DEUTSCHE NORM December 2008

DIN 1946-4

DIN

ICS 91.040.10; 91.140.30

Supersedes
DIN 1946-4:1999-03 and
DIN 4799:1990-06

Ventilation and air conditioning – Part 4: VAC systems in buildings and rooms used in the health care sector

Raumlufttechnik –
Teil 4: Raumlufttechnische Anlagen in Gebäuden und Räumen des Gesundheitswesens

Document comprises 68 pages

Translation by DIN-Sprachendienst.
In case of doubt, the German-language original should be consulted as the authoritative text.

English price group 23
www.din.de

Contents

Foreword

This standard has been prepared by the *Normenausschuss Heiz- und Raumlufttechnik* (Standards Committee for Heating and Ventilation) with the participation of the relevant experts and standards setters. The previous version of this standard has been extensively revised, taking into consideration current technical rules in German that are relevant to hygiene, namely VDI 6022 Part 1, ÖNORM H 6020 and SWKI 99-3.

The technical specifications regarding VAC systems given in this standard have been compiled from VDI 2167 Part 1:2007-08 and E DIN 1946-4:2007-06.

If, for medical reasons, any additional regulatory stipulations are to be placed on the dimensions and technical design of ventilation systems, or on the technical equipment for such, these stipulations shall only be laid down by the relevant health authorities on the basis of existing health regulations.

This edition of DIN 1946-4 not only gives design criteria but also specifies

— systems qualification for acceptance testing,

— flow visualization,

— the qualification of operating rooms (determination of turbulence intensity or, alternatively, the degree of protection), and

— microbiological monitoring.

Informative annexes giving information on the different project phases and system testing of operating rooms are also now included.

Amendments

The following changes have been made to DIN 1946-4:1999-03 and DIN 4799:1990-06:

a) This standard has been completely revised to reflect the current state of technology and the revised recommendations of the Commission for Hospital Hygiene and Infectious Disease Prevention of the Robert Koch Institute (RKI).

b) Infection control requirements, which were previously specified for entire areas (e.g. the operating department), now apply to specific rooms (e.g. operating rooms).

c) The requirements regarding the testing and evaluation of VAC systems in operating rooms specified in DIN 4799 have been fully revised and incorporated in this standard.

Previous editions

DIN 1946-4: 1963-05, 1978-04, 1989-12, 1999-03
DIN 4799: 1990-06

1 Scope

This standard applies to the planning, construction and qualification of ventilation and air conditioning (VAC) systems in buildings and rooms used in the health sector, particularly those used for medical examinations, treatments and operations on humans, including any rooms directly connected to such rooms via doors, corridors/hallways, etc. in:

— hospitals;

— day clinics;

— treatment rooms in doctor's offices/surgeries;

— operating rooms in outpatient facilities;

— dialysis centres;

— internal and external medical device sterilization facilities.

This standard applies to the operation of VAC systems only when they have been designed, built and accepted on the basis of this standard.

This standard does not cover the design of special treatment facilitates (for treating highly infectious, deadly diseases).

VAC systems may be necessary for the purposes of infection control or to fulfil special requirements, e.g. due to physical (heating and cooling loads), structural, climactic or toxicological conditions.

This standard does not affect the validity of standards dealing with the ventilation of special rooms or for special applications.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

DIN 1946-7, *Ventilation and air conditioning — Part 7: Ventilation systems in laboratories*

DIN 4109, *Sound insulation in buildings — Requirements and testing*

DIN 6844-1, *Nuclear medicine departments — Part 1: Rules for the installation and equipment for diagnostic applications of unsealed radioactive sources*

DIN EN 779, *Particulate air filters for general ventilation — Determination of the filtration performance*

DIN EN 1751, *Ventilation for buildings — Air terminal devices — Aerodynamic testing of dampers and valves*

DIN EN 1822 series, *High efficiency particulate air filters (HEPA and ULPA)*

DIN EN 1886, *Ventilation for buildings — Air handling units — Mechanical performance*

DIN EN 12599, *Ventilation for buildings — Test procedures and measuring methods for handing over installed ventilation and air conditioning systems*

DIN EN 12792, Ventilation for buldings — Symbols, terminology and graphical symbols

DIN EN 13053, *Ventilation for buildings — Air handling units — Rating and performance for units, components and sections*

DIN EN 13182, *Ventilation for buildings — Instrumentation requirements for air velocity measurements in ventilated spaces*

DIN EN 13779, *Ventilation for non-residential buildings — Performance requirements for ventilation and room-conditioning systems*

DIN EN 60601 (VDE 0750-1) series, *Medical electrical equipment*

DIN EN 61010 (VDE 0411) series, *Safety requirements for electrical equipment for measurement, control and laboratory use*

DIN EN ISO 14644-3, *Cleanrooms and associated controlled environments — Part 3: Test methods*

DIN EN ISO 14698-1, *Cleanrooms and associated controlled environments — Biocontamination control — Part 1: General principles and methods*

DIN EN ISO 14698-2, *Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data*

VDI 2078, *Cooling load calculation of air-conditioned rooms (VDI cooling load regulations)*

VDI 2083 Part 3, *Cleanroom technology — Metrology and test methods*

VDI 2083 Part 4.1, *Cleanroom technology — Planning, construction and start-up of cleanrooms*

VDI 2083 Part 5.1, *Cleanroom technology — Cleanroom operation*

VDI 2089 Part 1, *Building services in swimming baths — Indoor pools*

VDI 3803, *Air-conditioning systems — Structural and technical principles*

VDI 6022 Part 1, *Hygienic requirements for ventilating and air-conditioning systems and air-handling units*

VDI 6026 Part 1, *Documentation in building services — Contents and format of planning, execution and review documents*

VDMA 24176, *Inspection of technical installations and equipment in buildings*

VDMA 24186 series, *Programme of services for the maintenance of technical installations and equipment in buildings*

AMEV *Planen und Bauen: RLT-Anlagenbau 2004* (Planning and building VAC systems), published by *Arbeitskreis Maschinen- und Elektrotechnik staatlicher und kommunaler Verwaltungen* (Mechanical and Electrical Engineering Working Party of National, Regional and Local Authorities)[1)]

AMEV *Betrieb und Vertragsmuster: Wartung 2006* (Recommendations and sample contracts: Maintenance), published by *Arbeitskreis Maschinen- und Elektrotechnik staatlicher und kommunaler Verwaltungen*[1)]

1) Registered in the DITR database of *DIN Software GmbH*, obtainable from: Elch Graphics.

AMEV *Betrieb und Vertragsmuster: Bedien RLT 88* (Recommendations and sample contracts: Operating VAC systems), published by *Arbeitskreis Maschinen- und Elektrotechnik staatlicher und kommunaler Verwaltungen*[2)]

ArbStättV, *Verordnung über Arbeitsstätten (Arbeitsstättenverordnung)* (Workplaces Ordinance) including supplementary *Arbeitsstättenrichtlinien* (Workplaces Guidelines)[1)]

GefStoffV, *Verordnung zur Anpassung der Gefahrstoffverordnung an die EG-Richtlinie 98/24/EG und andere EG-Richtlinien (Verordnung zum Schutz vor gefährlichen Stoffen) (Gefahrstoffverordnung)* (Hazardous Substances Ordinance)[1)]

Strahlenschutzverordnung (German Radiation Protection Ordinance)[1)]

Anforderungen der Hygiene bei Operationen und anderen invasiven Eingriffen (Hygiene requirements during operations and other invasive procedures) issued by the Commission for Hospital Hygiene and Infectious Disease Prevention of the Robert Koch Institute (RKI), *Bundesgesundheitsblatt* (German Federal Health Gazette) 43 (2000): pp. 644–648

Anhang zur Anlage zu Ziffern 5.1 und 4.3.3 der Anforderungen der Hygiene beim ambulanten Operieren in Krankenhaus und Praxis (Annex to the attachment accompanying numbers 5.1 and 4.3.3 of the requirements for hygiene in ambulant surgery), *Bundesgesundheitsblatt* 40 (1997): pp. 361–365

TRBA 250, *Biologische Arbeitsstoffe im Gesundheitswesen und in der Wohlfahrtspflege* (Biological agents in health and welfare services) Technical Rules for Biological Agents (TRBA), published by the *Ausschuss für Biologische Arbeitsstoffe* (Committee for Biological Agents) (ABAS)[1)]

TRGS*, Technische Regeln für Gefahrstoffe* (Technical rules for hazardous substances), issued by the *Ausschuss für Gefahrstoffe* (Committe on Hazardous Substances) (AGS)[1)]

WHO, Air Quality Guidelines for Europe

MedPG, *Medizinproduktegesetz* (Medical Devices Act)[1)]

IfSG, *Infektionsschutzgesetz* (Protection Against Infections Act)

CHV4, Terms, definitions and abbreviations used in the *Arbeitsstättenverordnung* of 2007, published by the *Deutsche Gesetzliche Unfallversicherung* (German Statutory Accident Insurance)[3)]

3 Terms, definitions and abbreviations

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in DIN EN 12792 and the following apply.

3.1.1
system qualification
qualification of VAC systems carried out in a succession of steps to quality the installation, its functions and its performance, where each step does not begin until the preceding step has been successfully completed

1) See page 5.

2) Registered in the DITR database of *DIN Software GmbH*, obtainable from: *Bernhard GmbH*, Postfach 1265, 42905 Wermelskirchen, Germany.

3) Obtainable from: *Carl Heymanns Verlag GmbH*, *Verlagsgruppe Recht der Wolters Kluwer Deutschland GmbH*, Luxemburger Straße 449, 50939 Cologne, Germany.

3.1.2
invasive procedures
according to the recommendation *Anforderungen der Hygiene bei Operationen und anderen invasiven Eingriffen* (Hygiene requirements during operations and other invasive procedures) issued by the Commission for Hospital Hygiene and Infectious Disease Prevention of the Robert Koch Institute (RKI) (referred to below as the "RKI recommendations"), invasive procedures are classified according to the level of risk involved, as follows: *Operationen* (operations), *kleinere invasive Eingriffe* (minor interventions), and *invasive Untersuchungen und vergleichbare Maßnahmen* (invasive diagnostics and other similar procedures)

3.1.3
function qualification
series of tests and measurements carried out to ensure the correct functioning of all VAC system components, carried out after the successful completion of the installation qualification of that system

3.1.4
hygienist
(for the purposes of this standard): medical specialist in hygiene pursuant to the advanced training regulations of the German *Länder* having special expertise in ventilation and measurement technology, or an expert working in a governmental or other agency who is responsible for compliance with hygiene regulations, and who, in either case, has special knowledge and experience in the field of hospital ventilation and hygiene

3.1.5
installation qualification
systematic sequence of inspections, tests, and measurements carried out after a VAC system is installed in order to ensure compliance of all system components and documentation with the design requirements

3.1.6
servicing
measures for determining and assessing the actual state of the technical equipment of a system (inspection), as well as measures for maintaining the required condition of that equipment (maintenance)

3.1.7
repair
measures for restoring the required condition of a system's technical equipment

3.1.8
performance qualification
tests and measurements carried out to establish whether or not the entire system has reached the required operating condition after the successful completion of the functional qualification of that system

3.1.9
design qualification
once the design stage has been completed, demonstration of compliance of the final design with the requirements laid down in the specifications

3.1.10
system test
assessment of the design and construction of LTF (low-turbulence flow) systems, taking into consideration all relevant technical equipment (e.g. any necessary surgical lights, special flow stabilizers) and all spatial aspects of the operating room under the planned thermal loads (e.g. persons, equipment, basic heating, etc.)

3.1.11
room classes
rooms used for medical purposes are classed either as class I or class II rooms

3.1.12
protected area
in addition to the operating site or wound, the protected area includes the sterile cover (surgical drape), the table for the sterile instruments and materials, and the operating room team wearing sterile clothing

3.1.13
turbulence intensity
measure of the fluctuations in air velocity in relation to its mean value (relative standard deviation)

NOTE 1 The turbulence intensity is expressed in %.

NOTE 2 For the purposes of this standard, flows having a turbulence intensity < 5 % are designated “laminar” flows, those with an intensity between 5 % and 20 % are designated as “low-turbulence” flows, and those with an intensity > 20 % are designated “turbulent” flows.

3.1.14
low-turbulence flow (LTF) outlet
large supply air outlet with vertical air flow used to obtain a low-turbulence displacement flow throughout the entire protected area

3.2 Abbreviations

Abbreviation	Definition
ETA	Extract air
EHA	Exhaust air
BACS	Building automation and control system
HEPA	High efficiency particulate air filter, air filter class as in DIN EN 1822-1
CFU	Colony-forming unit
MIS	Minimal invasive surgery
FFL	Finished floor level
OR	Operating room
QM	Quality management
VAC	Ventilation and air conditioning
VAC system	Ventilation and air conditioning system
LTF	Low-turbulence flow
Tu	Turbulence intensity
AMEV	*Arbeitskreis Maschinen- und Elektrotechnik staatlicher und kommunaler Verwaltungen*
DGKH	*Deutsche Gesellschaft für Krankenhaushygiene e.V.*
DIN	*Deutsches Institut für Normung e.V.*
RKI	*Robert-Koch-Institut*
VDI	*Verein Deutscher Ingenieure e.V.*
VDMA	*Verband Deutscher Maschinen- und Anlagenbau e.V.*

4 Basic principles

4.1 General

The scrupulous maintenance of hygiene not only requires a well-trained, organized and disciplined medical and technical staff, but also the appropriate design and construction of the hospital and its facilities. Such considerations are of particular importance in the planning, construction, operation and servicing of the VAC system, and a hygiene specialist (referred to below as “hygienist”) shall therefore be involved throughout the entire planning and construction process.

Where this standard is agreed upon as being a basis for planning, any deviations from this standard shall be agreed by the client, the hygienist and the VAC consultant, and a detailed justification for such deviations duly documented. This agreement shall be included in the application for approval of the relevant health care authority and brought to the knowledge of the company installing the VAC system once approval has been granted.

4.2 Guidance on planning, construction and operation

In order to take account of the strict requirements for the planning, construction, and operation of VAC systems in medical facilities, all persons involved in the project (user, VAC consultant, installer, hygienist, building manager, etc.) shall be involved in the planning and construction process appropriately, and all shall have the same information at their disposal.

To this end, each stage of the planning and decision-making process is to be carried out in a strictly structured manner, and user information is to be documented accordingly, e.g. in the form of project specifications as in subclause A.3.2 of this standard.

A structured approach to all phases of the project is presented in Annex A (informative).

4.3 Purpose of VAC systems

The necessity for a VAC system is largely determined by the following criteria, i.e. the need for:

— maintaining physiological comfort within rooms;

— managing thermal loads;

— reducing harmful gases and annoying odours;

— reducing concentrations of microorganisms (infection control) and particle loading;

— compensating for unfavourable internal and external conditions (e.g. unopenable windows, internal rooms, highly polluted outdoor air);

— optimizing energy management.

NOTE In addition to meeting needs specific to hospitals, VAC systems are also to meet requirements regarding operational safety, fire protection, user-friendliness and ease of maintenance.

5 Room classes and ventilation requirements

5.1 Classification of rooms used for medical purposes into room classes

According to the RKI recommendations (see 3.1.2), rooms used for medical purposes are to be divided into the following room classes according to the level of (low) germ concentration:

— Room class I sub-divided into Ia and Ib;

— Room class II.

Rooms and areas having further or special requirements, and any deviations from this classification are to be agreed upon with the user, and the justification of such documented.

5.2 Room class I

5.2.1 General

A differentiation is made between:

— operating rooms provided with low-turbulence flow (LTF) ventilation systems to obtain a protected area that encompasses the operating area and sterile instrument tables (Room class Ia);

— operating rooms with mixed or unilateral flow (Room class Ib).

During the planning stage, the user shall specify in writing the types of operation being conducted in the room (e.g. implantation of alloplastic materials), the length of time the operations take, the size of the operating areas, and the number and location of operating tables or columns, and the size and location of instrument tables. The hygienist will then specify the room class on the basis of this information.

If operations performed under highly aseptic conditions (e.g. the implantation of foreign material) and those performed under less stringent hygienic conditions are to be carried out in the same operating room, the ventilation system shall ensure a degree of protection that is sufficient for the operation with the highest requirements with respect to low germ concentrations in the air.

If instrument tables are not prepared in the operating room but in a separate room or area (e.g. instrument table preparation rooms) the same aseptic conditions as in the operating room shall be maintained in the preparation room.

