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# Technical Functional Assessment of the Needs in Terms of Medical Devices for a Paediatric Hospital Under Construction

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**Abstract.** This study focuses on defining the technological needs, specifically medical devices, for the new Pavilion Zero at the IRCCS Giannina Gaslini Institute, which will be organized by intensity of care. Given the complexity of the project, already in progress with building works and infrastructures, the research employed a rigorous methodological approach. A preliminary analysis of regulatory frameworks was carried out alongside an assessment of the hospital's existing technologies was performed using the database, managed by the current global service consulting company, to identify the current state of the art of the medical equipment and to adapt it to the needs of the new hospital. Detailed reviews of floor plans, the Bill of Quantities (BOQ), and Building Information Modelling (BIM) project renderings were essential to verify the adequacy of selected technologies. Crucial to the process was the active collaboration with clinical staff through working groups, whose input was fundamental in shaping technology choices according to real operational needs. Furthermore, an analysis of existing technologies for potential transfer to Pavilion Zero was carried out to optimize resource management in collaboration with the current global service consulting company. Data modelling was carried out through a Structured Query Language (SQL) database to have the data structured in the design phase of the technological needs. Overall, the study presents a multidisciplinary approach to define the technological needs of Pavilion Zero, combining regulatory analysis, technological assessment, and clinical collaboration to develop a strategy that meets the future needs of the new hospital facility. Through this multi-phase methodology, it will be possible to define a structured approach in order to help the healthcare professionals to define the technological needs of a cutting-edge hospital facility.

**Keywords.** Decision Support for Hospital Technology Supply, Intensity of Care, Multidisciplinary Integration, Medical Device Nomenclature Standardization

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## 1. Introduction

This study is part of the expansion and modernization project of the IRCCS (Scientific Research And Treatment Institute) Giannina Gaslini, one of the world's leading paediatric centres, which is currently engaged in the development of the New Hospital Giannina Gaslini (NHGG) [1]. NHGG will introduce a transformative change in the functional organization of the hospital, shifting away from the traditional model based on medical specialties and instead adopting an organizational structure aimed on the intensity of care that prioritizes the level of care required by the patient. As part of the Gaslini Institute's broader expansion and modernization project, the NHGG, this study focuses on Pavilion Zero [2], a key new component dedicated to high-intensity care units [3]. By organizing the hospital's resources according to the severity of the patient's conditions and their need for specialized interventions, Pavilion Zero will create a more flexible and patient-centred care environment.

The planning of the necessary technologies for Pavilion Zero is crucial to ensure the success of the project, meeting both the set deadlines (2026) and budget constraints. The goal of this study is to define a structured multi-phase method that can help the clinical engineering team identify the medical device needs while ensuring compliance with regulations and specific clinical demand.

A central aspect of the work is the creation of a structured database [4] to systematically manage information on medical devices for the current needs and as a reference for future acquisitions. Additionally, the study integrates into the rigorous methodology for technological planning, close collaboration with healthcare staff, to ensure that the proposed solutions are suited to the day-to-day operational needs. This approach is essential to maintain the role of the Gaslini Institute as an IRCCS and a centre of paediatric excellence, assuring that technological planning combines not only clinical needs but also innovation and research, which are key elements of the Institute's mission.

## 2. Materials and Methods

In order to achieve the study's objectives, the multi-phase methodological approach is divided into different steps as follows:

- An in-depth analysis of the Manual of Requirements for Authorization issued by A.Li.Sa. (Region Liguria) [5] to determine the technical and operational standards for medical devices required in Pavilion Zero. However, given the forward-looking nature of Pavilion Zero, the study extended beyond these basic requirements to ensure the pavilion will be aligned with the institute's goals of innovation and research;
- A thorough evaluation of the existing medical devices at the hospital was carried out using the BiogestNT [6] internal database, which provided a detailed map of the medical devices currently in use, capturing both the quantity and the technical specifications;.
- Subsequently, the team focused on examining the Building Information Modelling (BIM) project for Pavilion Zero, essential for understanding the spatial layout where medical devices will be placed and to facilitate better informed decision making by integrating project information in all aspects [7].

The BIM project was accessed through two software platforms: Dalux that allowed for interactive 3D navigation of the floor plans, providing a clear visualization of room dimensions and equipment layout and dRofus, that offered both graphical and database capabilities, enabling detailed tracking of each element within the rooms. In addition, navigable 3D photographic surveys of the current structure were used to enrich the analysis of spatial and environmental information from medical devices in use.

- Direct collaboration with healthcare professionals organized into working groups based on hospital floors provided key insights on the needs for prototype rooms. The clinical engineering team facilitated this interdisciplinary dialogue, translating operational needs into technological solutions. This collaborative approach was instrumental in refining the technological needs, ensuring the selected devices were both technically suitable and practical for everyday clinical use.
- An assessment of the obsolescence of the current medical devices was conducted using the Obsolescence Evaluation Methodology (*OEM*), which evaluates the lifecycle and functional condition of equipment. This analysis identified devices that could potentially be transferred to Pavilion Zero, with further evaluations planned to match these devices with specific clinical needs in later phases.

