PROCESS OF DIAGNOSIS AND ANALYSIS OF ATTRIBUTES OF MAINTAINABILITY IN MEDICAL AND HOSPITALAR DEVICES

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Abstract. *Medical hospital devices (MHD) are used for health care and operated by health professionals in the hospital area. These devices are used in diagnosis and monitoring of the patient. In the last three decades, a growing development in health area technology has been observed. Such equipment is often diverse, expensive and complex, because it incorporates several hardware and software technologies and has become more and more necessary to the activities of heath care establishments (HCE). MHD must offer a minimal level of guaranteed function, including reliability and maintainability, for the whole process to achieve a satisfactory result and accomplish their function. This paper presents a process of diagnosis, identification and analysis of data for the maintainability variable of MHD, to provide information for the development of new devices, to improve existing ones and to facilitate the operator's work. The purpose is to offer a system for identifying a maintainability that can be observed at the moment of acquiring the device. The model of analysis is based on fuzzy logic, with the possibility of considering qualitative and quantitative aspects. The analysis system must supply results in the purchase, operation and MHD maintenance fields, increasing, thus, availability of these kinds of equipment.*

Keywords: *Maintainability, medical equipment, fuzzy logic.*

1. INTRODUCTION

Starting from the beginning of the 1950s, an increasing application of technology has occurred in the healthcare area, resulting in greater sophistication, complexity and the proliferation of technology in medical equipment. The healthcare system seeks to improve the quality of its services for the population; however, the intensive use of technology can cause a marked concern regarding costs with safety and reliability, and subsequently with the maintenance of medical equipment (BIT04, 2004).

Medical equipment includes systems employed in healthcare practice, which are typically multi-user, being operated by physicians, nurses and physiotherapists. These usually carry mechanical, electrical, electronic, hydraulic and pneumatic mechanisms, structures and software.

According to Bergamo Filho (1997), the work in the healthcare system is more and more concerned with medical equipment in which the incorporation of reliable technology tends to prevent failures, their effects and the consequences of these failures.

According to Back (1983), there are some basic requirements related to the operation of the equipment during its life cycle; that is, when the equipment is used, it is necessary to analyze the conditions and events which affect the equipment, taking into consideration: transportation, installation, assembly, tests, use, failure conditions and maintenance. Under failure conditions it is necessary to evaluate the ease of controlling failure and indication of proper corrective actions. The failure of medical equipment can originate from improper operation and handling, or failure of the equipment itself. Regardless, if a failure occurs during the operation of the equipment, it can cause accidents to the operators and patients. This directly affects the treatment, resulting in injury or even death.

Failure of the equipment can occur at the outset of the operation due to project, manufacturing or transportation problems. This is called youth failure and has significant economic consequences for the buyer. In the healthcare system, the demand for medical equipment is driven by urgent necessity. Youth failure causes great frustration to healthcare agencies, patients, and the society which finances the equipment. The critical nature of this situation increases because most of the time, there is no sufficient qualification for operation and maintenance of the equipment.

The unavailability of the equipment causes waste of time in the negotiation and definition of who will bear the cost of the failure. This maintainability aspect is not clear to the manufacturer and user, and it is usually not addressed in the equipment's handbooks, purchasing contract, training, packing, transportation, unpacking, assembly, tests, commissioning and final set-up.

In the normal phase of use, failure is called random and originates from the project or process. It is probably an operation failure due to operational problems, overload, or unknown random events. An appropriate maintainability for this phase is revealed in handbooks and qualification plans for the operation and maintenance of the equipment. In case of maintenance, the work plan must make explicit the execution of corrective, systematic preventive and predictive maintenance. At the end of the equipment's useful life failure shows gradually, presenting effects in form, such as wearing, fatigue, noise, vibration, temperature increase, smell, color loss, image definition loss, etc. In this case, the consideration of maintainability will indicate a process of deterioration, signaling the need for substitution, in order to avoid the failure condition from reaching complete failure and impeding the functioning of the equipment (DIAS, 2006).

This paper presents a process of diagnosis and identification of maintainability parameters. The process of analysis uses fuzzy logic, an appropriate tool for considering qualitative and quantitative variables. The maintainability analysis focuses on the phase of acquisition of medical equipment.

