SLOVENSKI STANDARD
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Prezračevanje za bolnišnice

Ventilation for hospitals

Lüftung für Krankenhäuser

Ventilation des hôpitaux

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Ventilation for hospitals

Ventilation des hôpitaux

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This draft Technical Report is submitted to CEN members for Technical Committee Approval. It has been drawn up by the Technical Committee CEN/TC 156.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (FprCEN/TR 16244:2011) has been prepared by Technical Committee CEN/TC 156 “Ventilation for buildings”, the secretariat of which is held by BSI.

This document is currently submitted to the Technical Committee Approval.

1 Scope

This Technical Report applies to health service buildings and rooms used for medical examinations, treatments and interventions to be carried out on people as well as to rooms directly connected to those rooms by doors, corridors/hallways, etc.

It establishes rules for planning, construction, qualification, and operation of ventilation and air-conditioning (VAC) systems and components intended to be used in:

— hospitals buildings;

— day hospitals;

— physician's practices with intervention rooms;

— outpatient surgery centres / facilities / ambulatories;

— dialysis centres;

— convalescent homes, rehabilitation facilities, sanatoria;

— long-term care facilities, senior retirement and nursing homes;

— facilities for internal and external (service) units for the processing of medical devices / sterilization areas.

In addition to that, air hygienically relevant guidance is given regarding building services / heating installations.

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.

EN 12792:2003, *Ventilation for buildings — Symbols, terminology and graphical symbols*

3 Terms, definitions, and abbreviations

For the purposes of this document, the terms and definitions given in EN 12792:2003 and the following (in alphabetical order) apply.

3.1
air lock
room located between two rooms of different room classes

NOTE It is used to reduce transmission of aerobic infectious agents between rooms of different classes. The air lock is supplied with air as well as vented by mechanical means and can be operated with overpressure or underpressure. Alternatively, air locks that should be passed before entering a class H1b operating room can also be supplied with air by over-flow from the operating room.

3.2
hygienist
according to this Technical Report, a medical specialist for hygiene pursuant to the advanced training regulations of the federal states with special expertise in the fields of ventilation technology or an expert working in an agency for the fulfilment of hygiene-related tasks, each with special knowledge and experience

in the field of ventilation and hospital hygiene (also called hygiene expert / specialist for hygiene / hospital hygienist in different countries, function needs to be described)

3.3
interventions
as distinct from operations

NOTE This differentiation is made in correspondence with the annex to the attachment accompanying numbers 5.1 and 4.3.3 of the requirements for hygiene in ambulant surgery (Anforderungen der Hygiene beim ambulanten Operieren in Krankenhaus und Praxis) published by the Robert Koch Institute, Berlin.

3.4
servicing
includes measures for determining and assessing the actual state of a system's technical means (inspection) as well as for maintaining the nominal condition of a system's technical means (maintenance)

3.5
resistant to disinfectants
according to this TR, ventilation and air-conditioning components and products are considered to be resistant to disinfectants if they are able to withstand a long-term application of disinfectants and disinfecting methods

NOTE The only disinfectants used are those included in the list published by the Robert Koch Institute (RKI) or the Association for Applied Hygiene (Verbund für angewandte Hygiene e.V., VAH), respectively.

3.6
repair
measures for restoring the nominal condition of a system's technical means

3.7
room classes
classes assigned to rooms used for medical purposes

3.8
protective isolation / sterile care
patients with a risk of infection

3.9
source isolation / infectious patients
patients with infection

3.10
VAC-central-plant
ventilation and air-conditioning system containing all components (sound attenuators, dampers, heat exchangers etc.) installed inside a central plant in order to facilitate cleaning and maintenance

3.11 Qualifications

3.11.1
system qualification
qualification of systems that includes the partial steps installation qualification, function qualification, and performance qualification

NOTE Each subsequent partial step should be started only after completing the improvements required and successfully passing the re-checks for the previous partial step.

