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Master's Program in Bioengineering

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Development of a Biomedical Equipment Management Platform: Obsolescence and Cybersecurity Assessment in Indian Hospital Settings

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Abstract

This study focuses on building a complete Web-platform for the management of biomedical devices within Hospitals, with particular attention to the construction of an India-first biomedical equipment obsolescence score and an automatic internet-research in databases of known vulnerabilities; these are not the only areas that have been focused on but various modules for the Web-platform have been developed, such as inventory management, breakdown management with the corresponding repair and management of scheduled maintenance. The study is set in a context of strong development from the point of view of the Indian economy and healthcare, where The Ministry of Health and Family Welfare (MoHFW), through the National Health Mission (NHM), initiated the Biomedical Equipment Management and Maintenance Program (BMMP) in the year 2015, aiming to improve functionality, reduce costs, and enhance healthcare quality [1]. The obsolescence algorithm developed, is the first India-algorithm for the obsolescence of biomedical devices, it is based on the fuzzy logic and includes parameters specifically selected after a deep understanding of which are the ones collected within different Indian hospitals: Homi Bhabha Cancer Hospital, Indus Hospital, RK Hospital and Apollo Hospital. The cybersecurity novel contribution focuses on

finding an automatic methodology to determine if biomedical devices have known vulnerabilities in Common Vulnerabilities Databases such as NVD, CIRCL and OSV.

Sommario

Questo studio si concentra sulla costruzione di una piattaforma Web completa per la gestione dei dispositivi biomedici all'interno degli ospedali, con particolare attenzione alla costruzione di uno score di obsolescenza delle apparecchiature biomediche specifico per il contesto indiano e a una ricerca automatica su internet in database di vulnerabilità note; queste non sono le uniche aree su cui ci si è concentrati, ma sono stati sviluppati vari moduli per la piattaforma Web, come la gestione dell'inventario, la gestione dei guasti con la corrispondente riparazione e la gestione della manutenzione programmata. Lo studio si colloca in un contesto di forte sviluppo dal punto di vista dell'economia e della sanità indiana, dove il Ministero della Salute e del Benessere della Famiglia (MoHFW), attraverso la National Health Mission (NHM), ha avviato il Programma di Gestione e Manutenzione delle Apparecchiature Biomediche (BMMP) nell'anno 2015, con l'obiettivo di migliorare la funzionalità, ridurre i costi e migliorare la qualità dell'assistenza sanitaria [1]. L'algoritmo di obsolescenza sviluppato è il primo algoritmo indiano per l'obsolescenza dei dispositivi biomedici, è basato sulla logica fuzzy e include parametri selezionati specificamente dopo una profonda comprensione di quali siano quelli raccolti all'interno di diversi ospedali indiani: Homi

Bhabha Cancer Hospital, Indus Hospital, RK Hospital e Apollo Hospital. Il contributo originale in ambito cybersecurity si concentra sul trovare una metodologia automatica per determinare se i dispositivi biomedici presentano vulnerabilità note in database di vulnerabilità comuni come NVD, CIRCL e OSV.

Acknowledgements

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Contents

Preface

This thesis grew from a strong and cultivated interest in clinical engineering, a field that represents, in my view, the Human expression of order, control, and the will to help others. I intensively looked for an opportunity to explore this field outside of Europe and, despite initial difficulties and limited available opportunities at that time, through perseverance I succeeded in my goal. I spent six months in Visakhapatnam, a city on the south-eastern coast of India that, while remote from a European perspective, represents a crucial port center for the state of Andhra Pradesh and a rapidly developing hub in many sectors, including MedTech. I had the opportunity to work at the Andhra Pradesh MedTech Zone Ltd (AMTZ), Asia's first exclusive medical devices technology and manufacturing zone and now one of the world's largest medical equipment manufacturing clusters, with over 100 companies working on research, development, and production of life-saving medical devices. My objective within this facility was to develop a comprehensive software system for biomedical equipment management, with particular focus on an automated system to assess biomedical device obsolescence with emphasis on cybersecurity. I collaborated with Indus and Homi Bhabha hospitals and visited several others, from smaller facilities to major institutions such as Apollo

Hospital. Additionally, in AMTZ, particularly in the Animal Research Center and Blood Bank, I had the opportunity to physically connect to two biomedical devices to attempt automatic detection of software and firmware versions. The work developed during this research period was presented at the World Health Innovation Forum (WHIF) 2025, an international congress on healthcare innovation and medical technology hosted at AMTZ in collaboration with the WHO Innovation Hub. This experience taught me lessons that extend far beyond technical knowledge. I learned some of the challenges of the healthcare systems in resource-constrained settings, where innovation must be aware not only of the effectiveness but also of the affordability, and I learned the process to build a product from the R & D department to the market. Personally, this experience taught me more than I could anticipate. Visakhapatnam wasn't just geographically distant, everything about daily life was different, I had to adapt and learn to accept uncertainty as part of the process, not something to fight against. I had the pleasure to build relationships with people not only from India but from various countries in the world, such as Chad, Nigeria, America, Haiti, Kenya, Tanzania, Zambia, Ethiopia, Democratic Republic of Congo and others. Every one of them brought their culture, unique worldview and life experiences, teaching me what it means to work and live in a huge multicultural environment. I learned that effective communication transcends language, that respect and curiosity open more doors than expertise alone, and that "Culture eats strategy for breakfast" (Peter Drucker). The India I discovered was far more complex, dynamic, and inspiring than any narrative I had encountered before my departure.

Part I

Introduction and Background

Chapter 1

Introduction

The management of biomedical equipment in hospital settings represents one of the most critical and operationally complex responsibilities in modern clinical engineering. This thesis presents the design, iterative development, and validation of an integrated web-based platform for biomedical equipment management, developed specifically for Indian hospital settings during a six-month research period at the Andhra Pradesh MedTech Zone (AMTZ) in Visakhapatnam. India represents one of the most significant and rapidly evolving healthcare technology markets in the world, with a population around 1.4 billion. Since 2015, the Ministry of Health and Family Welfare (MoHFW), through the National Health Mission (NHM), initiated the BEMMP to address the dysfunction rates of medical equipment that, following national inventory mapping, were found to range from 13% to 34% across the states.

Collaboration was established with four hospitals: Homi Bhabha Cancer Hospital (TATA partnership), a specialised oncology and research centre with

which an extended collaboration with the Chief Biomedical Engineer was developed and which provided the anonymized device inventory and maintenance data used for algorithm validation; Indus Hospital, which also provided device inventory and maintenance records; Apollo Hospital, one of the largest healthcare facilities in Visakhapatnam, where a consultation with the Chief Biomedical Engineer provided key insights into algorithm design requirements; and RK Hospital, a 50-bed multi-specialty facility. Additional interviews were conducted with biomedical engineering professionals including a senior engineer with over 40 years of experience and an engineer from Ghana's largest hospital.

The work addresses two interconnected challenges that in India but not solely, have remained unsolved in clinical engineering practice.

The first is the systematic assessment of equipment obsolescence. The decision of when to replace, reassess, or maintain a device involves the simultaneous consideration of several parameters that can be different among different facilities. A Field research conducted in Indian hospitals and a systematic review of the literature, highlighted that no obsolescence scoring systems are currently in use across the country.

The second challenge is cybersecurity. As biomedical devices have become increasingly networked cyberattacks are more likely to happen, and the consequences are not theoretical: in 2024, a cyberattack causing a delay in critical blood test results at a London hospital contributed to a patient death. The National Vulnerability Database (NVD), the CIRCL Common Vulnerabilities and Exposures database, the Open Source Vulnerabilities (OSV) database,

and others, contain thousands of documented vulnerabilities affecting medical devices, yet this information is never cross-referenced against installed device inventories in clinical engineering practice. As a concrete illustration, the ST-200cc Blood Gas Analyzer tested at AMTZ during this research was found to operate on Android 7.0 (a software that reached end-of-support in January 2019 and carries approximately 1,970 documented CVEs) illustrating vulnerability exposure that a real medical device can have.

The platform developed is built on a PostgreSQL relational database backend and a Streamlit-based web frontend, and is organized into six functional modules that together cover the full operational spectrum of clinical equipment management: Inventory, Ward & Rooms, Preventive Maintenance, Incidents & Repairs, Obsolescence, Cybersecurity module.
The obsolescence scoring module implements the fuzzy logic algorithm developed in this thesis, computing a Criticality Score on a [0,10] scale for each registered device and translating it into categories. The algorithm has configurable threshold parameters that allow hospital administrators to adapt it to internal policies.
The cybersecurity module allows the user to search for known vulnerabilities across NVD, CIRCL, and OSV databases, linking results directly to specific devices in the inventory.

The obsolescence scoring algorithm uses a hierarchical fuzzy inference architecture. Fuzzy logic was selected due to its characteristic capacity to handle uncertainty and the qualitative nature of many obsolescence factors,

and had already been applied in comparable studies at Galliera Hospital in Genoa and at IRCCS Giannina Gaslini [2, 3]. The hierarchical architecture was chosen to manage the combinatorial explosion of rules: with three membership functions per parameter over seven parameters, a non-hierarchical approach would require $3^7 = 2187$ rules. Building logical subsystems reduces the number of rules while preserving interpretability. The preliminary algorithm uses seven parameters organized into four subsystems (Mission Criticality, Support Level, Cost Level, and Age), resulting in 129 rules. Following field research in Indian hospitals, a gap analysis allow to refine the algorithm reducing the parameters and bringing the rules from 129 to 67. The parameter set that emerged from this field research and gap-analysis process showed close convergence with the parameters adopted in the study of Maggi et al [3].

The algorithm was validated against the RPV1 reference model on a dataset of 129 devices from Homi Bhabha Cancer Hospital, applying four complementary statistical metrics: Pearson correlation, Bland-Altman analysis, categorical agreement with Cohen's kappa, and confusion matrix analysis. The Pearson correlation coefficient of $r = 0.779$ ($p < 0.001$, $R^2 = 0.607$) indicates a strong linear relationship between the two scoring systems, while categorical agreement was 81.4% (105 out of 129 devices). The most clinically significant finding is the directional consistency of all discrepancies: of the 24 devices (18.6%) where the two systems assigned different categories, every single discrepancy consists of the fuzzy algorithm assigning a higher replacement priority than RPV1. No case was observed in which the fuzzy system assigned a lower priority than RPV1(zero false negatives). From a

patient safety perspective, this conservative bias is not a limitation but an added value, ensuring that no device approaching the replacement threshold is underestimated. This same conservative tendency had been previously observed by Maggi et al [3].

The cybersecurity module was tested on two physical medical devices available within AMTZ facilities: the ST-200cc Blood Gas Analyzer (Sensa Core) at the Animal Research Center, and the KB22 Auto Hematology Analyzer (Krish Biomedical) at the Kalam Blood Center. Firmware and software version identification was attempted through three access methods: serial communication, network communication via HL7 Laboratory Information System protocol, and passive boot sequence monitoring. For the ST-200cc, serial communication returned a proprietary undocumented binary protocol incompatible with standard ASTM E1394 commands (security through obscurity), while boot sequence monitoring successfully captured the internal firmware version string ULTRASMART.3R.013 during device initialization. Moreover, was found out to operate on Android 7.0, which carries approximately 1,970 documented CVEs. For the KB22, network communication via a virtual HL7 LIS server confirmed the device identity as Genrui KT-6300 V1.5, revealing its OEM/ODM nature.

Chapter 2

The Indian context

2.1 Indian context and population dynamics

"India is the world's seventh largest country geographically, the second largest demographically and third largest economically, accounting for around 7% of world economy in gross domestic product (GDP) measured by purchasing power parity (PPP) (International Monetary Fund, 2018)" [4]. One of its indistinguishable characteristics is the cultural diversity. India is characterized by coexistence of different religions, 22 languages officially recognized (hundreds of non-officially recognized) and thousands of different customs. After the independence in 1947 received by Great Britain, India followed an economic-planned development but because of several challenges, "structural adjustment programmes" were adopted, followed by the liberalization in 1991. "Since 2009, India has transitioned to a lower middle-income country (OECD, 2020) with sustained annual growth rates of over 5% in terms of real per capita GDP over the period 1990–1991 to 2018–2019.1 Despite this

rapid economic growth, improvements in physical infrastructure and human development (such as the status of women, education and health outcomes) have been lagging (UNDP, 2018)" [4]. India has some of the most crowded cities in the entire world, examples are Mumbai, Delhi and Kolkata (Known as "Calcutta" in Italian), and it is the world's second most populated country with around 1.4 billion in 2025 [5]. Considering the emerging cities, which are an example of India's growth, are Bengaluru, Hyderabad and Vishakapatnam (the city where I spent the 6 months). According to [6], India has its population distributed approximately one-third in the cities, while the rest, in the hundred-thousands of villages spread around the continent. A lot of people moved from small towns to the cities (rural-urban migration), mainly because of differences in employment opportunities, causing not only a decline in agricultural productivity but also policy-makers' concern and the formation of slums, where residential conditions are considered at risk for poor health. Effort was invested by the government through a Smart Cities campaign in 2014 which focus was on infrastructure development and a National Urban Health Mission (NUHM) which focus is the delivering health services for urban residents. "Health service delivery is not the only health-related challenge facing urban residents in India. Income inequality, water supply, unsanitary residential conditions, rising air pollution and emergence of communicable conditions such as dengue are important concerns for public policy on health" [4]. Furthermore, the vast cultural diversity influences health equity. Wealth, education and occupation are important as equity markers' indicators while religion, caste and tribal affiliations give a non-irrelevant contribution to inequity that influences health and health care in

India [4].

	2001	2011	2018–2019 (estimates)
Area of residence			
Rural	72.18	68.84	66.5 (2018)[1]
Urban	27.82	31.16	33.5 (2018)[1]
Total	100.0	100.0	100.0
Religion			
Hindu	80.46	79.80	NA
Muslim	13.43	14.23	NA
Christian	2.34	2.30	NA
Sikh	1.87	1.72	NA
Buddhist	0.77	0.70	NA
Jain	0.41	0.37	NA
Other religions	0.65	0.66	NA
Religion not stated	0.07	0.24	NA
Total	100	100	
Caste/tribe			
Scheduled Caste	16.2	16.63	NA
Scheduled Tribe	8.2	8.63	NA

Figure 2.1: Population distribution as % of total by ethnicity/caste/religion, 2001,2011,2018-2019 [4].

Life expectancy has increased exponentially in the last forty years, from 47.7 years in 1970 to 69.6 years in 2020, a gain of more than two decades, ven though Indian life expectancy is less than that of other countries in the same middle-income range, such as Sri Lanka (74 years), Brazil (74 years), China (75 years) and Costa Rica (80 years) [4].

