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Reliability analysis of hospital infusion pumps: a case study

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Abstract

Background: Infusion pumps (IPs) are medical devices used for the continuous and precise delivery of medications or nutrients. Their use has expanded and is now widespread in emergency rooms, ICUs, pediatrics, and other hospital departments. Failures in IPs can lead to adverse events, compromising patient health. In addition to the risks to patients, IPs are the medical devices most frequently associated with reports of adverse events in Brazil, highlighting the need to monitor their operational conditions to minimize failures during use.

Results: Thus, the objective of this research is to analyze the reliability of infusion pumps (IPs) in a Brazilian hospital using an internal database from Clinical Engineering software. Probability distributions for repair time and time between failures were modeled, and parameters such as reliability and availability were calculated, with a focus on investigating hospital departments with recurring failures.

Conclusion: In evaluating the operating equipment, a lack of detail in failure notes and service order openings was observed, which can hinder maintenance planning. The longest repair times were recorded in the ICU (Neurology), which houses the majority of IPs. Graphical analysis and testing demonstrated that the Weibull distribution effectively models both time between failures and repair time. The IP A model showed better results in terms of availability and reliability, thereby improving the security of the IPs.

Keywords: Medical device, Infusion pump, Reliability, Availability, Maintenance

Introduction

Medical devices (MDs) used to infuse substances into patients capable of providing a flow of a given fluid are called infusion pumps (IPs). Although developed and incorporated into hospital care since the 1960s, these devices are constantly being modernized. Today, they are widely adopted in Intensive Care Units (ICUs), emergency rooms, pediatrics, and several other sectors, having gained prominence in daily clinical practice [1, 2].

Its use is indicated for a variety of medical purposes, including the administration of chemotherapy, sedatives, hormones, nutrition, and other treatments [3]. It is the most commonly used equipment in Intensive Care Units (ICUs) and represents 19.4% of all adverse events (AEs) in the hospital setting, arising from drug administration failures [4].

The Agência Nacional de Vigilância Sanitária (ANVISA), responsible for regulating MDs in Brazil, classifies IPs as Class III, which refers to products intended for the administration of medications through an infusion system, when performed in a potentially risky manner, considering the method of application [5]. Thus, consistent pump care is essential, as most infusions are intravenous and failures can lead to severe complications such as phlebitis, pulmonary edema, and venous spasms [6]. In addition to potential harm to patients, infusion pump-related failures also have serious financial consequences for healthcare systems [7]. The essential requirements for pumps to perform well include safety, reliability, ease of maintenance, handling, and easy access. Although these conditions are frequently analyzed and improved in search of safety in infusions, incidents are common during the procedure and can compromise the patient's physiology [8].

With the increasing development of technologies aimed at the medical device sector, reliability has gained notoriety and greater importance [9]. Therefore, IP reliability must be periodically analyzed and compared with that initially indicated by manufacturers. This precaution and monitoring can prevent material losses and provide safety to both the patient and the operator. Actions involving reliability analysis are applied to maintenance and DM lifecycle management, allowing for increased availability, security, and functionality [10]. Reliability encompasses various concepts and techniques designed to ensure device safety and optimal performance. It is defined as the operation of the product without failures, breakdowns, or incidents that completes its function satisfactorily and in accordance with the design [11, 12]. According to Leemis (1995), in addition to proper functioning and the purpose achieved, the specification of the period of time and environmental conditions must be specified for the equipment or system to be reliable [13, 14].

Several studies on reliability in MDs are carried out around the world, aimed at reducing possible errors in diagnoses, tragedies, injuries, economic losses, and other possible damages [9, 15]. However, the previously published studies [16, 17] did not indicate that these aspects have been evaluated in IPs as they have in other MDs over the last 10 years. The systematic review [16] aimed to identify studies evaluating reliability and accuracy in IPs and concluded that there is a lack of research that clearly addresses aspects and concepts related to reliability. This lack of information primarily stems from fundamental studies, such as bench studies and those conducted in hospital settings. In most cases, the limitation is due to ethical criteria.

It is observed that metrological reliability in healthcare environments allows physical, biological, and chemical quantities to be evaluated with greater precision, which is essential for the proper treatment of health issues [18]. Therefore, it is common for the greater the reliability, the safer the MD will be, easier to handle, and more economically viable [19].

In this sense, the current study is an extension of the previous work, where a systematic literature review approach was proposed to investigate studies on the topic applied to IPs [17]. Thus, in order to explore existing gaps, this work aims to analyze the reliability and availability of infusion pumps in operation at a large hospital in Brazil, based on the history of failures, repair times, and other variables collected during their operation. This study adopts a different approach from previous research, which often relies on simulated or generic data [17, 20]. Instead, it analyzes the reliability of IPs using a real Clinical Engineering database.

Results and discussion

Preventive maintenance is an essential strategy to prevent failures and extend the useful life of all MDs, including the infusion pumps studied here. Healthcare institutions require a large collection of pumps, distributing them in varying quantities across different sectors. Initially, the distribution of equipment by sector was analyzed to identify the supply in the facility. Table 1 quantifies the equipment distributed by sector.

As demonstrated in [17], when evaluating the causes of failures, a lack of detailed information regarding the reason for the failure was identified. When opening the service order, the equipment operator must provide as much information as possible. The term "Doesn't work" stands out, as it is the most frequent description, prompting the question, "What doesn't work?" The specific details of each occurrence must be recorded to manage the technology park, conduct studies on failures, and predict potential problems with the equipment. In this way, it would be beneficial for the clinical engineering sector to train professionals to standardize the completion of these documents and ensure accurate data collection.

Figure 1 demonstrates that the causes identified by hospital professionals when opening the service order are generic and do not clearly specify the problem, hindering maintenance planning and the ability to predict future issues. In this regard, the clinical engineering sector requires improvement.

Once we understood the main occurrences reported by the professionals handling the pumps, the time taken for the equipment to be repaired was recorded. Table 2 presents the repair times across the hospital environment, with the maximum repair time being 1237.99 h for a pump operating in a neurological ICU. The occurrence was recorded as "does not work", preventing a clear specification of the actual reason for the failure.

Additionally, equipment with at least seven stops was analyzed, as shown in Table 3. It can be observed that most repair times are between 0 and 50 h, with some outliers. The maximum recorded time was 262.13 h, and the minimum was 0.0069 h, indicating a considerable range between the values.

