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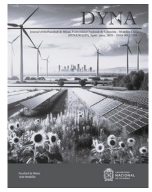

UNIVERSIDAD NACIONAL DE COLOMBIA

Design of an oxygen concentrator according to ISO 80601-2-69 standards

Vigil Wuilber Mamani-Cori [a], Nilton Juan Zeballos-Hurtado [b] & Arturo Jesús Cosi-Blancas [b]

[a] Bachiller en Ingeniería Mecánica Eléctrica, Universidad Nacional de Moquegua (UNAM), Moquegua, Perú. 04745011@ujcm.edu.pe
[b] Universidad José Carlos Mariátegui (UJCM), Moquegua, Perú. nilton_zh@ujcm.edu.pe, arcofe10@hotmail.com

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Abstract
This work focuses on the design, construction and economic analysis of an oxygen concentrator in the city of Moquegua, Peru, under ISO 80601-2-69 standards. The methodology used was experimental, consisting of the design and construction of an oxygen concentrator, as well as its economic analysis. The results of the prototype tests indicate that it provides oxygen with a concentration of 95%, up to 10 litres/min, consuming 280 W of power, being powered by 220 V alternating current, working under a process called oscillating pressure absorption. The final cost of the device was S/1220.80, which contrasts with the cost of similar equipment that in the market have a value of S/1500.00 and that in pandemic 2020 reached S/15000.00. In conclusion, the manufacture of an oxygen concentrator in Moquegua is both technically and economically feasible.

Keywords: oxygen; concentrator; design, feasibility; economics.

Diseño de un concentrador de oxígeno de acuerdo con las normas ISO 80601-2-69

Resumen
Este trabajo se enfoca en el diseño, construcción y análisis económico de un concentrador de oxígeno en la ciudad de Moquegua, Perú, bajo las normas ISO 80601-2-69. La metodología utilizada fue experimental, que consistió en el diseño y construcción de un concentrador de oxígeno, así como el análisis económico del mismo. Los resultados de las pruebas del prototipo indican que proporciona oxígeno con una concentración del 95%, hasta por 10 litros/min, consumiendo 280 W de potencia, siendo alimentado por corriente alterna de 220 V, trabajando bajo un proceso denominado absorción por presión oscilante. El costo final del dispositivo fue de S/1220.80, que contrasta con el costo de equipos similares que en el mercado tienen un valor de S/1500.00 y que en pandemia del 2020 alcanzó los S/15000.00. En conclusión, la fabricación de un concentrador de oxígeno en Moquegua resulta factible tanto técnica como económicamente.

Palabras clave: oxígeno; concentrador; diseño; factibilidad; economía.

1. Introduction

In 2020, the World Health Organisation (WHO) declared COVID-19 a pandemic; from 2020 to 2021, there was an estimated excess mortality of 14.9 million people [1]. Peru reported approximately 213,000 deaths caused by the COVID-19 pandemic, making it one of the countries with the most deaths per million inhabitants in the world. There is consensus that one of the causes of the magnitude of this tragedy in Peru was the lack of medical oxygen [2]. As a result, there has been a growing interest in research on the biological effects and medical importance of oxygen [3]. Alterations in oxygen availability can affect vital functions at the systemic and cellular level and potentially contribute to ageing through various mechanisms [4]. Molecular oxygen is the second most abundant element in the Earth's atmosphere [5]. It is available in gaseous form in our atmosphere at a concentration of approximately 21% [6]. Despite this, few of us are aware that, as human inhabitants of the Earth, we have a unique privilege. As air-breathers, we and most other animals on Earth are the only living creatures in the known universe that have an unlimited supply of oxygen [7].

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Precisely one of the key features that allow our planet Earth to harbour an active and diverse biology is the presence of free molecular oxygen (O2) in the atmosphere [8]. Oxygen is essential for the metabolism of many organisms. Oxygen acts as a terminal electron acceptor in humans, for example, where four electrons are used to create water, which is then lost through skin or respiration [9]. In this regard, a number of studies have suggested that oxygen appears to be inextricably linked to multiple ageing processes [10].

During the first wave of COVID-19, in the year 2020, the demand for medical oxygen quadrupled, i.e. 2,800 tonnes per day. Furthermore, with the second wave, the demand increased to approximately 5,000 tonnes per day [11]. By this time, diagnoses of COVID-19 severity were closely related to prognosis, and strategies for early detection of high-risk patients were developed, using oxygenation indices as an indicator of lung dysfunction [12]. Oxygen is therefore a drug and should be used as such, and prescribers should have a thorough understanding of its use and the existing interfaces for its administration [13].

