POLITECNICO MILANO 1863

SCUOLA DI INGEGNERIA INDUSTRIALE E DELL'INFORMAZIONE

EXECUTIVE SUMMARY OF THE THESIS

HIGH-TECHNOLOGY MEDICAL EQUIPMENT MANAGEMENT: IMPLEMENTATION OF A MULTIDISCIPLINARY DOSSIER FOR HUMANITAS RESEARCH HOSPITAL

TESI MAGISTRALE IN BIOMEDICAL ENGINEERING – INGEGNERIA BIOMEDICA

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ACADEMIC YEAR: 2020-2021

1. Introduction

The role of the clinical engineer within a hospital is essential to ensure promptness in the provision of services, to guarantee maximum efficiency for diagnostic and therapeutic treatments, for the management and maintenance of the entire machinery inventory and to control all of economic aspects related.
However, the management of certain equipment, called "High-Technology Medical Equipment" (HTME), is almost entirely left to the supplier companies, due to a lack of a single information collector and a deficiency in the training of internal technicians. This is despite the fact that this category has the greatest impact on the hospital's economy, both in terms of costs and profits.
The main goal of this work is to introduce a new multidisciplinary dossier for IRCCS Humanitas Research Hospital (Rozzano, Milan, Italy), in which all the most important features of the different HTME are summarized and it allows the Clinical Engineering Service (i.e., Servizio di Ingegneria Clinica or SIC) to have a full control of the HTME.

This dossier can be consulted directly by Humanitas internal technicians in case of minor faults or equipment malfunctions, reducing downtime and ensuring continuity of service while maintaining high efficiency. So, it is possible to quantify the hospital's benefit, both from an economic (savings on maintenance contracts) and performance point of view (timeliness with which the machine is put back into use after a breakdown).
One of the strengths of this work is certainly its novelty. The implementation of an HTME management model in a hospital currently does not exist in the literature.

2. PDCA and goals

This work is based on the philosophy of the PDCA (i.e., "Plan", "Do", "Check", "Act") cycle: iterative

management method used for the control and continuous improvement of processes and products. This method is based on four phases:

1) "Plan": establish the goals and processes necessary to provide results in accordance with the customer's requirements and with the organization's policies.

2) "Do": set up the definitive implementation of the process.

3) "Check": monitor and measure the processes and products against the policies, objectives and requirements relating to the products and report the results.

4) "Act": take actions to continuously improve process performance The most important phase of this cycle is the plan phase.

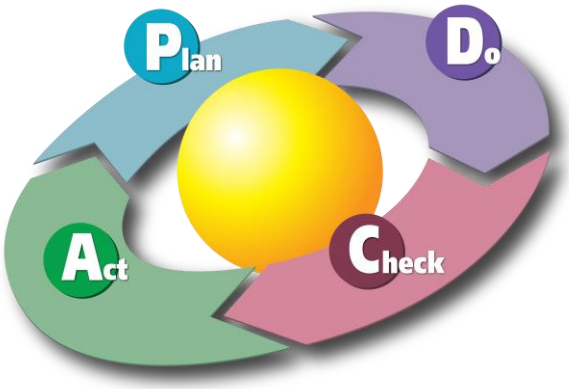

Figure 1: PDCA cycle

Among the phases considered, the most important is the "Plan" step; within this phase, 5 objectives are identified, both for the purpose of implementing the dossier (the aim of this work), and for setting up a complete HTME management model in Humanitas hospital.

I) Need to have a tool that allows to control all the High-Technology Medical Equipment.
It is still complicated to manage internally the set of (HTME) due to their high complexity and hospitals leave the complete management to the maintainer company. for this reason, the Humanitas clinical engineering service considers it useful to have a tool that encapsulates all the characteristics of the equipment, which can be consulted by internal technicians and which increases the hospital's independence from external companies.

II) Improvement of the internal technicians know- how.
In case of malfunctions or failures that can be solved in a short time (called "first-level diagnosis"), this tool allows internal technicians to act promptly, avoiding the intervention of external technicians and ensuring a continuous provision of healthcare services to patients.

III) Full risk contracts savings.
All HTME in the hospital are characterized by full risk maintenance contracts: these are full coverage contracts, leaving complete control to external companies. Thanks to the increased know-how of internal technicians, as mentioned above, first level diagnoses can be managed. In this way it is possible to negotiate with external companies to modify maintenance contracts from full risk to lower levels (gold or silver contracts), leading to cost savings.

IV) Training courses for internal technicians.
External companies are also guaranteed savings, as the intervention of their own technicians is not necessary for faults that can be solved internally. One of the most important purposes of this work is the possibility of planning training courses for Humanitas technicians, organized by the companies themselves. In this way, the know-how of the technicians would be further expanded, leading to further savings for all parties involved.

V) Management of services provided by HTME.
This is the last goal of this work, and it concerns the logistical part of the therapeutic/diagnostic health services that each HTME can provide.
Some HTME in Humanitas are similar and can provide the same diagnostic and therapeutic treatment. Once the services that each individual device can provide have been identified and collected, if downtime is necessary for any reason, it is possible to reorganize the provision of services between complementary HTME, avoiding postponed examinations and queues..

3. Material and Method

3.1 High- Technology Medical Equipment

The first step is the identification of the HTME. Thanks to the support of the Humanitas SIC, 41 HTME are assessed, divided into 11 classes: Linear Accelerator (5 devices), Angiograph (6), Gamma Kinfe (1), Mammograph (4), Bone Densitometer (1), Orthopantomograph (1), PET (2), Radiography System (7), Magnetic Resonance (6), SPECT (1) and CT scan (7). In order to standardize the language within the various departments, a sequence for naming is developed: the first part is composed by three
letters related to the class it belongs to. The second part is the manufacturer/maintainer. The last part is the model of the equipment:

e.g. TAC PHILIPS BRILLIANCE CT BIG BORE.

Moreover, a string is linked to each HTME, that allows to recognize the room in which the equipment is placed:

e.g. BLD3-P0-RTE-00-084-067

The first part corresponds to the building, the second to the floor, the third to the department and the last 7 numbers to the specific room (this last one was extracted thanks to InfoCad, an internal software used for reporting failures within the structure, where all the plans are present and in which each room is characterized by a sequence of 7 numbers).

3.2 Database

Through an Excel database, it is possible to start the collection of the data and the most important features for each HTME. The database is divided into six sections, which are associated with a specific field of interest:

1) REGISTRY: in this section the user can find information concerning to the proper characteristics of the equipment, such as: components name, cost, acceptance test date, supplier, manufacturer and so on.

2) PLANIMETRY: this section is composed by two parts: the first one collects all the data related to effective planimetry and the systems that characterized the room; the second one consists of some specifical information about the environment (internal temperature, internal humidity, heat emission, power supply, etc.).

3) TECHNICAL FEATURES: in this part, all the most important technical features are shown. Each HTME is characterized by specific requirements both for installation, optimal functionality, and management. These attributes are fractioned by a further subdivision: physical features related to the principal components (generator type, panel detector model weight of the entire system, etc.), and proper technical features (for instance, considering the generator, the own dissipation capacity, power, and cooling mechanism)

4) INFORMATICS: this section refers to the entire IT features that characterize the system, such as: PCs number, installed software, operating system, monitors number and so on.

5) PERFORMACE PROVIDED: this section includes all the services provided by the each different HTME. This data were collected with the support of the Humanitas Operational Management.

6) CLINICAL ENGINEERING: this section concerns the economical features and all the aspects that impact on the general cost, such as: annual full risk contract cost, downtime days number or end of assurance.

Once all the data have been collected and the final database is complete, a dossier for each HTME can be created. Initially, eleven different frameworks are created in Microsoft Word, one for each class of equipment: a five-page document showing all the features belonging to the different classes. These will be the basis for the "identity card" of each HTME. Once filled with the proper values for each equipment, they will be the actual dossier.
In order to make the process automatic, a macro is implemented using Visual Basic for Application (VBA): in this way, the completion of the document is automatic, avoiding manual filling and saving considerable time.

However, the code does not allow to insert the images. These images refer to different features of each HTME, such as the exam room, the workstation with which the equipment is controlled and the real location of the room in the hospital. This procedure has to be carried out manually, with the addition of four images for the finalization of the dossier:

1) Cover image: The cover image consists of a photo of the exam room, where all the components related to the HTME considered are shown.

2) Informatics: an image of the workstation is present to show the composition of that.
3) Planimetry: in this case there is the combination of the previous two images, plus an image of the general map of the HTME considered.

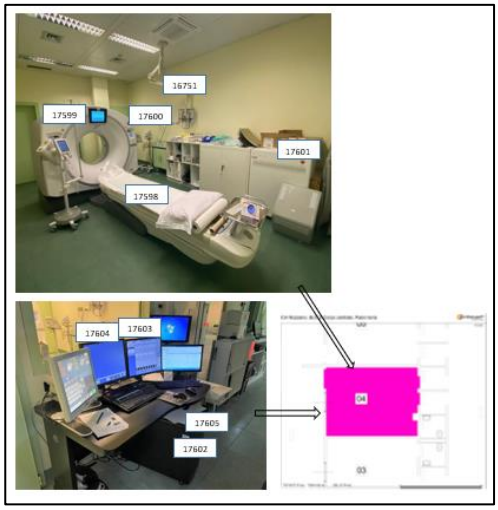

Figure 2: TAC GE REVOLUTION EVO VT200 planimetry image.

4) Manually reset procedure: this part shows the electrical panel of the HTME considered and the sequence of commands to be activated in the event of a power failure.

Once this process is finished, the dossier is complete, ready for use and available to the whole hospital, both in digital and paper format.

4. Data analysis and results

Thanks to the development of this dossier, it is possible to carry out economic analyses that were not possible before.
The multidisciplinary nature of the dossier makes it possible to carry out different types of analysis, thanks to the large amount of data present and information collected.
In particular, in this work, two types of analysis are presented: Data Envelopment Analysis (DEA) and Regression Analysis.

4.1. Data Envelopment Analysis (DEA)

Through the use of Stata by StataCorp (a general-purpose statistical software), it is possible to carry out a DEA to define a ranking based on the efficiency of the different HTME (i.e. Decision Making Unit or DMU). Specifically, the efficiency on which is based the ranking is evaluated by the comparison of costs due to the maintenance contracts (i.e., inputs) with the benefits produced for the hospital (i.e., outputs), identified in the daily average income generated, the daily average number of patients treated, and the guaranteed continuity of service, defined as the inverse of the number of downtime days occurred between 2018 and 2020. In other words, the first positions will be occupied by those production units that, for the same generated output, imply lower costs for the hospital (input- oriented analysis).
Moreover, this study is performed setting a constant return to scale (so that an increase in inputs causes the same proportional increase in output) and a two-stage model (so that it consists of two stages of regression).
The results obtained show that:
- A linear accelerator, the bone densitometer and an x-ray system are in the top positions. These devices obtain the best results, as their management is the most efficient when comparing costs incurred and income generated, number of services provided and continuity of service.
- Considering the bottom of the ranking, it is interesting to note that the three least efficient devices correspond to the most technologically innovative ones: the MRI Philips Panorama, the MRI Skyra 3 T, and the Gamma Knife. These three HTME are characterized by high maintenance costs and low number of services provided with respect to the other instruments, also because of the high specificity of the diseases treated.

```
      name:  dealog
       log:  C:\Users\HP\Desktop\Polimi\ESAMI SVOLTI\Economics Performance\progetti\essay #2\stata\dea.log
  log type:  text
 opened on:   6 Nov 2021, 18:17:42

options: RTS(CRS) ORT(IN) STAGE(2)
CRS-INPUT Oriented DEA Efficiency Results:

                                                rank                theta
        dmu:ACC_VARIAN_CLINAC_BUNK3                1                    1
          dmu:ACC_VARIAN_EDGE_BUNK2               12                .60324
       dmu:ACC_VARIAN_TRUEBEAM_BUNK4               11                .634315
       dmu:ACC_VARIAN_TRUEBEAM_BUNK1                5                .926702
   dmu:ACC_VARIAN_TRUEBEAM_STX_BUNK5                8                .655098
             dmu:GKN_ELEKTA_PERFEXION               35               .0654766
dmu:MAM_TECHNOLOGIC_IV_SELENIA_FIORD               18                .447757
   dmu:MAM_TECHNOLOGIC_SELENIA_AMB13               22                .306569
   dmu:MAM_TECHNOLOGIC_SELENIA_AMB15               18                .447757
```

Figure 3: Stata software when compiling the code for the DEA

4.2. Regression Analysis

Through the use of Gretl (a software for econometrics and statistical analysis), four regression analyses were developed:

1) The first analysis takes into account all HTME considered individually.
2) In the other three analyses, the observations are represented by the aggregation into classes of the devices.

These analyses make it possible to evaluate the correlation between a dependent variable and an independent variable (or regressor), so as to assess in greater depth the economic impact of such equipment and to be able to estimate the relationships between the cost of maintenance contracts (which will always be the independent variable) and the income/losses generated by the provision of services/downtime.
Gretl shows as output the regression coefficient and the standard error related to the estimation of each coefficient. In addition, the significance of the relationship between the dependent variable and the regressor is assessed through the p-value, which is automatically provided by the software.

The results of the linear regression tests are shown in the Table 1.

No.	*No. Observation*	*Dependent var.*	*Independent var.*	*Correlation (+/-)*	*P-value*
1	35	Daily income produced	Full risk contract cost	+	0.0001
2	10	Daily income produced	Full risk contract cost	+	0.0002
3	10	Downtime days occurred in 2018-2020	Full risk contract cost	+	0.49
4	10	Loss of income produced by downtime days in 2018-2020	Full risk contract cost	+	0.0002

Table 1: Results of the Linear Regression Analyses

5. Conclusions

In conclusion, the implementation of this tool is certainly of fundamental importance for the proper internal management of HTME. However, of equal interest to the company is certainly the training of internal technicians to ensure a timely first intervention in case of downtime, which in cases of minor failures could allow the immediate restoration of service provision.
This would also make it possible to save on the costs of maintenance contracts, abandoning the full risk coverage formula and adopting a contract that provides less coverage in critical cases, and an on-demand intervention contract in the case of devices that are easily replaced within the hospital. The savings generated as a result could be invested in adding a highly specialized technical professional in the field of HTME maintenance to the staff of internal technicians.
The development of both elements would lead to the creation of a unique model for the management of high-tech devices, allowing savings to be invested in the purchase of innovative equipment or the recruitment of new staff.

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Academic Year: 2020/2021

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Abstract

The fundamental task of the Clinical Engineering Service consists in the management of the whole machinery inventory present in the hospital, both from an economic-managerial point of view and from a technical point of view. However, it is still complicated to manage internally the set of High Technology Medical Equipment (HTME) for most of the health facilities, also considering their high technical complexity. For this reason it's usual to entrust the complete maintenance management to external companies, stipulating full risk contracts for a multi-year coverage.

In this thesis work, the development of a multidisciplinary dossier is presented, in which are summarized all the characteristics of the 41 HTME present in the IRCCS Humanitas, with the aim to extend the control and to carry out cost-benefit analysis to evaluate their economic impact. Moreover, This tool acts as a recap of personal, technical and planimetric characteristics of these devices, which previously were scattered within the hospital's specifications. Internal technicians can consult this tool in cases of minor failures or malfunctions, reducing downtime and ensuring high efficiency and continuity in the delivery of diagnostic and therapeutic performance.

Another potential impact aspect of implementing the dossier is the development of a systematic methodology for data-based decision making. For example, the tool has the role of supporting the decision-making process in evaluating the opportunity to change the type of maintenance contracts stipulated with external companies, moving from a full risk to a lower level of coverage. At the same time, it would be important to organize training courses for internal technicians at the same companies that provide the service, in order to increase the know-how of the technicians in the field of first intervention in the event of an HTME downtime; some of these have shown themselves willing to plan such courses for the end of 2021. Given that every machine downtime corresponds to an economic loss, the possibility of guaranteeing an in-house first intervention is a benefit for the company, in addition to the savings on the cost of contracts. This saving can be invested in different areas, such as hiring a new technician who can be integrated into the Clinical Engineering Service. In addition, external companies also have advantages: the presence of technicians at Humanitas is no longer necessary in case of failures that can be solved entirely.

Finally, correlation analyses have been carried out between cost variables; moreover efficiency evaluations are performed (Regression analyses and DEA). These have shown how the management of certain equipment and the organization of performance can be improved, for example through the use of equipment that can provide the same services in case of downtime of a device.

Key words: High-Technology Medical Equipment, dossier, management, hospital, performance.

Abstract in lingua italiana

Il compito fondamentale del Servizio di Ingegneria Clinica consiste nella gestione dell'intero parco macchine presenti in ospedale, sia da un punto di vista economico-manageriale, sia da un punto di vista tecnico. Tuttavia, è tuttora complicato gestire internamente l'insieme dei Dispositivi Elettromedicali ad Alta Tecnologia (HTME) per la maggior parte delle strutture sanitarie, vista anche la loro elevata complessità tecnica. Per questo motivo si tende ad affidare la completa gestione manutentiva alle aziende esterne, stipulando dei contratti *full risk* per una copertura pluriennale.

Nel presente lavoro di tesi si è voluto sviluppare un dossier multidisciplinare in cui vengono riassunte tutte le caratteristiche delle 41 HTME presenti nell'IRCCS Humanitas, con l'obiettivo di ampliare il controllo e svolgere analisi costo-beneficio per valutare il loro impatto economico. Questo *tool* funge, inoltre, da raccoglitore delle caratteristiche anagrafiche, tecniche e planimetriche proprie di tali dispositivi, le quali in precedenza erano disseminate all'interno del capitolato dell'ospedale. I tecnici interni possono consultare questo strumento nei casi di guasti o malfunzionamenti di lieve entità, riducendo i tempi di fermo macchina e garantendo un'elevata efficienza e continuità nell'erogazione di performance diagnostiche e terapeutiche.

Un altro potenziale aspetto d'impatto derivante dall'implementazione del dossier consiste nello sviluppo di una metodologia sistematica di *data-based decision making*. Per esempio, lo strumento ha il ruolo di supportare il processo decisionale nella valutazione dell'opportunità di modificare la tipologia dei contratti di manutenzione stipulati con le aziende esterne, passando da un *full risk* ad un livello inferiore di copertura. Contestualmente, sarebbe di fondamentale importanza organizzare corsi di formazione per i tecnici interni presso le stesse aziende fornitrici del servizio, per accrescere il know-how dei tecnici nel campo del primo intervento in caso di fermo di una HTME; alcune di queste si sono dimostrate disponibili alla pianificazione di tali corsi per fine 2021. Dato che ad ogni fermo macchina corrisponde una perdita economica, la possibilità di garantire un primo intervento interno costituisce un *benefit* per l'Azienda, che si aggiunge al risparmio sul costo dei contratti. Tale risparmio può essere investito in diverse aree, come l'assunzione di un nuovo tecnico che può essere integrato nel Servizio di Ingegneria

Clinica. Inoltre, anche le aziende esterne ne traggono benefici: non è più necessaria la presenza dei tecnici presso Humanitas in caso di guasti risolvibili interamente.

Infine, sono state svolte analisi di correlazione tra variabili di costo e valutazioni dell'efficienza (i.e., Regression analyses e DEA), che hanno dimostrato come la gestione di determinate apparecchiature e l'organizzazione delle performance possa essere migliorata, ad esempio attraverso l'utilizzo di apparecchiature che possono erogare gli stessi servizi in caso di fermo macchina di un dispositivo.

Key words: High-Technology Medical Equipment, dossier, management, hospital, performance.

1. Introduction, background and goals

1.1. Introduction

The clinical engineer is the responsible for ensuring continuity of service within the hospital structure and improving the quality of clinical outcomes. The management of maintenance and testing activities, which guarantee an adequate level of safety for both operators and users, are duties assigned to this professional figure; moreover, it deals with the innovation of the technological and methodological assets in a healthcare facility. The proposals for the introduction of new equipment or new processes are presented by the clinical engineering department, always aimed at making the way services are offered by the structure more effective.

Hence, it is noticed that the clinical engineer plays a fundamental role in raising the level of efficacy and effectiveness of the services provided, both through the adoption of the most innovative technologies and through the re-engineering of the processes currently existing. In this context, the introduction of a new multidisciplinary tool is presented, that allows the clinical engineer to have a full control of the so-called "high-technology medical equipment". This new tool represents the main focus of this thesis work and deals with the hospital's need to collect in a single document all the information considered useful for the management and control of a large number of devices. It is therefore configured as a multidisciplinary dossier, which supports the activities of the clinical engineer of managing the machinery inventory throughout the life cycle, and monitoring the performance offered to the patient, with a benchmarking purpose between high-tech equipment both from a performance point of view as well as from a cost point of view.

Although it may seem obvious that a hospital has special consideration for the most economically impacting equipment, the information on each of them is often scattered among the enormous amount of technical and economic data that a hospital must deal with. The beneficial impact of this tool is twofold: on the one hand, it can be extremely useful for carrying out the tasks of a clinical engineer, as it collects all the technical and economic data needed for the correct management of these devices in a single document. Secondly, in the

hypothesis of a certain number of technicians trained in an appropriate manner in the field of high-tech equipment, this tool could provide a fundamental support for realizing the internalization of the first intervention in the event of a breakdown of a high-tech device. To date, the technical know-how on this class of equipment is exclusive to manufacturers / suppliers, who stipulate very costly contracts with hospitals (*full risk*), which guarantee the intervention of the manufacturer's technicians for any type of problem within a certain time frame.

The ultimate goal of this thesis is, firstly, to quantify the hospital's benefit from a breakdown management model that starts from a preliminary internal diagnosis and eventually from an internal resolution of the problem, avoiding the involvement of external technicians. This benefit has to be intended both from an economic (savings on maintenance contracts) and performance point of view (timeliness with which the machine is put back into use after a breakdown). This transformation can only take place with the support of a tool that collects all the useful data from a technical and economic point of view on high-tech equipment, such as the multidisciplinary dossier, and through an internalization of the know-how on the first diagnosis and intervention on them (which, however, necessarily requires training from the producers).

Secondly, the purpose is to validate the potential of using the multidisciplinary dossier within the Humanitas Clinical Institute of Rozzano, with the presentation of cost-benefit analyses on the machinery inventory, that otherwise would have been almost impossible to perform. This work's aim is also to motivate other hospitals to recognize the positive impact of this innovative management model, in terms of hospital performance, cost savings, internal technical know-how and logistical organization.

1.2. Humanitas Clinical Institute

Humanitas is a Scientific Institute for Research, Hospitalization and Healthcare (*Istituto di Ricovero e Cura a Carattere Scientifico*, or IRCCS) accredited with the National Health Service, Research Center and university teaching center at Humanitas University, an international university dedicated to medical sciences.

It is a highly specialized hospital, which includes specialized centers for the treatment of cancer, cardiovascular, neurological and orthopedic, autoimmune and inflammatory diseases, as well as an Ophthalmology Center and a Fertility Center; it is also equipped with a Highly Specialized Emergency First Aid Unit (*Emergenza ad Alta Specializzazione*, or EAS).

The Humanitas Clinical Institute is the main of a group of 9 hospitals and 13 diagnostic centers (Humanitas Medical Care) on the national territory in Milan, Bergamo, Castellanza, Arese, Turin, and Catania.

The history of Humanitas

In the second half of the 1980s, the idea of creating a modern and efficient hospital was born, which focuses on the doctor-patient combination.

In 1996, the construction of the hospital was completed, and on March 4th Humanitas officially opened its doors.

In 1997, the agreement with the National Health Service (i.e., Servizio Sanitario Nazionale or SSN) for hospitalization services was endorsed.

In 2000, Humanitas became the teaching center of the University of Milan for the degree course in Nursing, followed by Medicine and Biotechnology.

In 2002, Humanitas became the first Italian hospital to obtain the accreditation of excellence from Joint Commission International, one of the most important hospital quality certification bodies in the world, and became a case study for the master's in Business Administration at Harvard University.

In 2003, the EAS First Aid and Radiotherapy were inaugurated.

In 2005, Humanitas was recognized by the Ministry of Health as a Scientific Institute for Research, Hospitalization and Healthcare (IRCCS). The Humanitas Research Foundation was born.

In 2010, the International Medical School was born in collaboration with the University of Milan, and in 2014 Humanitas University was born. At that time, it included three degree courses: single-cycle international master's degree courses in Medicine and Surgery, three-year degree course in Nursing Sciences and three-year degree course in Physiotherapy.

In 2013, the activities with the Diagnostic Center were expanded.

In 2017, the new campus, home of the University and the research activities, was completed.

In 2020, following the health emergency caused by the SARS Covid-19 pandemic, Emergency Hospital 19 was built, in response to emergencies related to the virus and in general to infectious diseases. It is a new facility within the hospital, with its own emergency room, diagnostics, intensive and sub-intensive care departments, two operating theatres and twenty-five hospitalization rooms.

Facilities and activities

The expansion in the hospital's activities went at the same pace with the construction of new buildings. In the main one, Building 2, there are high clinical intensity departments, including two operating wards of general surgery, two day-hospital operating wards, a Cardiac Surgery department, one dedicated to minimally invasive interventional cardiology, General and Heart Surgery Intensive Care departments, the Coronary Unit. In the same building there are diagnostic imaging services (radiology, nuclear medicine, ultrasound), day-hospital wards of Oncology, multidisciplinary wards, multi-specialty clinics, Endoscopy, Accident and Emergency (A&E) and Radiotherapy. All clinical activities related to the SSN, the Ophthalmic Center, the Fertility Center and the Women's Center (Mammography and breast ultrasounds), as well as the Blood Collection Center, are housed in two external buildings (Buildings 4 and 5).

The more recently built Cascina Perseghetto Center (CCP, Building 8) houses the convention hall and the Ortho Center, which is a day-hospital operating ward dedicated to orthopaedics and four rehabilitation wards connected to it.

Finally, the new University Campus houses the didactic activities as well as the research laboratories, which also includes the Simulation Center, whose purpose is to promote scientific research and technological development1 (Figure 1).

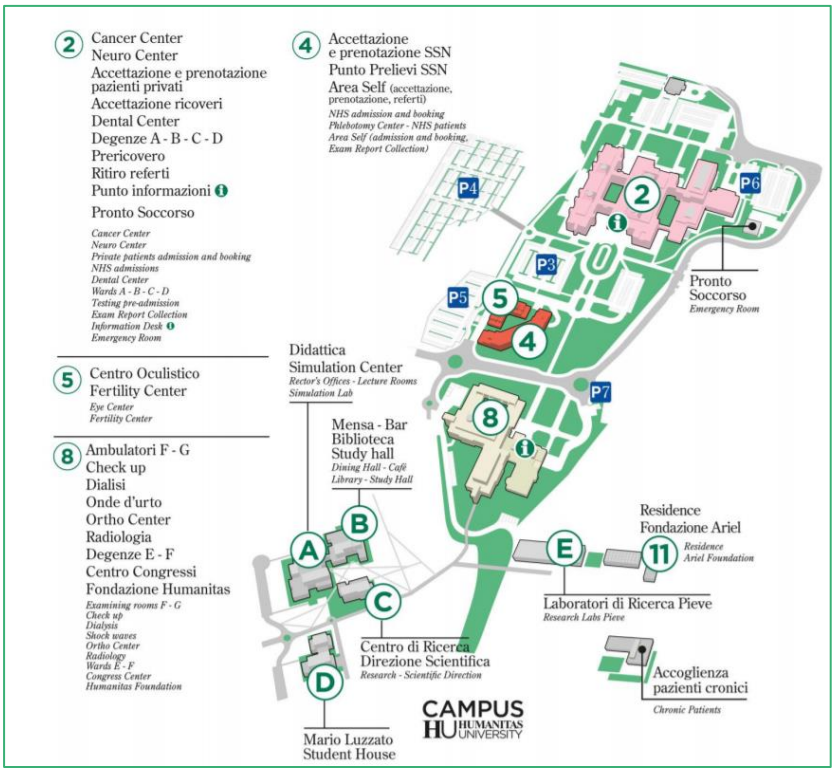


Figure 1: Humanitas Hospital Complex

In its entirety, the hospital facilities extend over 90,000 m². Among them, 75,000 m² dedicated to clinical activity, 6,000 m² to scientific activity, 4,000 m² for teaching, 5,000 m² for patient and family reception facilities. There are 747 beds, of which 73 in the medical, surgical and oncological day-hospital, 31 to Intensive Care, 154 to Cardio-Pulmonary, Orthopedic and Neuromotor Rehabilitation; there are 42 operating theatres, and more than 200 medical clinics.

Humanitas, deemed one of the most technologically advanced hospitals in Europe, has always considered technological innovation a central aspect of its corporate strategy; some examples are the high-tech radiotherapy devices, robotic surgery systems, innovative lasers for ophthalmological surgery, and the machinery inventory of CTs and angiographs.

In this highly technological context, the Clinical Engineering Service (i.e., Servizio di Ingegneria Clinica, or SIC) assumes a strategic role, because it allows operators to exploit the equipment to its full potential, through effective and efficient management. Starting from the choice of the most appropriate technologies (in terms of cost and quality of performance) and arriving at the guarantee of a safe use of the device for patients and operators, passing

through monitoring the quality of the service and a contextual optimization of costs: these are just some of the aspects that make the clinical engineer a necessary and strategic figure within the company. Considering the tasks mentioned above and the centrality of technology in a hospital, the clinical engineer is configured as a technology manager, and together with other

professional figures (laboratory technicians, health physicists, etc.) manages all the electromedical devices during their entire lifecycle.

1.3. Clinical Engineering Service in Humanitas

Acquisition	*Entering*	*Maintenance*	*Disposal*
Management of the devices on approval	Acceptance tests	Management of requests for technical assistance (i.e., Richiesta d'Intervento or RdI)	Out-of-order tests
Investments for replacement	Inventory update	Electrical safety tests	Disposal procedures
Health Technology Assessment (HTA)	Clinical staff update	Quality control	
	Technical staff update	Preventive maintenance	
	Administration deeds	Safety notice	
		Management of maintenance contracts	

Table 1: Humanitas' Clinical Engineering Service activities

The Clinical Engineering Service at Humanitas is an internal service, whose purpose is to manage the entire set of electromedical equipment that enters the hospital, either it is for purchase, rental, loan, personal property or viewing. Furthermore, the clinical engineer plays the role of interlocutor for the operators and for the operating units, in order to guarantee safety and compliance with regulatory, structural, technological and organizational

requirements, to always provide the best service possible in terms of quality and efficiency (Table 1).

At an organizational level, the Service is part of the Supply Chain structure (Logistics, Purchasing Office and Clinical Engineering Service). The SIC is composed of a responsible of the service and four engineers for the management part. As regards the technical part, it is composed by four technicians coordinated by an engineer, who is responsible for the maintenance of electromedical equipment of the entire structure, as well as the tests and acceptances of new equipment. Three employees with administrative tasks complete this structure (Figure 2).

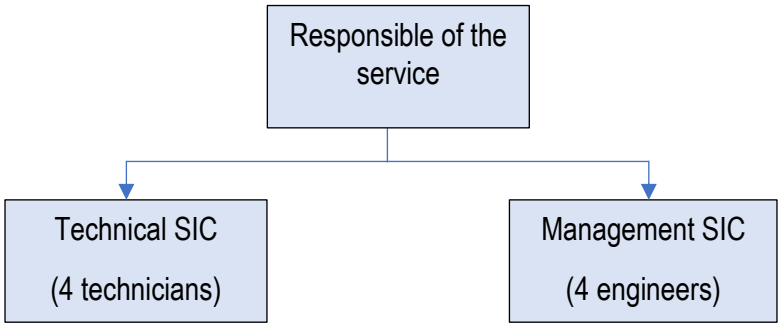


Figure 2: Organizational chart of the Clinical Engineering Service in Humanitas

The function of the SIC is therefore to carry out the following activities:

- Support for the acquisition and disposal of equipment.
- Updating of the inventory and technical documentation of all equipment, with an indication of the interventions carried out and / or required by law.
- Management of maintenance contracts (*full risk* or on demand) stipulated with suppliers based on directives and with the supervision of the Responsible, to ensure the efficiency of the machinery; definition of alternative times and methods of intervention, basing on the urgency, the complexity of the interventions and the existence of maintenance contracts; monitoring and control of the interventions provided by the staff of the Supplier Companies.