Table 1 Infusion pumps installed by hospital sector

Sector	Number of infusion pumps
Surgical center	06
Emergency	06
Clinical engineering	08
Medical specialties	32
ICU	96
Other sectors	45
Total	193 equipment

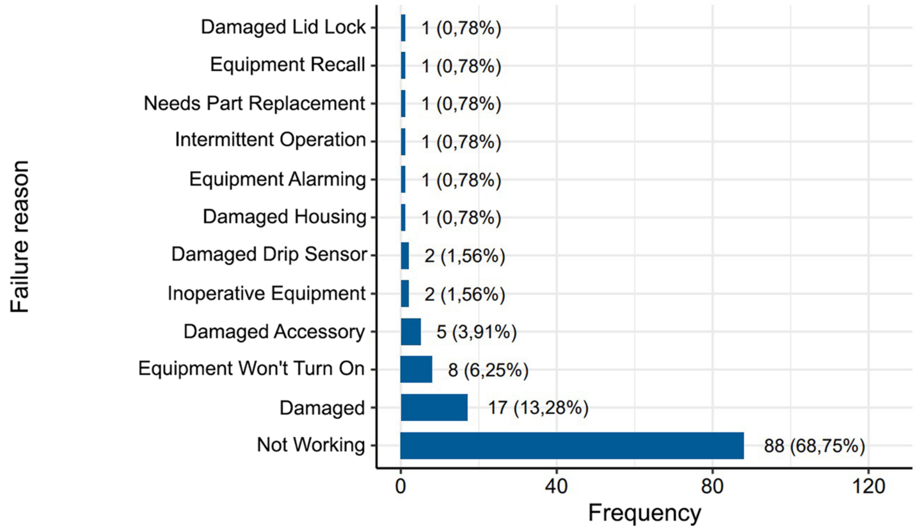

Fig. 1 Frequency of reasons for pump failures

To better understand the characteristics of hospital infusion pumps with at least seven stops, it is essential to assess whether the stoppage sector influences repair time. Before presenting the statistical tests, it is important to note that the "Stoppage Sector" is a qualitative variable, while "Repair Times" are on a quantitative scale, as shown in the graph in Fig. 2.

With the support of Fig. 2, it is possible to analyze in detail the behavior of downtimes by sector. From the graph, a significant difference in repair times across the different sectors can be observed. Furthermore, according to the Shapiro–Wilk test ($p < 0.001$), it can be concluded that the Repair Time variable does not follow a normal distribution. Therefore, to evaluate the relationship between the Downtime Sector and Repair Time, the Kruskal–Wallis test should be used.

From the p-value of the test (0.004), it is evident that there is statistical evidence to conclude that the Shutdown Sector influences Repair Time. To further evaluate the differences between sectors in relation to Repair Time, a Pairwise Test with Bonferroni correction was used for multiple comparisons. The results show significant differences between the pairs "Neurological ICU and Coronary Unit" and "Neurological ICU and Cardiac ICU".

Based on these figures, we have observed a failure to adequately monitor the repair time in a critical and essential sector such as the Intensive Care Unit. Since this is an environment that requires constant attention and functioning equipment, reducing repair time for its devices is crucial. However, it is important to consider that the prolonged repair times may be due to factors such as waiting for parts, obsolete equipment being replaced, and operator failure to close the service order. Therefore, we emphasize that professional training should also include proper completion of service orders and accurate information regarding part replacements.

To determine the probability distribution of the machines, graphs and hypothesis tests were performed, separating the analyses into time between failures and time to repair, as detailed below. All analyses were conducted using three graphs and one test table. The

Table 2 Summary measurements of repair time (h) by sector

Sector	Average	S. deviation	Variance	Minimum	Median	Maximum
Pediatriconcology	0.91			0.91	0.91	0.91
Cardiology surgical center	78.09	187.20	35044.13	0.02	1.67	501.92
General surgical center	75.28	189.29	35830.83	0.04	3.12	577.79
Medical clinic	17.67	20.34	413.55	0.02	7.20	59.73
Nursing coordination	21.02			21.02	21.02	21.02
24h Emergency	41.47	79.46	6314.02	0.01	11.86	338.23
General emergency	0.02			0.02	0.02	0.02
Clinical engineering	80.87	98.08	9619.53	20.14	38.56	308.88
Geriatrics	11.92	14.16	200.65	0.02	4.92	35.82
Annex 1	61.07	134.89	18196.55	0.06	10.26	471.76
Annex 2	18.11	31.63	1000.21	0.02	9.39	142.07
Hemodynamics	34.83	46.92	2201.54	0.01	19.29	114.01
Hospital/general	28.50	42.18	1778.89	0.00	10.88	173.05
Hospital maternity	18.92	23.44	549.50	1.11	9.29	59.73
Oncology hospital	65.42	69.32	4805.82	0.04	62.87	135.88
Women's Institute	29.60	37.58	1412.21	0.02	22.06	135.19
Nuclear medicine	24.10	20.86	435.00	1.27	23.57	47.98
Pediatrics	13.05	12.69	161.04	0.03	7.16	40.09
Oncological pediatrics	38.83	82.81	6857.89	0.02	1.72	257.84
Chemotherapy	22.14	48.10	2313.37	0.02	4.94	189.04
Coronary unit	33.27	55.00	3024.56	0.02	19.92	329.71
Chest pain unit	47.25	56.83	3229.31	3.17	27.19	111.39
Inpatient unit 1st floor	0.02	0.00	0.00	0.01	0.02	0.02
Inpatient unit	19.55	30.50	930.21	0.03	6.04	112.23
Adult ICU	30.92	19.84	393.67	18.92	20.02	53.82
Cardiac ICU	25.79	29.41	865.04	0.01	15.21	164.31
Surgical ICU	20.98	50.49	2548.98	0.04	0.40	124.04
General ICU	32.82	57.85	3346.34	0.00	14.11	321.08
Neonatal ICU	34.97	60.01	3600.89	0.02	7.75	189.03
Neurological ICU	38.82	115.44	13325.91	0.01	7.76	1237.99
Pediatric ICU	58.63	88.77	7880.11	0.16	20.92	321.92
Pediatric neonatal ICU	59.25	198.25	39302.59	0.02	8.91	1235.74
Respiratory ICU	27.82	46.69	2179.75	0.01	3.32	196.14

Descriptive statistics include mean ± standard deviation and median with minimum and maximum values, providing a comprehensive view of repair time variability across hospital sectors

Table 3 Summary measurements of repair time for devices that have failed more than 7 times

Statistic	Value (h)
Average	2114
Standard deviation	1084
Minimum	0,0069
1st quartile	099
Median	1008
3rd quartile	2385
Maximum	262,13

