COBEM 2021 26th International Congress of Mechanical Engineering

ABCM Associação Brasileira de Engenharia e Ciências Mecânicas
November 22-26, 2021, Virtual Congress, Brazil

COB-2021-0083
APPLICATION OF FAILURE MODE AND EFFECTS ANALYSIS (FMEA) IN THE MECHANICAL VENTILATOR INSPIRE: A CASE STUDY.

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Abstract. *The COVID-19 pandemic has led to an increase in the demand for mechanical pulmonary ventilators (MPV), causing a great challenge for health managers, both in providing this equipment to patients in sufficient quantity, and in keeping them working properly. Like all equipment, MPVs are composed of systems and subsystems. In order to guarantee the availability and proper performance of this equipment in a hospital environment, it is necessary to ensure the perfect functioning of the entire set of systems. This article aims to identify the main failure modes and their effects in MPVs, and to propose actions for the most critical ones using the Failure Mode and Effects Analysis (FMEA) method. To this end, the INSPIRE MPV developed by the Polytechnic School of the São Paulo University (USP), as part of the efforts to combat the COVID-19 pandemic, was taken as a basis. The nature of this study is applied and qualitative. A literature review was made about the main parameters of a MPV, its classification, modeling and main critical components that can cause failure modes in the equipment, highlighting the MPV INSPIRE equipment. The identification of the main failure modes was made based on data collected from the literature. Such failure modes have been validated by experts in the field. Also, to prioritize the failure modes, expert judgment was used. Based on the Risk Prioritization Number (RPR), actions were established to mitigate the main failure modes. Based on the results obtained, it is intended to generate knowledge regarding the operation of open source MPVs, such as INSPIRE, in order to increase their availability and reliability.*

Keywords: *Mechanical Pulmonary Ventilators, INSPIRE, FMEA*

1. INTRODUCTION

On January 30, 2020, WHO (World Health Organization) declared the outbreak of the new coronavirus as a Public Health Emergency of International Importance (ESPII) – the highest level of WHO alerts as provided in the International Health Regulations (IHR). On March 11, 2020, COVID-19 was characterized by WHO as a pandemic (PAHO, 2020). According to the brazilian Ministry of Health (MS), symptoms of COVID-19 can range from a cold to a flu-like illness to severe pneumonia. Among the possible symptoms, the most worrisome and challenging to health systems is dyspnea (shortness of breath), given the strong demand it places on hospitals for mechanical pulmonary ventilation equipment that must be provided to the patient in order to keep them stable (MS, 2020).

As the mechanical pulmonary ventilator (MPV) is classified as hospital life support equipment, it is important that it performs to the expected standards. It's perfect functioning requires the combination of the following features: input power, power transmission and control system, drive mechanisms, central control unit and output control systems. It is critical that all of these functions and features are working collaboratively and according to expectations. Otherwise, its use can put a patient's life at risk (Vestatech, 2017).

Aiming to meet the high demand for mechanical pulmonary ventilators in hospital environments during the COVID-19 pandemic, INSPIRE project emerged, developed at Escola Politécnica, the engineering school of Universidade de São Paulo (USP), by a group of approximately 40 people, including biomedical, mechanical, mechatronics, electronics and production engineers, students and representatives of the private sector (USP, 2021). This being a registered project with an open-source license, which means that anyone can access its manufacturing process and manufacture it. From an operational point of view, it is of fundamental importance that the main failure modes of a MPV are identified, analyzed and equally made available to the public, in order to ensure patient safety, thus increasing the reliability of such medical equipment.