2.2 Indian Healthcare system

The National Health System in India is organized in a three-level hierarchical system: primary (sub-centres and Primary Health Centres), secondary (Community Health Centres, taluka and district hospitals) and tertiary (medical

colleges and teaching hospitals) health-care facilities (Figures 2.1 and 2.2). The Central Government, through the Ministry of Health and Family Welfare (MoHFW's) role is to make policies, plan, guide, assist, evaluate and coordinate the work of state health authorities, because each state manages its own health facilities. The Central Government also finances health programmes (such as the National Rural Health Mission, the Sustainable Development Goals UN programme and others) to maintain health service availability and quality standards across different states despite economic disadvantages [4]. "Currently, the MoHFW has two independent departments:

- the Department of Health and Family Welfare (DoHFW)
- the Department of Health Research

The National AIDS Control Organization (NACO) functions under the Department of Health and Family Welfare (DoHFW). The Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homeopathy (AYUSH) services, which were earlier a department under the MoHFW, have now been established as a separate ministry. The departments are staffed by civil servants, technical advisors and administrative staff, supported by a network of public-funded autonomous research and training institutions such as the National Institute of Health and Family Welfare. The MoHFW is assisted by two technical advisory bodies:

- the Directorate General of Health Services (DGHS)
- the Central Council of Health and Family Welfare (CCH&FW)" [4]

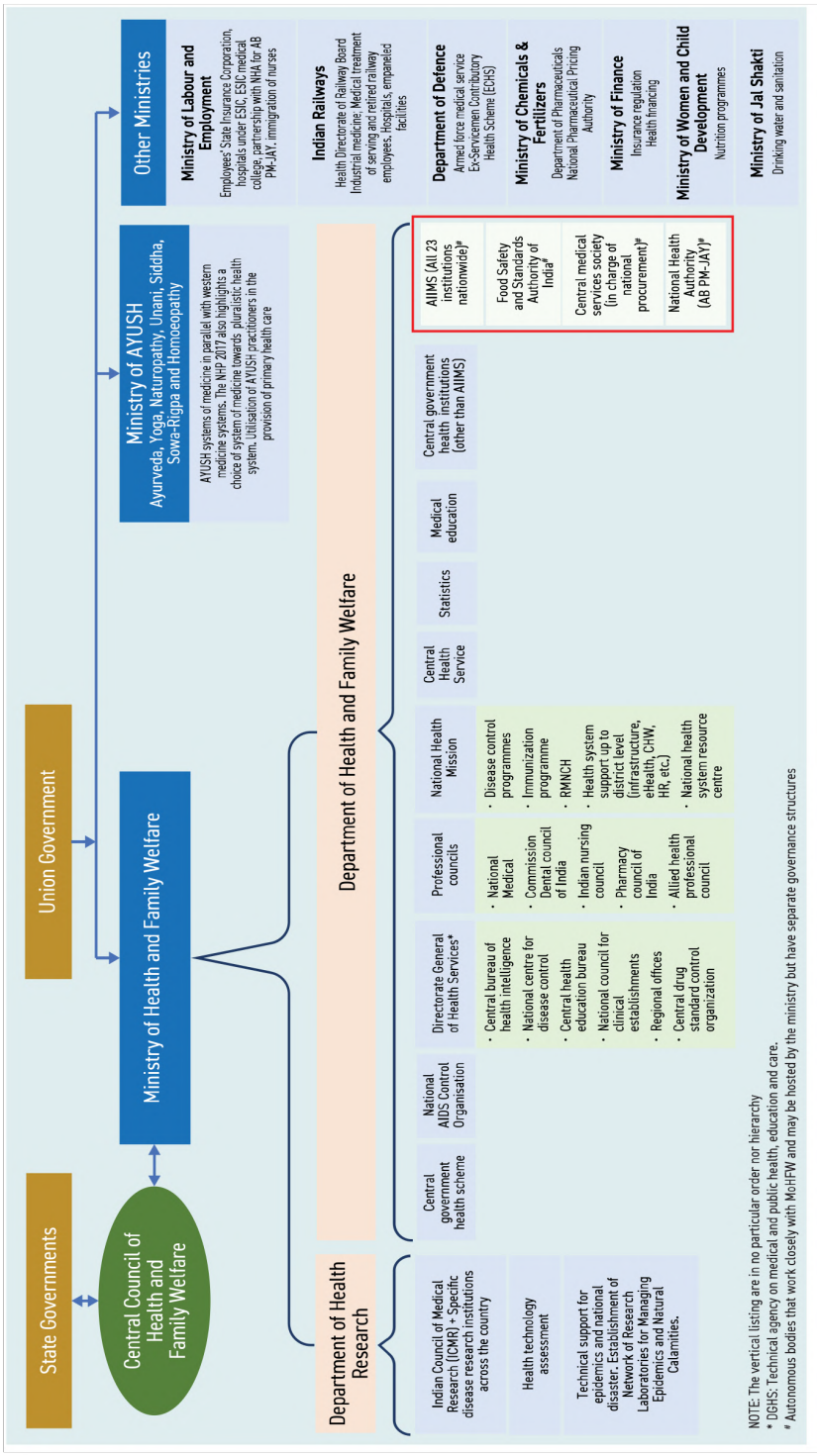


Figure 2.2: Health in India, roles and functions of key players at the national level [4].

The coordination between the central government and individual states is linked through the CCH&FW. The main responsibilities include "promote coordination between the Centre and states in implementing various national health programmes, preparing proposals for legislations and review of performance against grants given for health" [4]. The DGHS (Director General of Health Services) provides technical and operational guidance, which develops national protocols and clinical guidelines for disease management while collaborating with the state health departments. Several other government departments also contribute to healthcare financing and service delivery: the Ministry of Labour operates the ESIS insurance scheme for workers, while both the Defence and Railway ministries maintain dedicated healthcare systems for their dependents. The railway healthcare infrastructure covers 16 geographic zones across India, ranging from local health infrastructures to facilities that offer specialized tertiary care. In total, Indian Railways operates 125 hospital facilities with a total capacity of 13,963 beds. Military healthcare is organized under the AFMS (Armed Forces Medical Services), directed by the Director General Armed Forces Medical Services. The AFMS delivers medical services to all three military branches (army, navy, and air force) through: the Army Medical Corps, the Army Dental Corps, and the Military Nursing Service. Medical and nursing education for AFMS personnel is conducted at the Armed Forces Medical College, which provides undergraduate, postgraduate, and nursing training programs [4].

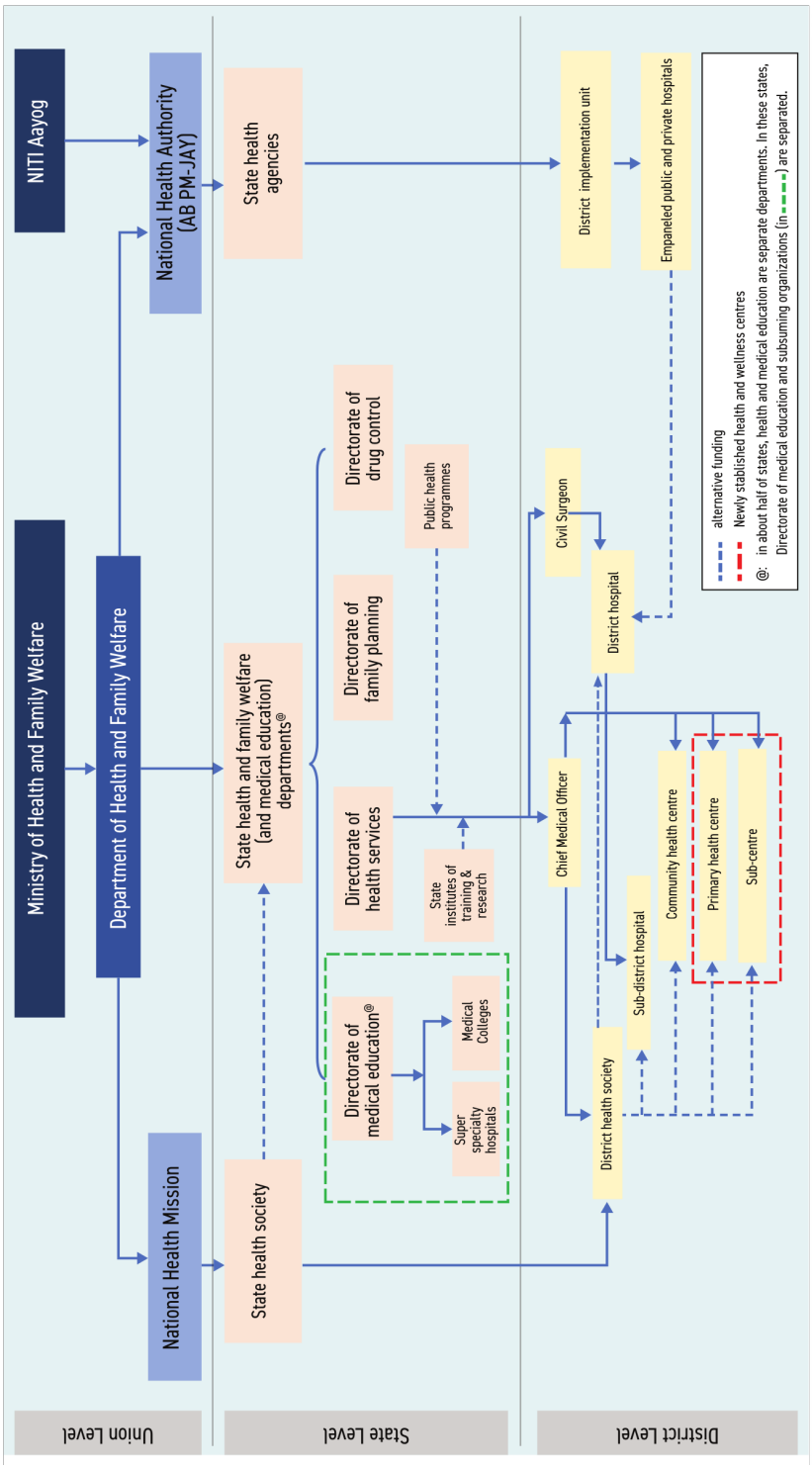


Figure 2.3: Organization of health: relationships between the Union, state and district levels [4].

In each state, the government health system is organized under the Department of Health and Family Welfare (DoHFW), headed by a state Minister of Health and Family Welfare and a state minister for Medical Education [4].

2.3 The problem of accreditation in India

In India there are several informal providers, without the National Accreditation Board for Hospital and Healthcare Providers (NABH). Despite lacking the formal accreditation, these providers maintain strong cultural ties to the communities they serve. Research from 2017–2018 revealed that approximately 25% of healthcare professionals lacked appropriate credentials. A survey covering 1519 rural villages during 2009–2010 demonstrated that private sector providers constituted 86% of all, with informal providers accounting for 68%, lacking formal medical training. A 2016 audit figured out that despite the lack of formal accreditation, private providers frequently demonstrated superior adherence to treatment protocols compared to the public providers. A 2012 study from Uttar Pradesh illustrated the prevalence of unqualified practitioners in primary care, revealing demographic patterns: female patients and Muslim communities showed preference for lower-quality informal providers, while male patients utilized informal providers more than women when having fever for 4 days. These informal providers work in an ecosystem, not in isolation, and they typically serve as initial contact points for patients. Research in Andhra Pradesh in 2010 shows that 40% of informal providers receive monetary compensation for patient referrals to private doctors, while others accept in-kind benefits including medical equipment.

Some researchers have proposed incorporating informal providers into the regulated healthcare system through structured training programs as an interim solution to enhance care quality [4].

Chapter 3

The Italian Healthcare System: A Reference Framework

3.1 The Italian Healthcare service (SSN)

"The Italian National Health Service (SSN) is a public system of universalistic and solidarity character: i.e. it guarantees health care to all citizens regardless of gender, residence, age, income, professional activity. The SSN ensures access to services in accordance with the principles of human dignity, health needs, fairness, quality, appropriateness of care and economic use of the resources" [7]. Citizens have the freedom to select their preferred healthcare facility and medical professionals. Any institution delivering services through or for the SSN must meet specified structural, technological, and organizational criteria.

The SSN operates through a hierarchical structure (simplified overview):

- Ministry of health

- Regions
- ASL (Aziende Sanitarie Locali)
- AO (Aziende Ospedaliere)
- IRCCS (Istituti di ricovero e cura a carattere scientifico)
- Accredited private providers (Strutture private accreditate).

The national healthcare service operates at national and regional levels. The national level safeguards universal healthcare access, particularly via the Essential Care Levels framework (Livelli essenziali di assistenza, LEA), which defines mandatory services (excluding procedures like cosmetic surgery). Regional authorities have direct operational responsibility for implementing national health objectives within allocated governmental budgets. These regional bodies have exclusive authority over service provision and financial supervision of ASL, AO, and IRCCS entities (aziende sanitarie locali, aziende ospedaliere, Istituti di ricovero e Cura a carattere scientifico).
Local Health Authorities (ASL) function as autonomous public entities possessing organizational, administrative, financial, accounting, managerial, and technical independence providing services across their designated territories through both public and certified private facilities. ASLs must deliver all services listed in the national Essential Care Levels (LEA).
AO represent major medical facilities serving regional or multi-regional populations, structured as independent corporations. These institutions provide services aligned with LEA. Some have partnerships with universities, becoming Aziende Ospedaliere Universitarie.

IRCCS (Istituti di ricovero e cura a carattere scientifico) Care and research institutes with scientific character are research hospitals of excellence that pursue research in the biomedical field and deliver health care services. The Ministry of Health supervises the IRCCSs to ensure that the research they carry out is aimed at the public interest with a direct impact on patients' care. IRCCS operate like all other Hospitals in the frame of the SSN. The "recognition of scientific character" is the procedure through which these emerging hospitals, treating pathologies of national importance, are qualified as IRCCS.

Scientific Research and Care Institutes (IRCCS) constitute premier research hospitals advancing biomedical science while delivering clinical services. The Ministry of Health supervises the IRCCS operations to ensure research activities aim at public welfare and directly impact patient treatments. These institutes work within the SSN framework like standard hospitals.

As of 2021, Italy had 101 ASLs and 80 AOs. By 2023, there were 23 public IRCCS institutions alongside 30 private ones.

The elderly care facilities (Residenza sanitaria assistenziale - RSA) were established in Italy during the mid-1990s. These non-acute healthcare institutions accommodate both independent and dependent individuals, primarily elderly persons, for temporary or permanent stays when specialized medical attention, including rehabilitative services.

Community Houses and Community Hospitals represent newly planned public infrastructure mandated by the National Recovery and Resilience Plan (PNRR) and Italian Ministerial Decree 77 [7].

3.2 The Italian institutional accreditation

"The so-called "Institutional accreditation" is the process by which the Region recognizes private health and socio-health structures with the possibility of providing health and socio-health services on behalf of the Regional Health Service" [7]. This certification assures citizens that accredited institutions respect certain quality benchmarks required by regional planning in the health care sector. Institutional Accreditation represents the mandatory qualification that enables healthcare service providers to sign agreements with private entities to provide healthcare within the SSN framework and receive SSN compensation. In Liguria Region the power to release the institutional accreditation is attributed to the Region through the Technically Accrediting Body (O.T.A.) of ALISA (Ligurian Company for HC Services). A 2017 regional decree established: the accreditation process methodology, the accreditation handbook detailing revised requirements for the accreditation of healthcare and social-healthcare services providers, and the annual self-evaluation documentation whereby accredited providers must annually certify the requirements. Both the accreditation process, its timeline, and the Accreditation handbook vary across Italian regions. However, an additional phase is required: although an accredited Provider meets the requirements to work within the SSN via the Regional Healthcare System (Servizio Sanitario Regionale, SSR), the actual participation requires a formal contract with Regional Healthcare Authorities. This contractual arrangement enables patients to receive services without direct payment, as the SSN compensates Providers directly. Furthermore, each Italian region maintains its Accreditation Manual [7].

Chapter 4

Biomedical Equipment and Management Program (BEMMP)

4.1 Indian and Italian medical device definition

In India there are different definitions regarding what is a medical device, but, all Medical Devices are regulated under the Drugs & Cosmetics Act, 1940 and Medical Devices Rules, 2017.

The definition of medical device in the Medical Device Rules, 2017 of the Ministry Of Health And Family Welfare (Department of Health and Family Welfare) [8] is: "(A) substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures,

blood and blood component collection bag with or without anticoagulant covered under subclause (i),
(B) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii),
(C) devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Drugs & Cosmetics Act,1940;" [8]

The definition on the website of the Central Drugs Standard Control Organization (CDSCO), that is the National Regulatory Authority (NRA) of India, refering to the Drugs & Cosmetics Act, 1940 and Medical Devices Rules, 2017 says: "All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of

- diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
- diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
- investigation, replacement or modification or support of the anatomy or of a physiological process;
- supporting or sustaining life;

- disinfection of medical devices; and
- control of conception. " [9]

The definition of medical device used in the BEMMP's technical manual is: "An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means" [10]. More specific is the **definition of the European normative 2017/745**: " any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilization of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point" [11].

