RESEARCH AND COMPARATIVE ANALYSIS OF THE OPERATIONAL RELIABILITY OF ITEMS FOR MEDICAL PURPOSE

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Abstract: This paper is focused on the reliability analysis of medical items by comparing of their reliability indices estimations in regard to three types of measurement items containing electronic and mechanical modules. The analysis is based on reliability block diagram approach and probability modeling through a Markov process. The basis of this research are statistical data obtained regarding operational events occurred during the system operation. The operational reliability indices estimations obtained, valid for the different types of medical items under study are compared for one-year-operation. As a result of the research, some practical recommendations regarding measures necessary to be undertaken for to increase the operational reliability of such items are suggested. The paper presents an extension of previous research concerning operational reliability of medical equipment.

Keywords: reliability, operational reliability, reliability estimation, Markov models.

ИЗСЛЕДВАНЕ И СРАВНИТЕЛЕН АНАЛИЗ НА ЕКСПЛОАТАЦИОННАТА НАДЕЖДНОСТ НА ИЗДЕЛИЯ С МЕДИЦИНСКО ПРЕДНАЗНАЧЕНИЕ

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Резюме: Настоящата статия се фокусира върху надеждностния анализ на медицински изделия чрез сравняване на техните надеждностни показатели по отношение на три типа измервателни устройства, съдържащи електронни и механични модули. Анализът се основава на структурна схема по надеждност и вероятностно моделиране, базирано на Марковски процес. Изследването се базира на статистически данни, касаещи събитията, настъпили по време на експлоатация. Сравнени са получените количествени оценки, валидни за различните типове изследвани изделия за срок от една година. Предложени са някои практически препоръки относно нужните мерки за увеличаване на експлоатационната надеждност на тези изделия. Статията се позовава на предишно проучване, касаещо експлоатационната надеждност на медицинска апаратура.

Ключови думи: надеждност, експлоатационна надеждност, оценяване на надеждността, Марковски модели.

Introduction

Traditionally, the provision of high electronic items reliability is realized by means of highly reliable elements [1], [2], [3] through a part duplication of the units and also of the modules [4], or by means of a well-chosen maintenance strategy [5], [6], where the breakdown and preventive repairs are optimized [7], [8], [9].
The object of this paper is to explore appropriate means for reliability researching, evaluating, and analyzing of electronic equipment used for medical purposes and also for medical research [10], [11], [12]. In order to achieve a high precision degree of the medical test results, it is necessary to have at highly accuracy [13], [14], equipment reliability [15], and expedient methods for medical statistic data processing as well [16], [17].
The rapid electronic industry development today and its inevitable deployment in all areas are facing the issues of meeting the needs of its consumers as well as ensuring high quality on the market. The growth rates of electronic technologies are dominated almost entirely from the reliability level. The significance of all the activities providing operational reliability increases

vastly, and is betting on at the article design process. An important precondition for its improvement is the adequate repairable electronic item maintenance. This is largely relevant to the optimization activities included into maintenance and the development of a specific mathematical model based on this optimization [5]. An important role for this purpose is played by collecting, processing and analyzing data on the apparatuses behavior in real-life conditions. The significance of these activities in resolving reliability issues is contained in two following aspects: defining, normalizing and controlling the reliability indices for availability, reparability, and effectiveness in performing the intended functions; improving all reliability indices through detecting and eliminating the failures and identifying the causes for their occurrence due to errors in design, construction, technology, operation, and maintenance [6]. The subject of a study in this paper is consist in analyzing the operational reliability of set of electronic items, composed in line with a serial reliability block diagram, referring to statistical data obtained from real data service regarding to their maintenance and repair. The operational reliability assessment analysis of this reliability block diagram is based on Markov probability modeling methods. This enables an algorithm development of isomorphic stochastic mathematical models that include the maintenance data [7], [8]. The possible states from the point of view of their workability are described.

Reliability block diagram and Markov process model

For the purposes of the study conducted, the serial reliability block diagram [1], [18] of a system is considered (*Fig.1*). As it is well-known, here the failure of any element results in a failure of the entire of system. The system performance characteristics [19] allow its reliability modeling over time to be achieved through Markov process.

