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A critical regard on Romanian regulations related to Indoor Environment Quality in Operating Rooms and a technical case study

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Abstract

Several areas from medical facilities, especially the critical areas such as operating theaters, postoperative rooms, anesthesia and intensive care rooms, require ventilation and air treatment systems to achieve a well controlled microclimate. This fact is indispensable, given the current technological evolution.

This article describes solutions for HVAC systems that can be implemented in accordance with the law regulating this field and makes a brief introduction to the norms and the current situation in Romania. The article also provides some technical solutions that can be applied or should be applied to HVAC systems destined for hospitals located in Romania, giving as example a case study. The technical solutions can be also applied to other areas, in accordance with local regulations, the needs of those areas and in accordance with the climate of the zone.

All the ideas and suggestions come as a result of studies made over the current situation of the norms (national and international) that are referring at the situation of the clean rooms in the medical sector, combined with research articles and guides from all over the world.

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1. Introduction

It is well known that many spaces from medical units require maintaining a good Indoor Environment Quality (IEQ) [1]. The need for a highly controlled microclimate comes from the perspective of achieving an aseptic environment to prevent infections, due to multi-resistant (MDR) germs [2]. Beside the desire to achieve an aseptic environment, according to the needs of the room, it is necessary to achieve the comfort for a good development of human activity in that sector [3]. The areas from the medical facilities that require having a very well controlled microclimate for hygienic reasons, for the prevention of infections, but also for achieving comfortable conditions for the activity of medical personnel and patients are: operating rooms (OR), postoperative rooms (POR) and intensive care unit (ICU). A hospital OR is one of the most complex indoor spaces in terms of usage purposes. If for the OR, a very well controlled microclimate helps to conduct in optimal conditions the activity of the personnel and prevents infection during surgery with MDR germs, for POR and ICU, it helps to accelerate the healing and to prevent the infections [2].

IEQ refers generally to the quality of an occupied space in relation to the health and well being of its users. IEQ is determined by multiple parameters from which the most important are Indoor Air quality and thermal comfort, In accordance with ASHRAE 55 [4] or EN ISO 7730 [5] standards, the IEQ of a space is determined by the level of indoor air pollution and other features, including the air temperature, the relative humidity or the air speed. In terms of thermal comfort, the parameters which must be taken into account are the air temperature, the mean radiant temperature, the air relative humidity, the speed of air in the occupied zone [5]. When we refer to the aseptic criteria [6-8], the parameters are the optimal air change rate, producing and maintaining overpressure in the room and the number of steps of filtration and the filtration classes. The air turbulence and the air circulation through the room influence both the conditions of thermal comfort, as well as the aseptic criteria [8]. Of course, there are other important aspects that go together with the ones mentioned and produce the optimal indoor conditions such as: lighting, noise pollution, the load of equipment with specific devices in the considered room, and so on.

This article will refer mainly on the aspects related to thermal comfort and to criteria that are necessary in order to attain the degree of hygiene in critical areas of health units.

The Romanian norm and guideline that regulate the area of Heating Ventilating and Air Conditioning (HVAC) for clean rooms are respectively NP-015 [6] and C 253/1-94 [9]. Both are outdated, from 1997 and respectively from 1994, and unreviewed. The guideline C 253/1-94 was the first Romanian standard in the domain of clean rooms, it was elaborate from the American standard FS - 209D [10], probably the oldest standard in this area. The American standard FS - 209D was first published in 1963 and revised several times until it was replaced by the series ISO
The standard NP-015 [6], is newer and it has as direct target the medical field and everything in it (space planning, buildings and related systems and services). Both classify clean rooms depending on their destination. If C 253/1-94 [9] proposes a classification of hospital zones in 6 categories a by the "maximum number of particles per cubic meter (0,028 m³)", in NP-015 the classification is done in 4 categories called "classes of rooms" and in this case it refers to "the absence of germs (pathogens)" (10 germ/m³ and below 200 germ / m³). Regarding the thermal conditions, there is no significant disagreement between the two and, sometimes, can be considered as a complementary on certain topics.