2. Materials and Methods

The developed prototype works on the principle of Pressure Swing Adsorption (PSA) technology, which uses ambient air as the raw material for oxygen generation. It also complies with the specifications of ISO 80601-2-69, which establishes the requirements that guarantee the safety and performance required for oxygen concentrators. The technology employed is used for the separation of the components of air in its gaseous state. It is therefore known as a selective process and operates in the ambient temperature range.

The currently existing methods for the production of oxygen for medical purposes are shown in the Fig. 1.

The pressure swing process allows a continuous flow of oxygen to be provided with a high level of purity (between 90% - 95%). This adsorption occurs when compressed air molecules tend to adhere to an adsorbent surface. The concentrator will draw in the ambient air and filter it in order to remove dust, pathogens and other impurities. A compressor will force the air into the cylinder containing a sieve, which will absorb the nitrogen and release the concentrated oxygen. For this purpose, molecular sieves containing Zeolite are used, and when each sieve is depressurised, N2 is released. For the oxygen separation stage, 2 vessels filled with Zeolite are used. There is a large variety of Zeolite, and it is classified by pore size distribution or the cations present. The type of Zeolite chosen is 13X Zeolite, preferably used in normal oxygen purification due to its higher nitrogen attraction. The operating scheme of the prototype is shown in the Fig. 2.

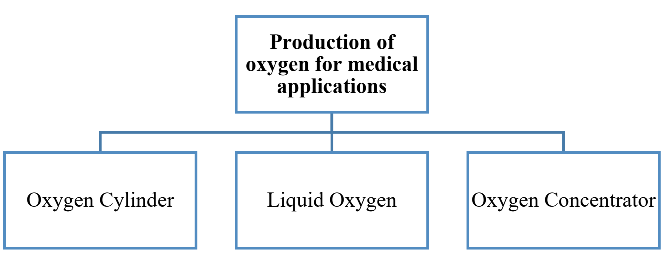

Figure 1. Classification of methods for the production of oxygen for medical applications
Source: Author made

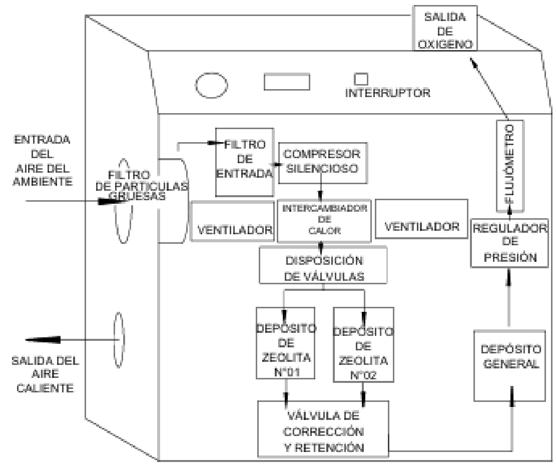

Figure 2. Operating diagram of the oxygen concentrator
Source: Author made

We can calculate the dimensions of the Zeolite container, knowing the following data:

Zeolite density: 40 lb/ft3

Type: 13X

Zeolite mass: 3 lb.

The mathematical expression for the calculation is:

$$\textbf{Volume } (\mathbf{V}) = \frac{\text{Mass (m)}}{\text{Density (p)}} \tag{1}$$

$$\textbf{Volume} = \frac{3 \text{ lb}}{\frac{40\ lb}{ft^3}} = 0.0075\ ft^3 = 2.123\ cm^3$$

Then the calculated total volume of Zeolite will be shared in the two identical columns, thus making each of them have a volume of 1,061 cm3.

- The components of the oxygen concentrator are:
- Piston-type motor and air compressor (pistons)
- Two cylinders filled with Zeolite pellets (Zeolite Strainer)
- One pressure compensation tank
- Flow meter adjustment valve
- Four-way solenoid valve
- Correction and Check Valves
- Silicone Hoses
- Hermetic Plate and Tube Heat Exchanger (Cross Flow)
- Product Tank
- Pressure Regulator with Knob
- Flowmeter (Flow Regulator)
- Coarse Particle Filter
- Inlet Filter

- Product Filter
- Exhaust Silencer
- Two Fans
- Condenser 14μF±5% Condenser

Once the necessary calculations had been made, it was necessary to draw up the detailed plans of the prototype to be built. To do this, the dimensions of the concentrator were detailed, ensuring that it could comply with the specifications of the ISO 80601-2-69 Standard. The specific views are shown in the Figs. 3–5.

