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Study about Quality of Medical Breathable Compressed Air in Hospitals. Medical Gas Pipeline Systems a Microbiological Approach

Diana-Ioana Bogdan (Petre)[1*], Alexandru Neagu[2], Octavian Niculescu[3], & Iulian Antoniac[4]

1PhD student, Faculty of Materials Science and Engineering, National University of Science & Technology POLITEHNICA Bucharest
2Manager of Department for Testing and Checking the Medical Gas Pipeline Systems, Hospital Technical Solutions SRL Company, Bucharest
3Technical Consultant, Hospital Technical Solutions SRL Company, Bucharest
4Prof., Faculty of Materials Science and Engineering, National University of Science & Technology POLITEHNICA Bucharest

[*]Corresponding author: Diana-Ioana Bogdan (Petre), PhD student, Faculty of Materials Science and Engineering, National University of Science & Technology POLITEHNICA Bucharest.

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Abstract

Medical breathable compressed air is a pharmaceutical product, according to European Pharmacopoeia, that must be dry and free of contaminants. It is administrated through ventilators for mechanical ventilation, incubators, anesthesia ventilators and it is necessary in critical hospital departments, like ICU (Intensive Care Units), ER (emergency Rooms), OR (Operating Rooms), etc. The quality of the compressed air is determined by the level of humidity and the impurities it contains, like oil, other gases, water vapors. Contaminants (impurities) enter the compressed air system from three sources: atmospheric air, the air compressor, distribution pipes. The removal of these contaminants is achieved by passing the compressed air delivered by the compressor station through a drying and filtering equipment. The requirements regarding the purity of medical compressed air are indicated in the ISO 7396-1 and 7396-2 standards and in the European Pharmacopoeia.

The presence of water in the medical air installation is a favorable environment for the development of bacteria. The amount of water vapor that remains in suspension without forming a liquid is determined by the air pressure and temperature.

As the pressure increases, the volume of the gas mass decreases and thus the ability to hold water vapor decreases. There will always be water in the compressed air system, regardless of the type of compressors used. The problem is to remove this amount of water and keep the air pipes dry.

The study compares the microbiological results obtained from two clinical hospitals. We tested the medical breathable compressed air in two points of the installation-at some point, after the bacteriological filters of medical air plant, and at the terminal unit.

Keywords: Medical Breathable Air, Hospitals, Copper Pipelines, Medical Gas Pipeline Systems, Microbiological Characterization.

Introduction

The quality of the compressed air is determined by the level of humidity and the impurities it contains. Contaminants (impurities) enter the compressed air system from three sources:

- atmospheric air
- the air compressor
- distribution pipes

The removal of these contaminants is achieved by passing the compressed air delivered by the compressor station through a drying and filtering equipment.

The requirements regarding the purity of medical compressed air are indicated in the ISO 7396- 1 standard and in the European Pharmacopoeia [1-2].

For Breathable Medical air, the allowed concentrations are as follows:

Table 1: Permissible air concentrations for Breathable Air

Impurities	Limit values
Oxygen:	≥ 20,4 % V/V and ≤ 21,4 % V/V
Oil:	≤ 0,1 mg/m3
Carbon monoxide (CO):	≤ 5 ml/m3
Carbon dioxide (CO2):	≤ 500 ml/m3
Water vapor content:	≤ 67 ml/m3
Sulfur dioxide (SO2):	≤ 1 ml/m3
Nitrogen oxides (NO + NO2):	≤ 2 ml/m3

For Instrumental air, the allowed concentrations are as follows:

Table 2: Allowed Air Concentrations for Instruments

Impurities	Limit values
Oil:	≤ 0,1 mg/m3
Water vapor content:	≤ 67 ml/m3

Water is most often found in compressed air systems and is a major source of problems. The amount of water in the atmosphere is between 2.5 g/m3 and 40 g/m3, depending on climatic conditions.