Within this context, the goal of this article is to identify and analyze the main failure modes found in the literature about the component pressure sensor/transducer – considered a critical component of MPVs – applying Failure Mode and Effects Analysis (FMEA) method, as the pressure sensor of the MPV INSPIRE has been presented as one of the possible causes for triggering several failure indicator alarms (USP, 2021), so this item was selected for the application of the case study. Examples of failure modes that can occur in strain gauge type pressure sensors/transducers in mechanical ventilation equipment are: open circuit (failure in the sensor cable); short circuit (sensor wire cables are touching); open circuit or diaphragm detachment; diaphragm leakage, rupture or deposition of foreign material on the surface; erratic reading due to electromagnetic inductions (EMI); deposition of impurities in the sensor line before the diaphragm and leakage due to incorrect fit or in the sensor output line. (CADWALLADER, 1996).

It is important to note that sensors and valves are common fail components and this often can lead to serious consequences. The non-functioning of such components can cause the equipment to lose control of the gas intake, which can lead to supply removal or sending of too much or too little gas. In all cases, the consequences can be fatal, which shows the importance of studying these components' potential failure modes and their effects (Vestatech, 2017).

Failure Mode and Effects Analysis (FMEA) is one of the tools used for continuous quality improvement (Pickard *et al.*, 2005). According to Stamatis (2003), FMEA purposes are:

- Identify known and potential failure modes,
- Identify the causes and effects of each failure mode,
- Prioritize the identified failure mode according to the risk priority number (RPN) – the product of frequency of occurrence, severity and detection and
- Provide problem follow-up and corrective action.

For this purpose, this article is structured as follows: the next section addresses a brief bibliographic review about mechanical pulmonary ventilators (MPVs) and FMEA tool. Section 3 presents the research method, the section 4 shows the main components of the INSPIRE MPV, as available by its Manual (USP, 2021). In Sections 5 is related the analysis of the result. And the last one, brings the final considerations.

Based on the results obtained, it is aimed to provide understanding and dissemination of reliability analysis in medical equipment, in particular for pressure sensors/transducers in mechanical lung ventilators. Also, to show the advantages obtained with the use of FMEA such as the reduction of failure modes in new projects.

2. LITERATURE REVIEW

2.1 FMEA

The FMEA method, which means Failure Mode and Effects Analysis was developed in the United States military industry in 1974. It was used as a reliability evaluation technique to determine the effect of system and equipment failures. Failures were classified according to their impact on mission success and personnel/equipment safety (Department of Defense, 1974).

ABNT (1994) defines FMEA as "the qualitative method of reliability analysis that involves the study of the failure modes that may exist for each sub-item, and the determination of the effects of each failure mode on the other sub-items and on the item's required function." Before presenting the steps of the FMEA method, it is important that some concepts related to failure be introduced for a better understanding of the method. According to ABNT (1994) and Siqueira (2005), there are the following concepts:

- Function: it is what the user wants the item to do within a specific performance standard.
- Failure: it is the termination of an item's ability to perform its required function.
- Failure Mode: it is defined as the way in which an item may fail to meet its project's requirements. Typical failure modes are crack, deformation, leakage, short circuit, fracture, oxidation, loosening, among others (Fogliatto and Ribeiro, 2009).
- Failure Cause: it is the description of why the failure occurs.
- Failure Effect: it is the consequence of the failure mode that impacts the main function.

Generally, FMEA method includes the following steps (Toledo et al., 2017):

- Planning: in this step, it is defined the system, the item, the process or the service to be analyzed. The work team, the planning of meetings and survey of all necessary documentation (history of failures, manufacturer's documentation, among others) are also defined.
- Analysis of Potential Failure Modes: in this step, the work team completes the FMEA form, defining the main function of the item, potential failure modes for each function, effects of the failure mode, possible causes of the failure mode and the current controls regarding the prevention and detection of failure modes.
- Risk Assessment: in the risk assessment are defined the following parameters: Severity (S) of the effect of each failure mode; Detection (D) which corresponds to the probability of current controls in detecting the causes of the failure mode and Occurrence (O) that it concerns the probability of occurrence of the cause of each failure mode. The scale for ranking each criterion is shown in Tables 1, 2 and 3, respectively as proposed by Stamatis (2003). Considering the selected value in each scale, then the risk priority coefficient (RPN) is calculated by multiplying these three indices.

