

Improvement of the Reliability of Anesthesia Machines Through the Application of the FMEA Methodology

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This work proposed the application of the FMEA (Failure Mode and Effects Analysis) methodology to the anesthesia carriage, for which a case study was carried out in a group of nine equipments, using the FMEA tool. The purpose of this research was to evaluate the reliability of the anesthesia machine, demonstrating through daily and semiannual data analysis, proving that preventive maintenance focused on reliability enables greater safety, both for the patient and for the hospital's multidisciplinary team. The methodology was developed with the purpose of analyzing failure indicators, to assist in the development of hospital maintenance strategies, exemplifying its application through the FMEA tool, seeking solutions with innovations in maintenance management, in order to reduce costs, through the speed in the analysis of results for health units.

Keyword: Clinical Engineering. FMEA. Anesthesia Machine.

According to Akao (1990) [1], there are three main items of reliability: (1) durability, related to the useful life of the product; (2) safety, and (3) maintenance. In data collection, it is possible to characterize parameters of a component, equipment or program, giving importance to different operating circumstances.

To implement a maintenance management method for medical devices, according to the Ministry of Health (2002) [2], it is crucial to understand the history of the equipment in the context of the Health Care Establishment (EAS), including its group or family, useful life, obsolescence, construction and the possibility of replacement during maintenance. These details support maintenance, ensuring safety and quality. This information guides the technician in the analysis of failures, urgency of the service, implementation of preventive maintenance and in the search for the level of reliability necessary to avoid risks to the patient's life.

In this context, this research work used failure parameters, generating reliability indicators, at the

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same time that it is possible to evaluate the conditions of use of the equipment, and consequently, direct maintenance actions through the characteristics of the failures, providing improvement in the quality of health services and generating conditions for Clinical Engineering to consolidate its integration into the technological process in health.

The objective of this study was to apply the FMEA (Failure Mode and Effects Analysis) methodology based on the reliability of the anesthesia carriage, using data analysis, with the main focus on the study of failures and a point of view on maintenance centered on reliability, using a case study carried out from a health unit.

Materials and Methods

To carry out this study, the authors performed a retrospective data collection of data on the history of corrective maintenance services, performed in a medical anesthesia cart, from January 1, 2021 to December 13, 2023, in a public hospital in the city of Salvador, Bahia, Brazil. The hospital under study has 120 beds, 30 of which are intensive care units, 8 operating rooms and 1 magnetic resonance room, performing 9,000 surgeries per year, justifying the high demand for the anesthesia cart and its criticality in the operating room.

The hospital has a team that carries out daily inspections of high-complexity equipment,

testing, before the first surgeries, in order to avoid inconveniences and delays during the day. Verification is carried out on all functional parts of the equipment such as: gas system, ventilatory modes, canister and anesthetic agents.

In this work we will introduce the concepts of reliability, time of intervention, probability of failure and MTBF (Mean Time Between Failures). According to Kardec [3], MTBF are the periods that are lost in the operation of a machine, and its average can be performed by means of Equation 1. We need to calculate the total fail-free operation time over a specific period and compare it to the number of errors that occurred during that interval. Then, the MTBF and failure rate as a function of time (λ) were calculated from Equations 1 and 2, respectively below, where N_f is the number of recurrent failures in the study time.

$$MTBF = \frac{(Total\ Time\ Available - Time\ Lost)}{(Number\ of\ stops)} = \frac{1}{\lambda} \quad (1)$$

Based on this conclusion, it is possible to develop approaches to gradually deal with equipment-related issues.

It is crucial for the maintenance manager to determine the possibility of failure of an item or equipment. In this regard, we have the reliability calculation. According to the NBR-5462 [4] standard, reliability refers to the percentage or probability of correct operation of machines, systems and/or items included in the production chain, as specified, during a specific period. Thus, it is up to the Engineering professional to measure how much it is possible to trust a piece of equipment and ensure that the production will have its production flow planned.

