# Specifications of the Modern Information System for Maintenance of Medical Equipment in Healthcare

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Effective management of the maintenance of medical equipment (ME), especially high-tech one, is one of the main issues for the quality of health care, for the provision of cost-effective health services and for saving, even in developed countries, insufficient resources. Medical equipment maintenance (EM) includes all activities related to ensuring an adequate level of service and limiting the downtime of medical equipment in a healthcare organization. Traditionally, EM is categorized as preventive maintenance (PM) and corrective maintenance (CM). The principle of PM is prediction. PM can be planned and predictive, ie. Just-In-Time (JIT) maintenance. Predictive maintenance can only be applied to new high-tech medical devices that have built-in self-testing.

Planned preventive maintenance is carried out in accordance with the maintenance plan for a certain period of time. As a rule, when creating the plan, we follow the manufacturer's recommendations for preventive maintenance of ME given in the technical documentation of the ME, especially in the instructions for the maintenance of the ME.

Predictive or JIT maintenance makes it possible to detect and solve the problem before problems and contingencies actually occur, and this is done on the basis of intelligent monitoring and analysis of the state of ME at the right moment, which ensures the optimal time for intervention, so that maintenance performed only when necessary.

The information system for the management of the maintenance of ME in healthcare institutions would interconnect healthcare institutions and enable the fast and safe exchange of data and information related to the maintenance of ME and enable the optimal maintenance of ME in healthcare institutions, increasing the availability of this equipment, especially high-tech equipment, with significant reduction of the total cost of maintaining ME (of the order of 30%).

One of the main reasons for the unsustainability of the existing approach to the maintenance of ME in the healthcare institutions of Serbia is that each healthcare institution independently takes care of the maintenance of its own ME. This approach is expensive and significantly affects high maintenance costs. This approach needs to change.

Key Words: maintenance, information system, health institution, costs, optimization

### 1. INTRODUCTION

The costs of maintaining medical equipment (ME) represent a significant part of the total costs of the functioning of the Serbian health system.

Depending on the specifics of each ME, mainte-

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e-mail: office@vtim.rs Paper received:13.07.2023. Paper accepted: 19.07.2023 nance costs during the lifetime of the ME can represent from 15 to 60% of the value of the purchase price of the ME [1, 2].

Some foreign references state that the broadly accepted figure for the annual cost of a sustainable program of ME maintenance is 6-8 % of the purchase value of the equipment [3].

The total value of ME placed in Serbian health institutions is estimated at about 800,000,000-900.000,000 \$, which would correspond to maintenance costs of 56.000,000-63.000,000 \$/year - which

is much more than the budget currently allocated by the Serbian Ministry of Health (MoH) to health institutions for the maintenance of ME [3].

The current fixed allocation of the budget to health institutions does not allow the management of any health institution to go beyond the budget allocation, so the revenues of health institutions are used to maintain the ME.

In the maintenance costs we can also include the "costs of unavailability" of any ME. These costs can have serious consequences for the reputation of health institutions, but also for the entire Serbian health system. And this is especially noticeable when high-tech medical equipment (e.g. computerized tomography (CT) scanners, magnetic resonance imaging (MRI) devices, mammography machines and radiotherapy equipment) does not work for several months, because then health institutions do not provide certain important medical services, waiting lists for these services are increasing, and patient dissatisfaction is also increasing.

Therefore, it is necessary that the maintenance program of medical equipment in any health institution should be well planned and implemented.

A well-planned maintenance program should achieve maximum availability of ME in any healthcare institution and ensure reliable and safe functioning of medical equipment, making it available for use when needed for diagnostic procedures, therapy, treatments and patient monitoring. In addition, such a program extends the lifespan of ME and minimizes its maintenance costs.

### 2. MAINTENANCE OF MEDICAL EQUIPMENT

One of the most important areas in Health Technology Management is the management of health equipment maintenance.

Maintenance of medical equipment (MME) in any medical institution includes all activities related to ensuring an adequate level of medical services given in that institution and limiting the unavailability (downtime) of medical equipment in use in that institution.

