Reliability Analysis Techniques Applied to Highly Complex Medical Equipment Maintenance

Marina Rezende, Rogério Santos, Fernando Coelli and Renan Almeida

August 25, 2023

Reliability Analysis Techniques Applied to Highly Complex Medical Equipment Maintenance

M.C.C. Rezende[1], R. P. Santos[1], F. C. Coelli[1], R.M.V.R. Almeida[2],

[1] Centro Federal de Educação Tecnológica Celso Suckow da Fonseca UnED Itaguaí, RJ, Brazil
[2] Universidade Federal do Rio de Janeiro / Programa de Engenharia Biomédica - COPPE/UFRJ, Rio de Janeiro, Brazil

Abstract— **Objective: The objective of this study was to apply reliability concepts to define adequate maintenance strategies for a group of highly complex equipment (Computerized Tomography) in the state of Rio de Janeiro. Methods: Equipment were located in 43 health units (private and public) Brazil. Failures claimed by customers and those observed by maintenance operators were identified. These data were collected considering all CT scanners and for each of the four brands present in the database. A FMEA was performed to identify failure risks and priorities thus allowing the ranking and prioritizing of the failures detected by the analysis. Each brand of equipment was thus classified according to its risk criticality (high-medium-low); and for each criticality, the most appropriate maintenance strategy (mitigation action) was defined. Additionally, with the observed times between failures, the maintenance indicators MTTF (Mean Time to Failure), MTTR (Mean Time to Repair) and MTBF (Mean Time Between Failure) were calculated. Results: About 200 repair requests from 2017 and 2018 had their information digitized. The most recurrent complained failure was "Failure of System Initialization, followed by "Generator failure" and "table malfunction". Two of these could be classified as needing "predictive maintenance", while the third (system initialization failure) was assigned "corrective maintenance). Conclusion: Reliability methods allowed for the definition of optimized maintenance strategies, with a resulting reduction in maintenance costs and an increase in equipment availability to patients.**

Keywords— ***Reliability; Maintenance; CT Scanner, FMAE, Clinical Engineering.***

I. Introduction

The business model of this century differs from the prior style of competitiveness, mainly because of the current technological changes and increasing globalization [1]. Thus, what used to be considered a competitive advantage, for example, a very high advertising budget, no longer has a place in the current scenario [2].

In this context, there is a strong incentive to increase the effectiveness and efficiency of operational activities, enabling not only equipment availability but also greater results for a company [3]. Based on these concepts, companies are increasingly seeking to achieve advantages by using management tools that result in greater productivity and quality for their products and services [4]. For instance, something that is widely observed in the maintenance field is the importance of reducing or eliminating failures [5].

Reliability techniques have been applied in several areas, such as aviation, since the 1940s [6], and have been consolidated as a strategy for performance and productivity gains [7]. These techniques are also great tools to assist in the maintenance management of medical equipment [8]. The application of these concepts allows, for example, for the rationalization of resources and the increase in equipment availability.

Therefore, besides the business sector, maintenance has a relevant role in other sectors, such as the Health Care [9]. Based on the studies of Coelli et al [10], it was possible to identify the need to deepen the analysis of the reliability of Computed Tomography (CTs) and to seek strategies for the reduction of their failure rates, considering their importance in the diagnosis of many serious diseases [13]. In this context, the *Failure Modes and Effects Analysis* (FMEA) is an important tool for analysis and definition of maintenance strategies. Its objective is to identify potential failures and how they impact in a process [5, 15]. Born in the American armed forces, it is widely used in the automobile and aeronautics industries. However, the use of this technique in Brazil´s Health area is still limited. One of the reasons for that is that despite its potential contribution, data on medical equipment maintenance is hard to obtain in the country.

The objective of this study was to apply reliability concepts such as Mean Time Between Failures (MTBF) and Failure Mode and Effects Analysis (FMEA) to a group of CT scanners maintained by a private company in Rio de Janeiro State, Brazil.

II. Materials and methods

Data were obtained from the Service Orders (SOs) of the years 2017 and 2018 of a hospital maintenance company located in the State of Rio de Janeiro, Brazil. The equipment were installed in 43 health units, representing 28 private and 15 public and/or SUS associated hospitals and radiology clinics. The equipment consisted of the four most present brands in our market.