3.11.2
installation qualification
systematic sequence of inspections, measurements, and tests (as well as adjustments, if necessary) carried out in order to ensure the compliance of all system parts with the planning requirements

3.11.3
function qualification
series of tests and measurements carried out in order to ensure the correct functioning of all system parts

3.11.4
performance qualification
tests and measurements proving that the entire system achieves the operating state agreed

3.11.5
planning qualification
planning ends with a qualification intended to demonstrate the compliance of the execution planning with the requirements defined in the task formulation (performance specifications)

3.12 Operating-rooms

3.12.1
low turbulence flow (LTF) plenum
supply air plenum with a vertical air outlet used to obtain a low-turbulence displacement flow ($Tu \leq 20$ %) in the entire protected area

3.12.2
turbulence level *Tu*
measure for the fluctuations of the air velocity in relation to its mean value (relative standard deviation), in %

NOTE A flow with a turbulence level of less than 5 % is designated as “laminar” and “low-turbulence” between 5 % and 20 %, respectively, whereas a flow with a turbulence level of more than 20 % is called “turbulent”.

3.13
overpressure / underpressure
positive or negative air balance

3.14
positioning analysis
Identification of floor space required specific for clinic of the protected area for which itself approximately 9 m² (e.g. 3 m × 3 m) have proved themselves as a standard size in the international operation practise

NOTE The standard construction situations are to be shown for the operating field, the tables for exposed sterile instruments and materials and the operating room staff wearing sterile clothing. The aforementioned potential disturbing factors should be considered very carefully in cooperation with the hygienist and the VAC-consultant taking into account that in any case the protection effect needs to be demonstrated.

3.15
pre-qualification
pre-qualification is carried out in order to assess the structuring and technical design of operating rooms with LTF systems as a system test

NOTE It is carried out in connection with all the relevant boundary conditions of the operating room under the planned thermal loads (e.g. persons, equipment, basic heating) as regards equipment (e.g. associated operating lamps, special flow stabilisers) and space.

3.16
protected area / fields operating-rooms
includes, in addition to the operating field/wound, the sterile covers for the patient, the tables for sterile instruments and materials as well as the operating room staff wearing sterile clothing

4 Abbreviated terms

ETA	Extract air
EHA	Exhaust air
BA	Building automation
BIU	Building instrumentation and control
HEPA	High Efficiency Particulate Air filter, air filter group in accordance with EN 1822-1
CFU	Colony forming unit
MIS	Minimally invasive surgery
UEPF	Upper edge of prefabricated floor
OR	Operating room
QM	Quality management
VAC (system)	Ventilation and air-conditioning (system)
LTF	Low-turbulence flow
Tu	Turbulence degree/level
RKI	Robert Koch Institute, Berlin

5 General requirements

5.1 Basic principles

In addition to good training, organization, and discipline of the medical and technical staff, scrupulous attention to hygiene calls for the hospital and its facilities to be designed and constructed accordingly. This should be considered in the planning, construction, operation, and servicing of the VAC system.

On account of the great variety of requirements a hygienist is to be involved during the entire planning and construction process of new buildings, re-buildings, and expansions.

The requirements for ventilation and air-conditioning systems given in this TR are minimum requirements. Higher requirements are possible, e.g. for medical, operation/organizational or technical reasons.

Any deviation from a standard should be agreed upon between the client, the hygienist, and the VAC-consultant and be kept on file together with a detailed justification. This agreement should be enclosed when filing the application for approval of the relevant health care supervisory authority and be brought to the knowledge of the company installing the VAC system once the approval has been granted.

The need for VAC systems is mainly determined by the following criteria:

— hospital specific indoor air hygiene as contributing to reducing the concentration of microorganisms and particle charges;

— ensuring the physiology/comfort including the management of thermal loads;

— reduction of the content of harmful, toxic gases and annoying odours;

— compensation for unfavourable external conditions (e.g. highly polluted outdoor air, high humidity loads, high sound pressure levels outside, strong wind loads in the case of exposed locations (great building height));

— compensation for unfavourable internal conditions (e.g. unopenable windows, internal rooms, rooms of great spatial depth, application of radioactive substances).

5.2 Guidance on planning, construction, and operation

In order to take account of the high requirements for planning, construction, and operation of VAC systems in medical facilities it is required for all the people participating in the project (user, VAC-consultant, installer, hygienist, building manager, etc.) to be involved in an appropriate manner as early as in the design phase of the planning process and to have the same information at their disposal.