Traditionally, MME are categorized as:

- preventive maintenance (PM) and
- corrective maintenance (CM).

PM can be planned and predictive, ie. Just-In-Time (JIT) maintenance [26]. Predictive maintenance can only be applied to new high-tech medical devices that have built-in self-testing [4, 5].

Planned preventive maintenance (PPM) is carried out in accordance with the maintenance plan for a certain period of time. As a rule, when creating the plan, we follow the manufacturer's recommendations for preventive maintenance of ME given in the technical documentation of the ME, especially in the Instructions for the maintenance of the medical equipment. Here, it is important to keep up-to-date records of preventive maintenance activities carried out and to provide clear periodic reports on the maintenance and condition of ME.

Predictive or JIT maintenance makes it possible to detect and solve the problem before problems and contingencies actually occur, and this is done on the basis of intelligent monitoring and analysis of the state of ME at the right moment, which ensures the optimal time for intervention, so that maintenance performed only when necessary. Therefore, the advantages of this approach in maintenance are great, which is primarily reflected in the increased availability of maintained ME and a significant reduction in maintenance costs compared to conventional approaches to maintenance.

Step one in a best practice of maintenance process in any health institution is to perform an inventory of medical equipment and current practices and consolidate information and responsibility into one centralized location, i-e. in Health Technology Management Unit of healthcare institution.

This process involves taking a complete inventory of every piece of medical equipment that helthcare institution has or think to have [14].

It is possible that healthcare institution pays for a maintenance contract on medical equipment that for whatever reason, no longer exists in healthcare institution. It should be said that this is not only a "specialty" of developing countries, but also of developed countries.

Here we should point out the importance of contract management [23-25] that a health institution or MoH concludes with a professional organization for servicing medical equipment. Contract management refers to the process of engagement and supervision of an organization that sells medical equipment maintenance services.

We suggest that any person or organization wishing to be a maintenance service provider should be registered with a "client", which is either a health institution or the MoH.

The person/organization should go through a registration process, which ensures the following: The profile of each person/organization is verified (in other words, whether it has a workshop, technical staff with the appropriate skills, transport, material...); Without registration, the client cannot pay the person/organization for services; A quick response is received from the registered person/organization. Without registration, the maintenance provider may not feel the need to respond quickly to requests for intervention;

Corruption is less likely to occur (for example, official registration prevents inappropriate employment of relatives as staff members).

Regarding training requirements for personnel using medical equipment and technical personnel who repair medical equipment, they should include:

- Induction of personnel in safe work procedures and work practices related to the acquired equipment;
- Assessment of personnel in terms of competence in the use of equipment, safe operating procedures and work practices;
- Providing sufficient training sessions to ensure that all relevant employees who use and repair the equipment are covered;
- Training at the manufacturer's/supplier's location (if provided for in the contract);
- Provision of a complete set of service manuals including operational, safety and technical information, maintenance information as well as contact lists for service and operational issues;
- Commissioning and training of technical and biomedical personnel relevant to the purchased equipment.

It should be pointed out that some countries, such as Germany and Austria, have introduced a medical products law (Medizinproduktegesetz) which regulates that PPM, and many other healthcare technology management activities, must be undertaken in order to guarantee the safety of medical products.

An advantage for maintenance departments in healt institutions is that as a result finances are automatically allocated for PPM as it is prescribed that it must be undertaken.

Such examples of strict regulations are a crucial prerequisite for the safety of medical products, provided that they can be enforced.

By reviewing the existing laws and regulations in Serbia related to healt, we could not find a provision related to mandatory PPM of medical equipment in health institutions. That's why we suggest that in one of our laws/regulations related to health, a provision should be unambiguously inserted that our health institutions are obliged to perform PPM of ME. As a result, budget funds would be automatically allocated to health institutions for PPM, as it would be a legal obligation.

# 3. MAINTENANCE COST OF MEDICAL EQUIPMENT

It is an obvious fact that the majority of health institutions within our health system do not monitor

and analyze the costs of maintaining the medical equipment used in the health institution.

