TECNAIR LV
SURGICAL ROOM AIR CONDITIONING

Air Ceiling
Unidirectional Filtering Ceiling

Lifeline

Air Ceiling
Unidirectional filtering ceiling for surgical rooms

EVOLUTION OF THE NORMS

Current Norms

The current Norms for surgical room air conditioning require:

- A lot of fresh air, from 6 to 20 volumes per hour according to each Country's local Norm, to reduce the contamination due to the anaesthetic gasses.

- Absolute filtration of fresh air, to eliminate bacteriological contamination coming from the external environments.

- Overpressure of the room in respect to the surrounding environments, to eliminate the bacteriological contamination coming from them.

Actual tendency

The tendency of surgical room air conditioning sees the use, more and more often, of unidirectional filtering ceiling systems, usually called "laminar ceilings". This comes from the request to have inside the surgical room an ISO 5 air quality class, according to the Norm ISO 14644. Practically, instead of launching sterile air inside the contaminated one and therefore gradually reducing the contamination by dilution, the new strategy is based on a dynamic protection focussing on the "aseptic nucleus" which includes the OP-table, the cloths of the OP-team and all instrument- and sterile material tables. This creates a sterile "piston" of perfectly clean air which comes down from the absolute filters at low speed so not to create any turbulence. This therefore allows for the certainty that the air is free from any form of particulate, at least inside the aseptic nucleus.

TÜV SÜDDEUTSCHLAND Hygiene according to DIN 1946-4

TÜV SÜDDEUTSCHLAND EN 1886:1998

ICIM

Advantages of ISO 5 rooms compared with ISO 7

The advantages of this solution are the following:

- Certainty that the particulate, possible vector of virological or bacteriological contamination, cannot come in contact with the wound or with the surgical instruments, and therefore giving the best protection to the patient.

- Unlike ambient overpressure, which is forecasted by the traditional systems and depends from the closing of the doors, the dynamic overpressure of the aseptic nucleus is independent from the closing of the doors and therefore grants more certainty of the continuous protection.

- Faster “Recovery time” of the room. This means that the time span necessary after each operation, in which the system dilutes the contamination present in the OT so to go back to the class of air quality required, becomes much shorter, therefore granting more possibilities to use the OT. The recovery time comes down from approximately 15 minutes with turbulent air flow systems (ISO 7) to just a few seconds for OT with unidirectional distribution systems (ISO 5).

- The diffusion of air at low speeds on all the filtering surface and at slightly lower temperature (approximately 2°C) than the ambient one, assures a high comfort level to the operator, much higher than with a turbulent air flow system which is often characterised by unpleasant air flows at low temperature and high speeds.

- Higher flexibility of the room. In some Hospitals the two different room classes already exist, and therefore there is the risk that an extremely urgent operation of high specialisation cannot be performed as the ISO 5 class room is not free whilst the ISO 7 one is.

New Norms

All these motivations have pushed many European Countries to update their Norms and raise the air quality level, in the surgical room from ISO 7 to ISO 5 class.

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THE PROJECT ACCORDING TO ISO 5

Main design criteria

It is known that the main design criteria's for surgical operating theatres able to achieve such a high class of air quality are:

Main design criteria

Operation type	Air quality class	Necessary Air flow	Terminal filter	Distribution
Generic Surgery	ISO 7	20 vol/h	H 13	Turbolent
Specific Surgery	ISO 5	250 vol/h	H 14	Unidirectional

To arrive to this ISO 5 class it is necessary that air follows an unidirectional flow. To obtain this type of flow it is necessary that air speed out from the terminal filters is between 0,20 and 0,40 m/s since beneath it we cannot be sure that the flow is unidirectional, while above it the operating costs would rise too much. The logic which takes to such an high air flow comes from the necessity of noticeably raising the air volume so that air passes as often as possible through the absolute filters. Each form of turbulence has to be carefully avoided so that air doesn't bring any form of contamination into the critical zone. In order to achieve this flow it becomes necessary that the launched air from the terminal filters has a speed between 0,22 and 0,40 m/s. Below this speed we don't have any certainty that the air flow is unidirectional, especially during winter period when temperature of supplied air is very close to the one of the room and therefore would tend to stratify on top not arriving to protecting the patient and his wound. A too low air flow would also bring, due to the necessity to eliminating the endogenous heat load, to a difference in temperature with the room which would be too high and therefore disturbing for the surgical team.

Aseptic nucleus dimensions

It is obviously necessary to reduce as much as possible the super controlled area for obvious reasons of energy saving. The most evolved Norms define the "aseptic nucleus" as an area of 3,0 meters by 3,0 inside of which the surgical bed, the surgeon, and the instruments table are inside. This aseptic nucleus is maintained in an ISO 5 class; outside of it the ISO 7 class is accepted. To obtain this protection it is necessary that the filtering ceiling is of a bigger dimensions; it has been therefore concluded that the optimal dimensions of the ceilings have to be a bit bigger measuring 3,2 m by 3,2 m.

