



OPTIMIZATION OF THE MEDICAL EQUIPMENT MAINTENANCE PROGRAMS

Col.Eng. George UDROIU, PhD Candidate*

In the context of the increasing costs of the medical equipment maintenance services in the recent years, as a result of the continuous development of the complexity of health technologies, the obvious shortage of specialized technical staff and the acute outsourcing of maintenance, clinical engineering structures in our hospitals are constantly looking for solutions to maximize device availability, ensure safety, performance and clinical efficiency, while reducing maintenance costs and increasing reliability. Performing maintenance operations at the intervals recommended by the manufacturers in the operating manuals or using another periodic preventive maintenance based on the experience of technicians and evidence from the service history of the equipment, as well as the selection of the most appropriate types of contracts are the main managerial challenges of optimizing the maintenance process. The integrated approach of these elements and the evaluation of clinical, technical and financial factors in the life of medical equipment are the pillars of the development of the most appropriate maintenance strategies, which tend to achieve a balance between performance, risk and cost.

Keywords: medical equipment; maintenance; clinical engineering; costs; efficiency; optimization.

Medical equipment is the most important investment in the healthcare industry that requires complex and accurate maintenance procedures to achieve the designed performance and the delivery of safe and quality medical services. Maintenance operations for the most critical equipment are more expensive every year, and the variety of technologies and regulatory constraints at European level, which limit the implementation of maintenance policy at the level of each health unit, make the action of optimizing the programmed maintenance a difficult process of analysis, evaluation and decision, to ensure the functionality of the medical device, minimize the failure rate and extend the life, in order to obtain the maximum benefit from the use of the device, as well as reduce total ownership costs.

Medical equipment life cycle management includes, in addition to the active management of the other structural stages, the dynamic control of maintenance costs, which, compared to other operational costs (that remain constant throughout the life of the device), increase exponentially in the second half the life of the equipment, due to the advanced wear of the components and the increase of the prices practiced by the service operators,

taking into account an average lifespan of 10 years and an annual cost for a complete maintenance contract of 8-10% of the purchase value¹. In order to optimize the value of the life cycle, the managers of the sanitary units must prioritize the equipment for the preventive maintenance, to find the balance between the maintenance executed with own forces or outsourced (through direct commitments with the equipment manufacturers or third party service operators, authorized and recommended by the manufacturer) and establish the most effective contract models. In this sense, in order to make the most of the costs allocated to this key theme in medical equipment life cycle management, maintenance, clinical engineering structures of hospitals in developed countries have implemented computerized equipment maintenance management systems, in order to support the decision-making process and distribution of the type of contract.

The added value is brought to the medical organization when, in implementing a maintenance strategy, clinical engineering structures develop evaluation schemes based on factors that take into account the maintenance needs of medical equipment, patient and user safety, but also criticality and importance functions of the analyzed equipment in relation to the mission and objectives of the medical organization, and define individualized support programs for each type of medical equipment, including operations planning, human, financial and material

* "Gl.dr.av. Victor Anastasiu" National Institute
of Aeronautical and Space Medicine
e-mail: uddy_74@yahoo.com

resources management, continuous monitoring of implementation and improvement of the system as a whole.

Maintenance actions pluri-valence

In addition to the acceptance tests performed at the reception of the equipment, before their commissioning, the term "maintenance framework" includes the maintenance operations of medical equipment divided into two broad categories², each covering other follow-up actions as part of the annual maintenance support programs:

- Inspection and preventive maintenance (IPM) – includes actions scheduled to be performed at a predetermined time, in order to reduce premature wear of parts or subassemblies and the failure rate of equipment, detection of possible hidden defects, and insurance of the device functionality; these operations have the role of extending the useful life of the equipment and include actions of calibration, cleaning, lubrication, replacement of consumables and spare parts with fixed life, etc.

- Corrective Maintenance (CM) – includes unscheduled actions to repair or restore technical and clinical performance, safety and integrity of defective medical equipment, and re-commissioning operations.

Within the IPM, performance and safety inspections are separately regulated activities, which include actions to test the technical parameters set by the manufacturer by specifying the equipment and service manual and actions to verify the electrical and mechanical safety of the device, measuring ionizing radiation, or of gas leaks, by comparison with certain national or international standards. These inspections are not intended to increase the life expectancy of the equipment, but only to assess its current condition.

