

# RESEARCH OF THE OPTIMAL VARIABLE DEFECTS OF THE PREVENTIVE MAINTENANCE OF MEDICINAL EQUIPMENT

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**Abstract:** The article clarifies the importance of maintenance in the exploitation of a particular medical device from the aspect of maintaining its availability, reliability and overall functionality. Particularly emphasized is the role of the preventive method or procedures that have a preventive character before the problems arise in the work. Through an analysis of the most common malfunctions and causes that occur during the exploitation, a basis for objective defining and proposing principles has been created – preventive maintenance with special emphasis on preventive maintenance according to an established condition. The article also shows a numerical way of calculating the periodicity of conducting preventive examinations on a particular device.

**Keywords:** failures; maintenance; maintenance by state; medical devices; preventive maintenance; systems

## 1 INTRODUCTION

The main task of maintenance is to support the working ability of the technical systems so that they can perform their function. During the period of the use of technical systems, medical devices are exposed to a large number of influential factors, which results in deviations of their features from their default and expected values. In the constant aspiration of the user to keep the working characteristics within the defined limits or to return to the default interval, different maintenance methods have been developed and they differ in their concept, technology and organization [1].

In general terms, technical exploitation systems can be found in two states, both "in operation" and "malfunctioning", that is, the systems may be correct or incorrect, with all faults that may occur.

The maintenance of technical systems includes activities, methods and various techniques to ensure their correct operation in a particular terminal unit to prevent or delay the occurrence of "malfunction".

From this approach to maintenance, three basic methods of maintenance of all technical systems, including the medical devices, can be defined:

- 1) Prevention,
- 2) Corrective and
- 3) Combined methods.

In practice, the choice of the method of the maintenance of technical systems and medical devices is based on the systematic impact analysis and procedures in terms of:

- the overall efficiency of the specific maintenance method,
- the time intervals needed for performing maintenance activities, and
- the interdependence of the total costs and the time of the maintenance activity.

It is obvious that there are many factors that decide which maintenance method to apply in this particular case. The maintenance method must originate from the cause, the

failure of component elements or the system as a whole. If the causes of the defects of all constituent components belonging to one device are different, then these different components will also have different maintenance methods that will be most acceptable for each component of the device. In such cases, the optimization of the maintenance method is performed in the most critical part of the system [2].

## 2 MAINTAINING MEDICAL DEVICES WITH THEIR ASPECTS AND RELIABILITY

The maintenance of medical devices in terms of the dynamics and the content of the activity must be carefully defined and in accordance with the actual needs. Otherwise, negative effects can be obtained. Instead of high reliability and availability, improper planning and implementation, especially complex and long-lasting maintenance procedures, can cause other, additional and even more major failures, and they can significantly reduce reliability and availability while increasing maintenance costs.

### 2.1 The Term of Availability

Availability is the property of a medical device expressed by the probability of being in a working position, i.e. being able to function satisfactorily at any point in time when required.

### 2.2 The Term "Reliability"

The reliability of a medical device can be defined as a probability that it will perform the required function under the default conditions and during a given period.

From the above definition of reliability, three basic elements of the definition can be noticed:

- "execution of the required function",
- "in the given time", and
- "under the given working conditions."

Executing a function means that the device has the intended purpose for which it was manufactured and purchased. The default conditions represent the environment (temperature, humidity, etc.) and the default time represents the time period required for satisfactory operation. It can be said that reliability is a characteristic of each technical system, whose initial value depends on a number of factors defined in the development phase.

It is important to note that there can be a fall in the values for the elements, circuits and the system as a whole due to various factors. It is equally important to note that the reliability maintenance activities can be raised by predicting falls of elements, circuits or the system as a whole.

### 3 CONTEMPORARY METHODS FOR THE MAINTENANCE OF MEDICAL DEVICES

Figure 1 shows the basic methods of the maintenance of medical devices with the corresponding variants [2].

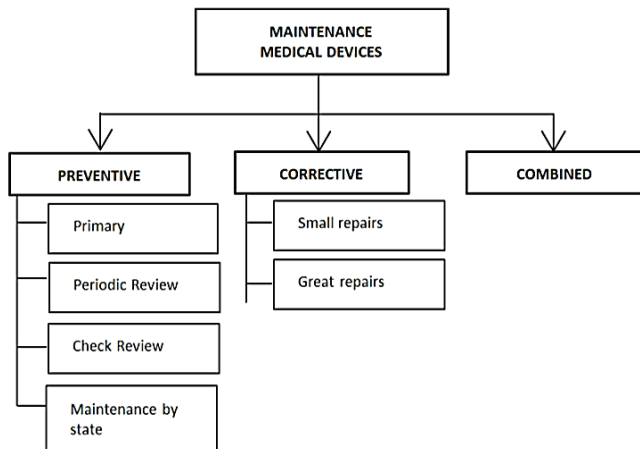


Figure 1 Methods of the maintenance of medical devices

The term preventive maintenance involves a series of actions being taken to prevent the occurrence of the condition "broken", and maintaining medical devices within the functional correctness and in a certain time interval. Preventive actions are then performed before the malfunction occurs, and require, unlike the corrective actions, to be planned and to determine the benefit of their performance.