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Possibility of Recirculation

The ceiling normally has a net area of around 10 m2. With an average speed of 0,26 m/s we obtain at least 2,6 m3/s. In one hour we have approximately 9.200 m3/h.

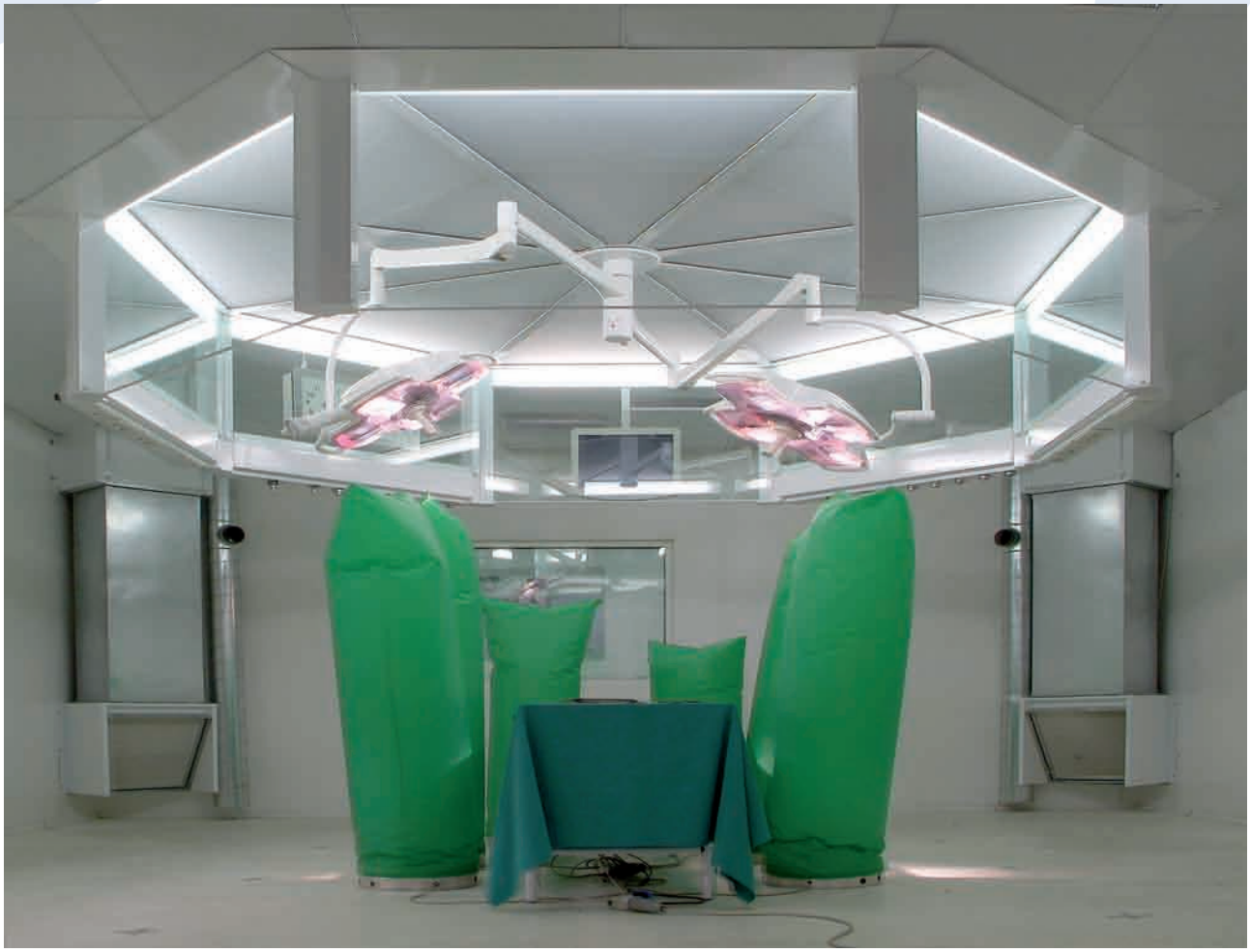
This huge air flow cannot be totally of fresh air and it is necessary to heavily use recirculation limiting the fresh air flow, necessary to dilute the chemical contamination from the anaesthetic gasses, to the one requested by the local Norms (normally not more than 1.500-2.000 m3/h).

The Norms allow for recirculation under 3 conditions:

1. re-circulation must be done in one single room. It is therefore not allowed to mix air from different rooms.

2. the re-circulated air must have, at least in the second filter stage (F9) and in the terminal one (H14), the same filtration efficiency of the external one.

3. the SPL at the centre of the room and at 1,7 m height, must not be higher than 48 dB(A).