The moisture in the compressed air supplied by the station can lead to corrosion of the pipes, or if the compressed air station is located far from the hospital and the gas pipes are not insulated, ice can form in winter. It can also enter the ventilators, or in the anesthesia machines where in combination with the anesthetic agent it leads to damage to the vaporizers. The metal parts of the terminal units can also be damaged due to moisture [3].

Furthermore, the presence of water in the medical air system also constitutes a favorable environment for the development of bacteria. It was found in the case of certain ventilated patients that they became ill with Pseudomonas bacteria [4].

The amount of water vapor that remains suspended without forming a liquid is determined by the pressure and temperature of the air.

As the pressure increases, the volume of the gas mass decreases (see Boyle Mariotte's law) and thus the ability to hold water vapor decreases.

This means that - when air is compressed from an atmospheric pressure of 1.01325 bar to a pressure of 10 bar, some of the water that is in the state of water VAPOR will condense into a LIQUID. Areas with cold winters favor this phenomenon, because the lower the temperature, the greater the amount of water.

In conclusion, there will ALWAYS be water in the compressed air system, regardless of the type of compressors used. The problem is to remove this amount of water and keep the air pipes dry. To monitor the amount of water in the compressed air station, the so-called “dew point monitor” is used.

Dew point - the temperature at which water condenses.

In the past, REFRIGERATION dryers were used to dry compressed air, but it was found that they did not provide efficient air treatment.

After 15 years of using refrigeration dryers, it was found that the compressed air pipes showed signs of oxidation and peeling on the inside, while in the case of desiccant dryers the pipes remained clean on the inside.

Currently, standards require that only DESIRCULATION DRYERS be used to produce breathable medical compressed air.

Desiccant Dryer

Unlike refrigeration dryers, desiccant dryers are highly efficient – they dry the air very well even when consumption is low.

Desiccant dryers use the principle of Adsorption.

Adsorption = the phenomenon of fixing molecules of a gas or a liquid on the surface of a solid body.

The dryer works as follows: the desiccant (substance with high affinity for water molecules) is located in two identical cylindrical column containers. Adsorption materials have a porous structure; generally used: silica gel (SiO2), aluminum oxide (Al2O3), etc. [4].

When the air passes through the first container, the water molecules “catch” - due to molecular attraction forces - on the surface

of the solid granules, and the air that comes out from the bottom is dry. At certain intervals, the air is switched to the second container. Part of the already dried air is sent to the first container in order to remove water from the surface of the desiccant. This process is called REGENERATION of the desiccant.

In conclusion, while in one column the air dries, in the other the desiccant regenerates. Desiccant dryers do not change the state of water - water vapor does not turn into liquid. Water is only in the form of vapor and the presence of water means that a malfunction has occurred in the dryer. Since desiccant dryers retain water molecules, the dew-point level reached is very low (generally - 40°C, but there are also dryers down to - 70°C - depending on the desiccant used).

The following Processes are used for desiccant regeneration:
- heat-free regeneration
- heat-regeneration from the inside
- heat-regeneration from the outside
- vacuum regeneration

In the medical field, the so-called "cold" regeneration is used.

Advantages
- the dryers have a simple construction
- can be used at ambient temperature
- the desiccant requirement is reduced
- a dew-point of -70°C is reached
- the drying and regeneration (switching) time is reduced (approx. 5 min.)

Disadvantages
Relatively high operating costs because "cold" regeneration dryers - use part of the medical air produced by the compressors for the regeneration process. The amount of air used is determined by the size of the dryer (volume of the columns) and the working conditions and reaches approximately 15%.

If an oversized desiccant dryer is used, the amount of air used for regeneration will also be higher, which means higher costs for the production of medical air [4].

In modern desiccant dryers, there is the option of using a controller to adjust the amount of purged air according to consumption. Thus, in installations where there is a large difference in the demand for medical air, this method represents an effective means of ensuring the reduction of electricity consumption, if the demand for medical compressed air is low.

