# MAINTENANCE STRATEGY BASED ON RELIABILITY ANALYSIS: A CASE STUDY OF MECHANICAL VENTILATORS

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*Abstract. Difficulty breathing is one of the most common symptoms of the new coronavirus. Depending on the case, respiratory care needs to be reinforced with the use of mechanical ventilators (MVs) in Intensive Care Unit (ICU). Good conditions of use and availability of MVs in the hospital environment can be crucial for the recovery and survival of patients. The correct maintenance strategy for this equipment becomes essential, since any failure during its operation can cause consequences in the patient treatment and even lead them to death. In this context, the development of a maintenance plan based on reliability indicators analysis is essential to formulate the best maintenance strategy for this equipment, in order to increase its availability and reliability. This paper aims to analyze the behavior of reliability indicators such as failure rate, Mean Time Between Failures (MTTF) and Mean Time To Repair (MTTR) of 118 MVs. First, a literature review is conducted on the main reliability indicators. Then, a brief study of MVs is presented. The failure behavior of the 118 MVs is modeled in terms of probability distribution using a free software called ProConf. After, an analysis of the failure behavior as a function of the Bathtub Curve is made in order to define appropriate maintenance strategies in terms of corrective, preventive and predictive maintenance. As a result, it is expected to help teams that are working on the maintenance of MVs in planning maintenance activities in a proactive way.*

*Keywords: reliability, maintenance, analysis, mechanical ventilators.*

## 1. INTRODUCTION

The World Health Organization (WHO) temporarily termed the new virus 2019 novel coronavirus (2019-nCoV) on 12 January 2020 and then officially named this infectious disease coronavirus disease 2019 (COVID-19) on 12 February 2020. Subsequently, human-to-human transmission of COVID-19 occurring within Hong Kong has been shown in clinical data. Since COVID-19 initially emerged in China, the virus has evolved for four months and rapidly spread to other countries worldwide as a global threat. On 11 March 2020, the WHO finally made the assessment that COVID-19 can be characterized as a pandemic (Liu, Kuo and Shih, 2020).

The mechanical pulmonary ventilator is the main medical equipment used in the treatment of COVID-19, as it helps the patient to breathe artificially, since it is a disease that is harmful to the lower respiratory tract, which involves the lower part of the trachea, bronchi, bronchioles, alveoli and lungs (Rosa, 2020).

WHO defines medical and hospital equipment (EMH) as medical devices that require calibration, maintenance, repairs, user training and obsolescence procedures and that are used for the specific purposes of diagnosing and treating illness or rehabilitation arising from illness or injury. To increase the effectiveness of medical equipment management, EMH are classified according to technological complexity. Mechanical pulmonary ventilators are classified as an equipment of medium technological complexity, as the human resource needed to carry out maintenance requires more specialized knowledge and adequate for the type of device (Calil and Teixeira, 1998, Brasil, 2013).

The correct maintenance strategy for this equipment is essential, as any failure during its operation can cause consequences in the treatment of patients, even leading to death. Within this context, the analysis of reliability parameters as a basis for formulating the best maintenance strategy for each equipment becomes essential to ensure greater availability of such equipment (Mendes and Ribeiro, 2014, Santos and Sellitto, 2016).

For this purpose, this article is structured as follows: the next section addresses a brief bibliographic review about the main concepts of reliability. Section 3 presents the main components of a Mechanical Ventilator. After, in Sections 4 the reliability analysis in pulmonary ventilators is developed. Section 5 presents the final considerations.

As contributions to the result of this article, we hope to understand the behavior of the main failures of a mechanical pulmonary ventilator and contribute to the identification of strategies to avoid or minimize them.

## 2. BIBLIOGRAPHIC REVIEW

### 2.1 Reliability

Reliability is the probability of an item to perform a required function under specified conditions, during a given time interval. Item is any part, component, device, subsystem, functional unit, equipment or system that can be considered individually (NBR 5462, 1994).