And no one monitors and analyzes the total costs of maintaining health equipment in the health system of Serbia in a systematic and adequate way.

When it is said that maintenance costs in the life cycle of medical equipment can represent 15 - 60% of the value of the purchase price of medical equipment [1, 2], it is not known whether this refers to the length of the life cycle of medical equipment of 5, 10 or NN years.

Or when it is said that [3] ,,the internationally accepted figure for the annual cost of a good maintenance program is 6-8% of the capital value of the equipment", it is not known what components make up the maintenance costs.

Health institutions founded by the state generally use public funds for the purchase of medical equipment. Formulations in the tender documentation, which is mainly the purchase price, are often a controversial topic for the professional public. Because of the long lifespan of sophisticated medical equipment, purchase price seems to be a misguided concept in the procurement process. This argument is supported by numerous studies based on the Total Cost of Ownership (TCO) method [6-10].

The total cost during the ownership of medical equipment often significantly exceeds the purchase price and therefore the TCO method seems to be suitable for thassessment of equipment in procurement process.

It was indicated that the purchase price might amount only to 20-25% of the TCO [6-10]. The TCO method takes into account all cost elements that should be evaluated before purchasing any health technology.

TCO usually includes the costs of [6-10]:

- procurement,
- energy,
- installation of equipment,
- preventive maintenance of equipment,
- corrective maintenance of equipment,
- upgrades,
- personnel training for working with the equipment,
- technical personnel training for equipment maintenance,
- labor costs of personnel, and
- costs of equipment disposal.

Equipment maintenance costs largely depend on the complexity of the equipment.

In order to get real indicators about the costs of maintaining equipment in healthcare institutions in

Serbia, we should collect real data on TCO for different types of equipment in our health institutions, primarily for high-tech medical equipment.

We suggest that the Serbian MoH initiates a study: "Determining the real costs of maintaining medical equipment", according to the approach given in Ref. [8]. In order to get real indicators about the costs of maintaining equipment in healthcare institutions in Serbia, we should collect real data on the TCO for different types of equipment in our healthcare institutions, primarily for high-tech equipment.

The Study would initially use historical data on the maintenance of specified medical equipment, and later data from the Information system for management of maintenance of medical equipment in health institutions, which should be developed by our experts and which would be available to all health institutions in Serbia.

## 4. INFORMATION SYSTEM FOR MANAGEMENT OF MAINTENANCE OF MEDICAL EQUIPMENT IN HEALTH INSTITUTIONS

Information system for management of maintenance of medical equipment in health institutions is a powerful tool that can improve the overall management of medical equipment (medical devices) at the level of a health institution [12, 13, 28]. The information included in such a system varies, but regularly includes medical equipment inventory [14] and typically includes information such as: maintenance services evidences, PM and CM procedures, mandatory equipment for maintenance of medical devices, maintenance personnel training records, list of maintenance personnel with qualifications and data on experience in the maintenance of certain medical devices, a list of service providers with whom the health institution cooperates and records of the success of their interventions, maintenance costs...

Information system for management of maintenance of medical equipment in health institutions in Serbia:

- would connect health institutions with each other,
- enabled fast and safe exchange of data and information related to the maintenance of ME,
- enabled optimal maintenance of ME in healthcare institutions,
- increased the availability of this equipment, especially high-tech equipment,
- significantly reduced the total cost of maintaining ME (of the order of 30%, i.e. over 20,000,000 \$).

One of the main reasons for the unsustainability of the existing approach to the maintenance of ME in the healthcare institutions of Serbia is that each healthcare institution independently takes care of the maintenance of its own ME.

This approach is expensive and significantly affects high maintenance costs.

In order to change this approach, we need a completely up-to-date database of medical equipment<sup>1</sup> that is located in the healthcare institutions of Serbia.

The next step is to create a complete database of technical personnel employed in the medical equipment maintenance units in Serbian health institutions. For each individual in this database, there should be information about his ability to maintain specific medical equipment. So, when there is a problem of fixing a malfunction of some medical equipment in a certain medical institution, the names, as well as other necessary data, of qualified engineers/technicians who can fix the malfunction would be obtained from this database.