The pressure in the two columns is generally indicated by pressure gauges, making it easy to monitor the operating mode of the equipment.

A problem with desiccant dryers is the desiccant.

This must be replaced at certain intervals (2-3 years) because the properties of the substance are altered by traces of oil or water and by the pressure differences that occur when switching between the two columns.

The dryers are equipped with systems to track the condition of the desiccant (it changes color over time).

The amount of oil and other impurities contained in the air leaving the compressor affects the efficiency of the dryer over time

Oil in Medical Air
Oil – is another contaminant found in medical air in the form of liquid, aerosols or vapors. In oil-lubricated compressors, oil is continuously injected, with the role of - cooling, sealing and lubrication.

However, oil can also be present in compressors without lubrication, in the form of hydrocarbon vapors. As mentioned, the oil level in the breathable air supplied by the station must be less than 0.1 mg/m3.

Compressors are equipped with filters and microfilters to separate and clean the oil before it re- enters the circuit. However, a small amount of oil and oil vapor reaches the dryer.

Therefore, the compressed air passes through several FILTERS before entering the dryer.

Compressed Air Filtration
Filter efficiency – expressed as the separation rate represents the difference between the CONCENTRATION of impurities before and after the filter. It is calculated with the following mathematical formula:

$\eta = 100 - [C2 / C1 \times 100]$

where: C1 = concentration of impurities BEFORE the filter C2 = concentration of impurities AFTER the filter

η = separation rate (filter efficiency)

Another size that characterizes the filter is the minimum size of particles that can be retained by the pores of the filter membrane, a size that is of the order of microns [µm]. The size of the pores of the filter element determines the size of the retained particles.

Depending on this value, filters are classified into:
- prefilters - which generally retain particles larger than 3 µm
- microfilters - which retain particles larger than 0.01 µm

Filters are also characterized by the pressure drop Δ p - which represents the difference between the outlet pressure and the inlet pressure in the filter [5].

The value Δ p increases over time; the more particles are retained by the filter element. In the case of a new filter,

Δ p = 0.02 to 0.2 bar (depending on the type of filter element) For a used filter: Δ p = 0.6 bar - represents the accepted limit.

If Δ p increases above this limit, the filter must be cleaned or replaced.

Differential pressure indicators are used to measure Δ p. Exceeding the limit value is signaled by the indicator needle reaching the area marked in red.

Water Separator Filter
The Water Separator Filter has the role of retaining water particles from the compressed air. The fibers of the filter element have a porous structure and a real labyrinth is created between the fibers as in the figure.

Following the laws of gravity, the condensate is collected at the bottom in the collection chamber.

Oil Filter
It is a highly efficient MICROFILTER, which retains water and oil vapors, ensuring a concentration of 0.01 mg/ m3 (0.01 ppm). It also retains solid particles with dimensions up to 0.01µm.

Activated Carbon Filter
After passing through the previous filters, the compressed air still contains hydrocarbon vapors and various substances that give it smell and taste.

Hydrocarbon vapors and the respective substances are retained by an Active Carbon Filter. Particle filter

It is a final filter, the purpose of which is to retain small particles that were entrained when the air passed through the filter element materials

Sterile Air Filter
The bacterial filter is used for the sterilization of compressed medical air (breathing and instrument) and is mounted before the final pressure regulators. The filter element housing is made of stainless steel, and the filter element is made of borosilicate microfiber. The sterile filter retains microorganisms with sizes up to 0.01µm.

Two filters mounted in the bypass are used to continuously supply sterile air.

Changing filters
The service life of the filters in the drying and treatment equipment varies from manufacturer to manufacturer and is indicated in the instructions for the compressed air stations. The service life depends on the degree of clogging of the filter.

Differential pressure indicators are provided for each filter in the dryer and for the sterile air filter. The filter housing must have a label stating the date of replacement of the filter element, in order to track the service life.

This is an additional safety measure in the event that the differential pressure indicator fails.

