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Determining the Optimal Maintenance Interval for Autoclave Machines using Reliability Analysis at PT XYZ

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Abstract

The autoclave machine in the Medical Device Department of PT XYZ is the most important sterilization equipment. There were 36 failure incidents from January 2023 to December 2025. These incidents could cause downtime and delays in production. This study aims to find the best preventive maintenance intervals based on reliability for five subsystems of the autoclave machine: the chamber, heat tank, valve and gas inlet, pump motor, and electrical system. The analysis was conducted using the Laplace test to identify failure trends. The Anderson-Darling test was used to select the best distribution, and the parameters were estimated using Maximum Likelihood Estimation (MLE). The heat tank subsystem, which showed an increasing failure trend, was modeled using a Non Homogeneous Poisson Process (NHPP) based on a Power Law Process (PLP), while the other components were modeled using appropriate statistical distributions. The results showed the highest MTBF value for the electrical components at 652,320 minutes and the lowest for the heat tank at 114,258 minutes. The reliability values at t = MTBF ranged from 0.4116 to 0.5000. The optimal preventive maintenance intervals to achieve a 90% reliability target are 74 days (chamber), 8 days (heat tank), 17 days (valve and gas inlet), 30 days (pump motor), and 443 days (electrical).

Keywords: Autoclave; NHPP; power law process; preventive maintenance; reliability

1. Introduction

The operational sustainability of a manufacturing company is highly dependent on the condition of its production machinery and equipment. Planned maintenance is one of the main pillars in ensuring the smoothness of the production process while enhancing the company's competitiveness amid increasingly intense industrial competition [1]. PT XYZ is a pharmaceutical company that has been operating since 1974 with a production center in Lawang, Malang Regency, East Java, specializing in healthcare product manufacturing. Autoclaves, used as sterilization equipment, operate by utilizing high-pressure steam at specific temperatures to kill microorganisms on products and equipment. The high frequency of disruptions in the medical products department indicates that autoclaves in that department are prone to breakdowns, which can ultimately disrupt the continuity of the sterilization process and hinder production schedules.

Several previous studies have looked into machine maintenance strategies using quantitative methods. Dwiyanti et al. (2023) used the RAM and FMEA methods to assess industrial machine performance. They showed that the components examined had a reliability rate over 80% and an availability rate above 99%. This supports better preventive maintenance planning [2]. Tyas et al. (2016) applied the NHPP model to find the best repair interval for heat exchanger components. They determined an optimal interval of about 8,900 operating hours [3]. Panta et al. (2019) discovered that autoclave sterilization systems in healthcare facilities are still at risk of failure due to inadequate monitoring and operating practices [4]. Fardan and Andriani (2024) showed that using FMEA helps identify critical parts in autoclave machines, like pneumatic valves and heating and cooling piping systems, which deserve the highest maintenance priority [5]. These findings highlight the value of data-driven methods in improving the reliability and efficiency of machine maintenance systems. This study aims to create an optimal preventive maintenance schedule that reduces autoclave downtime in the Medical Device Department of PT XYZ using a reliability-based approach. We conducted failure analysis using the PLP method within the Non-Homogeneous Poisson Process (NHPP) framework. This allows us to describe failure rates that vary over the machine's operating time. This method complements the

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Homogeneous Poisson Process (HPP) model, which is suitable only when failure rates are consistent. Therefore, combining these two methods enables a more accurate representation of the machine's failure patterns, which change throughout its lifecycle [6].

2. Method

2.1. Data collection and distribution test

This study uses a quantitative approach based on historical data to find the best preventive maintenance (PM) intervals for autoclave machines at PT XYZ. The focus is on the autoclave machine in the Medical Device Department, which is the sterilization unit with the highest importance in the production process. The data comes from records of machine failures over a complete three-year period, from January 2023 to December 2025. It includes 36 failure incidents across five main subsystems: chamber, heat tank, valve and gas inlet, pump motor, and electrical systems. The three-year data period is considered sufficient to represent the failure patterns of each subsystem and to support PM interval recommendations.