Predictive maintenance, part of the IPM, includes technical analysis and forecasting actions in order to determine the rate of wear or failure of consumables or spare parts currently used in maintenance and to determine the frequency of maintenance operations, so that used components are replaced before failure and medical equipment would operate continuously.

IPM can be executed according to two globally recognized models³, thus: Time-based maintenance (TBM) – equipment is maintained regularly, with regular budget allocations, easy to estimate and plan

and condition-based maintenance (CBM) – requires equipment condition assessments, statistical prediction tools and a high degree of expertise of the technical structure, in order to balance the annual budget, depending on the reliability of the equipment and the estimated remaining life.

The complexity of the functions of the maintenance programs also includes tasks of quality control, selection of the type of service contract and monitoring of their development, training and education of clinical and technical staff, as well as guidelines and substantiated directions for developing replacement plans with new equipment.

In order to effectively manage the costs necessary for the maintenance of medical equipment, any health unit, hospital or treatment or diagnostic center must develop and implement maintenance programs, whose complexity is strictly dependent on the mission of the organization, the type of equipment, financial resources and human resources available, the space and technical installations of the facility.

Preparation of maintenance programs

In order to obtain cost-effective maintenance programs, clinical engineering structures must allocate and direct financial resources in a balanced way and adapt the maintenance model (technical operations to be performed and their periodicity) with the criticality of equipment, hospital objectives and benefits obtained, following the risk / cost / benefit analysis of some critical factors, according to Figure 1.

Tasks and type of maintenance are grouped into 5 levels⁴, starting from level 1 which is performed exclusively with its own staff for simple maintenance actions (replacement of filters and batteries, cleaning pipes, mechanisms lubrication, etc.) and up to level 5, executed entirely outsourced with manufacturers of medical equipment for complex actions requiring installations, special equipment and software for high-tech medical equipment. It should be noted that due to the lack of special tools and devices, as well as specialized human resource, hospitals in Romania have contracted most maintenance services in recent years, even for the simplest preventive operations, which is a huge financial effort on the budgets of organizations.

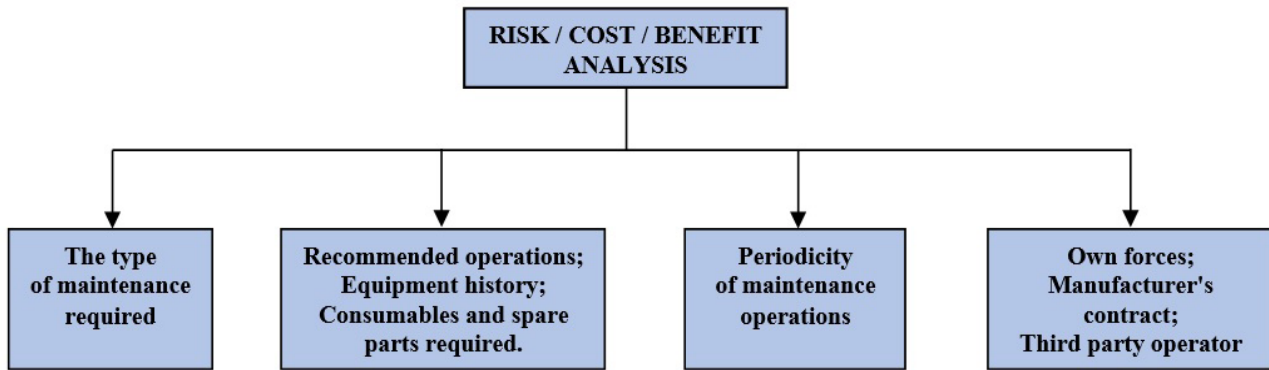


Figure 1 Elements of risk / cost / benefit analysis
(The author's conception)

The service options that can be considered in the risk / cost / benefit analysis are⁵: use of own human and material resources; acquisition of lifecycle maintenance with the delivery of equipment or negotiation of annual / multi-annual maintenance contracts (innovative approach that can bring substantial savings to the budget) with the manufacturer – OEM (Original Equipment Manufacturer) contract; the annual maintenance commitment concluded with third party operators (common service agents), other than its manufacturers or authorized representatives. For the last two options, health units must consider equipment response times, the possibility of making other spare equipment available during maintenance, the availability of repair procedures and the quality or origin of spare parts used, attributes that may affect equipment performance (in particular the case of third-party operators).

