and will depend on local circumstances*". Whilst this remains true, it is apparent that many would welcome some advice on infection control aspects of these matters. This report seeks only to interpret HTM 2025 in a manner appropriate to infection control practitioners; we are not rewriting the standards within it.

HTM 2025 (volume a – Management Policy) gives the following role (paragraph 2.29) "*Infection Control Officer – or consultant microbiologist, if not the same person, nominated by the management to advise on monitoring infection control policy and microbiological performance of the system. Major policy decisions should be made through an infection control committee.*"

It also states (paragraph 2.14) "*Increased health risks to patients will occur if the more specialised ventilation systems installed to supply high quality air to operating departments do not achieve and maintain the required standards. The link between post-operative infection and theatre air quality has been well established. Plants serving conventionally-ventilated operating departments, for instance, will be required to ensure the separation of areas within the suite by maintaining a specific direction of air flow between rooms, even when doors are opened. They will also maintain the selected operating department environmental conditions regardless of changes in the outside air conditions or activities within the space. In addition ultra-clean operating ventilation systems which are designed to provide an effectively particle-free zone around the patient while the operation is in progress, have been shown to significantly reduce post-operative infection in patients undergoing deep wound surgery. Their use for similar forms of surgery may well be indicated.*"

One role of the Infection Control Officer (ICO) in theatre commissioning and monitoring is to ensure the quality of the ventilation with respect to infection control issues. The ICO or Infection Control Team (ICT) should be familiar with the outline structure, function and interrelationship of those engineering aspects that have an impact on infection control. A list of common problems in this respect and possible actions forms Annex A to this report.

### 3. Overall principles

The function of operating theatre ventilation is to prevent airborne microbial contaminants from entering surgical wounds. Under normal circumstances, the main source of airborne microbial contaminants is microscopic skin fragments given off by staff in theatre. A proportion of these skin fragments will be contaminated with micro-colonies of bacteria resident, or perhaps transiently present, on that individual's skin. Whilst individuals will have different dispersion levels, overall dispersion is increased with movement and numbers of individuals present<sup>2</sup>.

Other sources of airborne micro-organisms are usually less significant. These include improperly-filtered outdoor air, contaminated fabrics worn by theatre staff and backtracking of contaminated air from outside the theatre. The patient is not usually a significant source of airborne contamination; their movement is usually minimal. However, there exists the potential that power tools can create an aerosol from the tissues and any micro-organisms within them.

Airborne micro-organisms can enter surgical wounds by one of two routes: they can either fall directly into wounds or they can land on exposed instruments, and possibly surgeons' hands, and can later be transferred into the wound. The significance of this latter route will vary with the area of exposed instruments and the duration of their exposure, but is thought usually to exceed the contribution of direct wound contamination<sup>3</sup>.

## 4. Commissioning

Commissioning must occur before an operating theatre is first used and after any substantial modifications that may affect airflow patterns in pre-existing theatres (as part of a re-commissioning process). It is important that the infection control team is involved at all stages from pre-design through to opening and that adequate time for commissioning is built-in to the schedule, including an allowance of time for microbiological assessments. This may need particular consideration for facilities built under private finance initiatives in that there may be need for a contractual condition to allow commissioning before handover of the theatre or for delayed acceptance after handover such that faults can be rectified.

### 4.1 Summary for conventionally-ventilated theatres

Conventionally-ventilated operating theatres must be commissioned before being used, after being built or modified substantially. Commissioning is a task for both the Estates Department and the Infection Control Team, and co-operation and co-ordination between them is important. Below is a summary of matters that should be addressed when commissioning conventionally-ventilated theatres (and by whom) *and the section covering it in this report*:

The theatre interior should be checked for obvious defects (ICT) 4.1.1

The air distribution within the theatre and between rooms in the theatre suite should be checked by smoke tracing (ICT) 4.1.2

The air handling unit supplying the theatre is properly constructed, the theatre is properly constructed, finished and functioning (Estates and reported to ICO) 4.1.2, 4.1.4 and Annexes D and E

Where "setback" (reduction of ventilation rates when theatre is not in use) is in place, there are indications in theatre of its function and there are safeguards against setback operating whilst the theatre is in use (Estates and ICT) 4.1.2.1

The air change rates in theatre and preparation room are satisfactory (either Estates, or ICT with data supplied by Estates) 4.1.3

Airborne microbial contamination in an empty theatre is satisfactory (ICT) 4.1.5

#### 4.1.1 Theatre interior

Inspection of the theatre interior before it is handed-over from the building contractors to the hospital is the last convenient occasion to rectify faults. The following observations should be made:

- pressure-release dampers should move freely and be partially or fully open when doors are closed and move to shut when doors are opened
- doors must close properly
- the flooring should have no cracks or gaps in it and its coving joins to the wall
- painted surfaces and finishes are smooth, complete and without cracks
- that there are minimal fixtures, shelves etc.
- the windows are sealed
- the ceiling is solid.

#### 4.1.2 Ventilation engineering

The risk from airborne micro-organisms is minimised in the ventilation of conventionally-ventilated theatres in three ways:

- 1) by filtration of supplied air
- 2) by dilution of contaminated air in the theatre
- 3) by preventing entry of contaminated air from areas outside the theatre

The ICO/T should carry out airflow visualisation (smoke testing) to ensure turbulent airflow in the theatre, particularly around the position of the operating table (a puff of smoke should disperse within seconds of creation). It should also be established that supplied air does not “short-circuit” i.e. take a direct route out of the theatre such that it can not entrain contamination generated in the theatre. Sources of such “airflow indicators” are in Annex B. Large volume smoke generators are useful for tracing larger airflow patterns (also in Annex B). Fire alarms systems in the theatres should be disabled during testing.

Airflow visualisation should also be used to establish that air flows in the desired direction between rooms in the suite (with all doors closed):—

from the theatre into

- the anaesthetic room
- the disposal room
- the corridor

from the anaesthetic room and scrub area into the corridor

air should either flow from the preparation room into the theatre if it is used for lay-up or they should be at equal pressure if used as a sterile pack store (i.e. no direction of flow between them) and should flow into the corridor from the preparation room.

Diagrams showing examples of suggested operating suite layouts (for example, with and without disposal corridors) and directions of airflow are in volume b of HTM 2025 (1994)<sup>1</sup>, Design considerations, figures 6.1 a & b.

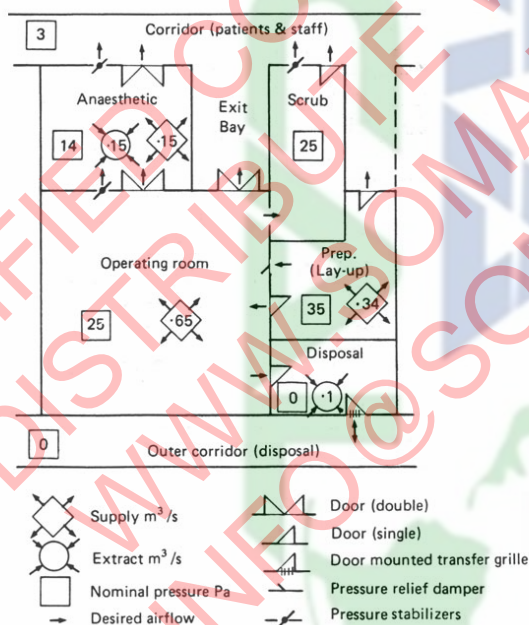


Figure 1 One of the eight “suggested air movement schemes” from HTM 2025, volume b, Design considerations (figures 6.1a and 6.1b, plan 5b).

The ICO should request a signed document from a senior member of the Estates Department that the ventilation to the theatre suite, including the air handling unit, has been inspected and that the theatre is satisfactorily constructed, finished and is functioning to specifications. A sample letter forms Annex D to this report. Guidance on completion of this letter forms Annex E.