Table 1 - Severity guideline for FMEA. Source: (Stamatis, 2013).

Effect	**Rank**	**Criteria**
No effect	1	No effect on product or subsequent processes.
Very slight effect	2	Customer more likely will not notice the failure. Very slight effect on product/process performance. Nonvital fault noticed sometimes.
Slight effect	3	Customer slightly annoyed. Slight effect on product/process performance. Nonvital fault noticed most of the time.
Minor effect	4	Customer experiences minor nuisance. Minor effect on product/ process performance. Fault does not require repair. Nonvital fault always noticed.
Moderate effect	5	Customer experiences some minor nuisance. Minor effect on product/ process performance. Fault does not require repair. Nonvital fault always noticed.
Significant effect	6	Customer experiences discomfort. Product/ process performance degraded, but operable and safe. Nonvital part inoperable. fault always noticed.
Major effect	7	Customer dissatisfied. Major effect on process; rework/repairs on part necessary. Product/process performance severely affected but functionable and safe. Subsystem inoperable.
Extreme effect	8	Customer very dissatisfied. Extreme effect on process; equipment damaged. Product inoperable but safe. System inoperable.
Serious effect	9	Potential hazardous effect. Able to stop product without mishap; safety-related; time – dependent failure. Disruption to subsequent process operations. Compliance with government regulation is in jeopardy.
Hazardous effect	10	Hazardous effect. Safety – related – sudden failure. Noncompliance with government regulation.

Table 2 - Detection guideline for FMEA. Source: (Stamatis, 2013).

Detection	**Rank**	**Criteria**
Almost certain	1	Current controls almost always will detect the failure. Reliable detection controls are known and used in similar processes.
Very high	2	Very high likelihood current controls will detect the failure.
High	3	Good likelihood current controls will detect the failure.
Moderately high	4	Moderately high likelihood current controls will detect the failure.
Medium	5	Medium likelihood current controls will detect the failure.
Low	6	Low likelihood current controls will detect the failure.
Slight	7	Slight likelihood current controls will detect the failure.
Very slight	8	Very slight likelihood current controls will detect the failure.
Remote	9	Remote likelihood current controls will detect the failure.
Almost impossible	10	No known controls available to detect the failure.

Table 3 - Occurrence guideline for FMEA. Source: (Stamatis, 2013).

Detection	**Rank**	**Criteria**
Almost never	1	Failure unlikely. History shows no failures.
Remote	2	Rare number of failures likely.
Very slight	3	Very few failures likely.
Slight	4	Few failures likely.
Low	5	Occasional number of failures likely.
Medium	6	Moderate number of failures likely.
Moderately high	7	Frequent high number of failures likely.
High	8	High number of failures likely.
Very high	9	Very high number of failures likely.
Almost certain	10	Failure almost certain. History of failures exists from previous or similar designs.

- Improvement – In the improvement stage, the team must list, using knowledge and brainstorming techniques, measures to prevent the failure mode, cause and effect of failure, as well as measures to limit tue occurrence and increase the detection of the cause of the failure mode.

- Continuity- The FMEA document must be revised whenever there are changes in the process or through a pre-defined schedule, with the objective of reassessing the failure modes already identified by the team and incorporating those that have not been yet identified.

The most important reason for conducting an FMEA is the need to improve. To receive all or some of the benefits of an FMEA program, the need to improve must be ingrained in the organization's culture. If not, the FMEA program will not succeed. Therefore, a successful FMEA is both a company and a supplier requirement for world-class quality (Stamatis, 2003).

Willis (1992) proposed in his work an adaptation of the FMEA for hospital clinical engineering applications, indicating that the correct use of this technique in medical equipment risk management applications generates benefits in the pre-production stage, both anticipating problems and proposing corrective measures, as improving the construction of equipment documentation, which can impact future designs and design modifications, increasing its levels of safety and reliability.