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TECNAIR LV CEILING TECHNICAL CHARACTERISTICS

Necessary air flow

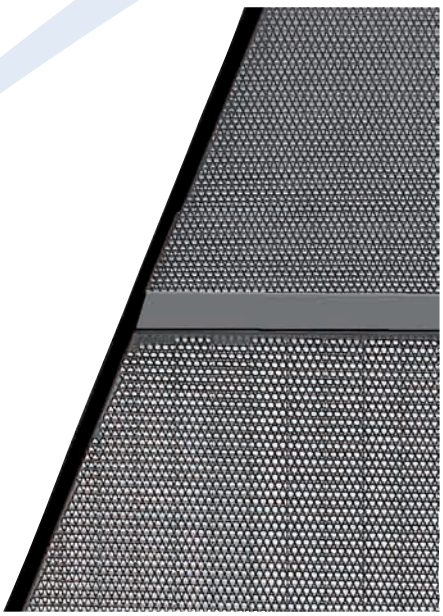
The costs of running an unidirectional ceiling is strongly related to the air flow, and therefore to the surface of the ceiling itself. Tecnair LV proposes an octagonal ceiling instead of square, so to eliminate the protection on the angles where there is no need for. The total surface of the ceiling therefore is smaller by approximately 20%. In regards to this the necessary air flow goes down to around 6.900 m3/h.