The good features of preventive maintenance are reflected in the fact that, with particular certainty, the required level of the reliability of the device can be guaranteed. This is shown in Fig. 2, which shows the relation between the reliability curve and the intensity of the failure, with preventive intervention.

The figure shows that the curve of reliability declines over time, and that the failure intensity is a constant value. In the point of time  $t$ , periodic inspection of the device was conducted and thus its reliability was taken to the next level  $R$ . Hence, the resource of a circuit on a device does not use a fault. In Fig. 2, the drawn part of the surface beneath the curve  $R(t)$  represents the area of the unused resource of an assembly of a device. Therefore, the justification of the methods of preventive maintenance must be examined and

assessed in each set, because the cost of preventive replacement and works, especially the more expensive and sophisticated equipment, can be considerably higher than the expected results.

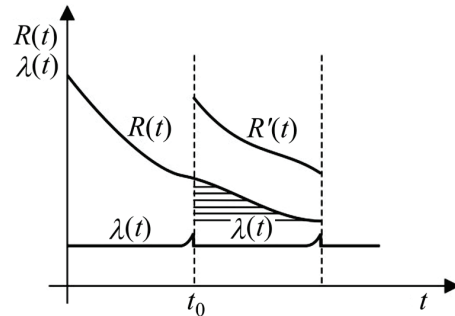


Figure 2 Relationship of reliability and intensity of failure

Preventive maintenance can be accomplished in several ways. This refers to the type and character of preventive maintenance procedures, and then, when the time is determined to carry out these procedures. Considering the fact that in practical situations of the maintenance of medical devices, it is difficult to find a system which applies to only one of these models of preventive maintenance, so usually it is a combination of several different methods. For this reason, the above mentioned principles briefly explain all the above mentioned principles of preventive maintenance.

*Basic maintenance* covers all methods, which are typically performed by the user of the medical device (operator) and the on-site use of tools and equipment from the composition of the sets of devices. For each specific device, basic maintenance technology should be prescribed if it is not elaborated in the instructions that the manufacturer is obliged to deliver with the device.

Basic maintenance, as the principle of preventive maintenance, should be introduced in all devices. To be effective in practice, it is necessary:

- that operators are perfectly familiar with the device on which they work,
- to specify the correct technology of work so that you know exactly what is being done, when, by whom, how long, how, under which conditions, etc.,
- to determine the person who will oversee the work done during basic maintenance.

*Periodic maintenance* also refers to preventive maintenance activities that are periodically performed in terms of the review of the critical points and their cleaning (sometimes lubrication) in order to detect or prevent the occurrence of failure. Checks are performed by means of: monitoring, measurement, reading, comparing, and listening to others. In one system, a multiple periodic review can also be planned, e.g.: weekly, monthly inspection, quarterly review, semi-annual review and annual review. These are the variants of preventive examinations, however, it should be noted that they all have the same purpose, but they differ in technology work (content and runtime). Usually, preventive reviews are planned to be performed along with some other

preventive maintenance variants using the manufacturer's recommendations.

A *Check review* by way of preparation and planning is similar to periodic reviews. They differ in their purpose and manner of performance. The purpose of the check review is to determine the ability of medical devices for a particular purpose (accuracy, quality, capacity, etc.) and to determine the safety of the environment (user safety and people in the environment, fire safety, poisoning, pollution, impact, etc.).

Control reviews have a specific way of performing; they have specific accessories that are commonly used (measuring resistance, dimensional accuracy, radiation, etc.). Moreover, these reviews are specific for their complex procedures of measurements, which often require the special training of the contractor. Most often, they are performed by external associates of authorized specialist institutions according to standard procedures and legal regulations (Technical Protection Act, ISO, EN, HRN, DIN, etc.).

*Maintenance by condition* is one of the preventive maintenance methods whose decision-making strategy for maintenance activities is based on periodic or continuous control of the device's technical condition in the exploitation process. According to the results of the control, necessary decisions are made and within the scope of the planned maintenance activities. Maintenance by condition is a diagnostic process that enables the technical state of each component or assembly of a particular device to be determined. This process enables insight into the state of the constituent part or assembly or the device as a whole, respectively, it denotes its "state" and allows the permanent planning of replacement or repair of a system based on the actual technical state, increasing the time of the effective operation of the medical device and eliminating unnecessary dangers.

Maintenance by this method is carried out in such a way that first, at certain time intervals, independent of the state of the damage of the component parts of the system, the diagnostic control of the technical condition is performed, and after that, depending on technical condition, activities on the component parts of the device are performed or they remain in the process of exploitation.

The characteristic size of a technical condition, which is typically taken to characterize a change of state, is a physical size that can be mixed and transmitted, most often by analogous means. As a rule, it is the most important size in the process of using the system.