4.2 BEMMP

Medical device availability and upkeep is one of the key interventions for mass access to diagnostic , therapeutic, preventive, and assistive healthcare services. The initial essential step toward situational assessment and strategic planning for medical equipment management involves inventory mapping. Upon completion of inventory mapping in approximately 29 States and Union Territories, was found that Government Hospitals experience dysfunction rates ranging from 13% to 34% of their medical devices. This means an estimated INR 4,500-6,000 Crores in idle medical inventory, a significant portion due to minor technical issues. States face considerable challenges in recruiting and maintaining sufficient trained biomedical engineering personnel capable of providing management and maintenance services, both in terms of availability and feasibility. To address this challenge, the Ministry of Health and Family Welfare (MOHFW) conducted consultative sessions with state officials to develop effective mechanisms that ensure the continuous

functionality of medical devices. Based on successful practices, stakeholders concluded that contracting external maintenance services with performance-based compensation would improve time bound maintenance delivery. This approach was was named the Biomedical Equipment Management and Maintenance Program (BEMMP). BEMMP represents a central government initiative through the Ministry of Health and Family Welfare, designed to assist state governments in outsourcing maintenance of medical equipment across all healthcare facilities. The Model Request for Proposal documentation and implementation guidelines were distributed to states on February 16, 2015. Financial assistance levels are determined through the actual procurement process following comprehensive state-wide inventory documentation. Funding allocations depends mainly on three factors: equipment density, existing dysfunctional rates, and geographic constraints specific to each state. The central government provides support for the inventory documentation exercise, which has been completed in most states [10].

4.3 BEMMP focus on Public-Private Partnerships

"The Biomedical Equipment Management and Maintenance Program (BMMP) represents a specialized PPP application, 20 States are now in PPP mode in the state of Andhra Pradesh, Arunachal Pradesh, Assam, Chhattisgarh, Jharkhand, Kerala, Madhya Pradesh, Maharashtra, Meghalaya, Mizoram, Nagaland, Puducherry, Punjab, Sikkim, Telangana, Tripura, Rajasthan, Uttar Pradesh, West Bengal, Jammu and Kashmir" [10].

4.4 Public-Private Parternships (PPP)

Public-Private Partnerships are a critical mechanism for infrastructure development following the economic liberalization in the 1990s.The Government of India, specifically the Department of Economic Affairs, defines PPP as follow:"an arrangement between a government / statutory entity / government owned entity on one side and a private sector entity on the other, for the provision of public assets and/or public services, through investments being made and/or management being undertaken by the private sector entity, for a specified period of time, where there is well defined allocation of risk between the private sector and the public entity and the private entity receives performance linked payments that conform (or are benchmarked) to specified and pre-determined performance standards, measurable by the public entity or its representative" [12].

In italy the PPP model is defined in "Nuovo codice degli appalti D.Lgs 36/2023" [13]. The PPP model is particularly important in the India's Healthcare environment, where the expenditure is only 1.13% in 2014-15 and 1.84% in 2012-22 of the GDP [14], significantly below the 5% suggested by Mcintyre D, Meheus F, Røttingen JA for progressing towards an universal health coverage in low and middle income countries [15]. In Italy we have an Health's expenditure that was 8.4% on 2025 [16].

4.5 Assignment of Responsibilities and Reporting Requirements

In the BEMMP manual [10], responsibilities are explained, along with reporting requirements for maintenance activities and medical device inventory. This document helped me understand who manages which activities and, more importantly, which parameters are mandatory and which are suggested to track in hospital records. This understanding was crucial to create an obsolescence algorithm that works with the real data available in hospital environments. Regarding the Assignment of responsibilities, in the Manual are explained the procedures for equipment tagging, complaint log, breakdown maintenance, preventive maintenance & calibration, user training, new equipment installation,Biomedical Equipment Not Found during Preventive/Corrective Maintenance, Warranty / AMC/CMC Management, Condemnation of Biomedical Equipment, Process the Bills for Payment and Documentation. Among them, the most relevant according to this project are:

- Equipment tagging:
  - "Objective: To carry out Tagging and Registration of Biomedical Equipment
  - Scope: All Biomedical Equipment under Contract
  - Responsibility: Service provider, dept. in charge of health facility, district medical officers" [10]

S.No	Activity	Responsibility	Record
1	Service Provider visits the hospital	Service Provider	–
2	Tagging Sticker is pasted by the SP	Service Provider	Tagging sticker
3	Service provider records this info in registration form	Service Provider	Registration form
4	SP keeps the record of registration form and updates the dashboard	Service Provider	Dashboard
5	Facility in charge provides the details of year of installation, warranty and etc.	Facility In charge	–
6	Facility in charge verifies the registration and approves it	Facility In charge	Copy of registration form

Figure 4.1: Procedure for "Equipment Tagging" [10].

- Complaint Log:
  - "Objective: To register a Medical Equipment maintenance complaint
  - Scope: All Biomedical Equipment under Contract
  - Responsibility: user of Medical Equipment, Facility In charge, Deputy In charge" [10]

S.No.	Activity	Responsibility	Record
1	User calls the toll-free no. to register equipment problem	End user	Call log
2	User provides the mandatory info to register the complaint Equipment Identification number Location User name and contact Nature of complaints	Users	Call log
3	Call centre register the request with work order no	Call centre	Work order no. via email and SMS
4	Call centre forwards the work order to respective technical staff and regional In charge	Call centre	email and SMS
5	Technical Staff resolves the problem and gets it acknowledged on a service report	Service provider	Service report
6	Closure of work order is followed by a SMS to respective user In charge	Facility incharge or Nodal officer through Call centre	SMS and work order

Figure 4.2: Procedure for "Complaint Log" [10].

- Breakdown Maintenance:

– "Objective: To ensure Breakdown Maintenance Activity is carried out for All Biomedical Equipment within specific time frame as per the contract agreement and replace number of spare parts (internal components) to be undertaken as per manufacturer recommendations. Wherever possible, PPP service provider shell use PM kit of manufacturer.

– Scope: All Biomedical Equipment under Contract

– Responsibility: Service report, Facility In charge, Deputy In charge, end users" [10]

S.No	Activity	Responsibility	Record
1	Service provider visits the facility after call registration	Service provider	–
2	Service provider performs necessary repairs	Service provider	–
3	Feedback is provided to the user if machine is not repaired in the 1st instance	Service provider	Email & SMS
4	Service report is signed and updated on the dashboard	Service provider	Dashboard
5	In charge verifies the functionality through Deputy In charge, end user	Facility In charge	Service report
6	Service provider prepares the Service report and submits to the In charge	Service provider	Service report
7	Call Closure	Facility In charge /Nodal Officer	Call Record and SMS

Figure 4.3: Procedure for "Breakdown Maintenance" [10].

Regarding the reporting requirements, they were essential to understand which are the mandatory and the suggested data fields to track, then used as parameters in the algorithm. The Reports to be Kept in the Each Health Facility are: Equipment List, AMC, CMC, Breakdown Service Report Copy, Preventive Maintenance report, User Training report, Walkthrough Report, Breakdown Feedback Report The two main examples of Reports and most usefull ones for the project are:

- Equipment Registration Form:
  - Objective: To register all the relevant informations about a Biomedical Equipment
  - Scope: All Biomedical Equipments

1. Hospital /Clinic Details			2. Equipment Details		
Hospital /Clinic Name*			Equipment No.*		
Hospital /Clinic Category	MC () DH () CHC () PHC ()		ME General name*		
Hospital /Clinic Address			Manufacturer*		
Department			Model*		
District Name			Supplier/Service Agent.		
Zone			Supplier Contact info		
State			ME functional Status		
Contact Details	Name*		Contract Start Date		
	Mobile		Type Of Equipment		
	Email		Date of Installation		
			Equipment Value		AMC/CAMC Value
			3. Remarks		

4. Standard Components /Accessories			
S. No	Part Description	Part No.	Qty.

Registration Done by(Engineer/Technician) Signature: Name: Date:	Verified & Approved by User Signature: Name: Date: Stamp:

Figure 4.4: Equipment Registration Form [10].

Note: In the status field, except for the condition "Functional Good", all other conditions should carry detailed explanation in the remarks field.

Abbreviations: FG: Functional Good; NW: Not Working; AMC: Annual Maintenance Contract; CAMC: Comprehensive Annual Maintenance Contract; DH: District Hospital; CHC: Community Health Centre; PHC: Primary Health Centre; MCH: Medical College Hospital.

* Mandatory fields to be filled.

- Breakdown service report:

– Objective: To register all the relevant informations about a Breakdown and its corresponding repair service

– Scope: All Biomedical Equipments with an issue

Hospital Type	DH		CH		PH	Work Order Number	
Hospital Name						WO Date &Time	
ME No						WO Respond Date &Time	
						WO Respond Date &Time	
Contract Equipment ()		Under Warranty ( )				Under AMC ()	
BER ()		Reimbursed Work ()				Standby Provided ()	
Problem Reported							
Action Taken							
Material Used						**Stand By Equipment Details**	
No	**Item Description**			**Qty**		Equipment No :	
						Equipment Provided Date:	
						Equipment Condition : Good () Damaged()	
						Equipment Returned Date:	
						Customer Acceptance for Stand By Equipment	
Breakdown Execution details							
Engineer/Technician Name	Date	Start Time		End Time			
Customer Remarks							
Engineer/Technician Signature Name:						Customer Signature for WO Completion Name: Designation Stamp	

Figure 4.5: Breakdown Service Report [10].

Chapter 5

Medical Device Nomenclature Systems

5.1 Global Medical Device Nomenclature (GMDN) & Classificazione Nazionale Dispositivi medici (CND)

"**The Global Medical Device Nomenclature (GMDN)** is a system of internationally agreed descriptors and is the leading global standard for the naming, classification and categorization of medical device products. The GMDN Database lists all the Terms, which are currently available to name and describe medical devices, although new Terms are regularly issued to cope with new medical device innovations. The GMDN is owned and managed by the GMDN Agency, a non-profit organization" [17]. The GMDN system employs five-digit numeric codes cross-referenced to specific Term Names

and Definitions, organized in a hierarchical structure that enables unambiguous identification of medical devices [18]. The GMDN is used by regulators in nearly 70 countries worldwide and has become a critical component of the global regulatory infrastructure for medical devices, serving as a primary tool to reduce medical device-related errors and facilitate data exchange between manufacturers, regulatory authorities, and healthcare providers [19].

The Classificazione Nazionale Dispositivi medici (CND) is the Italian national nomenclature system developed by the Italian Ministry of Health for the classification and registration of medical devices and in vitro diagnostic medical devices. Successfully utilized for years in three European Member States (Italy, Greece, and Portugal), the CND is characterized by an alphanumeric structure established in a seven-level hierarchical tree [20]. The European Medical Devices Nomenclature(EMDN) was founded on pre-established criteria and requirements and based on orientations provided by the Medical Device Coordination Group (MDCG), and the European Commission decided in favour of the use of the 'Classificazione Nazionale Dispositivi medici'(CND) as the basis for the EMDN [21] to support the functioning of the European database on medical devices (EUDAMED) (MDR 2017/745, Article 26). In 2020, the European Commission and the Italian Technical Committee announced the updated input and full alignment of GMDN in CND, establishing a mapping between the two nomenclatures [13].

5.2 Indian nomenclature system

During the process of collecting the data, I figured out that device nomenclatures aren't used in hospitals databases, which posed challenges in distinguishing different biomedical devices. However, this challenge is being addressed and explained in the methods section. In India there is a tendency to use GMDN as nomenclature, for example, AMTZ in 2017, joined hands with GMDN Agency as a partner [22], but as per now isn't mandatory at state level. The GMDN in India is not mandatory to use, and nothing in the Medical Device Rules, 2017 [8] refers to a medical device nomenclature; the GMDN nomenclature system is sometimes used for regulation in the private sector [18], but it is not used at national level.

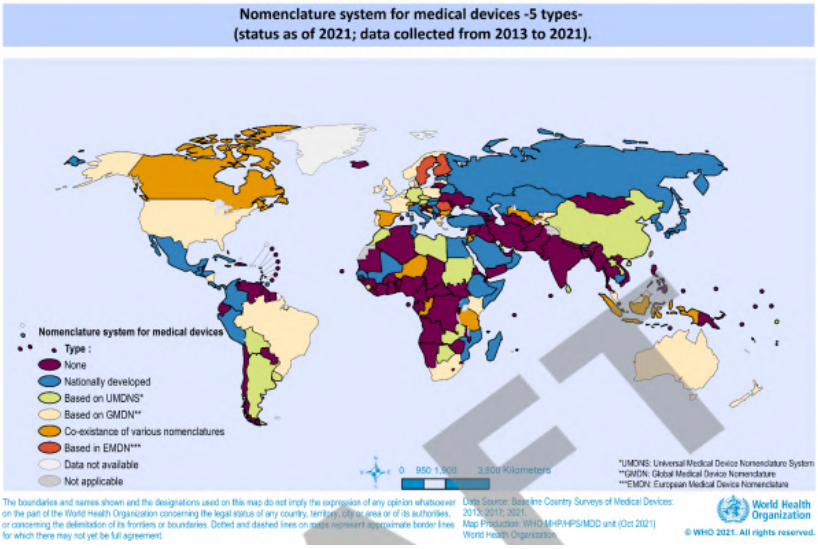


Figure 5.1: Nomenclatures used across the world [18].

5.3 Unique Device Identifier (UDI)

"The implementation of unique device identifier (UDI) in India remains limited compared to mature systems such as the FDA's Global UDI Database and the European Database on Medical Devices. Although the IMDR 2017 mandates UDI, its phased roll-out has been slow, and a centralized, publicly accessible database to capture and track device information is still lacking. This gap reduces transparency and undermines effective post-market surveillance" [23]. This issue is amplified when we talk about refurbished equipment from which low and middle income countries depend on, cause These machines provide huge financial savings—usually 50% to 60% lower than their new equivalents—without losing out on quality or performance [24]. "The utilization of refurbished medical devices, coupled with the integration of software, poses intricate challenges in terms of regulatory compliance, risk management, and patient safety, and uncertainty about device history, reliability concerns, and risks to data security are primary challenges" [25]. Fortunately, in a "letter dated 10 January 2025, issued by CDSCO to the Indian Customs Authorities, CDSCO has clarified that refurbished medical devices cannot be imported into India for sale and distribution purposes as there is no specific regulation under the Medical Devices Rules, 2017" [26].
"The unique device identification (UDI) is a unique numeric or alphanumeric code related to a medical device. It allows for a clear and unambiguous identification of specific devices on the market and facilitates their traceability. The UDI comprises the following components:

- a device identifier (UDI-DI),

- a production identifier (UDI-PI),

These provide access to useful information about the device. The specificity of the UDI:

- makes traceability of devices more efficient,
- allows easier recall of devices,
- combats counterfeiting,
- improves patient safety" [27]

"Device identifier (DI), a mandatory, fixed portion of a UDI that identifies the labeler and the specific version or model of a device. Production identifier (PI), a conditional, variable portion of a UDI that identifies one or more of the following when included on the label of a device:

- Lot or batch number within which a device was manufactured
- Serial number of a specific device
- Expiration date of a specific device
- Date a specific device was manufactured;
- Distinct identification code required by §1271.290(c) for a human cell, tissue, or cellular and tissue-based product (HCT/P) regulated as a device.