#### 4.1.2.1 Setback status

As an economy measure, ventilation rates can be “setback” when the theatre is not in use. Ventilation should not be turned off completely, but volumes can be reduced provided that pressure relativities are maintained between the different areas of the operating suite to prevent backflow of contamination into clean areas. If a setback system is in place, there must be a clear visual indication in the theatre of whether the ventilation is on setback or normal flow rates. If pressure relativities are maintained during setback, all air in the theatre will have passed through the filters in the air handling unit and there will be little microbial dispersion in an unused theatre; therefore we consider that the theatre will be usable 15 minutes after full ventilation has been restored. Control of setback is normally on a timed basis and there should be an over-ride linked to the operating light or a movement detector so that setback does not occur when lists over-run. There must be a setback override to allow for unforeseen use of the theatre to occur.

#### 4.1.3 Air change rates

Details of ventilation rates to the theatre should be obtained from the Estates Officer and used to calculate air change rates (see Annex D). An *air change* is defined as occurring when a volume of air equivalent to the volume of the room has been supplied to or removed from that room (whichever airflow is the greater). Design and commissioning engineers do not however express ventilation parameters in terms of air change rates; they will express ventilation rates in terms of volume of air supplied or extracted per unit time, usually as cubic metres of air per second. The rate of air change is usually given in terms of air changes per hour (ACH) and is derived from the volume of a room and the ventilation rate.

Worked example:

*Room volume:*

An operating theatre measures 7 metres long by 6 metres wide by 3 metres high: a total volume of 126m<sup>3</sup>.

*Ventilation rate:*

If it has 4 ventilation supply grilles with observed flow rates of 0.18, 0.19, 0.18 and 0.17 cubic metres per second (m<sup>3</sup>sec<sup>-1</sup>), it will have a total air supply (the sum of the individual grille flow rates) of 0.72 m<sup>3</sup>sec<sup>-1</sup> (engineering air supply data is usually given as volume per second – either in cubic metres or litres; one cubic metre is 1,000 litres) equivalent to 2,592 cubic metres per hour (m<sup>3</sup>h<sup>-1</sup>).

*Air change rate:*

The air change rate is calculated by dividing the air supply rate by the room volume: 2592 ÷ 126 = 20.6 ACH.

The *Joint working party on ventilation in operating suites (1972)*<sup>4</sup> (“The Lidwell report”) advised that clean areas (operating theatre and preparation room) had ventilation equivalent to 20ACH. If theatres are built to the size specifications in HBN 26<sup>5</sup> and have ventilation rates specified in HTM 2025<sup>1</sup>, there should be between 19.5 and 23 ACH in the theatre (i.e. ventilation rates in operating theatres should equate to around 20 ACH or above).

The air change rate in preparation rooms used for laying-up sterile instruments should be around 37 ACH; a greater air change rate than in theatres (the main route of airborne contamination entering surgical wounds is probably via instruments<sup>3</sup>). If preparation rooms are used only as sterile pack stores, the ventilation rate should be around 11 ACH.

If either the operating theatre or preparation room have been built to dimensions different from those in HBN 26<sup>5</sup>, ventilation rates given in HTM 2025 should be adjusted to achieve the required rate of air changes.

Effective air changes will only occur if airflow is turbulent and there is no short-circuiting. These should

have been established by smoke testing (see 3.1.2).

#### 4.1.4 Pressure differentials and airflow

The direction of airflow between rooms in a theatre suite is used to ensure that there is no backflow of air from either “dirty” rooms in the suite or from contaminated areas in the hospital. Air flowing between rooms can be measured in terms of the pressure differential between those areas. The pressure differential results from the volume of air flowing between those areas per unit of time and the size of the gap through which it flows. It is usually measured in units of “pascals” or sometimes in terms of inches or millimetres of water. Pressure differentials between rooms in the theatre suite are given in HTM 2025, volume b (Design considerations). The desired pressure differentials are small and not easily measured (usually either by an electronic micromanometer or inclined fluid manometer). The desired pressure differentials between the different rooms will vary from around 9 up to 30 pascals (1 pascal is equivalent to the pressure exerted by 0.004 inches or 0.1 millimetres of water i.e. a very small amount of pressure).

We advise that the ICO request a signed document from a senior member of the Estates Dept that the pressure differentials have been assessed by the commissioning engineer and are satisfactory (see Annex D). However as the value of the differentials are as much a reflection of the size of the gaps that the air flows through as well as the volume of air flowing through those gaps and the robustness of flow is related more to the volume flowing through a gap than the pressure across that gap, we do not consider the actual values of pressure differential to be vital in terms of infection control. The ICO/T should have carried out airflow visualisation with smoke tubes to observe robust directional flow at the same time as determination of turbulent airflow in theatre (see 4.1.2).

#### 4.1.5 Microbiological sampling

HTM 2025<sup>1</sup>, Volume C (Validation and verification) states (paragraph 5.33) *The level of airborne bacteria introduced by the supply air can be checked by closing all doors and leaving the operating room empty with the ventilation system running for one hour, after which a bacterial sampler mounted on the operating table should be activated remotely. Aerobic cultures on non-selective medium should not exceed 35 bacterial and/or fungal particles per cubic metre of ventilating air.*

**When:** The most appropriate time for microbiological commissioning of an operating theatre should be shortly before it comes into use. The theatre should have had an “in-depth” clean and be thoroughly clean and dust-free. The air handling unit should have been operating at normal flow rates (i.e. not on setback ventilation) continuously for at least 24 hours before sampling. Given the usual time-frame for sampling, it is usually only the production of satisfactory microbiological sampling that is required to enable a new or refurbished theatre to come into use. It is therefore vital that

- a) the checks on the engineering aspects listed above should have already occurred and be satisfactory before microbiological sampling is done
- b) false-positive microbiological results (primarily from airborne contamination dispersed by the person doing the test) do not cast doubt on the adequacy of the ventilation.

The protocol given in the HTM is skeletal and one purpose of these guidelines is to record the practical experience of those who have been involved in this field.

**How:** In a clean, well-ventilated operating theatre, the main source of airborne contamination will probably be contaminated skin particles dispersed from people, even when wearing theatre clothing. It is thus vital both that any microbial air sampler is only operated once all people are out of the theatre and in an area that does not feed air into the theatre (i.e. not in the preparation room). Also, before the sampler operates, sufficient time must be allowed for the ventilation to dilute and disperse the contamination generated during the setting-up of the sampler. It is not good enough to switch the sampler on and then stand away from it. This will be one of the considerations affecting the choice of a suitable sampler. Some samplers can be operated remotely via a cable from outside the theatre, by an infra-red remote control or by a time-delay mechanism on the sampler. HTM 2025 advises that the theatre be empty for one hour before sampling. This can make commissioning a suite with more

than one operating theatre time-consuming. Each change of air will, given perfect mixing, produce a 63% reduction in pre-existing air and its entrained contamination. If there are, for example, 20 air changes per hour in a operating theatre (one air change every three minutes), in one hour airborne contamination levels will be reduced to 0.0000002% of their former levels by dilution alone (there will be additional losses due to particles settling-out over this time). It does not seem unrealistic to leave the operating theatre unoccupied for 15 minutes before sampling, in which time airborne contamination should have been reduced to less than 1% (actually 0.67%) of its former levels, if the ventilation is working adequately. If the ventilation is defective, either in the rate of airflow or its distribution (such as short-circuiting out of the theatre without diluting pre-existing air), it may be more evident if left for 15 minutes rather than 1 hour (the contamination dispersed by the person setting the sampler up will not have been diluted out or have had a chance to settle-out). A gap of 15 minutes between set-up and sampling will also allow time for generation of a duplicate sample, useful for confirming unexpected results.

Clothes worn when doing microbiological testing in theatre are unimportant. Local dress codes should be observed but normal theatre wear does little to reduce dispersion; besides which remote operation of the sampler and the time gap between leaving the theatre and taking the sample make such dispersion unimportant.