Maintenance by condition, in conjunction with the classical methods of preventative maintenance, provides a close link between the process of changing the technical condition and the process of using the medical device. In practice, there are several methods of maintaining the state. All these methods are classified into two groups:

- maintenance by condition control the level of confidence and
- maintenance by condition with parameter control.

When maintaining by condition with a confidence level control, the constituent condition of the constituent parts and

the system as a whole is a permissible level of reliability ( $R_d$ ), which is most fully expressed by the intensity of the fault and is determined on the basis of the system usage test for a period of 3-5 years. The system is used without restriction of maintenance resources, as long as the actual level of reliability ( $R_s$ ) exceeds the permissible level of reliability. In the case of  $R_s < R_d$ , the cause of the fault should be investigated or the maintenance model must be introduced in the condition with the parameter check.

Maintaining by condition of the control parameters provides continuous or periodic control and measurement parameters which determine the technical state of the components or systems. The decision on maintenance activities is made when the value of controlled features reaches the "limit of usability", i.e. before the critical level.

Because of its advantages, the method of maintaining the state is increasingly used in the world, in various technical fields, as evidenced by numerous technical papers by authors from around the world. Benefits are reflected in increasing reliability, which is achieved by reducing the total scope of maintenance work in the case of maintenance. By reducing the total volume of work, future failure risk is reduced relating to the quality of the execution of maintenance procedures, and in this way, they maintain the required level of the reliability of the device. The maintenance costs of the device are then smaller.

The application of the method by condition was manifested particularly in an aircraft, where many general maintenance systems are developed using this method. One of the most famous is the so-called TARAN (Test and Replace as Necessary) system which translates to "Test and Replace if Needed". Similar situations are also in use in other modern technical systems, where many manufacturers have developed their "state tracking" systems (Renault, BMW, etc.).

The difference between the periodic maintenance "by time" and the maintenance method are essential, although both represent preventative activities. While in the case of preventive maintenance by "time", maintenance procedures are carried out after a prescribed time or exploitation resource, regardless of the state of the system, in the maintenance state, the "condition check-up" of the system component elements and maintenance procedures are undertaken only if the values of the parameter values are found beyond the prescribed limits.

#### 4 MEDICAL DEVICE FOR COMPUTER TOMOGRAPHY "ROTHOGRAPH EVO 3D"

Recently, in general and dental medicine, image-based devices are used with Cone Beam Computed Tomography (CBCT) method. It is about reconstructing the tomographic plane of the body; it is a type of radiological image which results in a visual representation of one part of the body or entire body and is generated by ionizing radiant radiation.

Manufacturer of the devices for computer tomography "Rothograph Evo 3D" is the company Villa Sistemi Medicali S.p.A. Buccinasco (MI), Italy, Fig. 3.



Figure 3 Rotograph Evo 3D display

The device is applied in traditional dental medicine and otorhinolaryngology. The specificity of the device is recording heads and the dental jaw (anomalies), the temporomandibular joint (TMJ - temporo-mandibular joint) in 3D (three-dimensional image) and image processing by a computer software called Dental Studio Plus Software 3D. The software provides various possibilities of reconstructing the recorded body parts and depths of view through the layers. The software also provides aesthetic treatment of dentures on the film itself and the addition of implants that the dentist or orthodontist can visualize to the patient's plan of action on the teeth. The device also allows diagnosis, reconstruction of the head and teeth by displaying the volume image. In addition to 3D recording, there is also the ability to record in 2D format. For 3D image capture, the detector performs a rotation of  $360^\circ$  around the patient's head, and the device rotates  $180^\circ$  to produce a panoramic image. The advantage of 3D imaging is to detect any irregularities and gum disease that eliminates the need for additional imaging and unnecessary X-ray radiation.

#### 4.1 Using the Device

The Rotograph Evo 3D is designed for installation in a separate room or is located in a room separated by special lead separators to reduce radiative power. The radius of radiation is 2 m. The operator enters the required parameters for recording via the touch screen or computer and manually adjusts the device to perform recording.

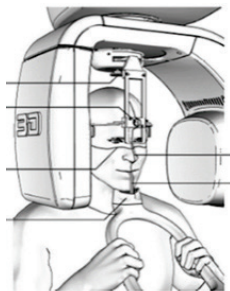


Figure 4 Displays an adjusting of a patient

Fig. 4 shows the patient's access to the device, the movable vertical column is adjusted to the patient's height so that the patient seizes the handle, and the radiology engineer adjusts the face depending on the type of shooting required.

Pressing the exposure button, we get a shot of the patient, the picture is at the same time transferred to the computer and is ready for further processing. The patient can be removed from the device with the radiologist's approval.

#### 4.2 Specifications

Rotograph Evo 3D is listed in Class II B for the European Directive for Medical Devices 93/42, the degree of protection is IPX0. It is manufactured for two types of power supply 220-240 V ~, 110-120 V ~, 50/60Hz.