NOTE On principle, a high level of discipline among operating room personnel is essential. Technical measures can contribute to reducing intraoperative germ entrainment – direct or via contaminated sterile goods – into surgical wounds. The air supplied to operating rooms shall therefore be filtered by means of terminal HEPA filters. Supportive measures include the strict application of the dynamic barrier concept, which consists of flooding the area to be protected in the operating room with a low-turbulence flow and flooding the operating room with overspill air directed to adjoining rooms. This prevents the penetration of contaminants from the peripheral environment into the operating room and the innermost protected area. Therefore, dilution ventilation concepts involving large air volume flow rates and expensive HEPA filters are no longer needed outside the operating room.

5.2.2 Room class Ia

In class Ia operating rooms the entry of particles and germs into the protected area is to be minimized. This requires:

— an air handling system for generating a low-turbulence flow (LTF) throughout the protected area, in particular;

— a minimum supply air velocity;

— a room temperature that is higher than the supply air temperature specified by the user;

— a vertical inflow into the protected area via HEPA filters, where necessary with flow stabilizers;

— taking into account the effects of potential disturbance factors (e.g surgical lights and satellites, ceiling mounted units such as support arms and equipment racks, monitors, heat emitters, etc.).

Because of the number of possible factors influencing the effectiveness of LTF systems, a pre-qualification system test is recommended for complex systems.

The size of the protected area depends on the type of operations carried out and shall encompass the operating field(s), the table for the sterile instruments and materials, and the operating room team wearing sterile clothing.

In national and international practice protected areas of 3 m × 3 m, usually achieved by an LTF plenum of 3,2 m × 3,2 m, have proven sufficient.

Any deviation from these dimensions requires a differentiated analysis of the space required for the protected area, including an analysis of the equipment positions, carried out at the planning stage. This analysis shall cover standard scenarios for the location of operating fields, instrument tables with exposed sterile instruments and materials, and the operating team wearing sterile clothing. The hygienist and designer shall be consulted when critically reviewing possible disturbances.

NOTE Class Ia operating rooms are recommended for operations such as the following:

- orthopaedic and trauma surgery (e.g. total endoprostheses (TEP) of the knee or hip);
- neurosurgery associated with a particularly high risk of infection;
- gynaecological surgery (e.g. breast prostheses);
- general surgery (e.g. net implants for hernia treatment);
- cardiovascular surgery (e.g. vascular prostheses);
- transplants (e.g. of whole organs);
- operations lasting over several hours (e.g. tumour operations with large operation field);
- operations where the total operation time is particularly long (including the approximate operating time, sterilization time of instruments, and incision-to-closure time).

5.2.3 Room class Ib

Class Ib operating rooms are used for operations which do not require low-turbulence conditions. For these operating rooms with mixed flow or restricted displacement flow it is not possible to mark off a defined protected area.

Class Ib rooms can also be used for operations such as inserting small implants (e.g. coronary stents), invasive angiography, heart catheterizing, MIS procedures and endoscopic examinations of sterile body cavities.

Class Ib operating rooms shall be operated with a positive air balance with the outside air flow rate being at least 1 200 m^3/h. In order to prevent germs and particles from being transmitted through the air when doors to operating rooms are opened and when persons enter the operating room during an operation, it is recommended that an air lock be built-in, particularly where there is a great difference between the air temperature in the operating room and that in adjoining areas. Such air lock-type rooms can be patient preparation rooms or wash rooms, etc. The locking function can by achieved directly (by supply air connection) or indirectly (by overflow from the operating room).

5.3 Room class II

Class II rooms are all rooms, corridors and areas for medical use which do not fall under room class Ia or Ib (see Table 1).

5.4 Ventilation requirements

Table 1 specifies ventilation requirements and measures on the basis of room use.

A mechanical ventilation throughout the entire operating zone and where the reprocessing of critical medical products is carried out (central sterilization) is imperative.

Where a VAC system is necessary in other rooms or areas due to the presence of one or more criteria as in 4.3, that system shall be designed in accordance with Table 1.

Actual values going above or below the specified temperature or relative humidity (see Table 1) are permitted on only a few days of the year.

When designing VAC systems the required outdoor air flow rate is primarily determined by internal loads (e.g. number of active persons or persons being treated) as well as other specific room uses (heat, humidity, contaminants, where appropriate). However, at least the minimum outdoor air flow rate defined in Table 1 shall be maintained, taking into account hygiene considerations.

DIN EN 13779 applies where no details are specified Table 1.

Where natural ventilation is an alternative, humidification is not needed even in case of mechanical basic ventilation. Problems with static charges on persons and equipment and their dissipation shall be solved by means of appropriate earthing of floors, building elements and users of the equipment (see also DIN EN 60601 and DIN EN 61010).

Where any specific humidities are necessary for the operation of medical equipment, the manufacturer's information shall be taken into account.

The German *Arbeitsstättenrichtlinien* and DIN 4109 apply as regards sound insulation requirements in all rooms other than operating rooms.

The specifications of the German *Gefahrstoffverordnung*, the *Technische Regeln für Gefahrstoffe* and TRBA 250 are also to be taken into consideration.

Table 1 — Ventilation requirements

Room use	Requirements	Measures
1 OP department	Total extract air flow < Total supply air flow To ensure directional flow, windows in the OP department shall not be openable (except for evacuation and smoke control purposes) Rooms shall be heated either by means of appliances that are smooth, without ribs, and are easy to clean and disinfect, or by means of thermally active room surfaces	
1.1 All OP rooms	Outside operating times such rooms shall have reduced outside air flow and/or recirculated air flow, and any cooling and humidification systems shall be shut off, while meeting the requirements of 6.9 Overspill of outside air forming part of the supply air flow shall be directed through the doors to adjoining room(s)	≥ 1 200 m^3/h outside air, rest as recirculated air from the OP room Supply air temperature 19 °C to 26 °C, adjustable 3-stage air filtration Suspended ceilings to ensure underpressure relative to the OP room Extract-air terminal units with fluff separators
1.1.1 Class Ia OP rooms	Low-turbulence flow (LTF) about 3,2 m^2 × 3,2 m^2 across the entire protected area, possibly with a fixed, rotating flow stabilizer placed about 2,10 m above FFL Heating available throughout the year by means of heating surfaces	Thoroughly mix outdoor air with additional recirculated air Permissible sound power level of system ≤ 48 dB(A), determined in the centre of the OP room 1,8 m above FFL Regulate room heating during room use so that the extract air temperature does not go below the supply air temperature
1.1.2 Class Ib OP rooms	Turbulent mixed or displacement flow Anteroom(s) with air lock function are recommended for entrances to class II corridors in special cases Extract-air terminal units with fluff separators	Permissible sound power level of system ≤ 48 dB(A), determined in the centre of the OP room 1,8 m above FFL

Table 1 *(continued)*

Room use	Requirements	Measures
1.2 Other rooms: Class II	Air supplied to rooms adjacent to the OP room provided by overspill from the OP room and any rooms used for sterile goods storage Additional outdoor air may be necessary to compensate for unfavourable internal and external conditions	2-stage air filtration Outdoor air 40 m^3/h per person
1.3 Recovery rooms, inside and outside the OP department		2-stage air filtration Outdoor air 40 m^3/h per person, where gaseous anaesthetics are used: 150 m^3/h per patient, room air temperature 22 °C to 26 °C
1.4 Non-sterile workrooms	Negative pressure with respect to corridors, room air exchange rate suitable for heat, humidity and odour loads	2-stage air filtration Outdoor air ≥ 40 m^3/h per person
1.5 Disposal rooms	Negative pressure with respect to corridors	
2 Examination and treatment areas		
2.1 Minor intervention rooms, treatment rooms (invasive) e.g. for endoscopies (gastroendoscopy, colonoscopy, bronchioscopy, ERCP), emergency treatment, major wound care and dressing change		Outdoor air 40 m^3/h per person, where gaseous anaesthetics are used: 150 m^3/h per patient, room air temperature 22 °C to 26 °C
2.2 Treatment rooms (non-invasive), e.g. for ultrasound, EKG, EEG, EMG		Outdoor air 40 m^3/h per person

Table 1 *(continued)*

Room use	Requirements	Measures
2.3 Radiation therapy and x-ray diagnostics	Depending on heating and cooling loads and equipment used	Outdoor air ≥ 40 m^3/h per person, taking radiation protection requirements (air filters) into account, where necessary
2.4 Physical therapy **Tub baths, kinotherapeutic baths, swimming pools**		As in VDI 2089 Part 1
3 Intensive care	Temperature stabilization is to be ensured at least for cardiology, neurosurgery and neo-natal patients	
3.1 Wards (intensive care)		Outdoor air 40 m^3/h per person or > 100 m^3/h per patient Room air temperature 22 °C to 26 °C Room humidity 30 % to 60 %
3.2 Isolation rooms, including anterooms (intensive care)	See: Table 1 line 5.3, in special cases lines 5.1 and 5.2	Outdoor air 40 m^3/h per person or > 100 m^3/h per patient Room air temperature 22 °C to 26 °C Room humidity 30 % to 60 %
3.3 Other rooms, corridors (intensive care)		Outdoor air 5 m^3/m^2 h
4 Supply and waste disposal areas		
4.1 (Central) medical product sterilization unit	Outdoor air flow depends on thermal loads, contamination level, number of persons	
4.2 Bed and bedding treatment, laundry	Outdoor air flow depends on thermal loads, contamination level, number of persons	
4.3 Pathology, autopsy rooms		Room air temperature ≤ 22 °C
In rooms 2.1 to 2.4, 3.1 to 3.3, 4.2 and 4.3 insect screens are necessary where windows will be openable.		

Table 1 *(continued)*

Room use	Requirements	Measures
5 Isolation care	Rooms for isolating patients who are either infectious or infection-prone	Wards with anteroom as air lock (about 10 m^2) Outdoor air flow > 100 m^3/h per patient
5.1 Rooms for infectious patients	All personnel and third parties are to be protected from infectious patients (e.g. patients with multiresistant tuberculosis, varicella)	Supply and extract air and negative air balance in relation to air lock Air lock has negative pressure in relation to neighbouring corridor area Where necessary, HEPA filter H13 as in DIN EN 1822-1 in extract unit of isolation room
5.2 Rooms for infection-prone patients	Infection-prone patients (e.g. patients with suppressed immune systems, burn or bone-marrow/organ transplant patients) are to be protected against infection (principle risk: airborne mould spores)	Terminal filter at least F9 as in DIN EN 779, where necessary HEPA filter H13 as in DIN EN 1822-1 in supply air unit As LTF only in special cases Air lock has negative pressure in relation to patient room and positive pressure in relation to neighbouring corridor area
5.3 Combined-use rooms	Rooms with ventilation systems which are appropriate for either infectious patients or infection-prone patients	Isolation room with positive air balance in relation to air lock Air lock has negative pressure in relation to all adjacent rooms In special cases: HEPA filters in supply air and/or extract air units

6 Requirements for ventilation and air-conditioning components

6.1 General requirements

6.1.1 General

All air distributing components of the VAC system shall be readily accessible and, for reasons of hygiene, shall preferably be arranged so that it is not necessary to enter class I rooms when carrying out cleaning and maintenance.

If such components can only be accessed via class I rooms, the rooms in question shall be cleaned and disinfected after every inspection or maintenance activity.

Supply air and recirculation air systems in all air distribution areas shall be designed, operated and serviced in such a manner that contamination of the supply air by inorganic or organic substances, e.g. harmful gases within the system, is avoided, and that the air is perceived as odourless. Where health-related guideline values regarding the concentration of germs or biological and chemical contaminants (e.g. MVOC [microbial volatile organic compounds], endotoxins, allergens) are not available, the outdoor air shall be taken as reference. The amount of dust, bacteria, fungi and biological contaminants in the supply air shall not exceed that of the outdoor air at the relevant site.

Guideline values and limiting values and any other regulations valid when the system is designed shall be complied with.

6.1.2 Surfaces and materials within the air flow

Supply air and recirculation air systems in the air distribution area shall be made of materials that do not emit harmful substances and do not provide a nutrient medium for microorganisms. For this purpose it shall be ensured that the devices and system components used do not release any harmful substances, fibres, or odours into the air flow or the rooms, and do not stimulate the growth of microorganisms. Any porous linings within the air flow shall be covered with suitable abrasion-proof material (e.g. glass silk).

Surfaces in the air distribution system shall be designed and manufactured so that the deposit of dirt is not promoted.

6.1.3 Cleaning management plan

All components shall be delivered in a clean condition and be protected against contamination or damage during the course of construction. For this purpose a cleaning management plan shall be established for all those involved in the construction. The VAC systems shall be installed in such a manner that all air distributing components are hygienically clean at the time of commissioning.

For subsequent operation it shall be ensured that the entire system can be inspected without considerable technical effort, and can be cleaned and disinfected, where necessary, with justifiable technical effort. A sufficient number of appropriately-sized openings shall be provided to facilitate access to the areas to be cleaned.

6.1.4 Labelling

All system components shall be visibly and permanently labelled or marked so that their function and coverage area is easily recognizable at all times.

6.2 Outdoor air suction, exhaust air plenums, and surrounding area

When planning VAC systems the type and position of outdoor air suction openings shall ensure that the least possible amount of polluted outdoor air is taken in. The requirements of DIN EN 13779 shall be complied with. The lower edge of the outdoor air suction opening shall be at least 3 m above the ground; openings shall also be at a sufficient distance to other reference levels relevant to air hygiene (horizontal surfaces, buildings, etc.).

Short circuits between exhaust air and outdoor suction air shall be avoided by providing sufficient distances or suitable technical or structural measures. Where possible the exhaust air is to be directed to the outside via the roof.

The following influences are to be taken into account:

— weather conditions (e.g. frequent strong winds);

— flue gas emitters, cooling towers/re-cooling plants (see NOTE below);

— odour sources or other sources of disturbances (e.g. sanitary ventilation systems);

— existing or planned neighbouring structures (e.g. tall buildings; see municipal development plan);

— streets or nearby (underground) car parks, parking lots, delivery areas, helicopter landing site;

— high external thermal loads.

In cases of doubt an expert opinion may be required.

NOTE Due to the particular hazards associated with cooling towers of re-cooling plants, special care shall be taken that the aerosols escaping from the towers do not enter suction openings of ventilation installations or enter occupied rooms through opened windows. Solid deposits or bio-films (biofouling, scaling) inside cooling towers shall be restricted by means of feed-water treatment suitable to the water quality in question.

The suction of larger-sized air contaminants shall be prevented by using a corrosion-resistant wire mesh grating (maximum mesh size 20 mm × 20 mm), which shall be accessible on the dirty side for mechanical cleaning. Suitable measures shall be provided to prevent icing, where necessary.

Furthermore, the floor area behind the suction opening shall be in the form of a basin (minimum length 0,5 m) for draining any cleaning water, precipitation, snow, etc. Basin requirements are given in 6.5.5.

The suction opening shall not be accessible to unauthorized persons.

6.3 Air ducts

6.3.1 General requirements

To facilitate cleaning and maintenance of air ducts, components such as sound attenuators, dampers and heat exchangers shall preferably be installed in the air handling unit (see 6.5).

Other components, e.g. for adjusting the pressure, etc., should be installed in the mechanical equipment room, wherever possible.

All ductwork shall be made of mechanically durable, non-biodegradable materials.

Their inner surfaces shall be abrasion-proof, corrosion-resistant and smooth (e.g. of sendzimir galvanized sheet steel).

All components and materials, including seals and sealants, shall be not be harmful to health, shall not emit odours or harmful substances and shall not provide a nutrient medium for microorganisms.

Fittings and connectors, braces and other fixtures shall be designed so as to avoid local deposits of particles and to facilitate both manual and mechanical cleaning. Braces shall preferably be installed on the outside. If an inside installation is required, e.g. due to higher pressure loads, the bracings shall have round profiles.

To avoid injuries, there shall be no sharp edges.

Connecting and fastening elements such as threads, shanks of screws, internal flanges, etc. shall not protrude into the air distributing area.

Structural cavities (e.g. installation shafts, plenums behind double walls, suspended ceilings or false floors) shall not be used for unducted air distribution unless they are intended to ensure underpressure. This does not apply to coated channels specifically designed and constructed for air distribution, such as channels made of concrete or masonry or false floors in equipment rooms.

Flexible air ducts may only be used for connecting air terminal devices and equipment and may only have a length up to ≤ 1 m. They shall be easily accessible when located in class I rooms, even when behind false ceilings.

Seals and sealants shall be smooth, abrasion-proof, have closed pores, and be resistant to disinfectants and ageing (see NOTE below). The materials used shall not be harmful to health. If only certain disinfectants, e.g. alcohol-based disinfectants, are considered suitable, this shall be pointed out explicitly in the manufacturer's maintenance instructions.