**How much:** The volume of air to be sampled is not specified in the HTM. It is left to the individual directing the sampling and will be determined by the microbial numbers being sought and the sampling equipment. We suggest that sampling volumes around one cubic metre (1,000 litres) are optimal. Using volumes above this generates no substantial problems until either the colonies on the incubated plate get too crowded to enumerate accurately or the agar starts to dry out due to the volume of air passed over it. Using volumes lower than this may result in interpretational difficulties and tends to make the data more qualitative as the volume decreases. It also gives undue weight to plate contaminants. We cannot be prescriptive on this matter, but advise sampling volumes greater than 0.25 m<sup>3</sup> (250 litres) and optimally around 1 m<sup>3</sup> (1,000 litres). Whatever air volume is chosen, the sampler used should be capable of sampling it without causing excessive drying of the recipient agar surface.

It is important to ensure that the sampler is clean before use. It should also be run briefly in the theatre before the agar is loaded to blow any contamination out of the sampler.

We recommend taking at least two samples per theatre, as this lessens the possibility of technical errors interfering with successful commissioning of a theatre.

A short summary of the attributes of the common samplers available is given in Annex C.

#### 4.1.5.1 Sampling media

HTM 2025<sup>1</sup>, Volume C (Validation and verification) states (paragraph 5.34): *The results should be examined to establish the broad category of organisms present. A high preponderance of fungal organisms may be an indication of inadequate filtration for the particular installation.*

The choice of growth medium and recovery conditions can be varied according to the nature of the exploration and perceived problems. Nutrient agar incubated for 2 days at 37°C is an acceptable method for general work. If there is a more specific investigation, appropriate media and culture conditions can be used. The larger the plate used, the greater volume of air it can sample before drying-out of the agar interferes with bacterial recovery (e.g. large volume slit samplers, which can sample several cubic metres of air, use 15cm plates). The plates should be poured such that the surface is flat (no lumps, no slope).

If the quality of the agar plates is at all suspect, pre-incubation (under conditions that match the incubation of the samples to be taken) will allow those plates with contaminants to be discarded.

## 4.2 Ultraclean ventilated (UCV) theatres

Ultraclean ventilated theatres must be commissioned before being used after being built or modified substantially. Commissioning is a task for both the Estates Department and the Infection Control



Team, and co-operation and co-ordination between them is important. The following matters relevant to infection control should be addressed (and by whom) *and the section in which it is covered*:

The theatre interior should be checked for obvious defects (ICT) 4.1.1, 4.2.1

The airflow between a preparation room used for instrument layup and the theatre is satisfactory (ICT) 4.1.2 and the preparation room has an adequate air change rate (either Estates, or ICT with data supplied by Estates) 4.1.3

The air handling unit supplying the theatre is properly constructed, the theatre is properly constructed, finished and functioning (Estates and reported to ICO) *Annexes D and E where applicable (see 4.2.2)*

The air velocities in the ultraclean zone are satisfactory (Estates and reported to ICO) 4.2.3.1 and *Annexes F and G*, the terminal HEPA filter is effective and the ultraclean airflow can resist particle penetration from outside (Estates and reported to ICO) 4.2.3.2 and *Annexes F and G*

The ultraclean zone resists ingress of air from outside, shown by smoke tests (ICT) 4.2.3.1

Airborne microbial contamination in the ultraclean zone is satisfactory (ICT) 4.3 (This test is not necessary if the tests of the HEPA filter and the ultraclean airflow above have been done but, if agreed locally, can still be done as a sample taken in the centre of the ultraclean zone)

#### 4.2.1 Theatre interior

See section 4.1.1. In addition the operating lights should ideally be of a type that offers minimal interruption to the airflow pattern, but in reality such a choice may well be a compromise between illumination efficacy and airflow considerations.

#### 4.2.2 Ventilation engineering

Control of postoperative infection caused by airborne micro-organisms is achieved in UCV theatres by exclusion of contamination from the wound. Filtered air descends in a uni-directional flow over the patient, creating a "clean zone", rapidly removing contamination generated within that zone and preventing entry of contaminated air. The large volumes of air required to maintain this zone make it necessary to recirculate air from within the theatre. Filtration of this recirculated air is essential to prevent contaminated particles also being recirculated. The filters used are HEPA (high efficiency particulate air) filters (see Annex H). The existence of this clean zone largely negates the need for control over air movement between rooms in the operation suite. However there is still a need for the preparation room to be at positive pressure to other areas and to have a high airchange rate if used for laying-up instruments.

#### 4.2.3 Air change rates and velocity

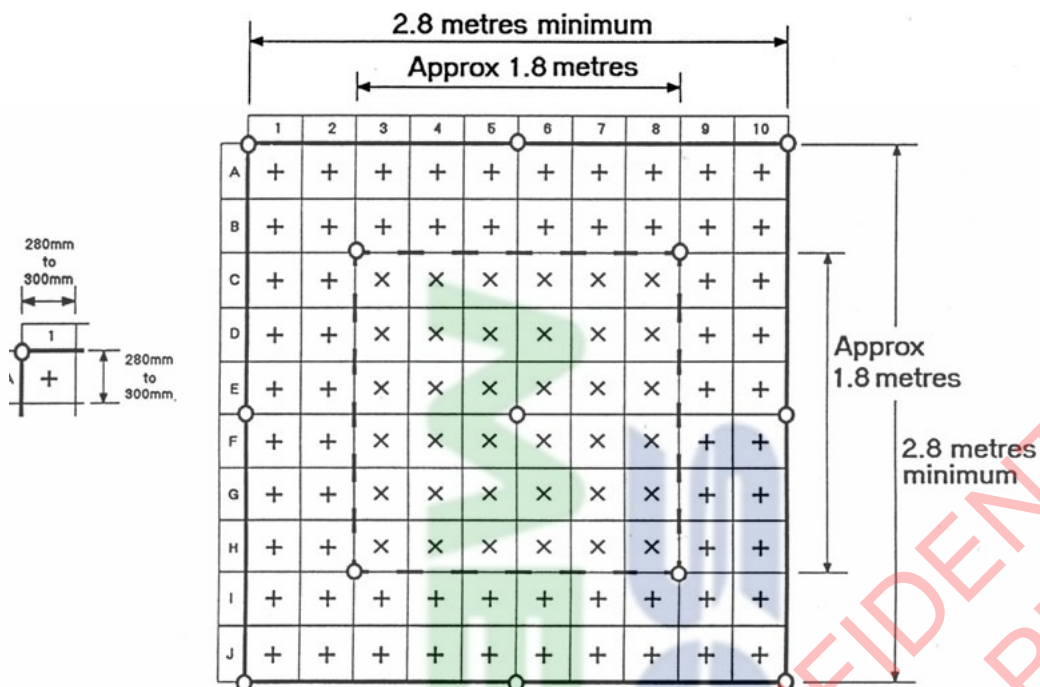
UCV theatres need to be tested to ensure:

that the velocity of air within the clean zone is sufficient to result in a robust, uni-directional flow capable of resisting ingress of contaminated air from outside the zone (section 4.2.3.1)

that filters are intact and properly seated so as to remove microbial contamination from both incoming and recirculated air (section 4.2.3.2)

##### 4.2.3.1 Air velocity and flow characteristics

A grid is marked out in the clean zone (at least 2.8m square) such that the area is delineated into 100 squares (10 by 10), each about 280 to 300 mm square. In each of these squares, air velocity measurements are taken at 2m above floor level. The air velocity should average  $0.38\text{ms}^{-1}$  if there are partial walls around the clean zone ending at a height of around 2m above floor level (the usual case), or  $0.3\text{ms}^{-1}$  if there are full walls to 1m or less above floor level. In the central 36 (6 by 6) squares, the velocity is also measured 1m above floor level and should be at least  $0.2\text{ms}^{-1}$ . These data should be generated by the commissioning engineer and passed to the local Estates Department.



### Key

- + Measure air velocity 2m above floor level
- x Measure air velocity 2m above floor level and also measure air velocity 1m above floor level (min 0.2ms<sup>-1</sup>)
- o Bacteriological sampling position

Figure 2 Ultraclean-ventilated theatre test grid. (from HTM 2025, volume C, Validation and verification, chapter 5, figure 1).