Table 1. Autoclave machine failure data for the period January 2023 to December 2025

Component	Time Between Failure (Minutes)	Time to Repair (Minutes)
Chamber	118,080	300
	384,480	120
	201,600	270
	145,440	120
Heat Tank	295,200	90
	341,280	150
	2,880	90
	14,400	150
	50,400	180
	161,280	90
	18,720	150
	594,720	180
	34,560	150
Valve and Gas Inlet	2,880	90
	76,320	30
	5,760	60
	210,240	60
	194,400	60
	169,920	90
	25,920	150
	21,600	120
	74,880	90
	69,120	60
	41,760	90
	60,480	60
	59,040	60
	113,760	90
	139,680	90
	195,840	120
	89,280	90
	15,840	30
Pump Motor	659,520	120
	537,120	60
	30,240	60
Electrical	659,520	180
	645,120	120

The number of observed failures differs markedly among subsystems: 17 for the valve and gas inlet and 10 for the heat tank, but only 4 for the chamber, 3 for the pump motor, and 2 for the electrical subsystem. With so few observations, goodness-of-fit tests have low power and parameter estimates, particularly the normal-distribution parameters for the pump motor and electrical subsystem, are sensitive to individual data points. The MTBF, reliability, and PM interval values for these subsystems should therefore be interpreted cautiously and updated as more failure data become available.

A trend test is performed on the dataset to determine whether the failure data are independent of one another and follow the same distribution. This allows for the selection of a statistical or stochastic distribution model to model the failure data and determine the reliability value. The formula for the Laplace test is as follows [7].

$$U = \frac{\Sigma X_i/(n-1) - T*/2]}{[T*/\sqrt{(12(n-1))}]} \quad (1)$$

$$p - value = 2 \times \left(1 - \Phi(|U|)\right) \quad (2)$$

where:
X_i = the i-th CTBF,
T^* = end of observation time

Then, the MIL-Hdbk-189 test was performed using Chi-Square distribution-based statistics with the Power Law Process approach

$$C = 2 \times [n \cdot ln(T^*) - \sum_{i=1}^{n} ln(X_i)] \times \hat{\beta} \quad (3)$$

$$DF = 2(n-1) \quad (4)$$

$$p\text{-}value = 2 \times min\left(F_{\chi^2_{DF}}(C),\ 1 - F_{\chi^2_{DF}}(C)\right) \quad (5)$$

The Anderson-Darling statistic is calculated using the values of the theoretical distribution function on the sorted data as follows:

$$AD = -n - \frac{1}{n}\sum_{i=1}^{n}(2i-1)\left[ln\,F(t_i) + ln\left(1 - F(t_{n+1-i})\right)\right] \quad (6)$$

If the Laplace statistic falls outside the critical limits, it can be concluded that there is a trend in the failure data, whereas the Anderson–Darling test is used to assess the fit of the data distribution to a specific model as part of a goodness-of-fit test [8].

2.2. Calculating the mean time between failure

The Mean Time Between Failure (MTBF) is a reliability indicator that reflects the average operating duration of a component between two consecutive failure events. The MTBF typically ranges from hundreds to tens of thousands of hours, depending on the type and condition of the component being analyzed. The MTBF formula is adjusted according to the failure distribution selected for each component [9]:

The MTBF for a normal distribution is

$$\text{MTBF} = \eta \quad (7)$$

The MTBF for a lognormal distribution is

$$\text{MTBF} = t_{med} e^{\frac{s^2}{2}} \quad (8)$$

The MTBF for a exponential distribution is

$$\text{MTBF} = \frac{1}{\lambda} \tag{9}$$

The MTBF for a Weibull distribution is

$$\text{MTBF} = \theta.\Gamma(\frac{1}{\beta} + 1) \tag{10}$$

2.3. Calculating component reliability and preventive maintenance intervals

Reliability is a probabilistic measure that reflects the ability of a component or system to operate according to its function within a certain time frame and under specified operating conditions. Mathematically, the reliability value R(t) is obtained from the complement of the cumulative failure distribution function, namely [10].