The device has the ability to adjust the parameters automatically according to the type of shooting and the exposure time depending on the recorded person and the recording type. The X-ray tube head MRE 5 is manufactured by Villa Sistemi Medicali S.p.A., and the X-ray lamp is CEI Bologna (Italy) type OPX 105. The sensitivity range of the sensor is  $130 \times 130$  mm. The minimum dimensions of the work environment according to the service documentation are  $130 \times 120$  cm and the recommended dimensions are  $130 \times 140$  cm without the additional CEPH equipment. [3]

#### 4.3 Dental Studio Plus Software 3D Driver

Using the "Dental Studio Plus 3D" software in Fig. 5, the video is simultaneously displayed on the computer screen. The 3D Reconstruction Module simultaneously reconstructs the volume of the recorded part of the head using a reduction algorithm.

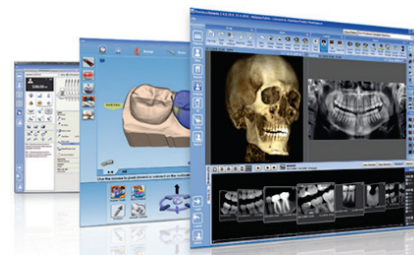


Figure 5 Software Dental Studio Plus 3D Software

The browser software on the screen is visually very practical and adapted to easy viewing and processing images. The software offers the ability to make various useful data such as measurement of the distance between teeth angles, visual implant placement etc.

#### 4.4 Procedures for Preventive Maintenance of the Device

As all medical devices, the Computing Tomography Device Rotograph Evo 3D also must be in the correct state for its full functionality. Therefore, preventive maintenance is required for the safety and efficiency of the device. Preventive maintenance refers to the device operator and service engineer who performs maintenance. For this reason, it is necessary to carry out the verification procedures for the preventive maintenance carried out by the operator and the periodic preventive maintenance performed by the service engineer once a year.

The process of performing preventive maintenance is performed according to a specific procedure prescribed by the manufacturer.

In this case, the following preventative activities are defined:

- Sensor calibration
- Calibrate and adjust the unit and the panorama recording detector
- Partial Volume Calibration
- Calibration of the CEPH ARM (the 2D head recording sensor)
- Set parameters of kV and mA
- Touchscreen calibration.

#### 4.4.1 Sensor Calibration

Sensor calibration is performed using a calibration tool and software to adjust parameter values

All calibrations are performed by performing tests using X-ray, and it is especially important to pay attention to the protection from possible exposure to radiation.

#### 4.4.2 Calibration Procedures and Setting of the Device and Sensor (Detector) for Panorama Recording

To calibrate the device properly, we must take the panoramic shooting first.

The procedure is done in several steps:

- 1) The unit turns on and the recording type is selected
- 2) The computer starts up with Dental Studio Plus, the icon on the "CBCT" desktop is pressed and a test program is opened.
- 3) Selection of the Panoramic exam, setting the special tool shown in Fig. 6 which serves for centring the head and chin support tool for calibrating the sensor in front of the sensor. In this position, the cover is fastened to the sensor.



Figure 6 Special calibration tool

The calibration procedure begins with the recording in the test mode. Set the parameters for shooting an adult 68 kV – 6 mA with a copper filter or recording mode 60 kV – 6 mA without copper filters and computer displays recorded tool that was previously located on the carrier chin.

Use the software to adjust the contrast and brightness. The measuring tape is switched on and the distance between

the outer points is measured. The distance between the points must be  $91 \pm 2$  mm, then the distance between the outer and middle points on the left and right sides, which must be half of a total length of  $95.5 \pm 1$  mm, has to be checked. If the measured values are not the same, then the numeric value must be set to "+" or "-" in Service mode under the "Y Axis zero EVO" parameter. The test recording is performed again by surveying the new value and the process is repeated until the moment when they receive the correct values shown in Fig. 7.

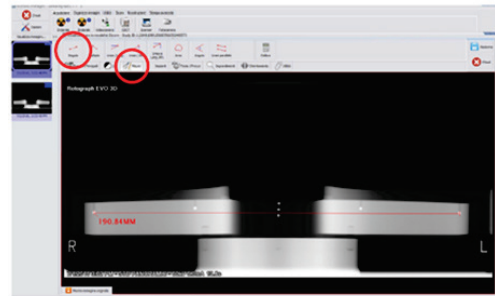


Figure 7 Phantom calibration tool capture and metered points

Entering the Dental Studio software, the "CBCT" application to capture the 3D full volume format will be launched. The centring tool is mounted on the chin carrier, the parameters 66 kV – 6 mA are adjusted and the recording is performed. A portion of the device with the 3D sensor rotates around the  $360^\circ$  tool and the shoot appears on the screen as shown in Fig. 8.

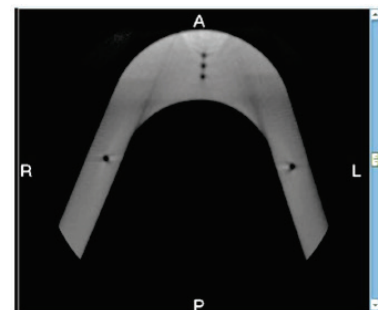


Figure 8 3D images of tools and the point where the measurements are taken

If the portliness is not correct, it is necessary to set the lateral displacement. In order for the portliness to be correct and not to overlap, adjust the parameters according to the instructions in the Service Manual.