The device labeler must provide the UDI in two forms on labels and packages:

- Easily readable plain-text

- Machine-readable form that uses automatic identification and data capture (AIDC) technology." [28]

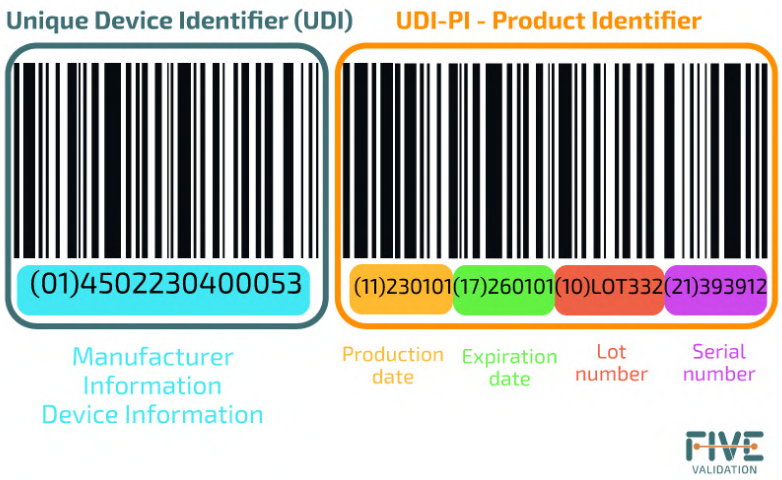


Figure 5.2: UDI-DI and UDI-PI example [29].

5.4 UDI in the Italian and Indian system

Although in Europe and Italy the Unique Device Identification (UDI) for medical devices is mandatory under Regulations MDR 2017/745, Article 27 [11], in India the UDI number was originally mandatory according to the 46th rule of the Medical Device Rules, 2017, with an implementation deadline on 1rst January 2022: "With effect from 1st day of January, 2022, a medical device, approved for manufacture for sale or distribution or import, shall bear unique device identification which shall contain device identifier and production identifier" [8]. Despite that, this Deadline was indefinitely

postponed just one day before its effectiveness; through an Amendment, the above rule (46th) was changed in :"With effect from such date as the Central Government may, by order specify, every medical device approved for manufacture for sale or distribution or import, shall bear a unique device identification in the manner as may be specified in such order" [30], removing a fixed implementation date. Currently no new orders have been issued.

5.5 Risk-Based Classification of Medical Devices: India and Italy

In the Indian system, the Rule 4(1) of the Medical Device Rules, 2017 [8], assess that medical devices medical devices shall be classified on the basis of parameters specified in Part I and II of the First Schedule, in the following classes, namely: (i) low risk - Class A;

(ii) low moderate risk - Class B;

(iii) moderate high risk - Class C;

(iv) high risk - Class D.

Similarly, in the Italian system, medical devices are divided in 4 categories of risk, according to MDR 2017/745 Article 51(1) [31], devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII, where correspondingly to the Indian classification class I is the low risk one and class III the high risk one.

Chapter 6

Medical Device Regulatory Pathways: Standards, Certification, and Market Authorization

6.1 National Regulatory Authorities: CDSCO and International Counterparts

"The Central Drugs Standard Control Organisation(CDSCO)under Directorate General of Health Services,Ministry of Health & Family Welfare,Government of India is the National Regulatory Authority (NRA) of India. Its headquarter is located at FDA Bhawan, Kotla Road, New Delhi 110002 and also has six zonal offices,four sub zonal offices,thirteen Port offices and seven labora-

tories spread across the country. The Drugs & Cosmetics Act,1940 and rules 1945 have entrusted various responsibilities to central & state regulators for regulation of drugs & cosmetics.It envisages uniform implementation of the provisions of the Act & Rules made there under for ensuring the safety, rights and well being of the patients by regulating the drugs and cosmetics. CDSCO is constantly thriving upon to bring out transparency, accountability and uniformity in its services in order to ensure safety, efficacy and quality of the medical product manufactured, imported and distributed in the country. Under the Drugs and Cosmetics Act, CDSCO is responsible for approval of Drugs, Conduct of Clinical Trials, laying down the standards for Drugs, control over the quality of imported Drugs in the country and coordination of the activities of State Drug Control Organizations by providing expert advice with a view of bring about the uniformity in the enforcement of the Drugs and Cosmetics Act. Further CDSCO along with state regulators, is jointly responsible for grant of licenses of certain specialized categories of critical Drugs such as blood and blood products, I. V. Fluids, Vaccine and Sera" [32].

The regulatory authorities equivalent to India's Central Drugs Standard Control Organization (CDSCO), which regulates both drugs and medical devices, in other countries are:

- **United States:** The Food and Drug Administration (FDA) regulates drugs, food, cosmetics, tobacco, and medical devices. The Center for Devices and Radiological Health (CDRH) is the specific division for medical devices and radiological health within the FDA [33].
- **Australia:** The Therapeutic Goods Administration (TGA) regulates

all therapeutic goods including medicines and medical devices [34].

- **Australia:** The Therapeutic Goods Administration (TGA) regulates all therapeutic goods including medicines and medical devices [34].

- **Italy and Europe:** In the EU there is a decentralized system, National Competent Authorities such as Italy's Ministero della Salute (Direzione Generale dei Dispositivi Medici) do not directly approve devices; instead, CE marking is obtained through Notified Body assessment, with national authorities responsible for post-market surveillance and vigilance (MDR 2017/745; D.Lgs. 137/2022).

- **United Kingdom:** was under the EU's decentralized system until Brexit, then it started to use its own UKCA system with the Medicines and Healthcare products Regulatory Agency (MHRA) that regulates both medicines and medical devices, as its name indicates [35].

6.2 International Standards: ISO and IEC Framework

The safety and quality of medical devices at international level are ensured through standards developed by two main international organizations: the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC).

The **ISO** is an independent, non-governmental international organization composed of representatives from national standards bodies, one per member country. Founded in 1947, it has published over 25,000 international

standards covering almost all aspects of technology and manufacturing [36]. Founded in 1906, **the IEC** (International Electrotechnical Commission) is the world's leading organization for the preparation and publication of international standards for all electrical, electronic and related technologies. These are known collectively as "electrotechnology" [37].

India participates in IEC through BIS (Bureau of Indian Standards) and adopts standards as IS/IEC. As a full voting member, India contributes to global standard development, enabling globally compliant manufacturing and supporting MedTech export growth under "Make in India." The Rule 7 of the Medical Device Rules 2017 asses that: "the medical device shall conform to the standards laid down by the Bureau of Indian Standards established under section 3 of the Bureau of Indian Standards Act, 1985 (63 of 1985) or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time. (2) Where no relevant Standard of any medical device has been laid down under sub-rule (1), such device shall conform to the standard laid down by the International Organisation for Standardisation (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards. (3) In case of the standards which have not been specified under sub-rule (1) and sub-rule (2), the device shall conform to the validated manufacturer's standards." [8]. In other words, every device has to conform to the standards of the BIS, and, if there are no relevant standards issued by the BIS, the device has to conform to ISO and/or IEC standards or others. Standards play an important role in allowing the rapid introduction of new medical device technology while meeting the expectations of the public and regulators that medical devices are safe

to use, perform as intended and offer benefits to patients that outweigh the risks [38].

6.3 India's Accreditation and Certification Infrastructure for Medical Device Manufacturers

India has **4** hierarchy levels through which medical devices manufacturers are accredited, from a global level represented by the International Accreditation Forum (IAF), to the individual conformity assessment bodies(CAB) such as the Kalam Institute of Health Technology (KHIT) that provides certifications such as the ISO 13485:2016 on the quality management system:

1. International Accreditation Forum (IAF), founded in 1993, was a worldwide association of accreditation bodies and other bodies interested in conformity assessment in the fields of management systems, products, processes, services, personnel, and validation and verification. Its primary function was to develop a single worldwide programme of conformity assessment, reducing risk for businesses and their customers by assuring the reliability of accredited certificates and verification statements [39].

2. Asia Pacific Accreditation Corporation APAC: India geographically rientar in APAC, it was formed on January 1, 2019 through the amalgamation of APLAC (Asia Pacific Laboratory Accreditation Cooperation,

established 1992) and PAC (Pacific Accreditation Cooperation, established 1995), and it is recognised by the IAF. APAC 's primary role is to manage and expand a mutual recognition arrangement (MRA) among accreditation bodies in the Asia Pacific region. The MRA facilitates the acceptance of conformity assessment results (e.g. test reports, test certificates, inspection reports, and certification) across the region and with other regions around the world [40].

3. Quality Council of India (QCI): Quality Council of India (QCI) was established as a National body for Accreditation on recommendations of Expert Mission of EU after consultations in Inter-ministerial Task Force, Committee of Secretaries and Group of Ministers through a Cabinet decision in 1996. The QCI is divided in several accreditation bodies such as the National Accreditation Board for Testing and Calibration Laboratories (NABL), National Accreditation Board for Hospital and Healthcare Providers(NABH), National Accreditation Board for Certification Bodies (NABCB), National Accreditation Board for Education and Training(NABET), National Board for Quality Promotion(NBQP) and others [41].

4. Conformity Assessment Bodies (CAB): these bodies are accredited by the equivalent board of the QCI and, these are the operational level of the hierarchy. According to ISO CASCO, the Policy Development Committee on Conformity Assessment, there are different types of CAB : Certification Bodies for management systems, persons, products, processes and services(ISO/IEC 17021,ISO/IEC 17024,ISO/IEC 17065)

Testing and calibration Laboratories(ISO/IEC 17025) Validation and verification bodies(ISO/IEC 17029) inspection bodies(ISO/IEC 17020) [42].

The KHIT, within AMTZ, is a CAB, specialized in providing ISO 13485:2016 and ISO 9001:2015 certification, specialized schemes such as BEMC (Biomedical Equipment Maintenance and Calibration) and HEALTEXPROF(Healthcare Textiles Processing Facility Certification), as well as training programs including ISO 13485 Lead Auditor courses. Having KIHT Certification Services within AMTZ represents a significant advantage for the over 100 medical device companies that can access the certification services mentioned above, deleting travel costs, long time procedures and coordination challenges typically faced with external CAB.

6.4 Medical device lyfecicle and regulatory process

During the 6 months period in AMTZ I had the pleasure to learn a lot on how to develop and to build market-ready medical devices. I want to share through this thesis what I learnt in that field, even though it is not strictly related to my project because it is a software for to management the biomedical devices and it is not considered a software as a medical device . The Lifecycle of a medical is:

1. Design and development
2. Testing and calibration

3. Validation
4. Manufacturing
5. Distribution
6. Technical support
7. Decommissioning

and parallely has to be considered the regulatory approval process that consists in:

1. Develop QMS in compliance with ISO 13485
2. Testing depending upon the type of device and its needs, it has to be tested form accredited labs for IEC 60601 (electrical safety testing), ISO 10993(biocompatibility), EMC testing, ISO11137/11135(sterilization), IEC 62304 (software validation) and/or others.
3. Documentation preparation such as Device Master File(DMF), Plant Master File (PMF), Risk Management File (ISO 14971)
4. If it is an electromedical device, application to Bureau of Indian Standards(BIS) Certification with test reports such as IEC 60601.
5. Application to the CDSCO application license submitting DMF, PMF, tests reports and ISO 13485 certificate to:
    - State Licensing Authority for Class A/B devices (form MD-3)
    - Central Licensing Authority for Class C/D(form MD-7) and imported devices(form MD-14) [8]

Depending upon the class of risk of the device the CDSCO does an inspection.

6. Market launch

Andhra Pradesh Medtech Zone has a lot of resources regarding testing medical devices, apart of KHIT that is specialized in providing ISO 13485:2016 to manufacturers as mentioned in the paragraph "India's Accreditation and Certification Infrastructure for Medical Device Manufacturers" the primary testing facility is TÜV Rheinland accredited by the NABL, that includes includes the following world-class laboratories to qualify products as per national and international regulations:

- 10 meter Semi-Anechoic chamber with dual antenna mast, 6-meter turntable with 6 tonnes load capacity, along with a measurement range up to 40GHz and complete EMI/EMC capability-it can accommodate a fully equipped ambulance for testing.
- Precision acoustics facility for measuring sound pressure and sound power from medical and non-medical devices
- High precision Scanning Electron Microscope (SEM) and Transmission Electron Microscope (TEM) to study the finest detail of material up to individual atom level
- 3D X-ray imaging of equipment with the latest Micro CT equipment and several other state-of-the-art testing facilities [43]

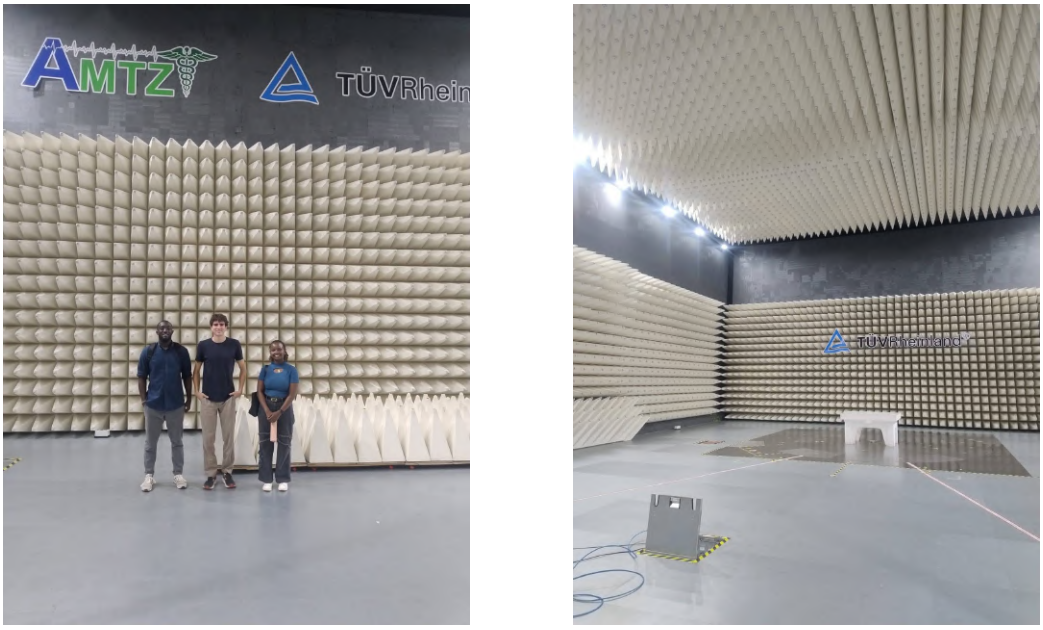
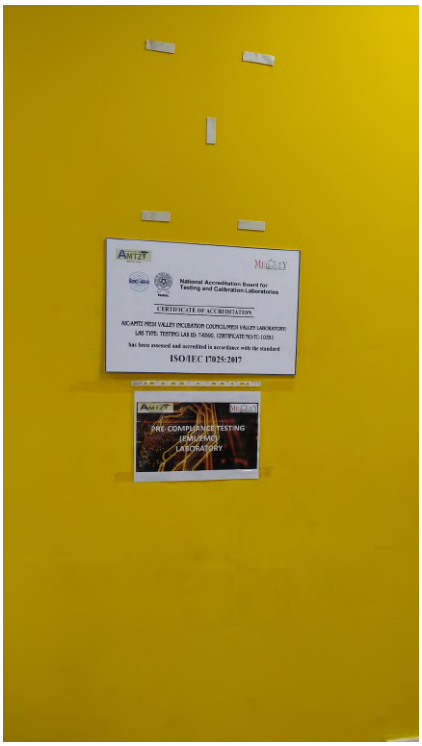


Figure 6.1: 10 meter Semi-Anechoic chamber in TÜV Rheinland for EMI/EMC.