One of the most stringent problem in our national health system is that even in our days, the majority of hospitals in Romania do not have properly designed ventilation and air treatment systems in critical areas or there is a total lack of systems and services of such kind (Fig. 1). Some of those medical units are poorly equipped in terms of medical devices, the interior design in some areas promotes favourable conditions for the breeding of germs. One particular problem is the one of the presence of windows that opens directly outdoors in OR and other critical areas like ICU and POR.

According to some studies, nosocomial infections represent an important cause of death and, in certain branches of medicine such as general surgery, it can reach a rate of 75% from the total cases of the number of postoperative deaths [12].

2. Design of HVAC systems for critical areas in hospitals

Generally, designing HVAC systems that are destined to service medical clean rooms brings a higher degree of complexity. In designing of such installations it must be taken into account the specification of the rooms which will be treated and the local standards governing this domain. It is noted that the rules governing this field suggest fresh air flow rates much higher than those resulting from heat and humidity loads calculations, and this can be explained only from air purity reasons. The fulfilment of the hygiene conditions for the chosen equipment is also imperious, and if it is not complied, this could have serious consequences on the people in that ventilated area. Hygiene conditions are required for all equipments that are comprsing the ventilation and air handling system, starting with the air handling unit (AHU), continuing with the sound attenuators, the flow regulators, the channel material, finishing with the the air diffusers for air introduction and exhaust and other devices that are involved in air handling and distribution systems. All of them must be water and air tight and composed of materials that cannot produce and support the development of microorganisms.

In general, AHUs for medical environment use have several design elements that offer high quality and reliability. An AHU should have, in general, double cover made in a watertight design, electrostatic painted panels and profiles, stainless steel for internal components, special gaskets EPDM type (ethylene propylene diene monomer), special filters, copper batteries (in general, medical quality copper) with aluminium finned coils and other components. All these components must be easy to clean, resistant to disinfectants and microorganisms. The
components of this kind of AHU are generally several filtration stages, a heat recovery stage, a water heating coil, a water cooling coil, an electric heating coil, a steam humidifier with immersed electrodes and ventilators for discharge and suction. Such an AHU also benefits from automation systems and remote control via internet, automatic dampers on the fresh air intake and on the exhaust (Fig. 2).

The first step filtration is used for the protection of the heat exchangers and heat recovery and usually employs filters of classes type G4 or F7 (efficiency $\varepsilon = 80-90\%$) [14]. In order to avoid aerosol deposition on the air channels, there is a second stage filtration, at the outlet of the AHU, with a class F9 filter ($\varepsilon > 95\%$). The air that will be released in the atmosphere, extracted from the critical rooms, should be filtered before with a F5 type filter ($\varepsilon = 40-60\%$) (see Fig. 2).

The term that is often associated with this type of systems is "hygienic design". The producers of this type of systems must provide conformity certificates that are attesting the hygienic design as well as the reliability of the involved equipment. One such kind of conformity test may be provided for instance by Eurovent, representing the European Committee of HVAC Manufacturers equipment. Also, there may be the mark TÜV which is conducted by a German organization with over 100 years experience in HVAC certification and it is consistent with a standard that regulates this area in several countries [15].

Generally, AHU manufacturers suggest ventilation and treatment of a single area which has the same specific (only OR), or a single OR and it's annexes. This is due to the difficulty of ventilating, with the same AHU, critical and ordinary zones in the same time, maintaining the critical zones in overpressure regime, having good aeraulic parameters in channels and a good function of the system in the other zones. However, in real applications, due to the economical aspects, sometimes the air handling and distribution is performed with the same unit, for both critical zones and for areas with very low degree of aseptic restrictions and microclimate.