2. MAINTAINABILITY

Maintainability, according to the MIL-STD-470-B (1989); MIL-STD-470-A (1997) and MIL-HDBK-472 norms (1984), is a characteristic that must be considered in the project phase and subsequently in the installation phase of a product. It shows how a system, subsystem or component behaves in specified conditions, in terms of probability, within a given period of time, when the maintenance is carried out in accordance with prescribed resources and procedures.

In Brazil, the norm which defines maintainability is the NBR 5462 (ABNT, 1994), for which maintainability means the ease of maintaining or restoring the equipment's functioning under specified use conditions and according to prescribed procedures and means.

Dias (1996) addresses maintainability as a function M(t) where t is the random variable related to the life cycle, and indicates the probability of putting the component, equipment or technical system back in operation in time (t), specified in the manufacturer's catalog. The time t indicates the probability of restoring the necessary conditions to operate in the "as good as new" condition.

The time $t_1>t$ is the variable required for the determination of the non-maintainability, that is, the time required beyond that predicted.

The maintainability function can also be used in order to return to operation in the condition "not so good as new", also called "as good as old". In this context a question can be asked: what can influence the maintainability function?

In order to correlate maintainability with the action of corrective maintenance one can consider ergonomics, since it helps in the access definition, tool form, and colors. But we also have to take into account the time taken to identify the cause, logistics to replace the item in failure, the cost of the failure, type of repair, and sequence of assembly. These elements will contribute to determining the mean time to repair (MTTR). This time is an important reference to obtain the repair rate which will enable the calculation of maintainability. A similar approach can be developed to the action of systematic preventive maintenance and predictive maintenance.

Maintainability influences the quantity and necessity of maintenance, average time of service, predictability, availability, operational regularity, cost, effectiveness, and it allows an easier maintenance or repair of an item (PATTON, 2005; BLANCHARD *et al.*, 1995).

According to Alvarez (2001), a more appropriate and updated definition must include characteristics of the project, logistics, labor, cost, ergonomics, safety and environmental impact.

Maintainability is related to factors of quality and productivity of the equipment. Quality is directly associated with maintainability, technical assistance and functionality demands. Productivity is linked to the reduction of equipment waste or unavailability.

The study of maintainability is essential due to technological advances and the complexity of modern and high performance equipment. When the maintainability attribute is not considered in the development of equipment, products or systems, the cost of maintenance becomes higher due to delays and the complexity of intervention.

According to Williams and Lemoine (1989), the costs of maintenance operations in the field are immediately identified by the maintainability condition. In order to increase the product's maintainability it is necessary to increase the logistical support, the effectiveness, and the system's value as well, and decrease the cost of maintenance, in accordance with Figure 1.

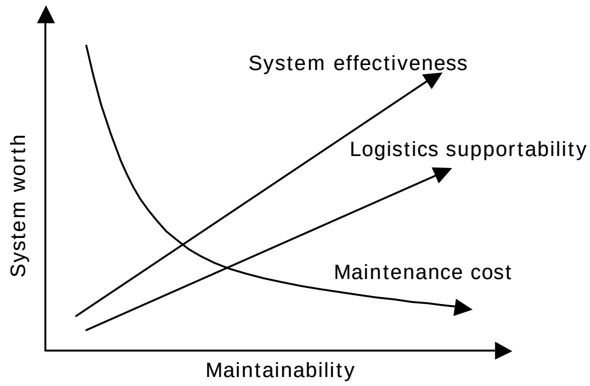


Figure 1. Relation between maintainability and total value of the system (WILLIAMS and LEMOINE, 1989).

Maintainability is an attribute of a product’s development project. In fact, it is necessary to consider it from the phase of product planning and project process planning. During the process of the project, in the informational phase, it must be part of the requirements of the user, and with QFD (Quality function Deployment) it must become a requirement of the project. It is an important attribute of the conceptual phase as well, and can influence the decision on the concept of the product, for example, in the use of a morphological matrix.

The process to select the concept which will be developed in the other phases of the project, that is, in the preliminary and detailed project of the product, is initiated with the creation of concepts for the product.

In order to select the created conceptions, (OGLIARI and BACK, 2000) propose a method of valuation of concepts which takes into account the clash between requirements of the project and the qualities of the concept. The qualities of the concept – functionality, projectability, moldability, etc – correspond to their “abilities”, that is, adequacy in a given life cycle process. The evaluation of conceptions takes place during the combination of principles of solution in a morphological matrix.