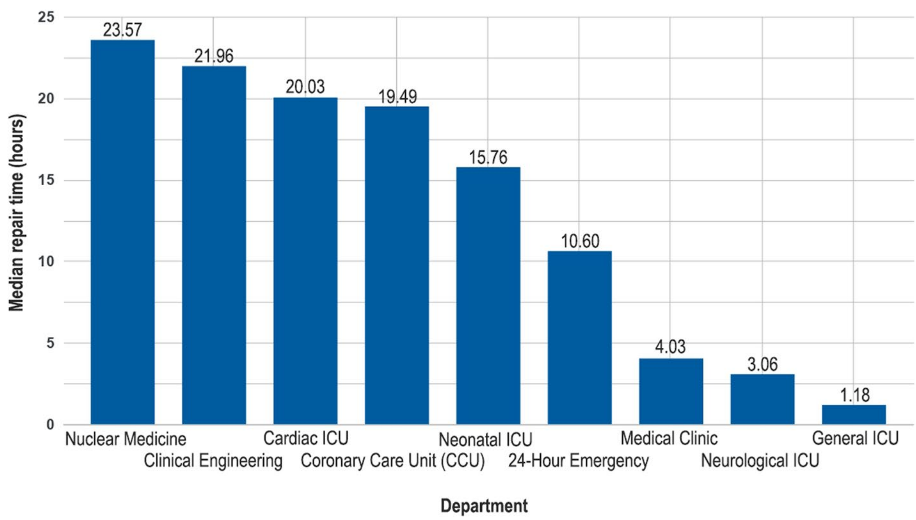

Fig. 2 Association of the downtime sector with repair times

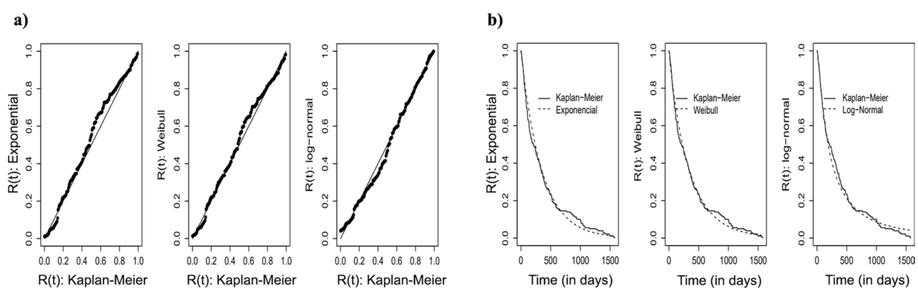

Fig. 3 **a**) Probability distribution of times to failure—model A infusion pump; **b**) Comparison with the Kaplan–Meier curve for times between failures—model A infusion pump

first graph shows the fit of the data to each distribution compared to the Kaplan–Meier estimator, with the best distribution expected to closely match the straight line. The second graph illustrates how linear the data is; the closer it is to a straight line, the better the distribution fit. The third graph, similar to the first, compares each distribution to the Kaplan–Meier estimator; the closer the curve is to the Kaplan–Meier curve, the better the distribution's fit. The table presents the test results for each distribution. For values of $p > 0.05$, we can consider the hypothesis that the distribution fits the analyzed data.

Time between failures

When analyzing Fig. 3a, it appears that all distributions are closely following the Kaplan–Meier estimator. Therefore, the linearized graph was created for a more accurate diagnosis. The Kaplan–Meier estimator was chosen due to its broad applicability in survival analysis, its increasing use in reliability studies, and its utility in tests to determine which probability distribution best represents the data [21].

The graph illustrates how closely the observations align with a straight line. As a result, it is evident that the second graph, which represents the Weibull distribution, is

Table 4 Distribution test—infusion pump model A

Model	Likelihood	TRV	value _p
Generalized Gamma	− 1223.70	0.00	1.00
Exponential	− 1225.88	4.36	0.11
Log-Normal	− 1227.34	7.29	0.03
Weibull	− 1225.30	3.20	0.20

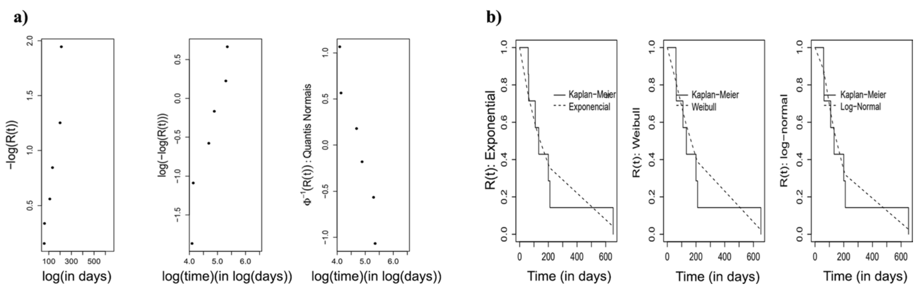

Fig. 4 **a**) Linearized graph for times between failures—model B; **b**) Comparison with the Kaplan–Meier curve for times between failures—model B

one of the best fits. The Weibull distribution is a continuous probability distribution, where the x-axis represents time, and the y-axis represents the cumulative probability of failure. It is capable of modeling lifetimes with decreasing, increasing, or constant failure or hazard rate functions, and it describes various physical phenomena [19]. In Fig. 3b, the proximity of the data distribution to the Kaplan–Meier estimator is clearly observed. Thus, it can be concluded that the Weibull distribution is the best fit for Model A.

For statistical analysis, the distribution test provides more accurate information about which distribution is most appropriate for modeling the data, as shown in Table 4.

As explained previously, the Generalized Gamma distribution serves as a basis for the other distributions, as it can accommodate the others. Therefore, its p-value will always be 1. From the graphical analysis and the test results, it is evident that the distribution that best models the data is the Weibull distribution. According to the test, the Log-Normal distribution was rejected ($p = 0.03$), while the Exponential and Weibull distributions were not rejected ($p = 0.11$ and $p = 0.20$, respectively), at a 95% confidence level. However, the value of the Likelihood function for the Weibull distribution was lower than that for the Exponential.

For Model B, there are few recorded observations, making it more difficult to determine which distribution fits the data well. However, through the graphs and additional tests, it was concluded that the Weibull distribution models the data distribution effectively.

When analyzing the first graphs, it appeared that all distributions performed similarly in relation to the Kaplan–Meier estimator. Therefore, comparison graphs were created alongside the Kaplan–Meier curve, along with tests for a more thorough diagnosis.

Examining the graphs shown in Fig. 4, it is clear that it is not possible to definitively determine which distribution best describes the data. It is observed that all three distributions exhibit similar performance, so to clearly define the best fit, the p-value test was analyzed.

Upon reviewing the result shown in Table 5, we concluded that either the Log-Normal or Weibull distributions could be used. For the sake of practicality and simplicity, we chose to use the Weibull distribution. However, it is important to note that, with the likelihood ratio test (LRT), it is possible to select the distribution with the lowest value of the function.