#### 4.4.3 Partial Volume Calibration

Partial volume calibration adjusts the mandibular volume (jaw volume). The 3D sensor is selected in the Dental Studio software, then we set the centring tool, the kV and mA settings are adjusted and the mandibular recording on the touch screen is displayed in Fig. 9.

Turn on the "Exam" button and follow the data transfer. Recording tools are read on the screen (Fig. 10) and if necessary, any irregularities are corrected.



In the next step (Fig. 11), the 3D volume of the sinus is recorded.

Any irregularities are re-detected and a corrective procedure is carried out.



Figure 9 Display of a mandibular hinge on the touch screen

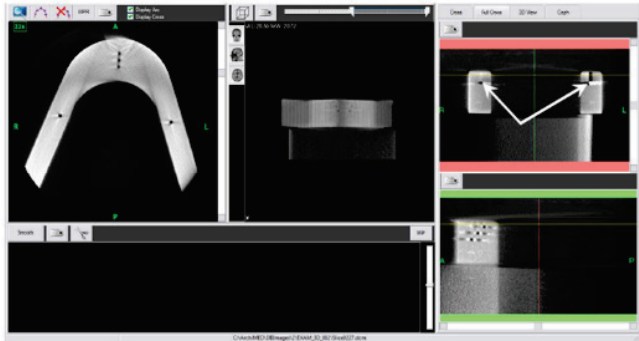


Figure 10 Jaw volume (mandibular) 3D view

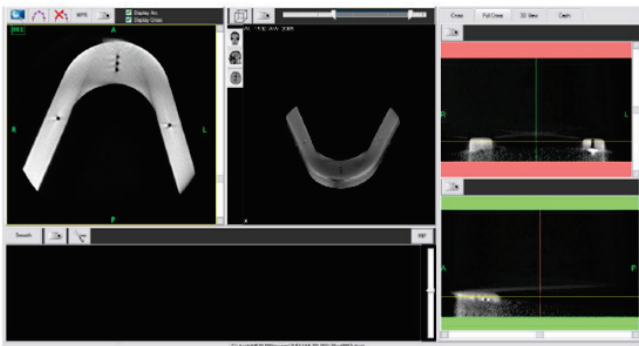


Figure 11 Volume of sinus 3D view, fantasy test

#### 4.4.4 Calibration of the CEPH ARM (2D Head Recording Sensor)

The 2D sensor calibration is also done in the Dental studio software. "CEPH ARM" mode is selected, the kV and mA values are set and the test mode is performed for the X-ray recording. Fig. 12 shows the calibration of 2D sensors using a special phantom head tool.



Figure 12 Calibration of 2D sensors using the head phantom

Vertical earrings are set so that the X-rays must pass through both earrings. Make the exam recording, and if you do not match the two earrings or if they are not symmetrical, the position of the holder is not correct and it is necessary to make a correction as instructed by the Service Manual. Adjusting the collimator (air beam adjustment) is done using the centring tool and the sensor centring software on the computer. Then the X-ray button (exam) is pressed and it visually detects an irregularity if it exists. The line must be vertical with the slot. Entering the service mode for setting the secondary collimator, a recording with the default parameters is performed (60 kV – 6 mA - 0.5 s), and it measures the distance between the canter of the earring and the soft tissue filter. The distance must be about 50 mm.

#### 4.4.5 Setting Parameters of the kV and mA Values

Parameter values can be set on the touch screen or on the computer. The automatic exposure mode (mAs) is adjusted according to the tables in the service documentation.

#### 4.4.6 Touchscreen Calibration

To calibrate the touch screen, a USB memory stick is used, which is inserted in the space provided on the panel. On the main switch, the device is turned on to start the calibration process. The calibration ending is displayed on the touch screen. The device is switched off and then on and the system is ready for operation after it is powered up.

Table 1 The most common causes of the problem with the Rotograph Evo 3D

No.	Causes of work difficulties	Percentage of failures%	Cumulatively
1.	Improper parameterization of kW / mA	40,8	40,8
2.	Computer error	34,4	75,2
3.	X-ray switch button	5,5	81,7
4.	Fuse failure due to voltage oscillation	5,2	85,9
5.	The zero position of the optical rotation sensor	4,1	90
6.	Faulty rails for lifting column	2,9	93,3
7.	Faulty cables	3,3	95,6
8.	Faulty electronics	2,2	98,4
9.	The zero position of the optical rotation sensor	1,4	99,8
10.	Faulty lamp x-tube	0,2	100
<b>Total</b>		<b>100</b>	

## 5 ROTHOGRAPH EVO 3D REMOVAL OF THE LATEST DAMAGE IN THE WORK OF THE DEVICE

### 5.1 Analysis of the Most Common Errors in the Work

After installing and putting the device into use, all the data on the problems that have disturbed the normal function of the device are recorded. The dental medicine device Rothograph Evo 3D appeared in the world market in 2009 and it has been technologically upgraded and adapted to the needs and requirements of the users based on user information. The Priority Method (Pareto) analysed the 10 most common causes, i.e. difficulties in the operation of the device mentioned. Tab. 1 shows the causes of difficulty in

the percentage by which the cumulative is obtained. According to the presented table, it is apparent that the first two problems cause almost 80% of the total difficulties of the analysed samples [3].