Airflow visualisation of the resistance of the unidirectional flow to ingress from outside provides useful reassurance of the robustness of the system. Smoke should be aimed at the unidirectional flow from outside the area with various objects that may interfere with the airflow, principally the operating theatre light, in a variety of realistic positions and lack of ingress observed.

#### 4.2.3.2 Contamination removal

That the that filters are intact and properly seated so as to remove microbial contamination from both incoming and recirculated air is assessed by either microbiological air sampling or exclusion of tracer particles generated outside the clean zone. Volume c of HTM 2025 (1994) (Validation & Verification), paragraph 5.36a states "air leaving the final diffuser or final filters should contain not more than 0.5 CFUs/m<sup>3</sup> of air. If the air filters have been tested after installation by a particle penetration test, this test is not necessary." We consider particle testing to be a better test of filter integrity than bacteriological sampling: it poses a greater challenge to the filter assembly (there will be a far greater number of tracer than microbiological particles) and is less prone to technical errors (sampling for very low numbers of airborne bacteria is a skilled exercise). In addition to this test, there is a test to assess the capacity of the airflow in the clean zone to resist penetration from outside. Details of this test can be found in the same volume, paragraphs 5.28 to 5.31. In essence, after the filter installation has been shown to prevent passage of particles (i.e. the filters are not holed or mis-seated), DOP (dispersed oil particles) or other appropriate particles are generated outside the clean zone and their ability to enter into the clean zone assessed. This test would be done by expert consultants acting for the Estates Department or the commissioning engineers and the ICO should be informed of the result.

As the uni-directional flow in the clean zone will resist contamination from outside, there is no necessity to have the air movement control schemes (i.e. air moves from the cleanest to progressively less clean areas) that should exist in conventionally-ventilated theatres. However there is still the problem of instruments receiving airborne contamination transferring that contamination into the wound<sup>3</sup>. Thus if instruments are laid up in a preparation room, that room should have air, filtered to the same specification as for the operating theatre, supplied such that it is at a positive pressure to surrounding areas. The air change rate in preparation rooms used for laying-up sterile instruments should be around 37 ACH.

It is important to prevent contamination of instruments exposed in the theatre, whether they have been laid up in a preparation room or in the theatre itself. Ideally, exposed instruments should be kept within the clean air flow, just as the wound is. However, the minimum size of the clean zone is 2.8 x 2.8 metres. It is, in practice, usually impossible to site all laid-up instruments within this area. Other than the diluting effect of ventilation on airborne contamination outside the clean zone, control of such contamination on exposed instruments can only be by limiting the duration of their exposure – this will require good co-operation between the team in only laying-up those instruments that can be accommodated within the clean zone yet providing all instruments as soon as they are required. If the clean area could be sufficiently large to accommodate laid-up instruments, there would be a higher quality assurance of contamination prevention. This matter should be considered at the design stage.

#### 4.2.4 Microbiological sampling

When commissioning an ultraclean theatre by microbiological sampling, HTM 2025 (1994) volume c, chapter 5, figure 1 shows thirteen sampling points reproduced in figure 2 of this document:

- one at each corner of the unidirectional airflow zone perimeter
- halfway along each side of the perimeter,
- one at each corner of the inner zone
- one in the centre

Volume c of HTM 2025 (1994) (Validation & verification), paragraph 5.36a states “*air leaving the final diffuser or final filters should contain not more than 0.5 CFUs/m<sup>3</sup> of air. If the air filters have been tested after installation by a particle penetration test, this test is not necessary.*” However, it is not uncommon, if the theatre has already been tested by particle generation, for single or duplicate microbiological samples to be taken at the centre of the clean zone. The air should contain less than 0.5 CFUm<sup>-3</sup>, or one colony for every 2m<sup>3</sup> sampled (HTM 2025, volume c, paragraph 5.36a). Accurate sampling for such low levels of bacterial contamination involves stringent technical requirements and operator skill. There is no need for the person operating the sampler to be outside the theatre when the sample is taken, as the unidirectional airflow should exclude ingress of contamination from outside that zone, but the sampler should still be operated remotely from outside the unidirectional flow canopy (someone bending over the sampler to switch it on and off would greatly compromise air quality). The sampler must be absolutely clean and should be run for a while in the clean air to remove any contamination from it before the plate is inserted. The ventilation should have been operating at full supply rate for at least five minutes before sampling occurs.

So that airflow patterns are not unduly disturbed by the act of sampling, the pump for the sampler should be either outside or close to the edge of the clean zone and its discharge, if directional, should be directed out of the clean zone. The larger the volume of air sampled, the greater the assurance of an accurate result; to detect 0.5 CFUm<sup>-3</sup>, the volume sampled must be at least 2m<sup>3</sup>, preferably more, so high volume samplers are essential. Using 15cm wide petri dishes, the agar will dry out to levels that discourage bacterial growth after more than about 10m<sup>3</sup> has been passed over its surface. As low numbers of plate contaminants can significantly affect results of commissioning UCV theatres, poured agar should be pre-incubated before use (under conditions that match the incubation of the samples to be taken) to exclude plate contaminants. Incubation, as with conventionally-ventilated theatres, should normally be at 37°C for 2 days.

## Monitoring

### 5.1 Conventionally-ventilated Theatres

#### 5.1.1 Routine monitoring

Provided that engineering parameters are satisfactory and regularly monitored, microbiological air sampling in conventionally-ventilated theatres need not be done on a routine basis, unless by local agreement. Microbiological air sampling of empty, conventionally-ventilated theatres should be done either as part of an investigation into theatre-acquired infection with a possible airborne element or after any changes that may affect airflow supply rates or distribution patterns. This would include alterations to the fabric of the theatre or changes to the ductwork distribution that may affect airflow to or within a theatre suite, but would not include routine filter changes. Such sampling should be identical to that on initial commissioning of the theatres.

#### 5.1.2 Sampling in a working theatre

Microbiological sampling during normal working can be done as part of the microbiological commissioning process. HTM 2025<sup>1</sup>, volume C (Validation and verification) states (paragraph 5.35): *A check of airborne bacteria should be carried out as soon as possible after handover. Unless there are unusually high numbers of personnel or extensive activity in the room, the number of airborne bacteria and/or fungal CFUs averaged over a five minute period, should not exceed 180 per cubic metre. This work should be carried out by the nominated infection control officer or consultant microbiologist if not the same person.* This standard has subjective elements to it: the existence of excessive numbers of personnel in the room and an assessment of their activity levels. The need to average the sample over a five minute period means, in effect, taking a continuous sample over that time or a sequential series of continuous samples.

The positioning of the sampler in relation to the incoming flow of clean air or the dispersing sources (theatre staff) will also have an effect on the microbial numbers recovered. Sampling in a working theatre is very much a secondary check on engineering parameters. If, for example, airborne counts in excess of 180 CFU m<sup>-3</sup> were to be found, remedies other than engineering-based are not readily applicable (these would be to reduce the number of staff in theatre, their activity levels or their individual dispersion levels). The only practicable course of action is reassessment of the ventilation parameters. This would comprise rechecking the commissioning engineer's airflow data with the local Estates Department; re-assessing air distribution patterns to ensure effective dilution and possibly re-balancing or redirecting ventilation output to achieve more effective contamination dilution.

Sampling in a working theatre is as much a check on how that theatre is being used as on the engineering parameters. We do not consider that it should be done as a routine exercise. Such sampling should be employed selectively where use of a theatre may have an effect on surgical wound infection.

#### 5.1.3 The air handling unit

Annex 1 of HTM 2025, volume d (Operational Management) requires that the humidifier and cooling coil in air handling units be disinfected at least six-monthly. It also states "if any suspicion arises as to the possible contamination of the system then the microbiologist should be requested to take swab tests from all drain trays and cooler battery/cooling coil tubes and fins". We consider it inappropriate to carry out such microbiological investigations on cooling coils as they do not contribute significantly to the microbial quality of air delivered by the system. We also consider it inappropriate to carry out such investigations on humidifiers since they should generate humidity via steam, in which case they pose a negligible risk. Humidifiers that aerosolise recirculated water (spinning disk humidifiers) pose too high a hazard to require routine microbiological assessment: they should not be used.