The Google Groups tools, Google Forms and Google Sheets were used to automate the analysis of the SOs. The programs Wolfram Mathematica, Tableau Desktop and Microsoft Excel were used for graphical visualization. For parameter estimation calculations and definition of probability distributions the R software was used, and for other calculations Wolfram Mathematica was used.

The type of equipment chosen for analysis was the Computed Tomography (CT) due to its high number of appearances in the maintenance database. In addition, this is a relevant equipment for the diagnosis of diseases and has very high costs in all utilization stages [10].

The maintenance claims were provided by a hospital maintenance company based in the city of Rio de Janeiro. These maintenance claims were standardized forms filled out on paper. To collect the data, the information on paper was transposed to an online form using Google Forms. As this form was fed with data from the claims, a Google Sheets spreadsheet was automatically fed, thus creating a digital database.

A) Data collection and analysis

In this step, an analytical survey of the information pertinent to the reliability calculations was performed. The following items were highlighted:

- The model with the highest number of SOs;
- Failure history in two years;
- Maintenance interventions performed.

The failures reported by customers and those observed by the maintenance operators were also collected. These data were collected both in an aggregated way (considering all CT scanners) and focusing on each of the four brands present in the database.

B) Elaboration of the FMEA

The FMEA technique consists of a systematic and progressive analysis of failures and their causes in a process or service. Once the most recurrent failures were identified, the FMEA was prepared, with the objective of qualitatively evaluating the risks provided by such failures. Thus, the failure analysis was performed using the PRN (Primary Risk Number) and RPN (Risk Priority Number) indicators of the FMEA. From these results, we may obtain the *severity*, *occurrence* and *detection* indexes, thus completing the risk classification and allowing for the definition of the maintenance strategy. In this study, only the three most frequent failures were analyzed.

With the definition of the RPN, each equipment brand was classified according to its risk criticality; and for each one, the most adequate maintenance strategy (mitigation action) was defined.

Thus, failures were classified and analyzed by two factors: *severity* and *probability of occurrence*. Each factor is defined by an integer value between 2 and 10, and the two factors are multiplied, resulting in the Primary Risk Number (PRN). After this first prioritization, another factor is added to the calculation: *detection*, also defined by the same range of values above, and which is multiplied by the PRN, resulting in the Risk Priority Number (RPN). Thus, RPN is the product of the three mentioned factors, as shown in equation (1) below.

$$\text{RPN} = \text{severity x probability of occurrence x detection} \qquad (1)$$

With the observed times between failures the maintenance indicators MTTF (Mean Time to Failure), MTTR (Mean Time to Repair), MTBF (Mean Time Between Failure), Availability and Failure Rate (ƛ) and Reliability (R(t)) were calculated, and, according to the NBR 5462 Standard [12], Equations (2-7) were used to this end [13]. These are most objective and simple implement indicators for reliability studies.

$$\text{MTTF} = (\text{Tt}) / (\text{Nf}) \qquad (2)$$

Where Tt = CT total operating time and Nf = Number of failures.

$$\text{MTTR} = (\text{Tr}) / (\text{Nf}) \qquad (3)$$

Where Tr = Repair time

$$\text{MTBF} = \text{MTTF} + \text{MTTR} \qquad (4)$$

(for repairable items).

$$\text{Availability} = \text{MTBF} / \text{MTBF} + \text{MTTR} \qquad (5)$$

$$ƛ = 1/MTBF \qquad (6)$$

$$R(t) = e^{-ƛ.t} \qquad (7)$$

III. Results

112 physical SOs from the year 2017 and 88 from 2018 (scanned) was studied. From these data, 200 records were generated referring to the maintenance services.

Figure 2 shows the histogram concerning the client claimed failures. The most recurrent failure was "System Not Initializing". The most recurrent item observed was "No failure". The second was "Generator failure".