$$R(t) = 1 - F(t) \tag{11}$$

Reliability from a normal distribution is

$$R(t) = 1 - \Phi\left(\frac{t-\mu}{\sigma}\right) \tag{12}$$

The reliability of the log-normal distribution is

$$R(t) = 1 - \Phi\left(\frac{\ln t-\mu}{\sigma}\right) \tag{13}$$

$$R(t) = 1 - \Phi\left(\frac{1}{s} ln \frac{t}{t_{med}}\right) \tag{14}$$

The reliability of the exponential distribution is

$$R(t) = e^{-\lambda t} \tag{15}$$

The reliability of the Weibull distribution is

$$R(t) = e^{-(t/\theta)^{\beta}} \tag{16}$$

This approach aims to evaluate the reliability level of the machine as a basis for developing more effective maintenance strategies [11]. The determination of the distribution of the time intervals between failures and repair times is performed using Power-Law-Process (PLP) analysis. In this model, the failure intensity function is expressed as [12]:

$$\lambda(t) = \beta\eta - \beta t\beta - 1 \tag{17}$$

where:
$R(t)$ = *machine reliability at time t*
$\lambda\,(t)$ = failure rate at time t,
β = shape parameter,
η = scale parameter,
t = system operating time.

3. Results and discussion

3.1. Distribution test

This test was performed using Minitab 18 software. Steps for testing the time-to-failure trend for chamber components.

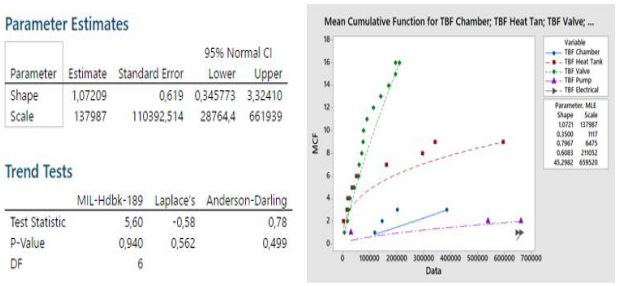


Figure 1. Trend test results

The following is a manual calculation of the trend test on the chamber.

a. Calculating $ln(T^*/X_i)$

Table 2. Calculation of $ln(T^*/X_i)$ for the trend test on the chamber

i	X_i (*CTBF*)	$ln(X_i)$	T^*/X_i	$ln(T^*/X_i)$
1	118,080	11.67	7.19	1.97
2	502,560	13.12	1.69	0.52
3	704,160	13.46	1.20	0.18
4	849,600	13.65	1.00	0.00
		Σ =		2.68

$$\sum ln(X_i) = 51.92$$

$$ln(T^*) = ln(849{,}600) = 13.65$$

$$n\ln(T^*) = 4 \times 13.65 = 54.61$$

b. Calculating the C statistic from MIL-Hdbk-189 (Power Law)

$$C = 2 \times \left[n\,ln(T^*) - \sum_{i=1}^{n} ln(X_i)\right]$$

$$= 2 \times (54.61 - 51.92)$$

$$= 2 \times 2.69 = 5.37$$

c. Calculating the corrected C using the MLE-estimated β:

$$C_{corrected} = C \times \hat{\beta} = 5.37 \times 1.07 = 5.75 \approx 5.60$$

d. Determine the degrees of freedom:

$$C = 5.60, \quad DF = 6$$

e. Calculate the *p-value* using the two-sided Chi-Square distribution:

$$p = P(\chi_6^2 \geq 5.60)$$

$$p = 0.500 - \frac{(5.60 - 5.34)}{(7.23 - 5.34)} \times (0.50 - 0.30)$$

$$= 0.50 - \frac{0.25}{1.88} \times 0.20$$

$$= 0.50 - 0.0268 = 0.4732$$

$$p = 1 - F_{\chi_6^2}(5.60) = 1 - 0.5298 = 0.4702$$

f. Calculate the *p-value* using the two-sided Chi-Square distribution:

$$p = 2 \times \min(0.47,\ 0.47) = 2 \times 0.47 = 0.94$$

Calculate the *p-value* using the two-sided Chi-Square distribution:

$$U = -0.58$$
$$p = 2 \times \left(1 - \Phi(|-0.58|)\right)$$
$$= 2 \times \left(1 - \Phi(0.58)\right)$$
$$= 2 \times (1 - 0.719)$$
$$= 2 \times 0.281 = 0.562$$

The Laplace test has a null hypothesis (H0) stating that the data show no trend (homogeneous Poisson process) [13], and an alternative hypothesis (H1) stating that the data indicates the presence of trend (non-homogeneous Poisson process) [14]. The null hypothesis is rejected if the p-value is less than the critical value or the 5 percent significance level [15].