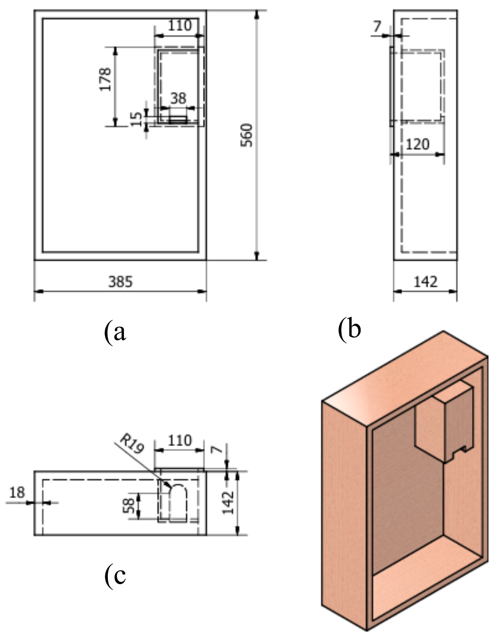

Figure 3. Main views of the rear casing. (a) Front View, (b) Side View, (c) Top View
Source: Author made

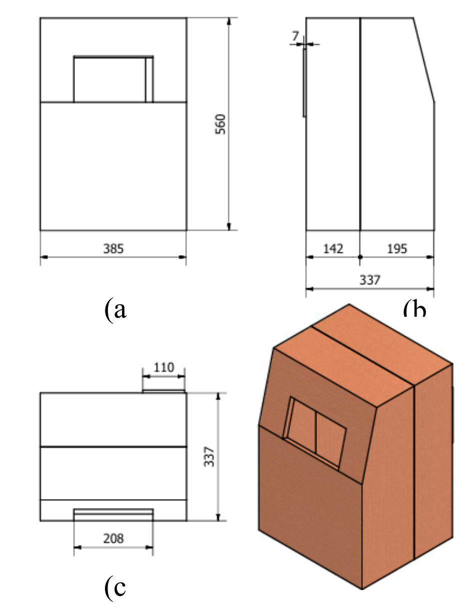

Figure 4. Main views of the assembled housing. (a) Front View, (b) Side View, (c) Top View
Source: Author made

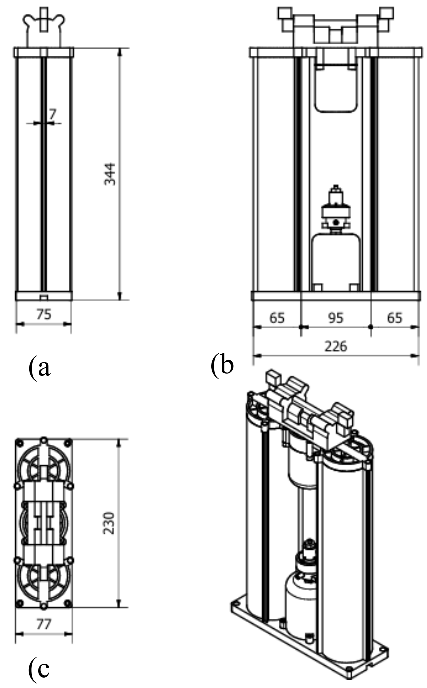

Figure 5. Main views of the Zeolite mechanism and cylinders. (a) Side View, (b) Front View (c) Top View
Source: Author made

3. Results and Discussion

Considering all the parameters, devices and requirements established by the ISO 80601-2-69 Standard, in addition to the technological limitations, a reliable prototype was manufactured, economically profitable, and easy to manufacture in series, capable of providing 95% concentrated oxygen, up to 10 litres/min.