In the preliminary project phase the attribute induces the planner to plan assays, tests, verifications of assembly/disassembly, life assays, tools, communication with the operator and maintainer, and others. In the detailed project all the communication is visualized by drawings in order to orientate the manufacturing, final tests and commissioning, planning of packages, colors, handbooks, qualification, sensors inclusion, development of tools, alert of operational security and maintenance, and others.

3. MEDICAL EQUIPMENT

Medical equipment is used in hospitals, clinics, rehabilitation centers, etc. The aim of the equipment is to render a service in the healthcare area, providing support with quality, effectiveness and efficiency, and sometimes assuring the patient’s life. Such equipment can be found throughout the healthcare system, from a simple thermometer to complex tomography equipment, as well as systems for radiotherapy, anesthesia and others. Most of them are used in medical procedures in order to provide parameters to help diagnosis, to assure the life of patients or to overcome health deficiencies.

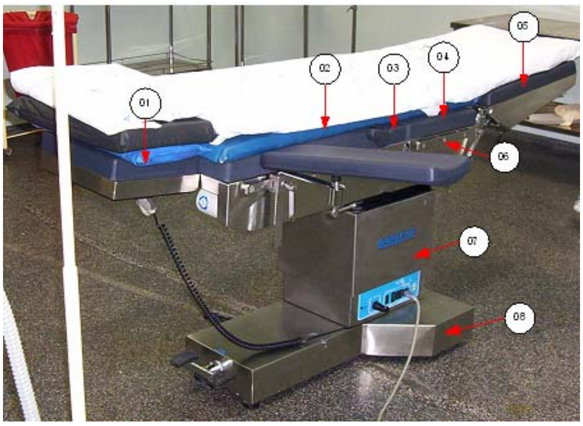
The National Health Surveillance Agency – ANVISA, presents the classification of medical equipment in Decree nº. 686, of 27 August 1998 (ANVISA, 1998), which includes: diagnostic equipment, therapeutic equipment, and medical support equipment.

Figure 2 illustrates a piece of medical support equipment used in surgical procedures. Surgical tables[1] are specially designed to aid the particular and highly specialized demands of surgical therapy. Figure 2 identifies the devices and accessories of the surgical table.

The concern with medical furniture has fostered the development of modern models in order to ensure the safety of patients while providing an ergonomic positioning to surgeons and assistants.

Perioperatory professionals evaluate the potential risk of the surgical table in order to prevent any accident to patients and members of the surgical team.

[1] According to the norm NBR IEC 60601-2-46 (ABNT, 2000), a surgical table is a table that supports the patient during medical/surgical procedures.



01 – Head Support: part where the patient rests the head; this can move up and down.
02 –Back Support: part where the patient rests the back; this can move up and down.
03 –Renal Support: part where the patient rests the lumbar region next to the kidneys; this can move up and down.
04 –Seat: part where the patient sits.
05 – Leg Support: part where the patient rests the legs; this can move up and down.
06 – Chassis: part that allows the table's movements through an electrical or hydraulic system.
07 –Jacketed Column: part that allows elevation through an electrical or hydraulic system.
08 – Base Cover: part where the table is fixed through

Figure 2. Surgical table - Model BF 683 (BARRFAB, 2006).

Surgical tables can be adjusted for width and length, and can be extended sideways, on both sides, and horizontally, with the headboard and foot. They are divided in three or more sections, which support the main parts of the body and allow positioning in extension or flexion. The headboard section is usually removable, and a foot extension can be added. The headboard support is used in cranial and eye surgery. The mattress and arms support are covered with rubber to provide comfort to the patient and to facilitate cleaning. Any kind of alteration in surface, due to wear and fatigue of rubber covered parts must be eliminated and replaced by the corresponding parts. All devices for positioning and accessories of the surgical table must perform three functions: to absorb compressive forces, to redistribute pressure and to prevent excessive stretching (MEEKER *et al.*, 1995).

