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EXECUTIVE SUMMARY OF THE THESIS

Medical Equipment Technological Assessment at ASST Fatebenefratelli-Sacco

TESI MAGISTRALE IN BIOMEDICAL ENGINEERING – INGEGNERIA BIOMEDICA

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Introduction

Nowadays, the management of electromedical equipment plays an increasing role in ensuring the efficiency and safety requirements of a health care facility. The present thesis work was developed at the Azienda Socio-Sanitaria Territoriale (ASST) Fatebenefratelli-Sacco in Milan and aims to implement a tool capable of capturing the urgency of replacement for electromedical equipment, in order to be able to monitor its functional status in real time. This study provides a strategy based on internal data from ASST Fatebenefratelli-Sacco and it aims to build a strong technology management instrument based on its specific needs, but it is easily adaptable to other public facilities in the Lombardy region. The ultimate goal of this project is to implement thoughtful choices in terms of investment and purchasing, in order to optimize the use of resources; therefore, once identified the major issues, a purchase plan has been elaborated for the resolution of the main problems present in the ASST.

1. Purpose of the study

The developed project is part of a group of activities aimed at innovation and rationalization of processes within the company. In the post-pandemic period of Sars-Cov-2, in fact, it has emerged the need to have supporting tools to help decision makers for the hospital management. These are increasingly directed towards the world of information technology. In this regard, several working tables operating on different fronts were inaugurated, developing interesting projects aimed at improving the treatment path. The purpose of this thesis is to illustrate the strategies undertaken regarding the objective planning of investments and purchases of medical equipment, in order to ensure an increasingly profitable efficiency and safety of the service. The goal is therefore the search for total harmony between health and decision-making bodies, providing for the involvement of nurses, active engine of hospitals, and doctors, to outline a shared strategy of technological modernization and better use of the resources offered by the Piano Nazionale di

Resistenza e Resilienza (PNRR). The common guideline of the Medical Direction is the search of ad hoc models for the ASST, that therefore they are not simply a valid contribution to the scientific research but useful to the Company and shared by all the actors involved in the operating processes, in the total conviction that only the communion of intentions can lead to the achievement of valuable goals. These were pursued through the implementation of a priority replacement index (RPI) that, although it is based on a careful analysis of the literature available on the subject, departs from it in relation to the needs of the ASST. This index consists of two distinct parts: first, an index has been created called internally "Technical" RPI, resulting from the weighted sum of technical parameters. This first construct serves as a filter for the identification of the equipment on which it is necessary to place an additional focus for the evaluation of the substitution. To implement an effective replacement plan and use the resources to purchase the necessary equipment, the second step of the work is focused on the direct involvement of users, namely medical and nursing professionals, to calculate the "Clinical" RPI. In this regard, thanks to the collaboration of internal experts in the hospital, a questionnaire was created to be submitted to employees to prioritize the urgency of renewal of the instrumentation on the basis of work activity.

2. State of Art

The first recognized work about an objective management strategy of electromedical equipment replacements is due to L. Fennigkoh. In 1992, he developed a replacement priority index model that still represents the basis for the implementation of innovative algorithms. The index is based on seven evaluation parameters for each device, each with its respective weight. [1]
Since then, there has been an increasing tendency for health agencies to use such tools; therefore, 41 articles from Pubmed or Scopus have been investigated. After evaluating the papers, it was chosen to use as the main inspiration model the RPI created by Ing. Elena Milani at Humanitas Research Hospital in Milan. This index consists of 10 indicators, which are shown in Table 1. and it is characterized by both objective and subjective parameters, such as technical adequacy and clinical fitness. Therefore, although there is no real conception of an RPI based on the opinion of users, the author entering these subjective parameters opens the way to strategies that integrate objective assessments with those of health professionals.
From this work, the subdivision of the values that the various parameters can assume has been resumed; in fact, each of it is worth 0, 0.5 or 1. The use of three beams to evaluate the parameters makes mathematical processing easier and allows a robust analysis of the different levels of criticality that a device can show in a specific evaluation criterion. [2]