The diagram shows the frequency of common faults in the operation of the unit (Fig. 13).

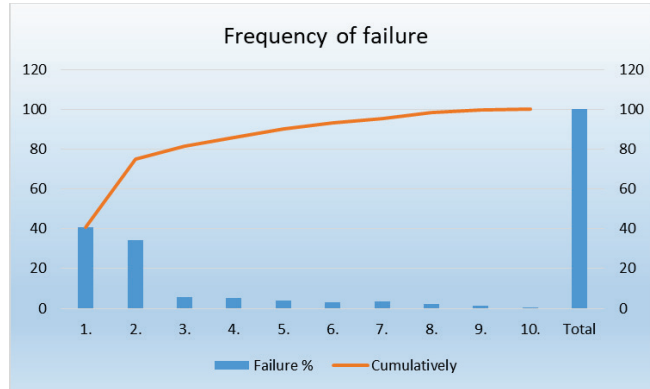


Figure 13 Frequency of malfunctions on the device

The most common cause of malfunctions on the device lies in the incorrect parameterisation and incorrect data entry into the computer by the operator or user of the device.

### 5.2 Analysis of the Causes of the Above Mentioned Errors

The most common errors in the work on the Rothograph Evo3D will be the analysis of the causes of the error.

Table 2 Description of the cause of the error

No.	FAILURE	DESCRIPTION OF FAILURE
1.	Low quality picture	Incorrectly set parameters kV and mA, incorrect positioning of the patient, improper handling.
2.	Computer error	Incorrect computer, insufficient knowledge of software work, error in communication with the processor, cable problem.
3.	Does not operate the exposure button	Wrench wear, broken button, or defective cable.
4.	The device does not work	Faulty power cable, safety fuse burner, rectifier or module error, PCB board.
5.	Incorrect position sensor	Faulty sensor, improper position of the home position, mechanical damage, motor, PCB board.
6.	The vertical column is not lifted	Roughing of the toothed guide rail, defective engine, PCB board.

According to Tab. 2, the cause of the failure of the device is mostly the same, but there is more to it that requires a good understanding of the operation of the device and the device itself and the experience of the servicer to eliminate the existing problem.

## 6 DEFINING THE ROTHOGRAPH EVO 3D PREVENTIVE MAINTENANCE PROCEDURES

### 6.1 Defining Preventive Maintenance Procedures

Based on the conducted analysis, procedures and activities related to the basic maintenance, periodic and control examinations [3-5] are defined (Tab. 3).

Table 3 Activities when viewing the device

Activities	Check review	Periodic review	Basic maintenance
1. Visual view of the devices	•	•	•
2. Outbreaks of external damage (radiation)	•	•	•
3. Installation on the drive parts	•	•	•
4. External cables	•	•	•
5. Interior cables and wires		•	
6. The stability of the device (wall and floor)	•		•
7. Electricity and lubrication of sliding circuits		•	
8. Lightness indicator light		•	
9. Exposure Parameter Check (kV, mA)		•	
10. Laser Positioning Easy		•	
11. Positioning the 3D Sensor (Calibration)		•	
12. Positioning 2D Sensors (Calibration)		•	
13. Positioning the collimator		•	
14. Sensor Rotation Check		•	•
15. Vertical column lifting	•	•	•
16. X-ray tube control		•	
17. Computer and software control (operating mode)	•	•	•

### 6.2 Investigating the Frequency of Periodic Reviews

The frequency of periodic inspection and the variants of preventive maintenance for this device, research and calculation of the optimum period of the implementation of preventive examinations [1, 3] was performed.

The essence of the calculation is to determine the momentum and time interval between performing the preventive inspection in order to determine the moment of failure, so that the maximum relative error, made therein, will be a constant at any control. The periodicity is determined without a major error by the most critical part or whole.

The fault of a critical entity is an event that occurs when any of its elements come out of a predefined domain of the working characteristics, Fig. 14.

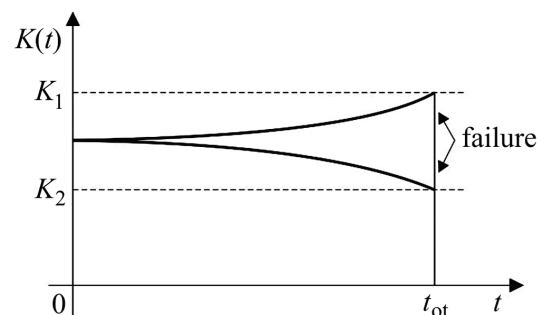


Figure 14 Exit key circuit characteristics from the specification boundary

In Fig. 14, the symbols have the following meanings:  $t$  - the operating time of the device;  $t_{ot}$  - moment of failure;  $K$  - vital characteristic of the most critical entity as a function of the time of use;  $K_1$  and  $K_2$  - the limit of the vital characteristics of the most critical unit of the device that tolerates the change.