- Execution of direct maintenance interventions, through internal and / or contracted staff.

Acquisition and Substitution

The technical support for the acquisition of medical technologies has a strategic role and takes into account the entire life cycle of the equipment; the objective is to support the Supply Chain function, as well as the clinical part, through market surveys, post-warranty technical assistance assessments, products comparison and verification of compliance with legislative directives, in order to identify suitable technologies for the needs of the hospital (Figure 3).

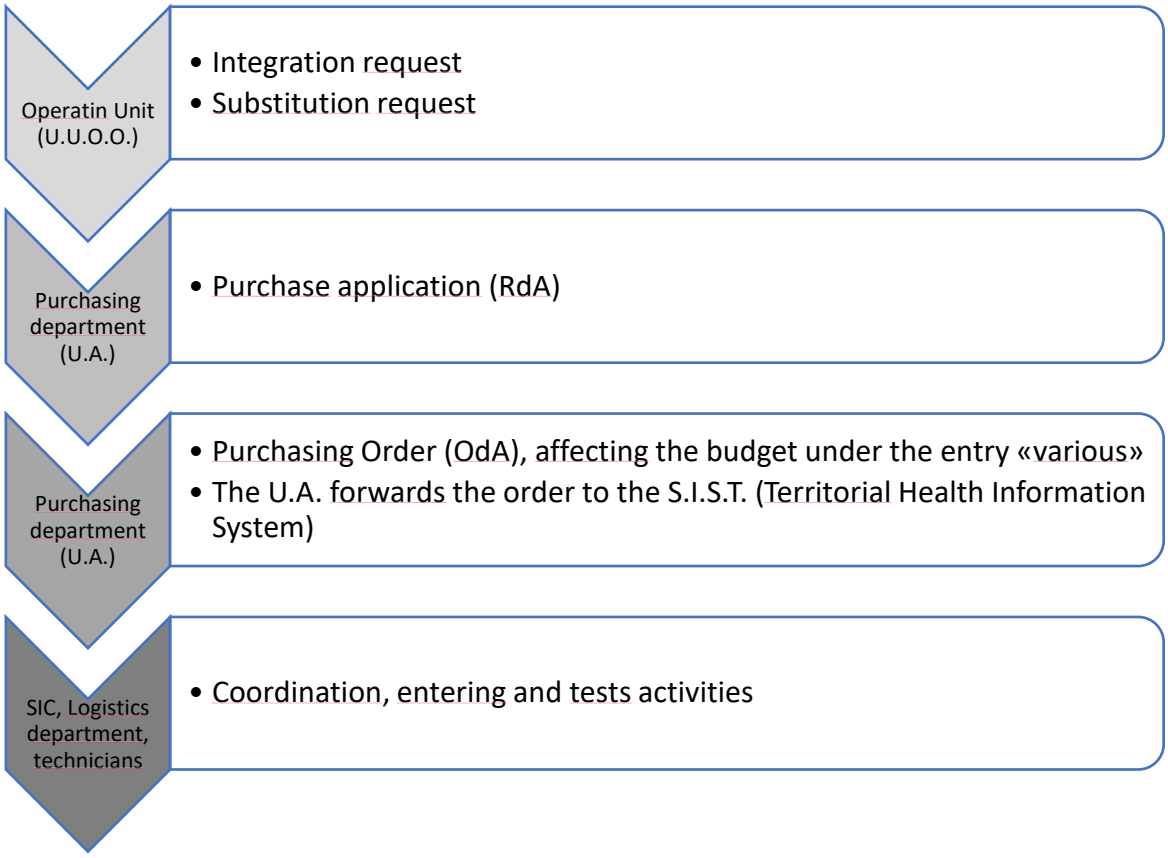


Figure 3:The acquisition process' actors and main phases.

Another important point in fleet management is the replacement planning for obsolescence. The excessively burdensome management of the equipment (due to recurring failures or the expenditure to make the hospital compliant to the new legal provisions), the technological evolution that inevitably makes the equipment obsolete, or the irreparability of the equipment itself, are factors that necessarily imply the proposal of replacement by the SIC, because of the obsolescence. Depending on the conditions of the various devices, it is

necessary to develop a plan for their replacement. It is made up considering problems due to management costs, low performances or the risk arising from the use of the technology. The replacement plan designed by the SIC is obtained thanks to the interaction of multiple Key Performance Indicators (KPI). Specifically, it is a set of indicators (age, operating cost, existence of spare parts, etc.) that provide the ability to assign a Replacement Priority Index (i.e., Indice di Priorità di Sostituzione or IPS) to each device.

Installation and Testing

The first fundamental step to ensure the safe use of the equipment is represented by the acceptance and testing procedure. Any entering device, either electromedical or laboratory, has to undergo this procedure which involves the execution of the activities listed below:

- Installation checks: verification of the environmental suitability of systems and arrangements.
- Compliance with the order: it is checked that there is a correspondence between what has been ordered and what has been delivered.
- Collection and verification of the documentation required during the acquisition phase (certifications, declarations of conformity and manuals).
- Tests of compliance with standards, on sight and instrumental.
- Functional tests.
- Inventory and registration in the management software of rating plate, administrative and technical data and archiving of documentation.
- Delivery of the equipment to the U.U.O.O. or to the requesting department, provided with the user manual.

Preventive Maintenance

Considering the user manual, and in particular the information reported about maintenance interventions, the SIC develops the Preventive Maintenance (MP) plan. Besides the type of activity expected, in this context the SIC defines the minimum time interval between one intervention and the next, and the personnel authorized to carry out these activities. Furthermore, depending on the risk associated with a specific intervention, the SIC determines whether the maintenance can be carried out by internal or external technicians,

and in the latter case, basing on the agreements with the supplier, there are two types of intervention: Full Risk and on demand MP intervention. In the case of a Full Risk type contract, the preventive maintenance interventions are shared with the supplier and scheduled on a calendar basis, as a result of a fixed annual installment. With on demand Preventive Maintenance, however, the scheduling of the interventions is not shared with the supplier, but the latter is contacted when the intervention is required, which is carried out following the economic negotiation with the supplier. Figure 4 shows the flow for the organization of MP.

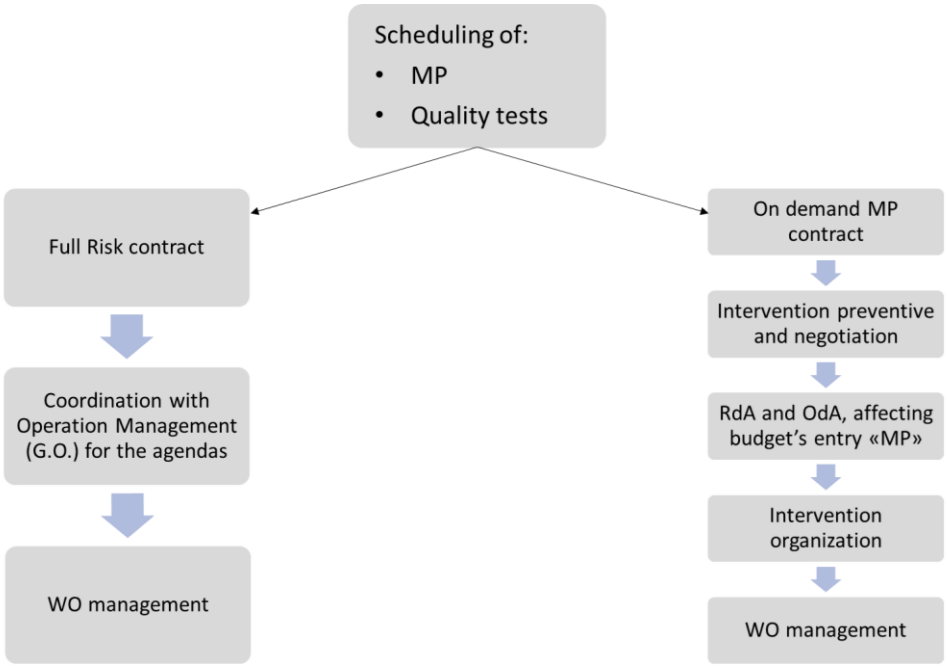


Figure 4: The preventive maintenance possible processes

Once the schedule for the planning and organization of preventive maintenance activities to be carried out throughout the year is ready, the budget reserved for this type of intervention can be defined.

Electrical safety and performance tests

Electrical safety checks are an essential activity to ensure the functioning of electromedical equipment as well as the protection of all those who come into contact with them, for work

or accidentally (health workers, patients, third parties, etc.). The Italian Electrotechnical Committee (CEI) defines the frequency of these checks:

- Annual frequency for equipment located in surgery or similar departments.
- Every two years for all other equipment.

In addition to electrical safety checks, some instruments require performance checks. This category includes defibrillators, electrocardiographs, infusion pumps, lung ventilators, anesthesia devices, etc. Once the checks have been carried out, these interventions are recorded and uploaded to the management software to have a complete traceability. In fact, there is a monthly-updated schedule, through which it is possible to follow whether all required interventions have been carried out. Obviously, in the event of unsuccessful tests or unusual and non-standard values, the equipment is subjected to specific checks with the aim of restoring the conditions of functionality and use. When this is not possible, the equipment is withdrawn and put out of use.

Corrective Maintenance

The Corrective Maintenance (MC) takes place in the event of equipment malfunctioning. The first intervention is carried out by internal technicians who are part of the SIC. If the first intervention does not lead to the resolution of the problem, external assistance is required from the supplier or a maintenance company, following the contractual conditions or economic agreements (equipment under warranty, covered by an assistance contract, etc.). Corrective maintenance takes place according to the flow shown in Figure 5.

A correct analysis of the corrective maintenance (resolution times, costs, machine downtime etc.) allows to evaluate the performance of the Clinical Engineering Service in terms of effectiveness and efficiency.

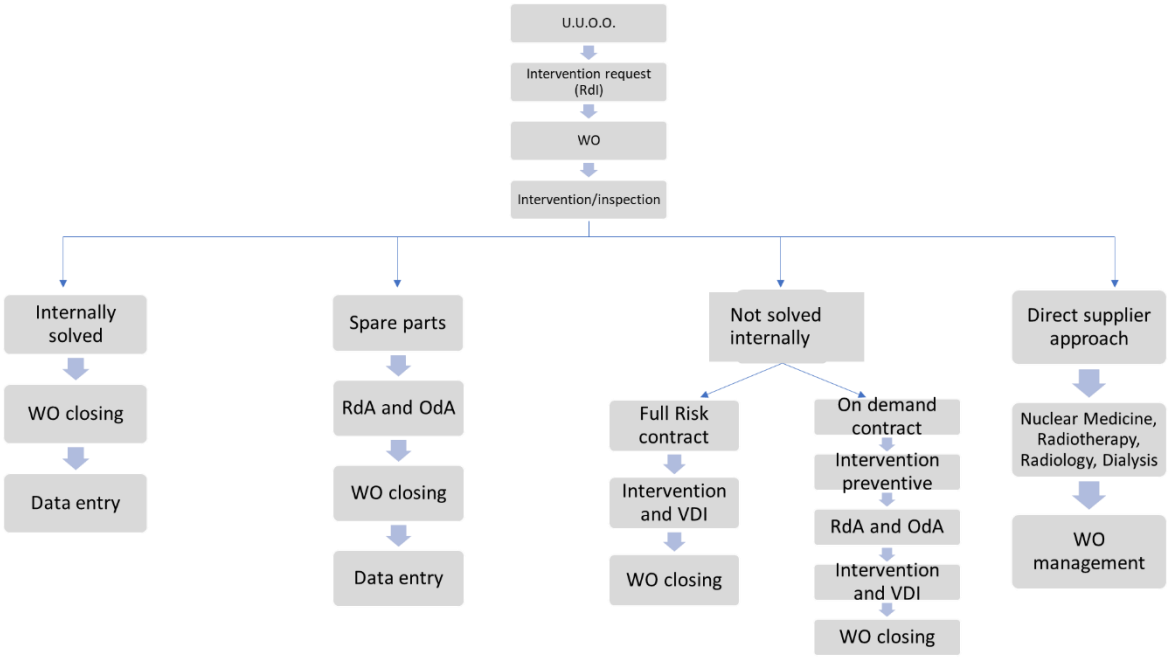


Figure 5: Corrective Maintenance process

Management of technical assistance contracts

Basing on the type of equipment considered, at the end of the warranty period, the SIC stipulates technical assistance contracts (which can be Full Risk, preventive maintenance, etc.). For the high technology equipment there is usually the stipulation of Full Risk contracts, which fully cover the maintenance interventions as a result of a fixed annual fee. Full Risks are advantageous contracts when it comes to valuable instruments, due to the high cost of labor and spare parts, which are difficult to find. Furthermore, the contracts provide for a reduced time for intervention or for the supply of a replacement device, in order to guarantee the continuity of the service.

Decommissioning and disposal

The decommissioning process concerns obsolete equipment, which is unrepairable or burdensome from an economic point of view due to the repeated interventions required, and non-functioning equipment. The SIC proceeds with the withdrawal of the equipment from the department, which is marked with a label with the words "decommissioned device", until the final disposal.

Computer system

All the activities carried out by the SIC are recorded on the "InfoHealth" management software (Figure 6). It allows you to have complete control over the activities carried out on all the equipment present in the structure.

Figure 6: InfoHealth management software

Thanks to the various attributes of describing each instrument, the software allows you to query the database according to the specific needs. In this way, thanks also to the implementation of dashboards of indicators, it is possible to have a complete picture of the machinery inventory, the progress of maintenance activities, existing contracts and other. The details about the functions of this software will be explain in the Materials and Methods chapter.

2. High technology equipment in Humanitas: working principles, uses and risks

2.1. Computed Tomography (CT)

Working principles

The "computed tomography", or CT, is a computerized x-ray imaging procedure which consists of two phases: acquisition and processing. During the first one, an x-ray tube is aimed at the patient; then, it is quickly rotated around the couch while producing x-ray beams. Thus, some output signals are produced and reconstructed by the machine's computer to generate cross-sectional images (i.e., slices) of the body. These slices are called tomographic images; overall, they present a more detailed information than the images produced by the conventional x-ray system. Instead, in the processing phase, once a certain number of successive slices are collected, they can be digitally "stacked" together to form a 2D or 3D image of the acquired district of the patient. In particular, the 3D reconstruction allows a better identification of the body structures, as well as possible abnormalities (e.g., tumors).

Unlike the conventional x-ray system, which uses a fixed x-ray tube, the CT scanner uses a motorized x-ray source that rotates along the circular opening of a donut-shaped structure called gantry. During the acquisition phase, the couch slowly moves through the gantry and the x-ray tube rotates around the patient, while emitting x-rays. The CT scanners use special digital x-ray detectors (it is usually made of amorphous silicon), which are located in the diametrically opposite position to the x-ray source, and which of course rotate along the gantry as well. As the x-rays leave the patient, they are picked up by the detectors and transmitted to a computer. The processes of acquisition of the signal and processing are common for all the x-ray-based technologies presented in this work; they will be explained better in Paragraph 2.4.

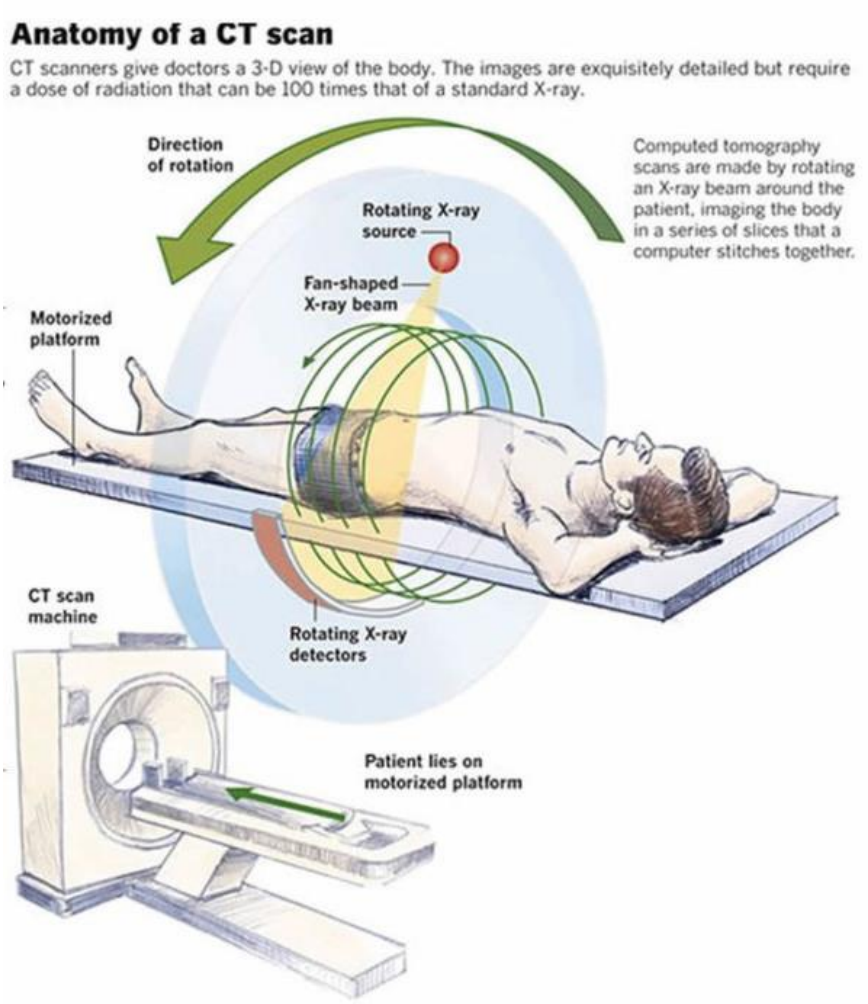


Figure 7: Explanation of a CT working principles.

Each time the x-ray source completes one full rotation, the CT computer uses complex algorithms to reconstruct a 2D slice of the patient. The thickness of the tissue represented in each image can vary depending on the CT and on the aim of the exam (i.e., what the physician is looking for), but usually ranges from 0.625 to 10 millimeters. When an image is completed, it is stored, and the motorized bed is moved gradually forward into the opening. The x-ray scanning process is then repeated to produce another slice. This process continues until the desired number of images is gathered. The maximum number of stacked slices from which an image can be composed is a representative measure for the machine: the higher the number of cross sections from which it is composed, the higher will be the image quality.

Contrast agents

As with all x-rays imaging procedures, dense structures such as bone are easily imaged. Instead, soft tissues vary in their ability to stop x-rays; thus, they may be hardly visible. In order to solve this problem, intravenous (IV) contrast agents are used. They are highly visible substances in CT scans, as they contain substances that are better at capturing x-rays and, thus, are more visible on an x-ray image. For example, to analyze the circulatory system, the technician injects in the patient bloodstream a contrast agent, usually based on iodine, to make blood vessels clearer. Through this procedure, the physician is allowed to investigate whether obstructions are present or not in patients' blood vessels. Oral contrast agents, such as barium-based compounds, are used for imaging the digestive system, including the esophagus, stomach, and GI tract.

Uses

CT scans can be used to identify disease or injury within various body districts. CT scans are commonly used when it is required to image complex bone fractures, eroded joints, or bone tumors. In fact, in these few cases it produces images with sharper definition than conventional x-ray systems or Magnetic Resonances. Other common applications are the following:

- A few CT scanners, for example the GE Cardio Revolution CT, perform an acquisition of the single slice in less than 0.3 seconds: this means that in the duration of one heartbeat, the x-ray source has completed between two and three complete rotations of the gantry. In this way, this machine allows the user to reconstruct the heartbeat cycle, just visualizing the images in succession, and therefore an anomaly in the patient can be identified more easily.
- CT can be used to scan the head to identify injuries, tumors, clots leading to stroke, hemorrhage, and so on. It is also one of the most used tools to image the lungs to reveal the presence of tumors, pulmonary embolisms (blood clots), excess fluid, and other conditions such as emphysema or pneumonia. Finally, it has become common also the use for detecting tumors or lesions within the abdomen, and in Figure 8 there is an example of CT of the human brain.

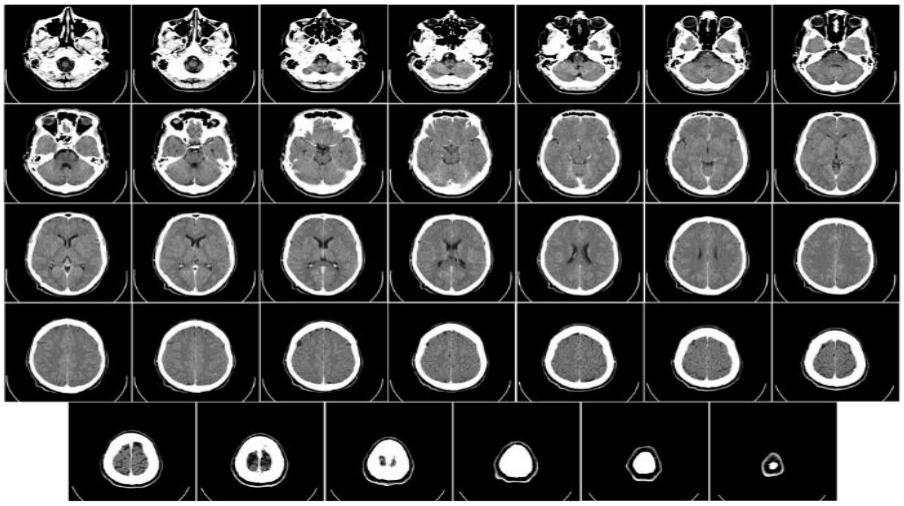


Figure 8: Computed tomography of human brain, from base of the skull to top. Taken with intravenous contrast medium.

Risks

CT scans allow to diagnose life-threatening conditions such the ones above mentioned. An early diagnosis of these conditions could potentially be lifesaving. However, CT scans use x-rays, and all x-rays produce ionizing radiations, which have the potential to cause a pathological condition in living tissues. This is a risk that increases with the number of exposures to radiations.

In some patients, contrast agents may cause allergic reactions, or in rare cases, temporary kidney failure. IV contrast agents should not be injected to patients with abnormal kidney function since they may induce a further permanent reduction of kidney function.

Children are more sensitive to ionizing radiation and have a longer life expectancy and, thus, a higher relative risk for developing cancer than adults.

2.2. Angiographic system

Working principles

Traditional angiographic systems use x-rays to obtain the representation of blood and lymphatic vessels for diagnostic purposes. Since blood normally has the same linear attenuation coefficient (therefore the same radiopacity) as the surrounding tissues, it is necessary to use a particular radiopaque, water-soluble contrast agent, that has to be injected near the vascular structure intended to be examined. The infusion of the contrast agent can be performed by direct injection, or, if the district to be imaged is not directly accessible (for example, the coronary artery), by catheterization. In this last case the catheter is let in through the arterial access point and pushed into the vessels, until it reaches the vascular district to be examined.

At the beginning of its development, traditional angiography was performed on a special x-ray plate: the image obtained was static, fixed on a fluoroscope or film. This specialty thus allowed only the evaluation of the morphology of the blood vessels. With the refinement of radiological techniques, new imaging methodologies have been developed, such as digitized ones that allow examining the circulatory dynamics in a less invasive way. Thanks to the equipment's ability to highlight even poorly opacified vessels, there is the possibility of reducing the quantity of the contrast medium used. Frames and films are no longer saved on plates or films, but on CD-ROMs or similar storage media. Digital angiographic techniques are based on computerized radiological reconstruction of the vessel. Normally, an image obtained before the introduction of the contrast medium is “subtracted” from the images highlighted by the agent. In this way, with the help of special software the static image structures, such as bones and other organs (which appear with the same intensity before and after the introduction), are eliminated from the patient's angiograms, resulting in greater sharpness of the blood vessels. This technique is called DSA (i.e., Digital Substraction Angiography). At the end of the diagnostic part, if any problem was encountered, it is possible to intervene through the angiographic system with specific endovascular treatments, aimed at resolving the pathological condition identified. An example is the application of

stents to restore the patency of an occluded vessel. These procedures are referred to as interventional angiography.

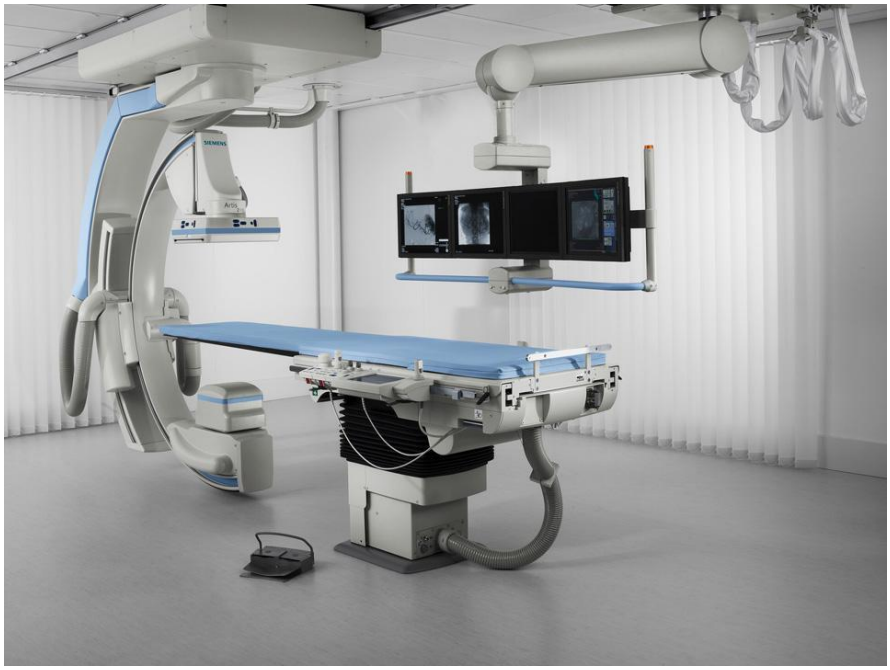


Figure 9: Siemens Artis Zee angiographic system.

The angiographic system (Figure 9) is a radiological equipment consisting of an x-ray tube placed above a radiolucent patient table, that allows the realization of multiple projections thus obtaining the visualization of the different opacified vascular districts in all their extension in extremely fast times. The tube is located at one end of a semicircular structure, called C-arm; at the other end there is the detector, which is oriented perpendicular to the direction of the x-rays. The system is positioned in such a way that the object of the scan is located between one extremity and the other.

An element of central importance is the configuration of the angiographic system within the environment. The structural options that define this characteristic are mainly two:

1. Ceiling- or floor-mounted system: whether the C-arm of the angiographic system is mounted on the floor or on the ceiling (which reflects on the structural constraints of the environment hosting the machine); in both cases, it is propped up by a multi-axis stand. However, this feature does not significatively influence either angiographic systems' cost, performance, or utilization fields.

2. Bi- or single-plane: the structural difference is that the bi-plane takes advantage of a two-axes detection method for capturing the images (i.e., it uses two C-arms, as shown in Figure xxx), while the traditional single-plane has got only one detector. This characteristic implies that bi-plane systems are able to acquire 3D images faster, especially useful in neurovascular and electrophysiology procedures. Even in the most recent products, the 3D reconstruction is a standard feature in the bi-plane, whereas it is an optional feature on the single-plane, in which additional software and hardware are required to implement it. However, the single-plane system can be flexible across a greater number of specialties (balloons, stents, etc.) with respect to the bi-plane; moreover, this latter requires a broader environment and a higher expense.

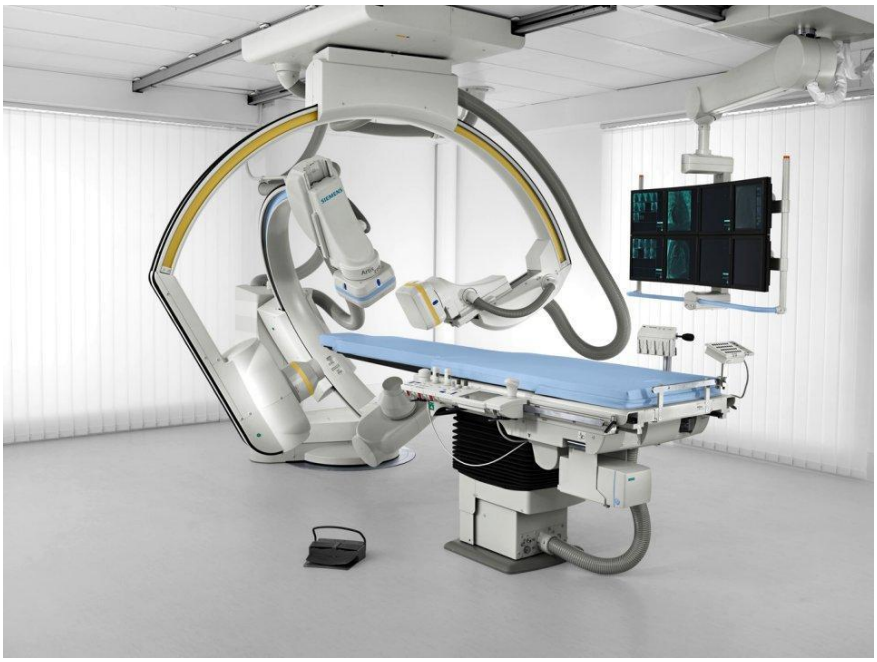


Figure 10: Siemens Artis Zee Biplane angiographic system

The main components of an angiographic system are listed below. These represent the elements common to all the systems; additional components differ from one manufacturer to another.

- X-ray tube.
- HDR detector: it is usually made up of amorphous silicon.

- Integrated Laser Cross: it is not always present, but it is very useful to simplify the patient positioning process. It is usually integrated into the detector housing.
- C-arm: it is the gantry of the angiography systems. The name derives from the C-shaped arm used to connect the x-ray source and x-ray detector to one another. Thanks to the many degrees of freedom available (shown in Figure 10), it makes possible an about 200° orbital scan of the patient and, consequently, the production of 3D images. This technique (called 3D C-arm computed tomography) uses two-dimensional x-ray projections acquired with a Flat Panel Detector to generate CT-like images. The C-arm system performs a sweep around the patient, acquiring up to hundred 2D views. They serve as input for 3D cone-beam reconstruction.

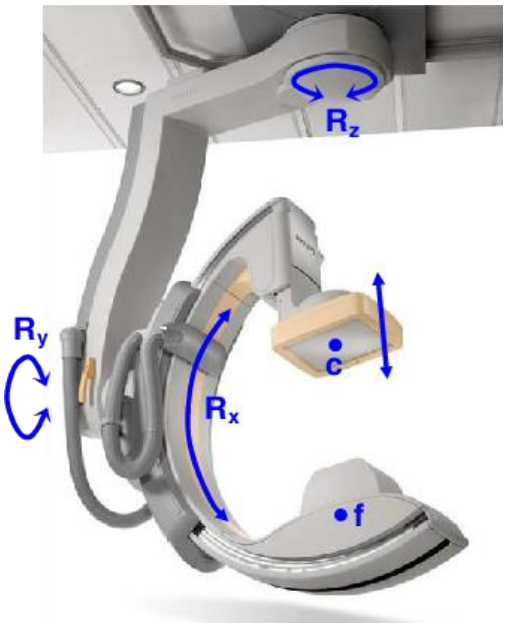


Figure 11: The x-ray angiography C-arm system's geometry, and its degrees of freedom. Rx corresponds to the angulation of the C-arm, Ry to the rotation, Rz is the L-arm rotation, f represents the focal spot of the x-ray tube and c is the centre of the detector.