At the same time, for equipment prioritized to outsourced service, contracts must provide requirements on the availability and traceability of replaced components in maintenance, notification of parts and response times, responsibilities for patient data management confidentiality), requirements for keeping records of maintenance and consumables used, training of staff and written instructions of the manufacturer, as well as ways to dispose of waste resulting from the repair process.

The most common types of legal outsourced maintenance commitments concluded between hospitals in the Ministry of National Defence's own network and service operators are:

- Type 1 contract – only the labor of maintenance actions, without materials included in the price, unlimited number of interventions and diagnoses

(usually, it is negotiated to perform at least one annual technical review in the offered price);

- Type 2 contract – labor and covered parts, except the subassemblies considered by the service operator as special components;

- Type 3 contract – full coverage of maintenance interventions and parts and accessories necessary to maintain the reliability of the equipment – contract indicated for the maintenance support of complex technologies, such as digital radiography installations, computed tomography, magnetic resonance systems and laboratory.

In practice in recent years, hospitals prefer a fourth type of contract (3+), by transferring all risks to the operator and introducing a minimum guaranteed availability clause (uptime), usually set at 95% of the duration of a calendar year or the contractual period.

Clinical engineering structures must compare, according to Table no. 1, the advantages and disadvantages, on the one hand, of the internalization or outsourcing of maintenance services, and, on the other hand, of entrusting the contract to the manufacturer or another third party operator.

Analysis of resources required for maintenance

For each maintenance option considered, multidisciplinary analysis teams or clinical engineering structures must design the resources useful for the adopted maintenance program, using as tools the service history of each equipment, the experience and skills of the technical staff, the requirements of specialists and the forecast the time of failure of the medical equipment.

Table no. 1

ANALYSIS OF THE INTERNALIZATION / OUTSOURCING OF MAINTENANCE SERVICES⁶

Type of services	Advantages	Disadvantages
Internal	Quick response to interventions; Flexibility in scheduling preventive maintenance operations, reducing downtime; Management and coordination of contracts with producers or third parties.	High specialization costs; Lack of support devices and testing software; Reluctance to poor training from manufacturers; Low spare parts storage possibilities for the whole range of equipment.
External	Equipment availability clauses; Setting intervention times; Replacement of defective equipment during periods of unavailability; Easy to plan costs (type 3 contract).	Sending the equipment for repair; Difficulty in obtaining commitments with full coverage for critical equipment; High maintenance costs.
OEM	Compliance with repair standards; Inclusion of original software changes and updates; Easy access to original components and spare parts; Possibility of remote monitoring and diagnostics (internet); Extended warranty on operation performed; Provided training and technical assistance.	Response time, most of the time, quite long; Requires annual negotiation and updating; Difficult coordination for a wide range of equipment; Very high costs.
Third party operator	Lower costs than the manufacturer; Specialist in the facility for short-term fault intervention;	Reduced equipment coverage area; Reduced staff training opportunities; Lack of technical information from the manufacturer; Generic spare parts.
In all cases, the monitoring, audit and management of contracts is the obligation of own clinical engineering structures in the organizational chart of the health unit, in order to control the costs allocated to maintenance.		

The requested budgetary resources include the costs prior to the maintenance program (investment in workspace, tools, control devices and testers, personal training) and the ongoing costs for running the program (utility costs, checking and calibration of special devices and installations, staff salaries, training continuous maintenance of technicians or, in the case of outsourcing, the settlement of service contracts, spare parts and consumables required for maintenance).

The physical resources dedicated to maintenance must include, in addition to the service facility/technical workshop, both the equipment and applications necessary for technology testing, calibration and diagnosis, as well as operation and service manuals and procedures / work protocols required for maintenance and repair and the maintenance guides developed by the manufacturer, documents difficult to obtain by the medical units, if they were not requested as part of the delivery contract at the time of initial purchase.

After determining the need for physical and human resources, based on the fleet of equipment included in the program, the type of maintenance chosen and the number of IPM actions, financiers can determine the initial/permanent costs, by calculating the estimated the workload and the hourly rate practiced at national level. The costs of outsourced contracts, with the exception of type 3, where an average annual cost of 10% of the purchase value of the equipment is planned, are difficult to assess in the first years of operation of the technology, but can be optimized based on the history of maintenance and experience of its own maintenance structure in the coming years.

In clinical engineering practice, a maintenance program selected for a particular medical device is generally considered to be financially efficient if the ratio between the total annual cost of maintenance and the purchase value of the equipment is less than 0.10⁷, objective that can be reached only with the consistent support of its own technical department.