From the Fig. 14 it arises, in order to determine as accurately as possible the moment of occurrence of failure, that it is necessary to constantly measure the vital feature of

the most critical of the whole device. However, this is very rarely done in practical work. Much more cases that are frequent are to check the critical entity from time to time and to ascertain whether a critical failure has occurred.

In this case, the actual moment of failure is transformed into a moment of preventive examination. It is understood that such a procedure of determining the time of performing a preventive examination makes a minor or greater mistake, because a critical condition could have occurred immediately before the examination, and much earlier, i.e. immediately after the last review.

The essence of the calculation is to define the time schedules of the inspection so that the maximum relative error of determining the exact failure time remains constant at any inspection.

If on some preventive inspection, a fault was identified on the critical entity (Fig. 15), it means that it will be declared that the critical entity has cancelled you at the time. However, the moment of the real failure of the fault lies somewhere between  $t_i$  and  $\Delta t_i$ .

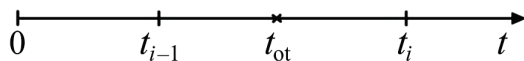


Figure 15 Determining failure on preventive inspection

Mathematical calculations lead to the formula for the first time of performing a preventive examination or the following expression to calculate check-ups.

$$t_i = K_\varepsilon(i) \cdot m_0 \tag{1}$$

$$\Delta t_i = K_\varepsilon^*(i) \cdot m_0 \tag{2}$$

Where:  $t_i$  - the time of the first preventive examination (hour);  $\Delta t_i$  - time of the next review (hour);  $K_\varepsilon$  and  $K_\varepsilon^*$  - maximum relative error coefficients;  $m_0$  - presumed medium value to failure (hour).

To determine the momentum of the time  $t_i$ , when to do the first preventive inspection and at what intervals of time  $\Delta t_i$ , it is necessary to adopt the value of the maximum relative error and the medium value to the fault  $m_0$ .

Fig. 16 shows the graph of the coefficient  $K_\varepsilon$  and  $K_\varepsilon^*$  for some values of the serial number of the preventive examination ( $i$ ), and  $\varepsilon = 0.10$ ,  $\varepsilon = 0.20$  and  $0.30$ .

The numerical values of the coefficient  $K_\varepsilon$  and  $K_\varepsilon^*$  can be calculated for some values of the ordinal number of the preventive review ( $i$ ), and for the different values of the maximum relative error.

It should be noted that after calculating the values for  $t_i$  and  $\Delta t_i$  it is necessary to perform optimization and correction, and then adjust time to real situation. There may also be more errors in the budget if it is adopted by a large value of the maximum relative error and the average error time. Therefore, for the application of this calculation, it is necessary to know the good operation of the device and to have a good theoretical basis for its application.

For specific application, it is necessary to adopt the values of the maximum relative error and to know the mean time to failure. For example, if  $\varepsilon = 0.30$  is known and the median time for a failure is 3 years (based on the data from exploitation),  $t_i$  and  $\Delta t_i$  can be calculated.

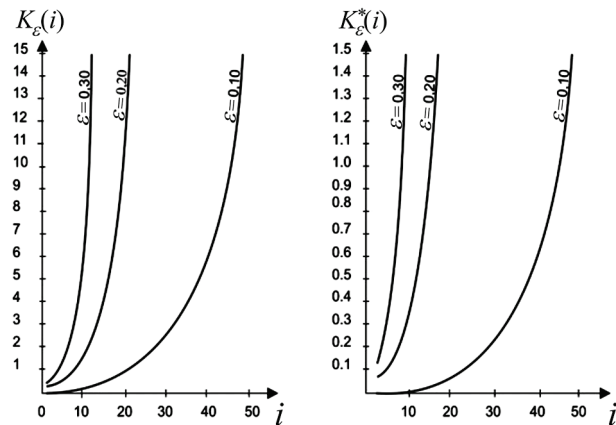


Figure 16 The graph of the coefficient and for some values of the serial number of the preventive review ( $i$ ), and  $\varepsilon = 0.10$ ,  $\varepsilon = 0.20$  and  $0.30$ .

Numerical values for  $t_i$  and  $\Delta t_i$  are calculated on the basis of the Eq. (1), and the results are shown in Tab. 4.

Table 4 Numerical values for  $t_i$  and  $\Delta t_i$

$i$	$t_i$		$\Delta t_i$	
	hours	days	hours	days
1	7884	328.50	2365	98.55
2	11263	469.29	3379	140.79
3	16090	670.41	4827	201.12
4	22985	957.73	6896	287.32
5	32836	1368.18	9851	410.45
6	46909	1954.54	14073	586.36
7	67013	2792.20	20104	837.66
8	95733	3988.86	28720	1196.66
9	136761	5698.38	41028	1709.51
10	195373	8140.54	58612	2442.16

Based on the data from the table, it can be concluded that the first preventive review of the critical entity or the device after being put into use should be performed after 328 days of exploitation, the other after 141 days, the third after 201 days, etc. Due to the simplicity of planning the preventive examinations, and following the maximum admissible values  $m_0$ , the following preventive inspection times can be adopted, as shown in Tab. 5.