To calculate reliability, we first need to calculate the failure rate (λ) which is the inverse of MTBF:

$$\lambda = \frac{1}{MTBF} = \frac{Number\ of\ stops}{(Unit\ x\ Time)} = \frac{N_f}{t} \quad (2)$$

With these values, we can calculate the reliability of the equipment for a given time. Then, reliability was calculated in equation 3, respectively below, where R is Reliability; t time to be measured, be a certain period or life cycle of the equipment (t 1);

(e) basis of the Neperian algorithms and is worth 2.71 and λ failure rate.

$$R(t) = e - (\lambda).t.100 \quad (3)$$

Given the cost associated with the occurrence of failures and taking into account the current capacity of the internal team, as it is an equipment with a high degree of criticality of the equipment, risks involved for employees and patients, it was established that each component must have a minimum reliability of 95%. The maximum time allowed for equipment intervention ($t_{0.95}$) is determined using Equation 4. [5]

$$t_{0.95} = - \frac{\ln(0.95)}{\lambda} \quad (4)$$

According to Piazzzi [6], reliability can be calculated from a given time interval, with this premise we can calculate the probability of failure (Q) of components for a life cycle, equal to the failure density $F(t)$, shown by Equation 5.

$$F(t) = Q = 1 - R(t) \quad (5)$$

Being sure of the reliability of the equipment is essential to ensure that the processes achieve the desired results within a stipulated timeframe. It is an essential maintenance indicator for competitiveness when combined with predictive maintenance and its computational analysis. Mainly to save on equipment maintenance costs and make more assertive strategic decisions. The data were collected from work orders, and the analysis was based on the maintenance process and the observations made by the Clinical Engineering team.

In accordance with the IEC 60812:2018 [7] standard, and based on the calculations, it was possible to use the FMEA tool, increasing the reliability of the equipment, suggesting maintenance based on a plan according to the failures analyzed in the study interval. The FMEA methodology uses the Risk Priority Number (RPN), multiplying from numerical indices of Severity (G), Occurrence (O) and Probability of Detection (D) of each failure, for a critical analysis of failure modes. By assigning values from 1 to 10, the most critical failure modes are assigned larger values, indicating higher

frequency or lower detection. Control actions are determined by RPN, helping the maintenance team identify the most important faults. In addition, shown in equation 6 we have, RPN combines semi-quantitative assessments of severity, occurrence, and detectability. Its value varies depending on the measurement scales, usually from 1 to 1000.

$$RPN = G \times O \times D \quad (6)$$

Results and Discussion

The study was carried out on 86 service orders, however 7 work orders will not be included in the calculation, (1 failure inconsistency, 1 failure not found, 1 failure due to assembly in manufacturing, 2 preventive, 1 installation and 1 uninstallation).

Operational Failures are related to the team not knowing how to operate the equipment or having doubts about its perfect functioning, but without causing damage to the equipment, these mistakes had 19.05% called.

Table 1 shows the number of failures during the analyzed period, together with the failure rate, the MTBF and the time required for intervention, considering a reliability of 95% ($t_{0.95}$), the reliability for each failure, in the period of 180 days, having performed the semiannual preventive test.

Table 2, similar to the Table 1, shows the reliability at 365 days, with annual maintenance and a mean difference of 17.01% between Tables 1 and 2. In Table 2, we consider the period of 365 days for the actual reliability of the components.

Table 3, similar to the previous ones, portrays the reliability in the period of 1 day, with inspections performed daily and the probability of failure for each component is completely non-existent, consequently making the reliability very high, approaching 100%.

They analyzed the work orders, and had some observations. For the CCI-0001 equipment, two occurrences were observed: in one of them, the medical team noticed that the equipment failed and considered it safe to continue the surgery, while at another time no failure was found, support was requested from the manufacturer.

In the case of the CCI-0002 equipment, there was an error in the assembly during the manufacturing process and was identified in the first days of use by the team, the nurse opened the call, but no failure was found, and the administrative staff was asked to pay attention to the equipment.

For the CCI-0003 equipment, a work order was linked to the balloon support arm, connected to the lung ventilator and anesthesia cart. However, there

Table 1. Failure rate, mean time between failures (MTBF), intervention time, and reliability over a 180-day period.