From the results of the trend test described above, conducted using Minitab 18 software, it can be seen that the p-value from the Laplace test is 0.562 and is therefore greater than the critical value of 0.05. From this, it can be concluded that the null hypothesis is accepted, meaning there is no trend in the chamber failure data. The following is a summary of the trend test results determined using Minitab 18 software.

Table 3. Trend test result

Component	p-*value*	Conclusion
Chamber	0.562	No Trend
Heat Tank	0.001	*Trend Present*
Valve and Gas Inlet	0.176	No Trend
Pump Motor	0.732	No Trend
Electrical	0.098	No Trend

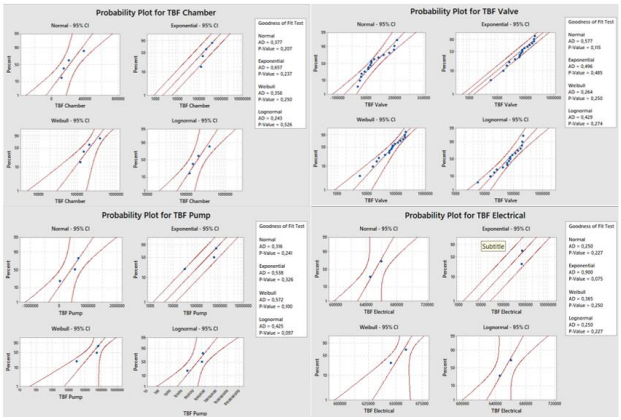


Figure 2. Results of the goodness-of-fit test

Trend testing was performed on all Time Between Failure data using Minitab 18 software. The primary objective of this test was to determine whether the failure data between subsystems were independent and identically distributed (i.i.d.), which is a prerequisite for selecting the appropriate statistical or stochastic distribution model. The testing process relied on the Laplace Test statistic, which was then supplemented with the Chi-Square distribution based MIL-Hdbk-189 Test to validate the Power Law Process model [7]. A goodness-of-fit test is then performed using the Anderson-Darling statistic, with the best distribution selected based on the highest p-value exceeding α = 0.05 and the smallest AD statistic value [8]. The distribution that meets both criteria is established as the representative failure model for each subsystem [16], [17].

After determining the distribution that best describes the failure data for each device, the distribution parameters will be calculated for each distribution selected from that device. Since each distribution has different parameters, the parameter calculations will be adjusted according to each distribution. Parameter estimation is performed using Maximum Likelihood Estimation (MLE), as this method provides more accurate results. The following are the distribution parameter calculations for the autoclave machine in the chamber component.

$$\mu = \sum_{t=1}^{n} \frac{ln\, t_i}{n}$$
$$\mu = \sum_{t=1}^{n} \frac{ln\, 118{,}080 + ln\, 384{,}480 + ln\, 201{,}600 + ln\, 145{,}440}{4}$$
$$\mu = 12.16$$
$$t_{med} = e^{\mu}$$
$$t_{med} = e^{12.16}$$
$$t_{med} = 191{,}010$$
$$s = \sqrt{\sum_{t=1}^{n} \frac{(ln\, t_i - \mu)^2}{n}}$$
$$s = \sqrt{\sum_{t=1}^{n} \frac{(ln\, 118{,}080 - 12.16)^2 + \cdots + (ln\, 145{,}440 - 12.16)^2}{4}}$$
$$s = 0.4466$$

The following is a summary of the calculations of the selected distribution parameters that have been performed.

Table 4. Summary of the distribution test for failure data

Component	Selected Distribution	Parameter
Chamber	Lognormal Distribution	$t_{med} = 191{,}010$ $s = 0.4466$
Heat Tank	NHPP Model	$\beta = 1.47$ $\theta = 341{,}708$
Valve and Gas Inlet	Weibull Distribution	$\beta = 1.36$ $\theta = 133{,}764.75$
Pump Motor	Normal Distribution	$\mu = 408{,}960$ $\sigma = 272{,}417.65$
Electrical	Normal Distribution	$\mu = 652{,}320$ $\sigma = 10{,}182.33$

Based on the summary results above, the selected distribution parameters for each piece of equipment have been obtained. The values from these calculations will subsequently be used in MTBF calculations and further processing.