Fig.1. Serial Reliability Block Diagram

Markov decision process provide a mathematical framework $[S; A; P_a; R_a; \gamma]$ for modeling decision making in situations where outcomes and partly under the control of a decision marker and S is a finite set of states; A is a finite set of actions; $P_a(s,s') = P_r(s_{t+1} = s' | s_t = s, \alpha_t = \alpha)$ is the probability that action α is state s at time t will lead to state s', due to action α; $R_a(s,s')$ is the immediate reward received after transitioning from state s to state s', due to action α; $\gamma \in [0;1)$ is the discount factor [19], [20]. Or loosely defined, the Markov process is a stochastic process (sequence) without after effect, i.e. satisfying the Markov property. The

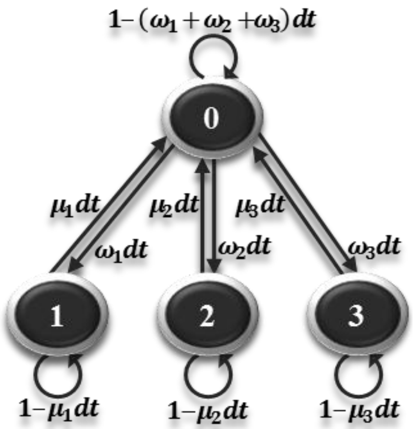

Fig.2. State transition diagram of three element state system

State	Block 1	Block 2	Block 3
0	1	1	1
1	0	1	1
2	1	0	1
3	1	1	0

Table 1.Possible states of a system of three elements

serial reliability block diagram presentment by means of the Markov modelling is realized using a geometric interpretation of the possible system transitions from one state to another in graphical form describing the various states of the system. The possible system states described in *Fig.2* are given in *Table 1*.

Regarding to the continuous-time Markov process, the Kolmogorov equations represent a differential equations system describing the time-evolution of the transition probability. A more detailed explanation of Kolmogorov's equations for this Markov model is considered in [19], [20]. Concerning the state transition diagram of *Fig.2*, the following differential equations where the unknown correspond to system probability in a particular state are presented as shown below:

$$\left\| \begin{array}{l} P_0'(t) = -(\omega_1+\omega_2+\omega_3)P_0(t) + \mu_1 P_1(t) + \mu_2 P_2(t) + \mu_3 P_3(t) \\ P_1'(t) = -\mu_1 P_1(t) + \omega_1 P_0(t) \\ P_2'(t) = -\mu_2 P_2(t) + \omega_2 P_0(t) \\ P_3'(t) = -\mu_3 P_3(t) + \omega_3 P_0(t) \end{array} \right. , \qquad (1)$$

where μ denotes the repair rates and ω denotes the failure intensity for any transition states.

Through $P_0(t)$, $P_1(t)$, $P_2(t)$ and $P_3(t)$ are denoted the state transition probabilities of the system presence in each of its four states. If the mean time between failures *MTTF* vastly exceeds the mean downtime *MDT* for any of system states, then the stationary availability and unavailability values of the system studied are:

$$A = P_0 \ , \qquad (2)$$

$$\bar{A} = 1 - A = 1 - P_0 = P_1 + P_2 + P_3 \ , \qquad (3)$$

where

$$\left\| \begin{array}{l} P_0 = \dfrac{\mu_1\mu_2\mu_3}{(\omega_1+\mu_1)(\omega_2+\mu_2)(\omega_3+\mu_3)} = \dfrac{MTTF_I}{MTTF_I+MDT_I}\dfrac{MTTF_{II}}{MTTF_{II}+MDT_{II}}\dfrac{MTTF_{III}}{MTTF_{III}+MDT_{III}} = A_I A_{II} A_{III} \\ P_1 = \dfrac{\omega_1}{(\omega_1+\mu_1)} = \dfrac{MDT_I}{MTTF_I+MDT_I} = \bar{A}_{nI} \\ P_2 = \dfrac{\omega_2}{(\omega_2+\mu_2)} = \dfrac{MDT_{II}}{MTTF_{II}+MDT_{II}} = \bar{A}_{nII} \\ P_3 = \dfrac{\omega_3}{(\omega_3+\mu_3)} = \dfrac{MDT_{III}}{MTTF_{III}+MDT_{III}} = \bar{A}_{nIII} \end{array} \right. \qquad (4)$$

Case study

In the life data analysis, there exist two fundamental statistical reliability approaches there for analyzing data: descriptive statistics which summarizes sample data using indices such as the mean or standard deviation, and inferential statistics which draw conclusions from data subject of random variation (e.g., observational errors, sampling variation). For the reliability research case, it is appropriate to be chosen the first approach.