The most important indicator for reliability is the Mean Time to Failure (MTTF), represented by Eq. (1):

$$MTTF = \Sigma\, TPF/N, \tag{1}$$

where TPF is the Time to failure and N is the Period number (hours/days). Thus, a period of time is defined in hours, minutes or the unit of measurement that makes the most sense for the organization and it is counted how many failures occurred during that time. Another important indicator is the Failure Rate ($\lambda$), denoted by Eq. (2):

$$\lambda = Number\ of\ failures/Number\ of\ operation\ hours, \tag{2}$$

In general, an item presents three distinct periods of failure behavior that can be illustrated by a graph called the Bathtub Curve. The Bathtub Curve seeks to describe the variation of Failure Rate of components during their life (in terms of time) as shows in Figure 1. The failures exhibited in the first part of the curve, where failure rate is decreasing, are called early failures or infant mortality failures. The middle portion is referred to as the useful life and it is assumed that failures exhibit a constant failure rate, that is to say they occur at random. The latter part of the curve describes the wear out failures and it is assumed that failure rate increases as the wear out mechanisms accelerate (Smith, 2005).
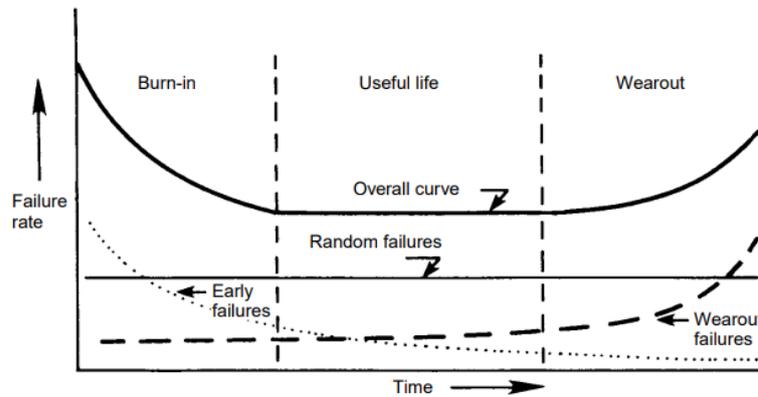


Figure 1 – The Bathtub Curve (Smith, 2005).

Early, random and wear out failures have different causes and different countermeasures to mitigate them. However, prevention through maintenance is an effective countermeasure for all three types of failure. The causes of early failures are often design and manufacturing errors and to combat them, it is necessary to conduct tests at the initial stage of item operation. Random failures are mainly caused by errors in operation, so the best countermeasure to be applied is to ensure that the operator uses the equipment correctly (Nakajima, 1988).

Fogliatto and Ribeiro (2009) presents the main variables related to reliability through the following equations. The fault density function f(t) corresponds to the variation in the probability of failures per unit of time, being graphically represented by a probability distribution (Fogliatto and Ribeiro, 2009). Mathematically, it is expressed by Eq. (3):

$$f(t) = dF(t)/dt, \tag{3}$$

In turn, the accumulated failure function **F(t)** shows the probability of failure over a period of time between **t1** and **t2**. Mathematically, it is expressed by the Eq. (4).

$$F(t_2) - F(t_1) = \int_{t_1}^{t_2} f(t) \cdot dt, \tag{4}$$

The hazard function or hazard rate is the amount of risk associated with a unit of time t as defined by Eq (5).

$$h(t) = f(t)/R(t) = f(t)/(1 - F(t), \tag{5}$$

Finally, reliability is expressed by the reliability function **R(t)**, in Eq. (6):

$$R(t) = 1 - F(t) = 1 - \int_0^1 f(u)du = \int_1^{+\infty} f(u)du, \tag{6}$$

## 2.2    Types of Maintenance

Kardec and Nascif (2019) cite six types of maintenance, which according to them can also be considered as maintenance policies or strategies, these are:

- Unplanned corrective maintenance;
- Planned corrective maintenance;
- Preventive maintenance;
- Predictive maintenance;
- Detective maintenance;
- Prescriptive maintenance;
- Maintenance engineering.