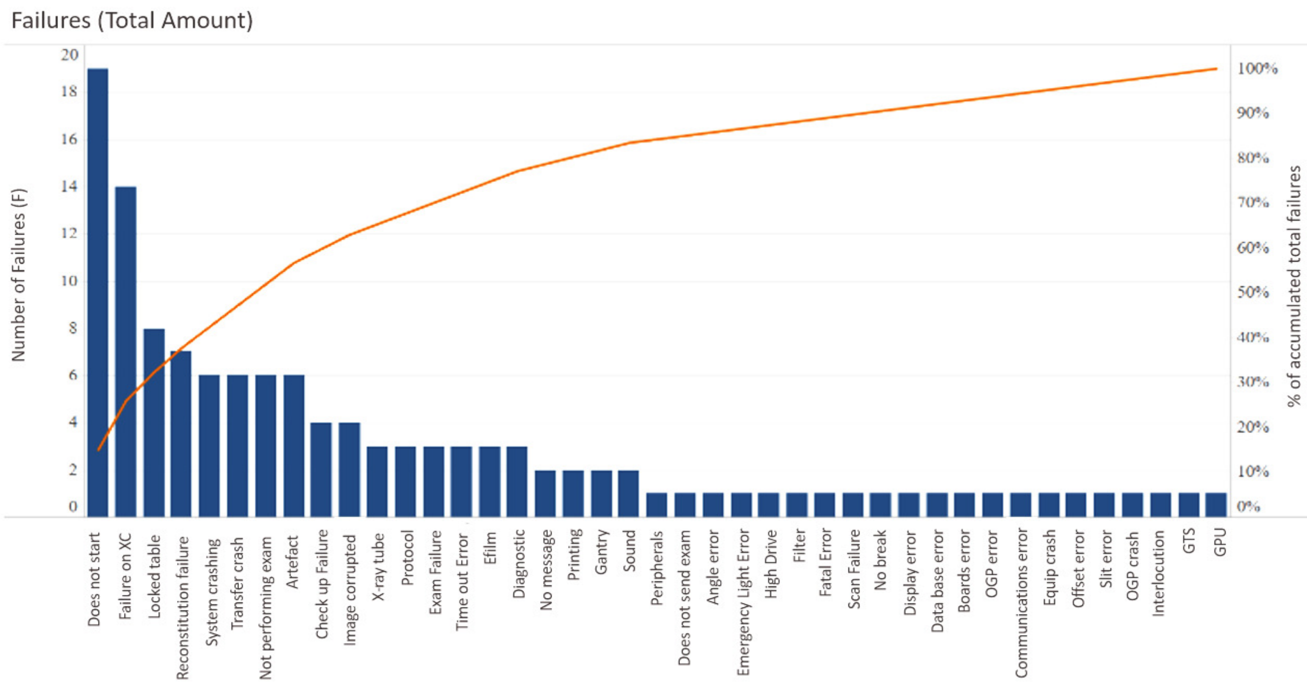

Figure 2: Histogram for claimed Failures in a database for the years 2017 and 2018. CTs, 43 health units in Rio de Janeiro State.