Pressure Reducing Panel
On the breathing medical air branch (AIR 4 bar) 2 pressure reducing valves are used, mounted in parallel, to ensure continuity of supply in the event of a fault. This is not necessary for the medical instrument air (AIR 7 bar).

The pressure reducing panel can be mounted:
- after the drying and filtering equipment, in the compressor room – in the case of single-stage distribution systems or,
- on the branch pipe on the floor – in the case of two-stage distribution systems

Materials and Method
The study compares the microbiological results obtained from two clinical hospitals, from Bucharest, named HOSPITAL I and HOSPITAL II.

Quality of the medical breathable compressed air was tested in two points of the installation- at a specific point of terminal units (in ICUs and OR), for each of the hospitals.

Figure 1: MGPS medical gas analyzer

The tests were performed by HTS Company from Bucharest, using the MGPS medical gas analyzer device.

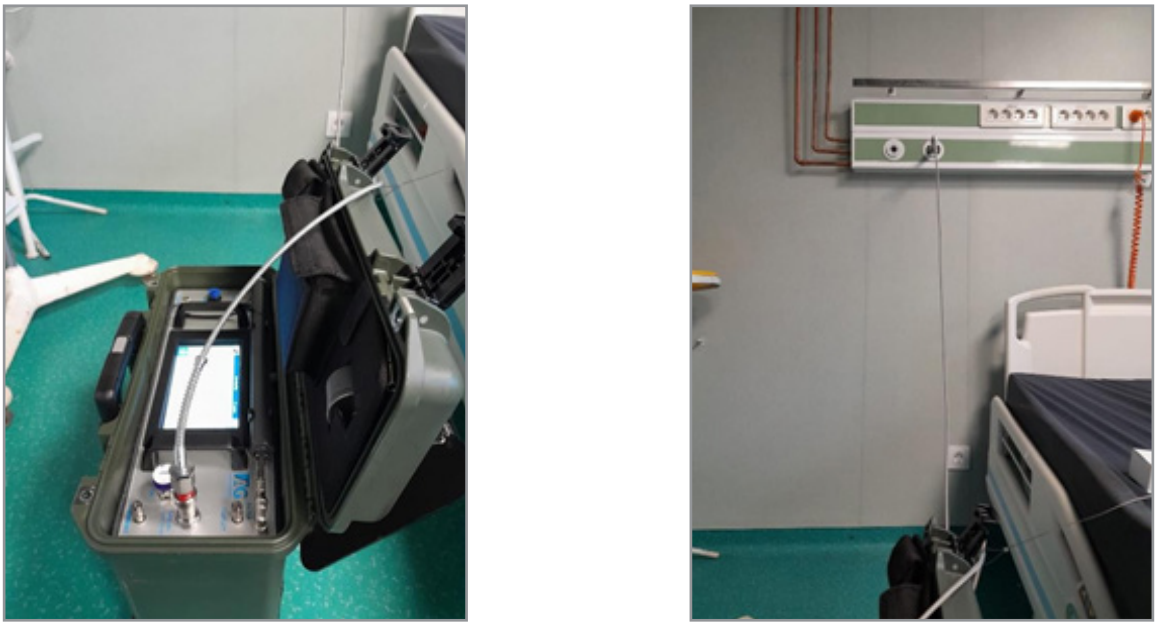

Figure 2: Tests performed in Hospitals from Bucharest

The MGPS medical gas analyser device measures O2, N2O, water vapor, CO2, CO, SO2, NO, NO2, gas pressure and vacuum.

- Integrated oil test, polytest and particles.
- Connects to any terminal or NIST units with a gas pressure up to 13 bar.
- Optional measurement of ambient hazardous gases for COSHH purposes.
- Optional for detection of anesthetic gas leaks.
- The most comprehensive, efficient and convenient MGPS testing solution available in the world.