Prioritize equipment and set time intervals for inspection and preventive maintenance

In the context in which the costs necessary for the maintenance of medical equipment during the useful life are often higher than the purchase price and the annual budget allocated to the maintenance of medical equipment represents about 1% of the total budget of a hospital⁸, clinical engineering departments are looking for solutions to optimize maintenance programs, due to budgetary constraints, by developing priority models for preventive maintenance and setting new time intervals, ensuring that they are safe to operate, accurate, efficient and reliable, even if for each piece of equipment the manufacturer provides in the service manual the periodicity of the IPM actions.

It must be kept in mind that performing IPM activities at short intervals, in order to guarantee the continuous functionality of the equipment, without incidents or technical failures, is a waste of resources and time and even the induction of failures caused by the aggressive disassembly of component subassemblies for maintenance.

In this sense, the paradigm shift occurred slowly and gradually, starting with routine maintenance interventions and fall repairs in the years 1940-1950 (no planned maintenance), passing through the TBM of the 1980s, then applying CBM and Reliability-based maintenance (RBM) in the 2000's and nowadays reaching Risk-based maintenance (RBM).

RBM, considered globally an empirical approach, prioritizes maintenance equipment based on monitoring its condition, assessing the causes of technical failure and examining needs, as a maintenance concept for low-duration medical devices. CBM, based on the operational monitoring of the equipment with the help of dedicated sensors, forecasts the availability of the equipment and increases their productivity and safety.

If in Canada, due to the difficulty of identifying and prioritizing risks, IPM programs are carried out in most hospitals according to the recommendations of manufacturers, in the United States of America (USA), the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has allowed health units to develop individual maintenance programs since 2004 through the balanced use of resources, depending on the priority of each organization, for safety and reliability reasons⁹.

Thus, clinical engineering structures can prioritize medical equipment to preventive maintenance by analyzing factors in a process of analytical ranking, taking into account multiple criteria, such as: type of maintenance (usually factor assessed by the 5 levels of complexity), the nature of the equipment (classification includes 4 main groups – therapeutic, diagnostic, analytical and auxiliary purpose), physical risk (the most important criterion in assessing the criticality of medical equipment), the role of medical equipment in the basic mission of the medical organization (its importance), the age of the medical device, the level of technical criticality (usually the periodicity of the IPM actions recommended by the manufacturer, the conditions of use and the registered CM actions are evaluated).

According to *the Fennigkoh and Smith model*¹⁰, the evaluation of the criticality of the medical equipment in order to introduce in the preventive maintenance program represents a list of analysis of some factors and parameters that define the risk probability of an equipment, based on the criticality score, which can be obtained by summing each of the elements presented below, on a grid set at the level of each element evaluated, as follows:

- critical function of the equipment within the hospital (score from 1 to 10) – maximum score can be given to life support and intensive care equipment and minimum score to analytical (laboratory analyzers) and auxiliary (patient-related devices);
- physical risk associated with equipment failure (score from 1 to 5) – maximum score is given to equipment that, by failure, can lead to patient death and minimum score, those that can cause only slight damage to the integrity of medical equipment or those for which no risks have been identified;
- maintenance requirements (score from 1 to 5) – maximum score is given to equipment that requires calibration and replacement of components at a certain time interval and minimum score, to devices that require only visual inspection.

Medical equipment that obtains a prioritization score higher than 12 points will be included in the IPM program.

Subsequently, the periodicity of IPM actions can be established after evaluating the data from the medical equipment history, assigning a new

score to each equipment (according to Table no. 2) and achieving the sum between the prioritization score and the failure factor, as follows: only medical devices with a lower score of 15 points will be checked annually, while the others will be planned for maintenance at least every six months.

Table no. 2
SCORING THE FAILURE FACTOR¹¹

Number of equipment failures	Failure factor
One or more at 6 months	+2
One in over 6 months	+1
One in over 9 months	0
One in over 18 months	-1
One in over 30 months	-2