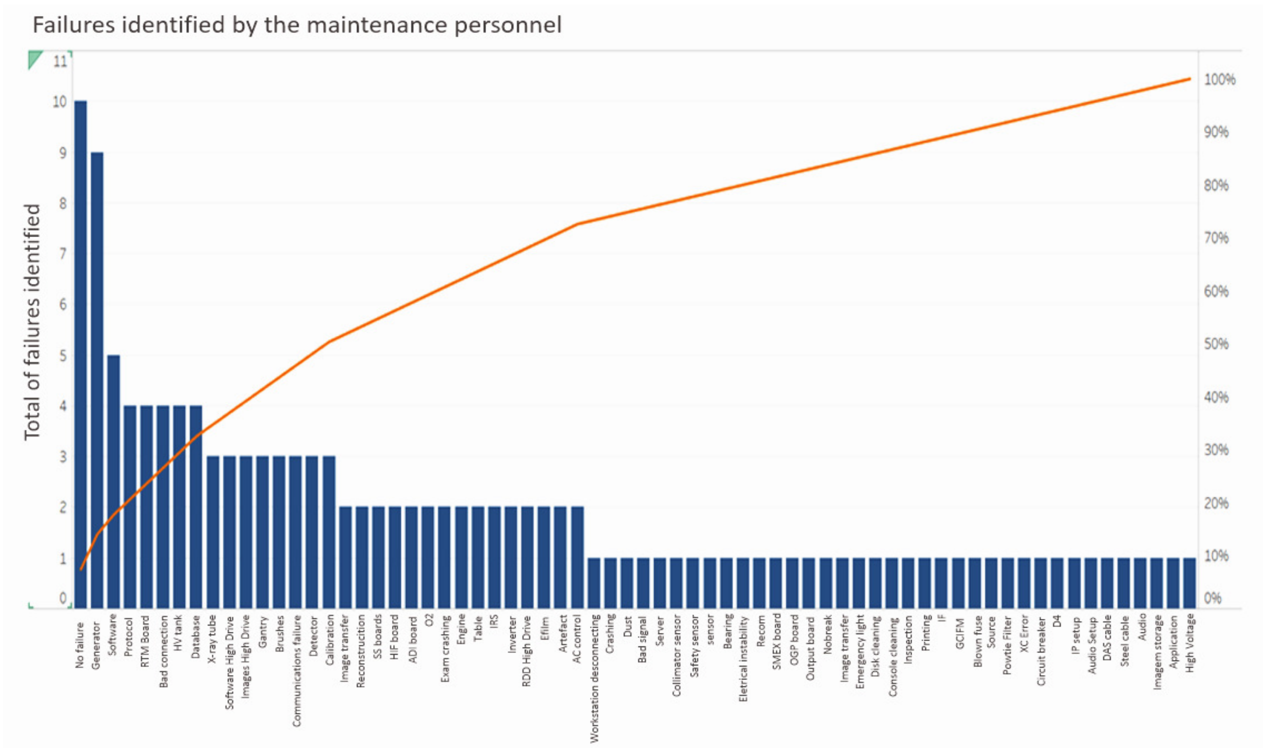

Figure 3: failures identified by the maintenance personnel.

Table 1 presents the number of equipment units for each brand, the number of failures in the analyzed period, and the number of failures per unit of equipment for each brand.

Table 1 - Number of equipment per brand, number of failures and failures/equipment in an FMEA of a database of CT maintenance SOs for 2017/ 2018, 43 health units, Rio de Janeiro State.

Brand	Number of equipment	Number of failures	Failures by equipment
1	30	113	3,76
2	12	32	2,66
3	8	35	4,37
4	1	6	6,0

Table 2 presents the main failure types, the components responsible for these failures, the risk classification, and the defined maintenance strategy.

Table 2 - Type of failure, component responsible for the failure, Risk Classification (RPN) and defined maintenance strategies.

Component/Function	Failures	Risk classification	Maintenance
System initialization	Software failure	Low	Corrective
	RTM board failure	Average	Predictive
XC board	HV generator	Average	Predictive
Table	Engine failure	Average	Predictive

Table 3 shows the MTTF, MTTR, MTBF, Availability, Failure Rate and Reliability for the studied equipment.

Table 3 - Results of the reliability indicators in a database of CT maintenance SOs for 2017/ 2018, Rio de Janeiro State (in days).

Indicator	Result
MTTF	615.2
MTTR	2.3
MTBF	617.5
Availability	99.6%
Failure rate (λ)	0.00161
Reliability (R(t))	85.04%

IV. Discussion

The failures found by the maintenance personnel did not always coincide with those claimed by the clients, denoting a mismatch in the understanding of a same problem. The importance of correcting this mismatch should be emphasized, given that a maintenance team is activated considering a received failure report. Also, Figure 2 shows the occurrence of claims such as "Equipment does not start" and "XC failure", problems that concern equipment software or X-ray generator, and which are somewhat generic.

Table 1 shows the number of failures by equipment manufacturer. In this case there may be a bias introduced by the small sample size and by the disparity in the number of devices of each brand. For example, while brand 1 had thirty devices, brand 4 had only one. For a more realistic comparison a more homogeneous sample would be necessary with regards to equipment brands. Once the aforementioned bias is controlled, this indicator can be interesting for inter-brand comparison.

Although 200 SOs were studied, only 186 pertained to equipment failures, the remaining 14 referred to calls where the equipment was not defective, services such as training and other miscellaneous client requests.