It is powered by Alternating Current (AC), consuming 280 W of electrical power, at a frequency of 60 Hz and for 220 V. voltage. Using this machine under the process called oscillating pressure absorption. This prototype can be easily moved from one place to another when it is required to attend patients, either in health centres or outside. Furthermore, this equipment represents an innovative and efficient solution that could be upgraded for mass production. The manufacturing

(a) (b)

Figure 6. Prototype construction process
Source: Author made

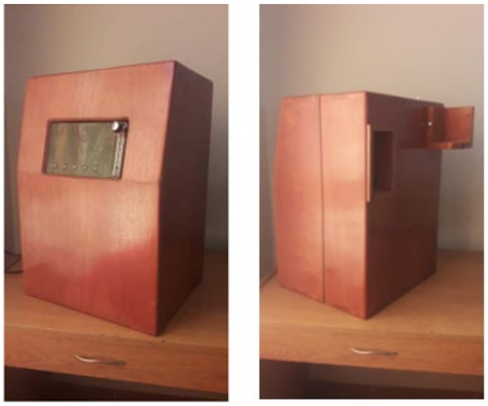
(a) (b)

Figure 7. Final prototype of the concentrator. (a) Front View, (b) Side View
Source: Author made

was carried out using commercial devices and materials available in the national market, facilitating its assembly in the area intended for this purpose. The Fig. 6., shows the assembly process of the oxygen concentrator.

Fig. 7 shows the prototype built ready for operation, the supply of oxygen in the detailed quantities is guaranteed thanks to the flow of oxygen circulating through the equipment.

Tests were carried out to determine its power consumption, and it was found to work adequately to provide oxygen at the right concentration for medical use. This type of technology is capable of working uninterruptedly and its maintenance costs are very low compared to other similar equipment. The viability of this equipment lies in the fact that low-cost materials and equipment have been used, in addition

Table 1.
Oxygen concentrator costs

Item	Description	Quantity	Unit price (S/)	Subtotal (S/)
1	Wooden plugs 18 mm thick for covering	----	----	450.0
2	Thin silicone hose	1 m	----	15.0
3	Thick silicone hose	1 m	----	30.0
4	Shipping costs from Lima to Moquegua	----	----	15.0
5	Clamps	4 pcs	0.50	2.0
6	¾ clamp bolt	10 pcs	----	1.0
7	1 - ½ clamp bolt	4 pcs	0.20	0.8
8	Millimetric bolt	4 pcs	0.50	2.0
9	Silent motor compressor	1 pc	----	230.0
10	Heat exchanger	1 pc	----	125.0
11	Flow meter (Flow regulator)	1 pc	----	42.0
12	Coarse particle filter	1 pc	----	45.0
13	Inlet filter (Epa filter)	1 pc	----	30.0
14	Check valves	1 pc	----	45.0
15	Fans	2 pcs	34.0	68.0
16	Condenser 14 microfarads ±5%.	1 pc	----	20.0
17	Electronic board (imported from China)	1 pc	----	100.0
			Total:	1220.8

Source: Author made

to guaranteeing the reproduction and improvement of this equipment, without taking into account that it is also adaptable to different working environments. The results also show that the objective of building a prototype capable of generating medical oxygen and that it complies with the standards established by the ISO 80601-2-69 Standard has been achieved.

The costs related to the construction of the oxygen concentrator are shown in the table below, specifying in detail each item related to the equipment (Table 1).

This article has been oriented from the beginning towards the development of a medical oxygen concentrator, with a therapeutic concentration suitable to be administered to patients with hypoxaemia (low oxygen saturation in the blood). The total cost of the assembled prototype amounted to the sum of S/1220.80 (one thousand two hundred and twenty soles and 80 cents) which is adequate and accessible in comparison with the costs reached in the year 2024 for similar equipment and which present a price of S/1500.00 and which also contrasts with the costs of the year 2020 in times of pandemic, which made prices around S/15000.0 for oxygen concentrators.

The components are readily available and can be found in the domestic market and some imported components, such as the electronic board, are produced to order in China.

It is important to note that similar studies, such as the one developed in [11] agree that the use of an oxygen concentrator using the pressure swing principle can be a life-saving solution at least in the primary stage of coronavirus infection. Similarly, according to the research developed in [14], for the primary care of hypoxaemic patients, their project is envisaged to provide portable oxygen delivery equipment. Offering a transportable and cost-effective configuration for the treatment of patients with severe hypoxaemia, as well as solving the problem of insufficient oxygen supply by presenting a technology that is affordable and accessible to all.