3.2. Reliability test for preventive maintenance intervals

After reviewing the data distribution for the TBF chamber, it was determined that the selected distribution was the log-normal distribution with the previously

calculated parameters *s* and t_{med}. The following is the MTBF calculation for the equipment.

$$\text{MTBF} = t_{med} e^{\frac{s^2}{2}}$$

$$\text{MTBF} = 191{,}010 e^{\frac{0.4466^2}{2}}$$

$$\text{MTBF} = 211{,}043.83\ minutes$$

Table 5 is a summary of the MTBF calculations carried out on the basis of the selected distribution.

Table 5. Summary of MTBF for each component

Component	Selected Distribution	MTBF (minutes)
Chamber	Lognormal Distribution	211,043.83
Heat Tank	NHPP Model	114,258
Valve and Gas Inlet	Weibull Distribution	122,470.17
Pump Motor	Normal Distribution	408,960
Electrical	Normal Distribution	652,320

Based on the results of the summary above, the MTBF values for each piece of equipment have been obtained. Testing the distribution of the chamber failure data revealed that the selected distribution is the log-normal distribution, with parameters s and tmed derived from the previous MTBF values. The following are the reliability calculations for the equipment.

$$R = 1 - \phi\left(\frac{1}{s} ln \frac{t}{t_{med}}\right)$$

$$R = 1 - \phi\left(\frac{1}{0.4466} ln \frac{211{,}043.83}{191{,}010}\right)$$

$$R = 0.4116$$

The following is a summary of the reliability calculations performed based on the selected distribution.

Table 6. Summary of component relaibility

Component	MTBF Parameter	MTBF (minutes)	Reliability
Chamber	$t_{med} = 191{,}010$ $s = 0.4466$	211,043.83	0.4116
Heat Tank	$\beta = 1.47$ $\theta = 341{,}708$	114,258	0.4135
Valve and Gas Inlet	$\beta = 1.36$ $\theta = 133{,}764.75$	122,470.17	0.4120
Pump Motor	$\mu = 408{,}960$ $\sigma = 272{,}417.65$	408,960	0.5000
Electrical	$\mu = 652{,}320$ $\sigma = 10{,}182.33$	652,320	0.5000

The reliability values obtained from each autoclave subsystem describe the probability of each component to operate without failure during a specified time period. Based on the reliability calculation results at time *t* = MTBF for each subsystem, it was found that the reliability values range from 0.4116 to 0.5000. Theoretically, the reliability value at *t* = MTBF for a symmetric distribution such as the normal distribution will always yield a value of 0.5000, while for an asymmetric distribution such as the log-normal distribution, the reliability value is 0.4116; the NHPP model (heat tank) yields a reliability value of 0.4135, and the Weibull distribution (valve and gas inlet) yields a value of 0.4120. These results are consistent with theoretical expectations because the pump motor and electrical components, which follow a normal distribution, yield a reliability value of exactly 0.5000, whereas the chamber subsystem (lognormal), heat tank (NHPP), and valve and gas inlet (Weibull) subsystem yield varying reliability values.

Each reliability value in Table 6 is evaluated at the component's own MTBF, so it is expected to lie approximately between 0.41 and 0.50 for the distributions fitted here (exactly 0.5000 for the normal distribution) and should not be compared directly with a 90% reliability target. The 90% target is instead applied to the operating time between preventive maintenance actions, which is why the recommended intervals in Table 8 are much shorter than the corresponding MTBF values. Because the five subsystems operate in series, a failure of any one of them stops the autoclave, and system reliability at a common operating time cannot exceed that of its least reliable subsystem. The preventive maintenance of the subsystems should therefore be coordinated, particularly for the heat tank, which has the lowest MTBF and the shortest PM interval.

These results indicate opportunities for improving the existing maintenance strategy. A scheduled preventive maintenance policy based on the failure pattern of each subsystem, and, where feasible, condition-based maintenance, could be considered to improve reliability.