This approach also implies the centralized procurement of spare parts for certain medical equipment, which could lead to:

- significant reduction of medical equipment maintenance costs and
- reduction of medical equipment unavailability time due to failure.

This approach would also ensure the engagement of qualified independent service organizations in cases where there are no technical personnel in our health institutions who can eliminate a specific malfunction that occurred on specific medical equipment. Normally, this implies the existence of a database of all independent service organizations for the maintenance of medical equipment operating in Serbia. This database would contain all the necessary information about each independent service organization.

Normally, this approach implies the existence of test devices in health institutions for testing the correctness of the operation of complex or risky medical equipment. Also, locating the failure of medical equipment can be done remotely by the medical equipment manufacturer, if this obligation of the equipment manufacturer is specified in the equipment pur-

<sup>&</sup>lt;sup>1</sup>As stated in Ref. [11]: "What is medical equipment? Medical equipment are defined as medical devices requiring calibration, maintenance, repair, user training and decommissioning – activities usually managed by clinical engineers." Also in Ref. [11]: "What are medical devices? Brief definition: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means."

chase contract (it is advised that when concluding the contract, it should be stated that this obligation refers to the entire lifespan of the purchased medical equipment).

Normally, this approach implies the existence of test devices in health institutions for testing the correctness of the operation of complex or risky medical equipment. Also, locating the failure of medical equipment can be done remotely by the medical equipment manufacturer, if this obligation of the equipment manufacturer is specified in the equipment purchase contract (it is advised that when concluding the contract, it should be stated that this obligation refers to the entire lifespan of the purchased medical equipment).

# 5. INFORMATION SYSTEM SPECIFICATIONS

The maintenance system of medical equipment used in a health institution, first of all, must be well documented in accordance with the requirements of international ISO management standards [29].

We emphasize: a documented system, not a system of documents. Basic documents in the medical equipment maintenance system are: procedures and documented information [15-20].

The procedure formulates how some (complex) maintenance process should be performed step by step.

Documented information refers to all important (vital) information within the maintenance system that must be maintained, controlled and periodically evaluated in an organized manner.

Database specifications are made on the basis of documented information, and information system specifications are made on the basis of procedures.

Regarding maintenance system procedures, we recommend, as a minimum, the following procedures:

- Internal quality control of medical equipment,
- Maintenance of medical equipment,
- Management of spare parts storage [27],
- Management of maintenance equipment,
- Monitoring and evaluation of manufacturers / suppliers of medical equipment,
- Complaints to manufacturers / suppliers of medical equipment,
- Contracting for the maintenance of medical equipment,
- Training of medical equipment users,
- Training of medical equipment repairers.

Regarding documented information necessary to support the operation of maintenance processes, we recommend, as a minimum, the following:

- Record of receipt of medical equipment,
- Record of medical equipment with all information about the equipment necessary for the comprehensive analysis of maintenance activities in order to improve maintenance,
- Carton of medical equipment,
- Carton of maintenance equipment,
- Plan of maintenance of medical equipment,
- Record of failure of medical equipment,
- Report of failure of medical equipment,
- Report on maintenance and condition of medical equipment,
- Report on the condition of the spare parts warehouse,
- List of approved manufacturers/suppliers of medical equipment,
- Complaint to the manufacturer / supplier of medical equipment,
- Complaint report to the manufacturer / supplier of medical equipment,
- List of medical equipment service providers
- Records of training of users of medical equipment,
- Records of training of medical equipment repairers.

# 6. APPLICATIONS OF INDUSTRY 4.0 TECHNOLOGIES

Industry 4.0 and its main enabling information and communication technologies are completely changing both services and production worlds.

This is especially true for the health domain, where the Internet of Things, Cloud (and Fog) Computing, and Big Data technologies are revolutionizing eHealth and its whole ecosystem, moving it towards Healthcare 4.0 [30, 31].

