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Effect of the stochastic weibull parameters on the reliability of the dialysis machine

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HIGHLIGHTS

- The Weibull parameters were calculated using several methods
- The uncertainties of the shape and scale parameters were estimated
- The random failure rate and reliability of the dialysis devices were studied
- The systematic inspection period of the dialysis devices was estimated in a stochastic environment

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ABSTRACT

Dialysis machines operate in an uncertain environment with several sources of disturbances; therefore, it is necessary to take account of the uncertainties during all their life phases. This paper presents a study of the random reliability of the dialysis machine in a stochastic environment through the two-parameter for Weibull distribution. The shape and scale parameters were estimated through analytical and graphical methods based on the failure history of the devices. The formulation of the analytical methods and their exploitation using numerical simulations was one of the objectives of this work. The uncertainties in the stochastic environment of the machines are related to variability in physical and geometric parameters, fluctuations in load conditions, stress boundary conditions, and also to physical laws and simplifying assumptions used in the modeling process. The Weibull parameters introduced these uncertainties, and their effect on the device's reliability was studied. The main contribution is the study of the effect of the uncertainties in Weibull parameters on the reliability of the dialysis machine. The question of the uncertainties in the Weibull parameters was treated. The involved parameters were considered a Gaussian variable, and their means and standard deviations were calculated in several configurations of the dialysis devices. The random failure rate and reliability were treated and discussed. The random systematic inspection period is studied to install an efficient preventive maintenance program.

1. Introduction

Recent medical machines and materials have become very sophisticated with high technology and operate under unfavorable conditions. Health establishments must guarantee that their essential medical equipment is accurate, safe, reliable, available, and operating efficiently. A surgical device is a critical component of an efficient healthcare degree in a medical institution. Currently, medical devices exceed 5000 varieties in the developed hospitals [1]. In the face of the objectives of current healthcare and the development performance of medical machines, several countries give particular importance to improving the quality and reliability of the operating materials in their hospitals. The Health Organization in the World (WHO) estimates that about 50% of medical equipment in developing nations is not functioning correctly because of inefficient maintenance, aging deterioration in equipment quality, and decreased services provided [2].

Medical device failure can disturb the efficiency of healthcare work, cause hard health problems for patients, and harm the environment [3]. Damage is defined as a loss of part or all of the properties of a component, which severely diminishes and can cause a complete lack of its functioning capability. This malfunction may be caused by its design, fabrication processes, installation, usage method, or even maintenance [4,5]. Various phenomena affect Any manufacturing system over time, such as aging and wear of its functional compartments [6]. These outstanding physical phenomena lead to failure, significantly impacting the equipment's operating cost and operational safety. In the literature, many researchers presented various classifications of damages [7,8] and studied the effect of fatigue and the aging of the mechanical mechanisms on availability, maintenance, and reliability [9,10]. Equipment degradation can result from several techniques, such as operating conditions, vibrations, fatigue, wear, strains, stresses, etc. Modeling the failure rate over time becomes essential for monitoring and

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diagnosing the risks of this sensitive equipment. Booher treated in his paper [11] the diverse origins of the degradation mechanisms of mechanical constituents, which include various, frequent, and complicated causes; let us cite cracking, wear, creep, fatigue, cracking, etc. These degradation modes are characterized by many parameters, such as material, geometrical and dimensional characteristics, operating conditions, external stresses. etc. [12].

The influence factors are external or internal parameters affecting the machine's reliability. A classification of these different factors, based on the life phase of the considered system, was offered by Brissaud [13]. There are several categories of these factors, and we can classify them according to their origins and cite design, manufacturing, system installation, operating, and maintenance factors. Organizational and human factors that generally cause a broader effect on the system can be added to this list [12,14]. This type of factor is defined as a multidisciplinary field focusing on how to increase safety, enhance performance as well as increase user satisfaction, and cover various axes such as usable procedures, training and competence, safety-critical communication, health and safety culture, maintenance, inspection, and testing error [15].

Dhillon [16] described in his work the maintenance of medical devices as an indispensable act to retain the equipment in the best working condition, ensure its reliability, or restore it to a specific operating condition. Mathematical maintenance can improve medical equipment reliability through many methods and procedures. The main objective of Khalaf and Hamam's [17] paper The aim of the work presented by Bahreini [18] is to extract the influencing factors affecting the maintenance management of medical devices. A good maintenance strategy helps reduce downtime and its costs and improves productivity, profitability, and competitiveness by ensuring the efficient operation of equipment [19]. In their study, Jiménez et al. [20] proposed an ontology model for maintenance strategy selection and assessment. An approach for an integrated maintenance strategy selection considering machine failures and the context of other machines within the value-adding network is developed in [21,22].

In current engineering developments, the best distribution characterizing a data set must be chosen thoroughly to present uncertain parameters [23] rigorously. The Weibull distribution is one of the most employed probability density functions in the industry domain. According to Lyonnet [24], the Weibull theory is the most appropriate for efficiently analyzing mechanical components' reliability. This distribution's principal benefit is its ability to account for little illustration of history failure data. However, the graphical method is suggested in the case of the probabilistic model with small-size data to guarantee the results' accuracy and precision [25]. The couples fit various failure models and simulate several other statistical distributions used in engineering, which is a major quality of the Weibull distribution [26]. The Weibull probability synthesis is widely used in treating life data and may be applied to various conditions. Weibull distribution is employed in several fields [27], such as civil aviation, aerospace, automotive industries, electronics, and materials [28]. This statistical method can efficiently study semi-conductor reliability, ball bearings, spot welding, engines, and biological organisms [29].

The study of reliability through a deterministic approach is insufficient to describe the random data in a stochastic environment. Indeed, all the uncertain reliability parameters are represented by unfavorable values. In that context, the behavioral prediction must be estimated through probabilistic approaches. The uncertainties and errors observed in the final results are attached to variability in geometrical and physical parameters, stress in boundary conditions, fluctuations in badly known load conditions, and simplifying assumptions and physical laws considered in the modeling process [30]. Several researchers [31] confirmed that the influencing factors mainly affect the shape and the scale parameter. This work introduced the uncertainties due to the methods used, the considered approximations, the modeling, and the influencing variables in the Weibull parameters, and their effect on device reliability was studied.

This paper presented a study of the random reliability of the dialysis machine in a stochastic environment through the two-parameter Weibull distribution. The stochastic environment has a random effect on the reliability of the device. The uncertainties, which depend on external factors, are diversified and have a difficult, complex, and inappropriate modeling because of their random behavior. In this paper, an approach that takes into account the impact of the influencing factors on reliability is proposed. The methodology consists of introducing perturbations on the shape and scale parameters of the Weibull distribution and studying their effect on the reliability indicators. Estimating the Weibull parameters is offered through analytical methods based on the failure history of the devices. These parameters are considered random variables following a Gaussian distribution. The mean and the standard deviation of the shape and scale parameters will be calculated. The numerical simulations presented the statistics of the random reliability of the dialysis machine.