Unplanned corrective maintenance is not done according to a pre-established program, but after receiving information related to the condition of an item (ABNT 5462, 1994). It usually entails high costs, since the unexpected breakdown can lead to production losses, product quality losses, and high maintenance costs (Kardec and Nascif, 2019).

In turn, planned corrective maintenance is characterized by acting on the equipment before the failure occurs. It is the action of correcting the performance lower than expected based on the monitoring of the equipment's condition parameters. This monitoring is done by predictive, detective, and prescriptive maintenance (Kardec and Nascif, 2019), to be presented below. According to NBR 5462, planned corrective maintenance is equivalent to preventive maintenance performed according to a pre-established program.

Preventive maintenance is performed at predetermined intervals, or according to prescribed criteria, designed to reduce the probability of failure or degradation of the operation of an item (ABNT 5462, 1994). This maintenance provides a prior knowledge of the actions allowing a good condition of management of the activities, it proves more convenient the greater the simplicity of replacement, the higher the costs of failures, the more the failures impair production and the greater the implications of failures on personal safety (Kardec and Nascif, 2019).

According to NBR 5462 (1994), predictive maintenance allows to ensure a desired quality of service, based on the systematic application of analysis techniques, using focused supervision or sampling means, to minimize preventive maintenance and decrease corrective maintenance. Its objective is to predict failures in equipment 18 or systems allowing the continuous operation of the equipment for as long as possible, when the degree of degradation approaches or reaches the previously established limit the decision to intervene is made.

Kardec and Nascif (2019) define detective maintenance as the action performed in protection, command and control systems, seeking to detect hidden failures or those not perceptible to operation and maintenance personnel. According to the authors, the identification of hidden failures is paramount to ensure reliability.

With the arrival of Industry 4.0 comes the prescriptive analysis that establishes prescriptive maintenance. This analytical capability of machines and systems will not only show what and when a failure will happen, but also why it is happening (Kardec and Nascif, 2019).

Finally, maintenance engineering is the technical support of maintenance that is dedicated to consolidating the routine and deploying the improvements (Kardec and Nascif, 2019).

## 3. MECHANICAL VENTILATOR

In view of the concepts of Mechanical Ventilation, the main responsible equipment that provides a effective treatment for patients with respiratory failure are the Mechanical Ventilators (MVs). In this article, will be analysed the MVs for Invasive Ventilation.

The Mechanical Ventilator is an equipment used to provide artificial pulmonary ventilation, whether temporary, complete or partial to patients with respiratory failure due to factors such as diseases, birth defects, and others (Romero, 2006).

A modern lung ventilator is defined as a device designed to provide life support using the combined action of hardware and software. The hardware is composed, in general, of pressure regulator valves - responsible for reducing the inlet pressure (in the ventilator) of the gases that are supplied to the equipment (Makhamed, 2017). The software, on the other hand, uses arrays of digital logic systems and artificial intelligence models to provide, through multiple configuration forms, the necessary air flow to a patient's airways (Martelo, 2015).

Going more specifically into the hardware of Mechanical Ventilators, this device is composed of the following components (Figure 2): pressure regulating valves, mixer, controls, bacteria filter, nebulizer, humidifier, exhalation valve, and alarms (Chang, 2013).