Table 2 presents the criticality of the failures and the defined type of maintenance according to the most frequent failures. For example, the system startup failure requires corrective maintenance since its occurrence impedes the use of an equipment. On the other hand, this failure does not allow the equipment to function, and therefore its associated risk is low.

Lack of information is frequently mentioned as one of the greatest difficulties in the implementation of the methodology of reliability centered maintenance (RCM) [14]. Therefore, a careful documentation of maintenance intervention events should be suggested to companies and/or health care units. As the present maintenance company did not have a digital database, the database developed in this work was made available for its use. Another important result of this study was sharing the theoretical and practical framework with the maintenance company. It was recommended to the company that, after this study, it should start collecting claims data digitally. As a consequence, the databases would be more organized and would generate reliability parameters for maintenance follow-up, also allowing for future studies with other equipment.

As said, for the criticality and failure strategy definitions, the three most frequent failures were considered in the study. This approach was used in order to simplify the work, although a deeper study would be possible by adding other types of failures.

The most recurrent failure claim was "System Not Initializing"; and the most recurrent observed failure was "No fault" (that is, the device did not present a defect when tested, although the user complained about an alleged failure). Therefore, this is evidence of training deficiencies in what concerns client failure identification. The better a "pre-diagnosis", the better the first intervention can be, since the maintenance team could readily decide on what components to use or, for instance who is the best person for dealing with a specific type of failure.

It was also observed that a common failure was related to the (high voltage) CT generator. This is a fundamental part of the equipment, which is susceptible to grid power supply failure. This component is obviously critical given that it operates with high voltages and power. As for power supply problems, units should keep their systems in optimal operating conditions, with periodic grounding and cabling revisions and a constant monitoring of variations in electrical supply levels. Another recommended prevention factor is to avoid using CTs during lighting storms.

Table jamming involves moving components, and can be attributed to wear, use under inadequate weather conditions and misuse, such as allowing paper jamming inside the mechanism.

From the reliability indicators in Table 3, it may be seen that 2.27 days were needed, on average, to repair an equipment. This represents a short period, given that in just over 48 hours the equipment was back into operation, despite its possible failure complexity. The time to failure (after the intervention) was 615.2 days. This high value shows that the equipment was well maintained, what can also be seen by the calculated MTBF of 617.5 days. Consequently, the availability indicator was 99.6%, denoting that an equipment was in operational conditions almost all of the time. In addition, the estimated reliability indicated that 85.04% of the equipment were working in nominal conditions in the 100 days after an intervention.

The risk assessment of the most recurrent failures (XC board failure, table jamming, and problems related to the high voltage generator) indicated a need for predictive maintenance strategies, allowing for a reduction in corrective interventions and in the clinics cost per visit. It is important to stress that predictive maintenance strategies detect failure at an early stage, therefore avoiding equipment downtime. Therefore, these interventions are relevant not only financially, but also in terms of equipment downtime, avoiding interruptions in patient care.

It should be noted that the technique applied in this study could be applied to different types of equipment in the Healthcare area. The improvement of maintenance management with these techniques can provide significantly longer equipment availability and resource savings [16-19].

The most commonly identified failures also show the need for clinic personnel training. On the other hand, the estimated reliability indicators point to a fast and adequate response capability of the company in charge of equipment maintenance. As an example, in a hospital in Rio de Janeiro city, 2003, the MTBF identified for a variety of hospital equipment was in the range 6-120 days [19].

V. Conclusion

The application of basic reliability techniques for CT equipment maintenance allowed for the identification of improvement opportunities in the definition of maintenance strategies. The dissemination of these techniques is very important, since they can significantly reduce equipment downtime, with a direct impact on patient care, with reduced waiting times, for example. In this sense, the adoption of this methodology by the public health system of the country could have a great impact in service improvement and resource optimization.

Conflict of interest

The authors declare that there is no conflict of interest in the present work

Acknowledgments

Our thanks to CAPES/ME (Proex Program, code 001) and CNPq for supporting this work.