Beyond TÜV Rheinland, AMTZ hosts several accredited testing facilities such as COBALTA (Gamma Irradiation Center), the first gamma irradiation facility in Andhra Pradesh using Cobalt-60 sources, it provides ISO 11137-compliant sterilization, STERILLA (EtO Sterilization Center) offers ethylene oxide sterilization per ISO 11135 standards, providing an alternative sterilization method for heat-sensitive devices and Medivalley Testing & Calibration Laboratories provides pre-compliance EMC testing, electronics testing, and biomedical equipment calibration.

(a) Some devices used to calibrate medical devices.



(b) NABL Certificate of accreditation.

(c) Electrostatic discharge (ESD) testing station.

Figure 6.2: Medivalley Testing & Calibration Laboratories.

Chapter 7

Obsolescence Assessment Methods and Cybersecurity: State Of The Art

7.1 The Critical Issue of Medical Equipment Obsolescence

The management of a hospital technology park, represents a critical challenge for Hospital facilities. In the last years, as highlighted by Maggi et.al , a rapid technological change has taken place in the last few years, but it has not been paralleled by the same extent of progress in management. "Medical Equipment requires very time-consuming and costly maintenance, which makes it crucial to introduce innovative technology management strategies focused on appropriateness, efficiency and cost effectiveness" [3]. Biomedical

equipment obsolescence can leads to significant consequences. As described by Mummolo et al, the increasing deterioration of the device (with resulting maintenance costs and risk of accidents due to devices that are out of order), an increase in operational costs and finally performance which is not in line with current technological standards. Unfortunately, accidents in hospitals involving patients which result from malfunctioning devices are all too commonplace and it is essential to provide health structures with suitable management tools [44].

7.2 Fennigkoh's model: the pioneering replacement priority system

The first mathematical model to evaluate medical equipment's obsolescence was proposed by Fennigkoh in 1992. This model introduce the concept of Replacement Priority Value (RPV), and index that quantifies the replacement priority of a medical device through a weighted combination of different Subattributes [45]. Fennigkoh divides the Subattributes into Attributes as shown in figure (7.1):

TABLE I
Replacement Model Attributes, Measures, and Scores

Attribute	Subattribute	Measure	Score
Equipment Service (40%)	Age	<,≥ 7 yrs	0,1
	Cost/price ratio	<,≥ 15%	0,1
	Downtime	<,≥ x+1s	0,1
	End of mfg. support	no, yes	0,1
Equipment Function (20%)	Life support		4
	Therapeutic		3
	Diagnostic		2
	Analytical/support		1
Cost Benefits (20%)	Increased revenues	no, yes	0,1
	Decreased costs	no, yes	0,1
Clinical Efficacy & Preference (20%)	Improved patient care	no, yes	0,1
	User preference	none, some, strong	0,1,2
	Increase standardization	no, yes	0,1

Figure 7.1: Replacement Model Attributes, Measures, and Scores [45].

The model formula is expressed as: The completed model, represented as a simple sum of possible attribute scores, becomes: RPV = 0.4 [age + cost + downtime + mfg.support]+ 0.2 [equipment function]+ 0.2 [cost benefits]+ 0.2 [improved care + preference +standardization] where RPV = replacement priority value and is confined to the range: 0.2 ¡= RPV ¡= 3.6. The model was tested on 146 devices at St. Luke's Medical Center in Milwaukee, representing 3.5% of the center's total equipment. Based on the distribution of obtained RPV values, Fennigkoh established the following decision thresholds:

- $RPV \geq 1.8$ = Urgent—replacement in the existing fiscal year is recommended.
- $1.4 \leq RPV \leq 1.6$ = Replace in the next fiscal year.

- $1.0 \leq RPV \leq 1.2$ = Advisory—re-evaluate at the end of existing fiscal year [45]

7.3 Evolutions of Fennigkoh's model

In 2001, Caimmi et all proposed a significant evolution of Fennigkoh's model, developed for Busto Arsizio Hospital (HBA) in Northern Italy [46]. The main innovation consists in introducing a two-phase procedure, where in the first phase only objective (i.e., technical) data are considered and a first, provisional RPV (RPV1) is computed. Only if RPV1 exceeds a given threshold the second step is entered, where subjective data are considered too. This two-phase structure offers several advantages: time, costs, and efforts saving, and reduced sensitivity to subjective factors . As the authors explain, only objective data are needed to compute RPV1, they are automatically provided by the hospital database of medical devices, and computation of RPV1 reduces to running a routine included in the database and subjective data are needed, in the second evaluation step, only for a subset of devices already identified as critical, so reducing the number of possible useless interviews to the medical personnel [46]. The parameters included in the RPV1 score are:

- Age (x1): Unlike Fennigkoh's model with a fixed threshold of 7 years, different thresholds (functional age) were adopted, depending on the device type: 4 years for clinical analysis laboratory devices, 6 years for clinical electrophysiology devices, 10 years for radiological devices.

- Maintenance Costs (x2): x2 = 0, 1, 2, or 3 depending on whether in the last three years the maintenance cost per-year never exceeded 10%

of the device's purchase price, or did exceed it 1, 2, or 3 times. As specified, The different threshold value (10% yearly, instead of 15% in a three-year period) accounts for the costs increase since the time of Fennigkoh's study [45].

- Downtime (x3): x3 = 0 if downtime for the considered device is less than 1.5 times the mean downtime of all the devices of the same category.

- Equipment Function (x4): Scored 1 to 4, same as in Fennigkoh's model.

- Manufacturer Support (x5): x5 = 1 if parts, consumables, maintenance service, or manufacturer support are no longer available or adequate; otherwise x5 = 0.

The formula for RPV1 is: RPV1 = 9(x1 + x2 + x3) + 7.5x4 + 25x5 with $7.5 \leq RPV1 \leq 100$. The decision thresholds are:

- $RPV1 < 40$ = good conditions, no need to proceed

- $40 \leq RPV1 \leq 60$ = critical device, enter the second step

- $RPV1 > 60$ = very critical device, replacement suggested as soon as possible

This Thesis project is developed solely on objective (i.e., technical) parameters, that's why the subjective part will not be much considered, but for further curiosity on behalf of the reader it can be further explored going through the relative citations.

Following the Busto Arsizio model approach, a model was developed for Galliera Hospital in Genoa maintaining the two-phase structure but simplifying it further. As Maggi et al explain, some difficulties deriving from the retrieval of data such as maintenance cost for individual devices have been avoided [3]. The parameters included in the Galliera RPV1 are:

- Age (x1):

$$x_i = \begin{cases} 0, & \text{if } \frac{\text{current year} - \text{year purchased}}{\text{functional age}} < 0 \\ 1, & \text{otherwise} \end{cases} \tag{7.1}$$

  Functional age is set generally to 10 years.

- Downtime (x2): Threshold set at 6 days (based on hospital outsourcing specifications) , x2 = 0 if $downtime < 6$ days, x2 = 1 if $downtime \geq 6$ days

- Equipment Function (x3): Same as Busto Arsizio and Fennigkoh models; scored 1 to 4

- Manufacturer Support, Maintenance Service, and Parts Availability (x4): x4 = 0 if parts, consumables, maintenance service, or manufacturer support are available/adequate (guaranteed by law for 10 years post-purchase), x4 = 1 if unavailable or inadequate

The formula for RPV1 in the Galliera model is: 9(x1+ x2)+7.5 x3+25x4
The study of [3] compared the linear formula with a fuzzy logic algorithm using the same parameters and thresholds, based on linguistic rules that

translate biomedical engineering expertise. This approach was chosen to handle data uncertainty, which is a common pattern in hospitals. The results were similar, but the fuzzy algorithm produced more conservative outputs. Following [3], the study of [2] applies fuzzy logic methodology at IRCCS Giannina Gaslini, a pediatric hospital in Genoa, analyzing over 8,000 medical devices in the context of major infrastructure renewal. The work compares the hospital's existing MVO (Obsolescence Evaluation Method) with a fuzzy logic approach.

7.4 Fuzzy Logic

The adoption of fuzzy logic-based systems has expanded considerably across diverse sectors in recent decades. Implementation domains vary from consumer electronics(including imaging devices, domestic appliances such as washing machines and microwave ovens) to sophisticated industrial applications encompassing process control systems, medical diagnostic equipment, decision-making support platforms, and financial portfolio optimization.
The concept of fuzzy logic was introduced by Lotfi A. Zadeh through his publication on fuzzy sets in 1965 [47]. This differs from classical binary logic, where elements are strictly assigned values of 0 or 1 based on set membership. Instead, fuzzy logic introduces a continuum of membership degrees represented by any value within the [0,1] interval. Fuzzy logic is built upon linguistic variables, a concept where system parameters are described using words (such as "high," "medium,","low" and others) instead of exact numbers, becoming a methodology that processes verbal information rather than

numerical data. Although words lack the precision of numerical values, they reflect more how humans think and make decisions. Additionally, accepting this imprecision, fuzzy systems can deliver practical solutions with lower computational demands and reduced implementation costs [48]. The core o fuzzy logic consists of if-then conditional statements (fuzzy rules) that define how input conditions translate into outputs. These rules are processed simultaneously in parallel, meaning their sequential order does not affect the final outcome. However, before implementing such rules, it is essential to define membership functions mathematical representations that characterize how each variable relates to its descriptive linguistic terms. For instance, to establish a rule about "hot water," one must first specify both the temperature range and the precise meaning of "hot" within that context through a membership function. This function assigns a degree of membership (a value between 0 and 1) indicating how strongly a given temperature belongs to the category "hot" [49]. To illustrate the complete fuzzy inference process, we present a practical example of a restaurant tipping system that determines an appropriate tip percentage based on two input variables: food quality and service quality.Consider a scenario where a customer needs to decide the tip amount after dining at a restaurant. The decision depends on two factors, both rated on a scale from 0 to 10. Traditional logic would simply combine these values linearly, but fuzzy logic captures the inherent uncertainty and mimics human reasoning more naturally:

1. **Fuzzification**:is the process of converting numerical crisp inputs into fuzzy degrees of membership. Instead of treating the input value as an exact points, fuzzy logic recognizes that this value partially belongs to

multiple linguistic categories simultaneously. E.g. we can say that if the quality of the food eaten is a 8 out of 10, the fuzzified value can become a 80% great and a 20% decent, corresponding to a membership degree of 0.8 great and 0.2 decent, depending on how the memberships are defined.

2. **Rule Evaluation an application**: The fuzzy inference system employs a rule base consisting of if-then statements that encode expert knowledge. E.g. we define a rule such as "IF Food is Great AND Service is Good THEN Tip is Good". In the most common fuzzy inference methodology, the Mamdami, the strength of the rule is define using the minimum function: $\min(\mu(\text{Great}), \mu(\text{Good}))$ where μ is the membership degree. Each rule's consequent membership function is truncated at the height corresponding to its strength, ensuring that rules with lower activation contribute proportionally less to the final output and viceversa.

3. **Aggregation and defuzzification**: Aggregation combines all the clipped membership functions into a single fuzzy. Defuzzification converts this fuzzy output back into a single crisp value. The most common defuzzification method is the centroid method, which calculates the geometric center of the aggregated membership function [48].

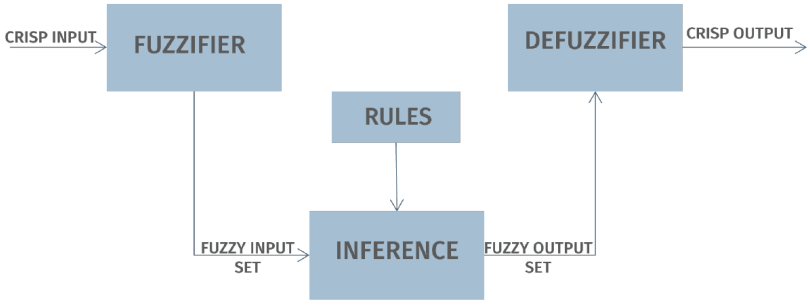


Figure 7.2: Schema regarding fuzzy system methodology [50].

7.5 Alternative approaches

Economic models:

Christer & Scarf (1994) announced a methodology specifically aimed for medical equipment replacement. This new work appears as an evolution of Christer's previous 1980 and 1988 papers, and tries to encompass as many factors as technological evolution, equipment deterioration and inflation. It also tries to include subjective aspects, particularly important when it comes to medical equipment, such as, patients' well being and safety [51]. The model introduces penalty costs to include the monetary value of the opportunity to replace a device with a newer one; moreover, the effects of the usage on equipment life are included in the cost model [44, 51]. Kierulff (2007) elaborated a work where he points out some limitations of the traditional economic methods applied in replacement decisions, and proposes some approaches to overcome these limitations [51].

Aging-Based Models :

Wang et al.(2024) developed an equipment aging model using three variables: Normal operational stress (also known as 'wear and tear')... heretofore abbreviated as stress; Durability (also known as sturdiness) built into the machine by its manufacturer... heretofore abbreviated as durability; Likelihood of excessive use or abuse... heretofore abbreviated as use" The aging score is calculated as: "$Agingscore(\%) = (stress + (10 - durability) + use)/30$, providing a framework distinct from traditional risk-based approaches [52].

Others Decision Making (MCDM) Approaches:

Taghipour et al. (2011) debated that although the risk is an important criterion, other factors should be taken into accounts such as utilization rate and mission criticality. To overcome this problem, they proposed a Simple Additive Weighting (SAW) of six criteria assessed using the Analytical Hierarchical Process (AHP) method [53]. Mahfoud et al. (2016) advanced beyond single-method approaches presenting a hybrid approach of Expert judgment, AHP and PROMETHEE) [53]. A Spanish research team developed a fuzzy multicriteria model using the FAHP to facilitate decision making in the renewal of healthcare equipment to give objective, transparent, consistent, and checkable results [54].

Chapter 8

Cybersecurity

8.1 Cyberattacks on Healthcare Infrastructures

"A cyberattack that caused disruption at hospitals in London last year contributed to the death of a patient, health officials have confirmed **for the first time**" [55]. Cyberattacks are not only theoretical, but they directly and indirectly affect patients lives: in June 2025, for the first time, due to a cyberattack that provokated a delay in critical blood test results, a patient died. Every country's hospitals experienced cyberattacks, here few examples:

- Italy: In the Lazio regional health system, during the Covid vaccination campaign, on 1st August the Lazio Region was hit by a cyberattack that encrypted every file stored in the data centre, causing 4 days to restore the covid-vaccine booking service and cauisng the lost of a bundle of 10 years of regional documentation [56, 57]. The ASL 1 in Abruzzo attack

in 2023 by Monti ransomware gang stole 500 GB of sensitive data [58].

- India: In India, the All India Institute of Medical Sciences (AIIMS) Delhi suffered one of the country's most severe ransomware attacks in November 2022. The LockBit ransomware gang encrypted all servers, stopping hospital operations for nearly two weeks and forcing reversion to manual patient records. The attackers allegedly demanded approximately 200 crore in Indian rupees (about $24.5 million) in cryptocurrency. The attack compromised data of approximately 40 million patients [59].

- America: In the United States, the Change Healthcare ransomware attack in February 2024 was the most significant cyberattack in U.S. healthcare history. Change Healthcare, which processes approximately 50% of all U.S. medical claims, disrupting billing and prescription processing for 900,000 physicians, 33,000 pharmacies, 5,500 hospitals. The cyberattack affected 190 million Americans and a $22 million ransom was payed [60].