Similar to Model B, Model C has few failure observations, so it is not possible to state with complete confidence that the result obtained is accurate. Analyzing the graph in Fig. 5a, it can be observed that the Weibull distribution appears to be the best fit for the data.

We prepared the comparison graph with the Kaplan–Meier curve, shown in Fig. 5b, to clearly identify the best-fitting distribution. From this, we can observe that the Weibull distribution best models the data.

To choose the appropriate distribution, we also prepared Table 6. As inferred from the graphical analysis, the Weibull distribution is the best for modeling the data, therefore it was used.

When modeling the distribution of Model D pumps, it is observed that the amount of data related to this model is higher compared to the others. We created the graph

Table 5 Distribution test—model B infusion pump

Model	Likelihood	LRT	valor _p
Gama generalized	− 41.24	0.00	1.00
Exponential	− 44.22	5.96	0.05
Log-Normal	− 42.98	3.48	0.18
Weibull	− 43.97	5.46	0.07

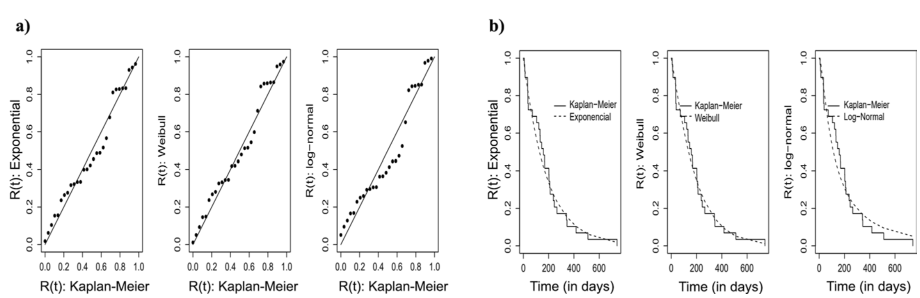

Fig. 5 **a**) Probability distribution of times between failures—model C; **b**) Comparison with the Kaplan–Meier curve for times between failures—model C

Table 6 Distribution test—model C infusion pump

Model	Likelihood	LRT	valor _p
Generalized Gamma	− 180.00	0.00	1.00
Exponential	− 180.26	0.51	0.77
Log-Normal	− 182.26	4.51	0.10
Weibull	− 180.03	0.06	0.97

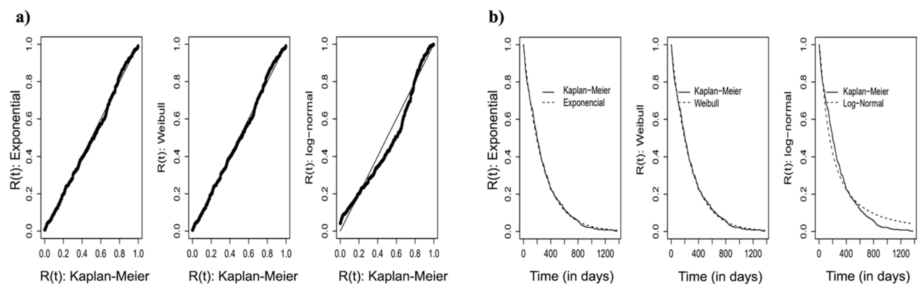

Fig. 6 **a**) Probability distribution of times between failures—model D; **b**) Comparison with the Kaplan–Meier curve for times between failures—model D

Table 7 Distribution test—model D infusion pump

Model	Likelihood	LRT	value _p
Generalized Gamma	− 2434.22	0.00	1.00
Exponential	− 2434.93	1.42	0.49
Log-Normal	− 2463.68	58.91	0.00
Weibull	− 2434.86	1.28	0.53

in Fig. 6a, which shows that both the Weibull and Exponential distributions fit the data well.

The graph below was created to identify the distribution that best fits the model. As shown earlier, the graph in Fig. 6b indicates that both the Exponential and Weibull distributions are suitable for modeling the data. Table 7 was generated to further define the data modeling.

Similarly to the graph, Table 7 shows that both the Exponential and Weibull distributions can be used. However, to maintain consistency in the analysis, we chose the Weibull distribution.

Repair time

Just as the times between failures were modeled, the repair times also need to be modeled, following the separation by models. The analysis of the repair time data (given in hours) revealed differences in behavior, necessitating a new modeling approach.

The graph in Fig. 7a leads us to completely discard the Exponential distribution. However, upon analyzing Fig. 7b, it becomes clear that the Weibull distribution is the most suitable.

The graph in Fig. 7b was produced for clarification. From the graphical analysis, it can be seen that the distribution that best models the data is the Weibull distribution, which also has the best p-value among the distributions, despite not exceeding 0.05, as shown in Table 8.

As previously mentioned, the data related to repair time does not follow a good distribution, mainly due to the lack of information on events in the sectors. It is possible that a part is needed but unavailable, or other unforeseen events that were not reported by those responsible.

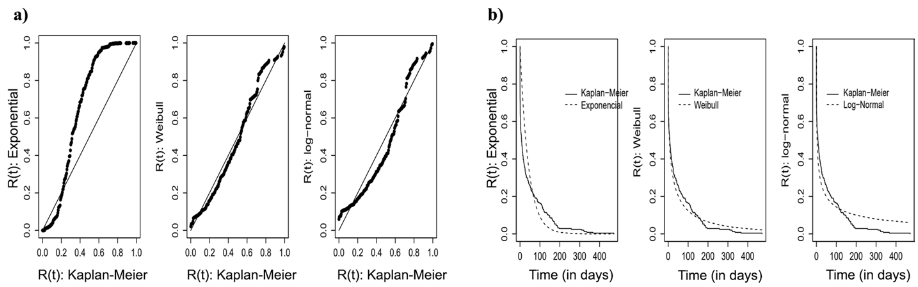

Fig. 7 **a**) Probability distribution of repair times—model A; **b**) Comparison with the Kaplan–Meier curve for times to repair—model A

Table 8 Testing distributions for repair time—model A

Model	Likelihood	LRT	valor _p
Generalized Gamma	− 916.47	0.00	1.00
Exponential	− 1165.75	498.56	0.00
Log-Normal	− 933.02	33.10	0.00
Weibull	− 920.61	8.28	0.02

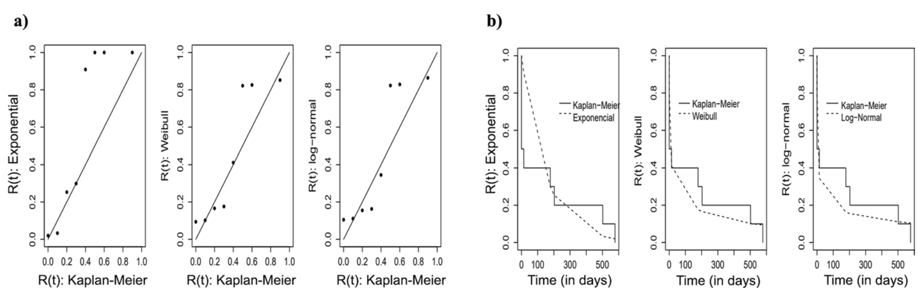

Fig. 8 **a**) Probability distribution of repair times—model B; **b**) Comparison with the Kaplan–Meier curve for repair times—model B

In the graph in Fig. 8a, it can be seen that, similar to the time between failures, there are few observations for this model, making it difficult to apply graphical and testing methods.