Studies dealing with the study of failures in pulmonary ventilators are also available in the literature. Heleno (2014) proposed a SMR-based maintenance management methodology for a pulmonary ventilator. For each of these equipments, an FMEA analysis was performed. As a result, the work presents the failure modes of a pulmonary ventilator and the proper maintenance policy to handle each failure mode. Also, the study demonstrates how to determine the best periodicity for carrying out preventive maintenance on this equipment.

Finally, Figueiredo (2016) evaluated data on the causes of failures of mechanical pulmonary ventilators in regional hospitals in the Brazilian state of Paraíba from 2012 to 2016. The following assessment instruments were used: device categorization form and structured argumentation. In the results of this research, failures in lung ventilators were identified, where failures in the battery, software, oxygen cell, calibration, keyboard, display and valves were the most frequent. The result of this research can provide support for the development of care protocols, in a systemic articulation between possible warning signs and the respective needs for administrative interventions together with clinical engineering.

2.2 Mechanical Pulmonary Ventilators

2.2.1 Fundamentals

Mechanical Pulmonary Ventilators (MPV) are, according to Major et al. (2018), the primary support for patients with respiratory failure or acute respiratory distress syndrome (ARDS), and an essential support to life. MPVs work by providing positive airway pressure and airflow to support the work of breathing, maintaining oxygenation and allowing the patient recovery.

A MPV can be classified basically on three parameters, summarized in Figure 1.

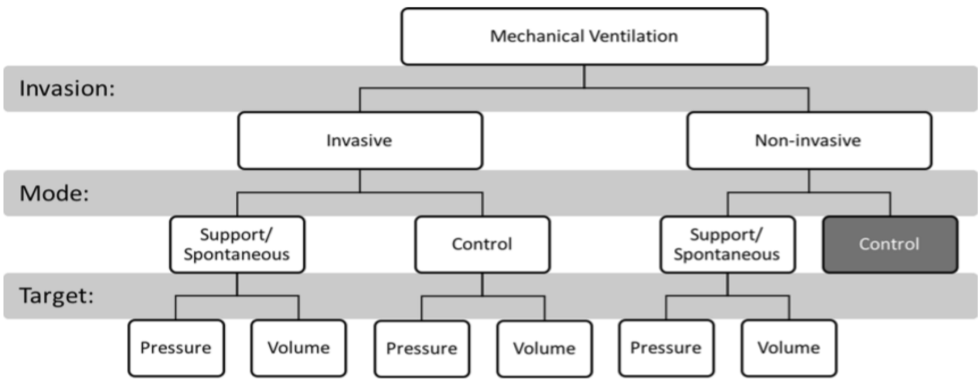

Figure 1 – Simplified Classification of Mechanical Ventilation. Source: (Major *et al.*, 2018).

The parameters of Figure 1 scheme are described below.

Invasion: dividing MPVs between invasive - that in which the equipment controls the entire respiratory rate of the patient, who is unconscious, through an endotracheal tube or a tracheostomy - and non-invasive, which ventilate the patient through a face mask. The INSPIRE fan is capable of operating at these two levels.

Operation Mode: MPVs can act in total control of the patient's breathing, being applied to sedated patients, or even as assistance support to their breathing. There are also hybrid models, which act most of the time as care, but when the patient fails to breathe, they take control. (Major et al., 2018).

Controlled variable (Target): it can be:

- Pressure Controlled (Pressure Controlled Ventilation – PCV): according to Major et al. (2018), it controls the inlet and outlet pressure of the ventilation. In this mode, airflow and tidal volume (Vt) are a function of pressure.
- Volume Controlled Ventilation - VCV: according to Major et al. (2018), in the volume-controlled mode, the tidal volume (Vt) is the controlled variable, and pressures are its function.