Another method of prioritizing equipment for introduction into the preventive maintenance program, promoted in the 2000s by *Wang and Levenson¹²*, defines the criticality of the mission and gives each medical equipment a critical score, assessing the following factors: the importance of the medical device in the hospital (analyzes how crucial equipment is in ensuring the continuity of health care services and depends on the availability of other spare medical devices), maintenance needs (analyzes their complexity and the availability of the three types of resources – *labor, cost and tools¹³*), the degree of use (as a percentage of the total autonomy time) and the physical risk of technology failure (analyzes the safety of patients and medical staff in case of failure, prediction of failure, frequency of technical failures and downtime, data extracted from appliance service history), according to the formula below:

$$\text{Score EMR} = [(\text{Mission critical} + 2 * \text{Maintenance requirements}) * \text{Utilization rate}] + 2 * \text{Physical risk}$$

Subsequently, starting from a model based on minimizing risk and improving profitability, presented in 2004, *Khalaf A.B¹⁴*, has developed a new type of hierarchy by further measuring the probability of availability of medical equipment depending on their age and the degree of ensuring preventive maintenance, by using data collected through management programs.

Moreover, in order to reduce the costs allocated to maintenance, the idea of performing preventive maintenance actions at intervals shorter than the mean time between failures (MTBF), calculated according to the formula, was promoted¹⁵:

$$\text{Interval SPI} = 2 * (1 - \text{uptime}) * \text{MTBF},$$

where *SPI* represents the planned maintenance, and *uptime* represents the time of availability of the medical equipment, calculated as a percentage of the total operational time.

Thus, implementing the ways of streamlining the studied maintenance and the field evidence based on data from the service history of the equipment, from the good ranking practices implemented at the level of the institution where I work, I can present the example of extending the IPM range in the last 4 years for a 9-year-old automatic steam sterilizer, used, on average 6 hours a day, from 1 year, according to the manufacturer's recommendations, to 18 months. The cost of a preventive maintenance operation, performed in closed regime (phenomenon of captivity in the service network or only service provider at national level), includes the standard equipment overhaul kit (water filtration and softening elements, solenoid valves, resin filter, gaskets) and was at the time of January 2021 of 3,000 euros (planned intervention, without service contract), representing 8% of the value of the initial acquisition.

Internalization versus outsourcing of maintenance services

After establishing the degree of prioritization and maintenance interval, the health units must make the decision to internalize/outsourcing maintenance services on levels, based on the analysis of additional criteria related to the availability and potential of human and material resources and the evaluation of annual maintenance costs. In this sense, multidisciplinary decision support groups can assess the following factors: the competencies of their own maintenance structure (according to the 5 levels of maintenance – level 1 is mandatory with internal specialists), the average time required for each level of the maintenance strategy), the need for specialists to perform technical operations, the cost of maintenance time (internal versus external), the cost of labor (the product between the volume



of work, the cost of working hours and the number of specialists).

system is a closed one, it is recommended to choose a type 3+ contract, with full coverage on all levels