METRIC	PARAMETER DESCRIPTION	ASSUMED VALUE	NOTES
X1	AGE	0; 0,5; 1	ASSIGNED WRT AN AVERAGE THRESHOLD VALUE OF THE CLASS
X2	FUNCTIONAL STATUS	0; 0,5; 1	
X3	SPARE PARTS AVAILABILITY	0; 1	
X4	DEGREE OF USE	0; 0,5; 1	
X5	CRITICALITY	0; 0,5; 1	
X6	RELIABILITY	0; 0,5; 1	ASSIGNED WRT AN AVERAGE THRESHOLD VALUE OF THE CLASS
X7	AVAILABILITY	0; 0,5; 1	ASSIGNED WRT AN AVERAGE THRESHOLD VALUE OF THE CLASS
X8	CLINICAL FITNESS	0; 0,5; 1	
X9	TECHNICAL ADEQUACY	0; 0,5; 1	
X10	MAINTENANCE COST	0; 0,5; 1	ASSIGNED WRT AN AVERAGE THRESHOLD VALUE OF THE CLASS

Table 1. RPI by Eng. Milani [2]

From the intuition of Eng. Milani to assign the thresholds of the various parameters based on an average value per class of equipment, was extrapolated one of the key concepts at the basis of the index implemented at ASST Fatebenefratelli-Sacco; the thresholds have been attributed since the historical of the maintenance interventions and the strategic choices undertaken within the structure to create an ad hoc model.
Milani's work attributes the same importance to each criterion in calculating RPI. In this project, the definition of the weights attributed to the parameters involved in the technical and clinical RPI has been implemented following the operating mode adopted by the Lombardy Region for the Regional Health Technology Assessment model, collecting expert opinion on the relative importance of the various criteria. [3]

3. Materials and Methods

The starting point for the analysis is the Coswin portal. It represents the Computerized Maintenance Management System (CMMS) at the ASST, from which the necessary information has been extracted. It has been provided by the Global Service and collects data about the equipment in dowry to the hospital. In addition, another feature of Coswin is the ability to store inside the historical maintenance carried out on the fleet. All the data of interest, related to the equipment registry and maintenance carried out in the last year, have been extrapolated and unified on an Excel spreadsheet. This calculation instrument allowed to compute at first the Technical RPI, which was then implemented on the company CMMS, as the call for the award of the service for the management and maintenance of medical equipment places the obligation on the part of the Global Service to make available to the institution such a tool.

TECHNICAL RPI CRITERIA	WEIGHT 1° STEP	WEIGHT 2° STEP
AGE	0.17	0.13
END OF SUPPORT	0.19	0.15
CRITICALITY	0.23	0.20
AFFIDABILITY	0.20	0.16
UPTIME	0.21	0.17
PRESENCE OF OTHER EQUIPMENT OPERATING IN THE SAME DEPARTMENT	/	0.19

Table 2. Technical RPI

Table 2. shows the parameters included in the calculation of the Technical RPI and the respective weights. A first step is implemented by calculating an RPI for each equipment considering only the first 5 indicators. At this point, the algorithm inserts a sixth parameter. It evaluates the number of devices of the same type working in a department. In fact, the number of equipment needed for each department of the ASST has been defined through comparison with the departments and the creation of "standard equipment" for the type of service offered. Therefore, the amount of equipment with RPI below the threshold defined as the necessary replacement alert is considered and, based on the comparison with the number set as standard, the technical RPI is recalculated.

CLINICAL RPI CRITERIA	WEIGHT
DEGREE OF RISK DERIVED ON THE PATIENT/OPERATOR	0.19
FREQUENCY OF USE	0.10
FUNCTIONAL STATUS	0.08
CLINICAL ADEQUACY	0.23
FAILURE CAUSED BY THE ABSENCE OF THE DEVICE	0.10
LEVEL OF TRAINING BY OPERATORS	0.06
DEGREE OF TECHNOLOGICAL INNOVATION	0.11
AVAILABILITY OF OTHER ALTERNATIVE EQUIPMENT	0.13

Table 3. Clinical RPI

Once the technical RPI has been calculated, the focus is only on equipment with an above-threshold value. For these, the Clinical RPI is calculated, composed of the parameters in Table 3. It was carried out by administering a questionnaire to health care professionals. The weights are assigned to obtain criteria of relative importance that fully reflect the structure. Various decision-making bodies of the ASST were asked to give their opinion on the relevance of the variables described above by filling in a Microsoft Forms module. In it, each criterion was summarized in a sentence, so that these could sort them by importance in relation to their accumulated experience during the years of work.
The weights have been normalized so that the total sum is equal to 1 and the values assigned to the parameters resume the setting of the Milani's RPI.
The definition of acceptability thresholds for RPI was also fundamental.