2. Estimation of the stochastic weibull parameters

The Weibull approach is widely employed to describe many kinds of reliability characteristics through an efficient estimation of Weibull parameters thanks to its flexibility. This distribution may be exploited with scale, shape, and/or location parameters. There are many analytical developments for extracting the Weibull parameters presented by Razali et al. [32]. These methods are considered more reliable and accurate than the graphical methods (GM), which are relatively fast but not recommended for this problem [25]. The Weibull distribution with a two-parameter is a probabilistic approach following a continuous distribution widely exploited for analyzing lifetime data and reliability [33]. The following paragraph details the different analytical methods used to estimate the two Weibull parameters.

2.1 Least square method (LSM)

The problem of regression is to find a relationship that may exist between two sets of data, $x=\{x_1, x_2, \ldots, x_n\}$ and $y=\{y_1, y_2, \ldots, y_n\}$, with size n, obtained experimentally or measured on a population. When the relationship sought is affine ($y=ax+b$), it is a linear regression. But even if such a relation is present, the measured data do not verify this relation exactly. To account for the differences (errors) observed in the mathematical model, the x and y data will be considered as realizations of two random variables, X and Y. The principle of the least squares method (LSM) consists in choosing the values of a and b, which minimize the squares of the deviations given by Equation (1) [34,35]:

$$E = \sum_{i=1}^{n} \varepsilon_i^2 = \sum_{i=1}^{n} \left(y_i - (ax_i + b)\right)^2 \quad (1)$$

where ε_i is the difference observed between y_i and (ax_i+b) and

$$a = cov_{xy}/s_x^2 \quad (2)$$

$$b = \bar{y} - a\bar{x} \quad (3)$$

where cov_{xy} is the covariance and s_x^2 is the variance, given by Equation (4):

$$cov_{xy} = \frac{1}{n}\sum_{i=1}^{n}(x_i - \bar{x})(y_i - \bar{y}) \text{ and } s_x^2 = \frac{1}{n}\sum_{i=1}^{n}(x_i - \bar{x})^2 \quad (4)$$

where

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i \ and\ \bar{y} = \frac{1}{n}\sum_{i=1}^{n} y_i \quad (5)$$

The Weibull parameters can be estimated using the LSM. The estimation of the shape parameter β and the scale parameter η can be done through the following mathematical development according to Equations (6) and (7), respectively [36]:

$$\beta = \sum_{i=1}^{n}(x_i - \bar{x})(y_i - \bar{y})/\sum_{i=1}^{n}(x_i - \bar{x})^2 \quad (6)$$

$$\eta = \bar{y} - \beta\bar{x} \quad (7)$$

where $x_i = \mathrm{Ln}(\mathrm{TBF_i})$, $y_i = \mathrm{Ln}\left(\mathrm{Log}(1/1 - \mathrm{F}(t_i))\right)$, $\bar{x} = \frac{1}{n}\sum_{i=1}^{n}\mathrm{Ln}(\mathrm{TBF_i})$ and $\bar{y} = \frac{1}{n}\sum_{i=1}^{n}\mathrm{Ln}\left(\mathrm{Ln}(1/1 - \mathrm{F}(t_i))\right)$.

Failure times, denoted by TBFi, were collected and arranged in ascending order to calculate the cumulative density function (CFD), denoted by F(ti), by using the Bernard's formula [33] to assign median ranks to each failure given in Table 1 [37].

Table 1: Formulae available for median ranking

Method	Formula F(ti)	Recommended for
Mean ranking	$F(t_i) = i/_{n+1}$	$n > 50$
Median rank	$F(t_i) = {}^{i-0.3}/_{n+0.4}$	$n < 20$
Systematic	$F(t_i) = {}^{i-0.5}/_{n}$	$20 < n < 50$

where i is the order of failure and n is the total number of data, Benard's formula approximates the median rank estimator [33]. Benard's median rank shows the best performance and is the most widely used to estimate F(ti) [38]. The procedure for ranking complete data consists of listing the time to failure data from small to large and then using Benard's formula to assign median ranks to each failure.

2.2 Maximum likelihood method (MLM)

The maximum likelihood method is an algorithm that attempts to fit the given observations to find parameters that maximize the likelihood function. For the two-parameter Weibull distribution, the shape parameter β and the scale parameter η are estimated using this technique for the probability density function [39] given in Equation (8):

$$f(t) = (\beta/\eta)(t/\eta)^{\beta-1}exp(-(t/\eta)^{\beta}) \quad (8)$$

The maximum likelihood estimators are obtained by maximizing, with respect to β and η, the following function given by Equation (9):

$$L(\beta,\eta) = \prod_{i=1}^{n} f(t_i,\beta,\eta) \quad (9)$$

The logarithmic likelihood is formulated in the following Equation (10):

$$Ln\left(L(\beta,\eta)\right) = \sum_{i=1}^{n} Ln\left(f(t_i,\beta,\eta)\right) \quad (10)$$

To determine the maximum likelihood estimators, the following system of Equations (11) and (12) must be solved:

$$\partial Ln\left(L(\beta,\eta)\right)/\partial\beta = 0 \quad (11)$$

$$\partial Ln\left(L(\beta,\eta)\right)/\partial\eta = 0 \quad (12)$$

The development of this system makes it possible to obtain the logarithmic likelihood for the two-parameter Weibull distribution according to Equation (13):

$$Ln\big(L(\beta,\eta)\big) = nLn(\beta) - nLn(\eta) - \sum_{i=1}^{n}(t_i/\beta)^{\eta} + (\beta-1)\sum_{i=1}^{n} Ln(t_i/\beta) \quad (13)$$

The following system Equations (14) and (15) can be extracted [40,41]:

$$\beta = \left[\left(\sum_{i=1}^{n} t_i^{\beta}\, Ln(t_i)\right)\left(\sum_{i=1}^{n} t_{i_1}^{\beta}\right)^{-1} - \frac{1}{n}\sum_{i=1}^{n} Ln(t_i)\right]^{-1} \quad (14)$$

$$\eta = \left[\frac{1}{n}\sum_{i=1}^{n} t_i^{\beta}\right]^{\frac{1}{\beta}} \quad (15)$$

The resolution of this system by Newton Raphson's method leads to calculating the shape parameter β and the scale parameter η.

2.3 Method of moments (MOM)

The method of moments is generally used because it is very simple to apply. It also makes it possible to provide parameter estimation when the maximum likelihood method does not converge. Moreover, the method of moments can be used to initialize the parameters of the iterative process in the case of maximum likelihood. The theoretical moments, first and second order, of the Weibull distribution are given respectively by Equations (16) and (17) [42]:

$$\mu_1(X) = \eta\Gamma(1+1/\beta) \quad (16)$$

$$\mu_2(X) = \eta^2[\Gamma(1+2/\beta) - \Gamma^2(1+1/\beta)] \quad (17)$$

where Γ is the gamma function.