When national regulations require functioning at 100% fresh air, like the Romanian norm NP-015[6], the heat recovery system is with intermediate agent circulating between two coils, on the exhaust and on the intake of air. This type of heat recovery system has the advantage of avoiding cross contamination. The intermediate agent is introduced in a closed circuit with water and if the risk of frost is present, glycol is added too. The circuit is composed of a circulation pump, an expansion vessel, gauges and thermometers. However heat recovery systems with intermediate agent have lower efficiency, but they are used in the favour of safety and compliance with the norms.

The idea of using a mixing chamber or the simple recirculation of air is strictly prohibited by certain norms. Nevertheless, this can be implemented in certain situations but only with the rise of filtration stages and classes. An example would be a local recirculation with filters applied both on the air diffusion grilles, as well as on the exhaust grilles, but with a higher retention. Anyway, the minimum hygienic fresh air rate must be respected.

For this type of systems, in order to save electric power, fans must have variable frequency. This is also an advantage in terms of maintaining a constant air flow with the beginning of clogging of the filters by increasing the fan speed to compensate for the pressure loss that is created in the filter.

Chillers that are used in such installations must employ ecological refrigerant, according to the Kyoto protocol. They are used either in direct expansion or with intermediate agent (water and glycol if there is danger of frost). In the absence of specific studies on the possible effects that may have a leakage of refrigerant agent, from the cooling coil with direct expansion in the AHU, and it's circulation to critical areas, the first option of the designer in choosing an equipment with intermediate agent (chillers) with water cooled at 7-12° C. These units must allow adjustment of cooling capacity as needed.

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Fig. 3 – General forms of laminar flow ceilings, rectangular and hexagonal [16]
The air distribution system employs for the channels materials as polyisocyanurate, galvanized or stainless steel. The joints between different pieces of tubing or between channels and equipments must be set so that there are no leaks or they are conform to the norms in force [17]. The channels can be circular or rectangular, the first option can be considered the better one in terms of technical, economic and deposition of particles, but has a major drawback by the fact that requires a larger space for mounting. So, often in buildings that do not benefit from this space, old buildings in general, rectangular channels are used. In designing the route it must be taken into account the aeralic principles, pressure loss and, if using rectangular channels, the optimal ratio of up to 3/1, corresponding to the width / height ratio of the channel. During production and installation of the channels, is recommended to seal with foil the free ends to the channels installed (or that will be installed) to prevent deposition of particles in them. Velocities in the channels must be within the limits of the regulations in use, like 2-4 m/s on secondary branches and 5-8 m/s on the main ones. Thermal isolation of air channels is made of polyuretane or glass wool, depending on the material used to make the channel, the medium through which passes and the needs. All equipment must be provided with visiting space and special devices in order to allow inspection and maintenance.

Fig. 4 – Examples of a) introduction grille with HEPA filter [12], b) Exhaust grilles layout and the percentage of air flow for upper and lower grille

The cleaning of the channels can be done before or after the commissioning. Cleaning, at the moment of commissioning, can be done by starting the AHU in various stages of flow without final filters installed and with the condition that the operation should be performed when rooms are not yet disinfected. Also, for cleaning them, an inspection robot with video camera may be used to verify the necessity. If it is necessary, after inspecting the videos, cleaning and disinfection will be carried out by a robot equipped with cleaning brushes [18].

Introducing air into critical areas is achieved in various flow means, laminar or turbulent, depending on the specific of the room. For the OR are used unidirectional laminar flow ceilings to ensure the appropriate level of hygiene in the work area, the area of intervention for medical personnel. All diffusers for introduction and exhaust of the air should have filters of various retention classes, according to the regulations and necessity. The filters used for introduction are HEPA (H13 or higher) [19] while those used for air evacuation from rooms are the type of F5 ÷ F9 (ε =40-90%) (Fig. 4). General forms of laminar flow ceilings are either rectangular or hexagonal (Fig. 3). This are embedded in the ceiling and placed above the operating table. The air speed in the area has values around 0.20 ÷ 0.45 m/s. Extraction grilles are placed in the four corners of the room, 2 grids on every corner, embedded in the walls. According to NP-015, grilles on the lower level must ensure the evacuation of 75% of the total flow while the upper level the rest of 25% (see Fig. 4). To ensure the overpressure in the OR, flow regulators in a variable air volume (VAV) scheme or in a constant air volume (CAV) will be used so that the overpressure is as the local norm suggested.