2.2.2 Mechanical Pulmonary Ventilator INSPIRE

The main components of INSPIRE are: valves, hoses, mixers, expiratory/inspiratory pressure transducer, ambu, respiratory flow transducer, minimum and maximum alarm controls, O2 cell and electric power supply (USP, 2021).

INSPIRE's mechanical design comprises two subsystems: the pump and the cabinet. The pump is the mechanical device for triggering and generating airflow for the patient's breathing. The cabinet is the structural element where subsystems are coupled such as the panel, sensors, actuators and accessories.

It is, therefore, an electromechanical component whose controlled variable, the air exhaled by the patient, is controlled by means of the PEEP pressure (Positive End-Expiratory Pressure), which in turn is electronically regulated by means of a stepper motor that it modifies the compression of a spring and maintains a diaphragm by obstructing the passage of this exhaled air. Figure 2 shows INSPIRE’s conceptual diagram (USP, 2021).

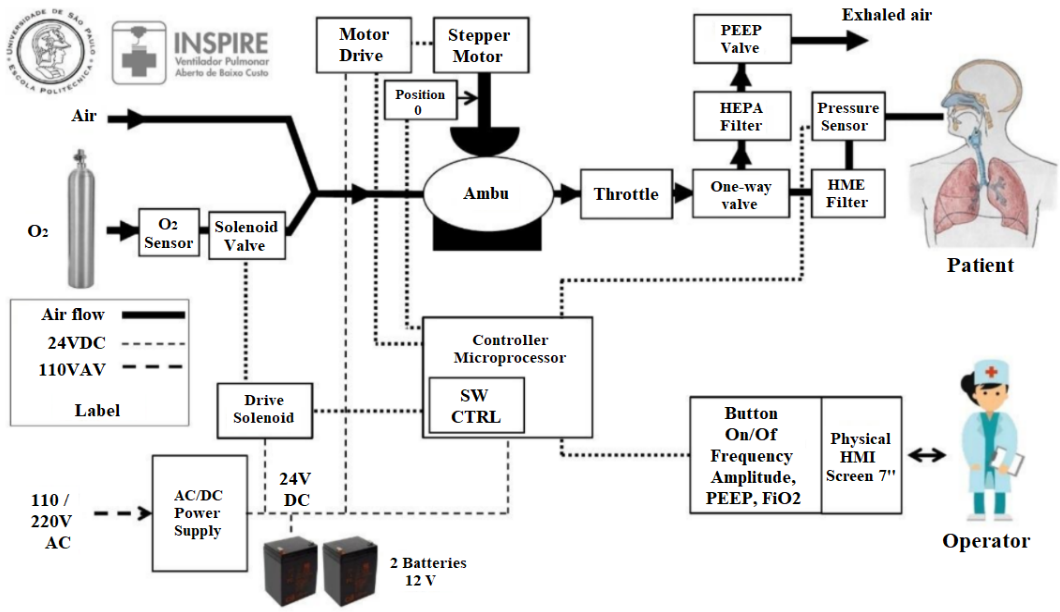

Figure 2 – INSPIRE MPV Conceptual Diagram. Source: (USP, 2021).

The pump subsystem has its central element in the ambu, a flexible element, activated by the stepper motor, which receives its rhythm and cadence from the Labrador-Pulga set, through the motor drive. The air mixed with oxygen is then propelled by the ambu and goes through a system of hoses, valves and connectors (USP, 2021).

To control the patient's expiration, the throttle functions as a proportional flow valve, used to set the desired pressure in the patient's flow circuit. A one-way valve, on the other hand, prevents the patient from inhaling the exhaled air again, which is known as pendular breathing. The pressure sensor, which is composed of a set of sensors, allows the inspiratory and expiratory flow - monitoring the air flow circuit that enters and leaves the patient's lungs, information of great value for the correct functioning of the ventilator (Tobin, 2012).

When dealing with incidents involving medical and hospital equipment, such as a MPV, three aspects must be analyzed: the equipment, the environment and the user.