NOTE For the purposes of this standard, "resistant to disinfectants" applies to ventilation system components and products which have a long-term resistance to disinfectants and disinfection procedures. Only disinfectants included in the list published by the *Robert-Koch-Institut* or *Verbund für Angewandte Hygiene* are to be used.

The use of injectable joint sealants shall be avoided and is allowed only in joints and only to a small extent.

Any installations leading through air duct walls are to be designed to meet the required air tightness. Installations which are not directly part of the VAC system are not permitted in air ducts.

The maximum specific leakage q_L in l/(s · m^2) of operable ducting systems shall be in accordance with class C as in DIN EN 13779 and is calculated as follows:

$$q_L = 0{,}003 \cdot p^{0{,}65} \quad (1)$$

where

p is the test pressure, in Pa.

The test pressure p shall be 1 000 Pa and may deviate in exceptional cases if so agreed by the parties concerned.

Where irregularities occur in supply ducts in structural cavities in class I rooms, the specific leakage of the ducting system shall be measured in accordance with DIN EN 12599.

Insulation shall generally be placed outside air ducts. Where the air in the duct is considerably cooler than the ambient air, the insulation shall be vapour diffusion tight if surface condensation cannot be ruled out.

If ductwork is to be partially or completely removed for cleaning purposes, the required structural provisions shall be planned and described.

Air duct sections which need to be cleaned using vapour or liquids shall be designed and constructed so that they are waterproof and slope towards a closable water discharge opening.

If ventilation channels are to be mechanically cleaned, appropriately sized inspection openings or easily removable duct parts or fittings shall be installed for inspection and/or cleaning purposes. Furthermore, access to the relevant duct parts or fittings shall be ensured.

6.3.2 Outdoor air ducts

The following additional requirements apply to outdoor air ducts:

— air ducts between outdoor air suction openings and the air handling unit (as in 6.5) shall be as short as possible;

— the ducting section between outdoor air suction openings and the air handling unit shall be provided with a sufficient number of appropriately-sized cleaning openings enabling a comprehensive inspection and mechanical cleaning of the inner walls;

— basins and discharge openings for cleaning water, precipitation water, snow etc. shall be provided (see 6.5.5).

6.3.3 Supply air ducts

The general requirement that air ducts be as short as possible applies especially to class I rooms. For this reason the air handling unit shall be located as close as possible to the room(s) to be supplied.

The leakage air flow rate in supply air ducts shall not lead to any overpressure in structural cavities.

The interiors of all air ducts immediately downstream of the 3rd filtration stage in the direction of air flow shall be accessible for manual cleaning by wiping and disinfection.

6.3.4 Smoke extraction ducts

If smoke extraction ducts are also to be used for other ventilation purposes, then a non-hygienic air transport shall only be possible during smoke extraction operations.

6.3.5 Inspection openings

The location and number of inspection openings is largely determined by the ventilation installation requirements and the cleaning methods used. The location and dimensions of inspection openings shall be included in the ducting system drawings. Access openings in walls and suspended ceilings should not be obstructed by constructions.

Inspection openings are to be permanently air tight as follows:

— dampers: on one side;

— fire dampers: on one side;

— heating/cooling coils: on both sides;

— sound attenuators: on both sides;

— heat recovery units: on both sides;

— flow rate control devices: on one side.

In the case of ducting systems with additional insulation (e.g. thermal insulation or fire protection casing) the design of the inspection openings shall not have an adverse effect on the protective qualities of the insulation/casing.

Rigidity and leaktightness requirements for the inspection openings and covers are the same as for rest of the ducting system.

The following conditions apply to the cleaning of walk-in air ducts:

— the dimensions of the air duct and its mounting shall be sufficient for the additional loads;

— the inspection opening shall be accessible and shall not be obstructed by suspended ceilings, cable routes, pipework or other installations.

Inspection openings shall be sufficiently large; if persons are to enter them, the openings shall be at least 500 mm × 600 mm.

If a required inspection opening cannot be provided at a certain location, a removable duct section shall be provided as an alternative.

6.4 Dampers

6.4.1 General requirements

VAC systems shall be designed so that wind or buoyancy pressures do not result in the transport of air through the ducting system that could have an adverse effect on the hygienic quality of the air in the building. As regards leakage performance, dampers shall meet the requirements for at least class 2 as in DIN EN 1751. If the individual damper blades are driven by gears, the gears shall not be in direct contact with the transported air.

The current damper position (open/closed) shall be visible on the outside of the damper.

6.4.2 Outdoor air shut-off dampers

Outdoor air shut-off dampers shall be located either immediately downstream of the outdoor air suction opening or immediately upstream of the 1st filtration stage. Dampers shall be corrosion-resistant, made of either stainless steel (e.g. material no. 1.4301) or an aluminium alloy (e.g. AlMg), at the manufacturer's discretion, and shall close automatically in the case of an interruption in the energy supply (spring return).

6.4.3 Dampers for increased tightness requirements (airtight dampers)

Airtight dampers shall meet the requirements of at least class 4 as in DIN EN 1751.

Motor actuated airtight dampers which close automatically in the event of a system standstill or an interruption in the energy supply shall be installed in the supply air and extract air channels:

— for systems supplying rooms of different room classes, at the interfaces between the different room class areas;

— at the boundaries of areas of the same room class where an air-side separation is to be ensured even in the case of a system standstill;

— in the supply air and extract air ducts of VAC systems supplying areas for which different hygienic requirements apply, at a location between the connected rooms and the air handling unit.

Airtight dampers upstream of the 3rd filtration stage are required only if the system cannot be shut down for filter replacement.

6.5 Air handling units

6.5.1 General requirements

The requirements specified below for air handling units apply to both central and local devices, as well as to the individual components used for air distribution, air filtration and thermodynamic treatment.

All components and materials, including seals and sealants, on the supply side of air handling units shall not be harmful to health, shall not emit odours or harmful substances and shall not provide a nutrient medium for microorganisms.

Casing materials which come in contact with the air flow shall be resistant to disinfectants.

Air handling unit components shall meet the requirements of DIN EN 1886 and DIN EN 13053.

Surfaces located within the air flow shall be at least sendzimir-galvanized and coated (25 µm minimum for coil coating, 60 µm minimum for powder coating or double-layered wet coating with base coat and top coat), and the lower part of the casing, including slide-in rails of components and all other surfaces which could potentially come in contact with (condensation) water, shall be corrosion-resistant and made of stainless steel (e.g. material no. 1.4301) or an aluminium alloy (e.g. AlMg). Where the outdoor air chamber is constructed on site a waterproof construction is required. Air handling units for special use (e.g. physical therapy) or which are not subject to hygiene requirements may also have other suitable surfaces.

Sealing profiles shall be of closed-pore materials and shall not absorb any moisture. Seals on doors and filter mounting frames shall be inserted, clamped or foamed; under no circumstances shall they be glued. Glued seals are only permitted on the filter insert and only for single use; they are disposed of when the filter is changed.

Air duct connections shall be smooth, elastic couplings of a closed-pore material without grooves and recesses; flexible connections with folds are not permitted.

In the case of non walk-in-type casings (enclosures) (clearance < 1,6 m), a sufficient number of removable covers or service doors shall be provided; a sufficient number of doors shall be provided for walk-in casings. For cleaning purposes, all air handling unit components shall be accessible from both upstream and downstream, or, as an alternative for clearances < 1,6 m, they shall be easily and safely removable. This shall be taken into account when planning piping connections.

For cleaning purposes, internal wall surfaces shall be smooth and free of exposed absorption areas, and the floor area shall be constructed without grooves and recesses so that the entire surface can be effectively cleaned by manual wiping or mechanical cleaning without leaving any residual matter.

6.5.2 Location of components

Air handling units and associated functional components should be readily accessible and, for reasons of hygiene, should preferably be arranged so that it is not necessary to enter class I rooms when carrying out cleaning and maintenance.

If such components can only be accessed via class I rooms, the rooms in question shall be cleaned and disinfected after every inspection or maintenance activity.

It shall be ensured that air handling units and their components can be easily inspected, maintained and repaired by making sure they are readily accessible and sufficient space is provided around them.

Air handling units for operating departments shall preferably be located in the storey immediately above the operating room or in the immediate vicinity. Adverse effects of electromagnetic fields on medical equipment shall be precluded.

6.5.3 Mechanical characteristics of the equipment casing

When designing the casings of air handling units the following requirements as in DIN EN 1886*) shall be met (test enclosure as in DIN EN 1886)*):

- mechanical stability: at least class D2;
- casing air leakage: at least class L2;
- filter bypass leakage: max. 0,5 % of the nominal flow rate;
- thermal transmittance of the casing: at least class T3;
- thermal bridging factor: at least TB4 to avoid condensation caused by the temperature dropping below dew-point. If the temperature inside the outdoor air chamber falls below –7 °C or where the casing is designed to be weatherproof, a thermal bridging factor of TB3 shall be maintained.

A test report issued by an independent body attesting compliance with these requirements shall be provided.

6.5.4 Outdoor air inlet

Air handling units with direct outdoor air suction via an integrated weather protection element (e.g. units installed outdoors) shall also meet the requirements specified in 6.2.

6.5.5 Basins and siphons

Corrosion-resistant basins made of stainless steel (e.g. material no. 1.4301) or an aluminium alloy (e.g. AlMg) are required for at least the following components:

- outdoor air suction chamber;
- cooler;
- humidifier/dehumidifier;
- heat recovery units on the supply and extract air sides.

The accessibility of the basin area shall be ensured by providing removable covers or service doors.

Condensate shall be completely drained off. To ensure this, condensate basins shall be sloped all around and be equipped with a suitably sized discharge nozzle at the lowest point. This requirement is deemed to be fulfilled if proof can be provided that, after filling the basin with 5 litres of water per m^2 of basin area, more than 95 % of the filled water has been drained off over a period of 10 min with the system in operation.

The connection drain pipe shall have a diameter of at least 40 mm and a sufficient slope and run via a siphon with backflow protection and free discharge into the sewer system; under no circumstance may the drain pipe be connected directly. Drains with different pressure levels shall be constructed separately with each having an individual siphon.

6.5.6 Dampers

Air handling units shall be equipped with (multiple leaf) dampers for outdoor, supply, extract, and exhaust air openings/duct connections and they shall at least meet the criteria for leakage class 2, and where stricter tightness requirements apply, those of class 4, in accordance with DIN EN 1751. This shall be demonstrated by a type approval test performed by an independent testing body.

The requirements given in 6.4 apply.

---

*) Translator's note. These requirements relate to the 2004 draft edition, DIN EN 1886:2004.

Dampers for weatherproof units shall be located on the inside. For units which are intended for indoor installation, the outdoor air dampers shall either be located on the inside or, if located on the outside, be provided with a double-layer of insulating material.

6.5.7 Air filters

6.5.7.1 General requirements

The filter chambers within the air handling unit shall be constructed so that they can be easily cleaned and so that the air filters can be easily accessed and inspected at any time.

The design and construction of filter frames and pockets, cassettes and their fixing devices shall facilitate easy, safe and damage-free mounting and ensure that the air filters are tightly fitted throughout the entire operating time. Filter chambers in the 1st and 2nd filtration stages shall be designed so that no dust reaches the clean air side when changing the filter. The air filters shall be changed on the dusty air side. Springs and clamps used for filter fastening and sealing shall not act against the air flow by themselves.

For maintenance purposes, the space required for filter change (at least the construction depth of the respective filter) shall be provided upstream of the filter unit ensuring accessibility through the door or inspection opening. Laterally extractable filter frames are not permissible for room classes Ia and Ib.

At the air handling unit design stage it shall be ensured that temperatures below the dew-point are prevented near air filters, especially during system standstill.

The filter area shall be ≥ 10 m^2 per m^2 of the cross-sectional area of the unit.

6.5.7.2 Filter materials

Air filter materials shall withstand the mechanical loads during all operation stages of the VAC system and after manufacturing they shall contain no residual matter which could be released during operation of the system.

6.5.7.3 Filter types, filter classes, and filtration efficiency

The filter classes and filtration efficiencies shall be declared in accordance with DIN EN 779 or DIN EN 1822.

Air filters shall perform with the filtration efficiency appropriate to the respective filter class throughout their entire service life.

The effectiveness of antimicrobial air filters shall be demonstrated, and during operation no harmful substances shall be released into the VAC system.

6.5.7.4 Filtration stages

A multiple stage filtration system is necessary to remove particulate contaminants, including microorganisms.

For class I rooms, a three-stage supply air filtration is required, with the first two filtration stages installed in the air handling unit and the 3rd stage installed at the end:

- 1st filtration stage: at least class F5 filters, class F7 filters are recommended;
- 2nd filtration stage: class F9 filters;
- 3rd filtration stage: class H13 HEPA filters.

For class II rooms, a two-stage filtration system (without HEPA filters) is sufficient.

To protect components in extract air systems with particle loading, a filter of at least class F5 shall be installed in the extract air area.

6.5.7.5 Filter arrangement

The first filtration stage shall be located within the air handling unit, near the outdoor air suction opening.

NOTE At the air handling unit design stage it shall be ensured that temperatures below the dew-point are prevented near air filters, especially during system standstill. At temperatures > 0 °C a high relative humidity (> 80 %) near air handling unit components can promote microbial growth, which leads to problems. A humidity higher than 90 % is problematic even over short periods of time. If sustained periods of high humidity at the installation site or moisture penetration of the air filters or sound attenuators can be expected at this temperature level (e.g. in foggy areas and areas with frequent and long periods of precipitation, or sites downstream of humidifiers) then suitable measures shall be taken to prevent microbial growth, especially on air filters or sound attenuators, for instance preheating the components by about 3 K. For the purposes of effective cleaning this can be achieved, e.g. by using preheaters with a fin spacing of at least 4 mm as part of the heat recovery system (fin thickness at least 0,2 mm) or bare-tube heat exchangers.

In principle, the second filtration stage shall be the last component of the air handling unit, i.e. it shall be installed on the pressure side downstream of the last air handling component.

Coolers with a dehumidification function and humidifiers shall be located so that moisture penetration of filters is excluded; under no circumstances shall they be installed immediately upstream of any of the filters.

For air recirculation devices, the 1st filtration stage may be omitted if, when using air coolers, dehumidification can be excluded with certainty.

If an air cooler with dehumidification or a V-belt-driven fan is installed outside the air handling unit, then another class F9 filter shall be provided immediately downstream.

The third filtration stage shall be installed on the pressure side of the supply air system immediately (< 500 mm) upstream of the entry of the air into class I rooms. Installation at a greater distance from class I rooms or locating the 3rd filtration stage within the air handling unit is only permitted in special cases and where justified (in the hygienist's report).

6.5.7.6 Filter equipment

First- and second-stage filtration shall be equipped with differential pressure gauges for each of the stages. An in-situ indication (without sealing liquid) is required, even in the case of remote indication.

On each filter system the following information shall be provided on a nameplate in a durable and readily visible manner:

— nominal air flow rate of the air handling unit;

— number of air filters installed in the filtration stage;

— filter type (number of pockets, where appropriate), filter class, dimensions;

— final pressure difference of the air filters in relation to the nominal air flow rate of the system.

The operator shall document the date of the last filter change, the type of filter installed, the initial pressure loss, and the differential pressures recorded during inspections, e.g. on a readily visible tag or label located near the nameplate.

6.5.7.7 Filter testing

The filter material shall not show any damage.

Prior to commissioning, filters at the 1st and 2nd stages shall at least be visually checked for damage and visible contamination, as shall their tightness of fit with their holders.

6.5.7.8 Changing filters

The original filter equipment supplied with the air handling unit shall be new or as-new when submitted for acceptance. In addition, the air filters are to be changed after any construction measures or modifications made to the air handling unit if there has been any filter loading during these measures.

The filters shall also be changed if the permissible final pressure difference of an air filter or the time interval for filter change is reached (see NOTE) or if the air filters show any functional defects.

NOTE For reasons of hygiene, the maximum service life should be limited to 12 months for the 1st filtration stage and to 24 months for the 2nd filtration stage.

6.5.8 Heat exchangers

6.5.8.1 General requirements

Heat exchangers shall be designed so that they can be easily cleaned and disinfected. For reasons of hygiene, thorough cleaning shall be ensured. To this end special measures are required for heat exchangers with construction depths of 300 mm or more (450 mm or more in the case of in-line tube arrangement) for a fin spacing of 2 mm; heat exchangers of the separate design allowing appropriate access are recommended. For greater fin spacings, a greater proportional and linear construction depth may be selected.