RPI < 0.5: the equipment does not need intervention.
$0.5 \leq$ RPI ≤ 0.7: the equipment must be monitored in the short.
RPI > 0.7: the equipment needs urgent replacement.

Ultimately, after appropriate tests and validations, it was decided to outline the final ranking as the weighted sum of the two indices, assigning a slightly greater coefficient to the Technical RPI. In this way, it is possible to reduce any biases due to the willingness of clinicians to replace equipment even if not necessary.

$$IPS = 0{,}55 * IPS_T + 0{,}45 * IPS_C$$

4. Results

Once the calculation algorithm was implemented, it was used to define the technical RPI value of all equipment installed at the ASST.

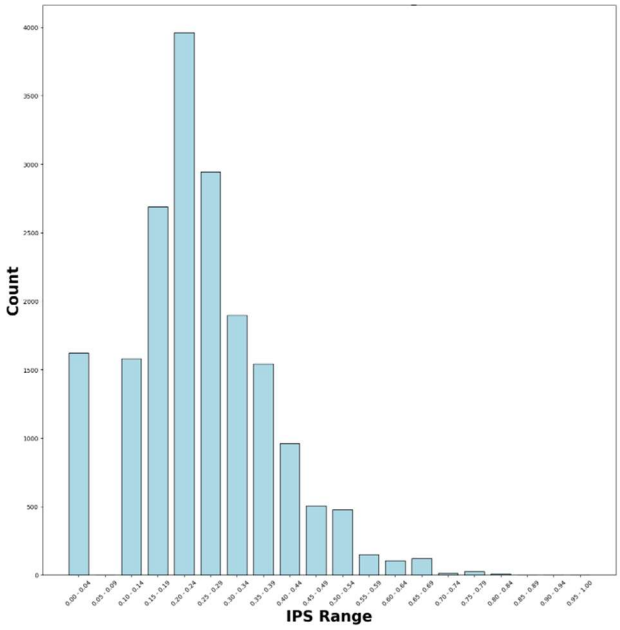

Figure 1. Devices' Count by RPI

In figure 1, the number of equipment showing a certain value of Technical RPI is shown. To sum up, out of a total of 18614 equipment, 925 should be used for further investigation. Of these, 91 are in urgent need of replacement.

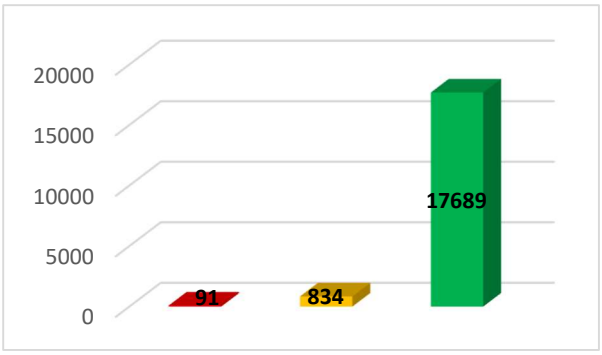

Figure 2. RPI Count

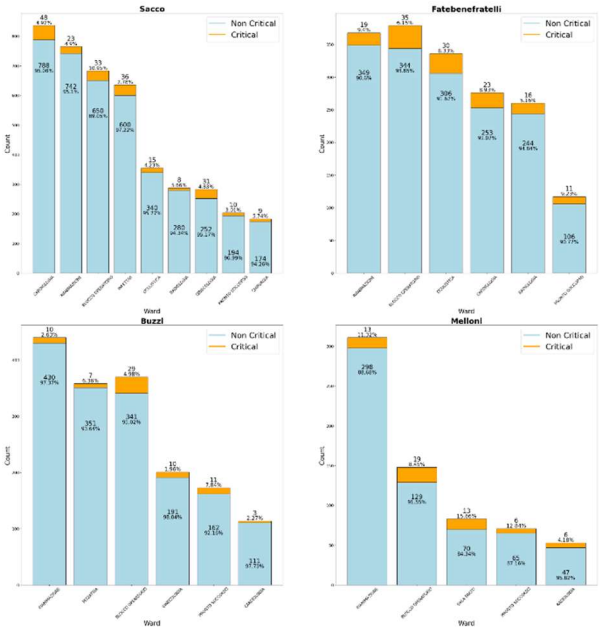

Figure 3. Critical Devices Proportion per Hospital

An analysis was carried out on the various departments, so that we could have insight into what they were in the most critical conditions. In Figure 3, you can view the results of this analysis, with the percentage of equipment that have a technical RPI to be treated.
In Figure 4, the number of equipment belonging to each criticality class has been counted for each criterion to understand what are the factors that cause the most urgent replacement.