With project development for the health care services it is important at first to determine the demand based on current and future obligatory user provisions in the form of a project performance specification-paper.

With interdisciplinary planning projects it is of great importance to ensure that the individual planning and decision making steps are executed in a strictly structured manner and that they are documented accordingly. A structured approach is therefore recommended in Annex A.

6 Classification of rooms used for medical purposes (room classes) and ventilation concepts

6.1 Room classes

Rooms used for medical purposes are divided according to the required low level of germs (hygiene requirements) into the following room classes:

— room class H1a (LTF with a protection field for the operating field and instrument tables (≥ 9 m^2);

— room class H1b (LTF with a reduced protection field (< 9 m^2));

— room class H1c (turbulent mixed flow);

— room class H2 (protective isolation, patients with a risk of infection);

— room class H3 (source isolation, infectious patients);

— room class H3a: H-13 extract air filter (e.g. multi-resistant tuberculosis);

— room class H3b: H-13 supply air filter and extract air filter (e.g. Lassa fever);

— room class H3c: e.g. radio-nuclides (see other bodies of rules and regulations);

— room class H4: other rooms used for medical purposes.

Rooms and areas of room classes H1, H2, and H3 should always be equipped with mechanical ventilation systems.

Rooms and areas of room class H4 should only be equipped with mechanical ventilation systems if requirements in accordance with 5.1 apply or if a compensation of the air volume balance is required or if natural ventilation is not possible.

6.2 Ventilation concepts and requirements

6.2.1 Air filtering

Technical measures can contribute to reduce germ-concentrations in the air. Therefore, the supply air should be treated by means of filters for suspended matter to be installed.

— room classes H1 and H2: supply air: 3 filtration stages, extract air: 1 filtration stage;

— room classes H3 and H4 supply air: 2 filtration stages, extract air: 1 filtration stage.

For separating particulate contaminations, including microorganisms, a multi-stage supply air filtration is required equivalent to the following filter classes:

— 1st filtration stage: filter class F7;

— 2nd filtration stage: filter class F9;

— 3rd filtration stage: filter class H13 for suspended matter.

For the extract air from class H3 rooms, it can, in addition, be necessary to install suspended matter and/or sorption filters.

If, for technical reasons (e.g. to protect heat-recovery systems), a filtration of the extract air is required, then this should correspond to at least equivalent to F5.

6.2.2 Ventilation concepts

6.2.2.1 Concepts for operating rooms, H1

6.2.2.1.1 General

The objective of all protective measures in connection with surgical interventions is to reduce the risk of post-operative infections and particle contamination of the wound. This risk is subject to great variation dependent on the nature of the surgical intervention.

In order to achieve this, measures can be of support such as the consistent application of dynamic shielding of the protected area by low-turbulence flow (LTF) and of the operating room by directional over-flow into the adjoining rooms connected by doors. Using these measures prevents contaminations from the surroundings from entering the operating room and the protected area. Outside the operating room the ventilation using high air flow rates and extensive filter technology for suspended matter can be omitted.

In the context of planning, the surgeon should specify in writing the intended utilization of the operating unit with detailed information regarding the types of operations (e.g. implantation of alloplastic materials), duration of the operations to be performed, dimensions and number of the operating field(s) as well as numbers and positioning of operating tables or columns, and dimensions and positioning of the instrument tables. Based on these data the hygienist then specifies the room classes and the air duct systems to be used.

Sterile instruments should be prepared under hygienic conditions equal to those prevailing in the course of the subsequent operation.

Version A: *It is permitted to reduce the air flow rate during periods when the operating room is not used although flow reversal should then be excluded.*

Version B: *When not in use (no person present in the room), the ventilation systems as well as the associated adjoining rooms supplied with over-flow air may be shut down. However, it is to be ensured that*

the ventilation and air-conditioning systems are allowed sufficient lead time to be reactivated before being used again (at least 30 min).

6.2.2.1.2 Concepts H1a

Operating rooms supplied by systems with low-turbulence flow (LTF) in order to obtain a protected area that includes operating field(s), instrument tables with sterile goods lying open as well as the operating room surgical team wearing sterile clothing.