For finned heat exchangers corrosion-resistant materials shall be used, such as:

— fins: aluminium;

— tubes: copper;

— collectors: copper, galvanized steel.

All air distributing surfaces shall be smooth and corrosion-resistant, and it shall be possible to inspect and clean them without the use of technical aids.

To facilitate cleaning all condensate connections shall be located on the same side.

For finned heat exchangers, only a fin spacing of $\geq$ 2 mm is permitted.

Pipe lead-throughs in the casing shall be designed taking the tightness requirements of 6.5.3 into consideration.

6.5.8.2 Air coolers

Air coolers shall preferably be designed for an air velocity that precludes the need for droplet separators.

The fin spacing shall be $\geq$ 2,5 mm. The frame of the heat exchanger shall be corrosion-resistant and be made from stainless steel (e.g. material no. 1.4301) or an aluminium alloy (e.g. AlMg). The collector shall be made of copper or an equivalent material. It shall be possible to inspect the air cooler from both sides (upstream and downstream) when it is installed.

Air coolers with air dehumidification shall be upstream of the 2nd filtration stage, if this will not cause the filter to become moist.

All wet surfaces shall be cleanable.

6.5.8.3 Droplet separators

It shall be ensured that droplets of water from humidifiers or air coolers cannot enter downstream components or system parts installed.

If this can only be achieved by means of droplet separators, they shall be positioned upstream of the 2nd filtration stage. They shall be corrosion-resistant, cleanable, and it shall be possible to remove them for cleaning purposes from the casing via covers or service doors.

6.5.9 Heat recovery systems

The specifications of 6.5.8 apply to heat exchangers installed in heat recovery systems.

When planning the system, the design shall take into account the installation of condensate basins in accordance with 6.5.5.

In rooms subject to stricter hygienic requirements and where air may not be recirculated between rooms, only heat recovery systems in which a transfer of substances can be excluded shall be used.

Heat recovery systems shall be installed on the supply air side downstream of the first filtration stage.

6.5.10 Fans

Supply air fans shall be located between the 1st and 2nd filtration stages to exclude any precipitation of water inside the fan.

The fans shall be easily accessible to operating and maintenance personnel.

Fans without spiral casings shall preferably be used because they are easier to be cleaned. For cleaning purposes, centrifugal (radial) fans with spiral casings shall be provided with a water discharge opening and a corresponding closure in the fan casing; for nominal sizes of 400 mm and greater an easily removable inspection lid is required.

The entire fan unit, including the impeller and the base frame of sheet steel and sectional steel, shall be protected against corrosion (at least sendzimir galvanized and coated).

The following information shall be permanently affixed to every fan chamber:

— type/year of construction/model;

— nominal flow rate;

— total pressure increase;

— nominal and maximum rotational speed;

— nominal motor power;

— rotational direction of the fan impeller (e.g. label attached to impeller or casing).

6.5.11 Air humidifiers

In general, air humidifiers shall be located upstream of the 2nd filtration stage (filter class F9) inside the air handling unit.

Air humidifiers shall be designed so that droplets do not form in the supply air flow downstream of the humidifiers during operation, in the event of a failure of the air handling unit, and when the supply air flow rate is too low or lacking. The relative humidity at the end of the humidified area shall not exceed 90 %. For this reason, the humidified area shall be sufficiently dimensioned and a homogeneous steam distribution across the cross-section of the air handling unit shall be ensured.

Only systems which do not pose a health risk shall be used. Air humidifier components shall be easy to access, inspect and clean from all sides.

For reasons of hygiene, only steam humidifiers are to be used in operating departments.

6.5.12 Sound attenuators

Sound attenuators shall be installed downstream of the 1st and preferably upstream of the 2nd filtration stage.

They shall not be installed immediately downstream of a cooler with dehumidification function or a humidifier, nor immediately downstream of the 3rd filtration stage in the direction of flow.

Splitters shall be designed so that their surfaces facing the air flow are smooth, abrasion-proof (protection of the absorbing material by means of ageing-resistant glass silk fabrics), water-repellent, and non-decaying.

6.5.13 Monitoring equipment

Air handling units shall be equipped with the following monitoring and status indicating equipment:

— inspection glasses/inspection openings (with a minimum diameter of 150 mm or equivalent cross-section) and internal lighting with smooth surface (ship's fittings with metal grid cover are not permissible) are required at least for monitoring the fans, filters, and humidifiers;

— differential pressure gauge(s) with local indication and without sealing liquid or pressure cell, for filters of the 1st and 2nd filtration stages;

— air flow rate indication at the fan chamber or the control board.

The respective set-points and limit values shall be indicated.

6.6 HEPA filters

For class I rooms, a three-stage supply air filtration is required, with a class H13 HEPA filter installed at the 3rd stage.

In principle, only HEPA air filters tested and marked in accordance with DIN EN 1822 shall be used. The filter material shall be hydrophobic.

Differential pressure monitoring is required for every particulate air filter or filter group. To this end, the provision of easily accessible test ports for connecting portable pressure gauges is sufficient.

NOTE A considerably longer service life can be achieved for 3rd filtration stage filters than for 2nd filtration stage filters.

No flexible air ducts, sound attenuators, dampers, or similar components shall be installed downstream of the 3rd filtration stage.

Filters shall achieve the filtration efficiency corresponding to their filter class throughout their entire service life. The use of electrostatic precipitation filters is not permitted.

No substances which are harmful to health shall be emitted into the air handling unit during operation even when antimicrobial filters or filters containing special materials are used.

HEPA filter components shall be installed in the filter casing so that they are permanently tight. Tightness of fit and integrity shall be demonstrated by means of particle number measurement (in accordance with DIN EN ISO 14644-3).

For the particle number measurement, only tightly closable test openings or test ports shall be provided upstream of the 3rd filtration stage, enabling the introduction of test aerosols or measuring probes. In

agreement with the hygienist, these openings or ports shall be located outside the operating room where they are easily accessible. The test aerosol used shall be homogeneously distributed in the main air flow upstream of the filter. A further easily accessible sampling port (inside diameter ≥ 6 mm) is required for measuring the upstream particle concentration.

6.7 Air terminal devices

6.7.1 General requirements

Air terminal devices shall have smooth, abrasion resistant and corrosion-resistant surfaces and shall allow effective manual cleaning and disinfection by wiping. For this purpose, air terminal devices shall be easily removable. Porous coatings/linings in the air flow are not permitted.

Extract air terminal devices in rooms where fluff is present shall be provided with fine-meshed sieves (mesh size ≤ 0,8 mm) for fluff separation. The sieves shall be removable without any technical aids and be mechanically cleanable.

When selecting and determining the location of air terminal devices, the relevant operational requirements, including those relating to noise, shall be taken into account.

6.7.2 Low-turbulence flow outlets (LTF outlets)

6.7.2.1 General

Low-turbulence flow outlets (referred to below as LTF outlets) are available with or without a mixing function.

The surfaces of the diffusers, as well as surfaces in any gaps or cavities associated with them, shall be resistant to disinfectants and accessible for effective cleaning and disinfection.

The use of air coolers in LTF outlets is only permitted where condensation will not occur.

NOTE In the case of so-called “dry cooling”, the formation of condensate can never be ruled out completely.

6.7.2.2 LTF outlets without mixing function

The distribution of recirculated air, mixing, and complete homogenization of outdoor air and recirculated air is carried out in a central air handling unit outside the operating room. The recirculated air from the operating room is suctioned through fluff separators with subsequent F7 filtration.

6.7.2.3 LTF outlets with mixing function

The distribution of recirculated air, mixing, and complete homogenization of recycled outdoor air and recirculated air takes place immediately upstream of the LTF outlet. The recirculated air from the operating room is suctioned through fluff separators with subsequent F7 filtration.

By using suitable constructive measures it shall be ensured that any air supplied to the operating room has passed through HEPA filters, even when there is a system failure. Any backflow through any of the recirculated air fans shall be precluded, even in the case of fan failure.

6.7.3 Overflow openings

In the case of overflow openings, the hazards associated with X-rays and any other radiation (laser) shall be taken into account.

Overflow openings shall be smooth and resistant to disinfectants, and shall be installed so that any dust deposits in wall openings can be removed without any technical effort during routine cleaning measures.

Any overflowing through air ducts is not permitted.

6.7.4 Recirculated air, extract air, and exhaust air terminal devices

Recirculated air, extract air, and exhaust air terminal devices shall be arranged so that the air flow throughout the room ensures that the limit values for harmful substances are not exceeded at any point in the room.

Only extract air from the room concerned and adjacent functionally related rooms shall be used as recirculated air (e.g. operating room with immediately adjacent class I sterile storage room).

Due to a pollution of the extract air with harmful gases (e.g. from disinfectants, preservatives) there may be hygienic and/or toxicological concerns regarding the use of recirculated air (see 6.1). The spread of airborne germs shall be completely ruled out, particularly in isolation wards.

Extract air openings shall be easily accessible for cleaning purposes.

The exhaust air from laboratories and isotope departments shall be discharged into the open air unfiltered and through a separate air duct network. Extract air filtration is required only if it is to be expected that the limit values specified in the *Strahlenschutzverordnung* will be exceeded.

6.8 Space heating systems and cooled ceilings/cooling devices

The surfaces of heating and cooling surfaces shall be smooth, closed-pored, cleanable and resistant to disinfectants. In rooms with increased hygienic requirements, heating surfaces shall be primarily of the radiation type.

Decentralized air coolers, room air conditioners, convective cooling systems such as cooling shafts and cooling convectors, and open cooled ceilings and suspended radiant ceiling panels are only permitted where a dry cooling system is used, and only in rooms which do not have more stringent hygienic requirements.

In the operating room, wall heating surfaces can be used. Other decentralized heating and cooling devices with a convective effect are not permitted. Floor heating systems or using heat generated in rooms below the room to be heated can have an adverse effect on the functioning of the LTF outlet in the operating room.

6.9 Building automation and control systems (BACS)

The building automation and control system (BACS) shall ensure that all operating parameters (e.g. flow rates, temperatures, temperature differences, humidities, pressure conditions) are maintained constant in accordance with the function in question, even under varying operating conditions. Any system malfunctions shall be indicated and documented.

The room temperature of operating rooms shall be freely selectable throughout the year within the limits specified in Table 1.

Control equipment shall be located so that it can only be actuated by authorized persons.

During the time in which operations can be carried out, the LTF flow in class Ia operating rooms shall be ensured by means of a constant control of the supply air temperature and control of the local room heating. During an operation, an increase in the supply air temperature shall be precluded.

Any malfunctions in the air handling unit shall be indicated as such at the system operator’s station.

In operating rooms, any deviations from the specified parameters (e.g. temperature, flow rate) which could have an adverse effect on hygienic safety shall be indicated by means of a visual signal that demands attention and which cannot be automatically acknowledged.

Outside the operating times a reduction of the flow rate in class I rooms is permitted; when doing so, a reverse in flow shall be precluded. In class II rooms a shut-down shall be possible.

A control system concept for operating rooms requiring underpressure for aseptic operations is technically unfounded.

6.10 Cleaning and disinfection

If, following a system failure, a restart is required for class I rooms, it shall be established in agreement with the hygienist whether and, if relevant, which additional cleaning or disinfection measures are required.

After completion of work on the 3rd filtration stage (e.g. filter change) or on the LTF outlets, the areas downstream of the 3rd filtration stage shall be disinfected, as shall the rooms connected to them.

6.11 Operation and maintenance

A detailed hygiene plan shall be prepared for the VAC system in accordance with the *Infektionsschutzgesetz*, taking into account the specifications of VDI 6022 Part 1 and the AMEV recommendations.

The VAC system shall be operated in compliance with the documentation (e.g. operation and maintenance instructions and hygiene plan).

Supply and extract air systems shall be regularly inspected and maintained in accordance with VDMA 24176 and VDMA 24186 or the AMEV recommendation *Wartung* 2006. All maintenance work shall be documented.

7 System qualification and acceptance testing

7.1 General

Ventilation and air-conditioning systems for rooms used for medical purposes are to be qualified in several steps. Each qualification stage shall not begin before the preceding stage has been completed and documented and before any defects established have been remedied and re-tested.

The installer shall install and commission a serviceable system satisfying the specified requirements, and shall hand it over along with the pertinent documentation

During the acceptance test, hygienists and technical engineers shall check the contracted technical and hygienic properties and quality characteristics as in the project specifications, as well as compliance with the generally accepted state of technology.

Acceptance of the system, including all defects established during the acceptance procedure, shall be documented.

All non-conformities identified shall be documented and assessed, and the measures to be taken to ensure compliance with the requirements shall be established. Deadlines for the implementation of such measures shall be established and made binding on the basis of hygienic relevance.

Once the system has been accepted in terms of technical and hygienic requirements, it shall be formally accepted.

NOTE It is expedient to have the acceptance tests for the technical and hygienic properties carried out by competent persons who are independent of the operator, the planners and the organizations carrying out the work.

Once the VAC system has been accepted for clinical use, the hygienist shall carry out microbiological monitoring to check whether or not the emission of germs by the personnel comply with the medical requirements defined in the user specifications. Guidance is given in Annex F.

7.2 System qualification

Examples of completed qualification steps are given below.

7.2.1 Installation qualification

The installation check is part of the check for completeness of delivery (parts and documentation) in accordance with the qualified planning (may be carried out during installation).

— All components delivered as contracted have been checked and are in working order.

— Any defects established have been remedied.

— The system is ready for powering up.

7.2.2 Function qualification

7.2.2.1 General

The step-by-step preparation for the function qualification includes the commissioning of components, initializing the system, checking safety functions, mounting filters, making fine adjustments, and optimizing functions. Once it has been checked and released, the documentation for each step provides proof that the function qualification has been achieved.

7.2.2.2 Commissioning

— The electrical connections have been checked.

— Air filters have been installed in the 1st and 2nd filtration stages.

— All components have been checked and are in working order.

— Any defects established have been remedied.

— The system is operational.

7.2.2.3 System adjustment

The following have been adjusted, measured and recorded:

— pressure and volume flow (for each room);

— supply air temperatures (in operating rooms under standard load conditions);

— humidification and, where applicable, dehumidification.

Control chains are in working order.

7.2.2.4 Safety functions

All safety functions have been checked:

— manual operation;

— frost protection;

— systems for emergency shut-off in case of fire;

— the remaining connections listed in the system description have been checked and recorded.

7.2.2.5 Air filter installation at the 3rd filtration stage/air filter test

All air filters have been installed.

— The serial numbers of the terminal air filters as given in the factory certificate have been documented in the air filter plan (ceiling layout).

— Inspection, seal-tightness tests and leakage tests of HEPA filters have been performed and documented in accordance with DIN EN ISO 14644-3 by a body independent of the supplier and installer.

7.2.2.6 Fine adjustment and optimization

After the HEPA filters have been installed and inspected, the fine adjustment and parameterization of the building automation and control system is carried out.

— Volume flow rates in rooms.

— Pressures and flow rates between rooms and to plenums behind suspended ceilings and to cavities in class I rooms, problem reports.

— Supply air temperature adjusted.

— Stationary room heating adjusted taking internal and external load conditions into consideration.

— Attention brought to any malfunctions relevant to hygiene.

7.2.3 Performance qualification

The performance qualification of the system shall be carried out on the basis of DIN EN 12599. In particular, at least the following measurements shall be carried out:

— supply air flow rate for each room;

— outdoor air flow rate (for each room, if possible);

— extract air flow rate;

— direction of overflow;

— leakage measurements on air ducts which are subject to increased tightness requirements;

— underpressure in plenums behind suspended ceilings in all class I rooms, also with door(s) open;

— system sound pressure level in each room, measured in the empty room;

— records of the data of all fine filters in the units, initial pressure loss at target volume flow rate;

— comfort parameters in the room.

The measuring points shall be selected in agreement with the respective consultant and clearly identified in drawings so that measurements can be reproduced at any time.

7.3 Technical acceptance test

The minimum scope of the technical acceptance test is shown in Table 2.