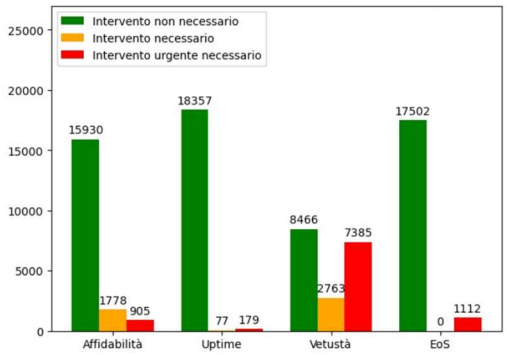

Figure 4. Analysis of technical RPI criteria

Once calculated the technical RPI for all equipment, interviews were arranged to validate the model and to have a complete view of the installed park to elaborate the renewal strategy. 38 departments were questioned for a total of 211 questionnaires collected for 258 devices.

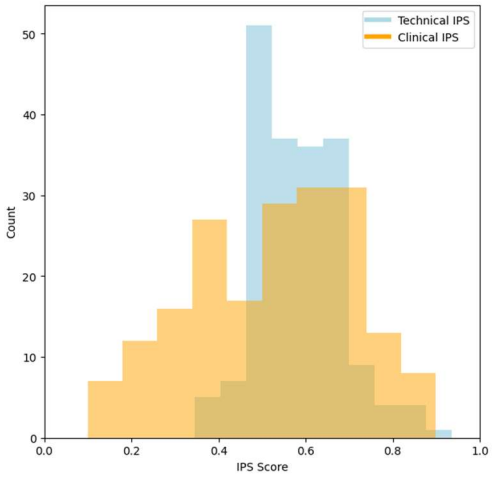

Figure 5. Technical RPI VS Clinical RPI

In Figure 5, the comparison between Clinical RPI and Technical RPI is represented, in which it can be noticed a prevalent leptocurtosis of the Technical RPI, against the evident platicurtosis of the clinician, which is therefore reflected in a greater variance in the distribution.
For the 91 devices whose Technical RPI value required urgent replacement, it was calculated for all Clinical RPI. For 58 of them, the Clinical RPI confirmed the urgency of substitution, for 22 reported a value of attention and for the remaining 11 it emerged that substitution is not actually necessary.
In Table 3, you see the ranking obtained after the weighted sum of the two RPI.

SIC	DESCRIZIONE TIPOLOGIA CIVAB	CODICE PRESIDIO	DESCRIZIONE REPARTO DI UBICAZIONE	IPS TOT
0001954	LAVAPADELLE	SACCO	CHIRURGIA GENERALE	0,94
0002373	MICROSCOPIO OTTICO	FBF	MICROBIOLOGIA	0,88
0001245	ECOTOMOGRAFO	SACCO	CARDIOLOGIA - DEGENZA	0,86
0003628	LETTO DA PARTO	M_MELL	SALA PARTO	0,84
0003803	LETTO DA PARTO	SACCO	SALA PARTO	0,83
0001018	DEFIBRILLATORE	M_MELL	GINECOLOGIA - REPARTO	0,81
0002410	DEFIBRILLATORE	FBF	NEFROLOGIA E DIALISI	0,78
0017825	ARTROSCOPIO	FBF	SALE OPERATORIE	0,78
0004016	TRAVE TESTA-LETTO	BUZZI	PRONTO SOCCORSO	0,78
0015407	CENTRALE MONITORAGGIO	SACCO	PEDIATRIA - PATOLOGIA NEONATALE	0,77
0001110	DEFIBRILLATORE	M_MELL	PUERPERIO - REPARTO	0,75
0004007	TRAVE TESTA-LETTO	SACCO	PRONTO SOCCORSO	0,74
0004008	TRAVE TESTA-LETTO	SACCO	PRONTO SOCCORSO	0,74
0004009	TRAVE TESTA-LETTO	SACCO	PRONTO SOCCORSO	0,74
0003656	AUTOCLAVE	BUZZI	SALA PARTO	0,74
0014200	SPETTROFOTOMETRO	FBF	ANATOMIA PATOLOGIA	0,74
0003801	LETTO DA PARTO	SACCO	SALA PARTO	0,72