The environment is a major risk factor when using this equipment. Questions such as electricity supply, the local electrical network, environmental conditions (temperature, humidity and electromagnetic induction) and also the supply of the gas network must be investigated.

Regarding the failures caused by the user, there is the misuse of the equipment and the wrong selection of parameters. The correct assembly of the circuit, the adequate power supply voltage and the correct adjustment of parameters according to the patient's needs are essential for patient safety, avoiding incidents.

3. RESEARCH METHOD

This research is exploratory, qualitative and characterized as a case study. In order to identify failures in MPVs, which are being used in the treatment of COVID-19, the Mechanical Pulmonary Ventilator INSPIRE, developed by the Polytechnic School of the University of São Paulo (USP), was chosen as a reference. Data collection took place through a structured interview with two specialist professors in the field of Mechanical Engineering at the University of Brasília.

The FMEA application included the analysis of the failure modes of the pressure sensor component (pressure transducer) of the analyzed ventilator. Experts validated the modes, effects, and causes of potential failures, as well as recommended actions, which were identified for the sensor from scientific papers and the INSPIRE Manual. Based on this validation, scores from 1 to 10 were assigned for the Severity (S), Occurrence (O) and Detection (D) indices, which originated the RPN (Risk Priority Numbers), which defines the priority of the actions that must be implemented.

Finally, all sensor failure modes were analyzed, and actions were recommended to ensure greater reliability to the component, and consequently, greater availability for the equipment.

4. FMEA APPLICATION TO MPV INSPIRE

The equipment selected for analysis was the “Mechanical Pulmonary Ventilator INSPIRE” version 1.0 (Figure 3). This equipment provides the treatment of adult patients affected by COVID-19 and who need invasive or non-invasive ventilatory support.

Figure 3 – INSPIRE Version 1.0 Model C in operation: (USP, 2021).

According to its Manual (USP, 2021), INSPIRE has a stepper motor, controlled by a microprocessor that, when rotating, generates a translation movement to the actuator that compresses the AMBU reservoir. The speed and position of this actuator are defined by a control algorithm that follows a pressure curve, using actual pressure information supplied by its pressure transducers.

INSPIRE Manual (USP, 2021), lists failures in the pressure sensor as “possible causes” for triggering several failure alarms. This alarm configuration, as well as the concern by its manufacturers, can indicate the importance that the failure of this item could represent on the performance and safety of the equipment in use by their patients. So it was decided to build the FMEA of this component as follows.

The FMEA application to INSPIRE’s pressure sensor (pressure transducer) was performed based on information available in the literature for this type of commonly used electromechanical sensor. The sensor's function is to measure the pressure of the patient's respiratory flow and presents 7 potential failure modes, namely, i. lack of sensor power; ii. open measurement circuit (failure in sensor cable); iii. short circuit (sensor wire leads touching); iv.

diaphragm failure due to leakage, rupture or deposition of foreign material on the surface; v. deposition of impurities in the sensor line before the diaphragm; vi. presence of noise in the output signal; vii. air leakage.

The specialist professors evaluated the Severity (S), Occurrence (O) and Detection (D) parameters, and originated the risk priority coefficient (RPN) as shown in Figure 4.

5. ANALYSIS OF THE RESULTS

Based on the Figure 4, it can be seen that the main occurrences of failures (parameter O) are related to the presence of noise in the output signal, followed by air leakage. The identification of occurrences showed that the pressure sensor is subject to a high frequency of failures, in the opinion of the interviewed experts.