Thus, another comparison graph was produced, shown in Fig. 8b. By analyzing it, we can conclude that the Weibull distribution appears to be the one that best models the data.

Due to the low number of observations, the test presented in Table 9 did not yield reliable results. Therefore, based on the graphical analysis, the ideal option is to use the Weibull distribution. It can be concluded that this distribution appears to be the one that best models the data.

The modeling of the repair times for Model C was obtained through the first graph created and statistical tests. The graph presented in Fig. 9a shows that the distribution that best models the data is likely to be Weibull.

As previously observed, the graph in Fig. 9b shows that the Weibull distribution is the most appropriate choice.

Table 9 Testing distributions for repair time—model B

Model	Likelihood	LRT	value _p
Generalized Gamma	− 34.95	0.00	1.00
Exponential	− 59.94	49.98	0.00
Log-Normal	− 38.11	6.31	0.04
Weibull	− 38.31	6.72	0.03

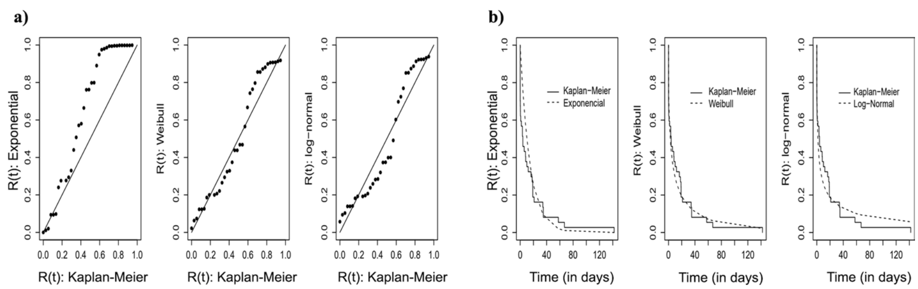

Fig. 9 **a**) Probability distribution of repair times—model C; **b**) Comparison with the Kaplan–Meier curve for repair times—model C

Table 10 Testing distributions for repair time—model C

Model	Likelihood	LRT	value _p
Generalized Gamma	− 107.27	0.00	1.00
Exponential	− 136.63	58.71	0.00
Log-Normal	− 108.75	2.96	0.23
Weibull	− 107.56	0.58	0.75

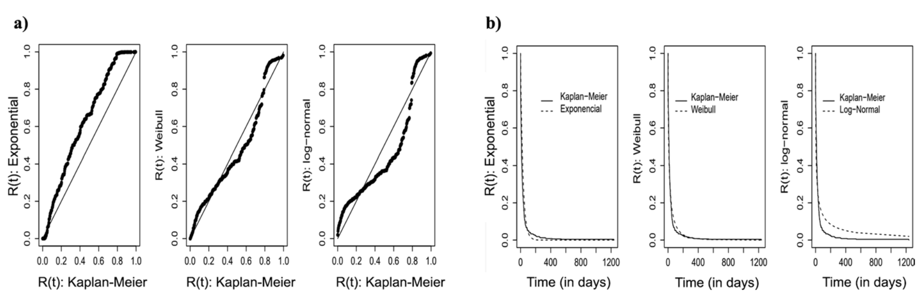

Fig. 10 **a**) Probability distribution of repair times—model D; **b**) Comparison with the Kaplan–Meier curve for repair times—model D

Below is Table 10 with the test results for this model. It can be confirmed that the Weibull distribution is the most suitable for this data.

To model Model D, we constructed the graph shown in Fig. 10a and performed some tests. The graphical analysis shows that the Weibull distribution models the data well, thus it is the one used in this study.

When creating the comparison graph with the Kaplan–Meier curve, according to the interpretation of the graph shown in Fig. 10, it can be observed that the Weibull distribution tends to be the most appropriate.

Table 11 Testing distributions for repair time—model D

Model	Likelihood	LRT	value _p
Generalized Gamma	− 1878.54	0.00	1.00
Exponential	− 2144.53	531.99	0.00
Log-Normal	− 1939.68	122.29	0.00
Weibull	− 1881.71	6.34	0.04

Table 12 MTBF and MTTR by pump model

	MTBF	MTTR
Model A	346.04	53.42
Model B	206.01	385.33
Model C	184.05	17.25
Model D	274.93	32.25

The p-value presented in Table 11 indicates that none of the distributions can be considered a good fit. This result is attributed to the limited number of observations collected for this model. However, as demonstrated by the graphical analysis (Fig. 10), the Weibull distribution adequately represents the data and is therefore selected for use.

Reliability and availability

The reliability study commences with an analysis of records, as outlined in the previous sections. By examining the operational history of infusion pumps, which includes failure data, it becomes possible to predict the failure behavior over a specified period.

Repair time assessments were conducted by categorizing the equipment by model. Table 12 presents the MTBF (mean time between failures) and MTTR (mean time to repair) values for the four analyzed models. The analysis was performed considering the Weibull distribution, where $\text{MTBF} = \eta \cdot \Gamma\left(1 + \frac{1}{\beta}\right)$.

It is observed that Model B has a high MTTR, which is attributed to the limited number of observations, as will be demonstrated below, and the occurrence of delayed repairs.

Regarding the time between failures, Model A exhibits superior performance, as it has a longer interval between successive failures. In terms of repair time, Models C and D were observed to have the lowest indicators.

A product's reliability is 100% at the moment it is placed into operation, gradually decreasing over time. In other words, the longer the operational period, the higher the probability of failure occurrence. Accordingly, the reliability of the equipment in operation at the hospital was analyzed based on its respective model, following the pattern of previous analyses.

Figure 11 illustrates the reliability percentage of the models, divided into 60-day intervals. It is evident that Model A outperforms the other analyzed models. This analysis indicates, for instance, that the reliability of Model A after 60 days of operation is 82%, while Model C's reliability is 75.7%.