Annex 1 of volume c (Validation and verification) makes similar recommendations for ventilation plant about to come into service. Again we consider that physical cleaning, rather than disinfection with microbiological monitoring, is more appropriate.

If there is a build-up of biofilm on a cooling coil, the 5 parts per million chlorine recommended for disinfection is unlikely to make any contribution to its removal, even on a temporary basis. Use of a steam cleaner, given as an alternative to chlorine, may be more appropriate but any effective method of physical removal of biofilm is acceptable.

## 5.2 UCV Theatres

### 5.2.1 Routine monitoring

The pattern of airflow in a UCV theatre should be stable given reasonably constant air velocities. HTM 2025 (Operational management, para 5.8 & 5.9) recommends that air velocity assessment and bacteriological air sampling in a working theatre are done annually. As has already been noted, sampling in a working UCV theatre is a difficult exercise and we consider that, given no change in the ventilation, equipment or use of the theatre, such sampling is unlikely to give fresh data and is thus difficult to justify.

We recommend that UCV theatres are re-commissioned annually and on HEPA-filter replacement or disturbance. We recommend that, in empty UCV theatres, such testing is best accomplished by using inert particles rather than by bacteriological testing. Sampling in a working UCV theatre, as with conventionally-ventilated theatres, need not be done routinely but can form part of specific investigations.

### 5.2.2 Sampling in a working UCV theatre

Microbiological sampling during normal working can be done as part of the microbiological commissioning process. HTM 20251, Volume C (Validation and verification) states (paragraph 5.36 b & c):

- b) *air sampled close to the wound site during operations, that is within 300mm of the wound should on average, contain less than 10 CFUs/m<sup>3</sup> of air using conventional cotton clothes. Levels less than 1 CFU/m<sup>3</sup> can be expected when using occlusive clothing or body exhaust systems;*
- c) *air sampled at the perimeter of the clean zone during surgery should contain not more than 20 CFUs/m<sup>3</sup> using conventional clothing and levels less than 10 CFUs/m<sup>3</sup> when using occlusive clothing or body exhaust systems.*

However, as with sampling in working conventionally-ventilated theatres (5.1.2), such a course of action is more an indirect assessment of operating theatre procedures, personnel and practices than of engineering parameters. Given adequate airflow and engineering controls, it is factors such as individual dispersal, behaviour and clothing that will affect the airborne bacterial count. It is unrealistic to expect that if it is satisfactory on one occasion, it will consistently be satisfactory (and vice versa). Such sampling provides only a "snapshot" of the effects of other parameters that could be better observed and addressed as matters of theatre practice (see the accompanying report on Behaviours and Rituals in the Operating Theatre). As such, these matters are best observed directly and dealt with as matters of theatre procedure and discipline; there should be no need repeatedly to prove their need by the results of bacterial sampling. In addition, sampling air within 300mm of the wound during ultraclean surgery is a highly exacting exercise where minor technical errors may lead to false positive or negative results. We therefore do not recommend air sampling in ultraclean ventilated operating theatres during surgery as a commissioning exercise. If performed by technically-skilled operators, it has a role in specifically-directed investigations but this is not interchangeable with routine, undirected sampling.

## 6. References

1. NHS Estates. Health Technical Memorandum 2025: Ventilation in Healthcare Premises. 1994; HMSO: London.
2. Noble WC. Dispersal of skin organisms. British Journal of Dermatology 1975; **93**: 477-485.
3. Whyte W, Hodgson R, Tinkler J. The importance of airborne bacterial contamination of wounds. Journal of Hospital Infection 1982; **3**: 123-135.
4. Joint working party on ventilation in operating suites (chair Lidwell OM). Ventilation in operating suites. London. MRC and DHSS. 1972.
5. NHS Estates. Health Building Note 26. Operating departments. (1991) ISBN 0113213859.
6. Whyte W The Casella slit sampler or the Biotest centrifugal sampler – which is the more efficient. Journal of Hospital Infection 1981; **2**: 297-299.

## 7. Additional references/documents: References and documents used in the model letters and certification for conventionally and ultraclean ventilated theatres (annexes D – H)

1. BS 3928:1969 Method for sodium flame test for air filters (other than for air supply to I.C. engines and compressors), BSI, London.
2. DD ENV 12097:1997 Ventilation for buildings. Ductwork. Requirements for ductwork components to facilitate maintenance of ductwork systems, BSI, London.
3. BS EN 779:1993 Particulate air filters for general ventilation. Requirements, testing, marking, BSI, London.
4. BS EN 1822-1:1998 High efficiency air filters (HEPA and ULPA). Classification, performance testing, marking, BSI, London.
5. BS EN 1822-2:1998 High efficiency air filters (HEPA and ULPA). Aerosol production, measuring equipment, particle counting statistics, BSI, London.
6. BS EN 1822-3:1998 High efficiency air filters (HEPA and ULPA). Testing flat sheet filter media, BSI, London.

## Annex A Problems and actions

A risk assessment should be carried out involving an assessment of the abnormal bacteriological results, the likely cause and the ease of rectifying this, the type of theatre and the procedures carried out there, and the consequences of theatre closure.

PROBLEM	ACTION
Conventionally-ventilated theatre fails bacteriological sampling (empty theatre)	Check that sampling technique is satisfactory, then repeat sampling. If it still fails, discuss possibilities with people experienced in theatre testing. Explore possible engineering causes of failure* (see table below). Infection control team to discuss implications and options.

PROBLEM	ACTION
UCV theatre fails bacteriological testing (empty theatre)	Check that sampling technique is satisfactory (check with someone experienced in such sampling), then repeat sampling. If still fails, test particle penetration of filters outside clean zone to inside zone; test air velocity within clean zone.
Conventionally-ventilated theatre fails bacteriological sampling (working theatre)	Test theatre empty, check airflow rates and distribution. If satisfactory, assess staff numbers inside theatre, activity levels and test again.
UCV theatre fails bacteriological testing (working theatre)	Test theatre empty as above; check that sampling technique is satisfactory. Repeat sampling. If still fails, discuss possibilities with people experienced in theatre testing.
Clusters of infection known or suspected (having excluded more obvious causes such as changes in operative procedures)	If an airborne component is suspected or needs to be excluded, do a full check on the ventilation: filters in air handling unit, ventilation rates, airflows in theatre (& prep room), airflows between rooms, bacteriological air sampling in empty theatre, ascertain if anything has changed since before the cluster occurred.
Theatre staff "uncomfortable"	This is primarily a problem for the Estates Department, but if staff are uncomfortable because of draughts i) ensure that ventilation rates are not altered and ii) if airflows are redirected by adjusting fins on outlets, smoke test to ensure air is still sufficiently turbulent at the table to disperse contamination.

\* The possible engineering causes causing or contributing to microbiological test failures of theatres are listed below:

PROBLEM	POSSIBLE ENGINEERING DEFECTS
Microbiological tests fail:-possible engineering causes	<p>Insufficient air volume</p> <p>Check no water-pooling in air handling unit or ductwork (condensation or faulty drainage)</p> <p>Incorrect airflow patterns between rooms in theatre suite</p> <p>Air flow pattern in working area poor</p> <p>Filters incorrectly fitted or damaged (gaps in filters or around filter housing)</p> <p>Filters very dirty</p> <p>Wrong filters fitted</p> <p>Temperature gradient too large across doorways from clean to dirty areas causing reverse flow</p> <p>Debris in ductwork and air handling unit</p> <p>Incorrect interlocking of supply and extract fans i.e. extract stops before supply</p>

## Annex B Airflow indicators

Smoke tubes ("air current tubes" or "airflow indicators") are available from:

Draeger Ltd,  
Kitty Brewster Industrial Estate,  
Blyth,  
Newcastle upon Tyne, NE24 4RG,  
UK  
Tel: +44 (0)1670 352891  
Fax: +44 (0)1670 356 266

Sabre Gas Detection  
Protector Technologies Group  
Matterson House,  
Ash Road,  
Aldershot GU12 4DE,  
UK  
Tel: +44 (0)1252 342352,  
Fax: +44 (0)1252 321921

MSA Britain Ltd.  
East Shawhead,  
Coatbridge ML5 4TD,  
Scotland;  
Tel +44 (0)1236-424966  
Fax +44 (0)1236-440881

Large volume smoke generators from:

Concept Engineering Ltd.  
7 Woodlands Business Park,  
Woodlands Park Avenue, Maidenhead,  
Berks, SL6 3UA,  
UK;  
Tel +44 (0)1628 825555,  
Fax +44 (0)1628 826261,  
Internet: [www.concept-smoke.co.uk](http://www.concept-smoke.co.uk)

## Annex C Air Samplers for Use in Operating Theatres

Up until the 1980s the only microbial air samplers commercially available for measuring the microbial concentration of the air in operating theatres were the slit sampler and the sieve impactor. All the microbial aerosol levels recommended in guidance and in the papers of Whyte, Lidwell and others are based on experiments carried out with the large volume (700 l min<sup>-1</sup>) slit samplers. New types of microbial air samplers have appeared since then. However, sampling air in operating theatres does not form a substantial section of this market, so many are not suitable.