Table 3. Total RPI

5. Discussion

From the analysis of the results, it was possible to develop improvement strategies for the installed park, to act in a structured way and therefore make the best use of the available resources and ensure greater safety of the service.
The results show how the instrument can capture the urgency of replacing an electromedical device, through a multicriterial tool and using a multidisciplinary approach.
From the interviews with the departments, it has emerged as the Technical RPI is actually able to define what are the equipment to be replaced.
From the analysis of Figure 5, most of the critical equipment for Technical RPI has also been evaluated by clinicians as a necessary replacement. However, as the present work wanted to demonstrate, some of the equipment was instead excluded from the urgent replacement plan since, although no longer suitable for clinical practice, it is not used in the department. An other reason, can be that, also in presence of outdated and out-of-support communication, it continues to work in compliance with safety requirements and therefore, it is not a priority for staff to have an immediate alternative.
One of the most visible results, which demonstrates the achievement of the goal set, is that the Clinical RPI effectively acts as an additional filter to be able to make the best use of economic resources and not invest in equipment

not strictly necessary. To this end, a violin plot is reported in Figure 6, for 258 devices subjected to Clinical RPI, demonstrating the filter role of the latter instrument.

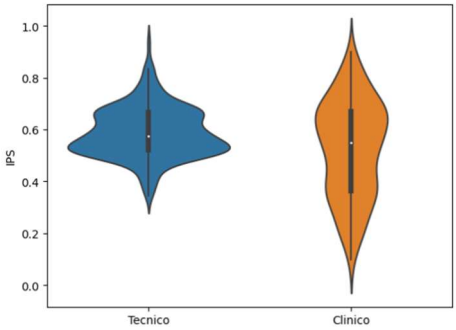

Figure 6. Violin Plot

6. Conclusions

The implemented model has allowed the company to have a tool for evaluating the state of electromedical equipment, developed ad hoc for the ASST. The present model finds its maximum application in the support to the Clinical Engineering for the definition of the substitution plan of the installed park, guaranteeing a greater objectivity and allowing to monitor the equipment in real time, reducing therefore the possibility of definitive break and therefore the onset of problems for the operativity of the departments.

As demonstrated, the developed model has led to the definition of a massive strategy of technological renewal, providing for the replacement of most of the equipment with a high degree of functional criticality, laying the foundation for future actions.

The implemented index has also found practical application in one of the major projects in place at the ASST, namely the construction of the New Buzzi Children's Hospital, next to the homonymous structure in Domodossola, Milan.

The role of Clinical Engineering was to define the equipment to be in the departments, in order to estimate the necessary resources and provide the request for funding to the Lombardy Region. In this sense, a model has been applied according to which, at first defined a set of basic equipment for each department, then integrated by those specific to each department and a group of generic devices with low technological complexity.

The study in being introduces some criticalities, dictated in the first place from the difficulty in finding all the necessary data to the implementation of the index. In fact, due to the alternation of 3 different Global Services in a few years and the consequent change of CMMS used, the master shows some holes. They can sometimes result in an incorrect assessment of the urgency of substitution; also, for this reason, the idea of integrating technical RPI with an evaluation by clinicians has matured.

While it gives value to work, the introduction of a subjective questionnaire can lead to inaccuracies. This is because operators could answer questions negatively and thus raise the value of the RPI more than the real value. Despite this, it was felt that it was necessary to give a voice to users, firmly believing in their professionalism and giving a little less specific weight to the Clinical RPI.

References

[1] L. Fennigkoh, "A medical equipment replacement model," *J. Clin. Eng.*, vol. 17, no. 1, pp. 43-47, 1992.

[2] E. Milani, "IPS e KPI: Best Practice Integrate nel Technology Management," 2019.

[3] G. Radaelli, E. Lettieri and C. Masella, "Implementation of Eunethta Core Model in Lombardia: the VTS Framework," *Cambridge University Press*, 2014.