The method of moments applied to the two-parameter Weibull distribution consists of equalizing the first and the second moment (mean and variance) of the sample to the corresponding theoretical moments (μ1 and μ 2) Equation (18):

$$\bar{x} = \mu_1(X), S^2 = \mu_2(X) \quad (18)$$

where $\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$ and $s^2 = \frac{1}{n}\sum_{i=1}^{n}(x_i - \bar{x})^2$

From the previous equations, the following system of Equations (19), (20) and (21) can be deduced:

$$\eta\Gamma(1+1/\beta) = \frac{1}{n}\sum_{i=1}^{n} x_i \quad (19)$$

$$\eta[\Gamma(1+2/\beta) - \Gamma^2(1+1/\beta)]^{\frac{1}{2}} = \left[\frac{1}{n}\sum_{i=1}^{n}(x_i-\bar{x})^2\right]^{\frac{1}{2}} \quad (20)$$

$$\left([\Gamma(1+2/\beta) - \Gamma^2(1+1/\beta)]^{\frac{1}{2}}/\Gamma(1+1/\beta)\right)\left(\frac{1}{n}\sum_{i=1}^{n} x_i\right) = \left[\frac{1}{n}\sum_{i=1}^{n}\left(x_i - \frac{1}{n}\sum_{i=1}^{n} x_i\right)^2\right]^{\frac{1}{2}} \quad (21)$$

This system cannot be solved explicitly; an iterative procedure must be used. The Newton-Raphson method can be further used to obtain β, and the parameter η is subsequently determined as a function of β.

2.4 Case study: dialysis machine

The reliability of dialysis devices is critical to ensure patient safety and the continuity and efficiency of treatment. Azar suggests in his study [43] that there is a correlation between patients' medical results and dialysis device maintenance. So, lack of maintenance causes high levels of complications and wrong dialysis seance. Therefore, it is primordial to implement a simple and practical approach to ensure the efficiency and safety of dialysis processes. A literature review concerning the maintenance and inspection of medical machines was shown in [44]. The electrical and mechanical damages in dialysis equipment were treated in [45] to explain their origins and their best preventive solutions. The work presented in [46] developed the maintainability and reliability of dialysis devices using Weibull distribution.

In this section, the reliability of 10 dialysis devices (Mi, i=1:10) will be developed. The failure history of these machines was collected during 9 years, from 2013 to 2022. Table 2 summarizes the data on the failure history of the machines. All the machines operate for 3.5 hours per day and 6 days per week. This work rhythm makes it possible to reach 288 operating days per year. For example, a machine put into service on 01/01/2013 detected its first failure on 05/06/2015. This machine has been operating for 700 days, so its uptime is 2450 hours. The estimation of the Weibull parameters through the graphical and analytical methods is given in Table 3. The shape and scale parameters were calculated based on the failure history and using the methods detailed in the previous sections.

The environment of the dialysis machine is uncertain. Indeed, such uncertain data are present in various fields, such as disease and healthcare. There are uncertainties related to the methods used in the formulation steps and the approximations in the mathematical development and modelings. A significant amount of missing values in the data can affect the results. The influencing external factors present a real origin of perturbation and can be classified according to [47] in various categories; let us cite for example, individual factors related to technical abilities, competence, training, motivation, stress or fatigue, physical and psychological state of operator, factors linked to team functioning such as communication and supervision, factors related to operational procedures such as dispatch, planning and availability, and factors caused by the working environment in relation to materials, sites and premises, equipment, supplies, working conditions.

In classical reliability analysis, deterministic unfavorable characteristic values describe The shape and scale parameters. To solve this problem, the two Weibull parameters are considered as random variables following a Gaussian distribution as given in Equation (22):

$$\tilde{\beta} = \beta + \sigma_\beta \varepsilon \ and \ \tilde{\eta} = \eta + \sigma_\eta \varepsilon \tag{22}$$

β and η are The mean of the random shape and scale parameters, respectively, σ_β and σ_η are the standard deviations of the Shape and scale parameters, and ε is a reduced centered Gaussian variable. The mean is calculated using the following Equation (23):

$$\beta = (1/N)\sum_{i=1}^{N}\beta_i \ and \ \eta = (1/N)\sum_{i=1}^{N}\eta_i \tag{23}$$

where β_i and η_i are the shape and scale parameters, respectively, for the i^{th} draw, and N is the total number of draws. The standard deviations of the shape and scale parameters are given by Equation (24):

$$\sigma_\beta = (1/N^2)\sqrt{\sum_{i=1}^{N}(\beta_i - \beta)^2} \ and \ \sigma_\eta = (1/N^2)\sqrt{\sum_{i=1}^{N}(\eta_i - \eta)^2} \tag{24}$$

Table 4 offers the mean and the standard deviation of the shape and scale parameters estimated for each device. The calculations are made according to equations 23 and 24. The N draws are the 4 methods used to calculate β and η (GM, LSM, MLM, and MOM). Based on the numerical results in Table 4, the dialysis machines can be classified according to their life phase. Indeed, M5 and M10, which have a shape parameter β>1, are in the aging life. M1, M2, and M6 are in the useful life with a shape parameter β≈1. M3, M4, M7, M8, and M9 have a shape parameter β<1 and work in early life.

This case study illustrates the behavior of Weibull parameters in a stochastic environment. The graphical and analytical methods used to calculate the shape and scale parameters present an origin of the errors because of the considered developments and mathematical approximations. The uncertainties observed make it possible to calculate the Weibull parameters' mean and standard deviation. Hence, our study consists of estimating the effect of the uncertainties of the shape and scale parameters on the reliability of the dialysis machines.

Table 2: The failure history (TBF) of dialysis machines

Failure number	M1		M2		M3		M4		M5	
	Failure date	TBF (h)	Failure date	TBF (h)	Failure date	TBF (h)	Failure date	TBF (h)	Failure date	TBF (h)
1	05/06/15	2450	05/06/15	2450	29/01/14	1085	17/04/15	2313.5	05/06/15	2450
2	09/11/15	427	20/11/17	2481.5	04/01/16	1904	05/06/15	119	15/05/17	1949.5
3	20/11/17	2047	23/01/19	1155	19/10/16	609	29/05/17	1988	20/11/17	514.5
4	27/07/19	1673	25/03/19	169	24/10/16	10.5	06/12/17	525	06/03/20	2268
5	06/03/20	595	06/03/20	1039.5	29/05/17	605.5	06/03/20	3276	18/09/20	385
6	05/09/21	1372			06/03/20	2792	24/06/20	154	16/09/21	990.5
7	01/11/21	147			12/11/20	392				

Failure number	M6		M7		M8		M9		M10	
	Failure date	TBF (h)	Failure date	TBF (h)	Failure date	TBF (h)	Failure date	TBF (h)	Failure date	TBF (h)
1	05/06/15	2450	04/01/16	3034.5	13/03/15	2226	22/01/13	73.5	29/05/13	413
2	29/05/17	2040	29/05/17	1389	04/01/16	766.5	15/07/13	448	12/07/13	101.5
3	07/08/18	192.5	12/06/17	42	13/01/16	3.5	01/03/14	717.5	01/09/14	1130
4	28/02/18	549.5	20/11/17	441	22/07/13	535.5	08/10/14	578	05/06/15	763
5	03/08/18	311.5	15/10/18	871.5	19/09/16	140	05/06/15	3650.5	09/11/15	427
6	06/03/20	584.5	11/09/19	903	02/08/17	878.5	29/05/17	192.5	07/08/17	1750
7	03/08/20	280	06/03/20	486.5	08/01/18	434	07/08/17	553	31/10/18	1228
8			29/03/21	896	05/02/18	66.5	28/02/18	73.5	09/08/19	780.5
9			22/07/21	304.5	28/02/18	63	07/05/18	213.5	06/03/20	560
10					10/08/18	336	03/08/18	28	29/07/20	255.5
11					06/03/20	1575	19/11/18	294	07/01/22	1456
12					08/07/20	203	18/09/19	829.5		
13					24/02/21	633.5	06/03/20	462		
14					05/11/21	703.5	02/12/20	560		