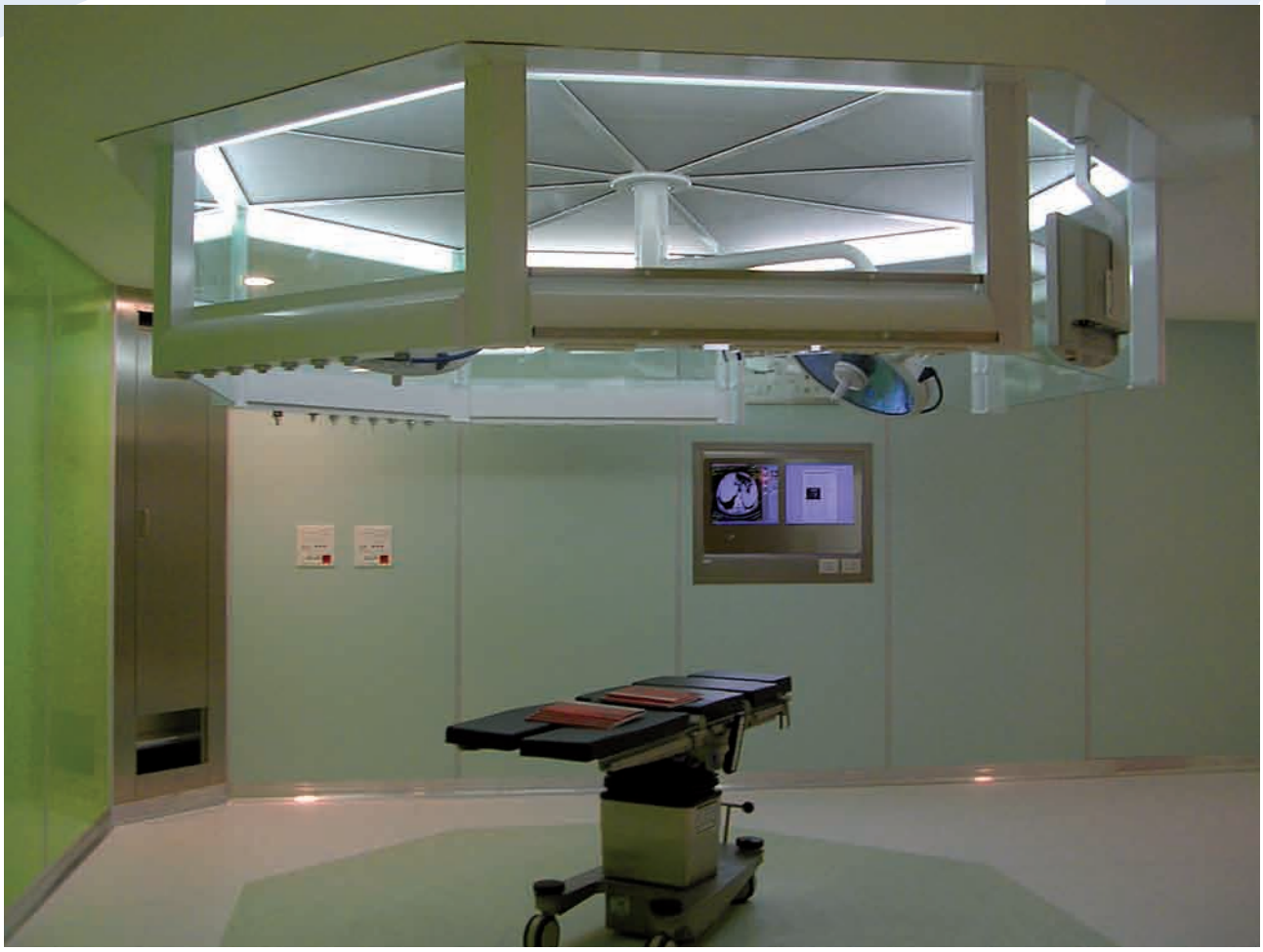
Trapezoidal absolute filters

All the Tecnair LV laminar ceilings have an octagonal shape 3,2 m by 3,2 m; there are 8 filters with efficiency H14 and their shape is trapezoidal. The absolute filters have a double density; greater in the centre of the ceiling so to have a higher speed and therefore guaranty a better effect of expulsion of the contamination from the aseptic nucleus. With the same filtering ceiling area the trapezoidal filters have a covered area greater by approximately 20% than the traditional standard rectangular filters. This shape also allows to reduce to the minimum the necessary space for the scialitic lamp connection, therefore allowing for more air in the centre. We also emphasis that with traditional rectangular shaped filters one central filter of size 600 x 600 mm has to be not installed so to allow for the installation of the scialitic lamp. This central area is exactly where the most air is needed as this is where the most sterile air level is demanded. We can therefore state that with our solution the pressure loss, the absorbed current and the noise level are all lower by approximately 30% than in a traditional solution.

Plenum for air distribution

Trapezoidal filters are equipped with a system to guaranty that air drops in a circular crown around the filters in case of air leakage from the gaskets around the filtering section. Keeping the crown in depression using the re-suction fans,allows for evacuation of the air wich bypassed the HEPA filter. Above the filters there's a galvanised steal plenum (accessory: stainless steel) for an optimal distribution of the primary air coming from the air conditioner and the re-circulated one coming from the ceiling. The connections are riveted and sealed. Under the filters there's a perfectly sterilisable lamination system in micro-holed tissue. At the centre of the octagon the scialitic lamp connection is foreseen.





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Crystal curtains

The lateral crystal curtains of the ceiling come down to 2,1 metres in height from the floor so to guaranty the side containment of the air, whilst not disturbing the surgeons during the operation. In case this wasn't installed the air flow would risk opening on the side and air flow losing speed therefore reducing the effect of expulsion of the endogenous contamination (of the patient and the surgeon). The curtains are in stratified crystal and guaranty the maximum security of non-breaking without limiting the surgeons visual range. The curtains also have lights installed in the side crystal curtains of the lamination system which give a magnificent indirect light effect in the operation field.

Media bridge (accessory)

The crystal curtains for containing the air come down to a height of 2,1 meters from the ground (2 meters if needed) therefore not allowing for the installation of normal pendants for the surgeon and the anaesthetists. Tecnair LV therefore forecasts the installation at the lower edge of crystal curtains of eight horizontal media bridges, four equipped with electrical connections and four for the gasses, each one completely independent from the other. The media bridges for electrical power can have each eight electrical plugs individually protected and with a led to indicate the presence of tension, two for earth connections and two for data transmission. The media bridges can incorporate also a system of guides for the suspension and movement of trolleys and supports which can sustain a weight of up to 80 kg and have a system to fix further protective tends in plastic material which can come down to 1,2 meters of height and can be applied for extremely delicate operations on the side not used for the surgical activity.