4. DIAGNOSIS AND ANALYSIS OF MAINTAINABILITY ATTRIBUTE IN MEDICAL EQUIPMENT

Despite the increase in the reliability of medical equipment, the clinical activity performed by operators (physicians, nurses, and others) is submitted to failure conditions which can occur during the functioning of the equipment. Sometimes failure is due to variables that can not be easily identified and controlled, since medical equipment is usually very complex, bearing electrical, electronic, mechanical, pneumatic and computational systems. Due to this complexity medical equipment can present different failure modes in accordance with the operational age. This fact demands the development of methodologies that improve the operation and maintenance of medical equipment, besides the continued training of operation and maintenance staff.

This study searched for information in healthcare institutions in order to carry out the diagnosis and analysis of maintainability. Medical equipment was identified and classified as support, therapeutic and diagnostic equipment. The initial identification allowed the classification of medical equipment and the verification of the user's opinion regarding the equipment's quality. Maintainability can already be evaluated in the identification phase through the consideration of some aspects of the equipment: number of repairs required during use; operational age; frequency of use; number of parts; as well as level of complexity: maximum, medium, minimum; and also through the existence of a self-test system.

The next step is the identification of systems of the equipment: mechanical, electrical, electronic, hydraulic, pneumatic and computational. Each system is composed of subsystems and components which present particular failure modes. In this phase, maintainability is assessed in function of: number of fixed and mobile parts, and ease of assembly/disassembly of fixed and mobile parts.

Considering the identification of subsystems and components of medical equipment, the analysis of maintainability is focused on interfaces, through the verification of aspects such as: connection between mobile and fixed parts; accessibility for maintenance; visibility; position of assembly and disassembly. The last phase is the identification of components of the subsystem.

Figure 3 shows the proposal of maintainability analysis through the determination of maintainability indicators. These indicators, along with quantitative data, such as time of maintenance, time of service, when the system becomes available, cost, etc, will be used to accomplish the analysis of maintainability of medical equipment. This analysis will employ fuzzy logic in order to determine a maintainability index.