Table 3: Estimation of the random Weibull parameters of dialysis machines

	LSM		MLM		MOM		GM	
	β	η	β	η	β	η	β	η
M1	0.928	1363	1.078	1504	1.179	1583	0.963	1358
M2	0.752	1957	1.058	1814	1.184	2028	0.866	1672
M3	0.388	1253	0.723	1472	0.658	1356	0.421	1214
M4	0.625	1342	0.859	1665	0.774	1552	0.586	1338
M5	1.232	1642	1.318	1764	1.405	1802	1.161	1524
M6	1.027	904	1.052	1036	1.061	1125	0.908	879
M7	0.844	934	0.892	1148	0.954	1176	0.862	970
M8	0.625	572	0.694	728	0.762	791	0.607	473
M9	0.785	486	1.024	814	0.998	745	0.842	573
M10	1.162	887	1.387	952	1.638	1050	1.105	823

Table 4: The mean and the standard deviation of the shape and scale parameters

	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10
Mean β	1.037	0.965	0.548	0.711	1.279	1.012	0.888	0.672	0.912	1.323
Mean η	1452	1868	1324	1557	1683	986	1057	641	654	928
σ_β	0.099	0.167	0.206	0.11	0.091	0.062	0.042	0.061	0.101	0.210
σ_η	95.684	136.8	208.26	162.7	109.18	99.992	106.23	125.55	131	83.913
Life Phase	useful	useful	early	early	aging	useful	early	early	early	aging

3. Random reliability analysis

3.1 The random failure rate estimation

The random failure rate is expressed as a random function following a Gaussian distribution as follows Equation (25):

$$\tilde{\lambda}(t) = \lambda(t) + \sigma_\lambda(t)\varepsilon \tag{25}$$

where λ(t) is the mean of the failure rate, and $\sigma_\lambda(t)$ is its standard deviation.

According to the two-parameter Weibull distribution, the random failure rate is offered in Equation (26) as a function of the shape and scale parameter by the following expression:

$$\tilde{\lambda}(t) = \left(\tilde{\beta}/\tilde{\eta}\right)(t/\tilde{\eta})^{\tilde{\beta}-1} \tag{26}$$

To formulate the mean and the standard deviation of the failure rate, the logarithmic failure rate can be used following Equation (27):

$$ln\left(\tilde{\lambda}(t)\right) = ln\left(\tilde{\beta}\right) - \tilde{\beta}\, ln(\tilde{\eta}) + \left(\tilde{\beta}-1\right) ln(t) \tag{27}$$

To linearise the random failure rate given by Equation (27), we will use the first-order Taylor series expansion of the random quantity of log(λ(t)), log(β), and log(η) in the vicinity of their mean, respectively in Equations (28), (29) and (30):

$$ln\left(\tilde{\lambda}(t)\right) = ln\left(\lambda(t)\right) + (\sigma_\lambda(t)/\lambda(t))\,\varepsilon \tag{28}$$

$$ln\left(\tilde{\beta}\right) = ln(\beta) + (\sigma_\beta/\beta)\,\varepsilon \tag{29}$$

$$ln\ (\tilde{\eta}) = ln(\eta) + (\sigma_\eta/\eta)\,\varepsilon \tag{30}$$

Introducing Equations (28), (29) and (30) in Equation (27), we can write the Equations (31):

$$ln\,\lambda + (\sigma_\lambda/\lambda)\,\varepsilon = [ln(\beta) - \beta\, ln(\eta) + (\beta-1)\, ln(t)] + \left[(\sigma_\beta/\beta) - (\beta/\eta)\sigma_\eta - \sigma_\beta\, ln(\eta) + \sigma_\beta\, ln(t)\right]\varepsilon \tag{31}$$

The identification of the different terms in Equation (31) leads to extracting the mean and the standard deviation of the random failure rate in Equations (32) and (33), respectively:

$$ln\ \left(\lambda(t)\right) = ln(\beta) - \beta\, ln(\eta) + (\beta-1)\, ln(t) \tag{32}$$

$$\sigma_\lambda(t)/\lambda(t) = \sigma_\beta/\beta - (\beta/\eta)\sigma_\eta - \sigma_\beta\, ln(\eta) + \sigma_\beta\, ln(t) \tag{33}$$

The mean and the standard deviation of the random failure rate can be given by Equations (34) and (35) respectively:

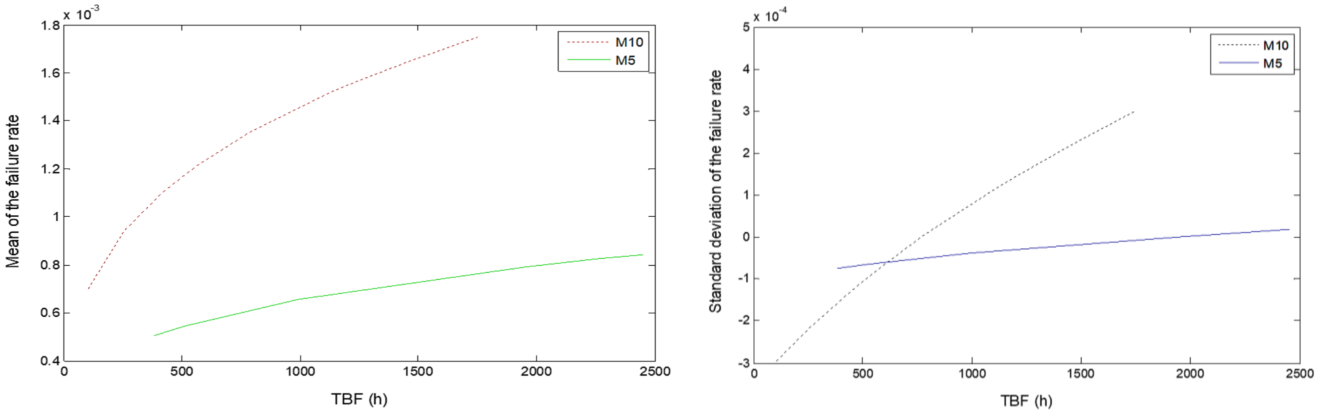
$$\lambda(t) = (\beta/\eta)(t/\eta)^{\beta-1} \tag{34}$$

$$\sigma_\lambda(t) = \lambda(t)\left[\sigma_\beta/\beta - (\beta/\eta)\sigma_\eta - \sigma_\beta\, ln(\eta) + \sigma_\beta\, ln(t)\right] \tag{35}$$

Figure 1 illustrates the mean Figure 1a and the standard deviation Figure 1b of the failure rate of dialysis machines in aging life (M5 and M10). The failure rates are classified according to the life phase. The machines M5 and M10 are in the aging life (β>1), and the mean of the failure rate λ(t) increases continuously over time Figure 1a. These machines must have permanent monitoring to avoid any possible failure. Figure 1b represents the standard deviation of the failure rate for the dialysis machines in aging life (M5 and M10). This study leads to analyzing the propagation of the uncertainties introduced in the shape and scale parameters and their effect on the failure rate. The curves have an increasing behavior over time, particularly in aging. The numerical simulations show that the uncertainties are amplified and the failure rates are strongly disturbed, so particular importance must be given to determining the Weibull parameters precisely.