8.2 Medical Device Vulnerabilities: Documented Cases

One of the breach points through which patients data and patients life could be at risk, are the biomedical devices. Here there are some few examples of vulnerabilities in biomecial devices:

- Infusion Pumps: The B. Braun Infusomat Space was found with lot

of and critical vulnerabilities such as Improper input validation, Insufficient verification of data Authenticy, missing authentication for critical function, cleartext transmission of sensitive informations and unrestricted upload of file with dangerous type [61]

- Medical Imaging Systems: The MDhex-Ray vulnerability affected several GE Healthcare product models—including CT scanners, MRI machines, and PET scanners; the vulnerabilities found are such as Improper input validation, improper restriction of operations within the bounds of a memory buffer, improper authentication, insecure default inizialization of resource and others [62]

- Cardiac Implantable Devices: In 2017, the FDA issued the first cybersecurity recall of implantable cardiac devices."The agency is instructing patients with certain implantable cardiac pacemakers from St. Jude Medical - now owned by Abbott Laboratories - to visit their physicians for firmware updates to address cyber vulnerabilities that can potentially be remotely exploited by hackers and that pose safety concerns. Approximately 465,000 such devices are in use in the U.S" [63]

8.3 CVE, NVD, OSV and non-awareness in hospitals

Cyber-security, has become a worldwide concern in Healthcare industry and hospitals in particular; cyber-attacks are growing along with the increase utilization of internet-connected devices, the healtcare industry has lagged in

protecting its main stake-holder (ie, patients) and now considerable capital and effort has to be spent to protect their systems [64]. Some of the weaknesses in these systems are represented by vulnerabilities within biomedical devices, that often they are known (Not by the hospital workers) and collected in databases for known vulnerabilities, such as CVE and NVD that are the two most importants but also others like CIRCL and OSV.

The Common Vulnerabilities and Exposures(CVE) system, provides an universal language in terms of cybersecurity-vulnerbaility. Operated by the MITRE corporation and sponsored by the U.S. Department of Homeland Security, CVE assigns an unique identifier to each publicly disclosed vulnerability, allowing an universal common language between stakeholders worldwide [65]. Every CVE identifier has a standard format: CVE-YEAR-NUMBER (for example, CVE-2025-14654 represents the 14,654th vulnerability collected trough CVE in 2025).

The National Vulnerability Database (NVD), maintained by the National Institute of Standards and Technology (NIST),is tasked with enriching each CVE once it has been published to the CVE List, after which it is typically available in the NVD within an hour [66]. NVD's most important enrichment is the Common Vulnerability Scoring System (CVSS), a numerical rating from 0 to 10 indicating vulnerability severity [67]. The scoring system has three categories: Critical (9.0-10.0), High (7.0-8.9), Medium (4.0-6.9), and Low (0.1-3.9).

For biomedical devices incorporating open-source components, the **Open Source Vulnerabilities (OSV)** database provides specialized tracking.

Despite the publication of thousands of of CVEs regarding biomedical de-

vices, hospitals often lack systematic processes to create a comprehensive inventory of internet-connected medical devices, track the firmware/software version of biomedical devices, cross-check the firmware/software on online databases for known vulnerabilitise such as CVE,NVD, OSV and others. This non-awareness from the hospital side can potentially lead to huge loss of patient data and patient lives. This non-awareness I'm talking about, is not something only theorical, but, I had the possibility to check it personally in India, and I can confirm that it is a real-world matter. I've been in some hospitals and, I've tried to create a way to detect automatically the firmware/software versions of some devices. I've been in Homi Baba Cancer Hospital, Indus Hospital, Apollo hospital and RK hospitals and I've tired to connect phisically to two devices in the Animal research center and in the Blood Bank within AMTZ.

Part II

Materials and Methods

Chapter 9

General Methodological Approach

The methodology used is based on an iterative, user-centered design approach, articulated in four main phases:

1. Initial development of the software prototype and the preliminary obsolescence scoring algorithm
2. field research based on hospital visits for requirements validation
3. iterative refinement of both software and obsolescence scoring algorithm
4. development of the cybersecurity module and physical connection trials in clinical facilities

This approach allowed me to continuously align the theoretical work with the real-world environment.

9.1 Initial Software Prototype Development

As soon I arrived at Andhra Pradesh MedTech Zone Ltd (AMTZ) in Visakhapatnam, and following an extensive literature review on obsolescence scoring algorithms for biomedical equipment, the development of a software prototype was started. This prototype was required by AMTZ as a prerequisite to obtain the authorization to conduct field research in some partner hospital facilities.

9.1.1 Tools

To develop a web-based platform was used: Python as programming language, Streamlit for the user interface, and PostgreSQL as the database management system.

Python was chosen for its:

- Simplicity and rapid development characteristics
- compatible for web interfaces, database connections, and computational tasks

Streamlit was chosen for its:

- User-friendly interface and intuitive design for nontechnical end-users(clinical/biomedical engineers)
- Rapid prototyping

PostgreSQL was chosen for its:

- Robust relational database and compatibility with Streamlit

- Open-source

9.1.2 Backend Database Architecture

The prototype was designed with a modular, database-driven architecture; The PostgreSQL relational database was utilized as the backend to manage:

- **User authentication**: login system with password hashing (bcrypt algorithm) and admin approval
- **Device inventory**: medical equipment informations such as description, brand, model, installation date, manufacturer date, serial number, UDI and GMDN.
- **Obsolescence scoring**: storage of scoring parameters and results

9.1.3 Frontend Architecture

The prototype was designed with three main functional modules:

1. **User authentication:**: Registration and Login pages, requiring administrator approval for new users
2. **Device inventory**: Interface for device registration, visualization, deletion, and editing
3. **Obsolescence scoring**: Interface for visualizing the score and to add, edit, and delete the necessary scoring parameters

9.1.4 Preliminary Fuzzy Logic Obsolescence Algorithm

A fuzzy logic approach was selected for the obsolescence algorithm due to its characteristic to handle the uncertainty of data and the qualitative nature of many obsolescence factors.

Hierarchical Structure

To manage the combinatorial explosion of fuzzy rules, a hierarchical architecture was chosen. Utilizing a non-hierarchical system the number of rules would have been

$$N_{rules} = m^n \tag{9.1}$$

where "m" is the number of membership functions, while "n" is the number of parameters; considering the 7 parameters that have been used in the preliminary algorithm, the number of rules would have been $3^7 = 2187$, illogical to write all of them. For this reason, the algorithm was structured into four intermediate fuzzy inference subsystems, decreasing the number of rules to 129.

$$N_{rules} = \sum_{i \in S} \prod_{j=1}^{n_i} m_{i,j} \tag{9.2}$$

where "S" is the number of subsystems which "n_i"≥ 2, "n_i" is the number of parameters of the subsystem "i" in "S", "m" the number of membership functions for each parameter "j" in each subsystem in "S". The subsystems that have been used for the preliminary algorithm were the following:

1. **Mission Criticality**
2. **Support Level**

3. **Cost Level**

4. **Age**

These four subsystems were combined to produce the overall **Criticality** score, ranging from 0 to 10 and classified into five linguistic categories: *very low*, *low*, *medium*, *high*, and *very high*.

Fuzzy rules within each subsystem encode expert knowledge about how parameters interact. For example, within the Mission Criticality subsystem, typical rules include:

- IF backup availability is *none* AND equipment function is *life-support* AND uptime is *high* THEN mission criticality is *very high*

Each subsystem processes its inputs through such rules to produce an intermediate output. For instance, the Mission Criticality subsystem might output a value of 7.5 on a 0-10 scale, which is then linguistically classified as *high*. The four subsystem outputs (Mission Criticality, Support Level, Cost Level, Age) are then used as inputs to produce the final **Criticality** output, for example:

- IF mission criticality is *high* AND support level is *low* AND Cost Level is *high* AND Age is *high* THEN overall criticality is *very high*

Input Parameters

The parameters for each subsystem were defined as follows:

- **Mission Criticality** assessed the operational importance of the device through:

- **Backup availability**: no backup (0), adequate backup (1-2 units), or backup (>3 units), similar to Taghipour et al study [68].
- **Equipment function**: classified as analytical/support, diagnostic, therapeutic, or life-saving/life-support, identical to the Fennigkoh study [45].
- **Uptime**: rated as low(<12 usage hours per week), medium(12≤usage hours per week<24), or high (usage hours per week ≥24) identical to Taghipour et al study [68].

- **Support Level** evaluated manufacturer support and supply chain factors:
  - **End-of-life/End-of-support status**: whether the manufacturer had declared end-of-life, end-of-support and end-of-life, or neither, similar to Fennigkoh study [45].
  - **Spare parts availability**: categorized into four scenarios combining production location (local/import) and availability of spare parts(available/not available); this parameters was completely theoretical, based on the fact that most of the biomedical devices are imported from outside the country, making the supply chain of spare parts slow.

- **Cost Level** was represented by a single parameter:
  - **Maintenance-to-acquisition cost ratio**: ratio of cumulative maintenance costs over the previous three years to the original device cost.It was divided in low (ratio<10%), medium (10≤ratio<15%),

high (ratio≥15%), based on Caimmi et al study and Fennigkoh study, where 10% and 15% were used respectively as threshold [45, 46].

- **Age** was represented by a single parameter as well:
  - **Device age**: categorized as (age<5), medium age(5≤age<10) and old(age≥10), similar to Capuano et al study [69].

As written in the paragraph "Hierarchical Structure", the use of subsystems significantly reduced the number of linguistic rules adopted.

$$N_{rules} = (3\times3\times4)+(3\times4)+(3\times3\times3\times3) = 36+12+81 = 129 \text{ rules} \quad (9.3)$$

Computational complexity was reduced while maintaining the interpretability.

Limitations and Validation Requirements

The preliminary algorithm was entirely based on theoretical considerations and existing literature. However, some critical limitations were recognized:

- Parameter availability and data quality in real hospitals were unknown
- The feasibility of collecting certain parameters such as maintenance cost history, was unknown
- membership functions and thresholds were based on the literature and not on local expert opinions(clinical/biomedical engineers)

These limitations necessitated the research on the field to validate the preliminary algorithm.

9.2 Field Research and Requirements Validation

9.2.1 Study Setting and Participants

The field research was conducted in multiple healthcare facilities in Visakhapatnam and within the AMTZ campus. The research involved a combination of facility visits and interviews. The facilities visited were the following:

- **Blood Bank (AMTZ campus)**: Recently established facility; limited data availability due to recent opening that precluded the obsolescence analysis.

Figure 9.1: The technical supervisor Kumar Patelkhan and I in front of the entrance of the Kalam blood center within AMTZ.

- **RK Hospital**: 50 beds multi-specialty. The facility rely on a small workshop for basic repairs and outsource the rest of the maintenance to service providers. The sole biomedical engineer of the facility was unavailable during the visit, limiting the collection of information.

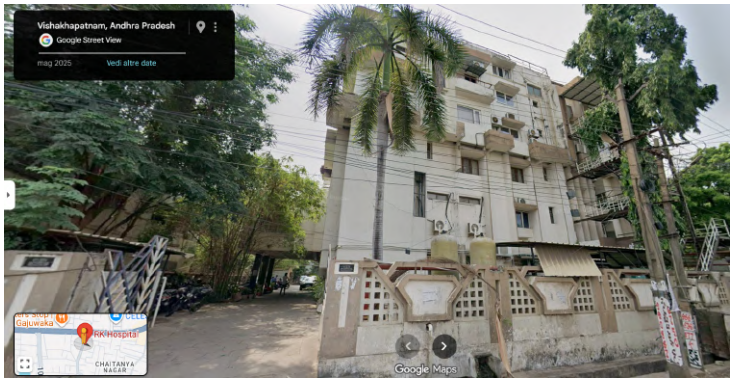


Figure 9.2: RK hospital entrance view from google maps.

- **Homi Bhabha Cancer Hospital** (TATA partnership): Specialized cancer hospital and research center . Extended collaboration was established with the Chief Biomedical Engineer, who provided insights regarding data and maintenance management. This collaboration was fundamental for the development of the entire project.Successful anonymized data sharing agreement enabled access to actual equipment inventory and maintenance records.

Figure 9.3: External view of Homi Bhabha cancer hospital.

- **Apollo Hospital**: One of the largest healthcare facilities in Visakhapatnam and one of the 70+ facilities all across India. A two-hour consultation with the Chief Biomedical Engineer provided valuable insights into algorithm design requirements.

Figure 9.4: external view of one of the Apollo hospitals in Visakhapatnam.

- **Indus Hospital**: one of the 100+ facilities all across India. Successful data sharing agreement enabled access to actual equipment inventory and maintenance records.

Figure 9.5: Entrance of one of Indus Hospitals in Visakhapatnam.

Additional interviews were conducted with biomedical engineering professionals, including:

- A biomedical engineer with expertise in Indian healthcare systems
- A senior biomedical engineer with over 40 years of professional experience
- A biomedical engineer from Ghana's largest hospital, providing another international perspective on equipment management.

Each interview lasted approximately 1-2 hours, focused on understanding equipment management practices and workflows, how and which data are

collected, and obsolescence assessment methodologies. Hospital visits typically lasted 1-2 days, with the exception of cybersecurity-focused work which required extended on-site presence.

9.2.2 Data Collection Methodology

The field research employed two main methods:

- **Interviews**: Discussions with biomedical engineers to understand equipment management practices and data availability. It followed similar questions, slightly changed based upon the specific context. The similar general questions were:

    1. How is the maintenance managed and which is the workflow?
    2. Do you use maintenance contracts?Which kind of contracts do you use?
    3. When and how do you decide to dispose a device?
    4. How do you currently assess replacement priorities? Do you use a scoring system or checklist?
    5. Which parameters drive your decisions? Age,cost, clinical criticality?
    6. Are aspects like end of technical support considered?
    7. Are devices under maintenance contracts still strategically considered?
    8. Is cybersecurity taken into account?

- **Request to access biomedical device management data**: Request to access to data related to equipment inventories, incident logs, maintenance logs and cost, and all other data that are related to the biomedical device management.

9.2.3 Data collection outcome

The outcomes of the field research are :

- **Interviews**: every interviews answer was slightly different, similar patterns recognized were the following:

    1. There is a significant variability in equipment management practices across facilities, reflecting differences in institutional size and resource availability.The Large hospitals performed the majority of repairs in-house, external service providers were needed for specialized repairs. Medium and small facilities are more dependent on external services respect to the larger facilities. Every facility tries to solve the issue in-house when possible. The maintenance workflow is the same in every facility, characterized by routine checks, preventive maintenances (such as calibration,inspection,cleaning, software update and part replacements), and corrective maintenances when a failure occurs.
    2. The contracts situation is also different across the facilities visited, but generally every device has a 2 years warranty and 8 years of AMC/CMC contracts.

3. It was told that every device is disposed after the contracts expiring date.

4. There are no obsolescence scoring systems used, but, replacements priorities are assigned based mainly on the return on investment and clinical criticality.

5. Return on investment and clinical criticality.

   One of the hospital visited, has its own clinical criticality class to differentiate the type of device; they differentiate the devices in class A,B and C, where A represent the most critical one, its devices are life-saving and monitored daily.

6. Not much considered.

   One of the interviews with a chief biomedical engineer revealed that facilities often do not purchase the latest-version devices. Devices with proven higher reliability and lower mean failure rates are preferred to minimize risk of less durability. However, this practice can lead to the end of manufacturer support while devices are still in use.

7. Beyond economic repair considered.

8. Standard protocols are taken into account, mainly regarding the security of the internet connection. Vulnerable devices(software/firmware vulnerabilities) are not taken into account.