The following points need to be considered in selection:



1. Can it sample a suitable volume of air (greater than 2 cubic metres may be needed in UCV theatres) within a reasonable length of time (e.g. ten minutes) or before dehydration effects may occur?
2. Can it be operated remotely (e.g. infra-red control or via extension lead)?
3. Is it easy to use and clean?
4. If unusual plates, strips or filters are used, how much do they cost? (Some can cost up to £5 per unit).
5. Is it required to get close to the wound in a working ultraclean theatres?
6. Has it been demonstrated to be reasonably effective in the published literature?

The table below gives the characteristics of most available microbial air samplers:

Sampler	Flow Rate (l/min)*	Collection Method	Plate/ Strip/++ Filter
Andersen Sampler	28.3	Sieve impaction	Standard plate (6)
Biotest RCS	40#	Centrifugal impaction	Pre-filled strips
Biotest RCS Plus <sup>1</sup>	50	Centrifugal impaction	Pre-filled strips
Biotest HiFlow <sup>1</sup>	100	Centrifugal impaction	Pre-filled strips
Casella (high volume) <sup>2</sup>	700	Slit impaction	150mm plate
Casella (low volume) <sup>2</sup>	30	Slit impaction	Standard plate
Mattson Garvin	28.3	Slit impaction	150mm plate
Merck MAS <sup>3</sup>	100	Sieve impaction	Standard plate
Microbio <sup>1</sup>	100	Sieve impaction	55mm contact plates
Microbio <sup>2</sup>	100	Sieve impaction	55mm contact plates
Millipore	140	Sieve impaction	Pre-filled cassette
Negretti	100?	Sieve impaction	55mm contact plates
New Brunswick	28.3?	Slit impaction	150mm plate
Saml'air	86-200	Sieve impaction	Standard plate
Sartorius MD8	42-133	Filtration	Gelatine filters
SAS 90	90	Sieve impaction	55mm contact plates
SAS <sup>2</sup>	180	Sieve impaction	55mm contact plates

\* 1 cubic metre is 1,000 litres

# see reference 6

1 Infrared remote operation possible

2 Remote operation via cable possible

3 Delay of up to 60 minutes possible

## Annex D Model letter for operating theatre engineering compliance

**This is a model letter requesting certification that an operating theatre has been assessed and complies with its design brief, HTM2025, the Component Data Base and other HTMs or standards relevant to infection control.**

*Letter should be on management's headed paper.*

*Microbiologist should check that the recipient of the letter is the person who is the Designated person (an individual who has overall responsibility for the operating theatre systems within the premises and who has a duty under the Health and Safety at Work Act 1974, to prepare and issue a general policy statement on health and safety at work, including the organisation of and arrangements for, carrying out that policy.)*

To [ (1) ]

Certification of compliance for operating theatres.

Please confirm that the following have been tested and certified as to be correct to the design brief and the relevant standards and guidance by signing and returning to me the attached certificate (Certificate of Compliance)

Location [ (2) ]

Signed (Microbiologist )

(1) Insert name of person who has designated authority for the operating theatres with respect to Estates matters.

(2) Insert location and Operating Theatre identification.

## CERTIFICATE OF COMPLIANCE

Location:.....

### Details of the installation

1) Does the system comply with the design brief : Yes  No

Details of departures (if any) from design brief:

2) Does the system comply with HTMs 2025, 55, 56, 60, 61, 63 & Model Engineering Specification CO4 (Mechanical ventilation and air conditioning) Yes  No

Details of departures (if any) from HTMs

3) Has the system been formally commissioned and independently witnessed ? Yes  No

Name of independent body :-

.....

Date of commissioning:- .....

Details of departures (if any) from HTM 2025

4) Ventilation system hygiene. Level of cleanliness of ductwork .

Does the ventilation plant and ductwork internal cleanliness Yes  No

comply with DHSS Standard Engineering Specification document CO4: DW/TM2 in the Guide to Good Practice Internal Cleanliness of New Ductwork Installations issued by the Heating & Ventilation Contractors Association

To what level :

External Reference

Basic

Yes No 

Intermediate

Yes No 

Advanced

Yes No 

Details of departures (if any) from guidance:

5) Level of filtration fitted to the air handling unit:

Primary filter -

Secondary filter -

Details of departures (if any) from guidance

6) Air change rate and room pressurisation for the following:  
(All areas not shaded should be filled-in)

Theatre suite zone	Room	Nominal pressure (Pa)	Air supply rate (m <sup>3</sup> /s)	Room volume (m <sup>3</sup> )	Air change rate (ACH)	Is an extract system in place & working?
"Sterile"	Operating room (and scrub bay)					
	Preparation room (Lay-up)					
	Preparation room (Sterile pack store)					
Clean	Scrub room					
	Anaesthetic room					
Transitional	Recovery room					
	Clean corridor					
	General access corridor					
	Changing rooms					
	Plaster room					
"Dirty"	Disposal corridor					
	Disposal room					

The notes are detailed in the guidance document question 6

Air flow direction between areas and rooms (check both with relevant door closed and door open), as

External Reference

in HTM 2025, volume b (design considerations), table 6.6:

From lay-up to operating room	Yes/no
No flow between sterile pack store and operating room	Yes/no
From operating room to disposal room	Yes/no
From operating room to corridors (clean and/or disposal)	Yes/no
From operating room to anaesthetic room	Yes/no
From anaesthetic room to corridor	Yes/no
From lay-up or sterile pack store to corridor	Yes/no
From scrub area/room to corridor	Yes/no
No flow between disposal corridor and disposal room	Yes/no
From clean corridor to disposal room	Yes/no

7) Confirmation of turbulent air distribution within operating theatre and other clean rooms, either by measurement of average air speed or by observation of turbulent smoke

Operating theatre table            average .....m/s) working height

OR turbulent smoke                Yes/no

Preparation lay-up                 average .....m/s) working height

OR turbulent smoke                Yes/no

8) Confirmation that drainage systems on the air-handling unit comply with HTM 2040 The control of legionella in healthcare premises code of practice.            Yes             No

Details of departures (if any) from guidance

9) Outstanding defects:

10) Comments related to possible microbiological problems:

Name (BLOCK LETTERS) ..... Position.....

Date .....

Signature .....

For and on behalf of : .....

Completed certificates returned to :

Name:

Address:

Queries regarding completion to:

External Reference

Name

Contact details

## Annex E Guidance for completion of the model letter for operating theatre engineering compliance certificate

### Submission of certificate:

Separate certification needs to be made for each operating theatre.

Certificates need to be completed for each operating theatre whether owned or leased by the Trust.

### GUIDANCE NOTES FOR INDIVIDUAL QUESTIONS

#### Question Number

#### 1 Does the system comply with the design brief? Details of departures (if any) from design brief.

Does the final project comply with design brief details and appropriate health building standards?