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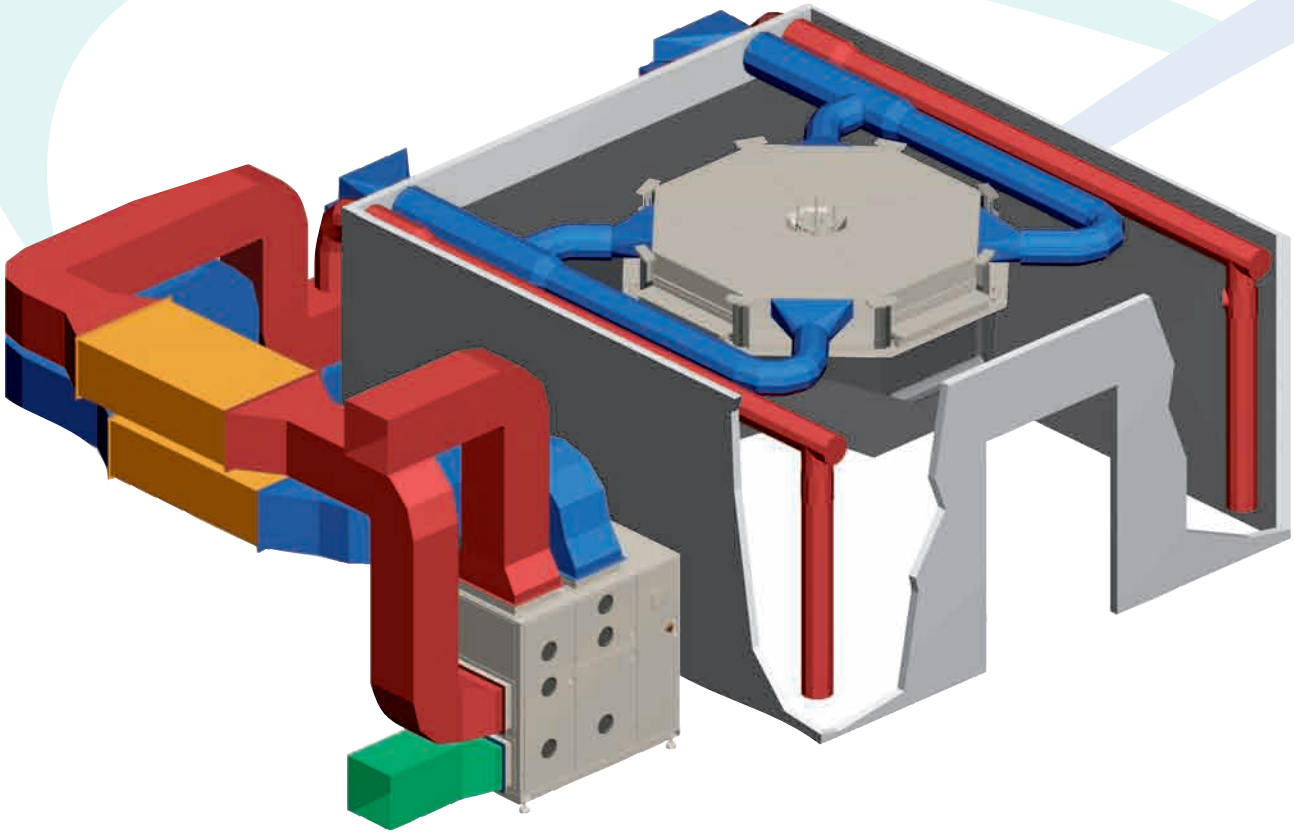
SYSTEM SOLUTIONS

To have a surgical room in class ISO 5 the system must work with very high air flows and recirculation is necessary. For this reason two system solutions exist, each differentiating itself by the way how recirculation is made.

Static Ceilings

The easiest solution is to bring back all the air flow to the air conditioner, expel a part of it, take the needed fresh air, recirculate in the unit and use the static laminar ceiling.

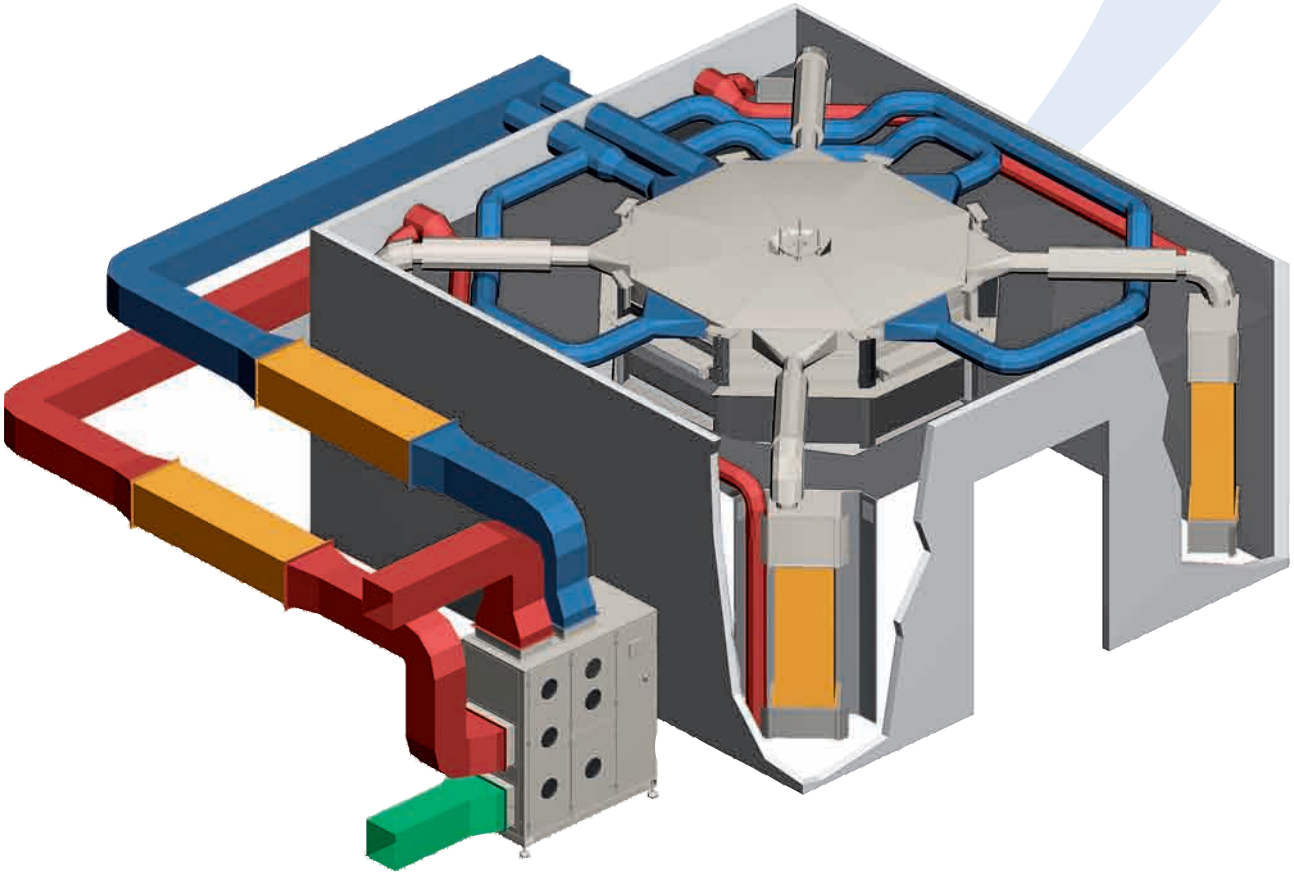
This solution, mandatory for brand new buildings, unfortunately often becomes extremely unrealistic with the reality of many Hospitals which foresees, especially for rooms to be restructured, areas for the ducts insufficient to bring back to the air conditioner all the air flow. To clarify this we emphasis that for 6.900 m3/h the necessary ducts (two: supply and suction) have dimensions of approximately 800 x 500 each.