Moreover, an affordable and sustainable PSA-based oxygen source was developed in the early 2020s and successfully implemented in several low-resource settings with the help of remote educational tools during the pandemic. Explanations via YouTube and a website have greatly contributed to the understanding of the gas separation process in an oxygen concentrator and aided its assembly. A survey and extensive correspondence with people at LRS through comments and emails have helped to summarise this experience in several documents related to the device, including an assembly manual and an optimisation report, which can be found in the Supporting Information [15].

The work developed in [16] studied the individual effects of the main PSA process parameters on the oxygen production performance at a product flow rate of 3.46-19.88 SLPM (standard litres per minute), based on a modified Skarstrom cycle PSA unit using Li-LSX zeolite adsorbents. The energy consumption was reduced by 10.56-18.10% compared to conventional devices. The results are beneficial for developing flexibly controlled oxygen concentrators for practical applications.

Research in [17] highlights that medical oxygen concentrators (MOCs) are designed for fixed product specifications, which limits their use to meet variable product specifications caused by a change in the patient's medical condition or activity. To overcome this difficulty, a flexible single-bed MOC system, capable of meeting different product specification requirements, was designed based on flexible PSA and pressure-vacuum swing adsorption (PVSA) systems.

The results indicate that LiLSX outperforms LiX, and can produce 90% pure oxygen at 21.7 L/min. Furthermore, the flexible PVSA system based on LiLSX can be manufactured for different levels of oxygen purity and flow rate in the range of 93 to 95.7 % and 1 to 15 L/min, respectively. Finally, the research in [18] has a bearing on the development of innovations in oxygen generation, highlighting that a novel oxygen control system was developed and tested to wirelessly control the flow rate of supplemental oxygen during home oxygen therapy. As an external complement to existing oxygen concentrators, demonstrating that this system is an accurate, precise and reliable method for oxygen therapy patients to wirelessly adjust their oxygen flow rate within 41 metres.

4. Conclusions

A physical prototype was made to obtain the real cost of the equipment, assembled in the city of Moquegua. The plans of the equipment were drawn up. Using the Autodesk inventor 2024 program. Where the components that make up the equipment are shown. The elaboration of the device was made, based on investigation, where the different calculations were determined. Resulting in a device with a value of S/. 1220.80 Peruvian soles. The current cost of this device is S/1500.00 in the year 2024 and in a pandemic, it will cost S/15000.00 each device in the year 2020. Justifying that it is easy to assemble.

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V.W. Mamani-Cori, earned his BSc. in 2001, and his BSc. Eng. in Mechanical Engineering in 2004, both from the National University Jorge Basadre Grohmann in Tacna, Peru. MSc. in Investment Projects at Universidad José Carlos Mariátegui in Moquegua, Peru. He has teaching experience at both the university and technical institute levels, and professional expertise as a mechanical draftsman, with knowledge in mechanical equipment symbology and software such as AutoCAD, SolidWorks, Autodesk Inventor, SAP2000, S10 (for cost estimation), and Microsoft Excel. He also has practical experience in structural assembly and CNC machine operation, having received training at EMCO-Austria. He served as Head of Mechanical Services and Equipment (UOSME) at the Provincial Municipality of Mariscal Nieto in Moquegua. His research interests include alternative energy applications and university-level education.
ORCID: 0000-0002-3417-3044

N.J. Zeballos-Hurtado, is BSc. Eng. in Electrical Mechanical Engineering in 1999, from the National University of San Agustín. MSc. in University Teaching and Educational Management in 2007, from the Private University of Tacna, and a PhD. in Education in 2018, from the César Vallejo University. He has been a professor at Universidad José Carlos Mariátegui since 2000, where he currently serves as a full professor and Director of the School of Electrical Mechanical Engineering. He has also held multiple administrative roles, including Head of Academic Services, Director of the Environmental Engineering Program, and Head of the Research Institute. His research interests include alternative energy sources and university-level education.
ORCID: 0000-0002-7057-1015

A.J. Cosi-Blancas, is BSc. Eng. in Electrical Mechanical Engineering in 2000, from the National University San Luis Gonzaga of Ica. MSc. in University Teaching and Educational Management, in 2006, and a PhD. in Administration in 2014, both from the Private University of Tacna. He began his academic career teaching mechanical production at the José Carlos Mariátegui Technological Institute and has served as a university professor since 2002. Currently, he is the Dean of the Faculty of Sciences at Universidad José Carlos Mariátegui. His research focuses on alternative energy applications and higher education.
ORCID: 0000-0002-3859-353X