The most complete models still count with sensors and computer interface that allows the visualization and control of several parameters, it is also possible to send to a control center and store the most critical measures, alarms and data about the procedure (Dias et al., 2012).
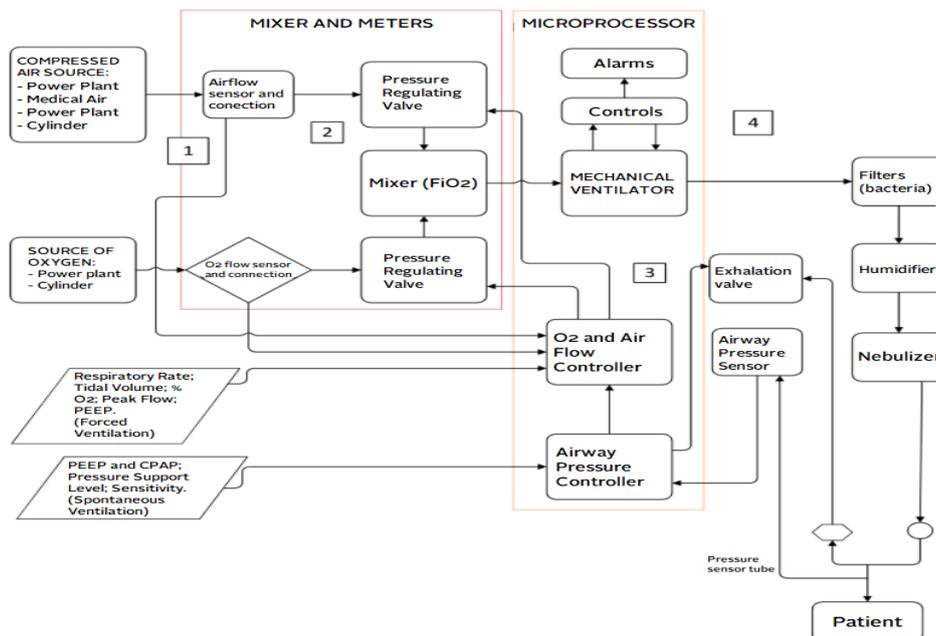


Figure 2. Schematic diagram of the control strategy (Button, 2002).

Mechanical ventilators usually have a control system, which is programmed by the professional and commands the operation of the equipment (Peixoto, Queiroz and Santos, 2013). Commonly MVs have a control system, gas valves, alarms and sensors, flexible breathing circuit, formed by flexible tubes to connect the patient to the ventilator, humidifiers and heaters (Uechi, 2012). The Humidifiers and Heaters, are used to condition the mixture that will be inhaled by the patient, the Alarms and Sensors measure the parameter values provided by the equipment and alert the healthcare team supervising the patient if any patient parameters are changed, and the Pressure Regulating Valves are responsible for reducing or increasing the pressure of the gases (Fornazier et al, 2011).

Most ventilators are microprocessor controlled and regulate the pressure, volume or flow of the delivered positive pressure breath, and the fraction of inspired oxygen (FiO2) based on control parameters, so the pressure sensor and flow sensor must be specified to act in the appropriate working ranges (Hasan, 2010).

Information such as control parameters, monitored variables, and alarm status are transferred to a monitor, information system, or other interfacing device, called a communication interface (Martelo, 2015). The energy required for the operation of the mechanical ventilator is supplied by the electrical network, made available directly at the power points and outlets of the health service, or by means of rechargeable type batteries that enable the operation of the equipment in the absence of electrical power or in the transport of the patient under ventilation (Fornazier et al, 2011).

During inspiration, compressed air and oxygen can be supplied through valves installed on the wall, and the flow of gas to the patient is regulated through inspiratory valves, this mixing can be done internally in the MVs, through the mixer (Ecri, 2007).

Oxygen is used as a form of therapy and not as the main source of gas. Therefore, in case of failure of the $O_2$ supply system, the equipment will continue to operate, providing atmospheric gas, with a concentration of 21% $O_2$.

## 3.1    Reliability analysis in Mechanical Ventilators

Based on the research developed by Heleno (2014), reliability variables are presented in order to model the behavior of failures in mechanical pulmonary ventilators.

For this purpose, ProConf software was used to generate the failure probability distribution graph, failure distribution function, risk function, accumulated failure function and bath curve. Furthermore, it is possible to obtain the Mean Times to Failure (MTTF) value (Fogliatto and Ribeiro, 2009).

As input data for the MVs reliability analysis, the MTTF's created by numerical simulation were considered, according to Heleno (2014). The MTTF values that were entered into the software, as shown in Table 1.