Failure Mode	Average No. of Failure (Nf)	Failure rate (λ)	MTBF (days)	Intervention time ($t_{0.95}$)	Reliability (t_{180} days)	Probability of failure
O2 Button Failure	2.20	2.01E-03	497.7	25.5	69.65%	30.35%
Uncalibrated O2 sensor	1.80	1.64E-03	608.3	31.2	74.39%	25.61%
Flow Sensor Failure	1.80	1.64E-03	608.3	31.2	74.39%	25.61%
Patient Circuit Failure/Leakage	1.40	1.28E-03	782.1	40.1	79.44%	20.56%
Uncalibrated flux sensor	1.20	1.10E-03	912.5	46.8	82.10%	17.90%
Power supply or battery	1.67	1.52E-03	657.0	33.7	76.04%	23.96%
Damaged O2 sensor failure	1.00	9.13E-04	1095.0	56.2	84.84%	15.16%
Fault in the front control display	2.00	1.83E-03	547.5	28.1	71.98%	28.02%
Uncalibrated vaporizer	1.00	9.13E-04	1095.0	56.2	84.84%	15.16%
Poor contact	1.00	9.13E-04	1095.0	56.2	84.84%	15.16%
Average	1.51	1.38E-03	789.9	40.5	78.25%	21.75%
Total	15.07	1.38E-02	72.7	3.7	8.40%	91.60%

Table 2. Failure rate, mean time between failures (MTBF), intervention time, and reliability over a 365-day period.

Failure Mode	Average No. of Failure (Nf)	Failure rate (λ)	MTBF (days)	Intervention time (t0.95)	Reliability (t365 days)	Probability of failure
O2 Button Failure	2.20	6.03E-03	165.9	8.5	11.08%	88.92%
Uncalibrated O2 sensor	1.80	4.93E-03	202.8	10.4	16.53%	83.47%
Flow Sensor Failure	1.80	4.93E-03	202.8	10.4	16.53%	83.47%
Patient Circuit Failure/Leakage	1.40	3.84E-03	260.7	13.4	24.66%	75.34%
Uncalibrated flux sensor	1.20	3.29E-03	304.2	15.6	30.12%	69.88%
Power supply or battery	1.67	4.57E-03	219.0	11.2	18.89%	81.11%
Damaged O2 sensor failure	1.00	2.74E-03	365.0	18.7	36.79%	63.21%
Fault in the front control display	2.00	5.48E-03	182.5	9.4	13.53%	86.47%
Uncalibrated vaporizer	1.00	2.74E-03	365.0	18.7	36.79%	63.21%
Poor contact	1.00	2.74E-03	365.0	18.7	36.79%	63.21%
Average	1.51	4.13E-03	263.3	13.5	24.17%	75.83%
Total	15.07	4.13E-02	24.2	1.2	0.00%	100.00%

Table 3. Failure rate, mean time between failures (MTBF), intervention time, and reliability over a 1-day period.

Failure Mode	Average No. of Failure (Nf)	Failure rate (λ)	MTBF (days)	Intervention time (t0.95)	Reliability (t365 days)	Probability of failure
O2 Button Failure	2.20	2.01E-03	497,7	25,5	99,80%	0,20%
Uncalibrated O2 sensor	1.80	1.64E-03	608,3	31,2	99,84%	0,16%
Flow Sensor Failure	1.80	1.64E-03	608,3	31,2	99,84%	0,16%
Patient Circuit Failure/Leakage	1.40	1.28E-03	782,1	40,1	99,87%	0,13%
Uncalibrated flux sensor	1.20	1.10E-03	912,5	46,8	99,89%	0,11%
Power supply or battery	1.67	1.52E-03	657,0	33,7	99,85%	0,15%
Damaged O2 sensor failure	1.00	9.13E-04	1095,0	56,2	99,91%	0,09%
Fault in the front control display	2.00	1.83E-03	547,5	28,1	99,82%	0,18%
Uncalibrated vaporizer	1.00	9.13E-04	1095,0	56,2	99,91%	0,09%
Poor contact	1.00	9.13E-04	1095,0	56,2	99,91%	0,09%
Average	1.51	1.38E-03	789,9	40,5	99,86%	0,14%
Total	15.07	1.38E-02	72,7	3,7	98,63%	1,37%

was an alarm indicating low flow in the anesthesia carriage, but the surgery continued, and it was later found that the equipment was working properly.

For the CCI-0005 equipment, faults were identified, such as leakage in the CO2 line and repair in the support system hose, although no errors were found after the tests were carried out.

In the case of the CCI-0006 equipment, there was the replacement of an unspecified part, and despite

an occurrence reporting the non-functioning of the flowmeter, the surgery continued.

For the HOD-0011 equipment, the anesthesia carriage was uninstalled for air conditioning maintenance, and a new work order was opened for installation in the original room, with a clinical engineering technician waiting for the equipment to be released by the operating room team to resolve the work order request.