Ventilated Ceilings

For installations where these duct dimensions are not compatible, Tecnair LV proposes the octagonal ceiling even in it's ventilated version with fans, so to allow for an efficient recirculation inside the surgical room. Innovative characteristic is the installation of the four fans for recirculation in the corners of the room, with ducts which house F9 efficiency filters and two large sound dampers able to lower by about 15 dB(A) the sound pressure level. By sucking the air at the floor level, unlike from the ceiling as many other laminar ceilings solutions on the market do, we do not disturb the unidirectional flow and don't reduce the protection to the patient.
The recirculation fans are installed in the corners of the surgical room and are connected by ducts downstream an F9 suction filter installed in the lower part of the room. The fans have an air flow of approximately 1.000 m3/h, each one with it's own electronic regulation integrated so to guaranty a constant air flow even in case of filter clogging.

Adding it up to the fresh air flow coming from the unit (approximately 2000- 2500 m3/h) this local recirculation system allows for achieving the necessary air flow. In case one of the fans was to break down the non return damper will guaranty that air cannot come back or return in the room. The presence of sound dampers allows to reduce by approximately 15 dB(A) the sound level generated in the room therefore allowing for a greater level of comfort for the surgical team. Finally by sucking the air at floor level, instead of ceiling level as done in the majority of ventilated ceilings, we are able not to disturb the unidirectional air flow therefore reducing the efficiency and protection of the patient



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BESTÄTIGUNG
CONFIRMATION

Nr./No. 002-2 RLT-E
Short Summary

Prüfstelle **Testing station**	**TÜV SÜD Industrie Service GmbH** **Center of Competence für**
Kälte-und Klimatechnik **Klima-und Lufttechnik** **Laboratorium für Kälte-und Klimatechnik**	
Prüfgegenstand **Test unit**	**Operationsdeckensystem mit turbolenzarmer Strömung** **Ausführungsart: TAV-System** **Air-supply ceiling with unilateral air flow** **Type of construction: TAV-System**
Auftraggeber **Orderer**	**Tecnair LB s.r.l** **Via Caduti della Liberazione, 53** **21040 Uboldo - Varese** **Italy**
Auftragsumfang **Scope of the order**	**Dichtheitsprüfung und Partikelmessung** **Ermittlung Partikelabscheidegrad und Schutzgradwirkung** **Leakage test and measuring of the particle concentration** **Determination of the particle separation efficiency and protective effect**
Prüfzeitraum **Date of testing**	**24.05.2005**
Prüfort **Place of test**	**Uboldo - Italy**
Grunlage	**TÜV-Report 002 RLT - E. dated 23.06.2005**

Basic of Confirmation
Conceptual formulation

The task of this test was to prove the operability of the air-suplpy ceiling and the determination of the protection class. The detailed results are written down in TÜV SÜD Report 002 RLT - E dated 23.06.2005.