The database for the ME maintenance management contains a huge amount of data and information. Therefore, when designing an information system for ME maintenance management, INDUSTRY 4.0 technologies, such as: Cloud Computing, IoT, Big Data, should be considered.

Here we also emphasize the great importance of the security of data, information and documents in the Information System for the maintenance management of medical equipment. The majority of the present IT security solutions are based on binary algebra. Particularly interesting is the research that is being done here in Serbia, which led to the development of a static absorber, based on binary algebra, which is capable of neutralizing any signal either in the physical or virtual domain. Dynamic version of absorber is still under development.

#### 7. CONCLUSION

Experience shows quite clearly that only a wellbalanced mix of in-house and external maintenance and repair services of medical equipment in any health institution leads to results that are both technically and financially satisfactory in settings with limited resources.

Experience also shows that maintenance units in health institutions in Serbia usually do not have adequate documentation (procedures ...) for work.

In order for a healthcare institution to have an effective computerized maintenance management system, the maintenance system for medical equipment used in any healthcare institution, first of all, must be well documented in accordance with the requirements of international ISO management standards.

We propose that, under the supervision of the MoH, the above-mentioned procedures and documented information should be written by a multidisciplinary expert team and that such 'sample' documentation should be distributed to all health institutions in Serbia.

This "sample" documentation should be the basis for the development of a computerized management system for the maintenance of medical equipment, which would also be developed by our experts. This information system should also be available to all medical institutions in Serbia.

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## REZIME

### SPECIFIKACIJE MODERNOG INFORMACIONOG SISTEMA ZA ODRŽAVANJE MEDICINSKE OPREME U ZDRAVSTVU

Efikasan menadžment održavanjem medicinske opreme (ME), posebno visokotehnološke, jedno je od glavnih pitanja za kvalitet zdravstvene zaštite, za pružanje isplativih zdravstvenih usluga i za uštedu, čak i u razvijenim zemljama, nedovoljnih resursa. Održavanje medicinske opreme (EM) obuhvata sve aktivnosti koje se odnose na obezbeđivanje adekvatnog nivoa usluge i ograničavanje zastoja medicinske opreme u zdravstvenoj organizaciji. Tradicionalno, EM se kategoriše kao preventivno održavanje (PM) i korektivno održavanje (CM). Princip PM-a je predviđanje. PM može biti plansko i prediktivno, tj. Just-In-Time (JIT) održavanje (blagovremeno održavanje). Prediktivno održavanje se može primeniti samo na nove visokotehnološke medicinske uređaje koji imaju ugrađeno samotestiranje.

Plansko preventivno održavanje se sprovodi u skladu sa planom održavanja za određeno vreme. Po pravilu, pri izradi plana sledimo preporuke proizvođača za preventivno održavanje ME date u tehničkoj dokumentaciji ME, posebno u uputstvu za održavanje ME.

Prediktivno ili JIT održavanje omogućava otkrivanje i rešavanje problema pre nego što se problemi i nepredviđeni događaji zaista pojave, a to se radi na osnovu inteligentnog praćenja i analize stanja ME u pravom trenutku, čime se obezbeđuje optimalno vreme za intervenciju, tako da se održavanje obavlja samo po potrebi.

Informacioni sistem za upravljanje održavanjem ME u zdravstvenim ustanovama bi međusobno povezao zdravstvene ustanove i omogućio brzu i sigurnu razmenu podataka i informacija u vezi sa održavanjem ME i omogućio optimalno održavanje ME u zdravstvenim ustanovama, povećavajući dostupnost ove opreme, posebno visokotehnološke opreme, uz značajno smanjenje ukupnih troškova održavanja ME (reda 30%).

Jedan od osnovnih razloga neodrživosti postojećeg pristupa održavanju ME u zdravstvenim ustanovama Srbije je taj što svaka zdravstvena ustanova samostalno brine o održavanju svoje ME. Ovaj pristup je skup i značajno utiče na visoke troškove održavanja. Ovaj pristup treba da se promeni.

Ključne reči: održavanje, informacioni sistem, zdravstvena ustanova, troškovi, optimizacija