Application of FMEA to the Sensor (Pressure Transducer) of the MPV INSPIRE

ITEM	FUNCTION	POTENTIAL FAILURE MODE AND CAUSE	POTENTIAL EFFECT OF FAILURE	SEVERITY (S)	ROOT CAUSE	OCCURENCE (O)	RECOMMENDED ACTIONS	DETECTION (D)	RISK (RPN)	CLASSIFICATION
Sensor (Pressure Transducer)	Measure respiratory flow pressure	Sensor power failure (1)	1. No output signal (sensor does not register pressure).	10	1. Physical damage from shock or vibration; 2. Power cable breakage; 3. Damage to the Power source.	3	1. Corrective maintenance (check sensor power supply).	1	30	4º
		Open measurement circuit (fault on sensor cable) (2)	1. No output signal (sensor does not register pressure).	10	1. Physical damage from shock or vibration; 2. Signal cable breakage; 3. Disconnection of the sensor in the reading circuit.	3	1. Corrective maintenance (observe equipment low pressure alarm, check sensor output connections)/ 2. Perform the tests prescribed in the Manual.	1	30	4º
		Short circuit (sensor cables are touching) (3)	1. Absence of output signal (sensor does not register pressure); 2. Sensor output is irregular (incorrect readings).	10	1. Cable physical damage;	2	1. Corrective maintenance (observe fluctuations in pressure readings, replace cables); 2. Preventive maintenance.	1	20	5º
		Diaphragm failure due to leakage, rupture or deposition of foreign material on the surface (4)	1. Absence of output signal (sensor does not register pressure); 2. Erroneous readings.	10	1. Physical damage from shock or vibration; 2. Lifetime reached; 3. Excessive pressure (overpressure).	1	1. Corrective maintenance (replace sensor); 2. Perform the tests prescribed in the Manual; 3. Preventive maintenance.	9	90	1º
		Deposition of impurities in the sensor line before de diaphragm (5)	1. Slower response time; 2. Innacurate readings.	7	1. Absence of the inlet air filter; 2. Lack of maintenance on the inlet air filter;	2	1. Corrective maintenance (perform system cleaning); 2. Preventive maintenance.	1	14	6º
		Presence of noise in the output signal (6)	1. Innacurate instrument readings; 2. Erratic instrument readings.	7	1. Power supply failure; 2. Oxidation in electrical contacts of power and sensor signal cables; 3. Electromagnectic inductions (EMI) from external noise; 4. Variation in supply voltage (excessive load or proximity to fluorescent lamps).	7	1. Corrective maintenance (check the power supply, check the state of the electrical contacts, keep away sources of electromagnetic interference, check the electromagnetic shield between the equipment and the cables that carry the sensor signals to the reading circuit); 2. Use nobreaks; 3. Preventive maintenance.	1	49	2º
		Air leakage (7)	1. Innacurate readings.	7	1. Incorrect fit of the air lines supplying the sensor; 2. Damage to the air lines supplying the sensor.	5	1. Corrective maintenance (check the fittings of the airlines, check the tightness of the air lines); 2. Preventive maintenance.	1	35	3º

Figure 4 – FMEA to the Sensor (Pressure Transducer) based on (Cadwallader, 1996), (Lukat, 2015), (Lish, 2015) and USP (2021).

The highest severity numbers (S parameter) and the highest failure detection chances (D parameter) were estimated for the following potential failure modes: diaphragm failure due to leakage, rupture or deposition of foreign material on the surface. The analysis of the results demonstrated that the permitted degree of risk of RPM ≤ 120 was not exceeded for any of the failure modes. The greatest degree of risk observed was for diaphragm failure due to leakage, rupture or deposition of foreign material on the surface RPN = 90 (O = 1, S = 10, D = 9). Although this failure has a high S parameter and is difficult to detect (D) it, the occurrence of the failure is low, according to experts.

In Figure 5 the FMEA result is represented. Most risk levels did not exceed RPM = 50. The highest values found were: presence of noise in the output signal RPN6 = 49 (O = 7, S = 7, D=1); air leakage RPN7 = 35 (O = 5, S = 7, D = 1); sensor power failure and open measuring circuit (sensor cable failure) RPN1,2 = 30 (O = 3, S = 10, D = 1).