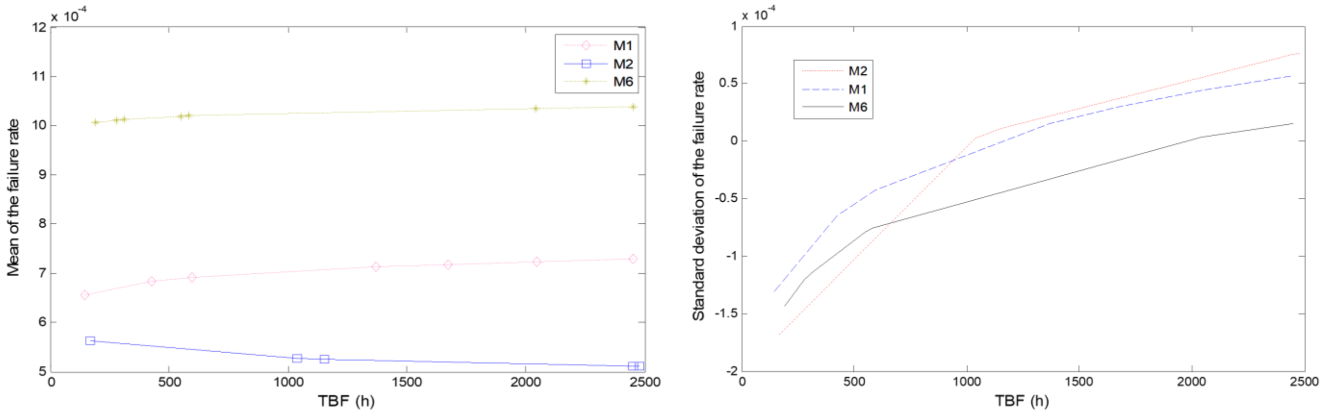
Figure 2 illustrates the mean Figure 2a and the standard deviation Figure 2b of the failure rate of the dialysis machines in useful life (M1, M2, and M6). In this life phase, the mean of the failure rate is constant during the time (β=1) Figure 2a. In Figure 2b, the standard deviation of the failure rate related to M1, M2, and M6 increases significantly, which proves that the uncertainties are accumulated and amplified. The uncertainties of the Weibull parameters have influenced the failure rate of machines in their useful life. This information is very important for the maintenance department to give particular importance to the determination of shape and scale parameters in a stochastic environment, whatever the life phase of the machine is.

M3, M4, M7, M8, and M9, which are in the early life, have a decreasing mean failure rate (β<1) Figure 3a. The standard deviation of the failure rate of the machine in the early life is illustrated in Figure 3b. The numerical results show the gravity of the uncertainties that affect the Weibull parameters and can seriously affect the failure rate and, consequently, the machine's operating safety in all life phases.



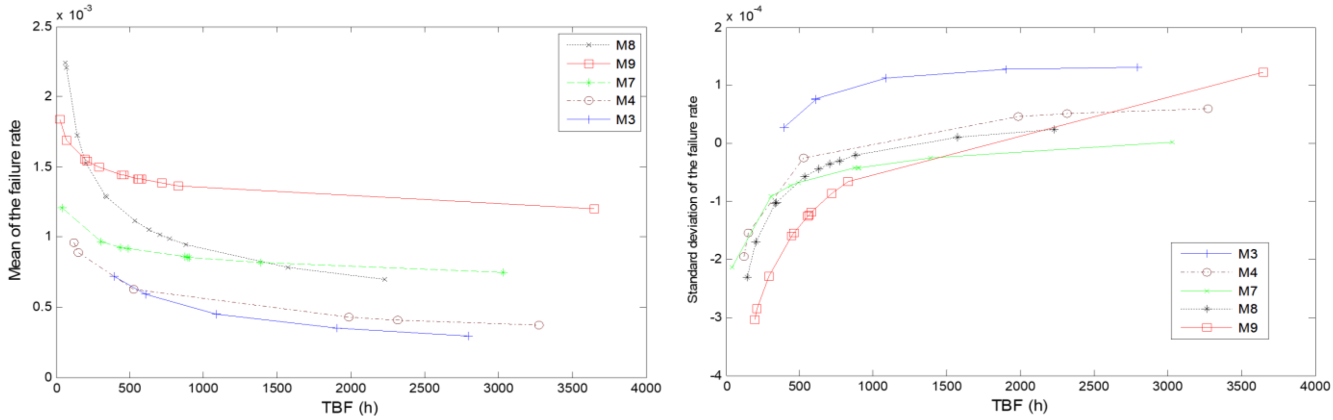
a. Mean **b. Standard deviation**

Figure 1: Mean and standard deviation of the failure rate of dialysis machines in aging life



a. Mean **b. Standard deviation**

Figure 2: Mean and standard deviation of the failure rate of dialysis machines in useful life



a. Mean **b. Standard deviation**

Figure 3: Mean and standard deviation of the failure rate of dialysis machines in early life

3.2 The random reliability estimation

The random reliability is expressed as a random function following a Gaussian distribution as follows in Equation (36):

$$\tilde{R} = R(t) + \sigma_R(t)\varepsilon \tag{36}$$

where R(t) is the mean of the failure rate and $\sigma_R(t)$ its standard deviation

According to the two-parameter Weibull distribution, the random reliability is offered as a function of the shape and scale parameter by the following expression Equation 37:

$$\tilde{R}(t) = exp(-t/\tilde{\eta})^{\tilde{\beta}} \quad (37)$$

The first-order Taylor series expansion of $\tilde{R}(t)$ is written in Equation (38):

$$\tilde{R}(t) = exp(-t/\tilde{\eta})^{\tilde{\beta}} = 1 + (-t/\tilde{\eta})^{\tilde{\beta}} \quad (38)$$

The logarithmic reliability is formulated in the following Equation (39):

$$Ln\left(\tilde{R}(t) - 1\right) = \tilde{\beta}(Ln(-t) - Ln(\tilde{\eta})) \quad (39)$$

To linearise the random logarithmic reliability equation, we will use the first-order Taylor series expansion in the vicinity of the mean. The first and the second terms of the Equation (39) are developed in Equations (40) and (41) respectively:

$$Ln\left(\tilde{R}(t) - 1\right) = Ln(R(t) - 1) + (\sigma_R(t)/R(t))\varepsilon \quad (40)$$

$$\tilde{\beta}\left(Ln(-t) - Ln(\tilde{\eta})\right) = \beta Ln(-t/\tilde{\eta}) + \left(\sigma_\beta Ln(-t/\tilde{\eta}) - (\beta/\eta)\sigma_\eta\right)\varepsilon \quad (41)$$