Consider *Table 2* and *Table 3* representing statistical data regarding respectively two types of identical models of automatic and of manual blood pressure monitors (*ABPMs* and *MBPMs*). In the first case, a number of *27* pieces of *ABPMs* are represented, among which approximately

19% demonstrate failures, approximately *7%* of which are due to failure in the electronic module. In the latter case (*Table 3*), a number of *27* pieces of two dissimilar *MBPM* models are exposed. The difference between them consists in the fact that at one model the stethoscope is built into the cuff and the other is a self-contained. This does not exert an influence over the study results. The failures observed in *MBPMs* are approximately *59%*, with the prevailing failures occurring in the 2-tube inflation bladder (*DTIB*) and manometer of the medical measurement items.

Let present one *ABPM* and one *MBPM* through the serial reliability block diagram from *Fig.1*, where the failure of any blood pressure monitor modules results in the entire medical devices failure. If the Markov model shown in *Fig.2* is applied to one *ABPM* and to one *MBPM*, the probability states are described as follows:

- P_0 – the device is functioning;
- P_1 – a failure occurred in the electronic module (for *ABPM*) or in manometer (for *MBPM*);
- P_2 – a failure occurred in the automatic pressure release valve *APRV* (for *ABPM*) or in pressure release valve *PRV* (for *MBPM*);
- P_3 – a failure occurred in the arm cuff or in inflation bladder.

№	Product	Model	Serial number	Adoption date	Transmission date	Guarantee	Status	Comment
1	Microlife	BP 3AG1	241308***	24.06.2015	24.06.2015	12.06.2014	repair	replacement of arm cuff, testing – without deviation
2	Microlife	BP 3AG1	001306***	03.07.2015	03.07.2015	04.11.2014	test	testing – without deviation
3	Microlife	BP 3AG1	141208***	06.07.2015	06.07.2015	18.12.2012	test	testing – without deviation
4	Microlife	BP 3AG1	421102***	28.07.2015	28.07.2015	12.10.2012	test	testing – without deviation
5	Microlife	BP 3AG1	141208***	28.07.2015	28.07.2015	04.08.2014	test	testing – without deviation
6	Microlife	BP 3AG1	261405***	31.08.2015	31.08.2015	04.08.2015	test	testing – without deviation
7	Microlife	BP 3AG1	511204***	30.11.2015	30.11.2015	17.04.2013	test	testing – without deviation
8	Microlife	BP 3AG1	491301***	30.11.2015	30.11.2015	10.10.2015	repair	replacement of DC power jack, testing – without deviation
9	Microlife	BP 3AG1	241308***	18.12.2015	18.12.2015	10.03.2014	test	testing – without deviation
10	Microlife	BP 3AG1	141501***	23.12.2015	23.12.2015	09.12.2015	test	operating instructions, testing – without deviation
11	Microlife	BP 3AG1	141500***	22.01.2016	21.01.2016	13.01.2016	test	testing – without deviation
12	Microlife	BP 3AG1	011407***	22.01.2016	22.01.2016	08.10.2014	test	unfounded claims, testing – without deviation
13	Microlife	BP 3AG1	261403***	14.03.2016	14.03.2016	01.02.2016	test	testing – without deviation
14	Microlife	BP 3AG1	031301***	30.03.2016	30.03.2016	15.12.2015	repair	repairing the AC adapter testing – without deviation
15	Microlife	BP 3AG1	261403***	26.04.2016	26.04.2016	13.01.2016	test	testing – without deviation
16	Microlife	BP 3AG1	011205***	27.05.2016	27.05.2016	05.05.2016	repair	adjusting of PRV, testing – without deviation
17	Microlife	BP 3AG1	281511***	20.06.2016	20.06.2016	16.04.2016	test	testing – without deviation
18	Microlife	BP 3AG1	031301***	20.06.2016	20.06.2016	30.12.2013	repair	adjusting of PRV testing – without deviation
19	Microlife	BP 3AG1	261406***	25.08.2016	25.08.2016	04.09.2015	test	operating instructions, testing – without deviation
20	Microlife	BP 3AG1	261403***	21.09.2016	21.09.2016	08.06.2015	test	testing – without deviation
21	Microlife	BP 3AG1	141208***	21.09.2016	21.09.2016	04.08.2014	test	testing – without deviation
22	Microlife	BP 3AG1	361506***	21.09.2016	21.09.2016	15.09.2016	test	testing – without deviation
23	Microlife	BP 3AG1	131402***	15.12.2016	15.12.2016	28.06.2015	test	testing – without deviation
24	Microlife	BP 3AG1	241307***	28.02.2017	28.02.2017	10.02.2014	test	cleaning of ADV, testing – without deviation
25	Microlife	BP 3AG1	047900***	28.02.2017	28.02.2017	15.07.2016	repair	transistor replacement, testing – without deviation
26	Microlife	BP 3AG1	341407***	19.05.2017	19.05.2017	10.04.2016	test	testing – without deviation
27	Microlife	BP 3AG1	481403***	22.05.2017	19.05.2017	23.01.2017	test	testing – without deviation