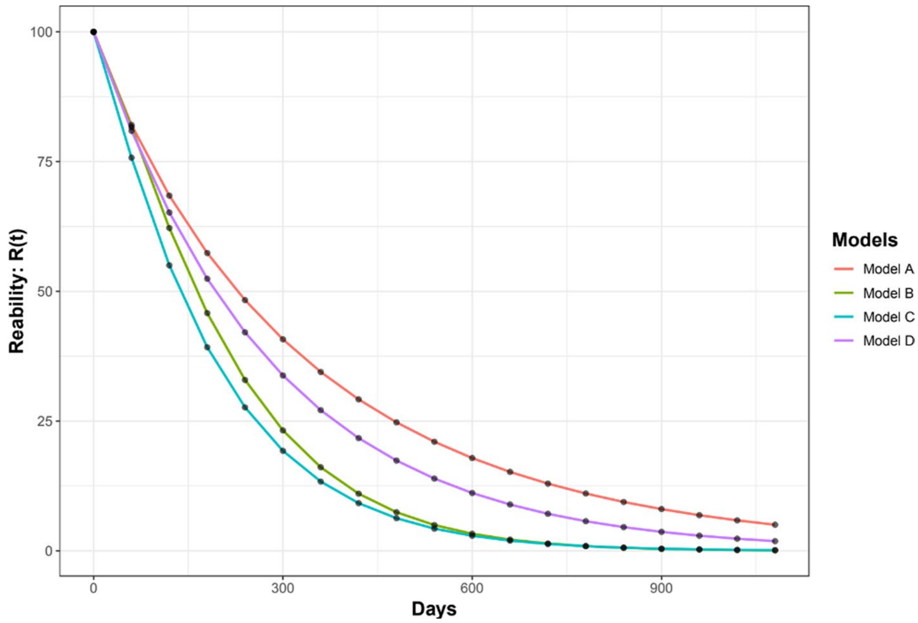

Fig. 11 Reliability in days of each model, divided into 60-day intervals

Table 13 Confidence interval for reliability

	5%	95%
Model A	5.78	83.86
Model B	0.13	83.48
Model C	0.16	78.17
Model D	2.27	82.84

It is important to note that most infusion pump manufacturers recommend preventive maintenance every two years, with corrective maintenance conducted as needed. Both types of maintenance are typically provided by the company's technical support or other authorized service providers. It is evident that the equipment does not meet the manufacturer's recommended service interval, which may be attributed to improper handling by operators and usability issues.

It is noted that Model B has the smallest number of records collected; however, its reliability after 60 days remained higher than that of Models C and D.

Table 13 presents the confidence interval for the reliability of the models. This confidence interval is based on reliability, that is, it is evaluated at the same times as Table 4.13. Therefore, the best model is model A, which even with confidence evaluated at the lower limit, still has the highest reliability among the models.

After defining the repair time and time between failure distributions, the MTBF and MTTR values were determined, allowing for the calculation of the average availability of each model, as shown in Table 14.

Table 14 shows that the availability of Model B is significantly lower than that of the other models. This is due to the fact that only 10 observations of this model are

Table 14 Availability by IP model

Model Availability (%)	
Model A	80.63
Model B	34.84
Model C	91.43
Model D	89.50

Table 15 IP reliability with at least three failures separated by days

Days	142545	225973	204466	BO9048	143548	B09320	202544	142529	204553	BO9070
0	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%
60	81.8%	81%	84.1%	71.8%	95.6%	75.7%	54.8%	90.3%	74%	97.8%
120	69.9%	70.5%	73.7%	56.7%	89.1%	59.8%	44.7%	79.5%	63%	92%
180	60.5%	62.5%	65.4%	45.9%	82%	47.9%	38.40	69.2%	55.2%	83.5%
240	52.8%	55.9%	58.4%	37.8%	74.7%	38.7%	33.9%	59.7%	49.2%	73.1%
300	46.30%	50.4%	52.5%	31.4%	67.4%	31.4%	30.50	51.2%	44.2%	61.8%
360	40.8%	45.7%	47.3%	26.3%	60.4%	25.7%	27.7%	43.6%	40.1%	50.6%
420	36.1%	41.6%	42.8%	22.2%	53.8%	21%	25.40	37%	36.6%	40%
480	32%	38%	38.8%	18.8%	47.6%	17.3%	23:50	34.2%	33.6%	30.6%
540	28.5%	34.9%	35.2%	16%	41.9%	14.3%	21.80	26.3%	30.9%	22.7%
600	25.4%	32%	32.1%	13.1%	36.7%	11.8%	20.40	22.1%	28.6%	16.3%
660	22.6%	29.5%	29.2%	11.8%	32%	9.8%	19.10	18.4%	26.5%	11.3%
720	20.2%	27.2%	20.7%	10.1%	27.8%	8.1%	17.9%	15.4%	24.6%	7.6%
780	18.1%	25.2%	24.4%	8.8%	24%	6.7%	16.90	12.8%	22.9%	5%
840	16.2%	23.3%	22.4%	7.6%	20.7%	5.6%	16.00	10.6%	21.4%	3.2%
900	14.6%	21.6%	20.5%	6.6%	17.8%	4.7%	15.1%	8.6%	20%	1.9%
960	13.1%	20.1%	18.8%	5.7%	15.2%	3.9%	14.4%	7.3%	18.7%	1.1%
1020	11.8%	18.6%	17.3%	5%	12.9%	3.3%	13.60	6%	17.5%	0.7%
1080	10.6%	17.3%	15.9%	4.3%	11%	2.7%	13.00	4.9%	16.5%	0.4%

available in the collected hospital database, which affects the MTBF and MTTR values, subsequently impacting the availability result.

Additionally, only machines with at least three observations were selected to ensure the model's functionality. By standardizing the minimum number of failures and aligning the operating period, the analysis can be improved and compared with the previously demonstrated results. The ten selected machines are identified as follows: 142545, 225973, 204466, B09048, 143548, B09320, 202544, 142529, 204553, B09070. As with the previously analyzed models, the repair time and time between failures were collected for each machine, the MTBF and MTTR were calculated, and the average availability and reliability over time were determined.

Table 15 presents the reliability of each machine analyzed at intervals of 60 days. It is evident that even after 1080 days, there were 6 machines that continued to have reliability above 10%.

The IP 225973 maintained the highest reliability rate (17.30%) after the 1080 days mentioned above. It is important to note that this IP belongs to Model A, and its operation spanned from 2016 to 2021. During this period, the equipment was initially located in an ICU and was later transferred to the chemotherapy sector.