Ramplacing the first and the second terms of the Equation (39) by their expressions developed in Equations (40) and (41), we can write:

$$Ln(R(t) - 1) + (\sigma_R(t)/R(t))\varepsilon = \beta Ln(-t/\tilde{\eta}) + \left(\sigma_\beta Ln(-t/\tilde{\eta}) - (\beta/\eta)\sigma_\eta\right)\varepsilon \quad (42)$$

The identification of the different terms in equation (42) leads to extracting the mean and the standard deviation of the random reliability in Equations (43) and (44) respectively:

$$Ln(R(t) - 1) = \beta Ln(-t/\tilde{\eta}) \quad (43)$$

$$\sigma_R(t)/R(t) = \sigma_\beta Ln(-t/\tilde{\eta}) - (\beta/\eta)\sigma_\eta \quad (44)$$

The mean and the standard deviation of the random reliability can be given in Equations (45) and (46) respectively:

$$R(t) = exp(-t/\eta)^{\beta} \quad (45)$$

$$\sigma_R(t) = R(t)\left(\sigma_\beta Ln(-t/\eta) - (\beta/\eta)\sigma_\eta\right) \quad (46)$$

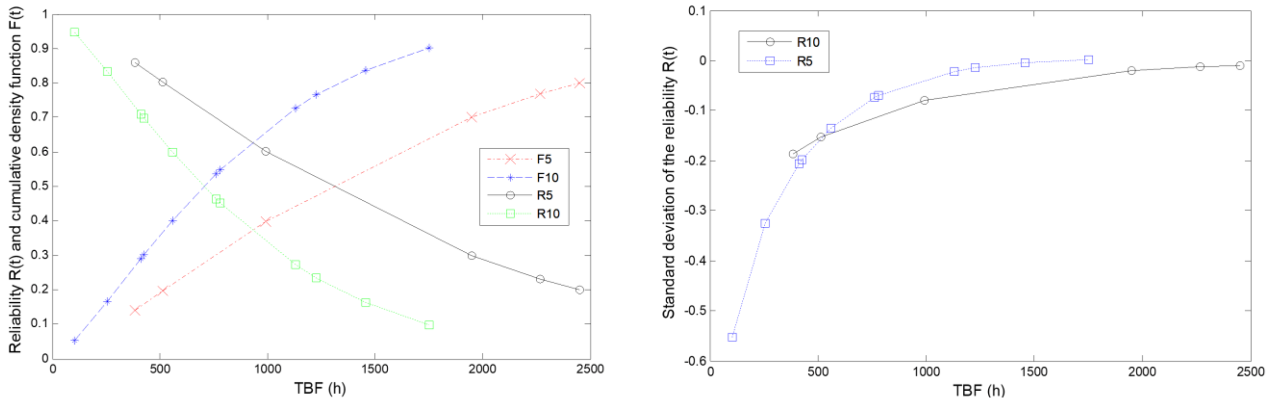
The random cumulative density function is expressed in Equation (47) as a random function following a Gaussian distribution:

$$\tilde{F}(t) = 1 - \tilde{R}(t) = F(t) + \sigma_F\varepsilon \quad (47)$$

where F(t) is the mean of the cumulative density function and $\sigma_{F(t)}$ is its standard deviation, given in Equation (48):

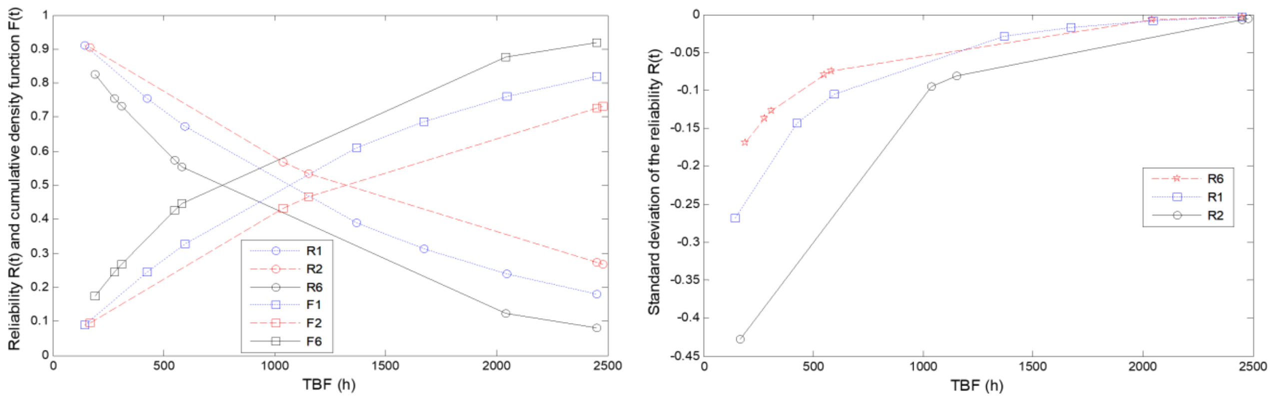
$$F(t) = 1 - R(t) \ \ and \ \sigma_F(t) = \sigma_R(t) \quad (48)$$

Figures 4, 5, and 6 illustrate the mean and the standard deviation of the reliability and the cumulative density function of dialysis machines in aging Figure 4, useful Figure 5, and early Figure 6 life. The simulations of the mean of the reliability of dialysis machines are presented in Figure 4a, 5a, and 6a. According to this study, The reliability R(t) of M5 and M10 must be revised immediately. Their reliability decreases significantly with time and must be supervised continuously (Figure 4a). The mean of the reliability of M1, M2 and M6 is showed in Figure 5a. The mean of the reliability of the machine operating in the useful life decreases slowly over time. The preventive maintenance must be respected to extend the life of the machine and its components. Figure 5a illustrates the mean of the reliability of 5 machines in early life. These machines operate correctly and need to pass a trial period to reach its maximum performance. The simulations of the standard deviation of the reliability of dialysis machines are presented in Figures 4b, 5b, and 6b show increasing curves over time, which proves that the effect of uncertainties becomes more dangerous. The reliability is seriously affected by the uncertainties in the Weibull parameters. The level of the disturbance, introduced on the shape and scale parameters, is amplified, which presents a significant risk to the correct and safe operation of the machine.



a. Mean **b. Standard deviation**

Figure 4: Mean and standard deviation of dialysis machines' reliability and cumulative density function in aging life



a. Mean **b. Standard deviation**

Figure 5: Mean and standard deviation of dialysis machines' reliability and cumulative density function in useful life

3.3 The random probability density function estimation

The random probability density function is expressed as a random function following a Gaussian distribution given in Equation (49):

$$\tilde{f}(t) = \tilde{\lambda}(t) \times \tilde{R}(t) = f(t) + \sigma_f(t)\varepsilon \tag{49}$$