Table 2 — Minimum scope of technical acceptance test

Test object	Test parameters	Type of test
Project documents	Completeness, deviations from project specifications or from this standard	Visual inspection, check
Rooms as in Table 1	Deviations from project specifications or from this standard	Inspection, check
	Minimum outdoor air flow rate and total flow rate per room	Measurement
Outdoor air and supply air	Room air temperature, room air velocity, relative humidity, sound pressure level and outdoor air flow rate	Measurement
Recirculated air	Guideline values of this standard	Measurement where necessary
Labelling of system components as in 6.1.4	Completeness	Inspection
Outdoor air suction and exhaust air outlet as in 6.2	Location, distance, accessibility, and expert opinion, if necessary	Check documents, inspection
Air ducts as in 6.3	Requirements of the project specifications, e.g. state of cleanliness	Check documents, inspection
— Outdoor air ducts	Accessibility Inspection openings Basins and discharge openings	Check documents, inspection
— Supply air ducts	Accessibility for inspection, cleaning/disinfection Measurement of the specific leakage	Check documents, inspection Class I rooms: All rooms Class II rooms: Random sampling
— Smoke extraction ducts for class I rooms	No inadmissible air transport	Testing
— Inspection openings	Location, dimensions	Check documents, inspection
Dampers as in 6.4 — Outdoor air shut-off dampers — Airtight dampers — Fire dampers	Location, function Location, bedding in mortar, test mark, function	Check documents, inspection, functional testing

Table 2 *(continued)*

Test object	Test parameters	Type of test
Air handling units as in 6.5 — Mechanical characteristics	Location, equipment, function, accessibility, macroscopic cleanliness Stability, leakage, insulation, thermal bridging factor	Check documents, inspection
— Air filters	Filter classes, filtration stages, location of filters, filter equipment accessibility, marking, monitoring facilities	Check documents, inspection
— Heat exchangers	Location, cleanability, accessibility, fin spacing	Check documents, inspection
— Fans	Location, accessibility, marking	Check documents, inspection
— Air humidifiers	Type, materials, accessibility, inspectability, cleanability	Check documents, inspection
— Sound attenuators	Location, cleanability, abrasion resistance	Check documents, inspection
— Monitoring and status indicating equipment	Type, location, lighting	Check documents, inspection, calibrate measuring chain from sensor to display/limit value monitoring, functional check
HEPA filters as in 6.6	Location, tightness of fit, leaktightness	Check documents, inspection, tightness of fit and filter integrity tested as in DIN EN ISO 14644-3
LTF outlets	Filter quality and equipment	Check documents, inspection
	Value and distribution of supply air exit velocities	Measurements 10 cm beneath diffusers, measuring grid ≤ 30 cm, calculation of average exit velocity and total supply air flow rate
	Value and distribution of supply air exit temperatures	Measurements 10 cm beneath diffusers, measuring grid ≤ 30 cm, calculation of average supply air temperature
	Value and distribution of room air temperature under standard conditions (room and surgical lights on, with 0,8 kW heating) once thermal equilibrium is reached	Measurements at 4 representative locations Calculation of average room temperature

Table 2 *(continued)*

Test object	Test parameters	Type of test
	Temperature difference between average room air temperature and average supply air temperature, ΔT [K]	Calculation and comparison with projected minimum value
	Comfort parameters (1,75 m above FFL, see Figure C.1), air velocity, turbulence intensity, air temperature, sound power level, relative humidity	Measurements
— Recirculated air and extract air terminal devices	Location, fluff filters, cleanability	Inspection
— Overflow openings	Location, cleanability, disinfectability	Inspection
Heating and cooling components as in 6.5.8 and 6.5.9	Location, cleanability, disinfectability, function	Inspection, check
Measurement and control equipment as in 6.9	Accessibility, performance, warning functions	Check documents, inspection, functional check

7.4 Hygienic acceptance tests

7.4.1 Basic requirements

The hygienic acceptance test shall be carried out by a hygienist and may only be performed when the technical acceptance test has been successfully passed.

The hygienic acceptance test of class Ia operating rooms begins with a preliminary test (flow visualization) as specified in Annex B.

The next step is to determine the degree of protection as in Annex C or the turbulence intensity as in Annex D. The acceptance procedure chosen shall be agreed at the start of the planning stage.

Where necessary, a system test shall be carried out using the same measurement procedure that will be used for the on-site acceptance test.

Determination of the degrees of protection for the system test shall be carried out using a simplified 1:1-model as in Annex C (where necessary, as in Annex E, E.1 to E.5).

Determination of the turbulence intensity for the system test shall be carried out in accordance with E.6.

Once the system has been accepted and operation has begun, the hygienist shall carry out microbiological monitoring in operating rooms, as described in Annex F.

7.4.2 Requirements for each room class

Hygienic acceptance tests shall be performed for each room class as specified in Table 3.

Table 3 — Minimum scope of the hygienic acceptance test

Room class/Tests	Procedure	Requirements
Room class I		
Hygiene inspection	All air handling units in the central air conditioning plant and all rooms supplied by the VAC system shall be subjected to visual inspection to assess the hygienically relevant criteria specified in clause 6.	Compliance with the requirements specified in clause 6
Room class I		
Check air flow directions	All access doors to the operating room shall be closed. The doors shall then be successively opened, one at a time, to give a gap of 1 cm into which the test aerosol is to be emitted at three locations (10 cm below the upper door edge, 10 cm above the lower door edge and at the door centre) using flow test tubes. The flow direction shall be recorded and documented. After testing, each of the access doors shall be closed before the next one is tested as described above. Suspended ceilings are at underpressure relative to the operating room; determine this is so with the door to the operating room open	All operating rooms shall have a **positive air balance** relative to the environment (i.e. all adjacent rooms) so that no particle-loaded leakage air can enter the operating room (e.g. through air flow connections leading outdoors). At every access door, the test aerosol shall flow from the operating room out to the adjacent rooms/corridors. Check for the presence of a test port and demonstrate the positive air balance relative to the suspended ceiling.
Flow visualization of the outflow behaviour below the *LTF outlet*	As in B.2.1	The test aerosol shall exhibit a uniform outflow. Neither localized disturbances of the emitted test aerosol nor inhomogeneities of the outflow behaviour shall be detectable at any position below the LTF outlet (including the light lead-through).
Flow visualization of the outflow behaviour of the *surgical lights/satellites*	As in B.2.2	The test aerosol shall exhibit a uniform outflow over the surgical light/satellite. Neither a reversal of the flow direction nor a lifting effect shall be detectable at any position.
Flow visualization of the outflow behaviour of the screen for the *protected area*	As in B.3	Compliance with the requirements of Annex B. In particular, there shall be no visible entry of test aerosol into the protected area.

Table 3 *(continued)*

Room class/Tests	Procedure	Requirements
Room class I		
Determination of the degree of protection (as an alternative to determining turbulence intensity)	As in Annex C	Compliance with the requirements of Annex C. In particular: Demonstration of the protective effect to be ≥ 4 (without surgical lights) or ≥ 2 (with surgical lights)
Determination of turbulence intensity (as an alternative to determining the degree of protection)	As in Annex D	Compliance with the requirements of Annex D. In particular: turbulence intensity (all test positions except the four corner positions): ≤ 20 %, in the four corner positions: ≤ 30 %
The boundaries of the protected area shall be marked permanently and in colour on the operating room floor.		
Test of the recovery time (recovery test) in rooms with turbulent ventilation	As in DIN EN ISO 14644-3	Reduction of the particle concentration by 99 % within 25 min Maximum particle concentration 3 500/m^3 (0,5 µm) in quiescent condition (room centre, 1,2 m above FFL)

8 Periodic tests

8.1 Technical test

The periodic technical tests shall have at least the scope specified in Table 2 and be performed over a period of not more than 36 months.

8.2 Hygienic test

The periodic hygienic tests shall have at least the scope specified in Table 4.

The hygienist, working with the surgeon and possibly a technical expert, shall interpret measurement results and recommend measures for reducing the emission of germs by personnel, taking the postoperative wound infection rates given in the *Infektionsschutzgesetz* into consideration.

Hygienic testing as in Table 3 shall be carried out whenever the medical requirements are modified, deviations in the hygienic requirements occur or any modifications have been made to the system.

Table 4 — Minimum scope of periodic hygienic testing

Room class/Tests	Procedure	Requirements
Room class I		
Check air flow directions	All access doors to the operating room shall be closed. The doors shall then be successively opened, one at a time, to give a gap of 1 cm into which the test aerosol is to be emitted at three locations (10 cm below the upper door edge, 10 cm above the lower door edge and at the door centre) using flow test tubes. The flow direction shall be recorded and documented. After testing, each of the access doors shall be closed before the next one is tested as described above. The test period is ≤ 12 months, the test may be carried out internally.	All operating rooms shall have a **positive air balance** relative to the environment (i.e. all adjacent rooms) so that no particle-loaded leakage air can enter the operating room (e.g. through air flow connections leading outdoors). At every access door, the test aerosol shall flow from the operating room out to the adjacent rooms/corridors.
Microbiological monitoring	Initially, testing shall be carried out after the air handling unit has been accepted and operation has begun After that, test intervals of ≤ 12 months; further monitoring may be carried out internally As in DIN EN ISO 14698-1 and DIN EN ISO 14698-2	To be included in the specifications, with the participation of the hygienist
Flow visualization of the outflow behaviour as well as the shielding of the protected area	As in Annex B, may be carried out internally. Test intervals ≤ 12 months	Undisturbed vertical outflow up to a height of 1,2 m
Room class Ib		
Recovery test in rooms with turbulent ventilation	As in DIN EN ISO 14644-3 Test intervals ≤ 24 months	Reduction of the particle concentration by 99 % within 25 min Maximum particle concentration 3 500/m^3 (0,5 µm) in quiescent condition (room centre, 1,2 m above FFL)

9 Requirements for documentation

Comprehensive documentation shall be drawn up for all technical and hygienic tests carried out, including results, and shall contain at least the following information:

a) Tester and test date

b) Test object and specified parameters

— Type of test room or operating room,

— Boundary areas,

— Air handling unit for test room or operating room,

— Type of VAC system ductwork in the test room or operating room,

— Equipment in the room that is associated with the VAC system ductwork (e.g. flow stabilizers, surgical lights and satellites).

c) Test conditions

— Usage conditions,

— Ambient temperatures,

— Number, clothing and activities of personnel,

— Precise location and description of measurement points,

— Any special circumstances which could influence testing (e.g. medical equipment).

d) Test methods and equipment

— Description of measurement method,

— Test equipment used,

— Copies of valid calibration certificates for test equipment used.

e) Evaluation of test results, by means of comparing specified values to actual values, e.g. at least the

— size of the protected area,

— air flow behaviour (according to flow type and direction),

— air velocity and temperature,

— degree of protection,

— recovery time, and maximum particle concentration in the quiescent state,

— specific colony count.

Annex A
(informative)

Project planning guidance

NOTE The following information serves to help the building client specify the planning process and building works.

A.1 Project phases and objectives

With interdisciplinary design projects involving numerous parties and strict technical and hygienic requirements it is of great importance that each planning and decision-making phase follows a rigid structure and is well-documented.

Table 5 illustrates the procedures for this. Each project phase is a self-contained module which begins with the necessary documents, which clearly indicate the fields of competence and responsibilities of each party involved.

Before concluding a module, its objectives which were defined at the start of the module shall be checked. Each module is concluded by a formal release before the next module is started. In practice, the reviewing of objectives often makes a certain degree of repetition and inference unavoidable, but as this cannot be known in advance the information required for completing each module is listed below.

Table A.1 — Overview of project phases and objectives

Project phase	Objective
1. Analysis	Determine current situation, establish basic considerations, declare general intent
2. Target definition	Draw up specifications, conclude target definition phase
3. Design	Translate specifications into design, conclude design phase
4. Implementation	Implement specifications, qualify system, draw up documentation, conclude implementation phase
5. Operation	Train personnel, update and supplement system documentation, set up maintenance management, dispose of consumables, carry out microbiological testing
6. Re-qualification	Optimize running of existing operating rooms

A.2 Analysis

A.2.1 Determine the as-is situation

Prerequisites for the “analysis” phase are a determination of the as-is situation and the resulting establishment of a need for VAC measures, of a deficit or defect, or of an obligation imposed by another party resulting in the need for a new system, or the modification, disassembly, decommissioning or extension of an existing system.

A.2.2 Risk analysis for existing operating rooms

The testing and evaluation requirements specified in this standard can also be applied to existing systems in operating rooms which have not yet been tested for compliance with the requirements and degrees of protection specified in this standard. It is therefore recommended that a risk analysis be carried out taking into consideration the type of operations being performed in the relevant room(s). This may require additional analyses.

A.2.3 Establish basic considerations

— Description of functions and activities.

— Description of processes.

— Relevant regulations, standards, guidelines.

— Resources.

— Site selection, room dimensions, infrastructure.

— Future prospects (laws, standards, new medical treatment procedures).

— Consideration of the medical tasks and strategic planning for new treatments and equipment required in the future.

A.2.4 Declare general intent

The phase “analysis” is concluded with a declaration of intent which serves as a basis for establishing the project targets.

A.3 Target definition

A.3.1 Prerequisites

The following documents shall be available and the following conditions met before implementing this phase:

— declaration of intent;

— knowledge of legal provisions and regulations, standards, guidelines, policies, and recommendations;

— medical task at hand;

— other user requirements;

— target dates.

A.3.2 Project specifications

Project specifications are to be drawn up by the client in cooperation with the parties involved in the project and contain project-related information covering the following subjects:

— project definition;

— project organization and quality management (QM master plan);

— intended use;

— room definitions (room programme, see VDI 6028 Part 1) with room data sheet containing at least the technical details concerning the concept for providing protection by means of VAC measures, as well as the specification of the room classes;

— electrical safety classifications;

— room-climate requirements (min./max. temperatures, min./max. humidities);

— maximum system sound pressure level;

— materials to be used (for walls, floor, ceilings, apparatus, etc.);

— operational equipment;

— performance definitions;

— energy concept;

— building automation and control system (measurement and control concept, BAS switching);

— safety and environmental protection manual;

— testing concept (system qualification, acceptance testing as in Annex C or Annex D);

— fire protection concept (specifying fire compartments, escape routes, smoke extraction, evacuation);

— waste disposal concept;

— cost accounting;

— approvals;

— time schedule.

A.3.3 Conclusion of target definition phase

The target definition phase is concluded when all the parties involved in target definition have approved the project specifications. These serve as a basis for design.

A.4 Design

A.4.1 Prerequisites

The following documents shall be available and the following conditions met before implementing this phase:

— project specifications;

— knowledge of legal provisions and regulations, standards, guidelines, policies, and recommendations;

— basic architectural concept (project drawings, thermal insulation factors, solar protection concept, materials to be used, etc.);

— room programme;

— approval or clearance for design.

A.4.2 Translation of specifications into design

The project targets defined in the project specifications shall be translated into system concepts and design. In doing so, the measures required for system qualification shall be incorporated as necessary.

At the design phase the following aspects shall be taken into account:

— structural measures;

— technical measures;

— measures regarding personnel and organization;

— cleaning and operation (of rooms and system);

— qualification, re-qualification;

— preventive maintenance;

— decommissioning, standstill and re-commissioning;

— modification and dismantling (shutdown), disposal;

— safety concept (for breakdowns).

Hygiene and safety perimeters, as well as influences affecting all rooms should be presented in drawings, possibly in schematic form. The hygiene and safety targets specified are the basis for

— checking the ventilation and air-conditioning measures,

— checking the system components within the context of the design (planning) qualification,

— the installation check, and

— system qualification performed in the course of the acceptance tests.

A.4.3 Conclusion of design phase

The design phase is concluded with the design qualification which serves as a basis for implementation.

A.5 Implementation

A.5.1 Prerequisites

The following documents shall be available and the following conditions met before implementing this phase:

— design qualification, including report;

— knowledge of legal provisions and regulations, standards, guidelines, policies, and recommendations;

— any administrative instructions, provisions or approvals.

A.5.2 Application of project specifications

The checks listed in the project specifications shall be performed continually during the implementation phase. These checks relate to the construction, hygienic design and materials of the building elements and components used, and self-checks by the executing companies, in particular of

— the duct and piping systems and other technical and medical system components;

— the use and application of measuring equipment and test methods in accordance with the QM system for the test equipment.

A.5.3 System qualification

It shall be verified that each component of the entire installation has been executed as designed. The system elements should operate as intended, whether running separately or in interaction with one another.

The system qualification concludes with the formal release for use (statement of acceptance), to be followed by periodic testing.

A.5.4 Documentation

The documentation shall include:

— a description of the structure and functioning of the systems;

— all drawings, block diagrams with performance data, diagrams, specifications and operational data (records) from the design and system qualification;

— hygiene, cleaning, and maintenance plans;

— type and extent of any potential hazards (technical and/or hygienic);

— circuit diagrams;

— I&C function charts, including BACS data points;

— list of recommended spare and wear parts;

— list of the suppliers' addresses.

In addition, it shall be ensured that the operating, inspection, and maintenance activities required for a smooth and energetically optimal operation of the systems are laid down in the system documentation (see also VDI 6026 Part 1).

A.5.5 Conclusion of implementation phase

The implementation phase is concluded with the system qualification, the checking, release and handing over of documentation, and formal acceptance.