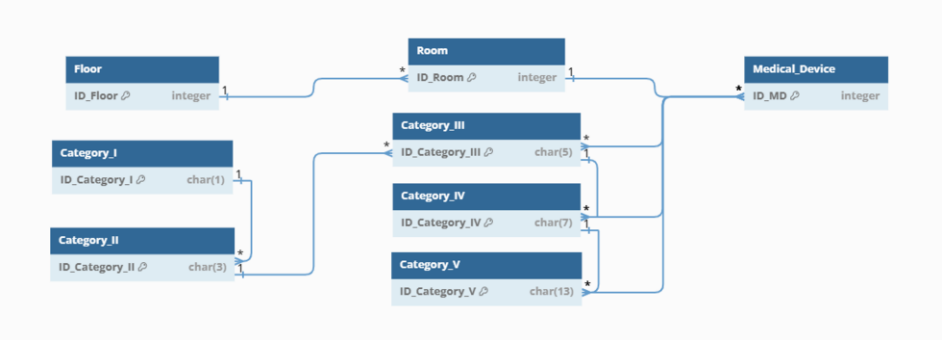


**Figure 1.** The Entity-relationship diagram (E-R) of the SQL database is designed to define the technological requirements for Pavilion Zero and it illustrates the relationships between the main entities in the system. This structure allows for efficient management of Medical Devices by combining their spatial placement (via Room and Floor) with a detailed functional classification (through the CND hierarchy).

The study employed a uniform nomenclature in order to ensure uniformity in the classification of medical devices, as done in other studies like [8] and [9] where reference is made to an international nomenclature. In particular, this work applied the National Classification of Medical Devices (Classificazione Nazionale dei Dispositivi Medici - CND) [10], the Italian national system for classifying medical devices aligned with the Global Medical Device Nomenclature (GMDN) [11].

This standardization ensured clarity and consistency throughout the technological planning process. All gathered data were systematically organized into a dedicated SQL database [4], structured using an entity-relationship model, as explained in Figure 1. This database serves as a vital tool for managing information on medical devices, providing an efficient framework for both current needs and future acquisitions. It ensures comprehensive, easily accessible data management, supporting informed decision-making throughout the project's lifespan. An integrated SQL database, which

standardizes the nomenclature of medical devices, not only improves the management of technological requirements but also enhances interoperability with broader healthcare systems.

This enables secure access to and updates of clinical and technical information, while providing key functionalities such as encrypted data access, content updates, and semantic management of clinical data [12]. These features are essential to ensure efficient interoperability and to assist the Decision Support Systems, seamlessly integrating technological requirement management with digital healthcare solutions.

## 3. Results

The results of this study provided a detailed and structured definition of the complex methodology developed, useful for the characterization of the total technological needs for Pavilion Zero. A key outcome of the process was the creation of a comprehensive medical device plan based on the building project. For each room across all floors, the specific medical devices required were meticulously identified and recorded, ensuring that the equipment would meet both clinical functionality and operational efficiency. Once these needs were established for every room and floor, the data were consolidated into the dedicated SQL database. This database became a central repository for all the information related to the medical devices required for Pavilion Zero. Each device entry included essential details such as the device's full identification, its specific location within a designated room as outlined in the BIM project, the associated classification code from the CND [10]. For those who are expected to be transferred from the current hospital, the registry and technical specifications are also included in the database.

Another crucial outcome of the study was the development of the Bill of Quantities (BOQ), a key document in the construction tendering process that provides a detailed breakdown, organized by floor and room of the items required for each space in Pavilion Zero. It included the furniture supplied by the construction contractor alongside the medical devices identified in the earlier methodological phases. By presenting this structured division of furnishings and devices for each room, the BOQ ensured that the equipping process was clearly organized and ready for implementation.

This results-driven approach offer a clear, organized, and efficient framework for the implementation of Pavilion Zero's technological infrastructure, ensuring that every clinical and operational need was addressed. The combination of an organized SQL database, precise spatial planning through BIM integration, and a comprehensive BOQ document provide a robust foundation for the successful realization of the project, meeting both immediate and future technological demands.

## 4. Discussion and Conclusions

The experience of the participants in the working group identified the need for a more structured method for carrying out technological needs analysis and assessment for the Pavilion Zero, which is satisfied with this work that involved multiple phases, integrating engineering, technical, and clinical aspects to create a structured plan.

The different phases of the analysis have led to an increase in step by step detail of the technological demand, which has allowed individual elements to be assessed more specifically.

In addition, the organizational change of the hospital for intensity of care is challenging [3] and that becomes more complex in the case of a hospital under construction that maintains the hospital and health activities running, as the subject of this study. In this respect, the multi-phase methodology developed has succeeded in bringing benefits to the change process by structuring the technological needs beforehand taking into account the patient's exigency. In fact, the data structure made it possible to make specific assessments that would otherwise not have been possible.

All the phases contributed to define the research's objective, but in particular the collaboration with health professionals was the most critical due to the organizational change to care intensity but at the same time the most important overcome the barriers dictated by the different professorships and define the medical devices at their best.

The evaluation of device obsolescence will be integrated and compared with various qualitative models, including fuzzy logic, to enhance the accuracy of the model itself [13]. Through this synergy, the aim is to develop a systematic and standardized approach that enables obsolescence assessments to be applied to all medical devices installed in the Institute.

The outcomes produced, including the BOQ and the defined SQL database, will continue to track and manage technological needs. This database will serve as repository for drafting technical specifications and supporting subsequent phases. Its integration with the current database will be assessed at a later stage. Further assessments will refine the final technological requirements, ensuring the pavilion is fully equipped to meet future clinical and operational challenges.

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