- High resolution displays, to show the movements of the catheter introduced into the patient in real time.
- Control panel or "case flows": it is used for the remote control of the movements and some parameters of the system. It is able to store a sequence of system settings (for example: C-arm position, SID, filter/collimation, display layout, zoom factor, imaging parameters, etc.), thus simplifying the standardization of the procedures.

- Multi-tilt table.
- Multi-axis stand (either ceiling- or floor-mounted).

Uses

In general, each angiographic procedure can be addressed in two different directions: it could be carried out exclusively for diagnostics, or it could be extended to therapeutic purposes; in the latter case, the field is referred to as Interventional Angiography, which is to date the methodology of greatest clinical interest.

At a diagnostic level, the angiographic exam allows to analyze the anatomy and the vascular morphology (Figure 11), highlighting any alterations in the vessels, which may occur as narrowing of the vascular lumen of different entity, real occlusions, or vice versa as abnormal dilations (ectasias or aneurysms). The duration of the examination is variable: it generally takes place in a short time (about 20-30 minutes), differently from interventional ones that certainly require longer periods. One of the most common reason for prescribing an angiographic scan is the presence of clinical symptoms that suggest the occlusion of an artery (which could be caused by the presence of blood clots, atherosclerosis, etc.). It is also quite common to carry out an angiographic exam for the study of the vascular anatomy in anticipation of surgery, for example due to the presence of an aneurysm. The examination is also indicated in the suspicion of some bleeding, allowing the precise identification of the site and at the same time the possible treatment. Finally, a possible field of application is also oncology, for the diagnosis and characterization of neoplastic lesions.

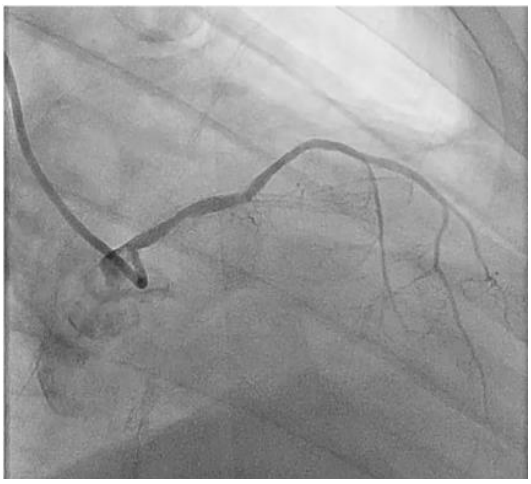


Figure 12: Coronary angiography image.

Thanks to the recent development of less invasive techniques, to the possibility of reaching very small caliber vascular districts through ultra-thin catheters, Interventional Angiography today represents a sector that has great potential in the medical field.

Once the "diagnostic" part of the study has been carried out, each procedure is completed by performing endovascular treatments, aimed at resolving the pathological condition identified. For example, in the case of vascular obstructions, the procedure uses angioplasty treatments and the positioning of stents or vascular prostheses, aimed at restoring the patency of the vessel.

Some examples of application fields of the Interventional Angiography technique at the Humanitas hospital are listed below.

- Treatment of atherosclerotic diseases (vascular stent placement or angioplasty).
- Treatment of aneurysmal pathologies (i.e., reduction of vascular dilations through the use of prostheses).
- Treatment of renal artery diseases.
- Embolization of bleedings.
- Trans-arterial chemo embolization (TACE).
- Transjugular Intrahepatic Porto-Systemic Shunt (TIPSS).
- Embolization of uterine fibroids.

Risks

The preparation for the angiographic examination requires the aforementioned precautions necessary for carrying out exams including the use of a contrast agent and an x-ray patient exposition. An additional potential risk factor is the insertion of the catheter, which can cause bleeding and infections, thrombosis, and blood vessel injuries.

2.3. Mammography systems

Working principles

Mammography is an x-ray imaging method used to examine the breast for the early detection of cancer and other breast diseases. It is used as both a diagnostic and screening tool.

During a mammogram, a patient's breast is placed on a flat support plate and compressed with a parallel plate called a paddle. An x-ray machine produces a small burst of x-rays that pass through the breast to a detector located on the opposite side. The detector can be either a photographic film plate (conventional mammographs), which captures the x-ray image on film, or a solid-state detector (digital mammographs), which transmits electronic signals to a computer to form a digital image. The images produced are called mammograms.

The breast needs to be compressed in order to minimize blurring of the x-ray image that can be caused by patient motion. Also, compression evens out the shape of the breast so that the x-rays can travel through a shorter path to reach the detector. This reduces the radiation dose and improves the quality of the x-ray image. Finally, compression allows all the tissues to be visualized in a single plane so that small abnormalities are less likely to be obscured by overlying breast tissue.

Four mammographs are in use at Humanitas hospital, all exploiting the digitization principle. In these devices, the solid-state detectors convert the x-rays that pass through them into electronic signals that are sent to a computer (similarly to the CT scanners). Then, the computer converts these electronic signals into images. Several advantages of using digital mammography over film mammography include: the possible manipulation of the image contrast for better clarity, the possibility to use Artificial Intelligence-aided detection of abnormalities, and the ability to easily transmit digital files to other devices, for example as part of a treatment planning. In addition, digital mammograms may decrease the need for the re-takes, which are common with film mammography due to incorrect exposure techniques or problems with film development. As a result, digital mammography can lead to lower x-ray exposures.

Moreover, Digital Breast Tomosynthesis, also known as 3D mammography, is an FDA-approved method for breast cancer screening in which x-rays of the breast are taken at

different angles to generate thin cross-sections. The result is similar to the 3D representation of CT images; tomosynthesis differs in that significantly fewer x-ray beams are projected than with CT and the x-ray exposure to the rest of the chest is way reduced.

The main limit of mammography is that in some difficult cases it may not be sufficiently sensitive or accurate in detecting cancer; therefore, additional imaging technologies, such as ultrasound or MRI may also be used in these situations.

Uses

On a mammogram, low density tissues, such as fat, appear translucent, whereas areas of dense tissue, such as connective and glandular tissue or tumors, appear whiter on a gray background.

A radiologist will examine a mammogram to search for high density regions or areas of unusual configuration that look different from normal tissue. These areas could represent many different types of abnormalities, including cancerous tumors, non-cancerous masses called benign tumors, fibroadenomas, or complex cysts. Radiologists look at the size, shape, and contrast of an abnormal region, as well as the appearance of the edges or margins of such an area, all of which can indicate the possibility of malignancy (Figure 13). They also

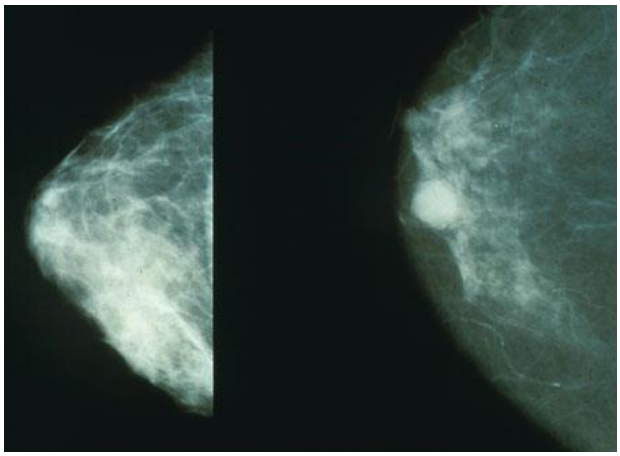


Figure 13: Healthy breast and a breast with a tumor.

look for tiny bits of calcium, called microcalcifications, which show up as very bright specks on a mammogram. While usually benign, sites of microcalcifications may occasionally signal the presence of a specific type of cancer.

Risks

As in the CT scanners, the main risk source is represented by the fact that breast images are generated through the use of x-rays, thus exposing patients to a small amount of ionizing radiation. For most women, the benefits of regular mammograms outweigh the risks posed by this amount of radiation. The risk associated with this dose appears to be greater among younger women (under age 40). However, in some cases, the benefits of using mammography to detect breast cancer under age 40 may outweigh the risks of radiation exposure. For example, a mammogram may reveal that a suspicious mass is benign and, therefore, doesn't need to be treated.

2.4. Radiography systems

Working principles

Radiography systems, also referred to simply as x-rays systems, are the simplest imaging tools, regarding the functioning principle, that are used in Humanitas hospital to assess an orthopedic problem. Differently from other more complicated and expensive systems, they are often available not only in hospital environments, but also in most doctors' offices. The obtained outputs may not be as detailed as an image produced with more sophisticated techniques, such as angiographic systems or CT scans. However, they are the first invented medical class of devices for imaging purposes, and and still the most used for diagnostic intent in Humanitas: on average, 50 services are provided per day using radiography systems (approximately 25% of the total services for diagnosis purposes), on a par with CT scans.

As in the other x-ray-based equipment, the body district being imaged is positioned between the x-ray machine and a photographic film or a digital x-ray detector, depending on the adopted technique. Then the process starts and the body part to be acquired is hit by x-rays, usually for a duration below one second. Therefore, output signals are transmitted and captured by the detector, and subsequently processed by the system. The phases of the process will be analyzed in detail during this paragraph. Differently from what was illustrated for the other imaging techniques based on the delivery of x-rays, in this case the

x-ray tube (i.e., the source of the beam) does not move around the patient. Hence, a step for the positioning of the tube and / or of the detector is necessary, contextually to the step for the placement of the patient (Figure 14).

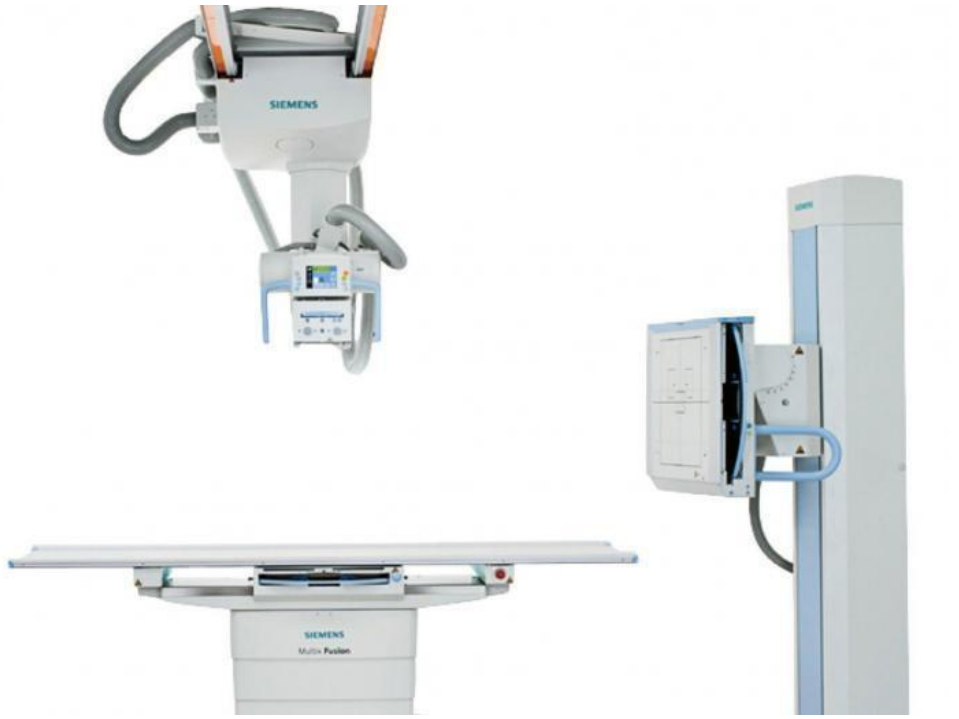


Figure 14: Siemens Multix Fusion Digital Radiography system, present in Humanitas hospital. At the top the x-ray tube structure, while at the bottom and on the right the Flat Panel Detectors. The use of one or the other depends on the body district to be imaged.

The patient may be imaged from several angles. An x-ray session usually lasts about 10 minutes. Then, images could be either developed from an x-ray film or written to a CD, depending on the used technique. Such as in the other x-ray-based devices, a contrast medium may be injected to the patient.

The advantages of these devices are their simplicity, low cost, sufficient image resolution for diagnosis purposes, good clinical efficacy, and flexibility to the situations of use. Nevertheless, radiographic technique has numerous limitations and constraints. Just to list a few examples: the fact that it provides a two-dimensional projection of a three-dimensional structure, thus losing depth information (limit overcome by CT technologies); the fact that

the geometry of the system could cause a low precision in the output, for example due to the presence of an enlargement factor.

The two possible functioning processes for radiography systems are analyzed below.

Conventional Radiography

The expression 'Conventional Radiography' refers to the first invented biomedical imaging technique, from which is obtained an image called Analog Radiography, through a print on radiographic plates (which represent the detector of the system). The radiographic film is covered on both sides by a sort of gelatin containing crystals of silver bromide (BrAg); this material is sensitive to x-rays and photosensitive, therefore the radiological image can be captured and developed, but not in real time. A low attenuation of the x-rays (due to the crossing a radiolucent structure, such as the lung tissues) results in a strong blackening of the radiogram; conversely, the higher is the attenuation of the beam (due to the crossing of a radiopaque structure, such as bones), the lighter is the image.

This methodology has been the best possible imaging technique for decades. However, it is now obsolete, since the digitization of this process leads to better results in less time. In Humanitas hospital, there are no technologies that adopt the conventional method of radiological imaging.

Digital Radiography

Conventional Radiography has increasingly evolved, taking great steps towards the complete digitization. This transition concerned the processes of acquisition, processing, visualization, whereas the working principles of the radiographs remained more or less the same. As explained before, in traditional Radiography the platform by which the analogic signal is recorded (i.e., the plate) is at the same time the support on which the image is visualized by the user. On the other hand, digital Flat Panel Detectors are used exclusively to acquire the signals making up the image, which are subsequently recorded, processed and visualized as a digitally stored radiogram.

Digital imaging is based on a semi-conductor technology, using matrixes of thousands of digital detectors that convert signals into numerical data. The working principle is based on the fact that high-energy x-rays interacting with the detector transfer a large number of electrons from the valence to the conduction band. As a consequence of the return of the

electrons to the lowest level, it occurs the emission of photons, which are converted in electric charges. Within a short time from the exposure (about 15-20 seconds), the acquired data are transferred from the detector to the computer by an optical fiber. The latent image is then digitally converted and processed to form a numerical image on a pixel matrix, and the user is allowed to visualize the image just acquired. Therefore, the digital image is basically a numerical representation of the object; numbers correspond to the extent of absorption of the radiation from the body, arranged on a two-dimensional matrix: each element of the matrix is called a pixel.

Digital Radiography offers several advantages over traditional radiology:

- Absence of disposables, such as films or reagents to fix the image on the traditional plate.
- Presence of a post-processing phase of the image.
- Possibility of quick storage in an electronic format.
- Possibility of image compression, with storage spaces saving.
- Possibility of fast transmission of the image, thus simplifying remote consulting activities (i.e., teleradiology).
- Decrease in time required to perform an exam.
- Reduction of the radiation dose to the patient.
- Enhancement in the image quality using the same dose.

However, Digital Radiography implies higher economic investments than the conventional technique; moreover, it shows a greater complexity.

Uses

The radiogram (i.e., the output of the radiographic exam) is mainly carried out to document bone degeneration (known as osteoarthritis), inflammatory changes (arthritis), any metastases or bone lesions in general, fractures following trauma. However, because of it is a low time-consuming exam, following which a very low dose of rays is delivered to the patient, and inexpensive both for the hospital and the patient, it is often carried out as an initial assessment to verify the possible presence of problems. If this presence were verified, the patient could move on to undergo more in-depth examinations.

Risks

The carrying out of the radiographic exams requires the aforementioned preventative measures necessary for carrying out exams including the use of a contrast agent and an x-ray patient exposition.

The provision of this performance often involves the use of reinforcement screens, formed by a transparent support covered with fluorescent material. They allow to considerably reduce the radiation doses with evident savings in terms of exposure; they have the function, in the case of adoption of the conventional technique, of emitting luminescence at the passage of photons x, reinforcing the photographic effect on the sensitive emulsion of the photographic films with which they are in contact.

2.5. Bone Mineral Densitometer (BMD) and Orthopantomograph (OPT)

Working principles

In this section, two systems based on the delivery of x-rays present in Humanitas hospital will be discussed; they are the Bone Mineral Densitometer (BMD) and the Orthopantomograph (OPT), which have been aggregated in the exposure for the following reasons:

- Common simplicity of the functioning principles with respect to the other presented devices.
- The fact that for both devices the dose delivered to the patient is considerably lower than in the other presented x-ray-based technologies.
- The fact that the area of competence of both is more restricted than the other technologies, which is reflected in a much lower number of services provided.

BMD working principles

Bone Mineral Densitometer (Figure 15) uses a very small dose of ionizing radiation to image a restricted body part (usually the lumbar spine and hips) to measure bone loss; the exam performed is named Dual-Energy X-ray Absorptiometry (DEXA or DXA; i.e., Mineralografia Ossea Computerizzata or MOC). It is commonly used to diagnose osteoporosis, a disease that leads to the progressive loss of quantity (and quality) of bone, ultimately leading to greater fragility of the skeletal system and to a greater risk of vertebral fractures, femur or other parts of the body. Respect to other imaging techniques, DXA is simple, quick, and noninvasive. It's also the most used method for diagnosing osteoporosis.

Figure 15: Hologic Horizon BMD, present in Humanitas hospital.

The exam is divided into two parts:

- The first represents the scan of the body district, which lasts a few minutes. The patient is supine on a couch, while an arched structure, positioned in such a way as to include the bed inside, moves back and forth in correspondence with the part of the body to be examined. This structure shifts along a linear path, without possessing additional degrees of freedom. At the end above the table there is the x-ray source, while in a diametrically opposite position (below the table) there is the detector. The BMD emits an x-ray beam with two different energy peaks passing through the body.

One of the two peaks is mainly absorbed by soft tissues (muscles and fat), the other by bones.

- The second represents the analysis and processing phase of the scan output, that is the achievement of the quantitative values of bone mineral density. By subtracting the part of x-rays absorbed by the soft tissues from the total emitted by the BMD, we obtain the bone mineral density, expressed through a few indices. The device is also connected to a computer, that first calculate through one or more software the output parameters, and then displays the results on a monitor or prints them for evaluation by the physician.

DXA scan and graph of a patient affected by Osteopenia (T score of -2.4), as the user visualize it after the scan

The DXA exam expresses two reference indices: the T score (that compares the patient's results with those of a population of considered-young people through a simple standard deviation comparison) and the Z score (that compares the patient's results, by standard deviation, with those of equal age and sex individuals). When T score and Z score are determined, the user is allowed to define the diagnostic picture (Figure 16).

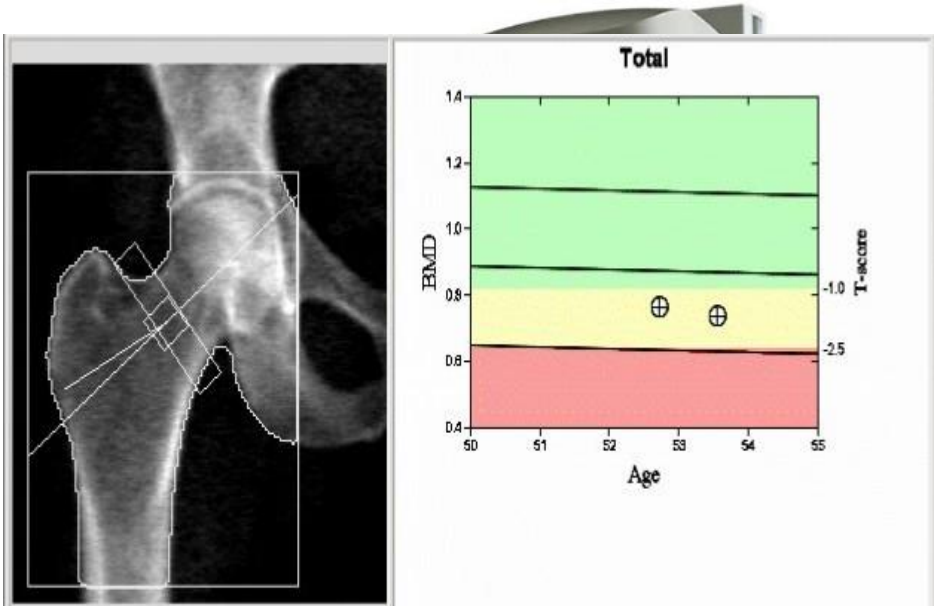


Figure 16:DXA scan and graph of a patient affected by Osteopenia

Figure 17: Kodak Ditech 9000C OPT, present in Humanitas hospital.

OPT working principles

The OPT scan or Dental Panoramic Radiography (DPR) is a quick and non-invasive radiographic exam that allows the study of the dental arches and the mandibular and maxillary bones, as well as the paranasal sinuses. With this imaging technique a "panoramic", or complete, representation of these bone structures is obtained, through which they can be visualized in a single radiographic image.

The dental arches have a curved configuration. To allow them to be viewed in a single flat image, the x-ray delivery system of the OPT must rotate synchronously with the “detector”,

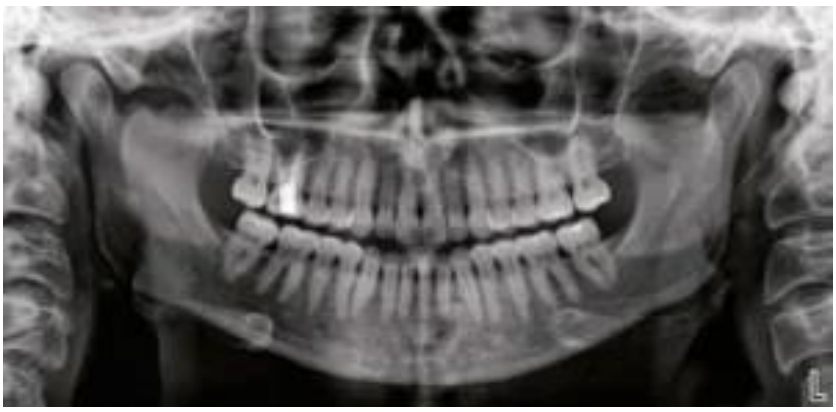


Figure 18: Dental panoramic obtained through OPT.

a radiographic film on which the image is captured (Figure 18). The patient's skull is positioned between the x-ray source and the film. This system slowly rotates around the patient's head, who has to remain still for the duration of the exam, which is about 15-20 seconds. The x-ray beam emitted by the tube is extremely thin, to cross each time a thin section of the arches and project the radiographic image on a precise point of the film. During the exam, the patient is standing in front of the device and is asked to bite a plastic plate, in order to obtain a stable position that at the same time allows alignment of the dental arches. Once the rotation of the tube-detector system is finished, the examination can be considered concluded. The output of this exam is a print on radiographic plates, such as in the Conventional Radiography method shown before (Figure 18).

Uses

BMD

As explained before, DXA is an assessment for the fragility of the bone structures and the presence of osteoporosis, particularly concerning the spine and limbs districts. However, it is also performed to evaluate the effects of a treatment for osteoporosis; in fact, using BMD it is possible to evaluate the therapeutic efficacy of the drugs used for the treatment of osteoporosis.

In general, in treating the following pathologies it is sometimes recommended to subject the patient to a DXA:

- Rheumatoid arthritis.
- Chronic renal failure.
- Chronic bronchitis.
- Syndromes that lead to malabsorption (celiac disease among all).

DXA indicates the relative risk of having a fracture. Although it is a valid method for measuring bone density, in some people it cannot be considered reliable. To cite two examples:

- In patients with spinal deformities, already known fractures of the vertebrae, or in those who have undergone surgery on the spine, the results of the BMD are considered not valid. In these cases, if required, it is necessary to perform a CT scan to obtain a bone density measurement.

- DXA of the wrist and heel are deemed valid, but the results cannot be directly compared with lumbar or hip exams. Furthermore, the wrist or heel test is not indicative for evaluating the effectiveness of treatment with osteoporosis drugs.

OPT

The DPR is a tool used to study the development of the dental structure in individuals in a specific age group, or to identify eventual problems related to the configuration of the dental arches or the fragility of single teeth. In general, it is recommended for the following situations:

- Study of granulomas and bone cysts.
- Study of wisdom teeth to evaluate and plan their extraction.
- Study of the dental arches in puberty subjects.
- Study of the paranasal sinuses.
- Dental evaluation before and after implant surgery.

Risks

DXA and OPT scan are tests that subject the patient to a minimal amount of ionizing radiation. Therefore, it is very unlikely that any kind of problem occur for the individuals examined. The risk factors are the same as for the x-ray-based devices listed above. For the OPT examination, any metal objects on the head (such as earrings or piercings, which could interfere with obtaining a good image), dental prostheses and dentures must be examined before the examination.

2.6. Magnetic Resonance Imaging (MRI)

Working principles

Magnetic Resonance Imaging (MRI) is a non-invasive imaging technology that produces tri-dimensional detailed anatomical images. It is based on a different mechanism than the x-ray scans: it consists in the excitation of the protons by applying a magnetic field, and then in the detection of the change in the direction of the rotational axis of protons found in the water of different tissues.

MRI scanners produce fields with different strengths, usually between 0.3 and 1.5 T; however, the intensity of the field can be even higher, as in the case of the Siemens Magneton Skyra (3 T). This intensity is a representative measure for the MRI scanner: the higher is the value, the higher will be also the Signal-Noise Ratio (SNR) of the output images. This means that, with a stronger magnetic field, the resolution of the image will be better, and it will be easier for a physician to detect a possible

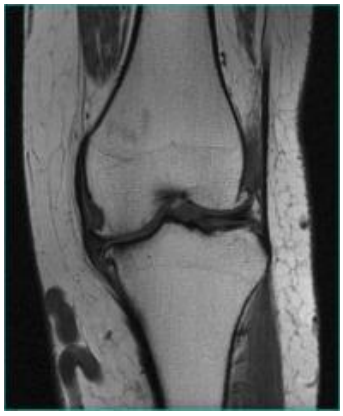


Figure 19: MRI of a knee.

disease in the patient. Moreover, also the velocity of the scanning will be higher.

The MRI scanner main component is the principal magnet. For medical purposes, there could be two different kinds:

- Permanent magnet: it is made of ferromagnetic material (e.g., steel). Although in this case the purchase price and the maintenance costs are substantially lower, it presents several problems: the magnet is bulky and weighs several tons, so its installation requires very stringent structural requirements. Furthermore, the maximum achievable intensity is rather low (about 0.4 T), and the homogeneity of the field in time and space are not excellent: consequently, the quality of the imaging is much lower than in the superconductive type. Finally, the fact that the field can never be deactivated is a security concern.
- Superconductive electromagnet: it is composed of a niobium-titanium alloy cable that, if cooled to temperatures close to 0°K, reduces its electrical resistance to zero. If current is allowed to flow inside this superconductor, a field with very high intensity and stability is obtained: most of the MR scanners for medical purposes are

built by exploiting these principles. On the other hand, the cooling is performed using liquid helium, which is costly, dangerous, and difficult to handle; moreover, the scanners exploiting these principles are more expensive than the permanent magnet ones.

When a strong magnetic field is applied, such as with an MRI scanner, the protons' axes all line up in the direction of the magnetic vector: they behave like small bar magnets (Figure 20). In fact, under normal circumstances, these protons lie with their axes randomly aligned. When additional energy in the form of a radio wave is added to the magnetic field, the magnetic vector is deflected. In the MRI procedure, these waves are produced by radiofrequency coils. The applied radio wave frequency (RF) that causes the hydrogen nuclei resonance is dependent on the element sought (hydrogen in this case) and the strength of the magnetic field. The strength of the magnetic field can be altered locally using a series of gradient electric coils. By altering the local magnetic field by these small increments, different slices of the body will resonate as different frequencies are applied: this is the principle exploited to create images.

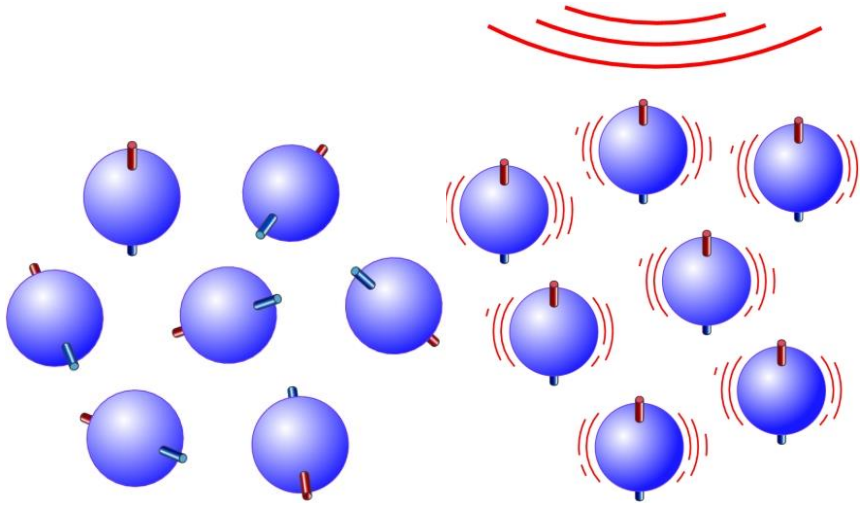


Figure 20:When a magnetic field is applied, protons line up in direction of it.

When the radiofrequency source is switched off the magnetic vector returns to its resting state, and this rotation produces a signal. This is the signal which is used to create the MR images. Receiver coils are used around the investigated body part to act as aerials, to improve

the detection of the emitted signal. The intensity of the received signal is then plotted on a grey scale and cross-sectional images are built up.

Multiple transmitted radiofrequency pulses can be used in sequence to highlight a certain tissues or abnormalities. This differentiation occurs because different tissues' protons return to the resting position at different rates when the transmitted radiofrequency pulse is switched off: the faster the protons realign, the brighter will be the image. Thus, the time taken for the protons to fully relax is a fundamental parameter to obtain this tissues discernment, and it is measured in two ways. The first is the time taken for the magnetic vector to return to its resting state and the second is the time needed for the axial spin to return to its resting state. The first is called T1 relaxation, the second is called T2 relaxation. An MR examination is thus made up of a series of pulse sequences. Because of the micro-structural variety of the components, they are made of (such as fat and water), different tissues have different relaxation times and can be identified separately.

Similarly with the CT scanning, contrast agents (often containing the element Gadolinium) may be given to a patient intravenously before or during the MRI to increase the speed at which protons realign with the magnetic field.

Uses

MRI scanners are particularly well suited to image the non-bony parts or soft tissues of the body. The brain and the spinal cord, as well as muscles, ligaments, and tendons are seen much more clearly with MRI than with x-rays systems; for this reason, MRI is often used to image knee and shoulder injuries. MRI can differentiate between white matter and grey matter in the brain, and it can also be used to diagnose aneurysms and tumors. Because MRI does not use x-rays or other radiation, it is the imaging modality of choice when frequent imaging is required for diagnosis or therapy. However, MRI is more expensive than x-ray imaging or CT scanning.