The occurrences recorded for the four identified failures were as follows: non-functioning, damaged accessory, inoperative functionality, and damaged display. For the first two failures, repairs were performed on the pump. The third failure was not addressed, as it was registered as a “false failure” by the technicians in the system. In the last occurrence, where a display issue was identified, the part was replaced. The maintenance recorded for this pump was classified as corrective and of low complexity, with the average repair time being up to 12 days.

The equipment B09070 recorded the lowest reliability rate (0.4%) after the 1080 days stipulated in the analysis. This pump is associated with Model D, which, as previously mentioned, is from a well-regarded brand in the medical-hospital market. It remained in operation from 2008 to 2013 in an ICU, during which five failures were recorded: damaged lid lock, non-functioning, equipment not turning on, and equipment removal. It is important to note that all the shutdowns were recorded as corrective maintenance; however, the final shutdown corresponds to the definitive removal of the equipment from the hospital’s technological park. Therefore, it is recommended that those responsible for entering data pay close attention to the nomenclature when filling out the records, as this will assist in evaluating equipment performance indicators. The first failure was classified as low complexity, while the second, third, and fourth were classified as high complexity. The final failure, being related to equipment removal, was categorized as a scheduled action. This pump experienced a long repair time, with the third failure alone resulting in a repair period of 538.12 days.

Given the above analysis of the pumps with the best and worst reliability performance, it is evident that both models are well-regarded in the market. However, it is clear that the proper functioning of the equipment requires careful attention not only from operators but also from technicians. As observed, the Model A pump had an average repair time of up to 12 days, while Model B experienced a repair time of 538.12 days for a single failure.

The repair time reflects the reliability of the equipment; however, it is important to note that the failure with the longest repair time was recorded simply as “not working”, and the service report only stated “general overhaul”, without providing further details. As a result, it remains unclear whether there was a delay in the technical service, whether replacement parts were required, or if other factors contributed to the prolonged repair time. Therefore, the importance of training for the proper completion of monitoring and control systems for medical equipment is emphasized.

Since equipment availability is one of the key indicators used in maintenance programs, we also analyzed the IPs mentioned above that have at least three failures. This analysis is based on the probability of the equipment being operational when requested, as presented in Table 16.

Table 16 presents the average availability of the ten machines. It can be observed that most of them have an average availability exceeding 90%, indicating that, on average, they will be operational and available for use more than 90% of the time. This analysis is directly related to the efficiency of the corrective maintenance actions performed by the responsible department.

Table 16 Availability of 10 devices with more than 3 failures

Serial number	Availability (%)
142545	74.54
225973	99.47
204466	97.59
BO9048	96.26
143548	92.95
B09320	86.46
202544	99.89
142529	99.07
204553	83.35
BO9070	75.42

Limitations

During the preparation of this study, several limitations were identified in both the data collection and analysis phases. In the data collection phase, it was observed that professionals were not adequately trained to input information into the clinical engineering software. They failed to consistently identify the reasons for infusion pump failures or the services performed, which complicated the identification of underlying issues and hindered analysis. Additionally, some service orders were not closed within the expected time frame, affecting the recorded repair durations. The ability to conduct more comprehensive studies on the routine use of infusion pumps in large healthcare facilities was also restricted by the ethical guidelines of certain hospitals. In addition, challenges such as difficulty accessing hospital data, data inconsistency, incomplete records, and disorganized data were encountered.

Conclusions

Regarding the hospital data collected, it was evident that Intensive Care Units (ICUs) have the largest number of operating infusion pumps (49.74%). As a result, failures are more frequent in this sector (54.29%). Although ICUs are considered high-complexity areas, repair times were identified that exceeded expectations (such as 1237.99 h), which compromise equipment availability. Another issue detected was the lack of accuracy in opening service orders due to equipment failures. The occurrences reported by professionals in the environment are often generic, hindering better planning for failure prevention; 68.75% of service orders were opened with the term "Not working" as the reason for the failure. Furthermore, the services performed were recorded using various different terms to designate the same procedure. To optimize error reporting, the department could offer periodic training to standardize nomenclature. Another alternative is to increase the use of auto-fill fields, incorporating pre-established terms into the software used by the institution.

Based on the graphical analyses and tests, it can be concluded that the Weibull distribution effectively models both the time between failures and the repair times of the machines. Consequently, the reliability over time and average availability were calculated for each of the four models and the ten machines with the longest operating/

failure periods, in addition to the MTTR and MTBF indicators. The model with the best results was Model A, as it had a substantial amount of data, its analysis was precise, and, therefore, it exhibited the best reliability among the models analyzed. Regarding equipment availability, Model B showed significantly lower availability (34.84%) than the others due to the limited number of observations collected, while Model C demonstrated the highest availability (91.43%) in the evaluated interval. In light of these findings, and in an effort to improve the reliability of the devices, it is recommended that procedures be implemented to verify the infusion pumps, integrating robust methodologies from the opening of service orders to the completion of repairs. It is important to note that actions aimed at enhancing reliability can reduce hospital maintenance costs, increase equipment availability, and ensure the provision of adequate healthcare services to patients.

In addition to the technical findings, this study highlights the importance of systematically and accurately collecting information on device failures as a crucial measure to prevent unintentional harm to patients. The results reinforce the need to raise awareness not only among technical specialists, but also among healthcare professionals who operate these devices, regarding the importance of properly recording adverse events and adhering to operational standards. The incorporation of such data can strengthen technovigilance efforts and support institutional strategies aimed at patient safety, promoting preventive interventions and continuous improvements in the management of medical technologies.

By utilizing real data, unlike most studies that rely on simulations, this study facilitated a more accurate analysis of operational failures and the routine use of infusion pumps. The findings can contribute to improving maintenance planning and enhancing equipment availability. Future research is encouraged to explore predictive models based on machine learning to improve failure prediction accuracy. Additionally, comparative studies across different hospitals could provide a broader perspective on the reliability of infusion pumps in various settings. As demonstrated in the analyses, to ensure the proper use of infusion pumps in healthcare services, it is recommended to improve the recording of failures and service orders to optimize maintenance planning, prioritize corrective and preventive actions in sectors with high repair times (e.g., Neurological ICU), and consider adopting infusion pump models with higher reliability and availability during acquisition.

Methods

Collection environment

The hospital where the data for this study were collected were carried out has been in operation for over 170 years, offering private services through agreements and also serving the public of the Unified Health System, in Portuguese Sistema Único de Saúde (SUS). The institution achieved qualitative success which resulted in resulting in the attainment of level 3 excellence in Accreditation. This certification is granted based on the Standards of the Brazilian Accreditation System and the Brazilian Accreditation Manual, demonstrating that the hospital adopts procedures, policies, and protocols focused on patient safety and quality of care. The establishment was also recertified by the National Accreditation Organization (ONA) and the Canadian Accreditation Organization (Qmentum), demonstrating the quality of its services.