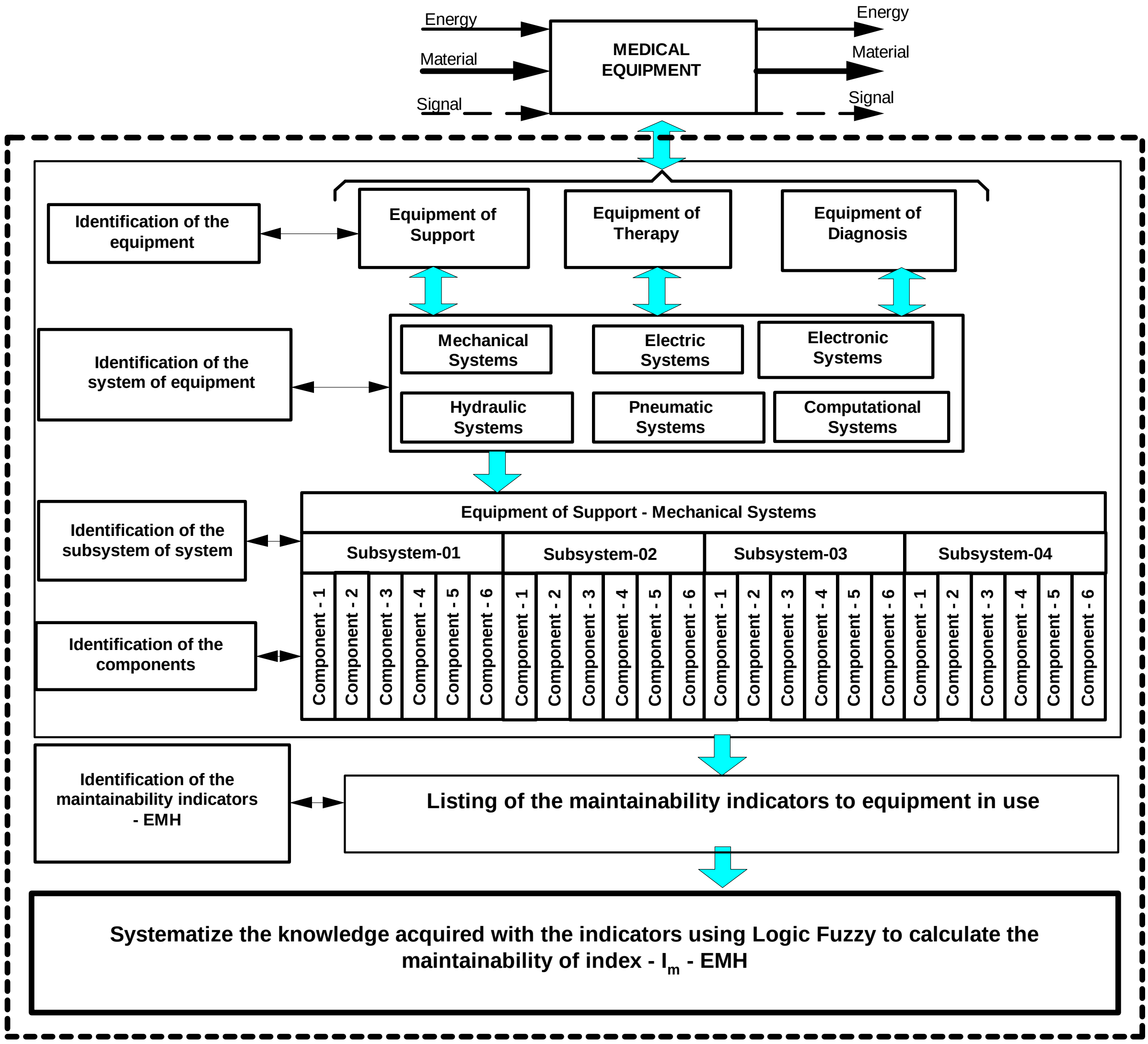


Figure 3. Chart model methodology to obtain the maintainability indicators of medical equipment (CARMO, 2006).

Fuzzy logic is an approach used to construct mental models which incorporate experience (heuristics) and human intuition in order to elaborate verbal models which describe dynamic patterns for highly complex systems or systems not completely known.

Fuzzy logic modeling is a linguistic structure capable of mixing verbal rules information, numerical data or other information. Therefore, a fuzzy logic system is a mechanism for reconciliation of mathematical modeling and human knowledge. It is applied mainly in the engineering field in order to analyze dynamic systems and diagnosis, control or decision systems (ARAÚJO FILHO, 2004).

Slavila *et al.* (2005) applied the fuzzy approach to evaluate the maintainability process in complex products. Fuzzy linguistic variables were employed to represent and treat data in the process of the project. The main reason for the employment of fuzzy logic principles to evaluate maintainability is the imprecision and uncertainty inherent to project data at the outset of the development process. In this phase, specifications and necessities of the project are changeable and the description of the project is incomplete. The measure of maintainability of the product or maintainability index can be expressed by a fuzzy numerical value, calculated according to the weighted mean of values of criterions used in the evaluation.

Figure 4 shows the model of maintainability analysis in medical equipment through fuzzy logic, where the inputs are the maintainability indicators listed in Figure 3.