Assessment should be based upon following:

Appropriate space standards (from HBN 26)

Layout of operating theatre which may compromise airflow control (e.g. dirty utility opening onto outdoors)

Engineering standards and installation (examples: position of fresh air inlet, situation of air handling plant, layout of plant & position of air inlet diffusers or grilles into the operating room)

Compliance with BSI DD ENV 12097 "Ventilation for buildings: Ductwork requirements for ductwork components to facilitate maintenance of ductwork systems"

#### 2 Does the system comply with HTMs 2025 (ventilation), 55 (windows), 56 (partitions), 60 (ceilings), 61 (flooring), 63 (fitted storage systems) & Model Engineering Specification CO4 (Mechanical ventilation and air conditioning)? Details of departures (if any) from HTMs.

Does the installation comply with the above standards and guidance for the following:

Minimum air volumes

Air pressures between areas and rooms

Air filtration

Ductwork cleanliness

(further details required under question 6)

#### HTM 55 Windows

Where windows are installed in Operating Theatre suites then the installation and materials used shall comply with HTM55. Areas which could affect microbiological standards are:

Weathertightness

Thermal performance (are windows correctly designed or specified to prevent air flow pattern distortion and condensation forming)

Amenable to cleaning, disinfection and maintenance

External Reference

## HTM 56 Partitions

Where partitions are installed in Operating Theatre suites then the installation and materials used shall comply with HTM56. Areas which could affect microbiological standards are:

- Stability to prevent cracking and movement
- Biological attack resistance
- Mechanical damage resistance
- Hygrothermal performance
- Hygienic finishes
- Thermal performance (may affect air flow patterns)
- Amenable to cleaning, disinfection and maintenance

## HTM 60 Ceilings

Ceiling installations in Operating Theatre suites shall comply with HTM60.

Areas which could affect microbiological standards must be scrubbable and have a completely sealed finish.

Lighting fitting shall be sealed fittings to IP56 (ingress protection number under Guidance note 1 of BS 7671& BSEN 60947-1 :1999), or Chartered Institute of Building Services Engineers LG2

## HTM 61 Flooring

Flooring in Operating Theatre suites shall comply with HTM61. Areas which could affect microbiological standards are:

- Stability to prevent cracking and movement from weight or use
- Hygienic finishes
- Manufacturer's information supplied on suitable cleaning, disinfection and maintenance procedures
- Impervious, smooth & jointless

## HTM 63 Storage systems

Storage systems in Operating Theatre suites shall comply with HTM63. Areas which could affect microbiological standards are:

- The performance and strength are such that the units will resist surface cracking, absorbance etc. (Manufacturer's data should be supplied)
- Surface finishes
- Hygienic finishes
- Moveable units can be easily disinfected (wheels etc)

### 3 Has the system been formally commissioned and independently witnessed ?

The independent body carrying out the witnessing shall be accredited by UKAS .

Is the theatre performing to the design intent in respect of:

- Air dilution and turbulence

All inlet air passes through the filters.

Air pressures

Air change rate

Plant layout and installation

Operating theatre suite configuration

#### 4 Ventilation system hygiene. Level of cleanliness of ductwork

Detail level of cleanliness of ductwork and air handling plant carried out under the contract. Model Engineering Specification CO4 (Mechanical ventilation and air conditioning) requires compliance with good practice guide DW/TW2 (internal cleanliness of new ductwork installations). There are 3 levels with 6 control means for cleanliness in the code of practice. DHSS standard specification for ventilation systems CO4 calls for intermediate level of cleanliness unless otherwise specified to a higher standard. Cleanliness should be to a minimum of "intermediate" standard.

Level	factory seal	protection in transit	protection during site storage	clean on-site	cap-off on site	Special clean once installed
Basic	no	no	no	no	risers only	no
Intermediate	no	no	yes	yes	yes	no
Advanced	yes	yes	yes	yes	yes	no

Note: Site storage shall be permanently clean, dry and dust-free.

#### 5 Level of filtration fitted to the air conditioning system

The level of air filtration to be installed is in HTM 2025. Filters should comply with BS EN 779 and should be installed in air handling units in accordance with figure 4.1 of HTM 2025, volume b; in essence the secondary filter should be the last piece of equipment installed in the air handling unit and must be situated after the fan.

Primary filter suitable G3 (possibly G2)

Secondary filter suitable F8 (depends on inlet air pollution level; F7 in lower particulate pollution areas and in much pre-existing ventilation plant)

#### 6 TABLE: Air change rate and relative pressures between rooms

Detail air change rates in the operating and preparation rooms.

The air change rate depends upon the control scheme for the operating theatre suite as detailed in HTM2025, volume b (design considerations) paragraph 6.19 and 6.20: systems 1a to 5b.

Target air change rates can be calculated from ventilation volume rates given in HTM 2025 and room dimensions given in HBN 26: The numbers (1a, 1b etc.) refer to suggested layouts given in HTM 2025, design considerations (volume b), figures 6.1a and 6.1b.

The air change rate for operating theatres should, as a minimum, be around 20 air changes per hour (ACH).

If room dimensions are as in HBN 26 and airflow rates are as in the various suggested layouts in HTM 2025, volume b, figures 6.1 a & b (this shows eight suggested layouts: 1 a & b, 2 a & b, 3, 4 and 5 a & b), air change rates should be as below:-

Conventionally-ventilated operating room plan:

1a, 2a & 5a	22.5 ACH
1b, 2b & 5b	19.5 ACH
3	24 ACH
4	23 ACH

(These do not apply to ultraclean ventilated operating theatres)

Preparation room plan:

1a, 2a, 4 & 5a 11 ACH (Preparation room suitable for sterile pack storage)

1b, 2b & 5b 37 ACH (Preparation room suitable for instrument lay-up)

(These also apply to preparation rooms for ultraclean ventilated operating theatres)

If room dimensions differ from those in HBN 26, ventilation rates should have been adjusted to compensate such that the above air change rates are still achieved.

Extract rate related to the pressure requirements see table 6.1 HTM 2025, volume b.

Notes on question 6 table

These values relate to the Figures 6.1 in HTM 2025 Design for suggested air movement control systems in conventionally-ventilated operating suites (shaded boxes do not need to be filled-in).

**Only the air change rates and pressures in preparation rooms and anaesthetic rooms are applicable to ultraclean ventilated operating theatres, but see the notes at the start of Annex F.**

Theatre suite zone	Room	Nominal pressure* (pascals)	Air supply rate (m <sup>3</sup> /s)	Room volume (m <sup>3</sup> )	Air change rate (ACH)	Extract system in place & working
"Sterile"	Operating room (and scrub bay)	25	0.65-0.75		> 20 <i>see note 6</i>	NO
	Preparation room (Lay-up)	35	0.33		> 37 <i>see note 6</i>	NO
	Preparation room (Sterile pack store)	25 +/-5	0.1		> 11 <i>see note 6</i>	NO
Clean	Scrub room	14-25 <i>see note 1</i>			<i>see note 2</i>	NO
	Anaesthetic room	14 <i>see note 2</i>	0.15 supply 0.15 extract		15ACH	YES
Transitional	Recovery room	3 <i>see note 3</i>	<i>see note 3</i>			YES
	Clean corridor	3 <i>see note 4</i>				YES
	General access corridor	3 <i>see note 4</i>				YES
	Changing rooms	3 <i>see note 4</i>				YES
	Plaster room	3 <i>see note 4</i>				YES
"Dirty"	Disposal corridor	0 <i>see note 5</i>				YES
	Disposal room	0 to -5 <i>see note 5</i>	0 to -0.41 extract			YES

\* A "nominal" pressure is the pressure relative to ambient (i.e. outside the theatre suites). A pressure differential or relative pressure is the difference in nominal pressures; for example, if an operating theatre is at a nominal pressure of 25 pa and the adjacent anaesthetic room is at 14 pa, the pressure



between these areas is 11 pa.

**Note 1 Scrubroom:** Normally the scrub and handwash facility are part of the operating room often a bay. If a separate room is required then a door between the scrub room and operating room is an inconvenience to scrubbed staff and should be replaced by a permanent opening larger than a doorway. In this case the room pressure should be 25 pa. (If a door is in place, the nominal pressure should be 14 pa).