VI. References

1. Ramos, N. K. Yamaguchi, C. K. da Costa, U. M. (2020). Tecnologia da informação e gestão do conhecimento: estratégia de competitividade nas organizações. *Brazilian Journal of Development*, *6*(1), 144-161.
2. Anning-Dorson, T. (2018). Innovation and competitive advantage creation: The role of organisational leadership in service firms from emerging markets. International Marketing Review.
3. Silvestri, L., Forcina, A., Introna, V., Santolamazza, A., & Cesarotti, V. (2020). Maintenance transformation through Industry 4.0 technologies: A systematic literature review. *Computers in Industry*, *123*, 103335.
4. Patil, A., Soni, G., Prakash, A., Karwasra, K. (2021). Maintenance strategy selection: a comprehensive review of current paradigms and solution approaches. *International Journal of Quality & Reliability Management*.
5. Lo, H. W., Liou, J. J., Huang, C. N., & Chuang, Y. C. (2019). A novel failure mode and effect analysis model for machine tool risk analysis. *Reliability Engineering & System Safety*, *183*, 173-183.
6. Anderson, R. T., & Neri, L. (1990). *Reliability-centered maintenance: management and engineering methods*. London: Elsevier applied science.
7. Shamayleh, A., Awad, M. and Abdulla, A.O. (2020), "Criticality-based reliability-centered maintenance for healthcare", *Journal of Quality in Maintenance Engineering*, Vol. 26 No. 2, pp. 311-334.
8. Sezdi, M. (2016). Two different maintenance strategies in the hospital environment: preventive maintenance for older technology devices and predictive maintenance for newer high-tech devices. Journal of healthcare engineering, 2016.

9. Zamzam, A. H., Wahab, A. K. A., Azizan, M. M., Satapathy, S. C., Lai, K. W., Hasikin, K. (2021). A systematic review of medical equipment reliability assessment in improving the quality of healthcare services. *Frontiers in Public Health*, *9*.
10. Coelli FC, et al. Estudo de Confiabilidade de Tomógrafos Computadorizados. Anais do XXIV Congresso Brasileiro de Engenharia Biomédica – CBEB 2014. Pp 2049-51. Uberlândia-MG.
11. Brasil. Ministério da Saúde. Secretaria de Gestão de Investimentos em Saúde. Projeto REFORSUS Equipamentos Médico-Hospitalares e o Gerenciamento da Manutenção: capacitação a distância / Ministério da Saúde, Secretaria de Gestão de Investimentos em Saúde, Projeto REFORSUS. – Brasília, DF: Ministério da Saúde, 2002.
12. NBR 5462: 1994. Confiabilidade e Mantenabilidade. Rio de Janeiro: ABNT, 1994. Associação Brasileira de Normas Técnicas.
13. Brenam J E, Sahay C, Lewis E E, (2022) Introduction to Reliability Engineering. John Wiley &Sons, New Jersey.
14. ABRAMAN, Associação Brasileira de Manutenção. Documento Nacional (2013): a situação da Manutenção no Brasil. Rio de Janeiro.
15. BS EN IEC 60812 2018. Failure modes and effects analysis (FMEA and FMECA).
16. Sezdi, M. (2016). Two different maintenance strategies in the hospital environment: preventive maintenance for older technology devices and predictive maintenance for newer high-tech devices. *Journal of healthcare engineering*, *2016*.
17. Blanch, P., An Evaluation of Ventilator Reliability: A Multivariate. Failure Time Analysis of 5 Common Ventilator Brands. Respir Care, vol. 46 no. 8 p. 789 – 797, EUA, 2001.
18. Santos, R. P. Análise da Ocorrência de Falhas em Equipamentos Cardiológicos em um Hospital de Emergência de Grande Porte no Município do Rio de Janeiro. Dissertação: Universidade Federal do Rio de Janeiro, 2003.
19. Santos, R. P., & Almeida, R. M. V. (2010). Hospital medical equipment maintenance schedules using the mean time between failures. Rio de Janeiro (RJ), Brazil, 18(2), 309-314.

Enter the information of the corresponding author:

Author: Rogerio Pires dos Santos
Institute: Centro Federal de Educação Tec Celso Suckow da Fonseca
Street: UnED
City: Itaguaí
Country: Brazil
Email: rogeriopires1@uol.com.br