3. Case study in a real Romanian hospital building

In this paragraph, we will show some technical solutions adopted in a project that presented a higher degree of complexity due to various problems encountered during it. The presentation will be concise and will not specify the steps taken in the design, but only the relevant issues. Several principle of design are presented here and discussed on some classical solutions. The systems have been designed according to the Romanian guidelines and the air flow
rates were calculated according to them. The project represented in implementing a ventilation and air handling system for 10 OR with annexes like washing instruments rooms and for physicians, POR and hallways. All were at the top floor of the building, the building being an old one (Fig. 5 and 9).

Old buildings usually bring the most issues in the design of such systems because many of them were not constructed to consider these types of installations. The reasons can be diverse, from a weak development of this specific technology in that period, to the fact that there were no studies and data about the hygiene conditions required.

![Architectural plan of the top floor with operating rooms and the annexes](image)

The positioning of the AHU is always close to the areas that are going to be served. Often, the terraces of the hospitals is the first choice, if the space that needs to be vented is on the upper floor. In this situation, the terrace was covered in large part by a helipad and other units that served other areas such as the Emergency Room (ER) (Fig. 6). Another problem was the low height of the structure of the heliport over the terrace of the building and the necessity that all the equipment and channels must be within a certain height. The channels route could not be achieved on the façade because it would have ruined the architectural design, also the possible problems which could occur regarding the urban design norms and not to mention the difficulty in mounting and maintenance.

As solutions, after determining the unoccupied zones on the terrace, they were occupied with compact equipments (AHU), eliminating the idea of AHU wagon type, and reserving space for the use of intermediary agent units (chillers) at 7-12 °C with water and glycol, in the perspective of hygiene safety. Rectangular tubing was used for the circulation of the air.

For introducing the ducts in the areas that were to be ventilated, punctures were achieved through the terraces in to the building, after the approval of the structural engineer. To reduce thrusting section of the terraces, because it was required eight punctures in total, they were designed in circular form with the diameter necessary to maintain optimum speeds. The piece that was needed to make the transition from rectangular to circular and to connect the exterior part of the channel with the interior one, had to provide a good sealing, a good aeraulic conditions and to avoid the reinforcement made by the structural engineer with ‘I’ beams of 20 cm height placed on the inside (Fig. 7). For safety reasons the punctures were made in areas that gave in to the annexes and not directly in critical areas. Also, these areas were chosen because they could go to several rooms with flows of air about equal, as a solution to avoid dimensioning large sizes of the channels that were to cross the ventilated areas (see Fig. 7). With this solution it was achieve a better and shorter route to the most important areas such as OR.
Another factor that required a special strategy was the small indoor free height of the space that needed to be ventilated, 3.1m up to the ceiling and 2.5m to the beams, resulting a free height up to the false ceiling of 2.3m. The air channels used for air distribution were made with a rectangular shapes and were mounted between the beams, respectively the ceiling, and the false ceiling.

To ensure the necessary flow in operating rooms it was chosen mounting the mounting of constant flow regulators or constant air volume (CAV). For the regulation of the overpressure, there were two methods to do it: automatic with VAV regulators on the exhaust channel of the operating room, measuring the pressure difference between room and hallway, or manual by closing the damper on the exhaust after the manual measurements. For the automatic system, the VAV and the CAV must be connected to the AHU and a logical plan must be thought, plan that will also include the fire emergency one. The problems that can occur when choosing an automatic equipment is the compatibility between the equipments and the logical schema to act, when you are ventilating critical and normal areas with the same AHU at the same time, and the problem of space that is, in general, for the old buildings.