Figure 3: MGPS medical gas analyser. Screen of the device

The quality of medical breathable compressed air was tested according to SR EN ISO 7396-1 standard

The tests performed are:

- Particle contamination of medical air,
- Quality of medical air produced by air compressor supply systems,
- The CFU content of bacteria and fungi, from medical breathable compressed air.

Figure 4: Air quality testing in hospital, with MGPS medical gas Analyzer

Also, was tested the medical air in two points of the MGPS system, according with European Pharmacopoeia, in order to determine the content of CFU bacteria and fungi.

The device used for microbiological tests is ActiveCount100- a high performance portable microbial sampler suitable for use in cleanrooms and aseptic environments. Continuous and periodic sampling enables complete control on sampling cycles and intervals. Autoclavable impactor head and subitizable stainless steel enclosure ensure ActiveCount100 does not contaminate the sampling environment.

Objective

Objective of the test was demonstration of the ability of the compressed air installation to keep within the limits of admissibility.

It is a quantitative analysis, it is verified by sampling 200 liters of air/sample (sampling point). Sampling is done with the Active Count 100H - Lighthouse air sampling equipment.

Figure 5: Active Count 100H-Lighthouse air sampling equipment

Petri dishes with a diameter of 90 mm are used, filled with Tryptic Soy Agar medium (for viable aerobic microorganisms) and Sabered Dextrose Agar (for the combined number of fungi and yeasts), for each sampling point.

Wipe the air sampling device with napkins soaked in disinfectant, then position a petri dish with culture medium. Above is positioned the funnel for directing the compressed air on the sieve. The device is set for sampling 200 liters. The compressed

air is turned on and adjusted to 3 bars with the help of the adjustment valve. The device for sampling the air volume is turned on.

Between taking the samples, wipe the device with napkins soaked in disinfectant.

After sampling, the Petri dishes are closed, stored in a refrigerated box whose temperature is monitored with a datalogger and transported to the testing laboratory.

On the cover of the Petri dishes it is written (at the beginning of the air sampling operation using the Active Count 100H - Lighthouse):

- the type of culture environment,
- the location where the exposure will take place,
- date of exposure.

The Petri plates are incubated at 30-35˚C (Tryptic Soy agar medium), respectively 20-25˚C (Sabouraud Dextrose agar medium), for 3-5 days, respectively 5-7 days.

The reading of the plates is done daily.

The result is obtained by counting the colonies (cfu - colony-forming units) on each petri plates and determining the arithmetic mean, for each type of medium.

The result is expressed as a number. cfu/ m3

Acceptance Criteria

The measured value must fall within the limits of cleanliness class B, C and D according to GMP [1].

Table 3: Recommended limits for microbial contamination

Recommended limits for microbial contamination	
C(Class)	**(Air sample CFU: c.f.u.**/m³)**
A	< 1
B	10
C	100
D	200

** c.f.u.= Colony Forming Units

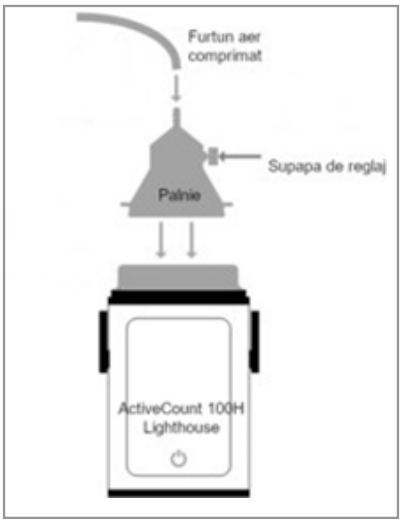

Figure 6: Active count100-Microbiological Test

Results

According to European Pharmacopoeia, medical breathable compressed air shall comply with the following:

Oxygen Concentration ≥ 20,4 % (volume fraction) and ≤ 21,4 % (volume fraction)
Total oil concentration ≤ 0,1 mg/m3 measured at ambient pressure
Carbon Monoxide concentration ≤ 5 ml/m3
Carbon dioxide concentration ≤ 500 ml/m3
Water vapor content ≤ 67 ml/m3
Sulfur dioxide concentration ≤1 ml/m3
NO + NO2 concentration ≤ 2 ml/m3