Table 1. MTTF of Mechanical Ventilators (Heleno, 2014).

| Mean Time to Failure (hours) | | | | |
|---|---|---|---|---|
| 6552 | 5899 | 6524 | 5181 | 2577 |
| 2269 | 3066 | 6265 | 4041 | 5122 |
| 7234 | 5074 | 5930 | 4068 | 5770 |
| 4908 | 4195 | 3485 | 5700 | 3513 |
| 4341 | 5113 | 3948 | 2460 | 5194 |
| 4360 | 2368 | 3444 | 5161 | 2757 |

The mechanical pulmonary ventilators considered in this study had 30 failures in the period considered for the research.

The ProConf software generated four types of probability distributions: Exponential, Weibull, Lognormal, and Normal (Fogliatto and Ribeiro, 2009). The probability distribution function that best fits the data was selected. It was concluded that the Weibull distribution would be the most appropriate due to the greater proximity to the points of the graph, especially those located at the extreme, as shown in Figure 3.
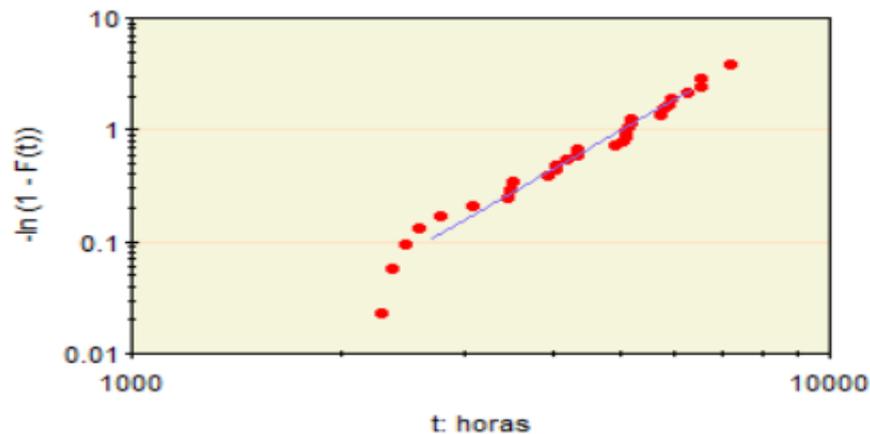


Figure 3 – Weibull probability distribution.

The basic Weibull distribution has two parameters: (i) a shape parameter, called gamma ($\square$), and a scale parameter, often called theta ($\square$). The scale parameter, $\square$, determines when, over time, a given portion of the population will fail (i.e., 5046,016 %). The shape parameter, $\square$, determines how the bathtub curve will behave over time. The $\square$ less than 1 models a failure rate that decreases over time, as in the infant mortality period. A beta equal to 1 model a constant failure rate, as in the normal life span. A beta greater than 1 model an increasing failure rate, as during the attrition period (Wilkins, 2002).

Figure 4 shows the values of the parameters $\square$ and $\square$ and the MTTF. The value of $\square$ obtained from 5020,435. A value of $\square$ equal to 3,6436 means that the failure rate increases over time.

**Distribuition: Weibull**

Location Parameter = 0

Maximum Likelihood Estimates:

| | | |
|---|---|---|
| $\gamma$ = | 3,8185 |
| $\theta$ = | 5046,016 |
| Var[$\gamma$] = | 0,2955 |
| Var[$\theta$] = | 64553,814 |
| Cov[$\theta$,$\gamma$] = | 43,2275 |

Unbiased estimate:

| | |
|---|---|
| $\gamma$ = | 3,6436 |
| Var[$\gamma$] = | 0,301 |
| $\theta$ = | 5020,435 |

95% of Confidence Interval:

| | | | |
|---|---|---|---|
| to $\gamma$ = | 2,5829 | to | 4,6027 |
| to $\theta$ = | 4497,012 | to | 5603,05 |