Due to the lack of space, but in the acknowledgment that the interior design was rebuilt with antimicrobial metallic panels which were joined very tightly (walls, ceiling, doors, pass through), the overpressure was made with
manual dampers on the exhaust, after measuring the pressure in the room and determined the evacuation flow at that overpressure (see Fig. 8). As for the thermal comfort in non critical areas, areas that could require higher temperatures, it was chosen to mount locally electrical batteries for preheating of air at the temperature needed. The battery is needed to be placed at a decent distance from the air diffuser in order not to affect the filters integrity [20].

The introduction of air in the OR was with unidirectional laminar flow ceiling, with significant size so that it can cover the activity area and to achieve a speed of 0.25 m/s. These have HEPA filters, type H14 (efficiency $\varepsilon=99.995\%$), as a final stage of filtration. The filters that have a higher retention than those specified by local regulations. In the architectural solutions, the ceiling and the metallic walls, it was embedded the laminar flow ceiling with the intake grilles. The AHU have been designed with 100% fresh air and many of the issues expressed in paragraph 2 have been implemented. For economic reasons, during downtime, the rooms can be ventilated only 50% of design flow and the fans are equipped with variable power frequency. In the same perspective, the electric battery located at the end of the treatment process, which is required to be operated summer, is modulated and heats according to needs. Of course, it can also function as the primary backup if the battery with thermal agent does not receive warm water in parameters design. The chillers are also with load regulations according to the needs.

The project was conceived in 4 stages of execution so that the whole activity of the operating block not be compromised. Today the first stages of the project with the first 6 OR, annexes and hallways are in perfect working conditions. Generally, different strategies can be implemented so that the microclimate and the hygiene in the medical areas, especially in critical areas, can be obtained. However, it is misunderstood the fact that an hygienic
type of AHU can be used, and works optimally, for ventilating at the same time rooms with strict and normal hygiene conditions, or for other situations like serving in pressurisation or smoke exhaust. For each situation it is necessary to create a plan of operation that works according to certain principles and with specific types of equipment. The economic aspect has, as in all the cases, the major role. *This project is an example of how delicate spaces like ORs came from unsanitary conditions (Fig. 1) to optimal hygienic conditions and areas where the medical activity can take place in very good microclimate circumstances (Fig. 8).*

4. Conclusion

In order to have a better knowledge about methods of ventilation and air treatment destined for clean rooms in medical units, as there is no complete norm to regulate or a compendium for a clear overview, it is necessary to study all national and international standards for implementing an optimal solution.

At a quick survey of the national and international regulations and guidelines for hospital and in particular for Ors, one could observe a slight lack of coherence between the recommendations especially in terms of indoor air quality and thermal comfort. This is a delicate problem because of the different activity provided in these type of rooms and other spaces and also because of the clothing that is worn. This brings complex problems because medical staff, which do not carry the same intensity as work, is under the same conditions of microclimate and, in some cases, with large differences between them in sense of clothing. We list some examples in this case: surgeon vs. anesthetist, surgeon vs. nurse, surgeon vs. residents and nurse versus residents. In this regard, it should be carried out more comprehensive studies on the conditions necessary for such spaces and for the needs of the people in it, studies that can help to achieve a more complete documentation suitable to the needs of these spaces and the people in these rooms.

In this article we present a case study of a project of rehabilitation of a section of an old Romanian hospital. Generally, different strategies can be implemented so that the microclimate and the hygiene in the medical areas, especially in critical areas, can be obtained. For each situation it is necessary to create a plan of operation that works according to certain principles and with specific types of equipment. The economic aspect has, as in all the cases, the major role. *This project is an example of how delicate spaces like ORs came from unsanitary conditions to optimal hygienic conditions and areas where the medical activity can take place in very good microclimate circumstances.*

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