Table 2. Statistical data regarding automatic blood pressure monitor (ABPM)

By means of (1) can be calculated the probability states of the system in each of its four states $P_0(t)$, $P_1(t)$, $P_2(t)$ and $P_3(t)$. It is assumed that the beginning of the study all *ABPMs* and *MBPMs* are functioning. Hence, the differential equations solution is under initial conditions as $P_0(0) = 1$, $P_1(0) = 0$, $P_2(0) = 0$ and $P_3(0) = 0$. Refer to the statistical table shown in *Table 2*, it is calculated that the study time is equal to the average time to first *ABPMs* failure with a duration $t = 9230{,}22\ h$.

№	Product	Model	Serial number	Adoption date	Transmission date	Guarantee	Status	Comment
1	Microlife	BP AG1-30	101401***	11.02.2015	11.02.2015	05.02.2015	repair	replacement of ARV, testing – without deviation
2	Microlife	BP AG1-30	001314***	04.06.2015	04.06.2015	03.02.2015	repair	replacement of stethoscope drum, testing – without deviation
3	Microlife	BP AG1-20	191401***	17.07.2015	19.08.2015	27.06.2015	repair	replacement of arm cuff, testing – without deviation
4	Microlife	BP AG1-20	001300***	28.07.2015	28.07.2015	19.11.2014	calibration	adjusting of manometer, testing – without deviation
5	Microlife	BP AG1-20	001302***	28.07.2015	28.07.2015	19.07.2015	test	testing – without deviation
6	Microlife	BP AG1-30	001212***	30.09.2015	30.09.2015	10.02.2015	calibration	adjusting of manometer, testing – without deviation
7	Microlife	BP AG1-20	001302***	02.11.2015	02.11.2015	15.03.2014	repair	adjusting of manometer, cleaning of ARV, testing – without deviation
8	Microlife	BP AG1-20	001305***	08.12.2015	08.12.2015	23.06.2015	calibration	adjusting of manometer, testing – without deviation
9	Microlife	BP AG1-20	261401***	18.12.2015	18.12.2015	07.12.2015	test	testing – without deviation
10	Microlife	BP AG1-20	101404***	18.12.2015	18.12.2015	03.11.2015	repair	fixing the dial (faceplate), adjusting of manometer, testing – without deviation
11	Microlife	BP AG1-30	341401***	18.01.2016	18.01.2016	27.11.2015	test	testing – without deviation
12	Microlife	BP AG1-20	341403***	25.02.2016	25.02.2016	06.01.2016	test	testing – without deviation
13	Microlife	BP AG1-30	341400***	14.03.2016	14.03.2016	07.02.2016	test	testing – without deviation
14	Microlife	BP AG1-30	431401***	16.03.2016	16.03.2016	07.03.2016	test	testing – without deviation
15	Microlife	BP AG1-30	281502***	27.05.2016	27.05.2016	26.04.2015	repair	fixing the dial (faceplate), adjusting of manometer, testing – without deviation
16	Microlife	BP AG1-20	281500***	22.07.2016	22.07.2016	27.06.2016	repair	replacement of arm cuff, testing – without deviation
17	Microlife	BP AG1-20	521500***	29.07.2016	29.07.2016	01.07.2016	calibration	adjusting of manometer, testing – without deviation
18	Microlife	BP AG1-20	461500***	31.08.2016	31.08.2016	11.08.2016	test	testing – without deviation
19	Microlife	BP AG1-30	521502***	31.08.2016	31.08.2016	05.08.2016	test	testing – without deviation
20	Microlife	BP AG1-20	361500***	18.11.2016	18.11.2016	11.06.2016	repair	replacement of DTIB, testing – without deviation