Figure 7: Clean air filter after the particle contamination test

Results Obtained after Particle Contamination Test

Hospital I

Oxygen Concentration = 20,9%
Total oil concentration = 0 mg/m3
Carbon Monoxide concentration = 0,06 ml/m3
Carbon dioxide concentration = 582 ml/m3
Water vapor content = 978 ml / m3
Sulfur dioxide concentration = 0,09 ml/m3
NO + NO2 concentration = 0,06 ml/m3

Hospital II

Oxygen Concentration = 20,84%
Total oil concentration = <0,1 mg/m3
Carbon Monoxide concentration = 0 ml/m3
Carbon dioxide concentration = 464 ml/m3
Water vapor content = >2000 ml/m3
Sulfur dioxide concentration = 0,18 ml/m3
NO + NO2 concentration = 0,04 ml/m3

- For Hospital I and II, wasn't detected any particles contamination.
- For Hospital I, the carbon monoxide concentration and water vapor in ICUs, exceeded the maximum concentration admitted by European Pharmacopoeia. For Hospital II, the water vapor concentration was very high.
- According to European Pharmacopoeia, chpt. 5.1.4, the CFU from medical breathable air must be <200.

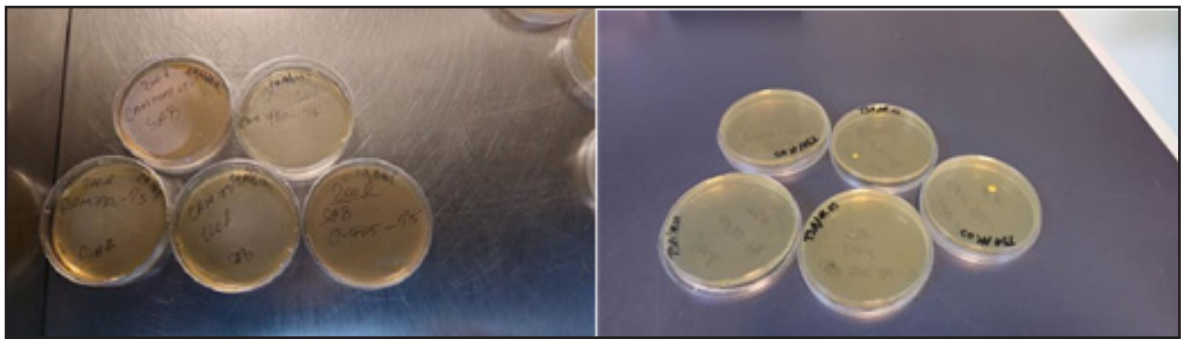

Figure 8: Aspect of the CPU from Hospital I and II

After performing the microbiological test, there were no microorganism count in medical breathable compressed air, for Hospital I and II, from Bucharest.

Conclusion

After testing the quality of medical breathable compressed air in the two Hospitals from Bucharest, the results showed that the Carbon dioxide concentration and Water vapor content, exceeded the maximum concentration admitted by European Pharmacopoeia.

Those results are not connected with the results obtained after testing the CFU content of bacteria and fungi, from medical breathable compressed air.

In ICUs from both hospitals, where the water vapor content exceeds the maximum concentration. Although, the concentration of CFU is very low, due to the antimicrobial properties of Cu, the material of pipelines.

The filters of the medical air plant are very efficient, according with the results of the tests.

The water vapor content exceeded the maximum concentration, due to the fact that the drying system of the medical air plants from both hospitals, doesn't work properly.

The carbon dioxide concentration could present higher values if the ventilation of the medical air plant room is not properly provided, or the location of the air plant is nearby a contamination source (like parking lot or heavily circulated road).

Total oil concentration showed good results for both hospitals. This emphasize that the filtration system of the medical air plants is functioning in normal parameters.

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