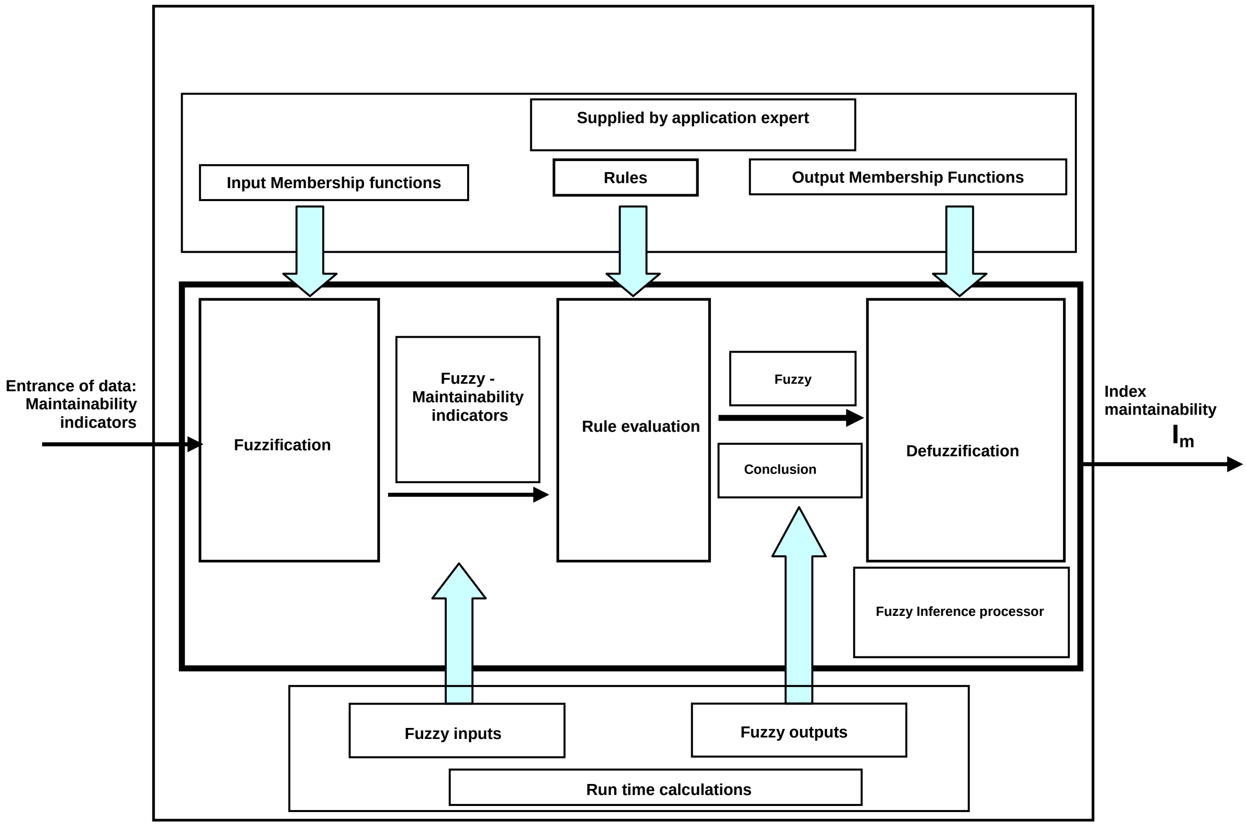


Figure 4. Overview of the model of maintainability analysis in medical equipment through fuzzy logic (BOWLES and PELÁEZ, 1995).

Figure 4 shows the model of analysis of maintainability through fuzzy logic. Fuzzy logic is derived from fuzzy set theory. Fuzzy set theory uses the concept of fuzzy set membership (i.e. *how much* a variable is in a set). Fuzzy logic allows for set membership values to range between 0 and 1, and in its linguistic form, imprecise concepts like “very high”, “high”, “low”.

Membership functions are constructed as combinations of IF-THEN rules which operate over base rules which are derived from the expert’s knowledge. The membership function is a graphical representation of the magnitude of participation of each input. It associates a weighting with each of the inputs that are processed, define functional overlap between inputs, and ultimately determines an output response. The rules use the input membership values as weighting factors to determine their influence on the fuzzy output sets of the final output conclusion. Once the functions are inferred, scaled, and combined, they are defuzzified into a crisp output which drives the system (KAEHLER, 2006). This output is a maintainability index.

Considering the membership values, some of the rules can be expressed as the following:

- If failure detection is very hard and easiness of component exchange is reasonable then maintainability index is high.
- If failure detection is very hard and easiness of component exchange is excellent then maintainability index is medium.
- If failure detection is medium and easiness of component exchange is very good then maintainability index is low.

The systematization achieved by the diagnosis and analysis of maintainability attributes is extremely important to help decision making regarding the acquisition of medical equipment. The purpose is to create a database to organize functions such as: failure modes, effects, utility level, and maintenance action, which will help professionals in the healthcare area and other areas, by providing assistance in the development of new equipment.

5. CONCLUSION

This study proposes systematization in order to evaluate maintainability in medical equipment. It highlights the importance of analyzing maintainability parameters, which can provide subsides for the acquisition of new equipment, improvement of current equipment, facilitating the training of maintainers and operators. This research will utilize fuzzy logic as a tool which allows the inclusion of quantitative and qualitative data in order to construct a model for the diagnosis and analysis of maintainability in medical equipment.

This study considers the maintainability aspects to be as important as the financial and technical aspects to the acquisition and use of medical equipment. The inclusion of maintainability aspects can contribute to increasing the quality of medical equipment, and to improving services rendered by healthcare professionals.

6. ACKNOWLEDGEMENTS

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