One kind of specialized MRI is functional Magnetic Resonance Imaging (fMRI). This is used to observe brain structures and determine which areas of the brain are "active" (i.e., consume more oxygen) during various cognitive tasks. It is used to advance the understanding of brain organization and it potentially sets a new standard for assessing neurological status and neurosurgical risk.

Risks

Although MRI does not emit ionizing radiations as well as in x-ray and CT imaging systems, it does employ a strong magnetic field. It extends beyond the dimensions of the machine and exerts very powerful forces on objects of iron, some steels, and other magnetizable objects.

When having an MRI scan, the following should be taken into consideration:

- Problems linked to the magnetic field: people with implants, particularly those containing iron: devices like pacemakers, implantable cardioverter-defibrillators, loop recorders, insulin pumps, cochlear implants, and deep brain stimulators should not enter an MRI exam room.

- Noise: the noise intensity is up to 120 decibels in certain MR scanners: thus patients may need special ear protections.

- Nerve stimulation: a twitching sensation sometimes results from the rapidly switched fields in the MRI.

- Contrast agents: patients with severe renal failure who require dialysis may risk a rare but serious disease called nephrogenic systemic fibrosis that may be linked to the use of certain gadolinium-containing agents. Although a causal link has not been established, the recommendation is that dialysis patients should only receive gadolinium agents when essential, and that dialysis should be performed as soon as possible after the scan.

- Claustrophobia: people with even mild claustrophobia may find it difficult to tolerate long scan times inside the machine. Factors that may help to overcome patients' discomfort are familiarization with the machine, as well as visualization techniques, sedation, and anesthesia. Additional mechanisms include listening to music or watching a video or movie. Although these measures are generally effective, in all MRI scanners there is at least one camera to monitor the patient during the acquisition procedure.

To make at ease those patients who are uncomfortable with the tunnel and noises of the traditional MRI, or whose size or weight represent a problem for the procedure, the open

MRI was introduced in the last decade. It is a machine that is open on the sides and so it does not fully surround the patient, differently from the most common type, which is tube-shaped and closed at one end. One example of this innovation is the Philips Panorama MR scanner.

2.7. Nuclear Medicine

Working principles

Nuclear medicine is a medical specialty that uses radioactive tracers (radiopharmaceuticals) to assess bodily functions and to diagnose and treat disease. Specially designed cameras allow physicians to track the path of these radioactive tracers. Single Photon Emission Computed Tomography (SPECT) and Positron Emission Tomography (PET, Figure 21) scans are the two main imaging modalities in nuclear medicine.

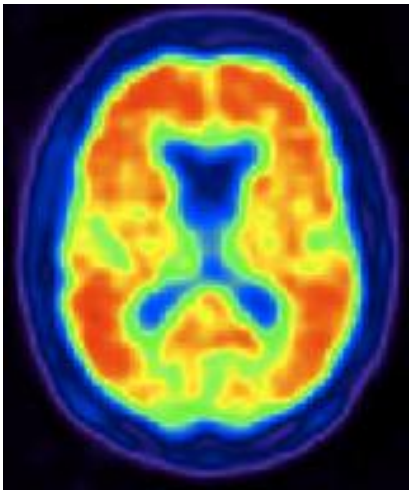


Figure 21: Positron Emission Tomography (PET) scan of the brain.

Radioactive tracers are made up of carrier molecules that are bonded tightly to a radioactive atom. These carrier molecules vary greatly depending on the purpose of the scan. Some tracers employ molecules that interact with a specific protein or sugar in the body and can even employ the patient's own cells. For example, in cases where doctors need to know the exact source of intestinal bleeding, they may radiolabel (i.e., add radioactive atoms) to a sample of red blood cells taken from the patient. They then reinject the blood and use a

SPECT scan to follow the path of the blood in the patient. Any accumulation of radioactivity in the intestines informs doctors of where the problem lies.

For most diagnostic studies in nuclear medicine, the radioactive tracer is administered to a patient by intravenous injection. However, a radioactive tracer may also be administered by inhalation, by oral ingestion, or by direct injection into an organ. The mode of tracer administration will depend on the disease process that is to be studied.

Approved tracers are called radiopharmaceuticals since they must meet FDA's exacting standards for safety and appropriate performance for the approved clinical use. The nuclear medicine physician will select the tracer that will provide the most specific and reliable information for a patient's particular problem. The tracer that is used determines whether the patient receives a SPECT or PET scan.

Single Photon Emission Computed Tomography (SPECT) working principle

SPECT imaging instruments provide tomographic images of the distribution of radioactive tracer molecules that have been introduced into the patient's body. The 3D images are generated during a post-processing phase from a large number of projection images of the body, recorded at different angles. SPECT imagers have gamma camera detectors that can detect the gamma ray emissions from the tracers that have been injected into the patient. Gamma rays are a form of light that moves at a different wavelength than visible light. The cameras are mounted on a rotating gantry that allows the detectors to be moved in a tight circle around a patient on a pallet.

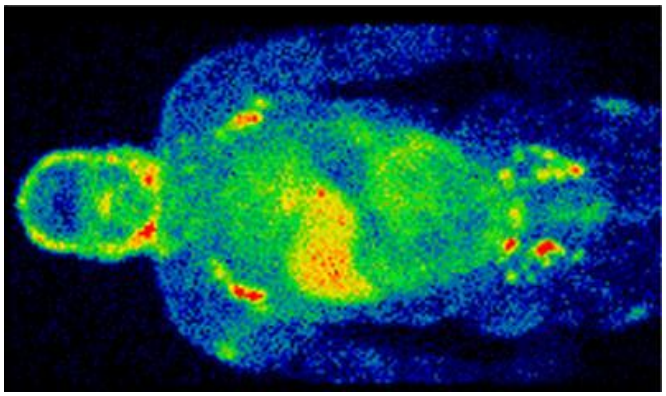


Figure 22:Single Photon Emission Computed Tomography (SPECT) total body scan.

Positron Emission Tomography (PET) working principle

PET scans also use radiopharmaceuticals to create three-dimensional images. The main difference between SPECT and PET scans is the type of radiotracers used. While SPECT scans measure gamma rays, the radiotracers used with PET scans produce small particles called positrons. A positron is a particle with roughly the same mass as an electron but oppositely charged. These react with electrons in the body and when these two particles combine, they annihilate each other. This annihilation produces a small amount of energy in the form of two photons that shoot off in opposite directions. The detectors in the PET scanner measure these photons and use this information to create images of internal organs.

Uses

SPECT scans are primarily used to diagnose and track the progression of heart disease, such as blocked coronary arteries. There are also radiotracers to detect disorders in bone, gall bladder disease and intestinal bleeding. SPECT agents have recently become available for aiding in the diagnosis of Parkinson's disease in the brain and for distinguishing this disease from other kinds of movement disorders and dementias.

The major purpose of PET scans is to detect cancer and monitor its progression, response to treatment, and to detect metastases. Glucose utilization depends on the intensity of cellular and tissue activity, so it is greatly increased in rapidly dividing cancer cells. In fact, it is possible to relate the degree of aggressiveness for most cancers and cells' rate of glucose utilization. In the last 15 years, slightly modified radiolabeled glucose molecules (F-18 labeled deoxyglucose, or FDG) have been shown to be the best available tracer for detecting cancer and its metastatic spread in the body.

A combination instrument that produces both PET and CT scans (Figure 23 and 24) of the same body regions in one examination (PET/CT scanner) has become the primary imaging tool for the staging of most cancers worldwide.

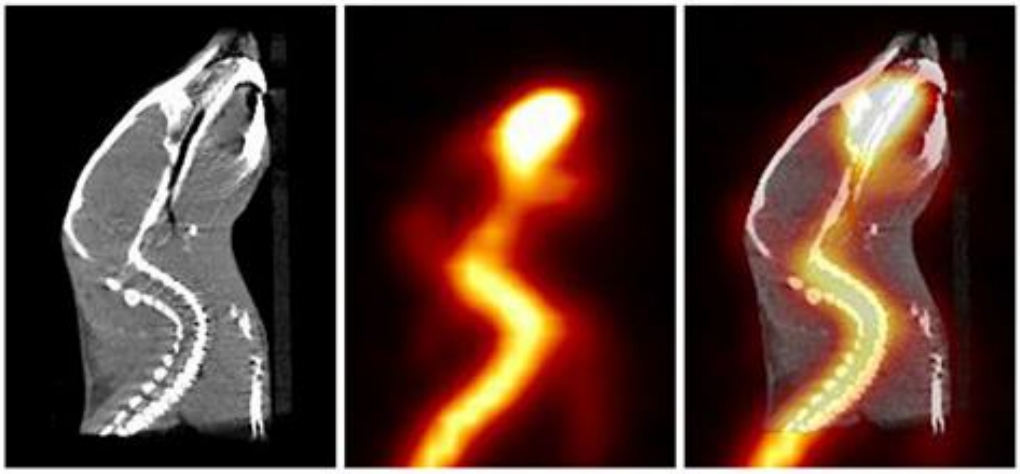


Figure 23:Researchers demonstrate that combined PET/CT (right) of a mouse provides a more complete view of the spine than CT (left) or PET (middle) alone.

Recently, a PET probe was approved by the FDA to aid in the accurate diagnosis of Alzheimer's disease, which previously could be diagnosed with accuracy only after a patient's death. In the absence of this PET imaging test, Alzheimer's disease can be difficult to distinguish from vascular dementia or other forms of dementia that affect older people.

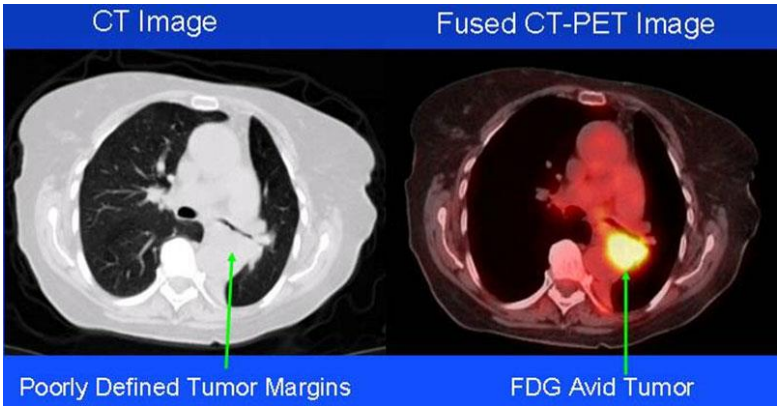


Figure 24:Fused CT-PET scans more clearly show tumors and are therefore often used to diagnose and monitor the growth of cancerous tumors.

Risks

The total radiation dose conferred to patients by the majority of radiopharmaceuticals used in diagnostic nuclear medicine studies is no more than what is conferred during routine

chest x-rays or CT exams. There are legitimate concerns about possible cancer induction even by low levels of radiation exposure from cumulative medical imaging examinations, but this risk is accepted to be quite small in contrast to the expected benefit derived from a medically needed diagnostic imaging study. However, nuclear medicine physicians are strongly committed to keeping radiation exposure to patients as low as possible, giving the least amount of radiotracer needed to provide a diagnostically useful examination.

2.8. Linear Accelerator

Working principles

In the field of radiotherapy, the linear accelerator (LINear ACcelerator, LINAC; figure) is the device that makes it possible to generate the particle beam (in particular, electrons in treatments that use X-rays or carbon ions in hadrotherapeutic treatments); the latter targets a tumor region in the patient and aims to neutralize the disease by acting on the ability of cells to reproduce. LINAC uses high frequency electromagnetic waves to accelerate charged particles; it is currently the prevailing technology in external radiotherapy. Also on the tomotherapy machines the radiation generation system is a 6 MV X-photon emission LINAC, more compact than the original version, which rotates on a ring gantry. The LINAC used in radiotherapy exploit electromagnetic waves, stationary or traveling, with a frequency of approximately 3000 MHz: the structural difference is represented by the fact that in the traveling wave structures there is, at the end of the structure, a load capable of absorbing energy. residual to avoid the formation of a reflected wave. A simplified illustration of its operation can be made with a block subdivision of its structure: these are the modulator, the treatment bed, the gantry and the stand. The main components of each of these large blocks are listed and briefly explained below; below, the operation of each of them will be considered in more detail.

The modulator contains the electrical circuits that distribute the voltage to the LINAC starting from the nominal one, and provides the high voltage peak to emit the electrons. The treatment bed can be controlled via a pendant and allows horizontal, vertical movements or can rotate around the isocenter. Furthermore, we must not forget the various centering systems such as lasers and the distance measurer, essential for the positioning of the patient

to be reproducible for the entire duration of the therapy, a necessary condition for correct treatment.

The stand is anchored to the ground and supports the gantry that rotates around the bed. In particular, the gantry can rotate up to 360 ° around the patient, more precisely around a particular point called isocenter, identified as the intersection between the axis of rotation of the gantry and the central axis of the beam, usually placed at 100 cm from the source of the rays. The isocenter that is used in this technique is a virtual isocenter, translated with respect to the real one by a known quantity (about 70 cm) along the axis of rotation in the negative direction. In this way, the initial positioning of the patient is made easier with the aid of a laser system that will be analyzed later. The accelerator structure is located in the gantry and rotates axially around the isocenter.

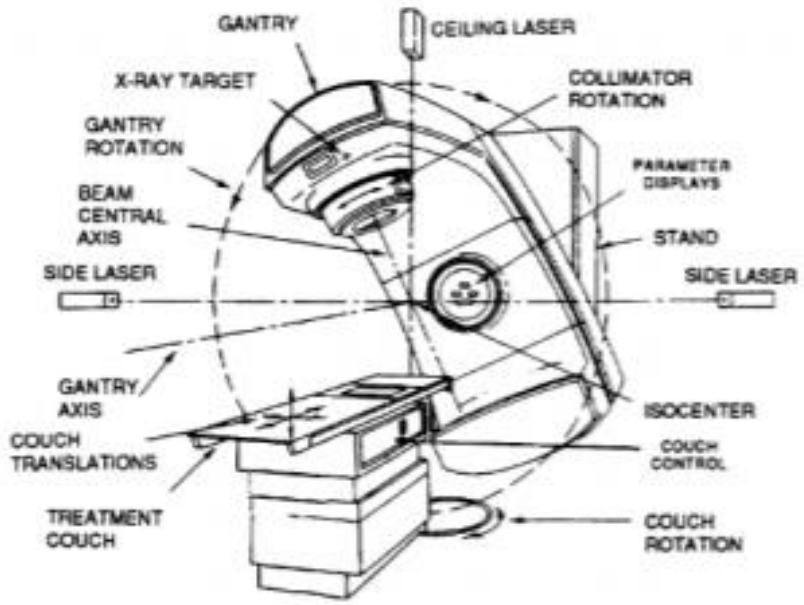


Figure 25:Schematic view of the treatment unit.

The most important parts inside the stand are:

- Klystron or Magnetron - generates power in the form of microwaves, to accelerate electrons and is electrically isolated, via an oil tank. The

difference is represented by the fact that the Magnetron is used only in the smaller LINACs and in the linear accelerators for tomotherapy machines;

- Waveguides - through which the microwaves are transferred to the accelerating cavity located in the gantry;
- Circulator - inserted in the wave guide, it isolates the high voltage generator from the microwaves reflected by the accelerator guide.

In the gantry instead we find:

- Electron gun - produces the electrons that will be accelerated;
- Accelerating structure - electrons are accelerated by high-power microwaves;
- Bending magnet - placed at the exit of the accelerator structure, it deflects the electrons to direct them towards the head;
- Head - contains the tools to measure the beam and shape it;
- Beam stopper - present in some LINACs, it is used to block the beam that has passed through the patient, thus allowing to reduce the external masonry shields.

The main components of a linear accelerator (Figure 26) and their operating principles are analyzed in detail below.

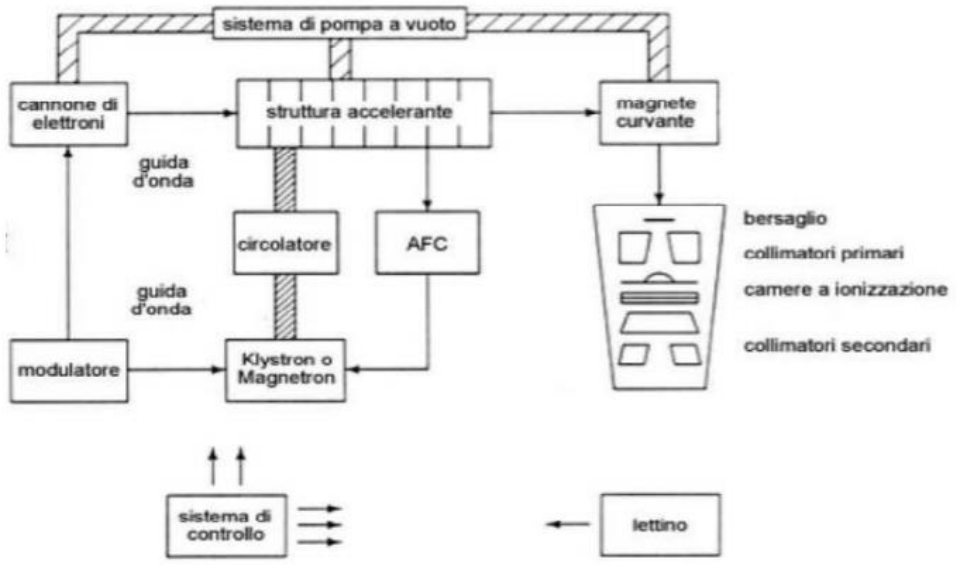


Figure 26: Block diagram of a linear accelerator

It should be noted that some "ancillary" components are needed to power and operate a linear accelerator correctly, but no less important: these are the generator, the cooling system and the vacuum pump system.

- The power supply supplies current to the most devices present in a LINAC, starting from a voltage of 380 V.
- The closed-circuit cooling system is usually made with filtered and cooled water from the water mains, through a heat exchanger (operating T = 26 - 29 ° C).
- The vacuum pump system (ion pump) is necessary to maintain the vacuum in the parts where it is needed, even with the appliance off (vacuum = 10-6 atm): as you can see from the block diagram, the latter is connected to the electron gun, the accelerating structure and the bending magnet.

The modulator is made up of a first circuit (called "fly back"), a transformer (called "charging transformer") which leads to a voltage of 600V, and a further part of the circuit consisting of "thyratron" and "pulse forming network". The thyratron is a switch through which a current of the order of 100 A can pass: its closure is controlled by the PRF (Pulse Repetition Frequency) pulse train which determines the production of pulsed type radiation. The pulse forming network is formed by a capacitor whose charge and discharge (in conjunction with the closing and opening of the thyratron) produces the pulse. This pulse is amplified by the pulse transformer up to a voltage of about 50 kV. The modulator thus produces high voltage pulses, at a frequency of a few hundred per second, which constitute the synchronous input signal that will then be transmitted: the length of the pulses is a few microseconds with intervals, between one pulse and another, of a couple of milliseconds, and it is the pulse repetition frequency that establishes the nominal dose rate of the beam produced. The pulse thus amplified is transmitted simultaneously to the Magnetron (or Klystron) and the electron gun.

Microwave production: Magnetron and Klystron

Magnetron and Klystron are two different devices suitable for the production of microwaves. The klystron is actually just a microwave amplifier, which must therefore be previously produced by a low-power oscillator. These low-power microwaves are conveyed into a cavity, and at the same time electrons are produced and introduced into the cavity: they will

be accelerated or decelerated according to their phase with respect to the microwaves. The electrons are then sent to a second cavity, and due to their passage current flows are generated that induce microwaves of greater power than the initial one. The amplification stages of a klystron for medical use are usually three or four. But the klystron has a big problem that does not allow us to use it in the tomotherapy machine: in fact, it must always operate with the same orientation with respect to the earth's magnetic field. Therefore, it is impossible to position it directly on the rotating gantry. The magnetron instead works as a high frequency oscillator: it consists of a cylindrical structure with a central cathode and an external copper anode with resonant cavities (between the cathode and anode there is a vacuum): the whole structure is placed in a field uniform magnetic with lines of force perpendicular to the cylinder section. By heating the cathode through an internal tungsten filament, electrons are produced by the thermionic effect. These electrons undergo the simultaneous action of the electric field that accelerates them towards the anode, and of the magnetic field perpendicular to the cylinder section: the result is a spiral motion of the electrons through the resonant cavities. When the cavities oscillate, the electrons can be either accelerated or decelerated by passing through the mouth of the cavity: they will tend to gather in a cloud of space charge, and radiation in the form of microwaves. In summary, the electrons produced by the cathode are accelerated by a negative potential difference, and arrive in the first cavity (buncher): the low-power microwaves establish an alternating electric field that "discretizes" the flow of electrons in packets (bunch). In the following cavity (catcher), resonating at the microwave frequencies of the packets, the bunches induce charge on its walls, generating a decelerating electric field: their kinetic energy is then converted into high-power microwaves (Figure 27).

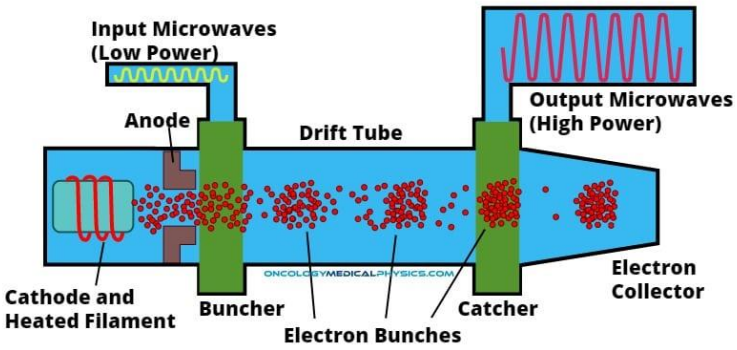


Figure 27: High-Power microwaves generation by magnetron mechanism

The production of electrons: electron gun

As previously mentioned, the impulses that the modulator sends to the magnetron are also sent simultaneously to the electron gun (electron gun): it produces electrons by thermionic effect and injects them into the wave guide with an energy of about 50 keV and a speed equal to about 40% of the speed of light (c = 299792.458 km / s). The emission of the electron occurs in synchronous times at the moment in which energy is supplied to the wave guide to accelerate the charged particles (radio frequency). The electrons reach the first acceleration cavity of the guide in phase with the microwave. The wave guide is a linear structure that conveys and confines electromagnetic waves within a path between the two ends, thus allowing their guided propagation. The total electromagnetic field propagating in a waveguide can be thought of as a linear combination of propagation modes (wave-field approach): each mode of propagation is a "simple" configuration of a field (or wave) that propagates in driving, remaining unchanged. An important feature is the ability of the waveguides to prevent the waves from traveling backwards along the traversed section: in doing so, the waves cannot (and cannot) return to the magnetron by reflection. Closely connected to the main functionality of the wave guide is the presence of the circulator (even more than one), which is an electronic component consisting of a circular cavity equipped with three or more ports on the perimeter: what characterizes it is the direction of rotation, highlighted by an arrow printed on the casing such that the signal introduced by a door exits from the adjacent door in the direction indicated.

Acceleration structure

In a traveling wave accelerator, the electromagnetic wave is introduced at the point where the gun injects the electrons. The wave, therefore, travels along the acceleration structure and can be reduced in intensity due to two events:

- A transfer of energy to the electrons.
- Induced currents in the walls of the structure.

The small amount of energy left is brought back to the starting point or, more generally, absorbed by a suitable load. The speed of the microwave is made to coincide, at the entrance, with that of the electrons injected by the gun: the electrons thus gain energy from the microwave, "riding" the crest, as happens when surfing. This is made possible thanks to the presence of rings that interact with the electromagnetic field of the wave. As the electrons gain energy by "surfing", the wave is also allowed to accelerate by varying the arrangement and structure of the rings along the waveguide. The electrons that are accelerated tend to diverge, partly due to "Coulombian" repulsion, partly because the electric field present in the structure has a radial component: to force the electrons not to diverge, a field is generated using suitable coils coaxial magnetic. Thus, when the electrons reach the end of the wave guide, they take the form of a "pencil beam" of about 3 mm in diameter.

The head: production and transport of the beam

Let us now turn to the production and transport of the particle beam, once these have been accelerated. All the mechanisms that deal with this part of the supply are included in the head of a linear accelerator, which consists of a thick cell of high-density shielding material, such as lead, tungsten, or their alloys. Inside we find:

- Target.
- Flattening filter.
- Collimators.

- Scattering foils.
- Light and rangefinder.
- Camera monitor.
- Any additional filters.

The target is built with a material with a high atomic number, such as tungsten W (Z = 74): it is cooled, and thick enough to absorb most of the incident electrons. Given the range of energies involved (MeV), the X-rays produced by “bremsstrahlung” have the “forward” direction as their preferred direction. The German term bremsstrahlung, literally "braking radiation", indicates the radiation emitted by charged particles when they undergo a strong acceleration or deceleration: this typically occurs when the particles are thrown against a metal target (to prevent it from melting, it is put into continuous rotation and water cooled); since electrons are much lighter than protons, electronic bremsstrahlung is the most common. According to Maxwell's four fundamental equations, accelerated charges emit electromagnetic radiation and, if the energy of the bombarding electrons is high enough, the emitted radiation is found in the X-ray region of the electromagnetic spectrum. Single lines are also superimposed on this continuous spectrum, since it may happen that the bombarding electrons cause electrons to escape from the innermost atomic layers of the target; the rapid filling of these gaps by electrons from the upper layers produces characteristic X-rays for each atom. As we have seen so far, LINAC accelerates charged particles through high frequency electromagnetic waves: these accelerators are capable of producing both electron and photon beams, based on the conversion applied in the machine head to the accelerated electron beam. Typically, accelerators for medical use are capable of producing photon beams with nominal acceleration potential of 6 MV, 15 MV and 18 MV and electron beams of 6 MeV, 9 MeV, 12 MeV, 16 MeV and 20 MeV: to obtain the lower energies the frequency of the wave is modified. The choice of electron or X-ray therapy depends solely on the location of the tumor to be treated; electrons are used for superficial pathologies, as they deliver the dose to the surface, while X-rays reach much deeper.

The electron beams exit the accelerator section with a diameter of about 3 mm, too narrow for clinical use. To widen the section of the beam, the electrons are made to diffuse through the passage in scattering foils, thin metal sheets of copper, aluminum or lead, of such thickness as to minimize the possibility that the electrons are subject to bremsstrahlung.

On the contrary, in the case of X-rays, a flattening filter (homogenizer filter) is usually used so that the intensity of the beam is uniform on the irradiation field, which is inserted directly into the beam. It is a bell-shaped object (larger in the center and degrading towards the edges) made of an absorbent material (generally tungsten) which has the task of attenuating the beam ensuring a homogeneous dose distribution (in the case of treatments with electrons it is excluded from the path of the beam). At energies of the order of MeV, as previously mentioned, the main direction of bremsstrahlung radiation is forward, therefore in the simplest accelerators the target is fixed and the accelerating structure is coaxial with the emerging X-rays (i.e. it is parallel to the direction of flight of the electrons, so as not to make it necessary to deviate them) and perpendicular to the patient's cranio-caudal axis. However, for energies above 6 MeV, the length of the accelerator tube is such as to make this solution impractical. In order to bring the photon beam to irradiate the patient from any angle, it is necessary to deflect the electrons of the beam by approximately 90 °: this is easily achieved with the use of deflecting magnets (or bending magnets).

The task of monitoring the quality of the beam, i.e. checking if the beam is homogeneous and symmetrical, is performed by two multi-channel ionization monitor cameras, usually flat and transmitting. The beam, after passing a system of fixed primary collimators and the various scattering foils and flattening filters, affects the monitor cameras. The function of these chambers is to monitor the “dose rate” (integrated dose), and the symmetry of the field (dose at the edges). The chambers are sealed so that their response is not affected by changes in temperature and pressure. The integrated dose reading is the one that commands, under normal conditions, the interruption of irradiation. Typically these ionization chambers have a thickness of a few tenths of a millimeter each, therefore such as to disturb the radiation beam only minimally: the signals of the monitor chambers are used as inputs to a system of coils called focusing coils and steering coils, which reposition correctly the photon beam if it does not affect the target optimally.

Above and below the monitor cameras there are two fixed collimators, Primary and Secondary collimator; they are made of material with high density and high atomic number, capable of shielding the beam, defining its maximum angular dispersion. Immediately below the secondary collimator there are two mobile collimators, perpendicular to each other: each of these is made up of two blocks of tungsten ("jaws") that move away or approach, driven by a computer, according to the desired dimensions for the field . Through this system it is

possible to create symmetrical or asymmetrical, rectangular or square fields, of different sizes (usually the maximum allowed is around 40 x 40 cm). However, in the case of electron beams the situation is more complex: the sensitivity of the output with respect to the opening of the two jaws is more significant; therefore further fixed collimators, called applicators or cones, are attached to the head. In recent accelerators there are particular Multi-Leaf Collimators (MLC) characterized by many blades (for example two banks of 40 blades each), controlled and moved by electric motors: this further collimator system allows the use of a greater number of fields shaped (which unlike the square or rectangular openings, are adapted to reflect the shape of the target) which contribute to the reduction of the dose to healthy tissues.

Immobilization system

Although the high-tech couch provides the necessary safety with regard to the patient's position and the respective accuracy (millimeter), this is still not enough. To obtain the greatest possible precision from the radiation treatment, it is necessary to obtain, for all sessions, the same position in which the patient must remain perfectly still for the entire duration of the session. For this reason, “auxiliary” (commonly used) immobilization systems are used. There are many forms and invoices, precisely to remedy the immobilization in any position (even the strangest) that must be maintained for irradiation in some tumor district. For example, if the patient has to undergo irradiation of the head and neck area, he will be immobilized through a mask, the cast of which is obtained by immersing a thin sheet of plastic material with special holes for eyes, nose and mouth in hot water. : the sheet, made soft and malleable, will be spread on the face and will take its shape. Subsequently, the mask (figure) will be attached laterally to the therapy bed, before each session.

Figure 28:Mask used for the treatment

Uses

The linear accelerator is used in radiotherapy, which uses ionizing radiation, such as those used in diagnostics but of much higher energy, and other types of radiation (gamma rays, electrons, heavy particles) to treat some diseases, in particular tumors.

In external beam radiotherapy, the linear accelerator, placed at a certain distance from the body, focuses the beam of radiation on a specific area (i.e., clinical target volume) to be treated in a painless way for the patient, who lies on the couch. The treatment is performed dividing the total dose dispensed into a certain number of sessions.

In the oncology field (cancer treatment), radiotherapy can:

- Stop the growth of the tumor temporarily or permanently.
- Alleviate, partially or completely, the disturbances caused by the disease.

The latest data indicate that this option is used in at least 60% of all cancer cases, often in association with other techniques. Linear accelerator radiotherapy is useful for almost all types of cancer, but there are some areas where evidence is more striking: one of these is prostate cancer, a high-incidence disease in males in which radiotherapy leads to results completely comparable to those of surgery. Another area where progress is notable is rectal cancer.

LINAC radiotherapy can have essentially three different roles in cancer treatment:

- As the first and only treatment, when the disease can be cured with radiotherapy alone.
- Before surgery, to reduce the size of the disease and improve the effectiveness and the tolerability of the operation.
- After surgery, to destroy the remaining diseased cells.

Radiation therapy is often used in conjunction with chemotherapy or other pharmacological therapies that increase its effectiveness.

The correct functioning of the accelerator and the elaboration of the treatment plan are guaranteed by the collaboration with the medical physicist. On the couch the patient is prepared by the radiotherapy technicians who position him accurately. The target volume is verified with a CT (sometimes mounted on the same accelerator; alternatively, such as in Humanitas hospital, it may be a separated machine). The positioning of the patient is verified by an onsite laser system; then, the actual treatment session begins.