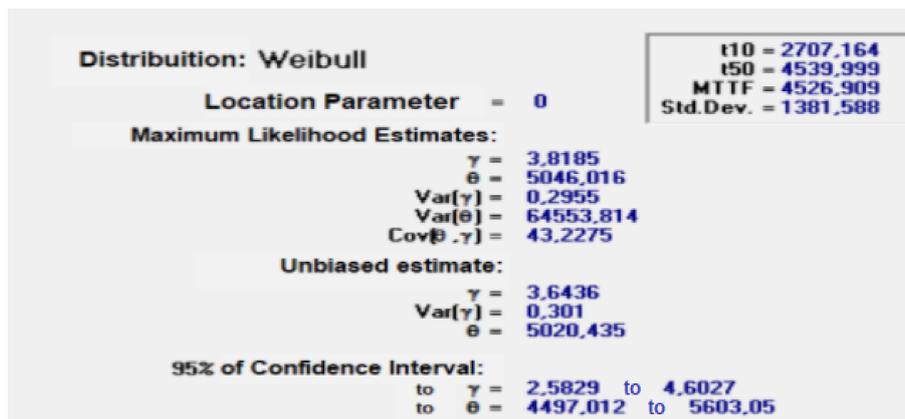| | |
|---|---|
| t10 = | 2707,164 |
| t50 = | 4539,999 |
| MTTF = | 4526,909 |
| Std.Dev. = | 1381,588 |

Figure 4 – Weibull probability distribution parameters.

Once the probability distribution was defined, the software ProConf indicated the associated fault density function (f(t)), accumulated failure function (F(t)) and reliability (R(t)), as showed in Figures 5, 6 and 7, respectively.
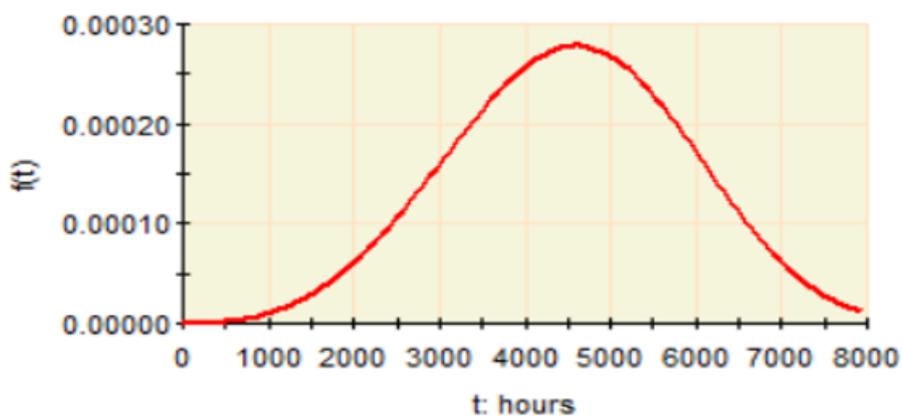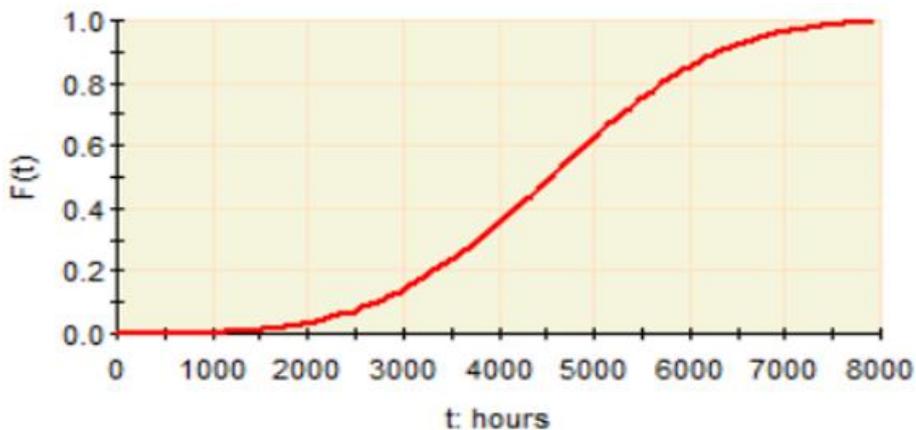