For the heat tank subsystem, which shows an increasing failure trend ($\beta > 1$ in the NHPP model), maintenance intervals should become shorter as the machine ages. Practically, the suggested maintenance intervals directly affect the company's maintenance workload and how resources are allocated. The heat tank subsystem, with an interval of just 8 days, needs the most attention. It requires dedicated technicians to make sure maintenance happens on time without interrupting production. In contrast, the electrical subsystem, with a 443-day interval, allows for longer planning cycles. This lets the maintenance team concentrate resources on components that require more frequent care. The different intervals for each subsystem highlight the principle of reliability-centered maintenance. Each part is handled according to its specific failure characteristics instead of a one-size-fits-all schedule.

Adopting the suggested preventive maintenance schedule is expected to reduce unexpected downtime and improve the reliability of the sterilization process. This is especially important for the heat tank. Its increasing failure trend ($\beta > 1$) shows it deteriorates faster with age, so sticking to the 8-day interval is crucial to avoid cascading failures that could stop the entire autoclave system. Next, inspection time calculations were done to find out how much time the company needs for preventive maintenance to reach a reliability target of 90%.

Table 7. Reliability of various trial times in the chamber

t (minutes)	Durations	$z=(1/s)ln(t/tmed)$	$\Phi(z)$	$R(t)$
43,800	1 month	-3.29	0.0005	99.95%
87,600	2 months	-1.74	0.0404	95.96%
106,000	74 days	-1.31	0.0937	90.63%
131,760	3 months	-0.83	0.2028	79.72%
175,200	4 months	-0.19	0.4233	57.67%
211,044	MTBF	0.22	0.5884	41.16%
262,800	6 months	0.71	0.7625	23.75%
525,600	1 year	2.26	0.9883	1.17%

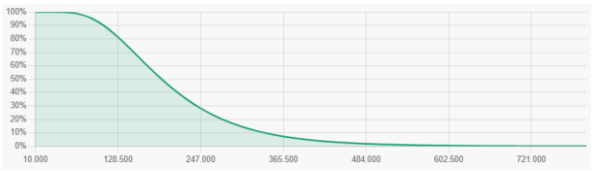


Figure 3. Reliability versus chamber operating time

From the above calculation, the time interval that can be used for preventive maintenance activities on the chamber to achieve a reliability value of 90% is 106,000 minutes, or approximately 74 days. A summary of the recommended maintenance intervals for other components can be seen in the following table.

Table 8. Summary of recommended time intervals for preventive maintenance

Component	Maintenance Time
Chamber	106,000 minutes or approximately once every 74 days
Heat Tank	11,000 minutes or approximately every 8 days
Valve and Gas Inlet	24,000 minutes, or about once every 17 days
Pump Motor	43,800 minutes or approximately every 30 days
Electrical	639,000 minutes or approximately every 443 days

4. Conclusion

Based on the results of the reliability analysis conducted on PT XYZ's autoclave, the following conclusions were drawn. The Laplace test indicated that only the heat tank subsystem exhibited an increasing failure trend (*p-value* = 0.001), and was therefore modeled using the NHPP-PLP with parameters β = 1.47 and θ = 341,708. The other four subsystems are homogeneous (HPP) and were modeled using their respective best-fit statistical distributions: log-normal (chamber), Weibull (valve and gas inlet), and normal (pump motor and electrical). The highest MTBF value, 652,320 minutes, was obtained for the electrical subsystem; however, this estimate rests on only two observed failures, and the results for the electrical subsystem, pump motor, and chamber should be interpreted cautiously. Conversely, the heat tank has the lowest MTBF of 114,258 minutes, indicating the highest rate of deterioration. The reliability values at t = MTBF ranged from 0.4116 to 0.5000, consistent with the theoretical behavior of the fitted distributions; the 90% reliability target is therefore met only by scheduling preventive maintenance well before the MTBF. The optimal preventive maintenance intervals to achieve a 90% reliability target are as follows: chamber every 74 days, heat tank every 8 days, valve and gas inlet every 17 days, pump motor every 30 days, and electrical components every 443 days. These different intervals among subsystems show unique failure patterns. This makes the recommendations more flexible and effective than a standard time-based maintenance schedule.

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