- **Request to access biomedical device management data**:

- **Homi Bhabha Cancer Hospital**: provided anonymized equipment inventory, incident logs, maintenance logs and, furthermore, an extended collaboration with the chief biomedical was established.
- **Indus Hospital**: provided anonymized equipment inventory, incident logs, maintenance logs
- **Apollo Hospital**: data weren't provided due to institutional administrative procedures.
- **RK hospital**: data collection was not possible due to unavailability of the sole biomedical engineering during the visit.
- **Blood Bank (AMTZ campus)**: data collection was not possible, few operational history due to recent opening.

9.3 Iterative refinement

The UI and database of the web-platform underwent continuous refinement to accommodate biomedical engineers feedback throughout the research period, while the primary focus of the iterative process was the obsolescence scoring algorithm itself, detailed in the following subsections.

9.3.1 Gap analysis

The field research focused on understanding the reality of the environment, which data were available and how the technology park was managed in a constrained-resource setting. As already explained in the subsection 9.2.4

and mentioned in the following table 9.1, the parameters involved in the preliminary algorithm were 7, divided in 4 subsystem in order to reduce the combinatorial explosion of fuzzy rules. Was figured out that the parameters involved in the preliminary algorithm had some discrepancies respect to the real environment, as shown in the following table 9.1:

Parameter	**Status**	**Action Taken**
Mission Criticality Subsystem		
Backup availability	Not tracked	Retained and managed manually
Equipment function	Not tracked	Retained and estimated automatically
Uptime	Not tracked	Replaced with downtime events(tracked)
Support Level Subsystem		
End of life/End of support	Not tracked	Replaced with service of repair availability automatically estimated based on the presence of a service contract(tracked)
Spare parts	Not tracked	Retained but the categories were modified, managed manually
Cost Level Subsystem		
Maintenance cost ratio	Not accessible	Entire subsystem eliminated
Age Subsystem		
Device age	Available	Retained

Table 9.1: Comparison between preliminary and revised algorithm structure

The gap analysis revealed that only 1 out of 7 parameters could be retained

without modification. The remaining parameters required substitution(2 parameters), managed manually(2 parameters), automatically estimated(1 parameter) or complete elimination(1 parameter).
Based on the gap analysis, the obsolescence scoring algorithm underwent systematic redesign. The selected parameters and subsystems are presented in the **result section**.

9.4 Cybersecurity Module Development

Following the completion of the obsolescence algorithm, a cybersecurity module was developed to allow the identification of softwares and/or firmwares vulnerabilities. The main objectives were:

1. extract firmware/software version through physical connection to biomedical devices

2. create a dedicated page on the web-platorm, where vulnerabilities can be verified if present.

9.4.1 Study Setting and Devices Utilized

The physical connection to biomedical devices was conducted in 2 healthcare facilities within the AMTZ campus. The facilities where the study has taken place were the following:

- **Kalam blood center(AMTZ campus)**: see figure 9.1

- **Animal research center(AMTZ campus)**

Figure 9.6: One of the corridors in the animal research center [70].

The devices used for the study were the following:

- **ST-200cc Blood Gas Analyzer (Sensa Core)** within the **Animal research center**

(a) ST-200cc Blood Analyzer. (b) Communication ports

Figure 9.7: ST-200cc Blood Gas Analyzer and communication ports.

- **KB22 Auto Hematology Analyzer (Krish Biomedical** within the **Kalam blood center(AMTZ campus)**

Figure 9.8: KB22 Auto Hematology Analyzer.

9.4.2 Firmware/Software extraction methodology

Software and firmware version identification was attempted through three access methods:

- **Serial communication**
- **Network communication**
- **Boot sequence monitoring**

Serial communication

Both devices had RS-232 and USB ports. The devices were interrogated using Python scripts implementing standard diagnostic command sets generated using AI development tools (Claude, Anthropic) and using respective cables and:

- **Communication interface**: RS-232 and USB-B port
- **Baud rates tested**: 9600, 19200, 57600, 115200 bps
- **Protocol**: ASTM E1394 (laboratory equipment standard)
- **Command sequences**: VERSION, VER, INFO, STATUS, ID, *IDN? (SCPI standard)
- **Implementation**: PySerial library for serial port communication
- **Version/Firmware extraction**: expected answer.

Network communication

Both the devices had the possibility to connect to the network, version information were tried to extract through Laboratory Information System (LIS) communication channel using an ethernet and RS-232 cable and AI development tools (Claude, Anthropic):

- **Communication interface**: ethernet and LIS-RS-232 port
- **LIS server emulation**: A virtual LIS server was implemented in a laptop.
- **Protocol**: HL7 (Health Level 7) messaging standard

- **Version/Firmware extraction**: Device identification strings and software/firmware versions were tried to extract from HL7 message headers (MSH segments)

Boot sequence monitoring

Device reboot sequences were monitored to capture boot message(while the device was turning on), using rs-232 and USB-B compatible cables and using AI development tools (Claude, Anthropic). When the device was turned on, the script captured all data transmitted during the initialization sequence. Python scripts implemented passive listening mode were configured to monitor the serial port without transmitting commands:

- **Communication interface**: RS-232 or USB-B port
- **Baud rates tested**: 9600, 19200, 38400, 57600, 115200 bps
- **Capture duration**: 60 seconds from device power-on
- **Version/Firmware extraction**:Expected message containing device's information

9.4.3 Known Vulnerabilities Database Connection and web-platform UI

The extracted software/firmware versions are being cross-checked with data in known database vulnerabilities. The software/firmware version was being typed in the apposite made UI on the web-platform, through which back-end allowed to connect to known vulnerabilities database such as:

- **National Vulnerabilities Database** (NVD)
- **Computer Incident Response Center Luxembourg** (CIRCL)
- **Open Source Vulnerabilities** (OSV)

In the UI, there is the possibility to type the Vendor name, the Product name, the Version name of the Software/Firmware and the IP Address of the device if connected to the network. The sole mandatory field is the name of the "Product".
(e.g. Vendor=Microsoft, Product=Windows, Version=XP).

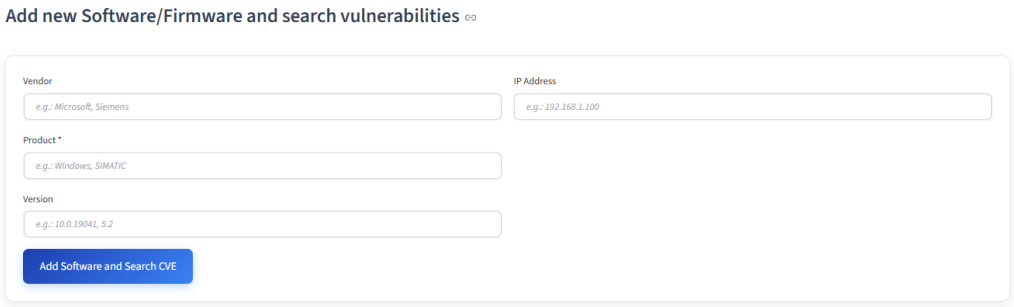


Figure 9.9: User-Interface of the web-platform for searching Software/Firmware vulnerabilities on Known Vulnerabilities Databases.

Different Known Vulnerabilities Databases required different connection methodologies:

NVD

The API that is being used is the NVD REST API 2.0 (`services.nvd.nist.gov/rest/json/cves/2.0`). Two complementary approaches were required:

1. **CPE-based search**: When complete version information was available in the database, queries utilized Common Platform Enumeration (CPE) 2.3(e.g.,`cpe:2.3:a:vendor:product:version:*:*:*:*:*:*:*`).

2. **Keyword search fallback**: When CPE queries returned no results, keyword-based searches combining product name and version were used.

OSV

The OSV API (`api.osv.dev/v1/query`) is being used and the query modality executed is POST requests with JSON payloads
(r = requests.post(API, headers=HEADERS, json=payload, timeout=15), where payload contain "Product" name and "Version". OSV provides native server-side version filtering.

CIRCL

The CIRCL API (`cve.circl.lu/api/vulnerability/search`) was queried via GET requests with vendor and product parameters in the URL path. CIRCL aggregates vulnerability data from multiple sources (NVD, FKIE, Debian, Red Hat and others) but does not support native version filtering.

For databases without native version filtering (NVD keyword search and CIRCL), a rule-based natural language processing approach was implemented to extract vulnerable version ranges from CVE descriptions. The algorithm identifies patterns including:

- Explicit version(e.g., "version 3.0.5")
- Version ranges(e.g., "versions 2.0 through 2.8.2", "before 3.0.0")

- Wildcard(e.g., "all 2.x versions before 2.8.2")
- Fixed version(e.g., "fixed in 2.16.0")
- Explicit exclusions (e.g., "excluding security fix release 2.14.2")

CVSS (Common Vulnerability Scoring System) scores were extracted based on a priority system, checking for CVSS v3.1, then v3.0, then v2.0 in structures including `containers.cna.metrics`, `containers.adp.metrics`, `impact.baseMetricV3` and `cvss`. This was necessary because of the diverse JSON schemas used by different vulnerability databases. Results from all three databases were unified and duplicates CVE ID were eliminated automatically, where NVD has the priority for CVSS scores due to its role as the uffical CVSS scoring source.

Part III

Results

Chapter 10

General Results Approach

A comprehensive web platform was developed, including modules for device inventory and ward management, maintenance and incident tracking, obsolescence assessment, and cybersecurity. The obsolescence and cybersecurity modules were further investigated through two different but complementary studies: a fuzzy logic-based obsolescence scoring algorithm and a physical connection protocol for biomedical devices aimed at extracting firmware and software version information.

10.1 Web-Platform: Login, Inventory, Wards & Rooms, Maintenance and Breakdowns management modules

10.1.1 Login and Registration

Registration and Login pages, require administrator approval for new users. The Login system is provided with password hashing (bcrypt algorithm) and admin approval. The figure 10.1 shows how the UI appears.

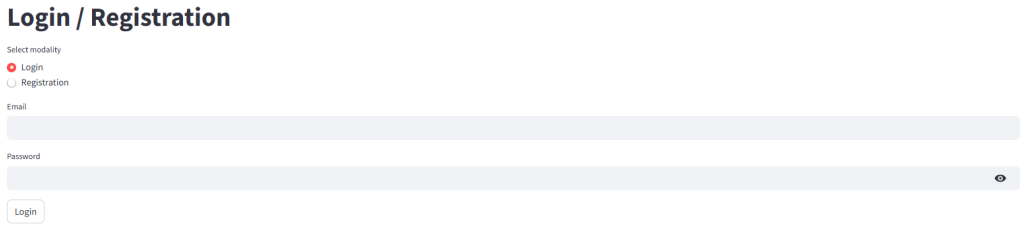


Figure 10.1: UI of the Login/Registration page.

The figure 10.2 shows an example of the Database on which the Users that tried to register are stored, with the respective encrypted password, pending for admin approval.

	email [PK] text	password_hash text	approved boolean
1	andreolimarco01@gmail.com	$2b$12$ClkkZ0qnCZdkwMCGV2KGc.pLsIQr1Bxen6QqJS7bAGRgWvbaxjwGi	true

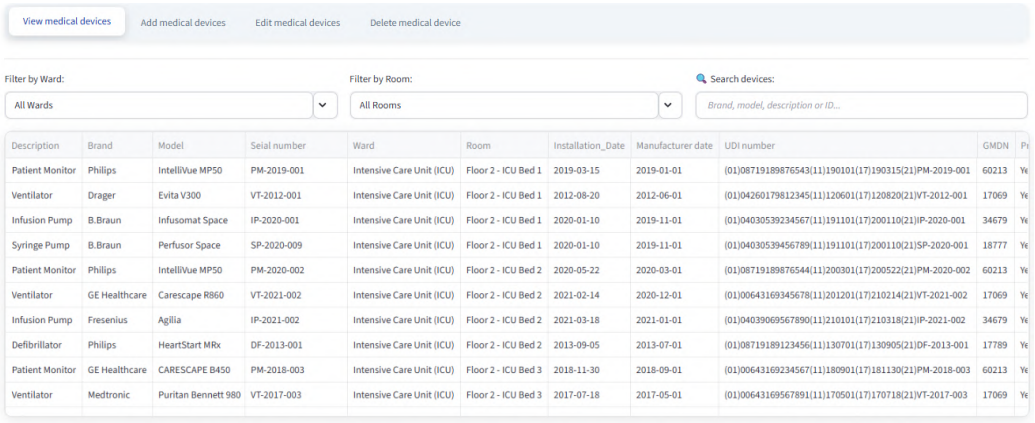
Figure 10.2: E.g. of a User approved.

10.1.2 Equipment inventory

The inventory module serves as the central repository for all medical device information.

View medical devices

The User can visualize the equipment information such as: Description, Brand, Model, Serial number, Ward, Room, Installation date, Manufacturer date, UDI number, GMDN, Present. The information can be filtered by Ward, Room, and by a keyword research applied to the Brand, Model, Description and Serial number.



Description	Brand	Model	Seial number	Ward	Room	Installation_Date	Manufacturer date	UDI number	GMDN	Pr
Patient Monitor	Philips	IntelliVue MP50	PM-2019-001	Intensive Care Unit (ICU)	Floor 2 - ICU Bed 1	2019-03-15	2019-01-01	(01)08719189876543(11)190101(17)190315(21)PM-2019-001	60213	Ye
Ventilator	Drager	Evita V300	VT-2012-001	Intensive Care Unit (ICU)	Floor 2 - ICU Bed 1	2012-08-20	2012-06-01	(01)04260179812345(11)120601(17)120820(21)VT-2012-001	17069	Ye
Infusion Pump	B.Braun	Infusomat Space	IP-2020-001	Intensive Care Unit (ICU)	Floor 2 - ICU Bed 1	2020-01-10	2019-11-01	(01)04030539234567(11)191101(17)200110(21)IP-2020-001	34679	Ye
Syringe Pump	B.Braun	Perfusor Space	SP-2020-009	Intensive Care Unit (ICU)	Floor 2 - ICU Bed 1	2020-01-10	2019-11-01	(01)04030539456789(11)191101(17)200110(21)SP-2020-001	18777	Ye
Patient Monitor	Philips	IntelliVue MP50	PM-2020-002	Intensive Care Unit (ICU)	Floor 2 - ICU Bed 2	2020-05-22	2020-03-01	(01)08719189876544(11)200301(17)200522(21)PM-2020-002	60213	Ye
Ventilator	GE Healthcare	Carescape R860	VT-2021-002	Intensive Care Unit (ICU)	Floor 2 - ICU Bed 2	2021-02-14	2020-12-01	(01)00643169345678(11)201201(17)210214(21)VT-2021-002	17069	Ye
Infusion Pump	Fresenius	Agilia	IP-2021-002	Intensive Care Unit (ICU)	Floor 2 - ICU Bed 2	2021-03-18	2021-01-01	(01)04039069567890(11)210101(17)210318(21)IP-2021-002	34679	Ye
Defibrillator	Philips	HeartStart MRx	DF-2013-001	Intensive Care Unit (ICU)	Floor 2 - ICU Bed 2	2013-09-05	2013-07-01	(01)08719189123456(11)130701(17)130905(21)DF-2013-001	17789	Ye
Patient Monitor	GE Healthcare	CARESCAPE B450	PM-2018-003	Intensive Care Unit (ICU)	Floor 2 - ICU Bed 3	2018-11-30	2018-09-01	(01)00643169234567(11)180901(17)181130(21)PM-2018-003	60213	Ye
Ventilator	Medtronic	Puritan Bennett 980	VT-2017-003	Intensive Care Unit (ICU)	Floor 2 - ICU Bed 3	2017-07-18	2017-05-01	(01)00643169567891(11)170501(17)170718(21)VT-2017-003	17069	Ye

Figure 10.3: Equipment inventory dashboard.