A.6 Operation

A.6.1 Prerequisites

The following documents shall be available and the following conditions met before implementing this phase:

— implementation concluded;

— system qualification and release, including the acceptance tests required under public law taking into consideration the relevant legal provisions and regulations, standards, guidelines, policies, and recommendations;

— complete documentation;

— operating licence.

A.6.2 Training of personnel

By implementing a suitable training management system, the system operator ensures that all staff members using the rooms and/or monitoring and servicing the systems are qualified as required for smooth and optimal operation, and he shall maintain records of a training activities.

A.6.3 Updating the system documentation

In principle, the system documentation shall be updated in detail whenever extension or modification work is performed. The responsibility lies with the operator.

A.6.4 Building automation and control system (BACS)

The BACS is an indispensable tool for running large buildings, especially where a link to maintenance data is available (see VDI 6009 regarding facility management).

The system provides the basis for the following operational tasks:

— fault detection, alerting (also alerting users in case of hygienically relevant systems);

— energy management and controlling;

— evaluation of message logs and trend diagrams;

— weak-point analyses;

— elimination of weak points, including suitable optimization;

— automatic preparation of orders to be placed for maintenance measures;

— assessment and optimization of the economic efficiency of maintenance measures.

A.6.5 Maintenance management

Well-organized maintenance requires the availability and completeness of a maintenance concept, system documentation, and maintenance, inspection, and repair plans, as well as a component identification system.

Depending on the size of the facility, it is advisable to use maintenance software, which can be part of a computer-aided facility management (CAFM) system, and which provides information on the following:

— maintenance planning;

— maintenance history;

— investment planning, maintenance and repair;

— documentation;

— replacement part lists.

A.6.6 Disposal of air filters

In cooperation with the supplier, the operator of the system shall record the following parameters:

— type, shape, quality, and quantity of the consumable in question;

— disposal instructions, address of the disposal facility.

During air filter replacement the required personal protective measures shall be observed, and the filters shall be disposed of in accordance with the environmental hygiene regulations.

Annex B
(normative)

Preliminary test (flow visualization)

B.1 Objective

The objective of the preliminary visual test is to obtain a qualitative description of the outflow behaviour below the LTF outlet, and of the light lead-through, surgical lights and satellites, and screen for the protected area. The system qualification is a prerequisite for this test.

This test requires aerosol generators which can continuously generate aerosols in a manner that can be documented in the form of images or videos.

NOTE Smoke tubes are not suitable because the amount of test aerosol generated is not sufficient.

Deviations from the following requirements shall be documented in images or videos.

B.2 Outflow behaviour

B.2.1 LTF outlet and light lead-through

B.2.1.1 Procedure

Move any lights/satellites which have already been installed out of the projection field of the LTF outlet so that the LTF can be examined without these disturbing factors.

After starting the aerosol generator, visually determine the outflow profile below the LTF.

Observe the distribution of the test aerosol and its flow direction to determine whether the emitted test aerosol sinks down to a height of at least 1,2 m.

If any local disturbances in the outflow behaviour or any turbulences occur, measure them by emitting the aerosol repeatedly and document the nature and extent of such disturbances/turbulences.

B.2.1.2 Requirements

The test aerosol shall exhibit a uniform outflow. Neither localized disturbances of the emitted test aerosol nor inhomogeneities of the outflow behaviour shall be detectable at any position below the LTF outlet (including the light lead-through).

B.2.2 Surgical lights and satellites

B.2.2.1 Procedures

Place the lights/satellites in the centre of the area below the LTF outlet. After preheating the lights/satellites to maximum operating temperature and starting the aerosol generator, determine the effect of the lights/satellites on the outflow profile by emitting the test aerosol at heights of 50 cm and 150 cm below the surgical lights/satellites and observing whether there is a lifting effect (in the sense of reversal of the flow direction in relation to the supply air direction) above or below the light/satellite.

Document any lifting effect occurring during any repeated aerosol emissions.

B.2.2.2 Requirements

The test aerosol shall exhibit a uniform outflow over the surgical light/satellite. Neither a reversal of the flow direction nor a lifting effect shall be detectable at any position.

B.3 Screen for the protected area

B.3.1 Procedure

Outside the protected area, emit the test aerosol along the four sides of the operating room and in the direction of each side at a height of 1,20 m above FFL and at a distance of 0,80 m from the outer edge of the LTF outlet.

B.3.2 Requirements

There shall be no visible entry of test aerosol into the protected area.

Annex C
(normative)

Determining the degree of protection

C.1 Objective

The objective of measuring the degree of protection is to obtain a quantitative evaluation of the level of protection provided against the entry of external and internal loads into the protected area, taking any bodies disturbing the flow and any cooling loads within the protected area into consideration.

C.2 Procedure

C.2.1 General

Successful system qualification and compliance with the requirements for flow visualization (Annex B) are prerequisites for this measurement.

Measurements of the degree of protection in class Ia operating rooms is a two-step procedure. First, proof shall be provided that the aseptic area (protected area) is sufficiently protected from its environment (effect of protection against load entry from outside).

The second part of the test, using a modified arrangement of the test-aerosol diffusers, is performed to detect any updraught of contaminated room air from the floor within the protected area (effect of protection against load entry from within).

C.2.2 Reference particle load

The protective effect is determined by measuring the particle concentration in the protected area while the background of the operating room is loaded with a reference particle load that has the same intensity (source strength, in particles/minute (P/min)) during all measurements.

This reference particle load simulates the loading of the operating room under test by a constant number of persons with constant emission of air-borne contaminations, including germs.

Specifying a constant source strength opens up the possibility of obtaining a characteristic reference quantity for evaluating the results of the hygiene test that remains the same for all situations.

The particle reference load consists of an aerosol flow that is constant over time, emitted into the room at six specified locations. The reference source strength Q_{Ref} (P/min) is determined as the product of the measured aerosol concentration (C_{Aer}) and the total aerosol flow rate (V_{Aer}):

$$Q_{Ref} = C_{Aer} \cdot V_{Aer} \qquad \text{(C.1)}$$

NOTE As an (idealized) reference quantity, a reference operating room is defined as having an LTF outlet with an area (A_{Ref}) of approx. 10 m^2 and an outflow velocity v_{Ref} of approx. 0,3 m/s. By means of the reference load, a reference particle concentration of $C_{Ref} = 35{,}3 \cdot 10^6$ P/m^3 (10^6 P/ft^3) shall be produced in the room's background. Assuming a particle reduction rate analogous to that obtained by disinfection (10^5), as defined, a concentration of 353 P/m^3 (10 P/ft^3) would be achieved in the protected area of the reference operating room, which can still be measured and evaluated statistically.

For the reference operating room, the required reference source strength of the particle source is therefore

$$Q_{Ref} = C_{Ref} \cdot A_{Ref} \cdot v_{Ref} \quad \text{(C.2)}$$

$Q_{Ref} = 35{,}3 \cdot 10^6\,\text{P/m}^3 \cdot 10\,\text{m}^2 \cdot 0{,}3\,\text{m/s} \cdot 60\,\text{s/min} = 6{,}3\ 10^9\,\text{P/min}$

The source strength should be adjusted to remain constant at this value of $6{,}3 \cdot 10^9$ P/min for all measurements. In doing so, it is essential that the aerosol generator in use is operated in a steady state which is constant over time and that equal portions of the aerosol flow are emitted at the specified locations, with the emission having low momentum and being isothermal. Values deviating from C_{Aer} and V_{Aer} are permitted as long as their product equals the defined value of $Q_{Ref} = 6{,}3 \cdot 10^9$ P/min.

NOTE Since the load imposed on operating rooms is independent of the size of the supply-air diffuser areas and their ventilation mode under practical conditions, specifying a constant source strength (reference load) is a logical consequence. If, on the other hand, a constant particle concentration in the background of the room were specified, the source strength would depend on the supply-air volume flow of the operating room under test. In that case, the load imposed on the operating room under test would not be an independent test quantity.

C.2.3 Reference loads, reference load test set-up

The reference loads described in this standard and their arrangement are intended to ensure reproducible and comparable conditions for all measurements. Due to the variability of the units to be measured (operating rooms) a defined measuring arrangement is required so that the operating rooms can be compared. In addition to the surgical lights operated at maximum load and positioned as shown in Figure C.1 and to the basic lighting of the room, an internal load with a thermal output of 800 W, supplied by six units (four units to the sides of the operating table, two units near the anaesthetist's workplace, see Figure C.1) shall be installed for the measurements. The heat sources shall be integrated in the units so as to obtain a surface temperature distributed homogeneously over the dummy.

In addition to the test with the standard load arrangement at the three standard measuring points given above, a test of the degree of protection shall be carried out at least on one instrument table in the protected area, selecting a typical load arrangement (e.g. on the surgeon's side of the table or at the head of the table) which shall be documented in the specifications.

This method is also suitable for testing modified positions when optimizing the protective effect under the given ventilation conditions.

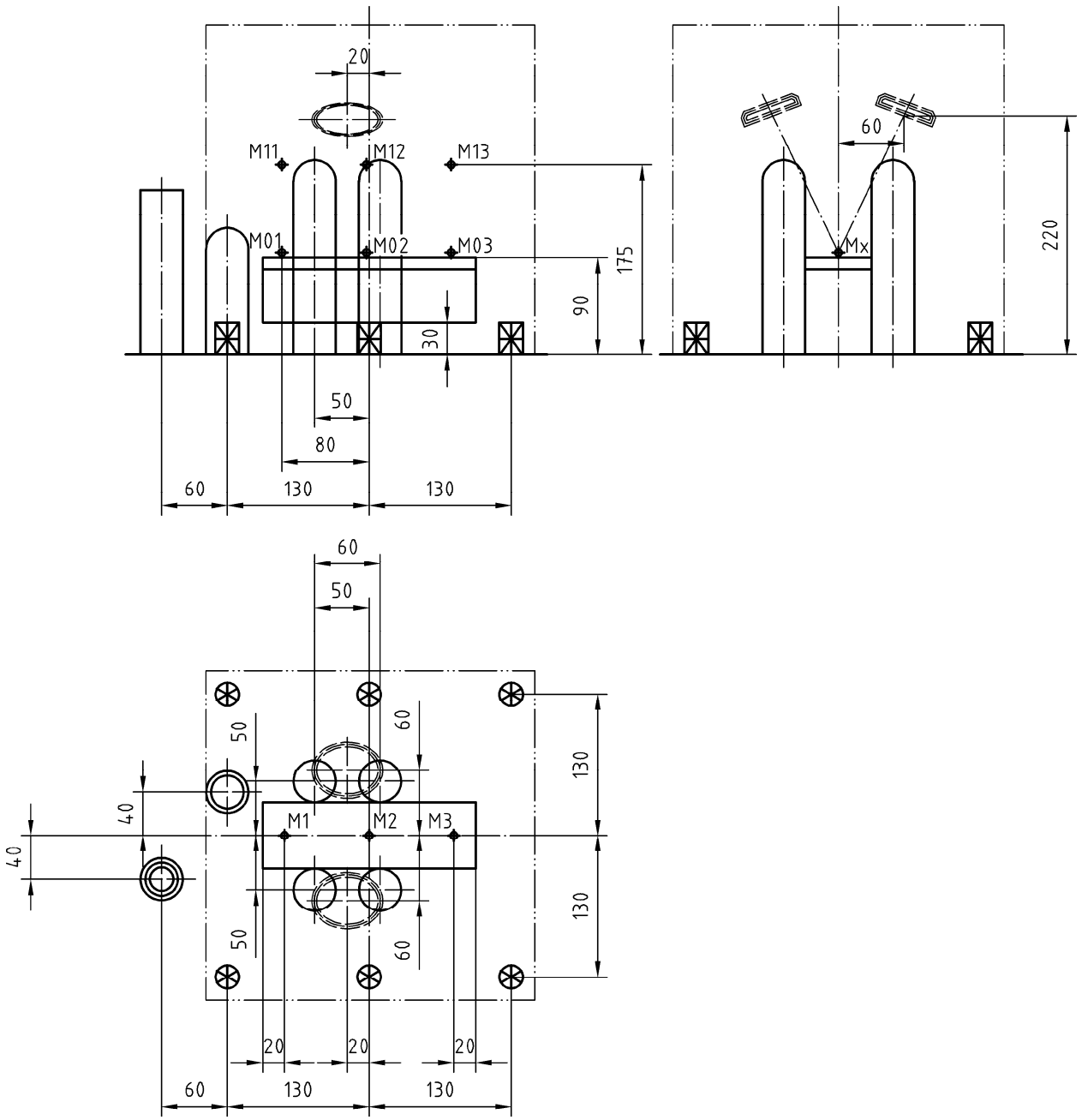
C.2.4 Effect of protection against load entry from the outside

The measurement is intended to yield evidence of the protective effect within the entire operating room to prevent air-borne particulate contamination from the operating room background from entering the protected area. Unless otherwise agreed, the standard loads are to be arranged as shown in Figure C.1.

C.2.5 Effect of protection against load entry from the inside

Two of the six aerosol generators are to be shifted so that they are located between the dummies (stand-ins for persons), as shown in Figure C.2, allowing the examination of any updraught in this area.

Dimensions in millimetres



Key

M01 Particle measuring point
(hyg. relevant measuring point)

M11 Comfort measuring point

Aerosol diffuser
Shell perforated e.g. d = 25 cm, h = 30 cm

Dummy, P = 300 W
d = 40 cm, h = 150 cm

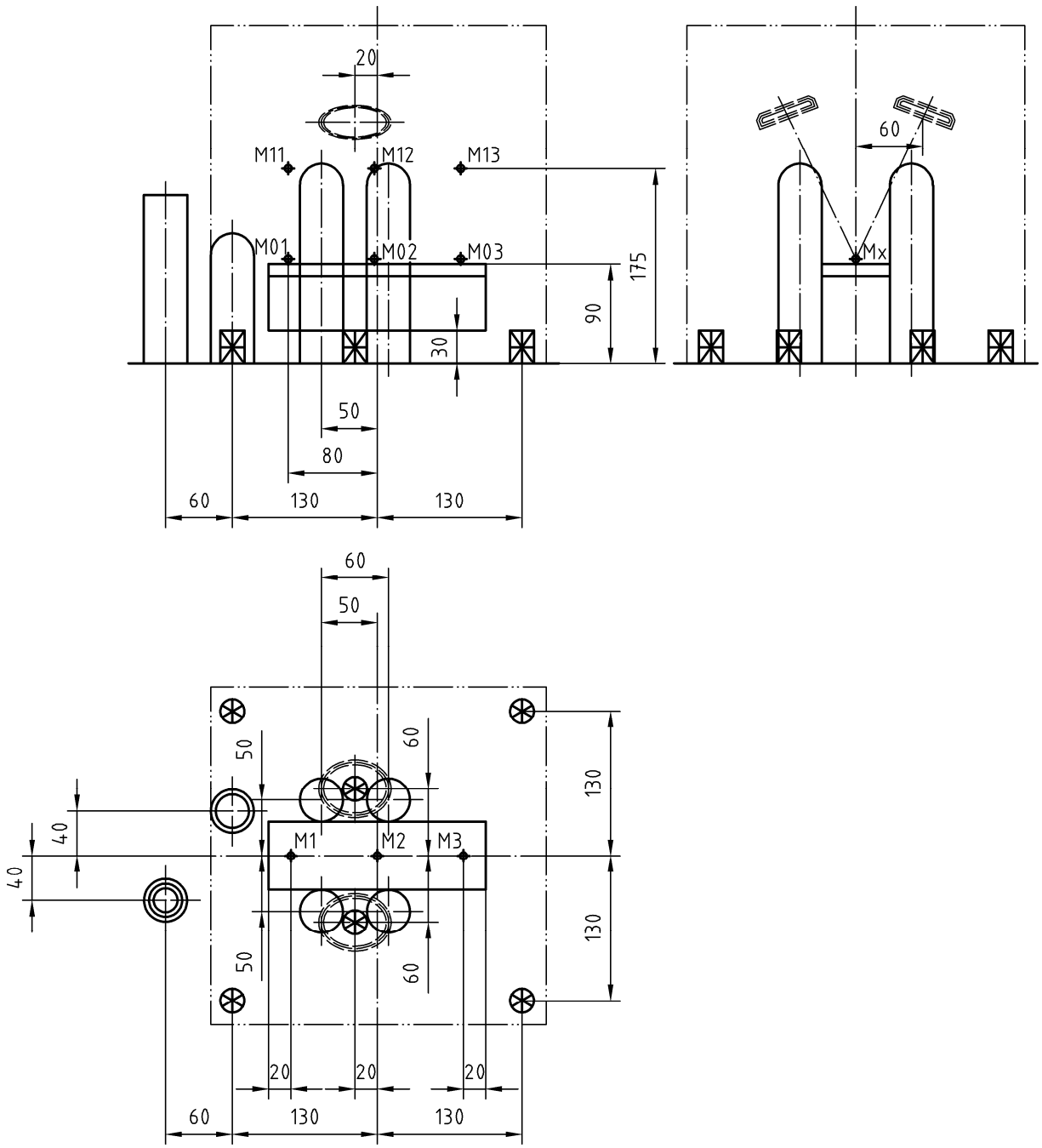
Dummy, P = 100 W
d = 40 cm, h = 120 cm

Dummy, P = 100 W
d = 40 cm, h = 180 cm

Surgical light focused on operating table

Figure C.1 — Standard load arrangement for testing the protective effect against load entry from outside

Dimensions in millimetres



Key

M01 Particle measuring point (hyg. relevant measuring point)

M11 Comfort measuring point

Aerosol diffuser
Shell perforated, e.g. *d* = 25 cm, *h* = 30 cm

Dummy, *P* = 300 W
d = 40 cm, *h* = 150 cm

Dummy, *P* = 100 W
d = 40 cm, *h* = 120 cm

Dummy, *P* = 100 W
d = 40 cm, *h* = 180 cm

Surgical light focused on operating table

Figure C.2 — Standard load arrangement for testing the protective effect against load entry from inside

C.2.6 Determining the boundaries of the protected area

When the operating room is subjected to the load of the reference load source, the measurable particle concentration rises abruptly at the boundary of the protected area

Dummies, surgical lights, and aerosol generators are positioned as shown in Figure C.1. The boundaries of the protected area are “traced” from outside the protected area, without disturbing the air flow, using a discrete particle counter having a long probe, with acoustical counting, that is guided on a mobile support at a height of 1,2 m above FFL, and are marked provisionally on the floor covering. Prior to handover for clinical use, the boundaries are marked permanently in colour on the floor.