The tests on the prototype have been finished with the following results:
1. The measurement of the separation affectivity on the new prototype design, first version of the air-supply ceiling, fulfils the requirement cnocerning the leakage.
2. Particle measurement according to draft VDI 2167 did not reached in first routine the required class 4.
3. To go ahead with tests, the decision was made to modify the Dummies. Flexible tube of the Dummies were replaced by aluminium foil with a thickness of 1mm and provisorily clo sed on the top similar to a collapsible tube.

Temperature inside the room after the modification of the Dummies:
Inside the unilateral air flow: 20,0 °C
Outside the unilateral air flow: 20,3 °C

The function of the unilateral air flow ceiling has to be assured trough a sufficientlarge temperature difference between the save area and the room within a spectra of ΔT from 0.5 to 3 K. In the case under consideration a temperature difference of 0.3 K was determined. Normally at least a temeprature difference of 1-2 K is necessary.
This edge conditions were not fullfilled by the existing experimental set-up.
4. The final test of the particle measurement, after all optimisation are given under optimal conditions; the prototype of unilateral air flow ceiling has protection class 4.4.
5. The previous command variable is an constant overpressure of 33 Pa inside the surgical room is not useful.
6. In the area of the unilateral air lfow ceiling actually slightest or no particles could be measured. The function of the ceiling according to draft DIN 1946-4 is fullfilled in principle.
7. The requirement of turbulent current ≤5% if fullfilled.
8. The hermetically sealed ending is coercible necessary, because in fact of eventually possible leakage on the filter sealing, this leakage will be sucked off with under pressure over a kind of hollow space around the filters frames.
This is amajor design feature of the complete system.

Center of Competence for
Refrigeration and Air Conditioning
Bernhard Schrempf

Expert for
Air Conditioning and Air flow Systems
Hermann Reif

CESI

Vs. rif.

Ns. rif. SRN-A6014841

Data Seriate, 30-mag-2006

Spettabile
TECNAIR S.r.l.
alla c.a. Ing. Almento
Via Caduti della Liberazione, 53
21040 UBOLDO VA

OBJECT: Seismic tests on a TECNAIR Air Ceiling.

In days November, 21 th - 25 th seismic tests on a TECNAIR Air Ceiling Unit have been performed in LPS laboratory of CESI - Seriate (BG).

Target of the test was to verify the dynamic behaviour of the unit during a possible earthquake assessing a reasonable experimental safety margin. Tests were made with reference to EN 1998-1 *"Eurocode 8 - Design of structures for earthquale resistance"*, december 2004 an to IEC Publication 60068-2-57, 1995 "Environmental Testing Part 2: Tests method. Test Ff: Vibration - Timehistory method".

The experimental activity includes:

dynamic tests for *critical frequencies evaluation*
triaxial multifrequancial seismic tests
static tests for *stiffness evaluation and deformation capacity*

During the tests no evident mechanical failure was detected on the unit, final and functional tests are of competence of TECNAIR.

Best regards

CESI
Centro Elettrotecnico Sperimentale Italiano
Giacinto Motta SpA
Business Unit SRN