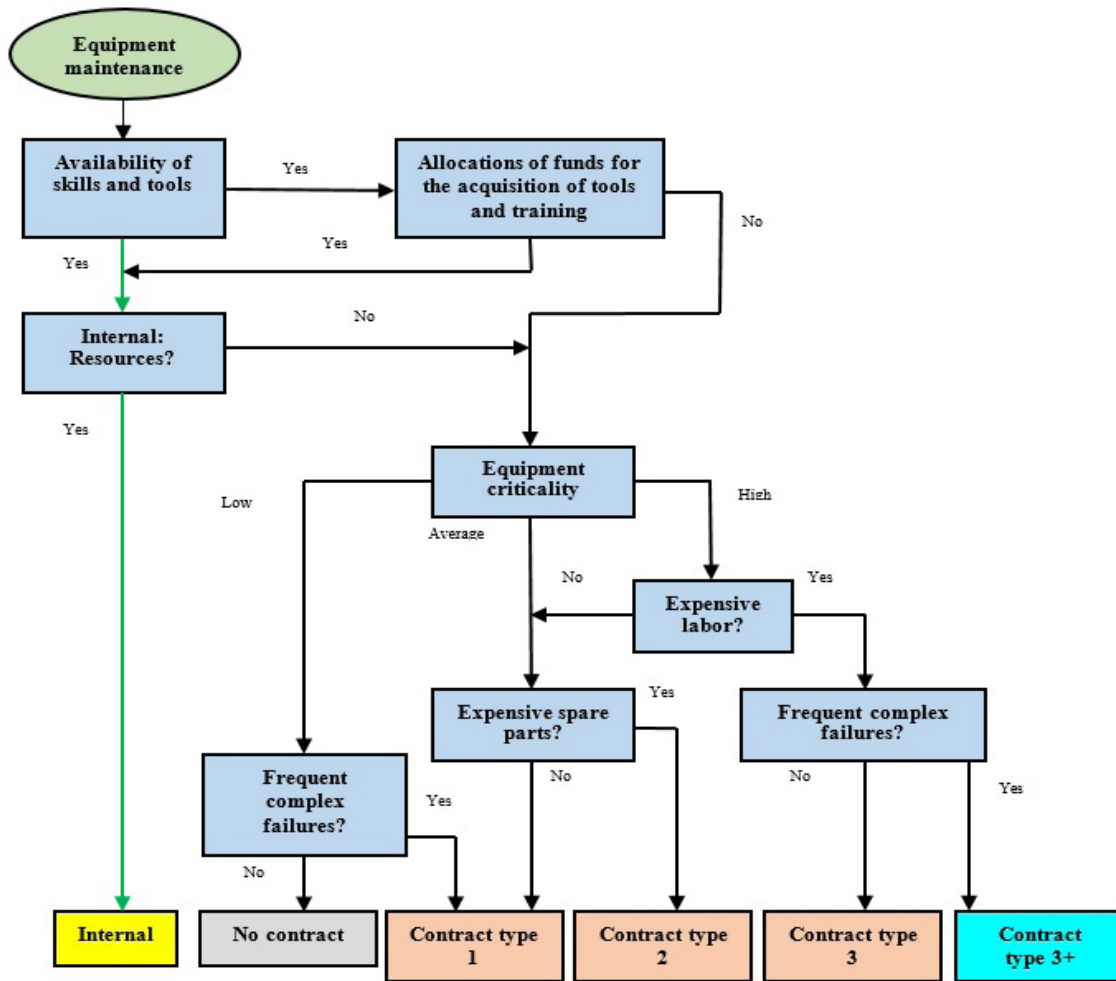


Figure 2 The decisional matrix of internalization / outsourcing of maintenance¹⁶
(The author's conception)

In the case of outsourcing services, the medical organization must make the decision to select the type of contract, analyzing elements such as cost-effectiveness of packages offered by economic operators, labor costs, spare parts costs and frequency of CM interventions in the equipment service history, according to Figure 2.

The types of contract are thus specific to each medical equipment and appropriate to each level of maintenance, depending on the degree of risk considered, the flexibility of service operators' packages, the number of IPM and CM interventions, the workforce and the parts required.

In this regard, we can say that, when budgetary resources allow it, for complex health technologies, such as magnetic resonance equipment or anesthesia machines, where the cost of technical diagnostics and spare parts is very high and the maintenance

and clauses imposed by minimum availability and maximum intervention time (usually 24 hours), while for equipment such as electrocardiographs or defibrillators, outsourcing can only be considered justified in the case of interventions of minimum level 3, by mandatory inclusion in the contract of IPM actions (at least annually) and spare parts.

Conclusions

The maintenance of medical equipment becomes more expensive every year, and to optimize maintenance programs and reduce total cost of ownership, clinical engineering structures of hospitals are constantly looking for solutions to extend the time of operation of equipment, in terms of safety and technical performance requested and through the efficient use of available resources.

In this regard, health facilities need to implement evidence-based maintenance strategies, through the development of prioritization procedures aimed at a balanced assessment of relevant factors in the life of medical equipment, through an integrated approach to the elements of reliability-based maintenance, maintenance-based on conditions and risk-based maintenance. This transparent ranking process analyzes elements of equipment availability forecast, their service history, maintenance intervals recommended by manufacturers, in light of regulations, consequences of failure and existing alternatives, costs and benefits of possible options and aims to obtain the most efficient maintenance regime in terms of the risks associated with equipment failure and the costs required for proactive maintenance, based on the interpretation of detailed and structured results.

The maintenance policy of the medical organization must establish the medical equipment included in the maintenance program and the periodicity of inspection and preventive maintenance operations, based on the critical scores obtained by each device, how to provide maintenance support and the type of contract selected, according to the complexity of medical technology, the level of maintenance appropriate to the category of equipment, the flexibility of service packages offered by operators and the availability of human and material resources.

The most effective tool for planning and recording the maintenance actions that hospitals should implement in order to organize the maintenance program and permanent cost control is the software system for medical equipment management during the life cycle. It allows real-time monitoring of the effectiveness of maintenance programs and supports the decision-making process of selecting the maintenance strategy through the data collected about each medical equipment in the organization chart of the health unit.

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