C.2.7 Determining the degree of protection

At each measuring point M_X carry out and immediately record at least ten successive measurements lasting 1 min each, using a cleanroom particle monitor (sample air volume flow 28,3 l/min). Where cyclic behaviour is indicated (e.g. due to unstable room air rollers), then the measurements are to be continued for a period of at least 15 min to 20 min (depending on the cycle duration).

To document the cleanliness of the measuring system (to exclude memory effects), measurements using zero filters attached to the probe shall be performed and documented at regular intervals.

The interpretation of the results shall be based on the minimum size of the particles which no longer significantly penetrate the air filter during the filter leakage test. For clarity’s sake and to facilitate interpretation, it is recommended that the degree of protection *SG* be calculated instead of stating the particle concentrations measured in the protected area. *SG* is defined as

$$SG_X = -\log(C_X/C_{Ref}) \qquad \text{(C.3)}$$

where

C_X is the mean particle concentration at measuring point X, in P/m^3 (P/ft^3);

C_{Ref} is the reference particle concentration $= 35{,}3 \cdot 10^6$ P/m^3 (10^6 P/ft^3).

Calculate the mean degree of protection SG_X from the mean value of all individual measurements taken at each measuring point M_X using equation (C.3) and document the result. Calculate the minimum degree of protection SG_{Xmin} from the highest particle concentration measured at each point, and document the result.

Referring to the constant reference particle concentration $C_{Ref} = 35{,}3 \cdot 10^6$ P/m^3 (10^6 P/ft^3) ensures that a change in the value for the degree of protection can only be attributed to a change in the numerator C_X. In fact, the efficiency of removing background contaminations before they can come near the protected area can also be evaluated in this manner, though this is not demonstratable.

C.2.8 Determining the protective effect

The least favourable local degree of protection (smallest numerical value) is used to characterize the actual protective effect of the operating room compared to the required protective effect against load entry from the outside and inside.

The task of the independent testing body is completed once the degree of protection against load entry from outside and inside and the overall protective effect have been determined and a full test report has been drawn up.

EXAMPLE

A steady-state setting of the aerosol generator and the overall test aerosol volume flow rate was achieved at the following values:

$C_{Aer} = 7{,}4 \cdot 10^9$ P/m^3 ($2{,}1 \cdot 10^8$ P/ft^3)

and V_{Aer} *= 0,85 m³/min (30 ft³/min)*

The reference source strength calculated using equation (C.1) is:

$Q_{Ref} = 6,3 \cdot 10^9$ *P/min*

and thus meets the procedural requirements.

The highest mean particle concentration at a measuring point M_X located in the protected area was 33 500 P/m³ (950 P/ft³) and the highest individual value for this measuring point was 68 800 P/m³ (1 950 P/ft³).

The degree of protection SG_X was calculated using equation (C.3) and rounded to one decimal place:

$SG_X = -log\ (950/10^6)$

$SG_{Xmin} = -log\ (1\ 950/10^6)$

$SG_X = 3,0$

$SG_{Xmin} = 2,7$

The operating room has a protective effect of level 3,0. The minimum level is 2,7.

The protective effect corresponds to the lowest of all measured degrees of protection.

A.7 Requirements

Class Ia operating rooms built or reconstructed according to the specifications of this standard shall have at least a protective effect of 4,0 (without surgical lights) or 2,0 (with surgical lights) at the nominal air flow rate. On instrument tables within the protected area the protective effect shall be at least 2,0.

NOTE When carrying out a risk analysis for existing, older operating rooms which have to meet very high requirements with respect to low germ concentrations in the air, it shall be determined whether a protective effect of at least 2,0 can be achieved.

Values for the protective effect range from > 5,0 (excellent) to below 0 (no protective effect in terms of effective displacement ventilation) to even negative values (contamination through thermal updraught, induction or pronounced air rolls in the room).

The protective effect required for invasive procedures during which foreign material is implanted is higher than that for simple interventions. The protective effect that can be achieved is significantly influenced not only by the quality of the ventilation systems, but also by that of the medical equipment. This quality can be assessed using the test set-up described above.

Operating rooms for invasive procedures involving the implantation of foreign material shall be allocated to class Ia and shall have a high protective effect when this test set-up is used. In principle, operating rooms used mainly or solely for invasive procedures in areas that are already contaminated may have a lower protective effect, or can even be allocated to class Ib, unless logistical reasons demand that they be suitable for all types of operations.

Annex D
(normative)

Measuring turbulence intensity

D.1 Objective

Turbulence intensity is measured using measurement grids to determine the extent to which the LTF outlet is effective in providing a low-turbulence air flow within the protected area.

If the turbulence intensity of sterile, filtered supply air flowing vertically out of the laminizer of an LTF outlet is ≤ 20 %, then the entry of airborne contaminants from the outside into the operating room is considered to be effectively prevented.

If no system-tested LTF outlets or surgical lights/satellites have been installed, then a system test (basic test conditions as in E.5 and turbulence intensity measurement as in E.6) shall be carried out with all objects installed. The limit values specified in D.3 shall be maintained.

D.2 Procedure

D.2.1 General

Before measurements are carried out, the system shall have successfully passed the system qualification and the preliminary visual test (flow visualization as in Annex B).

When carrying out velocity measurements to determine the turbulence intensity, Tu, a direction-independent measurement system shall be used with an averaging time of at least 100 s and where at least one measured value is recorded per second. The sensor shall have a response time (t 63, or time necessary to reach 63 % of its end value) of < 0,2 s. The error of measurement shall be no greater than ± 0,05 m/s and the accuracy of measurement shall be checked at the time intervals recommended by the manufacturer.

The turbulence intensity at each test location (measuring plane: 1,2 m above FFL) is determined by the highest of two measurements. For the first measurement the sensors are perpendicular to the flow direction in the measuring plane, while for the second measurement the sensors are then rotated by 90° (see Figure D.1).

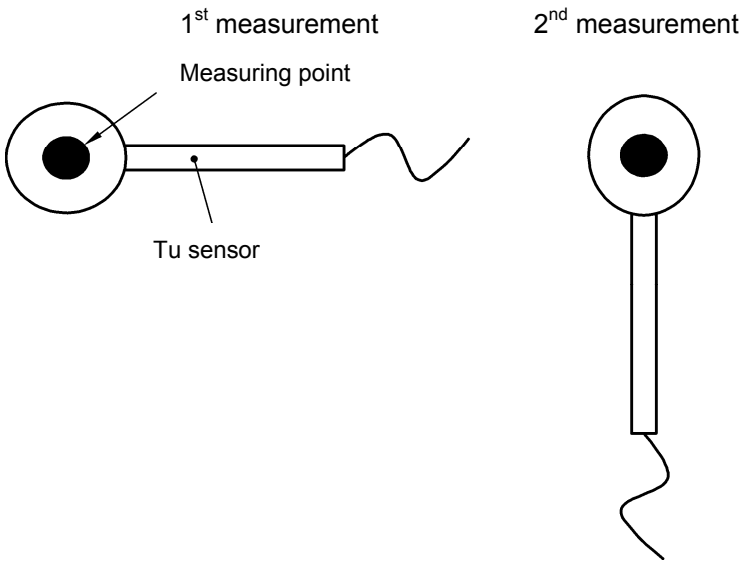


Figure D.1 — Position of turbulence intensity sensors in the measuring plane (2nd rotated by 90°)

All parameters and parameter constellations of the operating conditions tested shall be documented along with the relevant test results in a detailed test report.

D.2.2 Measuring and marking test positions

For the acceptance test, colour markings are placed below the LTF outlet as auxiliary and test positions. In the following example the laminizer size is 3,2 m × 3,2 m and that of the protected area is 3,0 m × 3,0 m; the colours used for the markings are by way of example only.

— Project the positions of the four outer corners of the laminizer onto the floor area of the test room or operating room by dropping a perpendicular, and mark these in red as auxiliary positions. Other laminizer shapes (round, oval, etc.) shall be marked analogously by marking at least four positions so that within these shapes a rectangle with a maximum area is formed.

— Then project the positions of the outer corners of the protected area onto the floor area of the test room or operating room using a series of black points to form a second rectangle.

— The red markings indicating auxiliary positions can be removed at this point.

— Make eight orange marks along the median lines of the diagonals and of the vertical and horizontal axes of the rectangle.

— Make a white mark at the intersection of the diagonal with the vertical and horizontal axes.

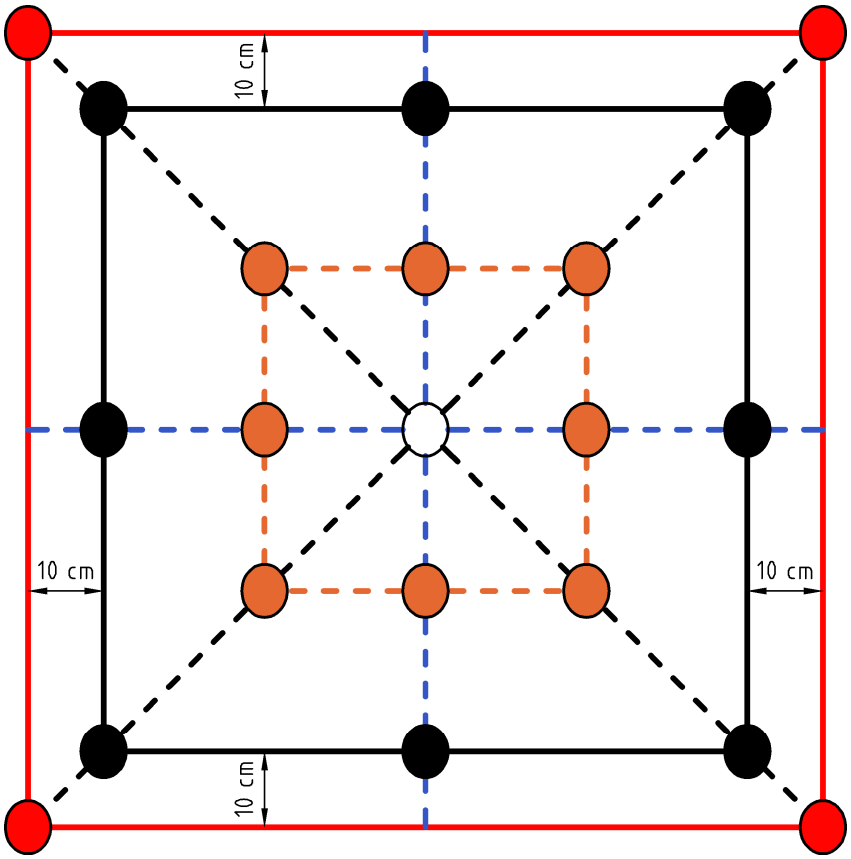


Figure D.2 — Auxiliary positions and test positions projected on floor beneath LTF outlet (red line: projection of laminizer; black line: boundary of protected area)

D.2.3 Procedure for Tu measurement

The measurements shall be performed without operating tables and instrument tables.

Using a sensor fixed above the perpendicular of the test position, determine the three parameters flow velocity, temperature, and turbulence intensity in the measuring plane 1,2 m above FFL. Take two measurements each above the black, orange and white marks (n = 17, see Figure D.2) and then average the two results for each position.

If the requirements for the protected area are not met during this test, then the effectiveness of the LTF outlet may be tested separately. To this end, temporarily (for the measurement only) install a flow stabilizer surrounding the entire outlet to a height of 1,0 m above FFL and repeat the turbulence intensity measurements. This allows a distinction to be made between external influences (e.g. room geometry, extract air flow) and the effects of the LTF outlet.

D.3 Requirements

D.3.1 Protected area

Mean turbulence intensity at each test position (except for the corner positions): ≤ 20 %

Mean turbulence intensity at each of the four corner positions: ≤ 30 %

D.3.2 LTF outlet, separate (with temporary stabilizer surrounding outlet)

Mean turbulence intensity at each test position (except for the corner positions): ≤ 15 %

Mean turbulence intensity at each of the four corner positions: ≤ 25 %

Annex E
(informative)

System test

E.1 Objective

The system test is a pre-qualification of the ventilation system carried out to evaluate the technical construction and design of reference operating rooms with LTF systems, and enhances planning reliability where the design and construction of actual operating rooms is identical with those of the reference rooms.

When testing complex systems a project-specific system test is recommended. This requires a model operating room equipped with all installations relevant to ventilation that should be designed, tested and optimized, if necessary.

E.2 General requirements

The examinations required for the system test shall be supervised by a hygienist.

Each step of the system test shall only be carried out after the requirements of the previous step have been met. It is, however, permissible to system test lights/satellites separately from the LTF outlets/ceilings.

All parameters and parameter constellations of the operating conditions tested shall be documented along with the relevant test results in a detailed test report.

The system test is deemed to have been successfully passed only when

— the equipment requirements for the LTF outlet given in 6.7.2 were met in one defined test room/operating room;

— all of the manufacturer's specifications listed below are available;

— once the flow visualization requirements (Annex B) were met, all other subsequent examinations were performed in the given sequence and the relevant requirements have been met.

After the system test has been successfully passed, the hygienist is to draw up a report that includes the system test report and the final evaluation.

The hygienist is responsible for assessing, on a case by case basis, whether the results of a successfully passed system test can be applied to other designs and whether the performance of this other design is equivalent to that of the system tested. Possible effects on the performance of the LTF system are

— modifications to the location of HEPA filters;

— type and arrangement of the primary or recirculated air inflow;

— modifications to the dimensions/height of the operating room or LTF outlet;

— modifications to the light lead-throughs and/or flow stabilizer.

If the performance is not deemed to be equivalent, then another system test is required.

E.3 Basic conditions for the examinations

E.3.1 Reference operating room

The system test is performed in a reference operating room (with VAC system) that simulates the design of planned rooms and that generally meets the following basic conditions:

— area of 6 m × 6 m to 7 m × 7 m;

— room height of 3 m;

— LTF outlet installed in the centre of the room ceiling;

— total heat loads adjustable between 1,5 kW and 5 kW;

— wall temperature adjustable.

E.3.2 VAC system

The VAC system for supplying the reference operating room shall satisfy the following criteria:

— system structure as in clause 6;

— outdoor air flow rate at least adjustable between 1 200 m^3/h and 3 000 m^3/h;

— supply air flow rate at least adjustable between 5 000 m^3/h and 10 500 m^3/h;

— primary air temperature ≥ 10 °C (at entry into the LTF outlet), adjustable;

— supply air temperature ≥ 18 °C (at exit from the LTF outlet), adjustable;

— room temperature 19 °C to 26 °C, adjustable;

— extract air openings in all 4 corners of the room (close to the floor and the ceiling), variably adjustable.