Risks

An important distinction about radiotherapy related disorders is to differentiate early or acute disorders (those that appear during the treatment period and gradually disappear after the end of treatment) from late or permanent disorders. With regard to early disorders, an interview and, if necessary, a check-up visit with the radiotherapist is scheduled during the course of treatment to assess their possible occurrence. The doctor eventually prescribes supportive treatments (painkillers, anti-inflammatories, etc.) to alleviate the highlighted complaints. Blood tests or other diagnostic tests may also be required to deepen the evaluation. In most cases, the early side effects caused by the radiotherapy treatment are temporary and tend to appear in the second half of the therapeutic cycle, and then gradually diminish after the end of the treatment. They depend not only on the part of the body irradiated and the dose administered, but also on the patient's general state of health, and above all on individual sensitivity factors that are difficult to predict. Most of the effects are bothersome but not serious, while in less frequent cases, supportive medical care may be required. Only in extreme cases hospitalization may be necessary to complete the planned treatment.

2.9. Gamma Knife

Working principles

Gamma Knife radiosurgery has become a popular technique in last few years, thanks to its relative non-invasiveness. It was introduced at the end of the 1960s to treat functional

Figure 29:Above: fixation of the head frame through the insertion of four screws, two in anterolateral and two in occipital positions. Below: setup of the head frame.

disorders of the brain, whereas today it is used mostly to treat tumors and vascular malformations. This type of radiosurgery is a frame-based technique that delivers radiation from a fixed radiation source; it operates on the principles of stereotaxis, to obtain a high level of precision in localizing the disease. Planning and treatment usually take place on the same day, in a single session. On the day of treatment, the first step involves placement of the stereotaxic frame under local anesthesia. This frame defines a reference coordinate system that allows to identify points in the brain with high precision. During imaging procedures (usually MRI) carried out to better identify exactly where the target is, a system of fiducial markers is also used with the frame, in order to know the relative position of all areas of interest within the images with respect to this stereotactic space. Then, a treatment planning system, specifically developed for the Gamma Knife, allows detailed dose distributions to be created, thus helping to ensure that the target of interest is covered by a clinically significant dose, while sparing normal brain tissue.

Typically, four points (two anterolateral and two occipital) are chosen to ensure suitable frame fixation. A mixture of 2% lidocaine with sodium bicarbonate is injected into the insertion points for local anesthesia. Bupivacaine can be injected simultaneously for long-term analgesia. The screws are then inserted into the frame and into the skull. The screws are appropriate if, after the insertion, they are perfectly aligned with the frame. If a screw is too long, it will be on the outside of the frame; this configuration, in addition to creating artifacts during the MRI, could interfere with the treatment beams.

The basic physics of the Gamma Knife has remained substantially the same since its conception. The device uses 60Cobalt (60Co) as a radiation source. 60Co decays through beta decay to a stable isotope of Nickel (60Ni) with a half-life of 5.26 years. As a part of the decay process, one electron with an energy of up to 315 keV and two gamma rays with energies of 1.17 MeV and 1.33 MeV are emitted. It is the gamma radiation that is used to clinical effect in the gamma knife and contributes to the naming of the device.

The details of the internal design of the Gamma Knife changes slightly among the four models currently in use around the world; the data reported in this work refer to the most recent of the four (whose name is Perfexion, produced by Elekta), as it is the model present in the Humanitas hospital. Inside the Gamma Knife unit, there is an array of 192 60Co sources, which are aligned with a collimation system. The collimation system (described in more detail below) focuses the individual beams of gamma radiation to a precise focus point. While an individual beam has a relatively low dose rate and causes minimal biological effect, the superposition of all beams at the focus point has a much higher dose rate. The Gamma

Knife can therefore target very precise areas of tissue without causing significant collateral damage to areas outside of the targeted area.

In the previous models of the Gamma Knife, the beam collimation is split between an internal collimation and a removable external helmet-based collimation system. Each external collimator helmet has an array of removable tungsten collimators (one per source) with

Figure 30:Elexta's Gamma Knife Perfexion, the model present in Humanitas hospital.

circular apertures, used to create different diameter fields at the focus point. Instead, in the new Gamma Knife Perfexion, the external helmet collimators have been replaced by a single internal collimation system. In this model, the 60Co sources move along the collimator body to locations where 4mm, 8mm, and 16mm apertures have been created.

Elekta's Gamma Knife Perfexion includes a variety of innovative improvements with respect to the previous models, such as:

- Internal collimator: it includes an internal collimation system, with the concomitant elimination of external collimator helmets. Rather than being fixed, the cobalt sources are grouped into 8 sectors. Each sector can move in a linear direction backwards and forwards over the internal collimation system, with several stopping

positions. Each position corresponds to a different size collimator (4mm, 8mm, 16mm or blocked). Therefore, there is no more requirement to manually change collimation helmets, which eliminates what has traditionally been a significant bottleneck in the treatment process

- Increased treatment range: the elimination of the external collimation helmets opens up a much larger potential treatment volume. This means that many disease locations, which could not be optimally reached in one treatment or that required potentially dangerous positional changes during the treatment, will now be easily reached by the beam. For example, the Perfexion has the potentiality to target a neoplasm situated in the lower cervical spine. Although this will require changes in fixation techniques and dose calculation algorithms, the new unit promises to significantly expand the pool of potential district allowed to be treated.
- Composite isocenters: because each of the 8 sectors of sources can move independently, it is possible to create composite shots where each sector is of different collimator size (for example, part 4mm, part 16mm, part blocked). The advantage of composite shots is that each isocenter can be more carefully tailored to match the shape of the target.

Figure 31: Perfexion model,.

- Simplified patient fixation: with the Perfexion model, the fixation of the stereotactic head frame to the Gamma Knife has been simplified. A special adapter is attached to the head frame, and this adapter fits into a head holder attached to the bed. The weight

of the patient's head is supported by the bed: it represents an improvement over the previous models, where the patient's head had to be supported by the operator.

Uses

Currently, the Gamma Knife is used primarily to treat benign brain tumors, arteriovenous malformations (AVMs), acoustic neuromas, pituitary adenomas, craniopharyngiomas, brain metastases, other tumors of the skull base, and pineal region tumors. Selected patients with movement disorders and trigeminal neuralgia can also be treated.

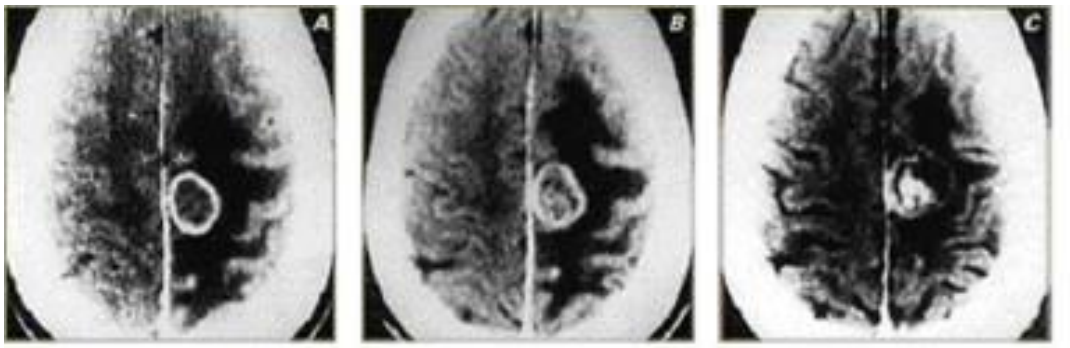


Figure 32:Transverse plane CT image of a metastatic brain tumor, before treatment (left), after 4 months (center) and 9 months (right) from a Gamma Knife radiosurgery. The tumor is smaller and the surrounding brain swelling is reduced.

For certain patients with various deep-seated tumors or AVMs, the Gamma Knife may be preferable to conventional surgery. This type of radiosurgery is safer than many existing procedures because patients need not undergo risky, open-skull procedures, and adult patients do not require general anesthesia. Thus, the Gamma Knife is especially useful when conventional surgical techniques would pose high risk, such as in the presence of other illnesses or when a patient's age prohibits standard surgery. Moreover, the surrounding brain tissue is spared harmful aftereffects, as the radiation falloff is very steep outside the target area. Finally, because the unit can "tailor" radiosurgical doses to lesions of suitable size (preferably less than three centimeters in diameter), it is also used as an alternative approach to standard microsurgical tools.

Risks

The risks associated with the use of Gamma Knife may be divided into environmental risks (for example, linked to radiations or patient positioning) and post-operative side effects.

Because this type of radiosurgery uses live sources, radiation exposure and safety are important issues. Exposure maps of the entire room and surrounding environment are therefore necessary. In regard to actual operation, only trained oncologists or therapists can operate radiosurgery units. The operator will ensure that all required safety checks have been performed and that the written directive has been completed. In addition, physicists play a major role in ensuring that radiation safety measures are in concordance with regulatory guidelines.

Regarding the head frame setup and the positioning of the patient, it might be beneficial that a pretreatment quality assurance program has been implemented. A typical program consists of three parts. First, a verification that the frame has not slipped is performed, by using a depth helmet to measure the distance from the patient's skull to the helmet by means of predefined access points. A measurement is taken before the patient is imaged, after the patient is imaged, and before the patient is set up on the floor stand. Only if all measurements are within 1 mm the treatment can proceed. Second, a pretreatment isocenter verification is performed. In this test, the coordinates of the first isocenter are determined independently on the floor stand and on a phantom. Third, a thorough pretreatment check is usually carried out by the attending physician, including verification of the isocenter coordinates, the collimator setting, the collimator angle, the cone size, the system interlocks, and a final check to verify patient positioning.

On the other hand, the side effects from Gamma Knife may be transient or permanent and may occur even years following surgery. They may be transient or permanent and may occur even years following surgery. Concerning the short-term immediate side effects, these are the typical consequences associated with conventional external beam radiation: nausea, vomiting, and headaches. Moreover, pain relief usually does not occur for 2 to 12 weeks after radiosurgery. Instead, long-term side effects include paresthesia, dysphagia, dysarthria, hemiparesis, corneal irritation (especially if the anterior screws are applied while the patient's eyes are open, and thus their complete closure during surgery might not be possible), vascular damage, hearing loss, and facial weakness, varying with dose plan and target areas.

A 2009 report indicates that over 2800 patients had been treated with the Gamma Knife throughout the world by 1999. **A**bout 80% of patients reported long-term benefit at follow-up periods from 4 to 10 years post-surgery. From 70% to 80% of patients are pain-free in

the short-term, although up to 50% relapse. Doses of 60 to 90 Gy were used in a single session and most of the patients responded to radiosurgery within 6 months of the procedure, with a median of 2 months and a low incidence of complications. In another recent study, despite an 81% early response rate, 56% of patients who experienced initial pain relief suffered treatment failure. As seen from this data, results are promising, but the recurrence rate and relapses rate remain quite high.

3. Technology management

3.1. Deming Cycle

"If you can't describe the process of what you're doing, you don't know what you're doing."

"Quality is satisfying the customer's needs and exceeding his own expectations by continuing to improve."

"Production must be seen as a system that includes all those who interact in the provision of the service: operators and users."

These are some of the most significant phrases of William Edwards Deming (1900-1993). Deming was an American engineer, lecturer, essayist, and manager who was credited with many studies that allowed for an improvement in production in World War II. However, he is mostly known for his work in Japan (1947), where he developed an iterative management method used for the control and improvement of processes and products: the Deming Cycle. In this chapter, there will be an analysis that will deepen and examine how this method has influenced the development of this work, from the initial idea to the actual creation of the different dossiers.

According to the Deming theory, any services provision procedure must be client/user-centred: the final goal of any process must be the client, and, in this specific case, the patient. Organizations/Hospitals must establish relationships with the own patients and suppliers, for a continuous improvement of the system with the aim of minimize failures and errors.

Any process can be seen as a cycle that has four moments: *plan* (design), *do* (act, implement), *check* (control) and *act* (stabilize or correct and restart the cycle).

This idea is not new, but is based on the scientific experimental method, which is based on the formulation of hypotheses, implementation and verification; if a satisfactory result is not reached, a new hypothesis will be formulated and the method restarts.

Deming built the cycle that starting from real phases of the industrial process, adding, however, some operations:

INDUSTRIAL PROCESS	
1.	Product design and qualification tests.
2.	Production with laboratory tests.
3.	Introduction into the market.
4.	Verification of the product during use, collection of user opinions, research of the reasons for the non-purchase.
5.	Product redesign based on market reactions (quality, performance, price).
6.	New qualification tests.

The novelty introduced by Deming is to apply this idea of the cycle to the complex system of organizations, which are considered as individual organisms.

There are many variants of the Deming cycle, but the best known version of the PDCA cycle is the one

developed by the Japanese Ishikawa:

Plan:

- determine objectives and recipients;
- determine methods to achieve the objectives;
- engage in education and training;

Do:

- develop the work;

Check:

- control the effects;

Act:

- take appropriate action.
-

However, it is important to specify that, in the context of this work, the final client is a patient and the final goal is to improve the efficiency of the services provided, in order to achieve an improvement of health, considering that the smallest error can lead to consequences that can compromise it and the patient life.

In general, the Deming cycle allows to test different possible solutions to a problem, to identify the most effective one before final implementation. In particular, it is structured as a method for identifying why a process or product does not meet expectations, developing hypotheses on possible changes and testing their effectiveness in a continuous loop. The following image graphically represents this method:

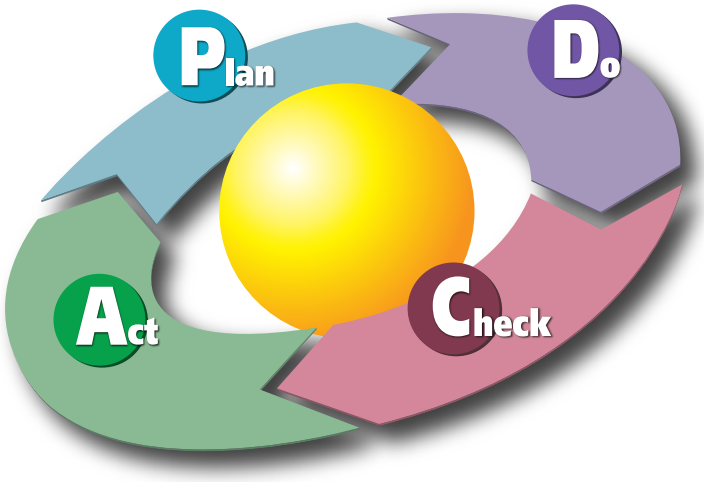


Figure 33:Deming Cycle

The 4 phases in a continuous loop, with the problem to be analysed and solved inside.

Considering the different phases, it may be useful to assess in more detail the characteristics and the roles they carry out:

- ***PLAN***

  The goal of this phase is to define the problem and the procedure that you want to improve.
  The planning phase of the Deming cycle can be divided into three sub-processes that serve to carry out three actions:

  1. Determine the opportunities for improvement and analysis of the starting situation. In

this action it is necessary to emphasize the causes that are generating the problem.
2. Set measurable goals: these must be specific, achievable, relevant and result-oriented. The goals must be quantified and must concern problems that the organization can solve with the collaboration of all functions, so, all operators must be provided with the necessary information.

3. Prepare the action plan: to achieve the objectives, rational and easy-to-follow procedures must be developed. This sub-process includes the study and selection of the most appropriate corrective options, who is responsible for each action and the dates of execution.

- ***DO***

This phase can be considered as the test phase. It consists in carrying out the chosen action and eliminating the causes of the problem. It is necessary to prepare instructions, train the employees involved and record any deviations from the initial plan. In this way, the operator applies what he knows and has learned, keeping in mind the standards, but using his own experience and skills.

- ***CHECK***

The goal is to evaluate the results by comparing the plan executed and the plan established, on the basis of the information collected.
Once the results have been evaluated, two scenarios may arise:

1. The objective has been achieved and the Deming cycle moves on to the next phase of regulation.
2. The goal was not achieved. In this case it may be necessary to analyse the previous phase and, if it is not sufficient, to return to the beginning of the Deming cycle and examine again the causes of the problem.

- ***ACT***

  Action to make definitive and/or improve the process; analyse differences to determine their causes and, if it's necessary, where to implement changes to achieve process improvement.
  It requires corrective action on significant differences between expected and real results.

PDCA has several advantages:

- It provides a standardized method that can be used in any business area to solve recurring problems.
- Saving time in finding the most effective solution.
- It works like a roadmap to guarantee the complete execution of a project.
- It ensures a detailed analysis of common errors, useful for their resolution.
- It is used to monitor and document the initiation of new processes.
- It establishes guidelines for eliminating the causes of a problem.
- It promotes teamwork thanks to the active participation of all those involved.

However the PDCA can have some disadvantages, such as:

- An inaccurate definition can lead to an incorrect application.
- The changes are long-term planned.
- With the PDCA cycle we tend to mostly react; we rarely act.

In summary, PDCA can be briefly described as follows:
Plan: establish the goals and processes necessary to provide results in accordance with the customer's requirements and with the organization's policies;
Do: prepare the basis for definitive implementation of the processes;
Check: monitor and measure the processes and products against the policies, objectives and requirements relating to the products and report the results;
Act: take actions to continuously improve process performance.

3.2. PDCA and dossier: how to

To explain how the Deming philosophy and the PDCA cycle is applied to this work, it is necessary to specify how it is used daily by the Clinical Engineering Service.
It is an iterative management method developed in four steps. It is a very useful tool for developing daily management procedures for the individual and / or the team and its peculiarity is represented by the pursuit of quality in long-term projects.
The main actor is the SIC, whose task is to intervene in the supply and control processes of the equipment with the essential aim of ensuring the best service for patient care.
As has been said previously, the main purpose of this thesis is to create a multidisciplinary dossier for the different HTME present in Humanitas Research Hospital. To each individual HTME, its own dossier will correspond, in which all the most important features will be presented. In this way, this tool will guarantee support for the management of these equipment to the entire clinical engineering team, both as regards the organization of preventive/corrective maintenance, and to the technicians, who will be able to intervene actively and promptly.
Focusing on the actual consequences that this tool will have on the company organization and daily activities, it is necessary to analyse how the implementation of the dossier is organized before the real start of the work.
Exactly in this step, the different phases of the PDCA are fundamental, in order to show the aims in more detail, organize the different steps of the work and establish the results that are expected to be found:

- ***PLAN***

The Plan phase is the most important, in which the final goals and processes necessary to deliver results in accordance with the expected results are established.
In the previous chapters the objectives have been mentioned, but analysing more in depth, they are:

1. **Need to have a tool that allows to have the High-Technology Medical Equipment under control**: the world of HTME is still unexplored from this point of view, as

they are very complex and high-cost devices. For this reason, hospitals leave the complete management to the maintainer company (which in most cases is the supplier company) through full risk contracts.

In this way, the hospital and the SIC are covered with respect to any malfunction problems that may occur; the only task is the organization of preventive maintenance, in which, in agreement with the respective department, a machine downtime is organized for a day, in which external technicians can carry out the necessary checks to ensure correct functionality.

The Humanitas SIC considers it useful to control the entire hospital machine inventory, including the HTME, both from an organizational and an economic point of view, with the ultimate goal of patient care and the best possible provision of services.

2. **Improvement of the internal technicians know how**: once all the physical and mechanical characteristics are grouped within the dossier, this will be a real tool that will allow internal technicians to be able to promptly intervene on "one-level diagnosis". These are minor malfunctions, which can be solved in a short time, where the presence of the external technician is not necessary if the internal technicians are able to intervene. In this way, internal technicians will be more involved in the entire lifecycle of HTME. Therefore, they will be more motivated and empowered.

   This aspect also has a direct consequence on patient care, since, if the possible problem occurred, it is solved internally, then there is a huge saving of time, and the equipment can be used immediately, avoiding the downtime and consequent intervention of the external technician.

   In general, the benefits concern both the hospital as a provider of diagnostic and therapeutic services and as a company.

3. **Full risk savings**: there are different types of maintenance contracts that can be stipulated between the seller (the company that supplies the HTME) and the buyer (the hospital): silver, gold and full risk. The differences between these concern the degree of assistance that is provided, such as the intervention timing, cost of spare parts, number of preventive maintenance included etc.

The silver contract consists of the lowest level, with low costs but relative assistance, gold is the intermediate level and while full risk consists of the best contract in terms of assistance.

As will be specified later, all the equipment considered are characterized by full risk contracts.

A consequence of the improvement in the know-how of the technicians consists in a notable increase in the management skills of the different HTME. Therefore, in case of problems that can be solved directly by the internal technicians, it is not necessary to organize a corrective maintenance.

The internal technicians will be contacted only for the "most important" failures, leaving the ordinary management to the SIC.

For this reason, once the necessary experience from the internal technicians has been acquired, it is possible to modify the stipulated contracts and move to a lower level, for example from full risk to gold contracts.

This would lead to economic savings, which can be invested again in other areas, or used for the hiring of a new technician which would allow an expansion of the team and the promptness of intervention within the hospital.

4. **Training courses for internal technicians**: this is one of the most important goal of this work.

   From a supply and maintenance point of view, in the medical field, the most important companies are Siemens, Philips and GE. These are called "BIG 3" and are among the major suppliers of HTME specifically.

   Once the ordinary interventions are the responsibility by the hospital, cost savings can also be associated with these companies: external technicians will be less and less employed by Humanitas, with consequent savings of a technician for the Big 3, available for other interventions.

   In this way it is possible to try to organize training courses for internal technicians programmed by companies, in order to further expand their know-how, leading to further savings both for the hospital and for companies.

5. **Management of services provided by HTME**: this is the last goal of this work, and it concerns the logistical part of the therapeutic/diagnostic health services that each HTME can provide to patients.

   Considering the 11 classes, in Humanitas there are very similar equipment (sometimes the same, like 2 identical TAC Philips Ingenuity Core 64 Slice). For this reason, it is useful to analyse all the different performances that such equipment can provide and group them into the individual dossiers: once an HTME is stopped for various reasons (malfunction, corrective maintenance, preventive maintenance) it is possible to reorganize the tests/treatments in the other HTME in a timely manner. In this way it does not cause discomfort both from the patients with delays or postponements, and to the hospital itself, avoiding the creation of queues and maintaining a high quality of service and efficiency.

In conclusion, this multidisciplinary dossier is associated with a proper change in Humanitas internal policy, and it's possible to identify three goals linked to the economic aspect and two to the logistical aspect: in the first case it consists in an improvement of the service by the internal technicians, both thanks to the summary of all the characteristics of the HTME, and through training courses organized by external companies, with the consequent possibility of stipulating new maintenance contracts at lower costs. In the second case, the possibility of possessing a tool that supports technicians during their interventions and the interchangeability between the different HTME that can provide the same services.
As the last step of this phase, the working method and the procedure are set, and these will be explained in more detail in the following paragraphs.

- ***DO***

This phase consists in the implementation of the procedure chosen to carry out the work.
The first step is to create an Excel database in which to select the most significant features of all the equipment.
Initially it is necessary to evaluate which macro-attributes are to be considered, therefore all the economic, registry, structural, technical and IT aspects.

Considering internal needs and with the support of the Clinical Engineering Service, six macro-attributes are identified:

1) Registry.
2) Planimetry.
3) Technical features.
4) Informatics.
5) Performance provided.
6) Clinical engineering (related to the economical aspect).

Thereafter, considering every single macro-attribute, it is necessary to analyse it and to understand and assess which features are fundamental to characterize the single HTME.

Once the most important aspects have been selected, through the use of user manuals, datasheets, and with the support of internal and external technicians, these are grouped within the database, in order to have all the data in a single file.

When the database is complete, it is possible to generate the different dossiers relating to HTME, in which the main characteristics are summarized.

Simultaneously with the development of the dossiers, once the data have been collected it is possible to carry out specific analyses. In the case of this work, two analyses are implemented:

1) Data Envelopment Analysis.
2) Regression Analysis.

- ***CHECK***

After performing the analyses, in the Check phase the obtained results are evaluated and compared with the expected results. One of the main aims is to assess if it is possible to modify maintenance contracts, allowing the hospital to save and distribute this money to other areas/staff.

The first step concerns the Data Envelopment Analysis: By setting efficiency frontiers, this analysis allows to identify which aspects have the highest influence on the costs and, consequently, which HTME/classes have the greatest impact.

In this way it is possible to direct the improvement actions in specific areas, imposing changes for those equipment in which the company return is not profitable.

The second step is the Regression analysis: the variables that have the most impact from an economic point of view are established; different combinations are performed and the results obtained are studied. It is necessary to specify that these analyses include both the individual HTME and the general classes, in order to have a complete overview of the different cases that can be considered.

- ***ACT***

The actual implementation and use of the dossier at a practical level takes place in this phase. The first direct consequence consists in possessing a tool in which all the data relating to the HTME are summarized, allowing immediate consultation, both as regards economic aspects (for instance, to compare the costs between the different equipment in terms of machine downtime, maintenance and price at the time of purchase) and for technical aspects (for example in case of breakdowns or failures).
The second direct consequence is to standardize communication with operational management. Indeed, each HTME will have a specific name, identified by a string, which will be used uniquely throughout the hospital. However this aspect will be better specified in the chapter of Materials and Methods.
From the point of view of internal technicians, training courses have already been scheduled with external companies at the end of 2021, in which technicians will be able to expand their know-how.

This point will also be deepened in the Conclusion chapter.
Moreover, as has already been anticipated, the real benefits will be assessed in the long term, approximately in 2/3 years from implementation. In this way, it will be possible to modify the investment plan thanks to the savings obtained, which can be used both for acquiring new equipment and/or for hiring a new technician, expanding the team of the Clinical Engineering Service. Furthermore, with the support of the studies on downtime, it will be possible to optimize performance, through the interchangeability of these, while maintaining very high standards of efficiency.

In conclusion, it can be noted that the PDCA influenced all the work, from the initial idea, to the implementation of the dossier in the following years.

Thanks to this philosophy, it is also possible to understand which changes can be useful for improvement, in which sector it is possible to expand the data and which errors can be corrected to increase the efficiency of the hospital, always keeping in mind that the ultimate purpose is the patient's health.

Each of the 4 phases is fundamental, even if not all are directly linked to the creation of the dossier, but only concern the results deriving from the economic analyses: for example, the check phase evaluates only the results of the Cost-effectiveness analysis and the Data envelopment analysis.

Summarizing the whole process:

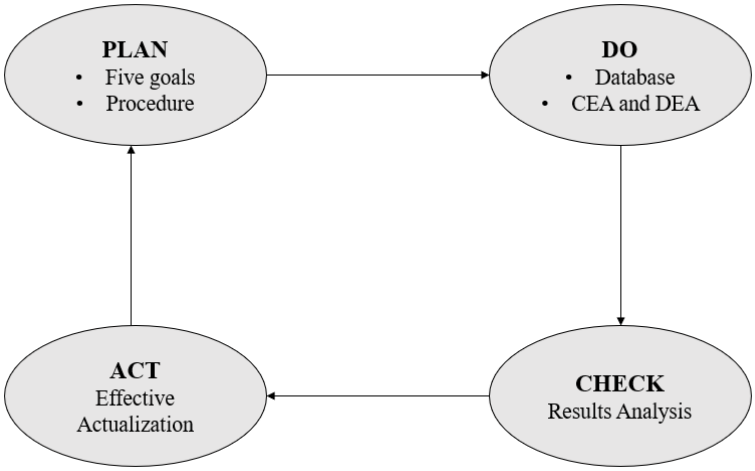


Figure 34: Workflow of the whole process

4. Material and methods

4.1. HTME and string

In this chapter the attention will focus on the actual creation of the dossier.
The first step is the identification of the High-Technology Medical Equipment (HTME) to be examined. HTME are all those equipment, characterized by fixed systems, high maintenance costs, high contract costs and characterized by full risk contracts.
In this way, through the collection of data and the main characteristics of these, with the following in-depth analysis, it is firstly possible to develop the dossiers relating to each HTME and then to evaluate the possible benefits that Humanitas can derive. All the set of the HTME to be analysed is provided by the Clinical Engineering Service and the list is the following:

NAME	*STRING*
LINEAR ACCELERATOR	
ACC VARIAN CLINAC DHX	BLD3-P0-RTE-BUNK3-00-084-027
ACC VARIAN TRUEBEAM	BLD3-P0-RTE-BUNK4-00-084-054
ACC VARIAN TRUEBEAM STX	BLD3-P0-RTE-BUNK5-00-084-122
ACC VARIAN EDGE	BLD3-P0-RTE-BUNK2-00-084-026
ACC VARIAN TRUEBEAM	BLD3-P0-RTE-BUNK1-00-084-025
ANGIOGRAPH	
ANG SIEMENS AXIOM ARTIS DFC MAGNETIC NAVIGATION	BLD2-P2-BOB-SOP4-02-036-032
ANG SIEMENS AXIOM ARTIS ZEE CEILING	BLD2-P2-BOB-SOP1-02-036-018
ANG PHILIPS AZURION 7 M20	BLD9-P0-BOH-00-902-015
ANG PHILIPS INTEGRIS ALLURA XPER FD10C CLARITY R8.2 FLAT DECT	BLD2-P2-BOB-SOP2-02-036-014
ANG PHILIPS AZURION 7 M12	BLD2-P2-BOB-SOP3-02-036-011
ANG SIEMENS AXIOM ARTIS ZEE BIPLANE	BLD2-P0-RAD-00-006-169
GAMMA KNIFE	
GKN ELEKTA LESKSELL GAMMA KNIFE PERFEXION	BLD2-P0-RAD-08-00-006-072

MAMMOGRAPH	
MAM TECHNOLOGIC M IV SELENIA	
MAM TECHNOLOGIC SELENIA DIMENSIONS	BLD8-P0-AMB.F18-00-721-009
MAM TECHNOLOGIC SELENIA DIMENSIONS	BLD5-P1-AMB.M13-01-502-043
MAM TECHNOLOGIC SELENIA DIMENSIONS	BLD5-P1-AMB.M15-01-502-018
BONE DENSITOMETER	
MOC TECHNOLOGIC HORIZON-W	BLD2-P0-RAD-08-00-006-072
ORTHOPANTOMOGRAPH	
OPT DITECH KODAK 9000C	BLD2-P0-RAD-08-00-006-072
PET	
PET SIEMENS BIOGRAPH LSO 6 HIGH REZ	BLD1-P0-NUCL-PETSIEMENS-00-015-020
PET GE DISCOVERY PET/CT690 FX VCT 64 STRATI	BLD1-P0-NUCL-PETGE-00-017-023
RADIOGRAPHY SYSTEM	
RAD VILLA APOLLO DRF	BLD2-P0-RAD-00-006-033
RAD SIEMENS DR AXIOM ARISTOS VX PLUS 50 KW	BLD2-P0-RAD-00-087-039
RAD SIEMENS MULTIX FUSION DIGITAL	BLD8-P0-RAD-00-734-007
RAD SIEMENS MULTIX FUSION DIGITAL	BLD2-P0-RAD-00-006-038
RAD AGFA DR 600	BLD2-P0-RAD-00-006-023
RAD GMM OPERA SWING	BLD3-P0-PS-RX-00-083-080
RAD NEUROMED EOS	BLD2-P0-RAD-00-006-063
MAGNETIC RESONANCE	
RMN GE OPTIMA HDXT 1,5T	BLD2-P0-RAD-00-006-196
RMN PHILIPS PANORAMA HFO	BLD2-P0-RAD-00-006-127
RMN PHILIPS INGENIA 1.5T OMEGA	BLD8-P0-RAD-00-734-039
RMN SIEMENS AERA 1.5T	BLD2-P0-RAD-00-006-157
RMN ESAOTE G-SCAN BRIO EXP 0.35T	BLD8-P0-RAD-00-734-041
RMN SIEMENS MAGNETON SKYRA FIT 3T	BLD2-P0-RAD-00-006-135
SPECT	
SPT SIEMENS SYMBIA INTEVO EXCEL	BLD1-P0-NUCL-GAMMACAMERA-00-015-009
TAC	
TAC PHILIPS BRILLIANCE CT BIG BORE	BLD3-P0-RTE-00-084-067
TAC PHILIPS INGENUITY CORE 64 SLICE	BLD3-P0-PS-TAC-00-083-079
TAC GE REVOLUTION EVO VT200	BLD9-P0-PS-00-901-051

TAC PHILIPS INGENUITY CORE 64 SLICE	BLD2-P0-RAD-00-006-106
TAC GE REVOLUTION EVO VT200	BLD2-P0-RAD-00-006-069
TAC GE REVOLUTION EVO VT200	BLD8-P0-RAD-00-734-013
TAC GE CARDIO REVOLUTION CT 512 SLICE	BLD2-P0-RAD-00-006-105

Table 2:HTME list and strings

Eleven classes are identified: Linear Accelerator, Angiograph, Gamma Kinfe, Mammograph, Bone Densitometer, Orthopantomograph, PET, Radiography System, Magnetic Resonance (MR), SPECT and CT scan. The entire machinery inventory is made up of 41 HTME, each of them related to the specific prior classes. Considering the NAME, it is a precise code that unites all the HTME.

es: ACC VARIAN CLINAC DHX

The first part (ACC) is composed by 3 letters related to the class it belongs to. The second part (VARIAN) is the manufacturer/maintainer. The last part (CLINAC DHX) is the model of the equipment. This sequence is chosen to standardize the list and to allow clear and precise identification.
Evaluating the STRING, it is a sequence that allows to recognize the room in which the equipment is placed, starting from the building up to the location, in particular:

es: BLD3-P0-RTE-BUNK3-00-084-027

BLD3 is related to the building, P0 is the floor (“piano 0”) and BUNK3-00-084-027 is a particular nomenclature of the specific room, extracted by InfoCad. InfoCad is a software that belongs to the Intranet, that is a private company network completely isolated from the external network at the level of services offered (via LAN), such as the phonebook and other applications that allow internal communication between the different departments. In particular, InfoCad is a tool used for reporting failures within the structure, from the hospital area where it occurs to the Building Management. For each department, there is the entire planimetry and all the rooms are identified by the last part of the string aforementioned. It is

useful to use this nomenclature, in order to standardize the identification of a specific location among the different hospital compartments.