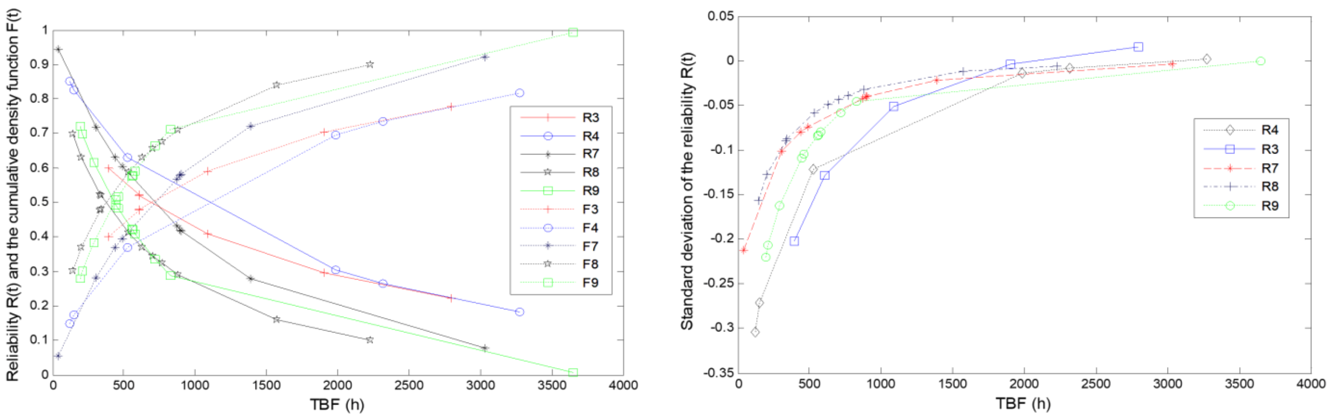
The development of the random variables leads to writing the Equation (50):

$$f(t) + \sigma_f(t)\varepsilon = \lambda(t)R(t) + \big(R \times \sigma_\lambda(t) + \lambda \times \sigma_R(t)\big)\varepsilon \tag{50}$$

The mean (Equation 51) and the standard deviation Equation (52) of the random probability density function can be extracted by the identification of the different terms in Equation (50):

$$f(t) = \lambda(t) \times R(t) \tag{51}$$

$$\sigma_f(t) = R(t) \times \sigma_\lambda(t) + \lambda(t) \times \sigma_R(t) \tag{52}$$

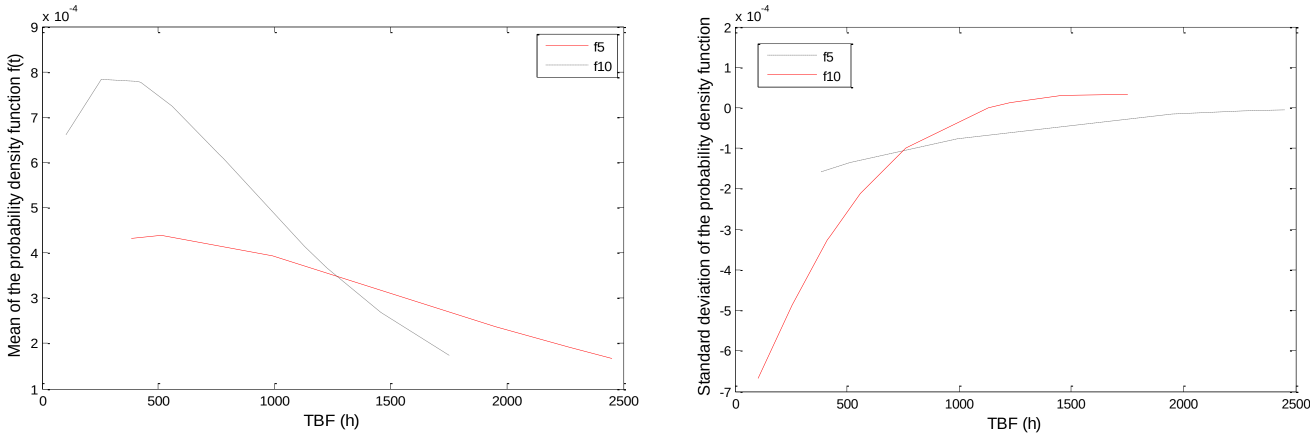


a. Mean **b. Standard deviation**

Figure 6: Mean and standard deviation of the reliability and the cumulative density function of dialysis machines in early life

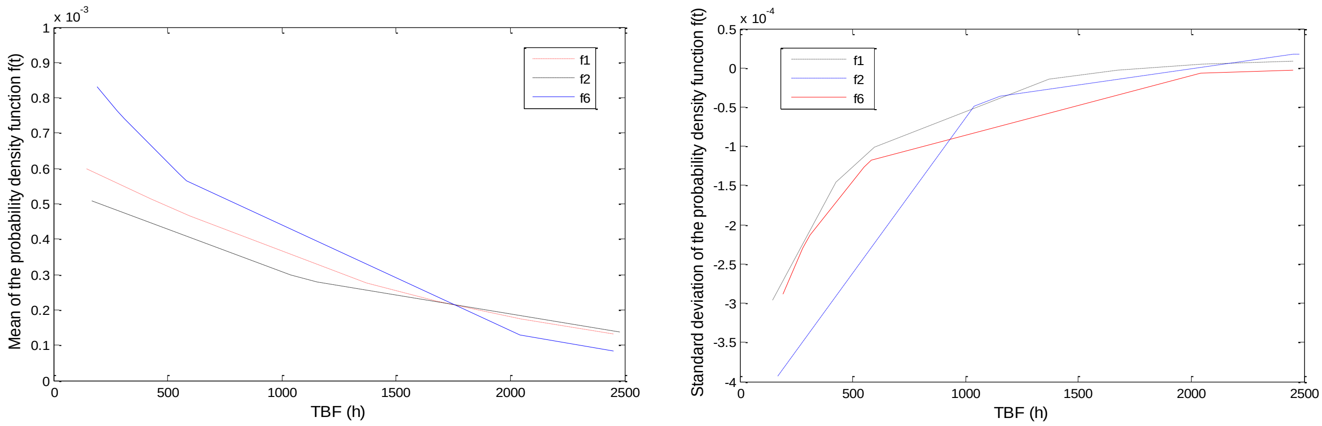
Figures 7, 8, and 9 show the mean and the standard deviation of the probability density function of dialysis machines in the different life phases: aging Figure 7, useful Figure 8, and early Figure 9 life. The mean of the probability density function of dialysis machines is given in Figures 7a, 8a, and 9a. These illustrations show the influence of the life phase on the probability density function. The simulations of the numerical results are offered using the Equation (51) to extract the mean of the probability density function and the Equation (52) to extract its standard deviation. The standard deviation of the probability density function of dialysis machines is given in Figures 7 b, 8b, and 9b. The stochastic environment affects the probability density function, and its standard deviation is amplified over time.

The study of random reliability leads to some recommendations concerning the maintenance of dialysis machines: To minimize the inconvenience of the failures on the dialysis system, it is recommended to upgrade the operation management. Moreover, the maintenance strategy must initially focus on the M5 and M10, which are in the aging phase. Dialysis machines operate in a stochastic environment that contains several sources of disturbances. Therefore, It is necessary to consider the uncertainties during all the calculation phases and for all the variables involved.