Figure 5. Graphic of fault density function f(t).
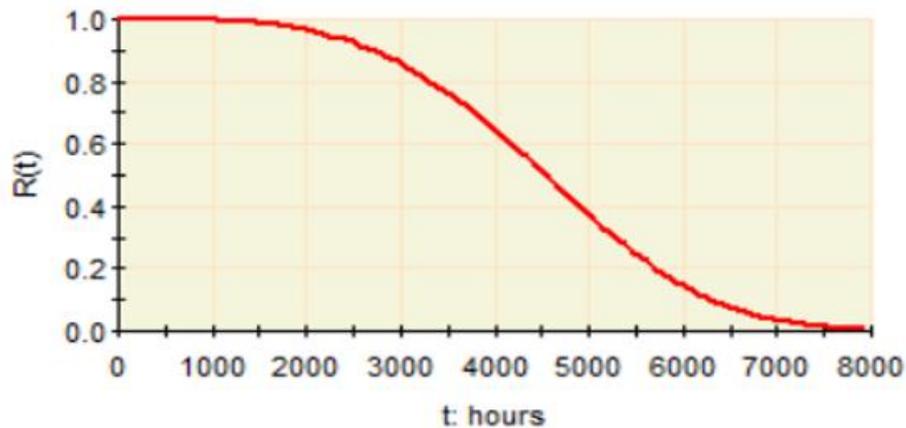


Figure 6. Graphic of accumulated failure function F(t).

Figure 7. Graphic of reliability R(t).

From the sample of 100 failure times generated by the software, it became possible to construct the so-called "Bathtub Curve" for the VPMs analyzed. This represents the phases in the life of a component or system, and is formed by the Failure Rate and Time ($\lambda$ x t). For the present case study, the result is shown in Figure 8.
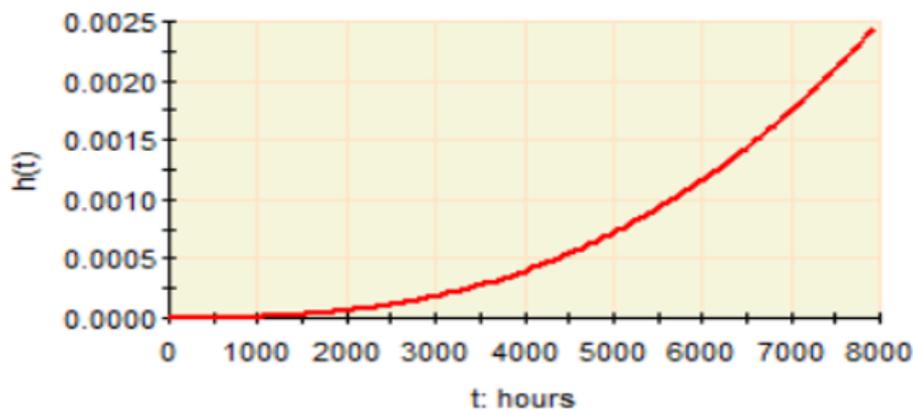


Figure 8. Graphic of VPMs Bathtub Curve.

The Bathtub Curve can be interpreted in conjunction with failure density, reliability, and cumulative failure function plots in light of the types of failures. Having the failure density as a normal, an increasing cumulative failure function and decreasing reliability, a bathtub curve with increasing behavior, and the shape parameter (gamma) greater than 1 (i.e., 3,8185) the system failure type is characterized as standard C (time failures).

Components that fail according to mode C have an increasing failure probability, but in no period of time can wear failures be detected. One possible cause for type C failures is fatigue.

### 3.2 Maintenance Strategies for Mechanical Ventilators

Based on the studies conducted by Lucatelli and Garcia Ojeda (2002) and Figueiredo (2016), the 10 main failure modes of MVs can be listed. In the present study, we will use failure modes that completely compromise the use of MVs and consequently the death of the patient. Therefore, the main failures can be seen in Table 2.