4.2. Database

The database consists of the collection of data relating to these HTME, then the final dossiers will be generated. Considering the entire database, it is composed of six macro-attributes:

1) REGISTRY (“ANAGRAFICA”): in this section there are all the information concerning to the proper characteristics of the equipment. The first column express the respective class, the second is the description, composed by the name, mentioned before, plus the own string. Furthermore, all the list concerning the single components of each HTME is present. Then, all the other attributes are expressed and these are the following:
    - ICH: it is the identification number of the equipment established by the clinical engineering service. All medical devices present in the hospital are characterized by this progressive number, with the aim of allowing an identification that is common to all, keeping track of them and guaranteeing appropriate management.
    - Description (“Descrizione”): it is similar to the name, but in this case the manufacturer is not considered. So the description is the set of class and model.
    - Acceptance test date (“Data di collaudo”): this is the date on which, following installation and all the necessary checks (such as the electrical safety test), the equipment is operational within the hospital.
    - Supplier (“Fornitore”).
    - Manufacturer (“Manutentore”): it is the same of supplier, except for the orthopantomography.
    - ODA (Ordine Di Acquisto): this corresponds to the order number of the given equipment and it is made up of the year of the purchase and an prefixed progressive value, consisting of 4 or 5 numbers

- Cost (“Costo”): it is the price at the time of purchase, valued in euros.

2) PLANIMETRY (“PLANIMETRIA”): this section is composed by two parts: the first one collects all the data related to effective planimetry and the systems that characterized the room; the second one consists of some specifical information about the environment. Considering the first part, the different planimetries gathered are:
   - Standard planimetry (“Planimetria standard”): the actual representation of the internal and external spaces of the room.
   - Other systems: such as the MR’s Faraday cage.

   The second part consists of:
   - Minimum room size (“Metratura minima della sala”): the necessary measures to ensure that all safety standards for patients and operators are respected.
   - Internal temperature range (“Range temperature sala”): this is essential for a perfect functionality of HTME, in order to avoid possible damages or issue.
   - Internal humidity range (“Range umidità sala”): equal idea of the internal temperature range.
   - Heat emission (“Calore emesso”): heat emitted by equipment, expressed in kW.
   - Power supply (“Alimentazione elettrica”): specifically it is the input power supply, expressed in Vac.
   - InfoCad: all the layouts (simpler planimetry) used for determining the location of all the systems within the dossier.

3) TECHNICAL FEATURES (“TECNICA”): in this part, all the most important technical features are presented. Each HTME is characterized by specific requirements both for installation, optimal functionality and management. Some of these parameters are common for all the device classes, while others are unique for one or few classes.

   Moreover, these attributes are fractioned by a further subdivision: physical features related to the principal components of the entire HTME, and technical features. Considering the first case, some examples are:

- Weight of the entire HTME.
- Weight, dimension, inclination range, translation (and so on) of the couch.
- Panel detector model.
- Diameter, inclination, configuration of the gantry (for those who own the gantry).
- Generator type.
- Number of cameras.

Regarding the second case, 42 different attributes are considered, each one associated to a specific class. The first level for the effective selection of these parameters consists in analysing the user manuals, in particular the equipment data sheet, and assessing which are the most significative. Otherwise, data sheet sometimes is not included and it is useful to consult the Image Technology News (ITN) website: it allows to compare different technologies based on the classes.

It makes possible to generate a huge part of the technical database.

Last parameters are obtained asking to the external technicians during the periodical preventive maintenance, that is necessary for each technology.

As has been said before, also in this case, some of these attributes are common for different technologies, such as:

- Generator dissipation capacity ("Capacità dissipazione generatore").
- Generator power ("Potenza generatore")
- Generator cooling mechanism ("Meccanismo raffreddamento generatore")

Others are unique:

- Magnetic field intensity ("Intensità campo magnetico")
- Range of emitted radiation ("Range delle radiazione emesse")
- Exposure time ("Tempo di esposizione")

4) INFORMATICS ("INFORMATICA"): this section refers to the entire IT features that characterize the system. Considering each HTME, this system is placed outside the exam room and corresponds to its own analysis room, where the operators perform the functions necessary for the diagnosis / therapy of the patient, from the

reconstruction of the acquired images to the monitoring of the doses emitted. The attributes considered are:

- PCs number (“Numero di PC”): number of PC present in the analysis room
- Monitors number (“Numero di monitor”): number of monitor connected to the different PC
- Station functions (“Tipologia stazione”): it refers to the main function performed by the station, such as acquisition, reconstruction and so on.
- Installed software (“software installati”): pc installed software. In this case it is necessary to distinguish the company's own software or traditional software; for instance, considering the Siemens RMNs, all the system are based on Syngo, which is a Siemens software; while, considering Philips RMNs, they are based on a generic Windows version.
- Printers number (“Numero di stampanti”).
- Burner (“Dispositivi di masterizzazione”): Burner presence in the system.
- Operating system (“Sistema operativo”): which operating system is installed on the PC.
- DICOM yes/no (“ DICOM si/no): DICOM (Digital Imaging and Communications in Medicine) is the international standard to communicate and manage medical images. Its mission is to guarantee the interoperability of systems used to produce, store, share, display, send, query, retrieve and print medical images. Generally all the devices present in Humanitas own this communication protocol. The version is also specified, in particular it is 3.0 for each HTME.
- DICOM license type (“Tipologia di licenza DICOM”): there are different type of DICOM licenses (worklist, query/retrieve, save, printing and RIS interface). This attribute reports the combination of the different typologies that belong to each HTME.
- Local storage or immediate/periodic elimination (“Archiviazione locale o eliminazione istantanea/periodica”): it refers to the images acquired. In particular it explains the workflow of the images storage; if the images are saved in a local storage (and consequently are sent to PACS) and the type of elimination of them, if these remain periodically and are automatically

eliminated after a certain period of time, or the elimination is performed directly by the operator.

- Static/dynamic IP ("IP statico o dinamico"): it is related to the web connection. A static IP address is always assigned to the same device that needs to stay with that address continuously. While a dynamic IP is selected among the various IP addresses available; it is assigned and changes automatically with each new connection. However, it's important to specify that in terms of the Internet connection speed, having a static IP address or a dynamic IP address makes no difference; it is a choice established by specific needs of the own device.
- Data flow among equipment ("Nodi comuni tra apparecchiature"): it shows if there is a communication between the reference equipment and others present in the hospital; if so, which kind of communication.

5) PERFORMACE PROVIDED ("PRESTAZIONI EROGATE"): thanks to the help of the Humanitas Operational Management, all the services provided by the different HTME are collected and combined within this section. The dataset is composed of the list of HTME on the rows, while on the columns there are all the services provided and, when a service belongs to the equipment considered, then in the intersection cell there will be an X. Those services that a HTME can provide but which currently does not provide have also been identified. These are marked with an O in the reference cell. An example that clarifies this composition is the following:

	A	B	C	D
1				
2	CLASSE	DESCRIZIONE	RMN RACHIDE LOMBOSACRALE SENZA CONTRASTO	MAMMOGRAFIA BILATERALE
3				
4	ACC	ACC VARIAN CLINAC DHX (BLD3-P0-RTE-BUNK3-00-084-027)		
5	ACC	ACC VARIAN TRUEBEAM (BLD3-P0-RTE-BUNK4-00-084-054)		
6	ACC	ACC VARIAN TRUEBEAM STX (BLD3-P0-RTE-BUNK5-00-084-122)		
7	ACC	ACC VARIAN EDGE (BLD3-P0-RTE-BUNK2-00-084-026)		
8	ACC	ACC VARIAN TRUEBEAM (BLD3-P0-RTE-BUNK1-00-084-025)		
9	ANG	ANG PHILIPS INTEGRIS ALLURA XPER FD10C CLARITY R8.2 FLAT DECT (BLD2-P2-BOB-SOP2-02-036-014)		
10	ANG	ANG PHILIPS AZURION 7 M12 (BLD2-P2-BOB-SOP3-02-036-011)		
11	ANG	ANG SIEMENS AXIOM ARTIS ZEE BIPLANE ()		
12	ANG	ANG SIEMENS AXIOM ARTIS ZEE CEILING (BLD2-P2-BOB-SOP1-02-036-018)		
13	ANG	ANG SIEMENS AZURION 7 M20 (BLD9-P0-BOH-00-902-015)		
14	ANG	ANG SIEMENS AXIOM ARTIS DFC MAGNETIC NAVIGATION (BLD2-P2-BOB-SOP4-02-036-032)		
15	MOC	MOC TECHNOLOGIC HORIZON-W (BLD2-P0-RAD-08-00-006-072)		
16	GK	GKN ELEKTA LESKSELL GAMMA KNIFE PERFEXION (BLD3-P0-RTE-GAMMAKNIFE)		
17	MAMM	MAM TECHNOLOGIC MIV SELENIA		O
18	MAMM	MAM TECHNOLOGIC SELENIA DIMENSIONS (BLD8-P0-AMB.F18-00-721-009)		X
19	MAMM	MAM TECHNOLOGIC SELENIA DIMENSIONS (BLD5-P1-AMB.M13-01-502-043)		X
20	MAMM	MAM TECHNOLOGIC SELENIA DIMENSIONS (BLD5-P1-AMB.M15-01-502-018)		X
21	OPT	OPT DITECH KODAK 9000C (BLD2-P0-RAD-08-00-006-072)		
22	PET	PET GE DISCOVERY PETCT690 FX VCT 64 STRATI (BLD1-P0-NUCL-PETGE-00-017-023)		
23	PET	PET SIEMENS BIOGRAPH LSO 6 HIGH RES (BLD1-P0-NUCL-PETSIEMENS-00-015-020)		
24	RAD	RAD VILLA APOLLO DRF (BLD2-P0-RAD-00-006-033)		
25	RAD	RAD SIEMENS DR AXIOM ARISTOS VX PLUS 50 Kw (BLD2-P0-RAD-00-087-039)		
26	RAD	RAD SIEMENS MULTIX FUSION DIGITAL (BLD8-P0-RAD-00-734-007)		
27	RAD	RAD GMM OPERA SWING (BLD3-P0-PS-RX-00-083-080)		
28	RAD	RAD SIEMENS MULTIX FUSION DIGITAL (BLD2-P0-RAD-00-006-038)		
29	RAD	RAD AGFA DR 600 (BLD2-P0-RAD-00-006-023)		
30	RAD	RAD NEURIDMED EOS (BLD2-P0-RAD-00-006-063)		
31	RMN	RMN GE OPTIMA HDxt 1.5T (BLD2-P0-RAD-00-006-196)	X	
32	RMN	RMN PHILIPS PANORAMA HFO (BLD2-P0-RAD-00-006-127)	X	
33	RMN	RMN PHILIPS INGENIA 1.5T OMEGA (BLD8-P0-RAD-00-734-039)	X	
34	RMN	RMN SIEMENS AERA 1.5T (BLD2-P0-RAD-00-006-157)	X	
35	RMN	RMN ESAOTE G-SCAN BRIO EXP 0.35T (BLD8-P0-RAD-00-734-041)	O	
36	RMN	RMN SIEMENS MAGNETON SKYRA FIT 3T (BLD2-P0-RAD-00-006-135)	X	

Figure 35:Composition of performance provided

In this case, the focus is on two types of performance: lumbosacral roots magnetic resonance without contrast and bilateral mammography. Considering the first case, it can be said that all MRI can perform this service. However, only 4 out of 5 actually perform this service, as Esaote MRI is focused on other types of interventions. In the same way, as far as bilateral mammography is concerned, only 3 out of 4 mammograms are employed for this performance.

Considering the entire set of the HTME, the total number of possible services that can be provided is 292.

To make the database more fluid from an operational point of view, a particular Macro has been implemented: given 292 exams, since viewing the exams of a certain class or a specific HTME is very complex, a macro has been created that allows to show only the performances relating to the HTME of interest. This is directly connected with filtering by class/HTME. Once the equipment of interest has been selected, this Macro allows to hide the empty columns, that is to hide those columns where there is neither an X nor an O. In this way, only the performances inherent to the own class/HTME are shown. This very simple Macro is the following:

```
Sub nascondi_col_vuote()

Dim cell As Range
For Each cell In Range("C100:ZQ100")
    If cell.Value = 0 Then cell.EntireColumn.Hidden = True
Next

End Sub
```

Figure 36:Macro to hide empty column

6) CLINICAL ENGINEERING: this section concerns to the economical features and all the aspects that impact on the general cost of each HTME. There is a focus on respective assurance, contracts and manufacturer trait. In particular:
    - Annual full risk contract cost ("Costo contratto full risk annuo"): how much the annual renewal of the full risk contract cost, agreed upon during the stipulation of the contract.
    - Downtime days number ("Numero di giorni di fermo macchina"): this parameter concerns the number of days in which the HTME has not been operational due to a breakdown or malfunction, reported by the specific department. The time window from 2018 to 2020 is selected to evaluate this information.
    - Cost per downtime ("Costo per fermo macchina"): referred to the previous parameter, it assess the loss of money due to each day of inactivity of the HTME. The proper cost varies considering the different equipment, for instance, the cost of a PET exam is estimated at 1000€, while an MRI has a cost ranging from 100€ to 170€. This single exam cost is determined by Humanitas Operational Management and, evaluating the average daily number of exams per HTME, the total cost is easily estimated.
    - End of assurance ("Fine garanzia"): expiration date of the assurance contract.
    - Contact supplier ("Contatto del fornitore"): this can be a either phone number or e-mail address. This corresponds to the contact of the supplier, in order to be able to contact him during a breakdown and to establish if it is necessary to organize a corrective maintenance with the exit of the external technician, or if it is possible to intervene internally.

- Manually reset procedure (“Procedura di riarmo”): the reset procedure is a particular operation that occurs following the switching off of the equipment, for different reasons. For instance, some maintenance can only be performed if the power is off, in this case, to allow the HTME to return operational, the first step is the reset procedure. Two other examples that may lead to power outage correspond to: a problem on the line (for example due to lightning or power failure) and periodic disconnection tests to verify the operation of backup systems, such as UPS system.

  It is important to specify that this procedure is a manual procedure, it does not take place either automatically or through a remote control. Indeed the technician must physically go to the electrical panel and manually activate the HTME. All the procedures are similar to each other, as they are based on the start and stop principle; what changes is the electrical panel itself and it is very useful to have the different steps that the internal technician must perform without making mistakes. Moreover, in addition to associating each procedure to the respective HTME, all these are grouped in a single file, so that, if the technician has to reactivate more equipment, it is not necessary to take all the dossiers, but just consider this booklet.
- Technical assistance contract: full risk / on demand (“Contratto di assistenza tecnica: full risk / on demand”): considering the type of technical assistance that Humanitas has stipulated with the supplier, they can be of two types: full risk or on demand. In both cases, the different maintenance operations (corrective and preventive) are the responsibility of the supplier. However, in the first case, the intervention takes place on site by external technicians. While in the second case, assistance takes place on demand, i.e. external technicians follow and guide Humanitas internal technicians remotely, in order to solve the various problems that may occur.

  In this case, given the high complexity of the various HTME, all contracts are full risk contracts.

4.3. InfoHealth

Figure 37:InfoHealth management software

InfoHealth is a complete and integrated platform for the management of the entire life cycle of the medical devices, starting from the test to the dismission, for the management of the traceability, for the planning of the preventive maintenance program of medical devices and technological systems, for the storing of each OdL (Ordine di Lavoro), which are every single intervention on the medical device during its whole hospital life.

It is also a communication tool between the departments involved and the specific operator, who will receive the request in real time and will be able to deal with it promptly. For instance, if a malfunction or a breakdown of a medical devices occurs, the proper department can open an RdI (Richiesta di Intervento), specifying the problem, and the operator can intervene immediately.

It is a system accessible with an Internet connection (the platform is completely web-based) with access protected by a username and password specific to each hospital function.

Generally, this is the tool most used by the Clinical Engineering Service and it is essential for the data collection. In particular, two sections are completely filled through the use of InfoHealth: Registry and Clinical Engineering.

The evaluation of the downtime days number is an interesting example: as was said, the operators of the hospital department can open a intervention request (RdI) through the use

of InfoHealth, to inform the clinical engineering service about each single type of functional issue. At this point the technicians take into one's care the request and, after the identification and solution of the problem, it is closed.

InfoHealth collects each single intervention request of every medical devices present in Humanitas, from the test to dismission. Considering the triennium 2018-2020, it is easy to evaluate the days of downtime for each HTME, starting from the number of requests for intervention, the type of issue and the analysis of the technical reports.

A clarification regarding technical reports is necessary: HTME systems are very complex, with high costs at the time of purchase and always include a full warranty period in the contract (12, 24, 36 months). When the warranty expires, it is common to enter into a full risk contract, in order to be covered for any type of damage, whether accidental or not. Thanks to this contracts, all the aspects related to the HTME maintenance are entrusted to the manufacturer, who act through his own specialized technicians. to certify the actual intervention, the external technicians redact a technical report, signed both by himself and by Humanitas. This technical report shows the description of the maintenance performed, the date, the working time, the sender and the recipient. All the technical reports are saved and collected in a shared folder with all members of the Clinical Engineering Service. After the analysis of each technical report, it has been established that if the working time exceeds 12 hours, it is considered one day downtime, as the system has not been operational for a whole day. The sum of all these days allows to calculate the total downtime.

In this case InfoHealth is essential for the assessment of this parameter.

4.4. VBA and Macro

At this point, once all the data have been collected and the final database is complete, each dossier can be created.

The first step consists in the development of a master for all the class of equipment: this master is a 5-page document where all the features are summarized and represent the proper "identity card" of the HTME.

A clarification is necessary: the main problem consists in the preparation of 41 masters, for which it takes a lot of time. This problem is solved in the following way: for each class a general master has been created, consisting of six chapters (one for each macro-attribute of

the database) in which the different characteristics are explained. In this way, instead of creating 41 masters, it is necessary to develop only 11 masters, like the 11 classes being analysed. This general masters corresponds to the basis of the specific masters, in which the characteristics that differ for each HTME are marked by bookmarks and a space. In particular, in the various sentences that compose the master, a bookmark is inserted using the appropriate Word function. Each bookmark is called with a particular name that is associated with the parameter itself in the Excel database. A clarifying example is the following:

"L' apparecchiatura è prodotta da . All'interno di ICH, è ubicata presso il reparto ; è stata introdotta nel parco macchine previo collaudo, avvenuto in data . È contrassegnata dal numero interno di inventario ."

This is the first sentence of the "REGISTRY" chapter, common to all the masters of the different classes. As can be seen, the sentence contains spaces where the parameters of each HTME will be inserted. For instance, after the word *"da"*, a space is present and it is associated with a bookmarks. This specific bookmark is called *"fornitore"*, because it refers to the name of the supplier of the HTME and it is present on the database under the item *"fornitore"* in the registry section.

This clarification and this association is necessary for the explanation of the next step: the creation of the Macro through the use of Visual Basic for Application (VBA). VBA is an integrated, very powerful and sophisticated programming language that allows to write different functions or commands in an Excel spreadsheet. For this reason, the Excel database is considered again.

At this point, a code is implemented to allow the database parameters to be directly associated with the corresponding master bookmarks, in order to have an automatic filling procedure, instead of manually completing each individual master. It is important to specify that 11 masters must be created, one for each class of equipment, just like the general masters created previously. In this way it is possible to associate each class to the specific code, without having to make changes or modifications for the compilation of the different masters. The codes are equal, except for the directory to which they refer, that is the master considered: this aspect will be analysed in more detail later.

Regarding different parts of the code, some explanations are needed; in this case TAC master is considered:

- *Set sh = ThisWorkbook.Worksheets("FUNZIONE")* :

  It is one of the most important aspects of the code. After initialization of sh as a Worksheet, to ensure that the code does not make mistakes and the filling process is automatic, it is necessary that the data present in the different worksheets of Excel (Registry, Planimetry..) are grouped into a single worksheet: it is called "FUNZIONE" (Function worksheet).
  This worksheet does not have to be updated manually, but, every time a parameter is changed or a new one is added, it updates automatically through a simple link function between the different sheets and the principal one.

- *With sh*

  ..

  Set objDoc = objWord.Documents.Open("C:\Users\HP\Desktop\humanitas\Tesi grandi macchine\MASTER\TAC_MASTER.docx")

  It is the aforementioned part: the selection of the directory. This is the only part that changes between the different codes. All general masters are saved in a single folder (in this case is “MASTER”) and to consider the master of interest, just name it at the end of the path to access that particular file (TAC_MASTER.docx). In this way, the code takes into consideration the selected master and can proceed with the automatic filling process.

- *objDoc.Bookmarks("nome").Range.Text = .Range("B" & 2).Value*

  It is the most repeated code line. This line allows the effective association between the parameter in the Excel database and the bookmark of the Word document. This function permits to "copy and paste" this parameter in the appropriate space of the master, avoiding manual compilation.

In particular, in the case shown, this function allows to select the value present in cell M2 (*.Range("M" & 2).Value*) in the Function file and insert it in the "name" bookmark of the master (*objDoc.Bookmarks("nome").Range.Text*). In this case, the parameter selected is the entire name of the HTME. By repeating this function for all the parameters present, it is possible to complete the master with all the data relating to the specific HTME.

However, at this point it's necessary to specify a problem with this code: the code allow to compile the master of a specific HTME, not all the masters of an entire class in one run. In fact, the second part of the code (*.Range("M" & 2).Value*) refers to the cells in which the data of a single HTME are present. For instance, if I want to compile the master related to the TAC PHILIPS BRILLIANCE CT BIG BORE, then in the second part of the code line I will insert the cells corresponding to the parameters of the same TAC. Once the compilation is finished, I will have to compile another master, for example of the TAC PHILIPS INGENUITY CORE 64 SLICE; in this case I will have to manually change all the cells of the code, in order to consider the new parameters of the new TAC. However, the Function worksheet is organized in a functional way.

	B	C	D	E	F	G
1	DESCRIZIONE (STR.)	ICH	DESCRIZIONE (o)	DATA COLLAUDO	FORNITORE	MANUTENTORE
2	TAC PHILIPS BRILLIANCE CT BIG BORE (BLD3-P0-RTE-00-084-067)	7768	TAC BRILLIANCE CT BIG BORE	38783	PHILIPS SPA	PHILIPS SPA
3	TAC PHILIPS INGENUITY CORE 64 SLICE (BLD3-P0-PS-TAC-00-083-079)	15588	TAC INGENUITY CORE 64 SLICE	25/08/2014	PHILIPS SPA	PHILIPS SPA
4	TAC GE REVOLUTION EVO VT200 (BLD9-P0-PS-00-901-051)	16744	TAC REVOLUTION EVO VT200	02/09/2015	GE MEDICAL SYSTEMS ITALIA SPA	GE MEDICAL SYSTEMS ITALIA SPA
5	TAC PHILIPS INGENUITY CORE 64 SLICE (BLD2-P0-RAD-00-006-106)	17214	TAC INGENUITY CORE 64 SLICE	28/04/2016	PHILIPS SPA	PHILIPS SPA
6	TAC GE REVOLUTION EVO VT200 (BLD2-P0-RAD-00-006-069)	17599	TAC REVOLUTION EVO VT200	31/08/2016	GE MEDICAL SYSTEMS ITALIA SPA	GE MEDICAL SYSTEMS ITALIA SPA
7	TAC GE REVOLUTION EVO VT200 (BLD8-P0-RAD-00-734-013)	19288	TAC REVOLUTION EVO VT200	27/03/2018	GE MEDICAL SYSTEMS ITALIA SPA	GE MEDICAL SYSTEMS ITALIA SPA
8	TAC GE CARDIO REVOLUTION CT 512 slice (BLD2-P0-RAD-00-006-105)	20626	TAC REVOLUTION CT	13/05/2019	GE MEDICAL SYSTEMS ITALIA SPA	GE MEDICAL SYSTEMS ITALIA SPA
9						
10						

Figure 38: Function woorksheet organization

To clarify the procedure, here is an extract of how the Function worksheet is organized, in particular the parameters related to the TAC registry. If I consider a parameter, e.g. TAC description, it is in one column, and all the values of this parameter of the different TAC are in the same column. In this way, in the line code, the value of the column ("B" in this case) will always be the same. What changes is the value of the row. But, since each line corresponds to one and only one TAC, then the value in the different lines of code will always be the same. Then through a simple "find and replace", with a single step it is possible to pass from one TAC to the next

one. By doing so, a new master can be compiled. However, this replacement saves time compared to manually compiling 41 masters.

- *objDoc.SaveAs ("C:\Users\HP\Desktop\humanitas\Tesi grandi macchine\DOSSIER\" & nomeDossier & ".docx")*

  Once the compilation has taken place without errors, this function allows to save the work as a new master, titled with the name of the HTME that describes. In this case, the masters are saved in a single folder called DOSSIER, but it is not the final dossier yet.

- *On Error GoTo RigaErrore*

  RigaChiusura:
  If Not objWord Is Nothing Then
  objWord.Quit
  Set objWord = Nothing
  End If
  Exit Sub

  RigaErrore:
  MsgBox Err.Number & vbNewLine & Err.Description
  Resume RigaChiusura

  This is the final part of the code.
  The first code line (*On Error GoTo RigaErrore*) relates to the possible presence of an error. Once this occurs during the master compilation, this line returns to the *RigaErrore*. This function allows to show a message showing the specific error codification. In fact, on VBA, each error has a specific encoding, which allows to identify the issue and solve it. Some examples are given below:
  - 75: Path/File access error.
  - 93: Invalid pattern string.

- 337: Component not found.

Once an error has been identified, the function returns to the last part of the code: *RigaChiusura*, which allows to interrupt the macro command.

As has already been said before, this code allows to have an automatic compilation of the master, avoiding a manual compilation and saving a lot of time.

4.5. Images

At this point, in the folder chosen as the destination of the results, 41 masters are present. However, these are not the final dossiers, because the code does not allow you to insert the images relating to the different chapters and different topics. All these images refer to different characteristics of each HTME, such as the exam room, the workstation with which the equipment are controlled and the real location of the room in the hospital. The first are acquired directly, with several photos of the real rooms present in Humanitas, while as regards the other image, these are extracted through the use of InfoCad. In fact, in InfoCad, there is a section in which there is the general plan of each floor of the hospital (as already mentioned previously when the string was generated to identify the different HTME). By analysing these planimetries, the corresponding rooms are identified where the equipment examined is present. to better clarify this aspect, an example will be provided in the third point: Planimetry.

It is necessary to consider images in 4 different sections:

1. Cover image: The cover image consists of a photo of the exam room, where all the components related to the HTME considered are shown. For instance, considering TAC GE REVOLUTION EVO VT200 dossier, the cover photo is the following.

Figure 39:Cover image

2. Informatics: regarding the Informatics chapter, an image of the workstation is present to show the composition of this one.

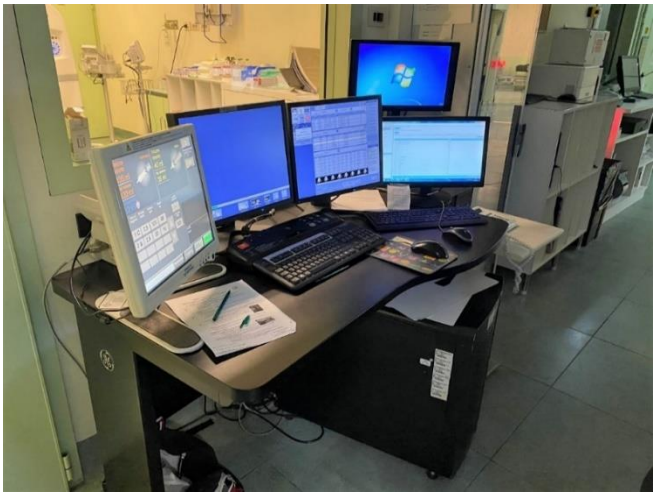


Figure 40:Informatics image

3. Planimetry: in this case there is the combination of the previous two images (exam room and informatics) plus an image of the general map of the HTME considered.