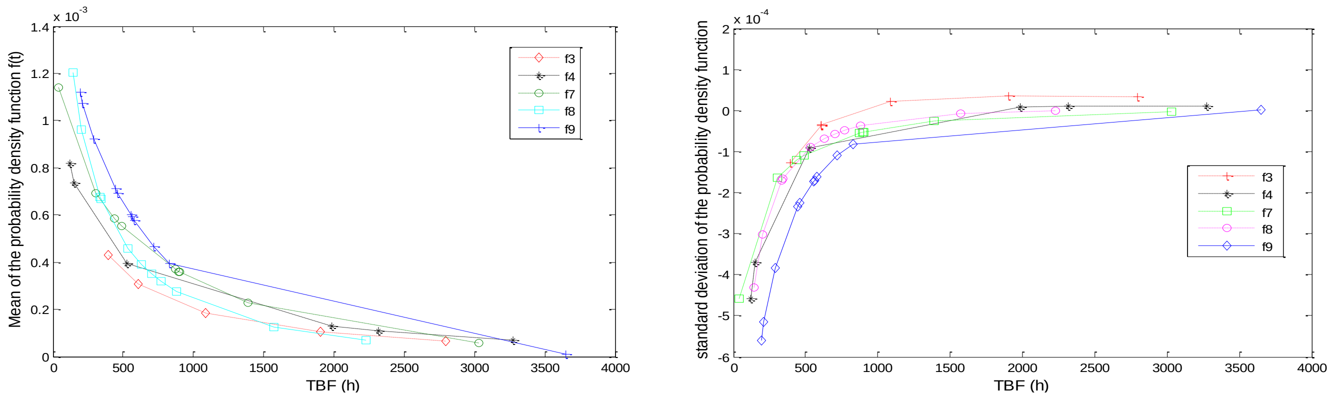
a. Mean **b. Standard deviation**

Figure 7: Mean and standard deviation of the probability density function of dialysis machines in aging life



a. Mean **b. Standard deviation**

Figure 8: Mean and standard deviation of the probability density function of dialysis machines in useful life



a. Mean **b. Standard deviation**

Figure 9: Mean and standard deviation of the probability density function of dialysis machines in early life

3.4 The random systematic inspection period of dialysis machines

The continuous monitoring of the failure data for the dialysis system is necessary. The re-estimation of the reliability indices can be carried out, and the maintenance strategy of the device group can be evaluated. This could help minimize failures and repair times, whereas the system's efficiency can be improved.

In practice, the aim is to have maximum reliability and operating safety, mainly for the machines in the aging phase (M5 and M10). Several experts in this field have estimated the reliability of R=0.95 to achieve the desired objective. Based on the required reliability level, the systematic inspection period (θ) of the machines in question can be determined using the expression of reliability as a function of time as given in Equation (53):

$$\theta = -\eta(LogR)^{\frac{1}{\beta}} \tag{53}$$

The calculations showed the systematic inspection period for the two dialysis devices in the aging phase (M5 and M10) in Table 5.

Table 5: The systematic inspection period

Devices	M5	M10
θ (h)	127	70

The results provide evidence of the propagation of errors that can affect a system and their significant influences on reliability, particularly during the aging phase. In the same context, the systematic inspection period (θ) is disturbed and can be expressed as a Gaussian variable. The standard deviation of the systematic inspection period is formulated through the following development Equation (54):

$$\tilde{\theta} = \theta + \sigma_\theta \varepsilon = -\tilde{\eta}(LogR)^{\frac{1}{\tilde{\beta}}} \tag{54}$$

The logarithmic form of the Equation (54) leads to writing the Equation (55):

$$\tilde{\beta}\left[Log\left(-\tilde{\theta}\right) - Log(\tilde{\eta})\right] = Log(Log(R)) \tag{55}$$

The first-order Taylor series expansion of the Equation (55) is developed in Equation (56):

$$\left(\beta + \sigma_\beta \varepsilon\right)\left[Log(-\theta) - (\sigma_\theta/\theta)\varepsilon - Log(\eta) - \left(\sigma_\eta/\eta\right)\varepsilon\right] = Log(Log(R)) \tag{56}$$

The standard deviation of the systematic inspection period can be extracted using Equation (57):

$$\sigma_\theta = (\theta/\beta)\left[-\beta\left(\sigma_\eta/\eta\right) + \sigma_\beta\, log(-\theta) - \sigma_\beta\, log(\eta)\right] \tag{57}$$

The standard deviation of the systematic inspection period (σ_θ) of M5 and M10 are given in Table 6.

Table 6: The standard deviation of the systematic inspection period

devices	M5	M10
σ_θ (h)	37	43

We can note that the standard deviation confirms the significant uncertainty affecting the systematic inspection period. This uncertainty can exceed 60% of the mean in the case of the machine M10. To guarantee the functioning and availability of the machines, it is necessary to consider the errors observed over the periods of the systematic inspection.

4. Conclusion

This paper evaluates the effect of the stochastic Weibull parameters on the reliability of the dialysis machine. The shape and scale parameters were estimated using analytical and graphical methods from the failure history. The analytical methods were formulated and exploited through numerical simulations. The uncertainties in the parameters of the distribution used were detailed. Weibull parameters were considered a Gaussian variable, and their means and standard deviations were calculated in several configurations of the dialysis devices. The failure rate and reliability of dialysis machines in uncertain environments were treated and discussed in different life phases. The reliability indicators' mean and standard deviation were extracted through the first-order Taylor series expansion. Dialysis machines operate in an uncertain environment with several sources of disturbances; therefore, it is necessary to take account of the uncertainties during all the life phases. The numerical results showed the necessity to study the uncertainties in the Weibull parameters, which can deeply affect the reliability of the machines. The level of the disturbance, introduced on the shape and scale parameters, is significantly amplified in the reliability indicators, which presents a serious risk to the correct and safe operation of the machine. The random systematic inspection period is investigated to install an efficient surveillance and monitoring program.

The study of reliability in a stochastic environment leads to the extraction of some recommendations for the maintenance department, such as the necessity to have a safety plan, i.e., a protocol defining and implementing a series of actions to reduce the unnecessary errors and risks inherent to medical care. The strategy to implement safety plans in healthcare based on failure mode and effects analysis should be used. After a certain time, the failure mode will be re-evaluated, and a new risk priority study will be assigned. The Dialysis device supervisor must establish a safety culture and direct the quality assessment and performance improvement process. A traceability system must be implemented to collect the data and identify the technician responsible for the action. A continuing training and refresher program for technicians helps improve the reliability and availability of machines. Increased operational safety of dialysis units requires that each machine have its safety plans, which must consider the failure history, the machine environment, and the operating methods.

It should be noted that the uncertainties found in the Weibull parameters are propagated and amplified and can seriously affect the reliability of the machines. The classical methods of reliability are insufficient to deal with these uncertainties. Hence, the maintenance department must reflect on new methods to control the reliability of machines in an uncertain environment. This work can be extended by introducing artificial intelligence to provide a permanent monitoring system, allowing a decision support tool for the maintenance department.

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Author contributions

Conceptualization, F. Bouchoucha., S. Jendoubi and S. Fenina; Methodology, F. Bouchoucha; software, F. Bouchoucha; formal analysis, S. Jendoubi; investigation, S. Fenina; data curation, S. Jendoubi; writing—original draft preparation, S. Fenina; writing—review and editing, F. Bouchoucha; supervision, F. Bouchoucha; All authors have read and agreed to the published version of the manuscript.

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Data availability statement

The data that support the findings of this study are available on request from the corresponding author.

Conflicts of interest

The authors declare that there is no conflict of interest.

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