LTF systems entire protected areas are characterized by the following:

— a minimum level air velocity for an stabilized LTF;

— a (defined) supply air temperature that is lower than the resulting indoor air temperature;

— a vertical inflow into the protected area via filters;

— taking into account the effects of potential disturbing factors (e.g. operating lamps and satellites, ceiling mounted units (support arms and equipment racks), monitors, (floor-) heating systems, etc.).

In operational practice protected areas of approximately 9 m^2 (e.g. 3 m $\times$ 3 m), usually achieved by LTF plenum of 3,2 m $\times$ 3,2 m have proven themselves to be sufficiently dimensioned standard areas.

Additional it may be necessary to stabilize the LTF by solid flow-barrier (e.g. glas).

However, already at the planning stage the dimensioning requires a differentiated analysis of the space required for the protected area (positioning analysis).

On account of the great number of possible factors influencing and / or affecting the effectiveness of LTF systems a system test in accordance with C.2 is recommended. By this test the performance of the air duct system within the context of the operating room is made transparent for users, VAC-consultant, hygienists, and the relevant authorities, thus enabling a basis for further planning to be obtained in addition to the manufacturer's information.

The aforementioned potential disturbing factors should be considered very carefully in cooperation with the hygienist and the VAC-consultant taking into account that fulfilment of the respective requirements is to be ensured. In any case the protection effect shall be demonstrated (C.3 or C.4 or C.5).

Operating rooms of class H1a are recommended, e.g. for the following operations and special requirements:

— orthopaedic and trauma surgery (e.g. on bones and large joints with implantation of foreign material, polytrauma);

— neurosurgery (e.g. at the spinal column);

— thoracic surgery (e.g. opening the sternum);

— transplantations (e.g. of whole organs);

— interdisciplinary use of the operating room;

— cardiac and/or vascular surgery (e.g. vascular prostheses);

— gynaecology (e.g. breast prostheses);

— general surgery (e.g. hernia net implants);

— operations with a duration of several hours (e.g. tumour operations with large operation field);

— operations with time sums (of approximate duration, storage time of openly arranged instruments, and incision-to-suture time), which ensure low levels of germ/particle in the protected area exposure only under LTF plenums.

6.2.2.1.3 Concepts H1b

By means of a LTF plenum of smaller size a protected area reduced to < 9 m^2 can be marked off within these operating rooms. Class H1b operating rooms are used for operations that do not require to be carried out in rooms of class H1a.

This can be the case in special clinics performing operations of a clear-cut catalogue of indications.

6.2.2.1.4 Concepts H1c

For these operating rooms with mixed flow it is not possible to mark off a defined protected area. Operating rooms of the room class H1c are used for operations such as:

— inserting small implants (e.g. coronar stents);

— invasive angiography;

— heart catheterizing.

Class H1c operating rooms should be operated with overpressure.

In order to prevent germs and particles from being transmitted through the air when opening an OR door and entering the operating room during an operation, the construction should comprise an air lock. Such air lock-type rooms can be patient preparation rooms or rest rooms, etc. The locking function can be achieved directly (by supply air connection) or indirectly (by over-flow from the operating room).

Operating rooms of class H1c should not be connected directly to any corridors by doors.

6.2.2.2 Concepts for patients with a risk of infection, H2

This room class comprises rooms for patients with a risk of infection requiring protective isolation / sterile care. The main risk as far as airborne germs are concerned is caused by Aspergillus spores.

Room class H2 can be required for patients before and after bone marrow transplantations.

These patient rooms have an anteroom serving as an air lock (of approximately 10 m^2) and they show an overpressure compared with the air lock. Furthermore, the air lock is of high pressure compared to all adjacent rooms.

The use of LTF plenum outside the operating area has led to a significant reduction of the infection frequency only for certain purpose (e.g. burning patients).

6.2.2.3 Concepts for infectious patients and source isolation, H3

This room class comprises rooms for infectious patients as well as rooms in which health-threatening substances can be released. Due to the aerogen transmission path a source isolation is required.

With these rooms, the primary focus is on the protection of staff and third parties. Therefore, contaminated air from these rooms should not be released into the surroundings.