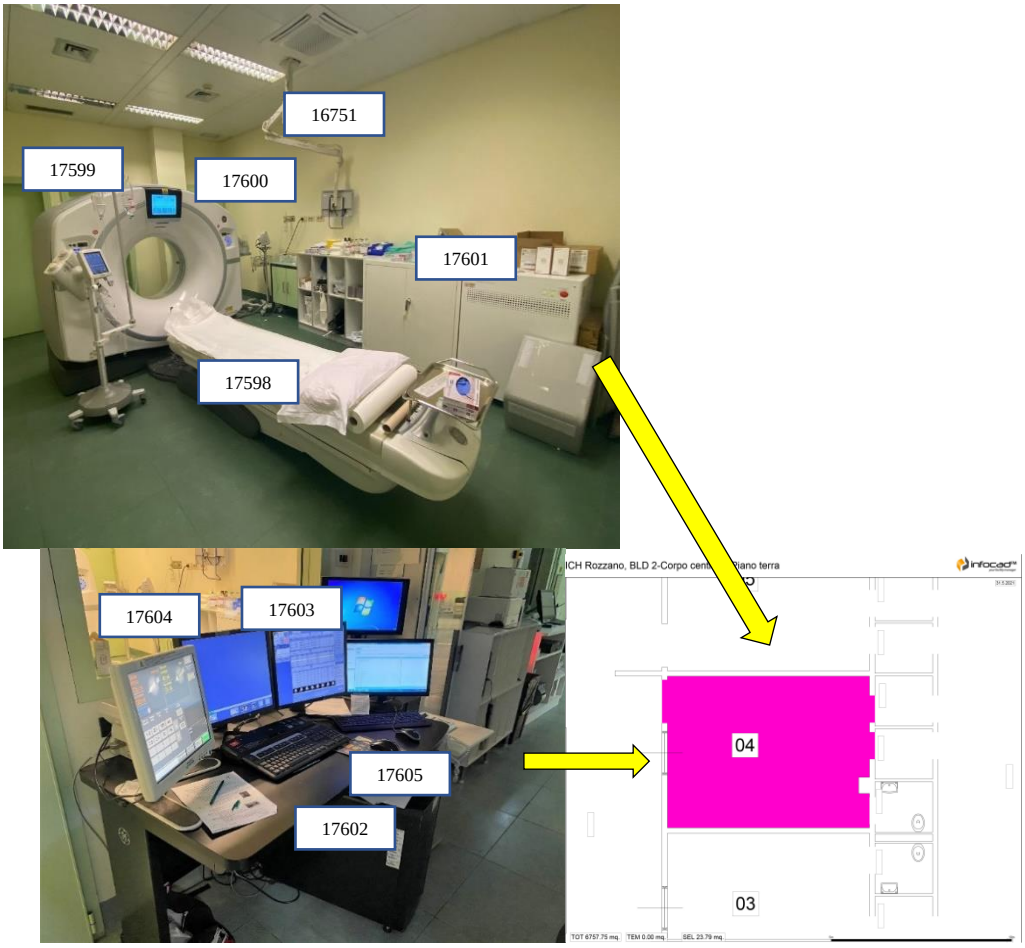


Figure 41:Planimetry image

As it can be seen, the two rooms are shown as images and are connected to the general map, in the exact position in which they are found (the examination room is highlighted in fuchsia). Moreover, it can be noted that the ICH numbers of the different components of the HTME are shown in the images. In this way, whoever uses the dossier, can identify correctly and instantly the real positions of the different rooms and the exact location of the components.

4. Manually reset procedure: this part shows the electrical panel of the HTME considered.

Figure 42: Control panel image

In this section, in addition to the image reported above, the entire reset procedure that the internal technician must carry out is shown, with the actual sequence of the buttons to be pressed and the contact of the supplier in case problems occur in the functionality of the HTME. In this way, if the reset procedure is not enough, the internal technician has the possibility to promptly contact the external technical assistance provided by the supplier, in order to solve the malfunction that has occurred, or to organize a corrective maintenance.

An example of a complete dossier is given in Appendix A(TAC GE REVOLUTION EVO VT200).

Adding the images is the last step in the compilation. At this point the various dossiers are completed, grouped in a single folder and ready to be used for the different needs.
In conclusion, a summary of the entire workflow is provided below:

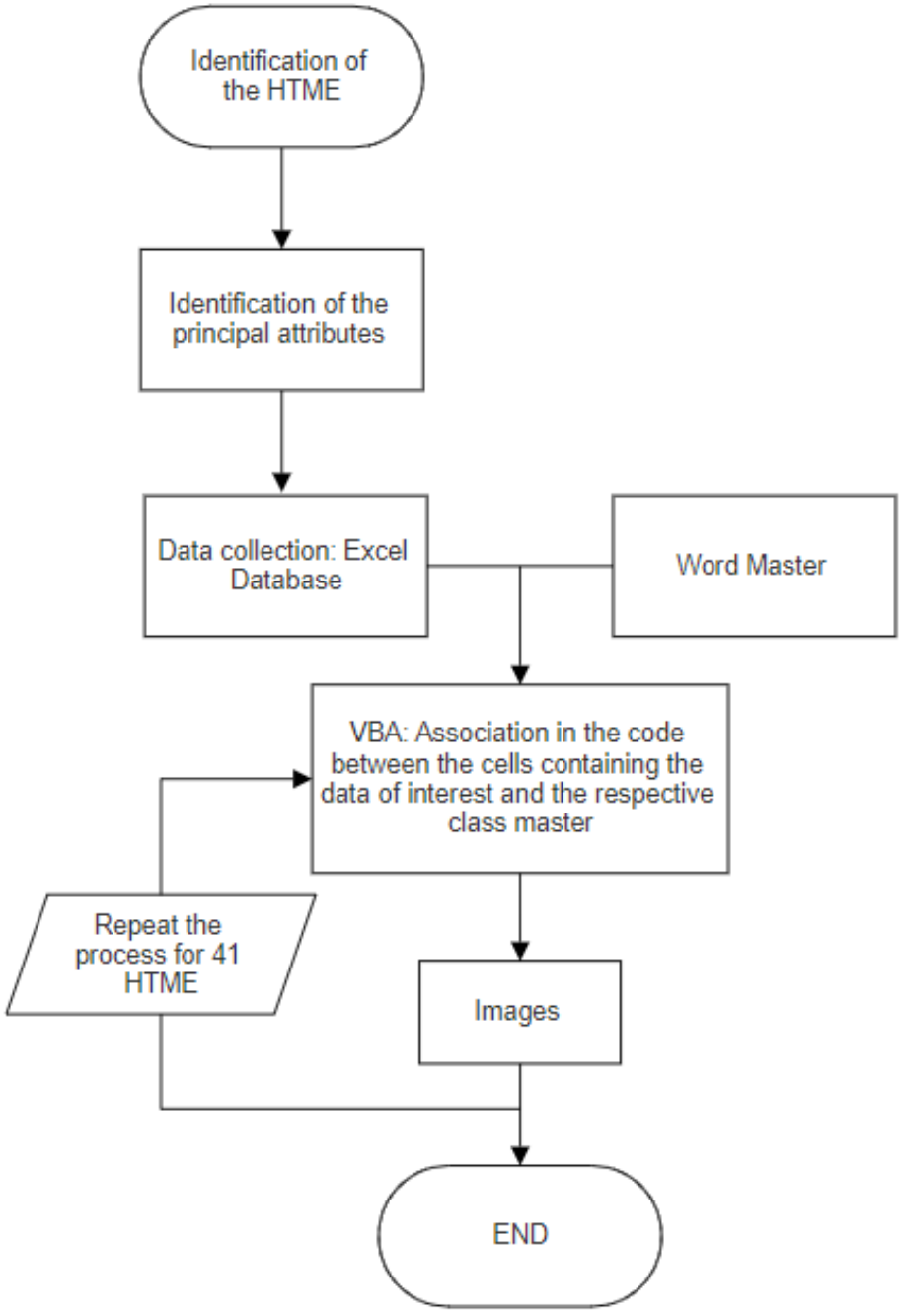


Figure 43:Workflow

5. Analyses and results

Once the dossier has been created, it can be used in various circumstances: consultation by internal technicians for the manually reset procedure, consultation by the SIC for economic aspects, planimetric aspects, etc.

One of the possible direct consequences of the implementation of this dossier is the possibility of carrying out economic analyses that could not be done before. In fact, all the data was scattered within the system, and therefore impossible (or at least very difficult as it takes a long time) to group in a single file.

However, it must be specified that these analyses are only examples and not exhaustive: they are examples of analyses that can be carried out, in reality many other types of analysis can be developed, thanks to the enormous amount of data presented and information collected.

Moreover, to implement an innovative model of HTME management, the dossier is only one of the two tools needed, the other being the training of internal technicians to enable them to intervene promptly and effectively in the event of a minor failure.

Two types of analysis are presented in this work:

1) Data Envelopment Analysis

2) Regression Analysis

5.1. Data Envelopment Analysis (DEA)

DEA is an analysis methodology that could prove effective from the point of view of a Clinical Engineering Service, but which is complicated to carry out without a multidisciplinary dossier that collects all the useful information relating to the HTME of a hospital.

Data Envelopment Analysis was born as a non-parametric technique to measure the performance of production units. Introduced in 1978, it enables the efficiency of a production unit (DMU - Decision Making Unit) to be assessed in relation to a given set of production

units chosen for comparison. In the past, this technique has been used, among other things, to assess the efficiency of banks, hospitals, transport systems, etc.

The advantage over a purely "statistical" approach (i.e., comparing production units with an average production unit), or over a parametric approach (for example, Deterministic Frontier Analysis or DFA, where it is necessary to make explicit an upstream production function) is that the results of non-parametric methods do not require a priori specification, decreasing the degree of subjectivity of the computation. In fact, the method on which DEA is based is to compare each DMU with each of the most efficient DMUs, assuming that each unit operates using specific inputs and produces specific outputs. In the end, the objective is to assess the relative efficiency of the individual unit.

In general, we have that a given DMU A is more efficient than another DMU B if:

i. with the same amount of input, it produces more output, or if
ii. with less input, it produces (at least) the same output.

DMUs with a higher efficiency index will form the so-called productivity or efficiency frontier, the final output of the analysis. They will have an efficiency of 1, as opposed to the remaining units which will have an efficiency index between 0 and 1, inversely proportional to their distance from the frontier. In this work, it was chosen to represent the efficiency frontier as a "ranking" between the HTME considered, according to their score.

Assumptions and mathematical fundamentals

This mathematical methodology starts from at least three fundamental assumptions:

1. There are n DMUs, each of which exploits (or is affected by) an amount of m different inputs to produce s different outputs.
2. Each DMUj uses an amount Xji of the i-th input and produces an amount Yjr of the r-th output.
3. Each DMU has at least one non-zero input and one non-zero output.

The essential feature of the DEA method is the fact that the focus of the analysis moves from the multi-output/multi-input ratio to the ratio between a single "virtual" output and a single

"virtual" input. In this way, for each DMU the ratio of a single virtual output and a single virtual input provides a measure of the productive efficiency of the unit itself.

This ratio has to be maximized and constitutes the function describing a particular DMU being evaluated. In mathematical language, this concept is expressed as:

$$\max_{u,v} h_0(u,v) = \sum_r u_r y_{r_0} / \sum v_i x_{i_0}$$

The problem can be approached in two ways: by maximizing the numerator and set the denominator constant or, vice versa, by fixing the numerator and minimizing the denominator. This distinction determines the type of efficiency being evaluated: whether it is, respectively, output-oriented or input-oriented.

A DMU is said output-efficient if there is no other unit that produces a greater output with the same inputs; instead, a production unit is said input-efficient if there is no other unit that realizes the same output using a smaller amount of inputs.

Stata software and application

In this work, the Data Envelopment Analysis is carried out using Stata, a general-purpose statistical software package written in C language and developed by StataCorp for data manipulation, visualization, statistics, and automated reporting.

Two DEAs are carried out in parallel: the difference lies in the fact that individual devices are first identified as DMUs, and then aggregated, according to the division into classes already illustrated above. Angiography systems do not take part in this analysis, as the lack of availability of some essential data for the assessment did not allow their involvement. Therefore, the two analyses are carried out starting from two datasets of 35 and 10 observations respectively. Regarding the variables used, both studies are carried out by setting as the only input variable the annual cost of the full risk maintenance contract signed between the Humanitas Hospital and the HTME suppliers; as output variables, however, three parameters are selected as indicative of the productivity and efficiency of the devices. Specifically, they are:

- The average income produced every day by each production unit, calculated as the product of the average price of the service for each patient and the average number of examinations carried out by each unit.
- The average number of services provided by each unit, calculated as the ratio between the average operating time of a unit during a day and the average duration of a service.
- Number of days of downtime of a unit that occurred in the three-year period 2018-2020; as an efficient DMU is supposed to minimize such an output variable (differently from the other ones), and since the aim of this DEA is to maximize the outputs once the inputs are given, it is necessary to transform the score for each unit. Hence, for this analysis the inverse of the days of downtime is used, so that even this variable is directly proportional to the efficiency of each observation. For those units whose days of downtime in the examined period are equal to zero, a value of 2 is set by default as the score for this parameter, so that outliers are not taken into account in the analysis, but the higher score than the other units is retained.

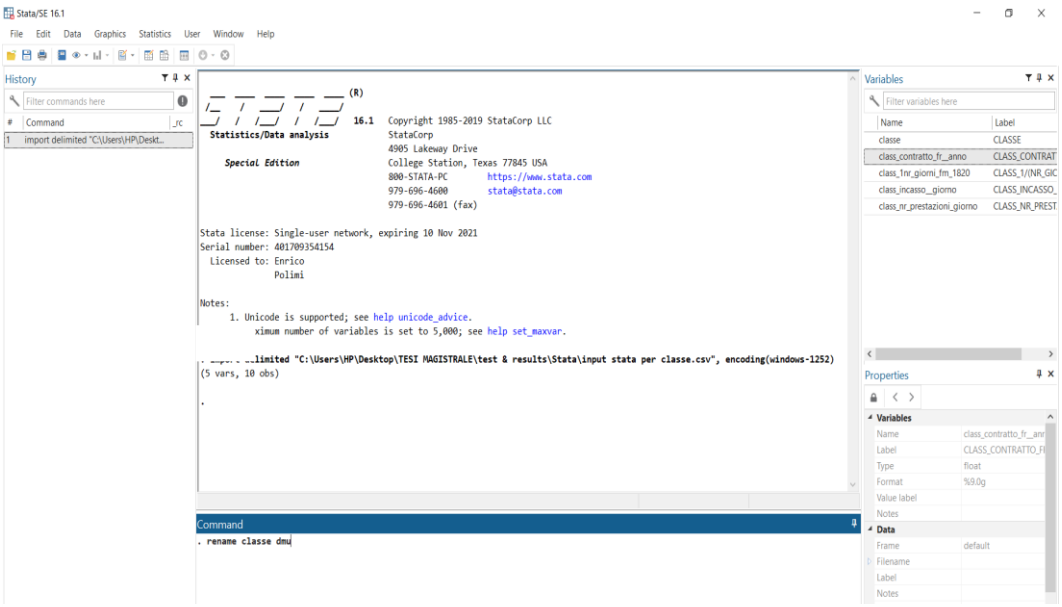


Figure 44: Stata analysis software.

Regarding the database in which each observation is represented by a class of devices, the analysis was carried out using the following code:

. import "input stata per classe.csv", varnames(1) encoding(windows-1252) clear

. rename classe dmu

. rename class_contratto_fr__anno fr

. rename class_1nr_giorni_fm_1820 fm

. rename class_incasso__giorno income

. rename class_nr_prestazioni_giorno nr_prestazioni

. dea fr= fm income nr_prestazioni

```
. import delimited "C:\Users\HP\Desktop\TESI MAGISTRALE\test & results\Gretl\input stata per gm.csv", varnames
> (1) encoding(windows-1252) clear
(5 vars, 35 obs)

.
. . rename descrizione dmu

.
. . rename contratto_fr__anno fr

.
. . rename nr_giorni_fm_1820 fm

.
. . rename incasso__giorno income

.
. . rename nr_prestazioni_giorno nr_prestazioni

.
. . dea fr = fm income nr_prestazioni
-------------------------------------------------------------------------------
      name:  dealog
       log:  C:\Users\HP\Desktop\Polimi\ESAMI SVOLTI\Economics Performance\progetti\essay #2\stata\dea.log
  log type:  text
 opened on:   6 Nov 2021, 18:17:42

options: RTS(CRS) ORT(IN) STAGE(2)
CRS-INPUT Oriented DEA Efficiency Results:

                                                      rank                theta
         dmu:ACC_VARIAN_CLINAC_BUNK3                     1                    1
           dmu:ACC_VARIAN_EDGE_BUNK2                    12                .60324
       dmu:ACC_VARIAN_TRUEBEAM_BUNK4                    11                .634315
       dmu:ACC_VARIAN_TRUEBEAM_BUNK1                     5                .926702
   dmu:ACC_VARIAN_TRUEBEAM_STX_BUNK5                     8                .655098
            dmu:GKN_ELEKTA_PERFEXION                    35               .0654766
dmu:MAM_TECHNOLOGIC_IV_SELENIA_FIORD                    18                .447757
   dmu:MAM_TECHNOLOGIC_SELENIA_AMB13                    22                .306569
   dmu:MAM_TECHNOLOGIC_SELENIA_AMB15                    18                .447757
```

Figure 45: Screenshot of the Stata software when compiling the code for the DEA.

As shown above, the analysis is performed using the "*dea*" command, setting as DMUs the classes of HTME and after the renaming of the abovementioned variables ("*rename*" command, which specifies the new name of the attribute at the end of the code row). As optional parameters for the development of the DEA, the default settings are set, which are: a constant return to scale (so that an increase in inputs causes the same proportional increase

in output); an input-oriented characterization (so that it allows to measure how the inputs can be reduced, keeping outputs constant); a two-stage model (so that it consists of two stages of regression). As shown, the command is run in this way: "dea *inputs* = *outputs*". The results of the DEA are shown in the tables below; they will be further discussed in the next sub-chapter.

HTME Description	*Rank*	*Score*
ACC VARIAN CLINAC BUNK3	1	1
MOC TECHNOLOGIC HORIZON-W	1	1
RAD SIEMENS MULTIX	1	1
RAD SIEMENS MULTIX CCP	4	0.988235
ACC VARIAN TRUEBEAM BUNK1	5	0.926702
RAD AGFA DR 600	6	0.840000
RAD VILLA APOLLO DRF	7	0.740741
ACC VARIAN TRUEBEAM STX BUNK5	8	0.655098
TAC PHILIPS INGENUITY	9	0.646019
TAC GE REVOLUTION VT200 BLD9	10	0.634938
ACC VARIAN TRUEBEAM BUNK4	11	0.634315
ACC VARIAN EDGE BUNK2	12	0.603240
RAD GMM OPERA SWING	13	0.549918
TAC GE REVOLUTION VT200	14	0.548163
TAC PHILIPS BIG BORE RTE	15	0.546005
TAC PHILIPS INGENUITY PS	16	0.540005
TAC GE REVOLUTION VT200 CCP	17	0.517268
MAM TECHNOLOGIC SELENIA AMB15	18	0.447757
MAM TECHNOLOGIC IV SELENIA FIORDAL	18	0.447757
RMN ESAOTE G-SCAN 0.35T CCP	20	0.392571
RAD SIEMENS DR AXIOM ARISTOS	21	0.336000
MAM TECHNOLOGIC SELENIA AMB13	22	0.306569
SPT SIEMENS SYMBIA INTEVO	23	0.258282
MAM TECHNOLOGIC SELENIA CCP	24	0.222037
OPT DITECH KODAK 9000C	25	0.200000
RMN PHILIPS INGENIA 1.5T CCP	26	0.190944
TAC GE CARDIO REVOLUTION	27	0.184277
PET SIEMENS BIOGRAPH	28	0.175384
RAD NEUROMED EOS	29	0.155556

RMN GE OPTIMA 1.5T	30	0.154083
RMN SIEMENS AERA 1.5T	31	0.147706
PET GE DISCOVERY	32	0.143956
RMN PHILIPS PANORAMA	33	0.123833
RMN SIEMENS SKYRA 3T	34	0.073543
GKN ELEKTA PERFEXION	35	0.065477

Table 3: Results of the DEA, setting as DMUs the individual HTME.

HTME Class	*RANK*	*Theta*
Linear Accelerators	1	1
BMD	1	1
X-ray systems	1	1
CTs	4	0.809983
OPT	5	0.467435
SPECT/CT	6	0.463646
Mammographs	7	0.419667
PET/CTs	8	0.218250
MRIs	9	0.205851
Gamma Knife	10	0.082880

Table 4:Results of the DEA, setting as DMUs the aggregated classes of devices.

5.2. High Precision Ordinary Least Squares (OLS) regression analysis

Regression analysis is another method of analysis that could be a useful and implementable analytical tool for many problems faced by a Clinical Engineering Service. In this work, the aim of using this technique is to verify and characterize an eventual correlation between two different variables, regarding the economical aspect of the HTME management.

In statistics, OLS is a linear least squares method for estimating unknown parameters in a linear regression model. The primary objective of OLS is to explain the correlation that exists between two groups of variables: one or more dependent variables (i.e., to be explained) and one or more independent variables (i.e., explanatory or regressor variables). The fundamental step to do this is to define the coefficients of the set of independent variables within a linear function, through the least squares principle (where "least squares" stands for the minimum squares error, or SSE). This method consists in minimizing the sum of squares of the differences between the values assumed in the dataset by the observed dependent variable and those predicted by the linear function of the independent variable. By determining the coefficients of the linear function, the relationship between the two sets of variables is explained. Conceptually, the output can be considered as a weighted sum for each observation (i.e., each medical device), where the final weights are the elements expressing the correlation.

On the other hand, from a geometrical point of view, this method is represented by the sum of the squared distances, parallel to the axis of the dependent variable, between each value assumed by the dataset of independent variables and the corresponding point on the regression surface: the smaller the differences, the greater the compliance of the model to the dataset (i.e., the better the dependent variable is explained).

Assumptions and mathematical fundamentals

Such as in the Data Envelopment Analysis, OLS regression method starts with three assumptions:

1. Observations of the dataset are independent one to each other.
2. Variance is homogeneous across the dataset.
3. Residuals follow a normal distribution across the dataset.

Specifically, in a model with an amount of p independent variables, the OLS regression is configured as follows:

$$Y = \beta_0 + \sum_{j=1}^{p} \beta_j X_j + \varepsilon$$

where Y is the dependent variable, β_0 is the intercept of the model, X_j corresponds to the j-th explanatory variable of the model, and ε is the random error with expectation 0 and variance σ^2.

The OLS method consists in minimizing the sum of square differences between the observed and predicted values. This minimization leads to the following estimators of the parameters of the model:

$$\beta = (X'DX)^{-1}X'Dy$$

where β is the vector of the estimators of the β_i parameters, X is the matrix of the explanatory variables, y is the vector of the n observed values of the dependent variable, and D is a matrix expressing on its diagonal the weight of each observation.

Given this last formula, the vector of the predicted values can be written as follows:

$$y = X(X'DX)^{-1}X'Dy$$

Gretl software and application

In this work, the OLS regression analysis is carried out using Gretl, a software for econcometrics and statistical analysis, which also includes a scripting language.

Such as in the DEA, two groups of regression analyses are carried out in parallel, depending on whether individual devices or the aggregation of devices into classes are used as

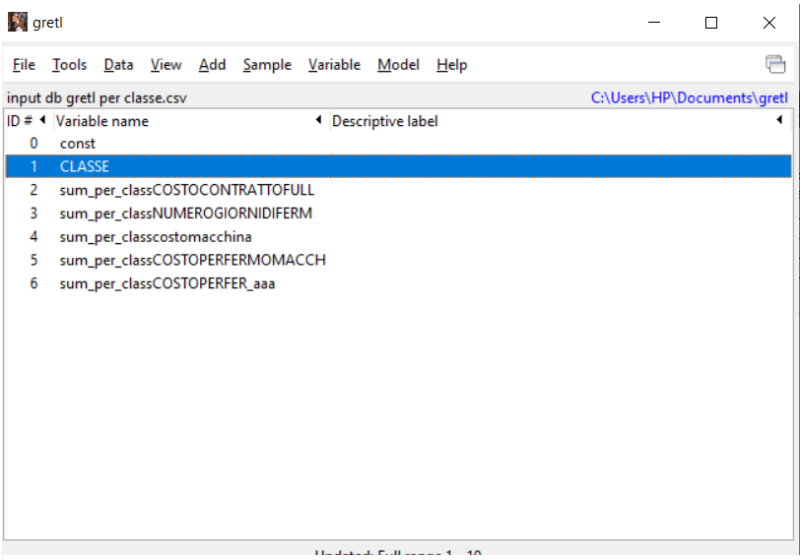


Figure 46:Gretl software.

observations. Moreover, as well as in the previous evaluation, angiography systems do not take part in this analysis, because of the lack of income generated and services provided data. Hence, the two datasets include 35 and 10 observations respectively.

Four linear regressions were carried out for each dataset, one using alle the 35 HTME as observations, while the other three using the classes as instances. All analyses carried out include the use of a single independent variable and a single dependent variable, between which a correlation is checked. The variables used are listed below.

- The cost of the full risk maintenance contract, which represents the regressor/independent variable for each analysis.
- Number of days of downtime that occurred in the three-year period 2018-2020 for each observation.
- The average income produced every day by each device/class of devices, calculated as the product of the average price of the service for each patient and the average number of examinations carried out by each unit.
- The loss of earnings generated by the days of downtime that occurred in the three-year period 2018-2020, calculated as the product between the average daily income produced by each observation and the days of downtime in the three-year period

No.	No. Observation	Dependent var.	Independent var.	Correlation (+/-)	P-value
1	35	Daily income produced	Full risk contract cost	+	0.0001
2	10	Daily income produced	Full risk contract cost	+	0.0002
3	10	Downtime days occurred in 2018-2020	Full risk contract cost	+	0.49
4	10	Loss of income produced by downtime days in 2018-2020	Full risk contract cost	+	0.0002

Table 5:Results of the Gretl

Gretl shows as output the regression coefficient and the standard error related to the estimation of each coefficient. In addition, the significance of the relationship between the dependent variable and the regressor is assessed through the p-value, which is automatically provided by the software. The results of the linear regression tests are shown below and will be discussed in detail later.

5.3. Data Envelopement Analyses results discussion

The conclusions that can be drawn from the results are the following:

- The HTME that are placed at the top of the ranking are those devices that, for the same output, imply a lower expenditure (input) per hospital. In other words, these devices have the best economic impact on the hospital, as their management is the most efficient when comparing costs incurred and income generated, number of services provided and continuity of service. Focusing on specific equipment, it is interesting to note that among the top three performers is a Linear Accelerator. This class of devices is characterized by a considerably greater annual maintenance expenditure when compared with the others; however, the results show that the costs

incurred for this specific DMU (and in general for the entire class of Accelerators) are fully justified with respect to the benefits obtained, both economic and otherwise. In particular, of great impact for this set of HTME is the variable related to the services provided: on average, in fact, 40 radiotherapy patients per day are treated; it is fundamental, in fact, for the Humanitas company policy, that therapeutic treatments are guaranteed to as many patients as possible, maintaining the same level of efficiency and minimizing economic losses due to factors that inhibit service continuity. Secondly, taking into consideration the BMD (here expressed with the acronym MOC), the score can be explained by the very low annual maintenance cost, an average income produced, and number of services provided; moreover, in the three-year period 2018-2020, the device has always been operational, with a number of downtime days equal to zero. Finally, almost all x-ray systems are in the top positions of the ranking; this is because more than 25% of the total services provided by the equipment considered are related to this class of HTME, together with the fact that the costs of full risk contracts are low, as is the frequency of downtime.

- Considering the bottom of the ranking, it is interesting to note that the three least efficient devices according to this analysis correspond to the most technologically innovative ones: the Open Magnetic Resonance Imaging (MRI Philips Panorama), the Magnetic Resonance Imaging Siemens Skyra 3 T, and the Gamma Knife Elekta Perfexion. In this case, what has a negative impact is certainly the very high cost of the full risk maintenance contracts borne by the hospital, which is justified by the novelty of the technology and the fact that the presence of this equipment in the hospital represents a point of excellence. Focusing on the Gamma Knife, another factor that determines this positioning is the number of services delivered per day: being a highly specific device (as it only treats head tumours), the number of patients treated is 2.5 per day on average, which causes a low positioning despite very high income per service and a minimal occurrence of downtime.

  A similar argument can be applied to other equipment: although the number of services provided is higher than for GK (around 20 per day), the cost of full risk contracts has a significant impact on the final score obtained by DMUs.

However, it is necessary to specify that Skyra MRI has been recently acquired, therefore is covered by warranty until 2023; nevertheless, the data is to be considered valid because from 2023, the economic impact will be the one obtained through the variables used. Another example of an HTME still under warranty is the CT Revolution Cardio (ranked 27th).

In conclusion, even though the DEA highlights the low efficiency of these devices, it is important to underline the irreplaceability of these HTME, given the high specificity of the services provided.

- Looking at the ranking as a whole, it is possible to notice that the overall situation of HTME in Humanitas is extremely varied. This assumption is supported by the fact that the score obtained by the different devices proceeds homogeneously from 1 to 0, without evident discontinuities. Therefore, the HTME management model should be implemented by the SIC according to an ad hoc methodology for each individual device, and not considering the class as a whole.

The same analysis is carried out by considering the aggregation in classes. The results obtained (shown in table xx) substantially confirm what was shown in the analysis performed for each device. Linear Accelerators, BMD and X-ray systems rank first, followed by the class of CTs, which is characterized by a very high number of services provided per day. Gamma Knife and MRIs are at the end of the ranking, for the reasons explained above.

5.4. OLS regression Analyses results discussion

In this work it is decided to evaluate all regression analyses separately. The results are presented below with the respective considerations. In particular, the first analysis presented is carried out considering HTME individually (i.e., using 35 observations). The remaining three analyses are implemented by the entire classes (i.e., using 10 observations)

5.5. First analysis: Daily income produced vs. full risk contract cost per year

Coefficient	*Std. Error*	*p-value*
0.840971	0.123823	0.0001

Table 6:Results of the first analysis: values of the estimated coefficient and its standard error for the cost of the full risk contract (dependent variable) in the liner regression equation. This value is validated by a low p-value

It can be deduced from the values obtained that there is a positive correlation between the two variables. In fact, the value of the coefficient is positive, identifying that an increase in the cost of the full risk contract corresponds to an increase in the average daily income produced; in other words, every time there is a downtime, the higher the cost of the maintenance contract, the greater the economic loss due to the lack of services. Looking at the individual HTME in detail, it can be seen that the equipment with the highest maintenance contract cost (e.g., linear accelerators) is the one that generates the highest average daily income. The significance of this analysis is supported by a p-value of 0.0001.

5.6. Second analysis: Daily income produced vs. full risk cost per year

Coefficient	*Std. Error*	*p-value*
0.227737	0.0348597	0.0002

Table 7:. Results of the first analysis: values of the estimated coefficient and its standard error for the cost of the full risk contract (dependent variable) in the liner regression equation. This value is validated by a low p-value.

This analysis includes the same variables used in the first one; however, in this case the class aggregations of devices, rather than individual HTME, were used as observations. This study shows that the more a class of devices produces a profit for the hospital, the higher the cost of its contract is; this output corresponds with the expected result. This outcome is indicated by a positive correlation (coefficient of 0.227) between the dependent and independent variable. The significance of the conclusion is also supported by a low p-value (0.0002).

The chart below shows graphically the correlation between these two parameters. In all the charts produced in this work during the regression analyses, in order to better visualize the results and as a matter of data sensitivity, the experimental values of the two variables were normalized in a range from 0 to 10.