21	Microlife	BP AG1-30	281501***	31.01.2017	31.01.2017	04.01.2017	test	testing – without deviation
22	Microlife	BP AG1-20	461505***	31.01.2017	31.01.2017	29.09.2016	repair	replacement of DTIB, testing – without deviation
23	Microlife	BP AG1-30	341402***	28.02.2017	28.02.2017	19.01.2016	repair	replacement of arm cuff, testing – without deviation
24	Microlife	BP AG1-30	281500***	28.02.2017	28.02.2017	01.05.2016	repair	replacement of arm cuff, testing – without deviation
25	Microlife	BP AG1-30	281503***	25.04.2017	25.04.2017	11.01.2017	repair	replacement of DTIB, testing – without deviation
26	Microlife	BP AG1-30	341402***	03.05.2017	03.05.2017	07.10.2015	test	testing – without deviation
27	Microlife	BP AG1-20	211346***	09.05.2017	09.05.2017	06.06.2015	repair	replacement of DTIB, testing – without deviation

Table 3. Statistical data regarding manual blood pressure monitor ($MBPM$)

Similarly, concerning the *MBPMs* data on the *Table 3*, it is calculated $t = 4056{,}89$ h. Based on informal data (statistics summarized from customer relationships), the mean downtime *MDT* including the items downtime, repair and/or prevention time, and time spent in transit to and from the service, is *MDT=25,9 h* for the both *ABPMs* and *MBPMs* cases [19]. The statistical point estimation of failure intensity for any transition states is given by the formula:

$$\omega^{*}(t)=\frac{n(\Delta t)}{N.\Delta t} \qquad (5)$$

Therefore, through the resulting findings for the both *ABPMs* and *MBPMs* and by means of (1), the following probability system states are evaluated as follows:

$P_0(9230,22) = 0.999480$
$P_1(9230,22) = 0.000208$
$P_2(9230,22) = 0.000208$
$P_3(9230,22) = 0.000104$

$P_0(4056,89) = 0.996231$
$P_1(4056,89) = 0.001649$
$P_2(4056,89) = 0.000236$
$P_3(4056,89) = 0.001884$

As a result of (4), the stationary probability of system states for each of the four states P_0, P_1, P_2 and P_3 of the *ABPMs* and the *MBPMs* respectively are solved as shown below:

$P_0 = 0.999480$
$P_1 = 0.000208$
$P_2 = 0.000208$
$P_3 = 0.000104$

$P_0 = 0.996224$
$P_1 = 0.001652$
$P_2 = 0.000236$
$P_3 = 0.001888$

The availability and unavailability of the both *ABPMs* and *MBPMs* given by (2) and (3) is evaluated as:

$A_{ABPMs} = P_0 = 0.999480$
$\bar{A}_{ABPMs} = 1 - P_0 = 0.000520$

$A_{MBPMs} = P_0 = 0.996224$
$\bar{A}_{MBPMs} = 1 - P_0 = 0.003776$

Based on additional data results from a previous research concerning semi-automatic blood pressure monitors (*SABPMs*) [19], the probability states assessments obtained of the different types of measuring items can be compared. As is well-known in the reliability theory, $\omega(t)$ is characterized through low and constant time value ω_0 and the failure modes are modeled mathematically by means of exponential distribution law ($\omega(t) = \omega_0 = const$) during the useful life period. This provides with an opportunity for data comparison, with the probability states estimates are compressed into the uniform one-year lifetime (*Table 4*).