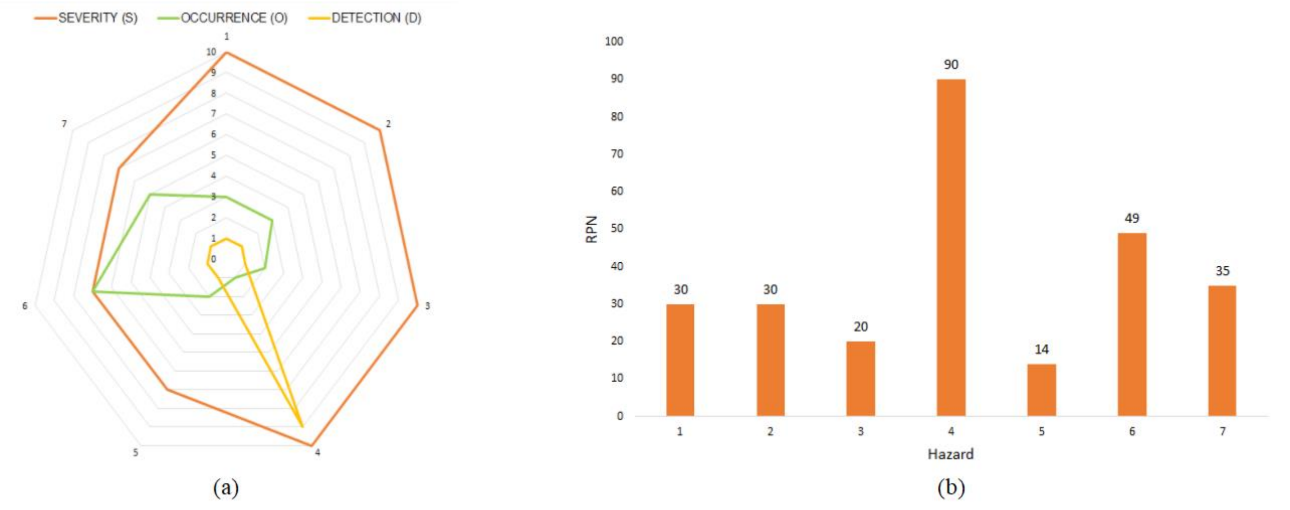

Figure 5 – (a) Presentation of FMEA results - S, O, D parameters and (b) Representation of FMEA results - RPN.

According to specialist professors, the failures should be prioritized are diaphragm failure due to leakage, rupture or deposition of foreign material on the surface (first one); presence of noise in the output signal (second one), followed by air leakage (third one).

Most of the recommended actions involve preventive maintenance of the sensor components and the system that makes it up, as a way to ensure its proper functioning.

6. CONCLUSION

It is important that Mechanical pulmonary ventilator (MPV), an important hospital life support equipment, like INSPIRE, performs to the expected standards. To fulfill this goal it is of fundamental importance that the main failure modes of a MPV are identified, analyzed and equally made available to the public, in order to ensure patient safety, thus increasing the reliability of such medical equipment.

The FMEA qualitative method of reliability analysis was used as reliability evaluation technique to determine the effect of system and equipment failures in a specific pre-selected item, the pressure sensor (transducer).

Following FMEA analysis, the main occurrences of failures (parameter O), the highest severity numbers (S parameter) and the highest failure detection chances (D parameter) were estimated. The analysis of the results demonstrated that the permitted degree of risk of RPM ≤ 120 was not exceeded for any of the failure modes, while the greatest degree of risk observed was for diaphragm failure due to leakage, rupture or deposition of foreign material on the surface RPN = 90 (O = 1, S = 10, D = 9).

In view of the importance of this type of equipment for the treatment of patients in a critical situation, it is recommended that the implementation of the FMEA as a method of risk analysis be used in other components such as flow transducers, among others, in order to ensure their safer and more reliable use.

A limitation of the research was the evaluation of the FMEA by only two specialist professors. It is suggested that research involve more subject matter experts.

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