The technology park currently consists of 4,622 items, divided into different technologies across various sectors. The IPs total 614 devices, 491 volumetric pump units, and 123 syringe units. The sectors that use this equipment have at least 5 backup pumps and, if necessary, additional ones are available in the Clinical Engineering Sector. Professionals in the sector perform corrective and preventive maintenance, calibration, validation, installation, training, inspection, patrols, among other services. Despite the various services provided, it is the manufacturer's responsibility to collect obsolete pumps and perform their maintenance. Furthermore, calibrations follow the established maintenance plan and with calibration performed after each corrective maintenance.

After authorization from the hospital's Teaching and Research Center, IP data collection was conducted using information acquired from the Clinical and Hospital Engineering software. This software was designed to manage the technological park of healthcare environments, including all MDs and other assets integrated into the infrastructure. The system allows for the monitoring of the entire lifecycle of inputs, from purchase planning to disposal, as well as maintenance stages and other processes. Spreadsheets containing data from 2008 to 2021 were exported for analysis.

The raw data provided contained a large amount of information (over 4,600 records), with the IPs completely scattered without any logical sequence. Therefore, the tables generated by the software were carefully checked, manipulated using R programming, and the columns of interest were retained. Initially, the devices were counted and separated by hospital sectors. The arrangement of the equipment allows the assessment of demand in healthcare environments, as well as estimating failures, maintenance, and planning directed by sector.

Reliability and availability assessment

At this stage, some treatments were performed on the originally acquired database to ensure clearer and more objective results. Only the variables "Opening", "Stopping", "Operation", "Closing", "Repair Time", "Serial Number", and "Model" were used. The "Repair Time" variable was manipulated first to generate results measured in days instead of hours, for better visualization of the data. To this end, a column called "Repair Time (hours)" was added to the original database via Excel to avoid errors during the data import into RStudio Desktop software version 4.0.2. The variables "Opening" and "Stop" were used to create a new variable within the code, called "Between Failures", which indicates the time elapsed between each failure of each machine.

To adjust the data to the probability distributions, the times between failures and equipment repairs were analyzed. Several graphs were used to visualize the data, including the Kaplan–Meier graph, linearized graphs, and Meier curves. Three possible distributions for the data were considered: Exponential, Weibull, and Log-Normal.

In this analysis, the equipment was categorized according to the four machine models available in the collection environment. Model A corresponds to a linear peristaltic pump, designed for greater accuracy in infusions and the administration of high volumes of solutions. This model is from a leading manufacturer in the market, and the hospital analyzed rents the equipment at the highest price compared to other IPs.

Model B refers to a volumetric pump that can be used for intermittent or continuous administration and also supports different administration routes. The hospital has a smaller number of this model due to the constant production of more modern technologies, which offer a greater number of features to assist users in their daily tasks. This IP is considered intermediate, with its market value being lower than that of the other models presented, and the hospital operates a loan program for this equipment.

Model C consists of a volumetric infusion pump used for administering enteral nutrition. Its cost is comparable to Model A, and this IP is also provided to the hospital on loan. Finally, the equipment associated with Model D is a volumetric pump that can be used for both parenteral and enteral administration. It is ideal for situations where the patient requires multiple simultaneous infusions, and its cost is similar to that of Models A and C. It is provided to the hospital through a loan agreement.

Hypothesis tests were also conducted for each distribution, providing more accurate results regarding the fit of the models to the data. These tests are based on the Generalized Gamma distribution, which encompasses all the other distributions mentioned above. The Kaplan–Meier plot is generated from its estimator, which is the most widely used in clinical and reliability studies, as it is a nonparametric estimator. The Kaplan–Meier estimator for $R(t)$ is defined as:

$$\hat{R}(t) = \prod_{j \epsilon J_t} \frac{n_j - 1}{n_j}. \tag{1}$$

This estimator is based on the fact that the probability of survival of a unit in an interval (t_i, t_{i+1}) can be estimated as the ratio between the number of units that did not fail during the interval and the number of units tested at the beginning of the interval [12].

The parameters of the distributions identified during the data modeling were determined with the support of the R EnvStats package. The respective reliabilities were calculated by categorizing the equipment by model and then selecting a sample of the 10 infusion pumps that operated for the longest period (from 2008 to 2021). For this purpose, the reliability function used was:

$$R(t) = e^{-\left(\frac{t}{\theta}\right)^{\gamma}}, \tag{2}$$

where t represents the time between failures or repairs, depending on what is being modeled, and θ and γ correspond to the scale parameter and the shape parameter of the Weibull distribution, respectively.

The availability analysis was performed using the mean time to repair (MTTR) and mean time to failure (MTTF) of the machines (or models, depending on what is being modeled). These are calculated using the expected distribution, which in our case is Weibull. Therefore, the difference between them will represent the data to which they refer, with MTTF corresponding to the time between failures and MTTR corresponding to the repair time. We use the formula below for the calculations:

$$MTTF = \theta\Gamma(1 + 1/\gamma). \tag{3}$$

Finally, the formula for calculating the average availability was used:

$$Availability = \frac{MTTF}{MTTF + MTTR}. \quad (4)$$

The value of the availability parameter provides a consistent indicator for planning preventive maintenance activities for this equipment and can be evaluated based on variables such as manufacturer, model, or the sector of the hospital where it is operating.

Abbreviations

IP	Infusion pump
ICU	Intensive Care Units
AE	Adverse events
ANVISA	National Health Surveillance Agency, in Portuguese Agência Nacional de Vigilância Sanitária
MD	Medical device
SUS	Unified Health System, in Portuguese Sistema Único de Saúde
MTBF	Mean time between failures
MTTR	Mean time to repair

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Author contributions
The authors developed the idea and prepared, edited and finalized the manuscript. The author Silva, M.S. and the author Piratelli-Filho, A. were responsible for collecting the databases using the software of the hospital studied here. The authors Nunes, M. A. A. and Rosa, S. S. R. F. processed the data to be analyzed by all the authors. We jointly created the methodology to be followed, with better analyses to be done and then all the authors wrote the sections study. All authors contributed to the article and approved the submitted version.

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Data availability
The datasets used and/or analyzed in the current study are available upon request from the corresponding author. The original contributions presented in the study are included in the article/Supplementary Material. Further inquiries can be directed to the corresponding author.

Declarations

Ethics approval and consent to participate
Not applicable.

Consent for publication
Not applicable.

Competing interests
The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential competing interests.

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