Table 4 shows the FMEA that was calculated, highlighting the most common failure modes, organized according to the highest RPN calculated. The value of RPN helps us prioritize maintenance actions, with the goal of increasing equipment reliability. The time intervals for the maintenance procedures are determined according to the calculated t0.95, as it is a high-risk equipment, its failure can generate serious losses for the hospital, comparing them with the frequency indicated in the preventive maintenance plan established by the outsourced team.

Cleaning the Plate

In anesthesia practice, some of the most critical components of equipment are the internal pipes, which over time can dry out, rupture, or develop

cracks. A common fault occurs in the patient circuit, dried out pipes due to repeated sterilization processes. The flow sensor is subject to misuse by the patient in the course of movements. Battery replacement is also an essential consideration, it is recommended to do annual testing, although this period may vary by manufacturer. Another important aspect is the bellows and sealing rings, which require lubrication and replacement to ensure perfect sealing.

The analysis of work orders revealed significant operational failures, with impacts in terms of working hours. Lack of technical knowledge accounted for 19% of the cases, while misuse of equipment resulting in damage corresponded to 11% of occurrences. The implementation of regular training and awareness are essential measures. These actions are carried out monthly by the technical team, which employs a rigorous

Table 4. FMEA developed for anesthesia carriage failure analysis.

Component	Function	Failure Mode	Crash Effects	Severity	Cause of Failure	Occurrence	%	Forms of detection	Detection	RPN	Corrective / Preventive maintenance
Button Circuit	Release O2 to the patient	O2 Button Failure	Stuck	5	Natural wear of plastic and button mechanism	8	13	Visual	2	80	Replace the button
Fluxo sensor	Measures gas flow	Flow sensor failure	Failure to control/monitor O2 flow in ventilation	1	Natural wear and tear	7	11	Alarm	5	35	Calibration or replacement
Sensor de O2	O2 concentration	Uncalibrated O2 sensor	Failure to control/monitor O2 in ventilation	1	Natural wear and tear	7	11	Alarm	5	35	Calibration or replacement
Patient Circuit	Bring the gases to the patient	Patient Circuit Failure/Leakage	No piece on the line	6	Natural wear and tear caused by stress	6	8	Alarm	3	108	Patient Circuit Exchange
Fluxo sensor	Measures gas flow	Uncalibrated flux sensor	Failure to control/monitor O2 flow in ventilation	1	Natural wear and tear	5	7	Alarm	5	25	Calibration or replacement
Power supply system	Provides and adjusts electrical voltage	Power supply or battery	Won't turn on/risk of shutdown	7	Wear and tear and no connection at the source	4	6	Without turning on the equipment	3	84	Change the battery and check if it is connected to the network
Sensor de O2	Check Expected O2	Damaged O2 sensor failure	Out of proper parameters	1	Natural wear and tear	4	6	Alarm	5	20	Calibration or replacement
Dashboard	View patient information	Fault in the front control display	Be parameter	8	Wear and tear of the internal component of the screen	3	5	Operator	2	48	Panel replacement
Vaporizer	Controls anesthetic gas mixed into fresh gas	Uncalibrated vaporizer	Incorrect anesthetic delivery parameters	9	Natural wear and tear	2	2	Technician & Operator	4	72	Calibration or replacement
Circuits & Electronic Components	Componente control and data handling	Poor contact	General equipment failure	3	Oxidation, natural wear and tear	1	1	Checking the connection of the equipment	3	9	Cleaning the plate

checklist of competencies before accessing the operating room, thus ensuring the maintenance of the necessary skills and the safety of the operations.

Conclusion

The results highlight the importance of reliability engineering tools in the analysis of maintenance plans for anesthesia carts in hospitals. They point to the need to review the preventive maintenance plan to reduce failures and ensure reliability above 98% for each component. The FMEA tool proved to be efficient in improving the operational reliability of the equipment.

The reliability and probability of failure analysis revealed that the most critical failure mode is operational failures, general maintenance, and O2 button failure, largely caused by natural wear and tear. This data highlights the urgent need to enhance maintenance procedures and review action plans to mitigate risks.

In practice, anesthesia equipment is composed of several critical parts, such as internal piping, patient circuit, and sensors, which are susceptible to natural wear and tear. However, calibration of the

components and annual replacement of the batteries are necessary to ensure the desired performance. Even with the high demand in public hospitals and the limitation of resources, it is possible to maintain the perfect functioning of the anesthesia equipment, ensuring patient safety.

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