Table 2. Main failure modes of Mechanical Ventilators.

| Main Failure Modes | |
|---|---|
| 1.   Mixer maladjustment | 6.   Turbine failure |

| | | | |
|---|---|---|---|
| 2. | Pressure difference between O2 and Air | 7. | Blown fuse or faulty power supply |
| 3. | Lack of electric power | 8. | Bad contact in connectors |
| 4. | Electronic Failure | 9. | Ventilator battery failure |
| 5. | Humidifier cup failure | 10. | Switch failure (micro switch) |

From the reliability analysis presented and the main failure modes of MVs it is possible to formulate maintenance strategies for mechanical ventilators. The maintenance strategies for MVs are guided mainly by preventive maintenance. The preventive maintenance procedures and the frequency of inspections, involve cleaning procedures, visual inspection, safety and functionality tests (Lucatelli, 1998).

In order to have a compilation of the best maintenance strategies for MVs, the studies by Lucatelli (1998) and Button (2002) were used. The strategies listed were based mainly on the usage time of the ventilators, since as mentioned in the previous section, the MVs tend to have higher failure rates over time. The main maintenance strategies for MVs are shown below.

Daily:
- Check all bacteria filters (air and $O_2$) to verify correct positioning and ensure proper functioning of the ventilator;
- Check and empty the exhaled gas collector, filters and water collectors;
- Clean the outside of the unit and valves.

Biweekly:
- Check the pressure difference of all reusable filters to verify that there are no ruptures and that the safety limit has not been exceeded.

Biannually:
- Inspect for loose or damaged components;
- Check the physical condition of all controls and the pressure gauge;
- Inspect condition of diaphragm, replace if necessary;
- Inspect condition of breathing - tubes, nebulizers, and other accessories connected to the patient to the unit;
- Inspect all filters and their compartments;
- Check that the unit is cycling correctly;
- Check the proper pressure and flow rate.

Every 250 hours:
- Clean the filter in the compressor's cooling compartment;
- Perform calibration of the entire fan with the preventive maintenance kit;
- Clean the cooling fan filter.

Every 500 hours:
- Clean the air inlet filter and the oxygen filter.

Every 1000 hours or annually:
- Perform calibration of the entire ventilator with the preventive maintenance kit;
- Replace all reusable bacteria filters in the system.

## 4. CONCLUSIONS

The present paper aimed to perform a reliability analysis on Mechanical Ventilators (MVs), used for the treatment of patients with COVID-19.

The study conducted by Heleno (2014) was used to construct the failure probability distribution graphs, failure distribution function, risk function, cumulative failure function and bath curve, which in the future would serve as a foundation for consolidating the most appropriate maintenance strategies for MVs.

Based on the work presented by Lucatelli and Garcia Ojeda (2002) and Figueiredo (2016), it was possible to elucidate the main failure modes and consequently the best maintenance strategies for MVs. In the present article, it was used mainly strategies based on preventive maintenance and the time of use of the equipment.

With the preventive maintenance strategies outlined, it is noted that they bring several benefits to various stakeholders, because they are essential to maintain the operability and quality of operation of machinery and equipment, so the main benefits brought with the implementation of a good preventive maintenance strategy are:

- Prevents machine damage and data loss: Machines, just like human bodies, need periodic care. Therefore, just like humans who should have checkups every year, machines do this through preventive measures, with the goal of avoiding major and more serious damage throughout their operation;
- Ensures equipment life: Preventive maintenance seeks methods to maintain the performance and life of the machine through action plans and by checking its components. An example is the general cleaning of the machine components that, because it is something basic and simple, is not identified the due value of the action;
- Cost savings: The cost of preventive maintenance is much lower when compared to the interventions that must be performed to solve some problem and the like. This cost difference can be identified by exemplifying the following situation: performing the exchange of parts and inspection of your equipment during its operation, instead of waiting for some problem to occur on the machine to investigate and solve the cause by stopping the operation of the equipment. Through these periodic cares, it is a consequence the reduction of equipment that needs to be replaced, an advantage in the medium and long term.

Therefore, based on the benefits brought by the implementation of assertive maintenance strategies for mechanical ventilators, it is noted that these are indispensable for a good functioning of the equipment, besides that they bring a survival for patients affected by COVID-19.

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