Il Responsabile: Gualtiero Baldi

GP/nl

Mod. LETT v. 03

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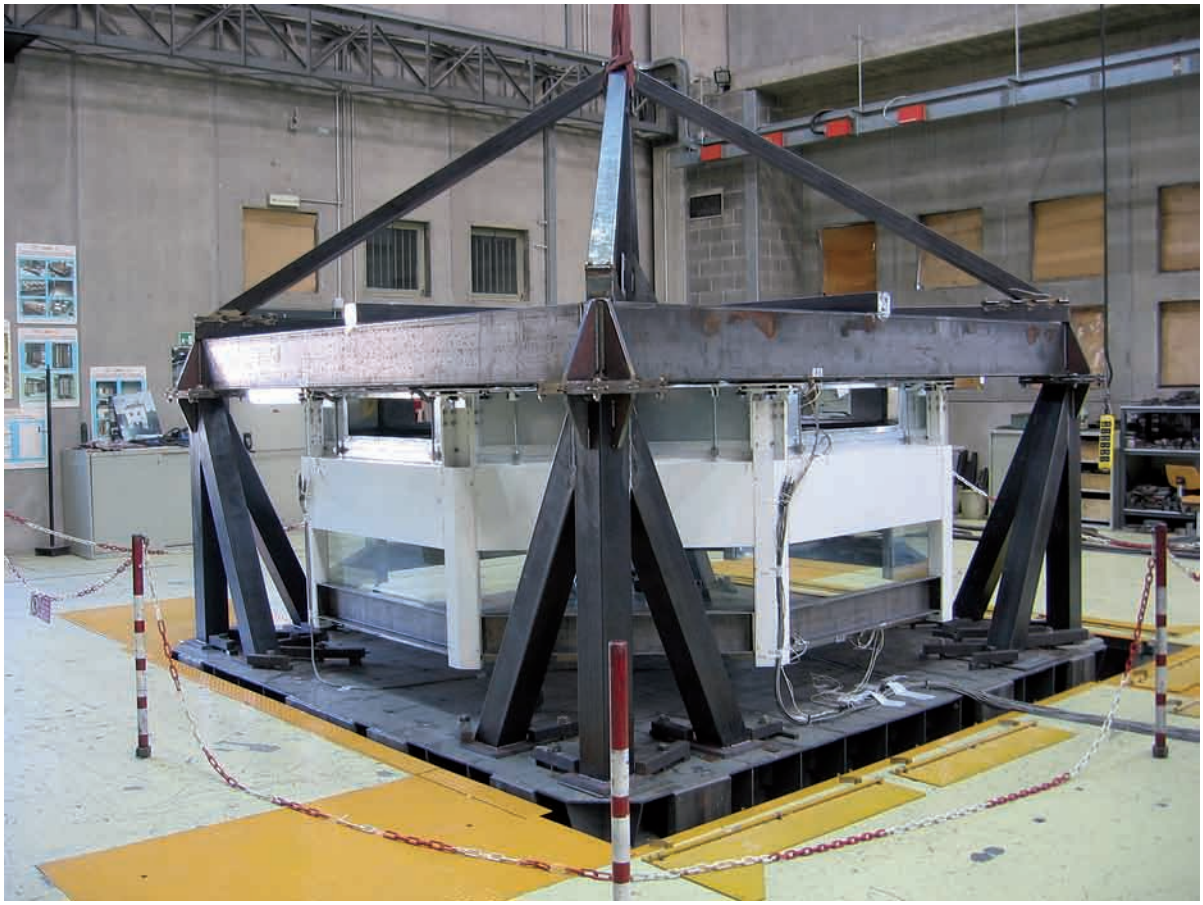
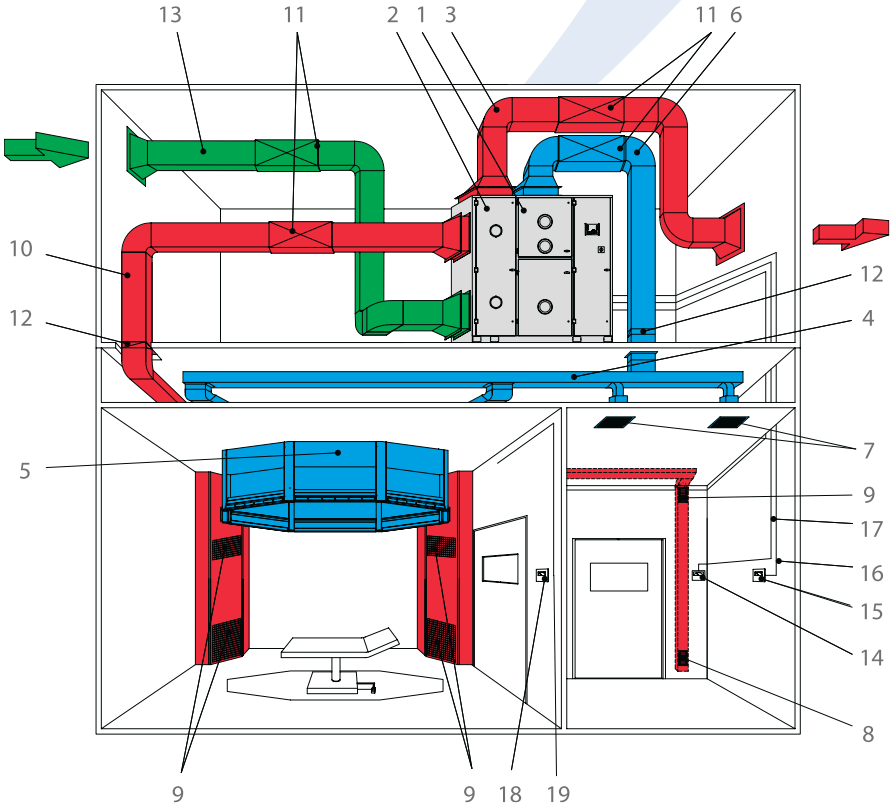


H Series
Surgical room air conditioners

1 Supply fan
2 Exaust fan
3 Exaust duct
4 Electric or water reheating coil
5 Unidirectional filtering ceiling
6 Supply air duct
(thermally insulated)
7 Air diffuser with absolute filter
8 Lower filtered air intake (G4)
9 Higher filtered air intake (G4)
10 Air suction duct
11 Sound damper (hospital type)
12 Cut fire damper
13 Fresh air intake duct
14 Differential pressostat supplied loose
15 Interface for remote control (accessory)
16 Telephonic cable for remote interface
(6 wires, max 100m)
17 Shielded cable for remote
presostat (3x0.5 50m. max)
18 Temperature and humidity feeler
(supplied loose)
19 Connecting cable between
the feeler and the unit (6x0.5m max)



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