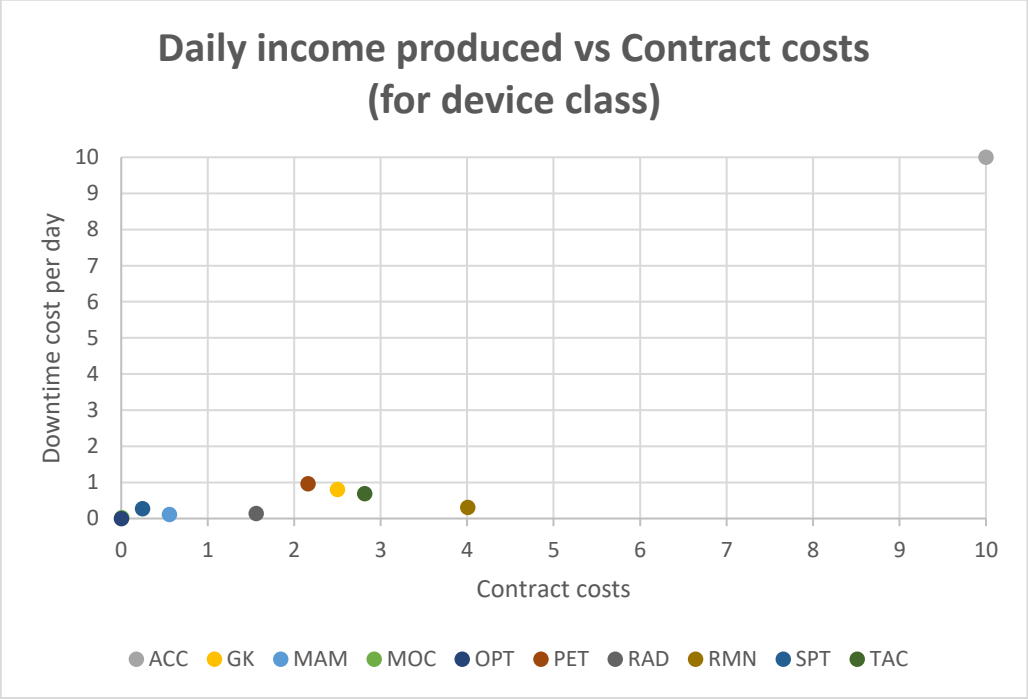


Chart 1. Grafical correlation between the daily income produced and the contract of maintenance cost variables.

5.7. Third analysis: Downtime days occurred in 2018-2020 vs. full risk cost per year

Coefficient	*Std. Error*	*p-value*
5.55096e-06	7.68896e-06	0.4909

Table 8:Results of the first analysis: values of the estimated coefficient and its standard error for the cost of the full risk contract (dependent variable) in the liner regression equation. This value cannot be validated, due to a too high p-value.

Considering the results obtained, it can be seen that there is a positive correlation between the two variables. This indicates that full risk costs are not associated with adequate coverage, as the more expensive is the full risk contract, the higher is the number of downtime days occurred. In other words, the more an HTME impacts economically on the hospital, the more downtime days per class increase.

However, this analysis is not statistically significant, given a very high p-value (0.49); therefore, the results obtained through this analysis are not to be taken into consideration with regard to the definition of a management model for HTME.

The chart below shows graphically the correlation between these two variables.

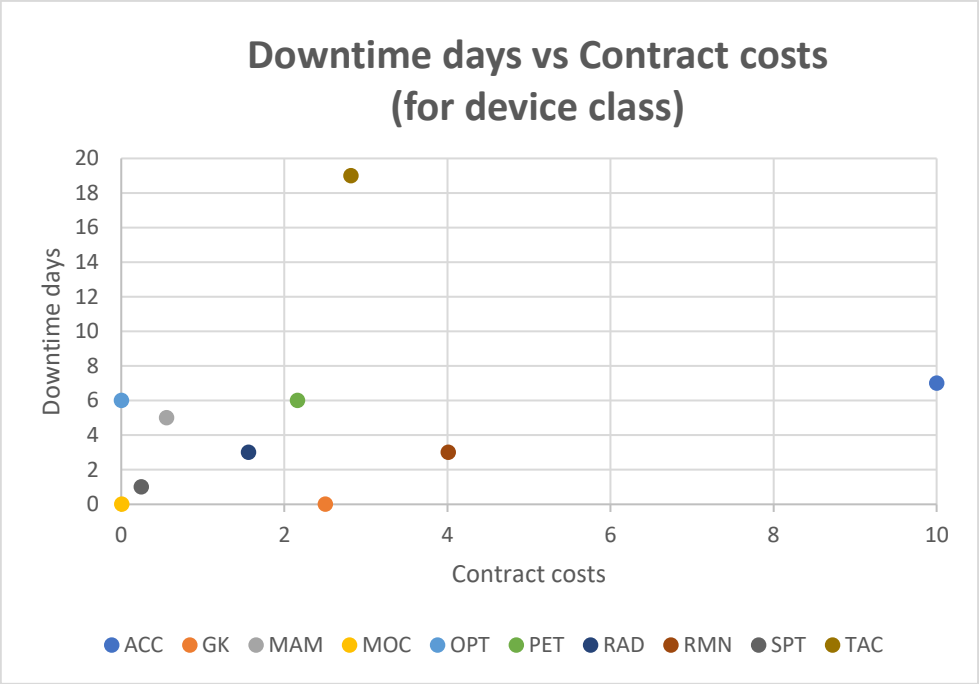


Chart 2. Grafical correlation between the downtime days occurred in the three-years period 2018-2020 and the contract of maintenance cost.

5.8. Fourth analysis: Loss of income produced by downtime days in 2018-2020 vs. full risk cost per year

Coefficient	*Std. Error*	*p-value*
1.61296	0.254820	0.0002

Table 9:Results of the first analysis: values of the estimated coefficient and its standard error for the cost of the full risk contract (dependent variable) in the liner regression equation. This value is validated by a low p-value.

This last analysis is a summary of the previous two. The result indicates that there is a clear positive correlation between the cost of the maintenance contract and the loss of profit due to a lack of continuity of service, which occurred in the three-year period 2018-2020. The

significance of this result was also confirmed by a very low p-value. In other words, the more Humanitas spends in full risk contracts to avoid interrupting the continuity of service, solving the problem as soon as possible, the more the loss of income that occurs for this reason is burdensome for the hospital's finances. Certainly, this is largely due to the fact that the devices with the highest coverage costs are also those that generate the highest profit, and therefore also the highest losses when they stop working. However, on the other hand, the result of this analysis suggests that there is a case for moving away from costly full risk cover to less costly full risk cover, if internal technicians are trained to intervene promptly in the event of a breakdown. In such a case, the correlation would probably remain positive due to the fact that the devices generating the most income require highly specialized (and therefore expensive) assistance from the supplier; however, in this scenario it could be assumed a lowering of the values for both the maintenance costs and the loss of profit due to the days of downtime (which would be reflected in a decrease of the linear regression coefficient, currently 1.613).

The chart below shows graphically the correlation between these two parameters.

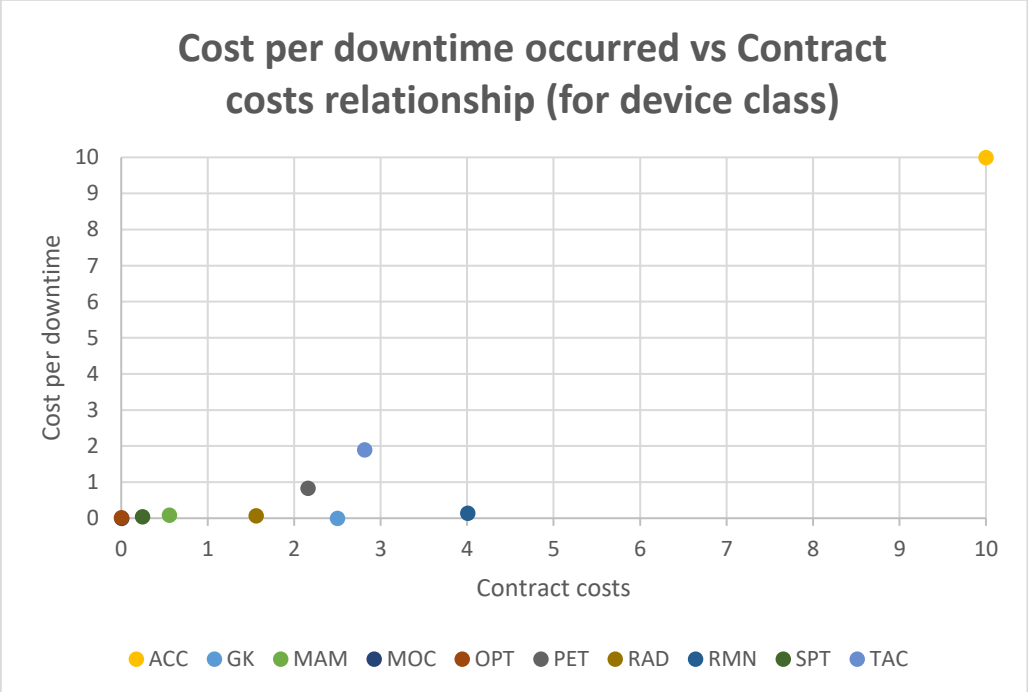


Chart 3. Grafical correlation between the loss of profit due to downtime days occurred in the three-years period 2018-2020 and the contract of maintenance cost.

6. Conclusions and future developments

The Clinical Engineering Service of the Humanitas Hospital is in charge of managing the life cycle of about 20,000 electromedical devices in the Rozzano facility and other outpatient clinics in Lombardy. However, there is still no management model for the equipment that has the greatest economic impact on the hospital (in terms of both expenditure and profit), the so-called High Technology Medical Equipment. The management of the life cycle of these devices, in fact, is almost totally entrusted to external suppliers, who deploy their own technicians for both preventive and corrective maintenance. The full-risk contracts concluded with these parties, as mentioned above, entail considerable costs for the hospital. However, as things stand at present, this is the only way to provide adequate support for the life cycle of such equipment, both because of the lack of a single collector of information on master data, technology, services that can be provided and the economic aspect, and because of the lack of adequate know-how among the staff of internal technicians on how to intervene on these highly complex devices in the event of a breakdown.

The objective of this thesis is to provide Humanitas Hospital with the first of these two tools, so as to make available to the staff of the SIC a multidisciplinary dossier containing all the information necessary for the economic management (how much does each HTME cost and how much does it profit), technical management (from which technological components is a device composed) and performance management (which services are provided by each HTME and which service can be provided by another HTME in case of failure). This therefore consists of gathering in one single set of specifications all the internal know-how, which was previously scattered in the hospital's archives, in the instruction manuals or in the technical data sheets of the equipment, or not reported anywhere and gathered through interviews with external technicians.

The implementation of this tool is an element of primary interest for the company, since, as already mentioned, it is considered by the Clinical Engineering Department as one of the two requirements necessary to take control of the electromedical equipment that most affects the hospital's economy. Moreover, thanks to the multidisciplinary nature of the file and the vastness of the parameters it contains, it is possible to quantitatively carry out a

series of analyses that were previously impossible to set up due to the lack of a univocal database. Within this work, as an example, a Data Envelopment Analysis and a regression analysis were carried out, in order to assess the efficiency of HTMEs and the correlation between a set of parameters connected to them.

In conclusion, the implementation of this tool is certainly of fundamental importance for the proper internal management of HTME. However, of equal interest to the company is certainly the training of internal technicians to ensure a timely first intervention in case of downtime, which in cases of minor failures could allow the immediate restoration of service provision. This would also make it possible to save on the costs of maintenance contracts, abandoning the full risk coverage formula (which in the worst cases involves hundreds of thousands of euros of annual expenditure for a single device) and adopting a contract that provides less coverage in critical cases, and an on-demand intervention contract in the case of devices that are easily replaced within the hospital. The savings generated as a result could be invested in adding a highly specialized technical professional in the field of HTME maintenance to the staff of internal technicians. This training should take place through the sharing of the know-how of intervention on the equipment by the manufacturers, who would have to give up part of their profits with the implementation of this model. However, in this scenario, the external technicians of the suppliers could be employed for technical support in other hospitals, using their own effort only where the problem could not be fixed internally. In fact, after starting a dialogue with the manufacturers, some of them have shown themselves willing to start the training activity of Humanitas technicians by the end of 2021.

The development of both elements would lead to the creation of a unique model for the management of high-tech devices, allowing savings to be invested in the purchase of innovative equipment or the recruitment of new staff.

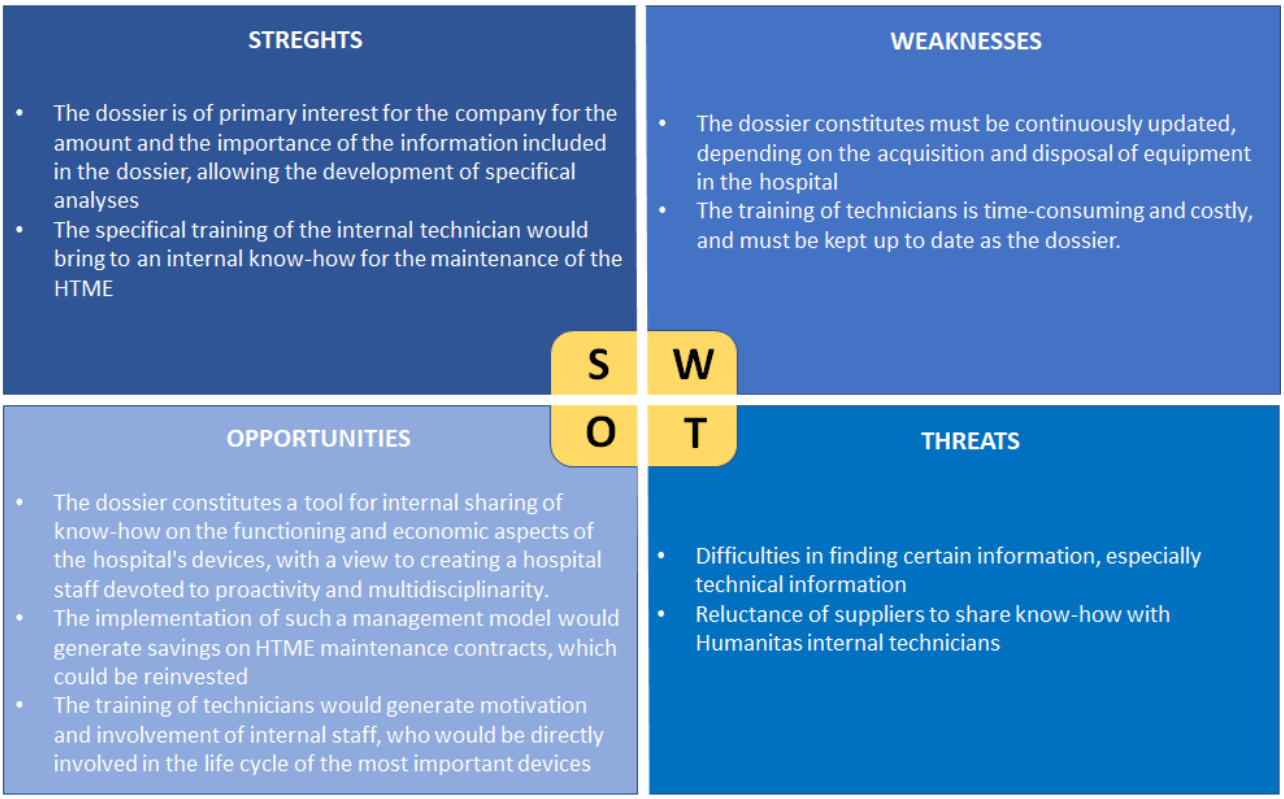


Figure 47. SWOT matrix.

The pros and cons that the implementation of this model would bring, together with the associated opportunities and risks, are summarized in the SWOT matrix (Figure 47).

The major limitations in the implementation of a comprehensive HTME management model can be summarised in two points; from the resolution of each of them it is possible to define the future development of this work.

- Firstly, the impossibility of carrying out a cost-benefit analysis of the second phase of the implementation of the HTME management model, namely the training of in-house technicians. This necessary evaluation would use as cost variables those related to the training of internal staff, and as potential benefits savings on maintenance contracts and greater involvement and motivation of internal technicians (the latter benefit, of course, does not include direct economic benefits, but is considered of fundamental importance). In case of a positive output of this assessment, the hiring of a new technician could be considered, as mentioned above.
- Secondly, the reticence of most HTME producers on sharing specific information on the conduct of training courses for Humanitas' technical staff represented an obstacle

in the delineation of the aforementioned cost-benefit analysis relative to the entire management model.

Finally, the lack of information, especially technical, regarding HTME was a problem often encountered during the preparation of the database, the starting point for the preparation of the dossiers, the real focus of this thesis work. In addition, the lack of data on the economics and performance of the angiography class prevented an analysis covering the entire fleet of equipment analysed in this work.

7. Appendix A

TAC GE REVOLUTION EVO VT200

ANAGRAFICA

L' apparecchiatura TAC GE REVOLUTION EVO VT200 è prodotta da GE MEDICAL SYSTEMS ITALIA SPA. All'interno di ICH, è ubicata presso il reparto RADIOLOGIA; è stata introdotta nel parco macchine previo collaudo, avvenuto in data 31/08/2016. È contrassegnata dal numero interno di inventario 17599.

La stringa univoca che individua l'impianto è la seguente: BLD2-P0-RAD-00-006-069.

L'apparecchiatura è costata al momento dell'acquisto € XXX; il corrispondente riferimento è rappresentato dall'Ordine di Acquisto nr. XXX.

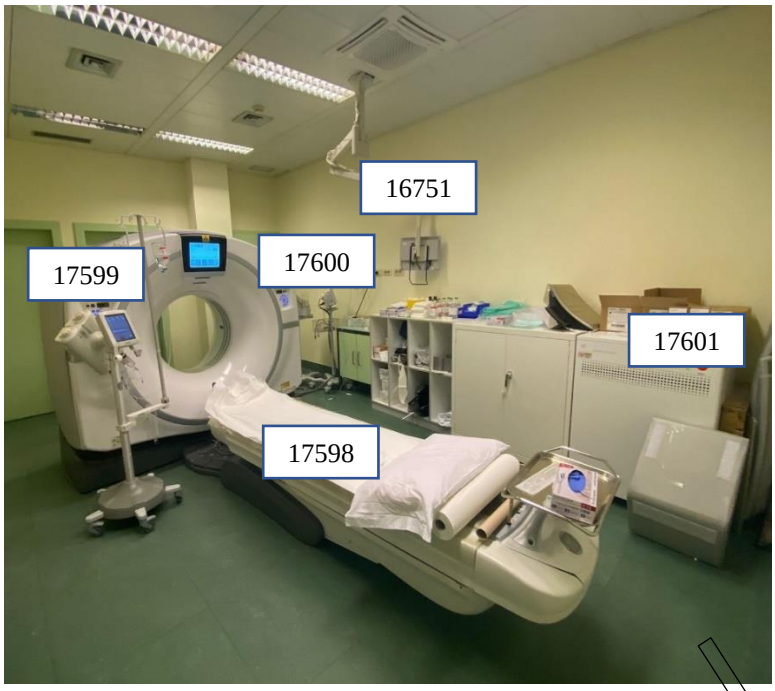
Presso ICH, la manutenzione è fornita da GE MEDICAL SYSTEMS ITALIA SPA.

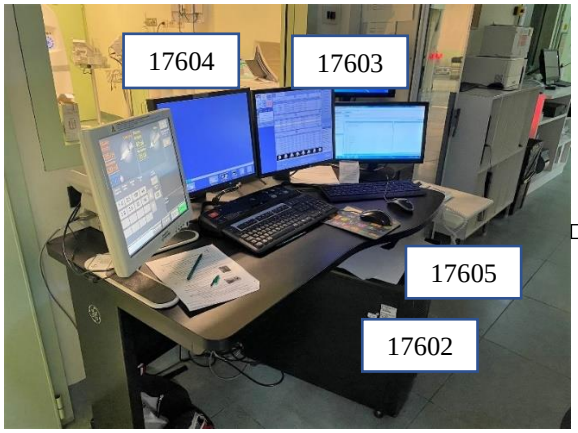
L'impianto nel suo complesso è formato da 9 componenti, il cui elenco è riportato di seguito.

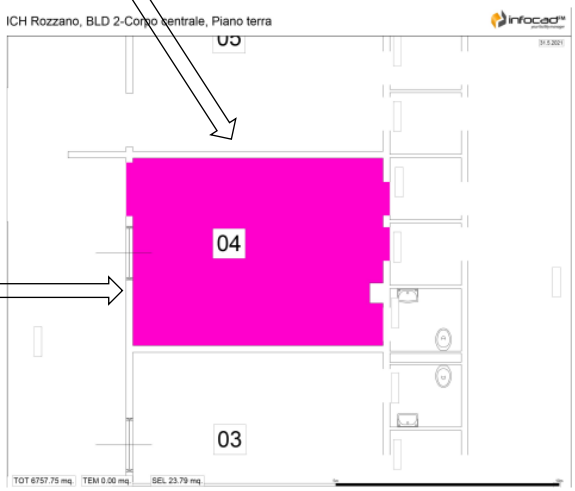
ICH	DESCRIZIONE BENE
17599	TAC REVOLUTION EVO VT200
17605	MASTERIZZATORE DMS-SC12
17601	MODULO PDU 2326492-81
17598	TAVOLO PAZIENTE 5122080-12
17600	MONITOR CARDIAC TRIGGER MONITOR 7800
17603	DISPLAY FLEXSCAN S1923
17604	DISPLAY FLEXSCAN S1923
17602	CONSOLLE (RICOSTRUTTORE ASIR-V) 5441626-32
16751	DISPLAY FLEXSCAN S1923

PLANIMETRIA E CARATTERISTICHE AMBIENTALI

Di seguito sono riportati la planimetria e i layout degli impianti energetici del locale dove è ubicata l'apparecchiatura.







Al fine di un funzionamento ottimale, la temperatura all'interno deve essere di 22 ± 4 °C e l'umidità relativa registrata deve essere compresa nel range 30- 60%. Il calore emesso dall'apparecchiatura nell'ambiente si attesta intorno ai 6,78 kW. Infine, la tensione di alimentazione dell'apparecchiatura è pari a 380 Vac.

DATI TECNICI

Caratteristiche meccaniche

L'apparecchiatura, nel suo complesso, pesa circa 2255 kg. Di seguito sono riportate le principali caratteristiche meccaniche di alcuni componenti rappresentativi dell'impianto.

- **Lettino:**

Peso: 227 kg;

Dimensioni (p x l x h): 650 x 2370 x (430-990) (p x l x h) mm;

Traslazione longitudinale: 100 (sito 170-200) cm;

Portata: 306 kg;

- **Detettore:**

Modello: HiLight DAS;

- **Gantry:**

Peso: 1810kg;

Inclinazione: ±30°;

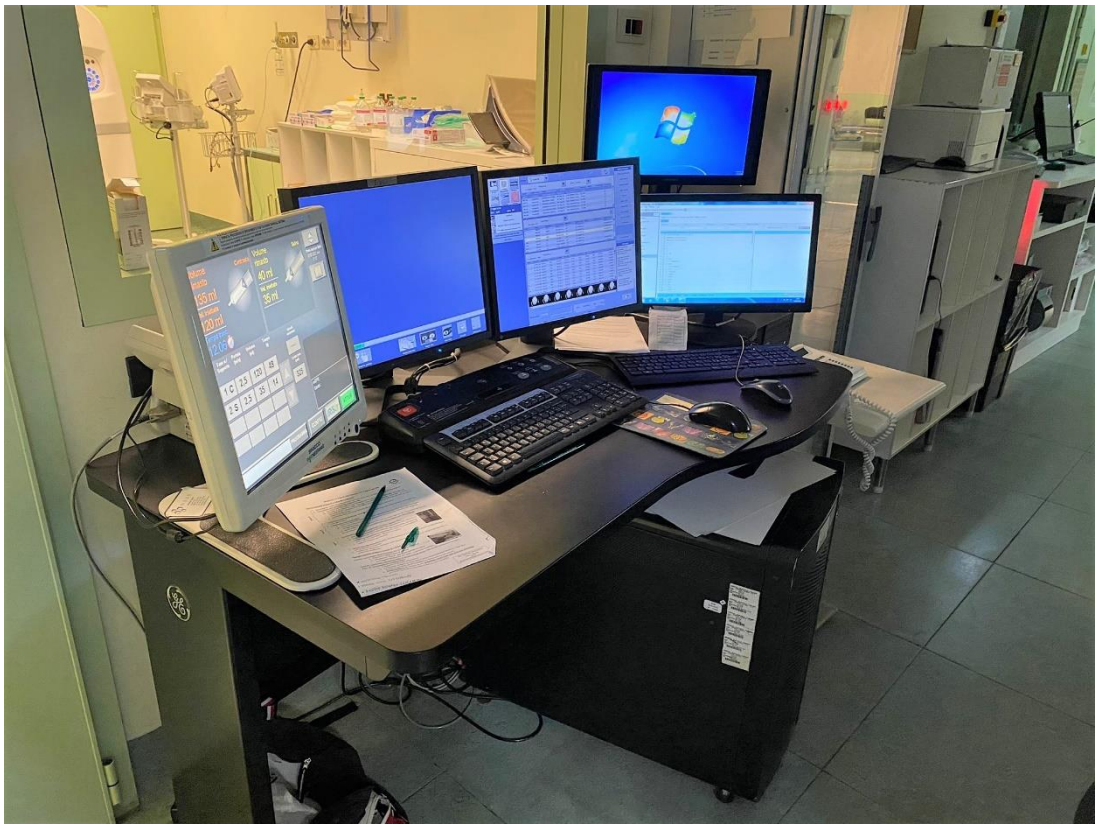
Diametro: 70cm.

Caratteristiche tecniche

Caratteristica [u.d.m.]	Valore
Numero di slices	128
Capacità dissipazione tubo radiogeno [Hu/min]	1070000
Corrente alimentazione tubo radiogeno [mA]	10-560
Dimensione punto focale [mm]	modalità small - medium - large
FOV [mm]	50
Frame rate	max 55 ips
Massimo diametro esplorabile [cm]	200
Meccanismo raffreddamento tubo radiogeno	Olio con radiatore
Meccanismo raffreddamento generale	Aria
Formato acquisizione	2D, 3D, 4D
Dimensione image matrix [pixels]	N/A
Potenza tubo radiogeno [kW]	33,6 - 72
Risoluzione spaziale [LP/mm]	18,3 max
Slice thickness (mm)	0,625-5
Tempo di acquisizione	max 60
Tempo di ricostruzione	nell'ordine dei secondi
Tensione di picco generatore (kVp)	80-140

INFORMATICA

All’esterno della sala macchina è presente una stazione informatica, con funzione di Acquisizione, ricostruzione, review. Sono presenti 1 + 1 ricostruttore pc e 3 monitor. I software installati sui diversi pc sono Linux. Il complesso dei pc è collegato a 1 dispositivi di masterizzazione e 1 di reparto stampanti.



Data flow

TAC GE REVOLUTION EVO VT200 rispetta gli standard di visualizzazione e archiviazione DICOM, presente nel sistema informatico nella sua versione DICOM 3.0. L’archiviazione è di tipo 0.

Le immagini, una volta acquisite, possono essere inviate ad altre apparecchiature (in particolare a 0) nell’ambito della programmazione di un trattamento.

Infine, l’indirizzo IP dei pc del sistema informatico è di tipo 0.

COSTI, CONTRATTI E FERMO MACCHINA

Per la manutenzione dell'apparecchiatura TAC GE REVOLUTION EVO VT200 è stato stipulato un contratto di tipo *full-risk,* dal canone annuo di € XXX. La data di fine garanzia è fissata al 02/09/2018.

Non si sono verificati giorni di fermo macchina NON programmati nel triennio 2018-2020.

Nella seguente tabella sono riportati nel dettaglio i dati legati a costi, servizi erogati e operatività, relativamente a questa apparecchiatura.

Variabile [u.d.m.]	**Valore**
Prezzo per prestazione [€]	XXX
Media prestazioni erogate per giorno	50
Durata media per esame [minuti]	10
Operatività macchina per giorno [ore]	11
Rimborso SSN per prestazione [€]	XXX

Per quanto riguarda la procedura di riarmo, qualora si interrompesse l'alimentazione elettrica all'apparecchiatura, il tecnico deve:

- Recarsi presso il quadro elettrico generale della macchina, accanto alla workstation;
- Premere il pulsante contrassegnato dalla dicitura "PULSANTE ACCENSIONE MACCHINA".

Al verificarsi di un problema nel funzionamento dell'apparecchiatura, per mettersi in contatto con il fornitore si può utilizzare il seguente contatto: tel: 800827164 – mail: assistenzagenord@ge.com.

PRESTAZIONI EROGATE

Di seguito sono riportate le prestazioni erogate dall'apparecchiatura TAC GE REVOLUTION EVO VT200 presso l'Istituto Clinico Humanitas:

- Tac addome completo con e senza contrasto
- Tac torace con e senza contrasto
- Tac torace senza contrasto
- Tac massiccio facciale senza contrasto
- Tac addome completo senza contrasto
- Tac encefalo senza contrasto
- Ricostruzione tac in 3d
- Tac encefalo con e senza contrasto
- Tac collo con e senza contrasto
- Tac rachide cervicale senza contrasto (3 metameri e 2 spazi)
- Angio-tac aorta addominale
- Angio-tac arterie renali
- Angio-tac arto inferiore dx
- Angio-tac arto inferiore sx
- Angio-tac arto superiore dx
- Angio-tac arto superiore sx
- Angio-tac distretto intracranico
- Angio-tac tronchi sovraortici
- Ricostruzione tridimensionale tac massiccio facciale
- Tac addome inferiore con e senza contrasto
- Tac addome inferiore senza contrasto
- Tac addome superiore con e senza contrasto
- Tac addome superiore senza contrasto
- Tac bacino e articolazioni sacroiliaca
- Tac caviglia/piede dx con e senza contrasto
- Tac caviglia/piede dx senza contrasto
- Tac caviglia/piede sx con e senza contrasto
- Tac caviglia/piede sx senza contrasto
- Tac collo senza contrasto
- Tac coxofemorale/femore dx con e senza contrasto
- Tac coxofemorale/femore dx senza contrasto
- Tac coxofemorale/femore sx con e senza contrasto
- Tac coxofemorale/femore sx senza contrasto
- Tac del cranio sella turcica, orbite con e senza contrasto
- Tac del cranio sella turcica, orbite senza contrasto

- Tac dell'orecchio senza contrasto
- Tac dell'orecchio con e senza contrasto
- Tac ginocchio/gamba dx con e senza contrasto
- Tac ginocchio/gamba dx senza contrasto
- Tac ginocchio/gamba sx con e senza contrasto
- Tac ginocchio/gamba sx senza contrasto
- Tac gomito/avambraccio dx con e senza contrasto
- Tac gomito/avambraccio dx senza contrasto
- Tac gomito/avambraccio sx con e senza contrasto
- Tac gomito/avambraccio sx senza contrasto
- Tac massiccio facciale con e senza contrasto
- Tac polso/mano dx con e senza contrasto
- Tac polso/mano dx senza contrasto
- Tac polso/mano sx con e senza contrasto
- Tac polso/mano sx senza contrasto
- Tac rachide cervicale con e senza contrasto (3 metameri e 2 spazi)
- Tac rachide dorsale con e senza contrasto (3 metameri e 2 spazi)
- Tac rachide dorsale senza contrasto (3 metameri e 2 spazi)
- Tac rachide lombosacrale con e senza contrasto (3 metameri e 2 spazi)
- Tac rachide lombosacrale senza contrasto (3 metameri e 2 spazi)
- Tac rachide sacrococcigeo con e senza contrasto (3 metameri e 2 spazi)
- Tac rachide sacrococcigeo senza contrasto (3 metameri e 2 spazi)
- Tac rachide: metamero aggiuntivo
- Tac spalla/braccio dx con e senza contrasto
- Tac spalla/braccio dx senza contrasto
- Tac spalla/braccio sx con e senza contrasto
- Tac spalla/braccio sx senza contrasto
- Tc cervicale senza contrasto
- Tc dorsale senza contrasto
- Tc lombo-sacrale senza contratto
- Tc total body senza contrasto
- Tc total body senza e con contrasto

Tuttavia, TAC GE REVOLUTION EVO VT200 potrebbe erogare le seguenti prestazioni, per esempio al verificarsi del fermo macchina di un’altra apparecchiatura della stessa classe:

- Artro-tac spalla dx
- Artro-tac spalla sx
- Routine "dacrio tac"

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