Table 5 Moments of review

MOMENTS OF REVIEW				
$t_0$	$t_1$	$t_2$	$t_3$	$t_4$
months				
0	12	6	6	12

The second method for determining the periodicity of conducting preventive examinations is based on knowing the data from the exploitation of the device in practice. The essence is to know the values of the intensity of the unit malfunction and the average duration of one preventive examination.



If these data are known, then the time of the preventive review can be calculated according to the formula:

$$P_{pp} = \sqrt{\frac{2T_{pp}}{\lambda_{p0}}} \quad (3)$$

Where:  $\lambda_{p0}$  - intensity of system failures (failure/h);  $T_{pp}$  - average duration of one preventive examination (h).

The term  $P_{pp}$  graphically shows Fig. 17 for some parameter ranges.

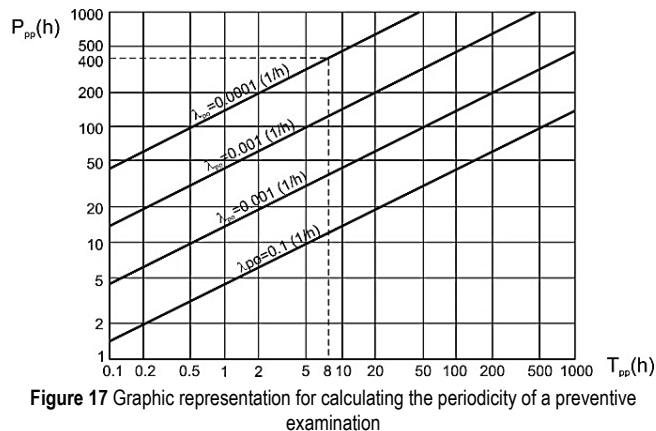


Figure 17 Graphic representation for calculating the periodicity of a preventive examination

For example, a concrete medical device can be taken in exploitation that has the intensity of gradual failures

$\lambda_{p0} = 0.0001$  failure/h. It is necessary to determine the optimal period of preventive examinations, which last an average of 8 hours.

From the graphical display, read  $P_{pp} = 400$  hours. The same result is obtained by computing using the expression for optimal periodicity. These results should be commented on. It should be noted that the scope of the preventive review is evaluated over the average time of the execution of a preventive examination, which is closely related to the choice of operations being carried out. This depends on the number of parameters of the device to be controlled, the scope of the disconnection for checking, the metering methods, the control-measuring equipment, the benefits of the metering system or diagnosis, etc. In addition, this method optimizes the maintenance period only from the point of view of a gradual defect, which can be detected by control. A gradual malfunction occurs when some parameter of the device changes gradually from the permissible limits. This entails the need for adjusting or replacing the elements - a cause of a gradual failure. It is clear that preventive action can not affect the occurrence of current malfunctions.

All the operations that make the content of the preventive review should be systematized and grouped for a particular device, paying attention to limitations (maximum time of a preventive review, equipment, personnel qualifications, space, etc.). From such grouped actions, the average time of the preventive examination can be estimated or determined.

In this way, the periodicity of performing a preventive examination is impractical and inoperative, and planning on

it would be complex. However, it is the basis for determining the rules on the periodicity of the review.

Actual periodicity comes from estimating and rounding calculation values (always taking into account the experience with such or similar systems) by following the following principles:

- a large number of related devices should have the same periodicity (easier planning, execution, and review control),
- the periodicity has to be determined specifically for devices in continuous work, in occasional work and guarding,
- if the reliability of the device cannot be affected during a preventive review, a review is required only for insight into the condition.

The process of determining the periodicity of a review is an interactive process, and at each stage, it can be repeated and reviewed and the scope of the review can be changed, and thus the viewing time can be changed. The ultimate goal is achieved when objectives with minimal costs, simple planning and maximum reliability of the system are satisfied, all under the conditions and limits.

## 7 CONCLUSIONS

Maintaining medical devices and technical systems in general is today unimaginable without the use of preventive maintenance methods and in particular the maintenance of the state and the use of modern diagnostic procedures and diagnostic equipment. For these reasons, during the design and development of new devices, designers and constructors require that the development of diagnostic equipment is installed or specifically supplied with medical devices.

This ensures the convenience of the service system and its greater availability and reliability, i.e. increases its overall quality and increases the customer's satisfaction and the satisfaction of the people responsible for its service and maintenance. All this requires the operator's and the maintenance service's enviable technical knowledge, and it also requires from the employers to invest in the procurement of adequate diagnostic equipment and training.

Combined with other preventive methods in maintaining the technical systems, the maintenance based on the state of controlled features has no alternative.

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