E.3.3 Proof of stability of the supply air volume flow rate and temperature

E.3.3.1 Procedure

The parameters supply air velocity and temperature for the test room shall be measured in the centre of the supply air duct, applying the usual methods and using fan performances of P_{80} = 80 % and P_{30} = 30 %.

After reaching steady-state at full load operation, begin the first period of measurement of 60 min and measure the two parameters, recording the results at intervals of 1 min.

After that, switch the system off (without power) for a period of 30 min.

Switch the system on again and, after reaching steady state at full load operation again, begin the second measuring period of 60 min and measure both parameters in the same manner again.

Determine the mean values, standard deviations, and coefficients of variation for each series of values measured at P_{80} and P_{30} during both measuring periods.

E.3.3.2 Requirements

Coefficients of variation for the flow velocities (P_{80} and P_{30}): < 3 %
Maximum deviations from the mean temperatures (P_{80} and P_{30}): ± 0,3 °C

E.3.4 Checking air flow directions

The test room shall have a positive air balance relative to the environment (i.e. all adjacent rooms) so that no particle-loaded leakage air can enter the test room (e.g. through air flow connections leading outdoors).

E.4 Manufacturer's specifications

E.4.1 General

When carrying out a system test on LTF outlets or lights/satellites, the manufacturer shall submit to the hygienist the following specifications prior to commencing the examinations.

E.4.2 LTF outlet

Specifications for the LTF outlets shall include:

— a definition of the product and operating conditions to be examined in the LTF outlet system test (definition of the test requirements);

— detailed drawings of the product to be tested (LTF outlet including its supply-air and recirculated air connections, built-in parts, light lead-through, laminizer, flow stabilizers and other accessories). The system test includes the lead-throughs of the surgical light's stand pillar;

— the means of mixing the outdoor and recirculated air (e.g. in the central air-conditioning unit or the LTF outlet);

— the means of extract air distribution, including the location and size of extract air terminal devices.

E.4.3 Lights/satellites

Specifications for the lights/satellites shall include:

— detailed drawings of the lights and satellites to be tested, including their arms;

— technical specifications for the lights/satellites, including wattage and maximum surface temperatures.

E.5 Minimum test conditions

E.5.1 General

Regardless of the specified manufacturer's test requirements, at least the following parameters and test constellations shall be examined during the system test and the test requirements shall be complied with.

E.5.2 LTF outlet

The test constellation for the LTF outlet shall be as follows:

— laminizer size (free air outlet area): approx. 3,2 m × 3,2 m;

— flow velocity: mean value between 0,23 m/s and 0,25 m/s (measuring points at 1,2 m above FFL);

— thermal loads of up to 3 kW for evaluating their influence on the mixing function of the LTF outlet (implemented, e.g. by means of basic room lighting, wall heating, dummies, etc.), which can be installed outside the protected area.

E.5.3 Lights/satellites

The test of the lights/satellites shall be carried out below an LTF outlet with vertical outflow and at the maximum operating temperatures of the light/satellite at a luminance of ≥ 75 000 lux (measured at a distance of 1 m from the light).

— Distance between the laminizer and the centre of the light: 1,0 m;

— Distance between the centre of the light and the measuring probes: 0,8 m;

— Distance between the measuring probes and FFL: > 0,6 m;

— Flow velocity (mean values) at the measuring probes: 0,23 m/s ± 0,011 5 m/s;

— LTF supply-air temperatures: 20 °C ± 0,5 °C.

E.6 Turbulence intensity measurement

E.6.1 General

Colour markings are placed below the LTF outlet and below the light lead-through and the lights/satellites as auxiliary and test positions; the colours used for the markings used are by way of example only.

A differentiation shall be made between the size of the laminizer (area through which air flows) and the protected area defined in the project specifications. In general, the laminizer (e.g. textile distributor) is larger than the protected area.

In the following example, the laminizer size is 3,2 m × 3,2 m and that of the protected area is 3,0 m × 3,0 m.

E.6.2 Measuring and marking test positions

E.6.2.1 Laminizer and protected area

Before performing the turbulence intensity measurement, the following test positions shall be marked as follows:

— Project the positions of the four outer corners of the laminizer onto the floor area of the test room or operating room by dropping a perpendicular, and mark these in red as auxiliary positions. Other laminizer shapes (round, oval, etc.) shall be marked analogously by marking at least four positions so that within these shapes a rectangle with a maximum area is formed.

— Then project the positions of the outer corners of the protected area onto the floor area of the test room or operating room using a series of black points to form a second rectangle.

— Starting from the centre positions, mark further black points spaced 30 cm apart along the median lines of the length and width of the rectangle formed by the black corner points. This results in a measuring grid of 30 cm × 30 cm (121 measuring positions, see Figure C.1). For the 40 outer measuring positions (periphery), the measuring grid spacing may be less than 30 cm × 30 cm.

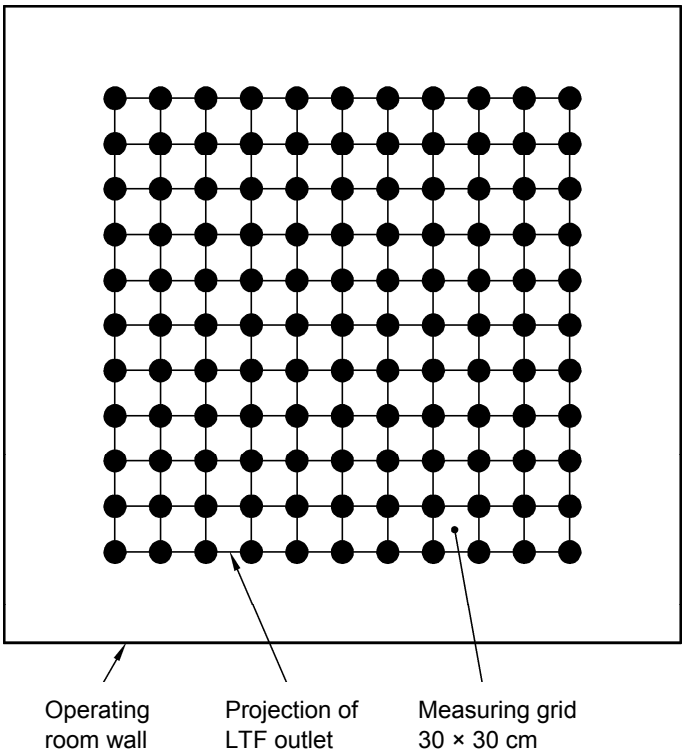


Figure E.1 — 121 test positions projected on the floor below the LTF outlet, forming a measuring grid of 30 cm × 30 cm

E.6.2.2 Surgical light lead-through

— The position of the centre of the light lead-through through the laminizer is represented by a green mark on the floor area of the test room or operating room; determine this position by dropping a perpendicular.

— Mark four additional positions in green around the green floor marking of the light lead-through so that they represent the corner points of a square with a side length of 20 cm formed around the perpendicular point in the projection of the centre of the light lead-through.

E.6.2.3 Surgical lights/satellites

The lights/satellites which can be swivelled around the three room axes shall be positioned as follows, with the light centre (intersection of the three room axes in a hemisphere around which the light can be swivelled) at an inclination angle of 45° of the light emergence plane:

— in the laminizer projection field, with each light centre at a distance of > 100 cm from the external sides;

— on one side of the laminizer bars, if the laminizer is divided into two or more framework constructions.

Position the perpendicular of the light centre above the black point specified in C.6.2.1. Then mark in blue the positions of the light centre as well as the surrounding measuring grid of 120 cm × 120 cm (corresponding to 5 × 5 marker points).

E.6.3 Procedure

The system test examinations shall be performed without operating tables and instrument tables.

Using a sensor fixed above the perpendicular of the test position, determine the three parameters flow velocity, temperature, and turbulence intensity (measuring plane for protected area and light lead-through: 1,2 m above FFL).

Carry out these measurements at all test positions of the measuring grids for the “laminizer and protected area”, “surgical light lead-through”, and “surgical lights/satellites”.

If the requirements for the protected area are not met during the test, then the effectiveness of the LTF outlet may be tested separately. To this end, temporarily install a flow stabilizer surrounding the entire outlet to a height of 1,0 m above FFL and repeat the turbulence intensity measurements. This allows a distinction to be made between external influences (e.g. room geometry, extract air flow) and the effects of the LTF outlet.

E.6.4 Requirements

E.6.4.1 Protected area

Mean turbulence intensity at each test position (except for the corner positions): ≤ 15%

Mean turbulence intensity at each of the four corner positions: ≤ 25 %

E.6.4.2 LTF outlet, separate (with temporary stabilizer surrounding outlet)

Mean turbulence intensity at each test position (except for the corner positions): ≤ 15 %

Mean turbulence intensity at each of the four corner positions: ≤ 25 %

E.6.4.3 Light lead-through

Mean turbulence intensity at each of the 5 test positions: ≤ 15 %

E.6.4.4 Surgical lights/satellites

Mean turbulence intensity for the 25 test positions: ≤ 37,5 %

Annex F
(normative)

Microbiological monitoring

F.1 Objective

Microbiological tests are carried out to determine and evaluate the extent of the load in operating rooms of microorganisms capable of reproduction that are released during room use. Regular evaluation with staff involvement promotes greater discipline among personnel and helps identify VAC system malfunctions.

F.2 Procedure

The microbiological method used to assess the level of biocontamination in operating rooms shall be selected and validated in accordance with DIN EN ISO 14698-1.

F.3 Requirements

The requirements to be fulfilled in the operating room under examination shall be specified by the hygienist in accordance with DIN EN ISO 14698-1.

F.4 Evaluation

Measurement results shall be evaluated and interpreted by the hygienist in accordance with DIN EN ISO 14698-2.

If the requirements are met, it can be assumed that the emission of germs by personnel does not exceed the maximum values laid down in the specifications and that the ventilation system works effectively from a hygienic point of view.

If the requirements are not met, the hygienist shall carry out further tests to determine the cause. The type, scope and priority of improvement measures will depend on the number of values exceeding the specified limits for the room in question, and by how much these limits are exceeded.

Only the technical and hygienic tests described in tables 2 and 3 of clause 7 may be used to check the functionality of the VAC system.

NOTE Part 1 of DIN EN ISO 14698 describes the principles and basic methodology of a formal system for controlling biocontamination. Part 2 gives guidance on the evaluation of microbiological data and the estimation of biocontamination data, but does not specify any application-specific requirements.

The hygienist shall select the location of the sampling device in class Ib rooms, and this location shall be maintained in all repeat tests.

Location of sampling devices:

— Class Ia rooms: Exposure at the 3 black marks on the surgeon’s side and on both median lines as in Figure D.2;

— Class Ib rooms: Exposure at 3 different representative positions in the operating room (e.g. near the operating field, on the instrument table, elsewhere in the ventilated area).

A simple method of microbiological monitoring using settle plates is described below:

Procedure (example using settle plates):

During 5 successive operations with incision-to-closure times ≥ 45 min (for class Ia rooms) or ≥ 10 min (for class Ib rooms) place several commonly-used Petri dishes filled with CASO agar (diameter ≥ 8 cm; sterile packaging), as settle plates, at the above-mentioned positions on instrument tables or separate tables at a height of 1,2 m above FFL, and simultaneously expose them by opening them at the start of the incision-to-closure period.

Immediately upon closure of the incision, close the settle plates with the covers and mark them with the date, operating room, time and incision-to-closure time. Then, incubate them for 48 h at (36 ± 1) °C using a common method. Evaluate them by counting the number of colonies per settle plate. It is not necessary to carry out species identification or determine species sensitivity.

For the 5 operations, normalize the colony counts per settle plate for an evaluation area of 50 cm^2 and an operating time of 60 min (“specific colony counts”). Finally, calculate the mean specific colony count for each operating room.

Requirements (example using settle plates):

— Class Ia rooms: Mean specific colony count: ≤ 1 CFU/(50 cm^2 · 60 min);

— Class Ib rooms: Mean specific colony count: ≤ 5 CFU/(50 cm^2 · 60 min).

When using settle plates, care shall be taken that the total number of viable particles in the air is not counted but the rate at which the viable particles settle on the surface. This rate is a function of the turbulence intensity in the ambient air at the exposure site; in operating rooms with turbulent ventilation this rate will be higher than in the low-turbulent protected area.

If a high specific colony count is obtained in the protected area of a class Ia operating room, this does not necessary mean the VAC system is faulty or the protective effect is not sufficient, but indicates a high, unquantifiable germ emission by the personnel in the operating room.

If, however, with repeated use there is a load increase in the aseptic area with no accompanying change in personnel behaviour, this can indicate a malfunction in the VAC system. The automatic control system specified in 6.9 shall immediately indicate any deviations from the hygienically-relevant requirements (e.g. supply-air volume flow rate).

Bibliography

RKI, *Empfehlungen der Kommission für Krankenhaushygiene und Infektionsprävention am Robert-Koch-Institut*. (Recommendations of the Commission for Hospital Hygiene of the Robert Koch Institute) (published in the *Bundesgesundheitsblatt* (German Federal Health Gazette) and on www.rki.de)

Anforderungen an die Hygiene bei der Aufbereitung von Medizinprodukten (Hygiene requirements when preparing medical devices). *Kommission für Krankenhaushygiene und Infektionsprävention beim Robert-Koch-Institut, Bundesgesundheitsblatt* 44 (2001), pp. 1115–1126

Anforderungen der Hygiene beim ambulanten Operieren in Krankenhaus und Praxis (Hygiene requirements for ambulatory operations in hospitals and practices), *Bundesgesundheitsblatt* 40 (1997) Vol. 7, pp. 361–365

CDC (Centers for Disease Control and Prevention, USA): Guideline for the Prevention of Surgical Site Infection

Desinfektionsmittel-Liste der Desinfektionsmittel-Kommission im Verbund für Angewandte Hygiene (VAH) (List of Disinfectants issued by the Disenfectant Comission of the Association for Applied Hygiene (VAH)) (available at www.mhpverlag.de)

European Commission, Good Manufacturing Practice (GMP) Guidelines, Vol. 4: The rules governing medicinal products in the European Union

DGKH/ÖGHMP/SGSH, *Leitlinie Ausführung und Betrieb von raumlufttechnischen Anlagen in Krankenhäusern* (Guidelines for the design and operation of VAC systems in hospitals). Issued by the *Deutsche Gesellschaft für Krankenhaushygiene* (DGKH), Germany, the *Schweizerische Gesellschaft für Spitalhygiene* (SGSH), Switzerland, and the *Österreichische Gesellschaft für Hygiene, Mikrobiologie und Präventivmedizin* (ÖGHMP), Austria (available at www.dgkh.de), 2002

Gesetz zur Verordnung der Sicherheit von technischen Arbeitsmitteln und Verbraucherprodukten (Article 1 of the *Geräte- und Produktsicherheitsgesetz* (GPSG) (German Equipment and Product Safety Act))[1)]

LAGA-Mitteilung 18, *Richtlinie über die ordnungsgemäße Entsorgung von Abfällen aus Einrichtungen des Gesundheitsdienstes* (Guidelines for the proper disposal of medical waste), published by the *Bund/Länder-Arbeitsgemeinschaft Abfall* (LAGA)[3)]

Liste der vom Robert-Koch-Institut geprüften und anerkannten Desinfektionsmittel und -verfahren, mit Informationsblatt und Vorwort (List of disinfectants and disenfecting methods tested and approved by the Robert Koch Institute, with information and foreword) (available at www.rki.de)

OENORM H 6020, *Ventilation and air conditioning plants for locations for medical use — Design, construction, operation, maintenance, technical and hygienic inspections*[4)]

VDI 6009 Part 1, *Facility Management — Building management in practice*

VDI 6009 Part 2, *Facility Management — Introduction of building management in several properties — Examples*

1) See page 5.

3) Registered in the DITR database of *DIN Software GmbH*, obtainable from: *Erich Schmidt Verlag GmbH & Co*, Postfach 304240, 10724 Berlin

4) Obtainable from: Austrian Standards Institute.

VDI 6009 Part 3, *Facility Management — Introduction of a Computer Aided Facility Management System (CAFM)*

VDI 6028 Part 2, Assessment criteria for building services — Requirement profiles and valuation criteria for sanitary engineering

SWKI 99-3, *Heiz- und Raumlufttechnische Anlagen in Spitalbauten (Planung, Bau, Betrieb)* Heating, ventilation and air conditioning systems in hospitals (design, construction and operation), published by the *Schweizerischer Verein von Gebäudetechnik-Ingenieuren* (Swiss Society of Heating and Air-conditioning Engineers)