SABPMs	ABPMs	MBPMs
$P_0(1\ yr) = 0{,}998843$	$P_0(1\ yr) = 0{,}999506$	$P_0(1\ yr) = 0{,}991862$
$P_1(1\ yr) = 0{,}000267$	$P_1(1\ yr) = 0{,}000197$	$P_1(1\ yr) = 0{,}003561$
$P_2(1\ yr) = 0{,}000801$	$P_2(1\ yr) = 0{,}000197$	$P_2(1\ yr) = 0{,}000509$
$P_3(1\ yr) = 0{,}000089$	$P_3(1\ yr) = 0{,}000100$	$P_3(1\ yr) = 0{,}004068$

Table 4. The state transition probabilities of the medical measurement items for one-year operation

The major reliability indices for operational reliability assessment of repairable items are the availability and the unavailability respectively [9]. The values of availability and unavailability of the different types of blood pressure measurement items are shown on *Table 5*.

SABPMs		ABPMs		MBPMs	
A	$\bar{A}$	A	$\bar{A}$	A	$\bar{A}$
0.998797	0.001203	0.999480	0.000520	0.996224	0.003776

Table 5. Availability and unavailability estimation values of the different types of blood pressure monitors

Final remarks

The results and conclusions of the study conducted are based on both the data service processing and the technical characteristics of the blood pressure monitors (*BPM*). The measurement precision depends not only on the accuracy of the medical item, but also on the correct manner the user handles it, as well as on the user's condition. The experts suggest special recommendations related to blood pressure measuring that directly affects the measured values accuracy. In some types of cardiovascular disease (*CVD*), non-specially designed medical items demonstrate an error in measurement values. Therefore, for people with such problems, specialized electronic *BPM* (different technologies as *AFIB*, *MAM*, *PAD* or *Risk Classification*) [21] or manual *BPM* is necessary. On the other hand, a number of factors affect the measurement accuracy with a manual *BPM*. In addition, it must take into account the subjective decision factor regarding to determination of systolic and diastolic blood pressure.

The electronic module accuracy of the *ABPMs* model studied does not exceed the deviation permissible value during the test procedure conducted in the service center (static accuracy: pressure with in $\pm 3mmHg$; pulse accuracy $\pm 5\%$ of the readout value).

As opposed to *ABPMs* featuring a built-in air pump, the most frequently ascertained *MBPMs* failures are in the 2-tube inflation bladder by reason of both to wear and/or aging process as well as to over-pumping, which leads to inflation bladder puncture. The experts advise to pump up about $+20mmHg$ of systolic blood pressure. As an over-pumping result, there is also a manometer cracking risk there. According the *MBPMs* technical characteristic, the measurement deviation permissible values are $\pm 3\ mmHg$. Many MBPMs calibration procedures are also determined. The main reason for this are: the manometer impact, shifting the dial (faceplate), repair attempts by users or a misuse.

According to an empirical data, the most common failures are in the arm cuff or the inflation bulb and are inflicted by wear and/or aging of the rubber sheet stock [19]. Based on statistical data obtained, among the 27 *ABPMs* sample, only one demonstrates a failure in the arm cuff. Among the 27 MBPMs pieces, the most frequently ascertained failures are in the arm cuff, as well as in manometer. The data service shows that an amount of approximately 41.18% of the failures occurs in the manometer.

As a result of reliability research case, the high availability and unavailability *BPM* assessment values in comparison with other electronic items are determined. It is due to the low mean downtime *MDT* of the medical measurement devices. From the comparison of the different types of *BPM*, it is obvious the highest availability value is the *ABPMs* availability, followed by *SABPMs* availability.

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