**Note 2 Anaesthetic room:** This ventilation is primarily for the dilution of anaesthetic gases, not infection control. It should have a balanced inlet and extract (i.e. equal volumes supplied and extracted) with the air entering from the operating room sufficient to pressurise the room to 14pa, being lost to the corridor.

**Note 3 Recovery room:** The precise pressure differential of 3pa is very difficult to achieve or measure and in general it should have a pressure of 0 or be slightly positive. If the recovery room is positioned as indicated in HBN26 or HTM 2025 then the room should have a negative pressure with respect to sterile and clean areas and positive with respect to dirty areas. The extract rate of 15ACH is for the removal of anaesthetic gases with the inlet air volume being balanced to the extract rate. The supply and extract rate will depend upon the size of the recovery: e.g. for a suite of four theatres, the recovery extract and inlet will be 1m3s-1.

**Note 4 Clean corridor, general access corridor, changing rooms & plaster room:** A slightly pressurised or zero value is acceptable as long as the area is positive in respect to dirty areas and negative in respect to sterile or clean areas.

**Note 5 Disposal room and disposal corridor:** Dirty areas should be negative with respect to clean, transitional and sterile areas. From a practical point of view dirty areas should have a negative air pressure of 25 – 30 pa with respect to the operating theatre.

**Note 6** This is the variable that is important in terms of dilution of airborne contamination. If room volume varies from standard, air supply volume should be adjusted to achieve an adequate air change rate.

Air movement control transfer devices and open door shall comply with Table 6.6b and 6.6c of HTM 2025 Design considerations.

## 7 Confirmation of turbulent air distribution within operating theatre and other clean rooms

This test is to confirm that there is an air flow in the region of the operating table to ensure that dilution of pollutants takes place.

## 8 Confirmation that drainage systems on the air-handling unit comply with HTM 2040 The control of legionellae in healthcare premises code of practice

This is a visual check to ensure that HTM2040 paragraph 7.0 is being adhered to, in particular the existence of an air break soon after the outlet from the air handling unit drain point. This will prevent contamination of the ventilation system by the drainage system.

Typical air-conditioning plant drain.

## 9 Outstanding defects

The outstanding defects listed should be those that relate to hygiene, air change rate and air flow pattern.

## 10 Comments related to possible microbiological problems

The comments should be concerns relating to possible microbiological contamination.

## Annex F Supplementary certificate for UCV theatres.

This should be completed in addition to the basic certificate (Annex D)

**General note:** Whilst it states in HTM 2025, volume b (Design considerations) paragraph 6.77 “There is no strict requirement when using a UCV system to have an air movement control system, except in the preparation room”, surrounding areas should be controlled such that they do not interfere with the integrity of the UCV enclosure. In general, if those areas surrounding UCV operating theatres are ventilated as for similar areas surrounding conventionally-ventilated theatres, this will not compromise the integrity of airflow in the UCV enclosure.

### 1) HEPA grade and efficacy of filter assembly

Grade of HEPA filter fitted:

Results of *in situ* particle testing:

- a) Terminal filter installation test (HTM 2025, volume c, para 5.26)
- b) Lack of entrainment from outside clean zone (HTM 2025, volume c, para 5.28-31)

### 2) Monitoring system to show clean and dirty state of HEPA filter: Specify system

Clean/dirty pressure differentials

### 3) Type of system fitted:

Vertical flow

Horizontal or cross flow

### 4) Test procedure for verification of system parameters:

Brief description of tests and results:

### 5) Vertical discharge ultraclean system.

(a) Discharge within the clean zone velocity at 2metres above floor finish (average velocity 0.38m/s with fixed walls terminating 2m above floor or 0.3 m/s with fixed walls terminating 1m above floor):

test results:

(b) Discharge within the clean zone velocity at 1metre above floor finish (average velocity 0.2m/s)

test results:

### 6) Comments related to possible microbiological problems:

Name (BLOCK LETTERS) ..... Position.....

Date .....

Signature .....

For and on behalf of : .....

External Reference

Specify

## Annex G Guidance for completion of supplementary certificate for UCV theatres.

To be completed on commissioning and on annual re-commissioning

### 1 HEPA grade and efficacy of filter assembly

The HEPA filter should comply with BSEN1822 and be site tested to BS 3928 or BSEN1822 parts 4 and 5.

The penetration resistance of the UCV clean zone is set out in HTM 2025 Validation and verification, paragraphs 5.30 and 5.31.

The grade of HEPA filter depends on the specification of the manufacturer of equipment.

### 2 Monitoring system to show clean and dirty state of HEPA filter

Describe monitoring method and indicate pressure readings on filters when clean and when dirty.

### 3 Type of system fitted

Indicate manufacturer and type of system. Horizontal or cross flow systems are not recommended by HTM2025.

### 4 Test procedure for verification of system parameters

Test method should follow HTM2025, volume c (Validation and verification), paragraph 5.0: The following test applies to a typical UVC system. Any unit which does not comply with this standard design should have its method of verification agreed and documented.

Data should include discharge area, diffuser height (from 2.45m to 2.9m from finished floor level subject to local conditions and operating lamp selection) and whether full or partial walls are fitted.

#### AIR VELOCITY TEST

Grid size:2800mm x 2800mm

Test measurements taken at 2.00metres above finished floor level

	1	2	3	4	5	6	7	8	9	10
A										
B										
C										
D										
E										
F										
G										
H										
I										
J										

Average Velocity over area = m/s

Note: average velocity must not be less than 0.38m/s for fixed partial walls finishing 2metres above

finished floor level

average velocity must not be less than 0.3m/s for full walls finishing 1metres above finished floor level

Comments:

#### AIR VELOCITY TEST

Grid size: 1800mm x 1800mm

Test measurements taken at 1.0metres above finished floor level

	1	2	3	4	5	6
A						
B						
C						
D						
E						
F						

All grid velocities must not be less than 0.2m/s

#### 5 Vertical discharge ultraclean unit.

Test results inline with HTM2025.

The test results should comply with HTM2025 Validation and verification chapter 5 (Performance tests) and the results tabulated as detailed in tables above.

#### 6 Comments related to possible microbiological problems

Comments regarding any problems that could compromise microbiological standards.

## Annex H

### AIR FILTERS

Sub-HEPA filters are classified by BS EN 779: 1993. Under this standard they are graded by either percentage retention ("arrestance") of a test dust of assorted particle sizes (grades G 1-4) or by the passage ("efficiency") of a finer test dust, again of assorted particle sizes.

Arrestance (%)

G1	(A) <65
G2	65> (A) <80
G3	80> (A) <90
G4	>90

Efficiency (%)

F5	40< (E) <60
F6	60< (E) <80
F7	80< (E) <90
F8	90< (E) <95
F9	(E) >95

As the test dusts used are of assorted sizes, it is not possible to make accurate predictions about retention of particles of any particular size.

High efficiency particulate air (HEPA) filters are tested against particles of a definite size range relevant

to microbiological applications (mean particle diameter 0.4µm). The efficiencies (H) of HEPA grades 10 to 14 are:

Initial Efficiency (%)	
H10	95<(H)<99.9
H11	99.9<(H)<99.97
H12	99.97<(H)<99.99
H13	99.99<(H)<99.999
H14	(>99.999(H)

There also exist "ultra low penetration air" filters ("ULPA") Grades U15 to U17. These are not relevant to operating theatre ventilation.

### Filter Applications

G2/3 Filter for air handling systems not requiring any great degree of cleanliness. Primary filter for operating theatre air handling plant.

G4 Where low to moderate cleanliness is required.

F5 Final filter where decor protection is not required.

F6 Final filter but better decor protection than 5.

F7 Final filter used when decor protection is required.

F8 High degree of protection no dust staining.

F9 High quality filtration but where HEPA filters are not justified. (if manufacturer agrees, rigid F9 filters can be tested to BS3928 and therefore classified as a HEPA filter.)

H13 Fitted in ultraclean ventilation terminals, but the grade used will depend upon manufacturer's specifications.

External Reference