The information visualized in the dashboard in Figure 10.3 can be exported as file excel. The equipment location within the hospital can be easly visualize on a sunburst interactive chart as shown in Figure 10.4

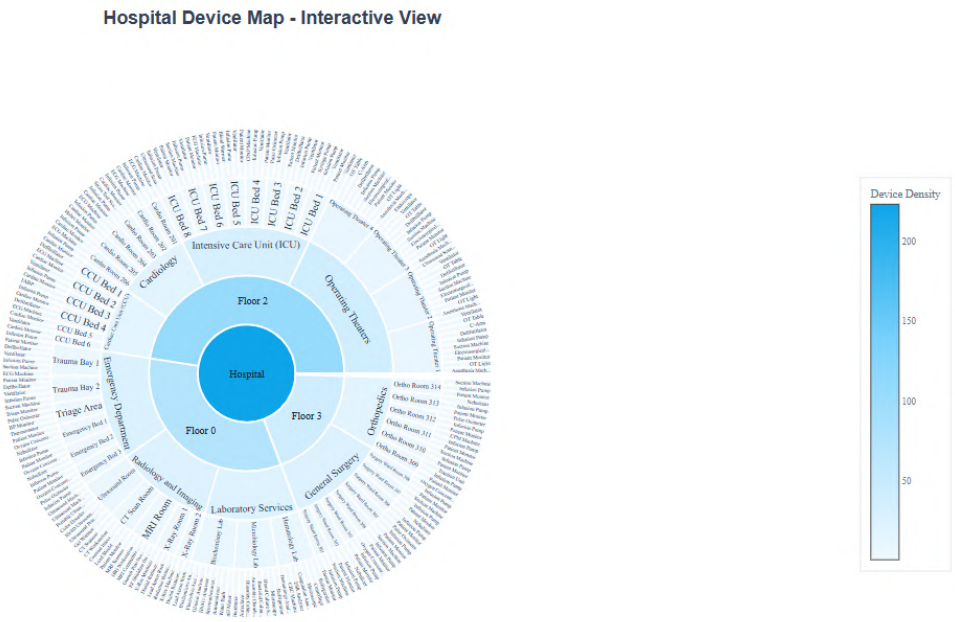


Figure 10.4: Sunburst chart of the equipment location.

Add medical devices

The User can add new the equipment information such as: Description, Brand, Model, Serial number, Room, Installation date, Manufacturer date, UDI number, GMDN. Description, Model and Brand fields are mandatory.

Edit medical device

The User can Edit the equipment information already added in the database, such as: Description, Brand, Model, Serial number, Room, Installation date, Manufacturer date, UDI number, GMDN and Present. Present. To choose the device to edit, the User can search for it filtering by Ward, Room, and by a keyword research applied to the Brand, Model, Description and Serial

number.

Delete medical device

The User can delete equipment. To choose the device to edit, the User can search for it filtering by Ward, Room, and by a keyword research applied to the Brand, Model, Description and Serial number.

10.1.3 Ward & Rooms

The Wards & Rooms module allow to add and remove Wards and rooms.

Add Room

In this page the User can Add a room and its floor, in an already existing Ward. All the Rooms and information regarding the respective floor and ward are displayed in the same page.

Delete Room

The User can select a Room and delete it.

Add Ward

In this page the User can add a ward choosing its name. All the wards already existing are already displayed in the same page.

Delete Ward

The User can select a Ward and delete it.

10.1.4 Preventive maintenance

The preventive maintenance module enables tracking of the preventive maintenance with useful metrics to increase efficiency of the maintenance planning.

Dashboard

The User can visualize some useful key metrics such as the total number of preventive maintenance executed, the overdue ones, the upcoming ones and the completion percentage. Furthermore, the User can visualize:

- A pie chart of different maintenance categories such as Cleaning, Inspection, Calibration, Parts Replacement, Software Update, Preventive.
- A bar chart of the comparison between completed and pending maintenance activities.

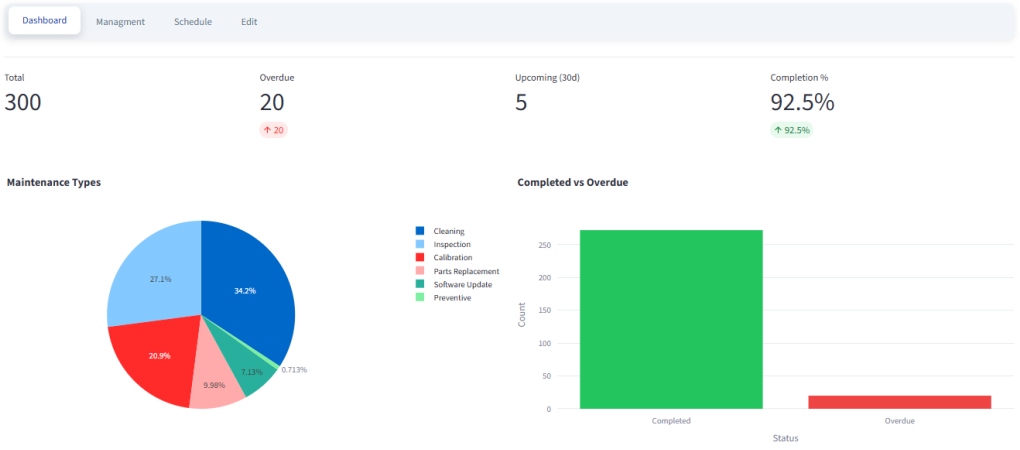


Figure 10.5: Dashboard page of preventive maintenance.

Management

In this page, the User can visualize the information regarding the preventive maintenance such as: Device, Type of maintenance(Cleaning, Inspection, Calibration, Parts Replacement, Software Update, Preventive), Scheduled date, remaining days, status(scheduled, completed, in progress, cancelled), Piority(Critical, High, Medium, Low), Technician, Description. The information can be filtered by type of maintenance, Status and Priority.

The color of the rows of "Days" and "Status" fields, change depending on the amount of days remaining to the the "Scheduled Date": Red if overdue without completion, Yellow if less than 7 days, Green if completed, otherwise no colors are assigned.

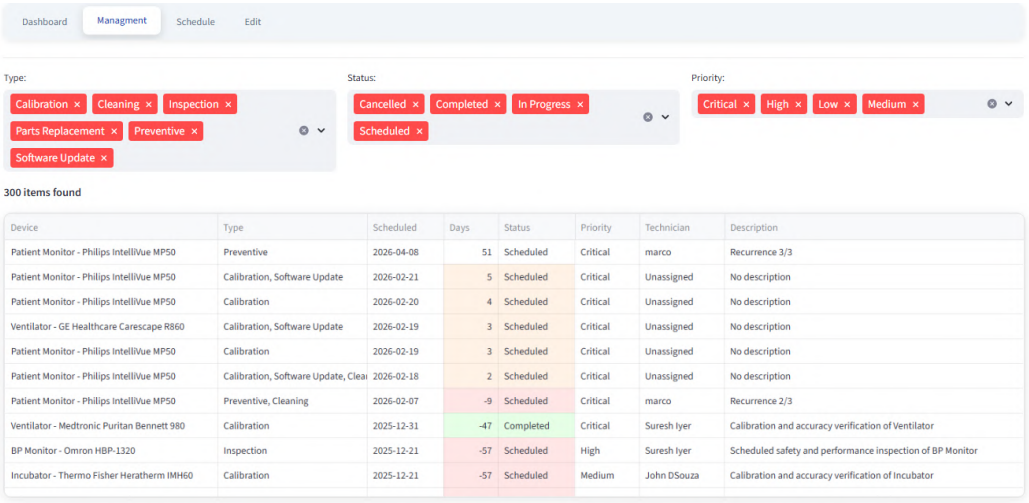


Figure 10.6: Preventive Maintenance Management page.

Schedule

The User can schedule new maintenance activities. The User can select a

device filtering by Ward, Room, and by a keyword research applied to the Brand, Model, Description and Serial number. Once the device is selected can be chosen: the type of maintenance(multiple choice allowed because more type of maintenance are often performed in one time), the Priority, Scheduled date, Technician name, if activate the recurring maintenance(if yes, Frequency in days and max recurrences are mandatory to be added) and Description.

Edit

In this page the User can modify or delete scheduled maintenance activities. The fields that can be modified are the same of the paragraph "Schedule".

10.1.5 Incidents & Repairs

The Incidents & Repairs module provides structured recording of equipment failures and the respective repair.

Dashboard

In this page the User can visualize some useful key metrics such as the total number of incidents, number of opened and closed calls and the number of critical incidents. Furthermore, the User can visualize:

- A pie chart of different priority categories such as Critical, High, Medium, Low.
- A bar chart of the comparison between closed call and opened ones.

- A monthly incident trend graph, where the X-axis represent the months and the Y-axis the number of incidents

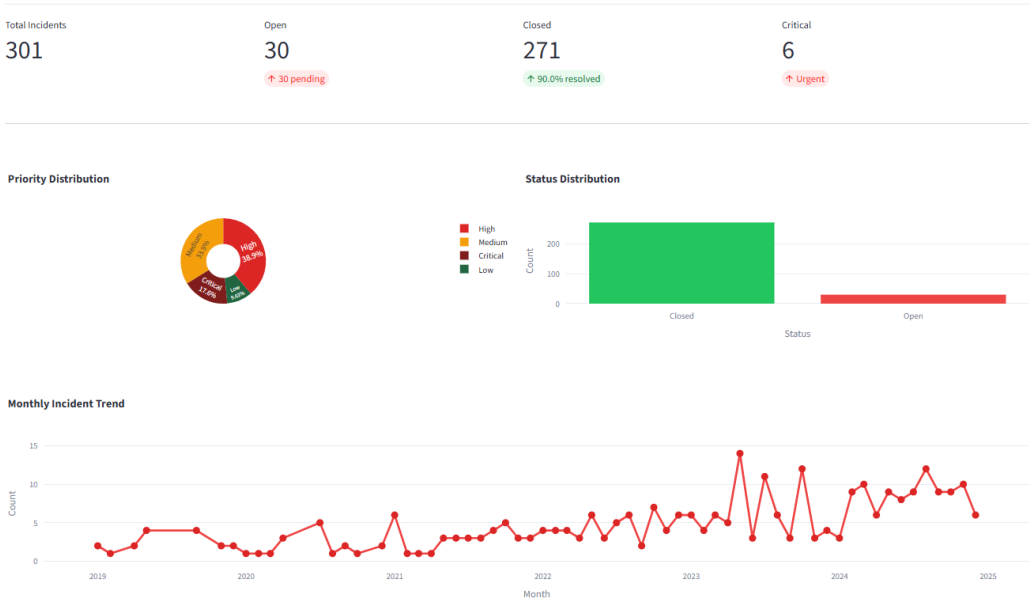


Figure 10.7: Dashboard page of Incidents & Repairs.

View all

The User can visualize the information regarding the Incidents & Repairs such as: Device, Serial number, complaint, Called by, Call date, Call time, Days since, Priority(Critical, High, Medium, Low), Status(Open or Closed), Service Type(in house, warranty, AMC,CMC), Attended by, Attended date, Attended Time, Action Taken, Rectified Date, Rectified Time, Remarks, Time taken to resolve. The User can filter the information by Status, priority, Date and by a keyword research applied to the Brand, Model, Description and Serial number.

The color of the rows of "Status" field, change depending if the call is open or closed: Red if open, green if closed.

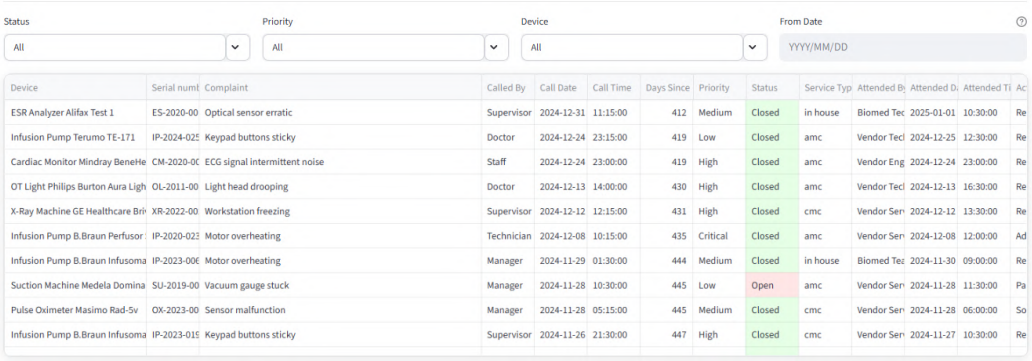


Figure 10.8: View all incidents & repairs page.

Register New

In this page the User can register a new incident and a new repair selecting a device by a keyword research applied to the Brand, Model, Description and Serial number. Once the device is selected can be added: Called by, Call received date, Priority, Call Received Time, Nature of Complaint, Attended by, Attended Date, Time of Attendance, Action Taken, Rectified Date, Rectified Time, Type of Service and Remarks.

Edit/Delete

The User can modify or delete Incidents and repairs registered. The fields that can be modified are the same of the paragraph "Register New".

10.2 Web-platform: Obsolescence module

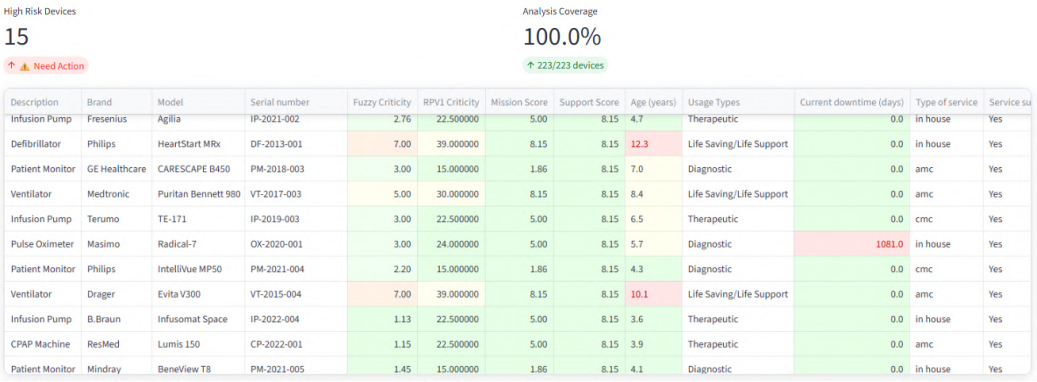
Analysis dashboard: Overview Table

The User can visualize obsolescence score for each device and all the parameters used to compute it. There are two key metrics, one regarding the number of High and Very-High Risk Devices and the other regarding the Analysis coverage percentage.

A table is displayed containing: description of the device, brand, model, serial number, Fuzzy obsolescence score value, RPV1 Criticity score use as comparison and for the validation [3], Mission score(score of the subsystem Mission Criticality), Support score(score of the subsystem Support), Age(years), Usage Types(e.g diagnostic, Life saving/Life support ...), Current downtime(days), Type of service(AMC, CMC, Warranty, in house...), Service Support, Spare parts availability, Backup Available, Ward, Room.

The rows of the following parameters assume generally 3 different colors, green, yellow and red, sometimes also a darker green and orange, based on the thresholds of the parameters as explained in "Revised Fuzzy Logic Obsolescence Algorithm": Fuzzy obsolescence score value, RPV1 Criticity score [3], Mission score, Support score, Age(years), Current downtime(days), Backup Available.

All the data contained in the table can be exported as file excel.



Description	Brand	Model	Serial number	Fuzzy Criticity	RPV1 Criticity	Mission Score	Support Score	Age (years)	Usage Types	Current downtime (days)	Type of service	Service su
Infusion Pump	Fresenius	Agilia	IP-2021-002	2.76	22.500000	5.00	8.15	4.7	Therapeutic	0.0	in house	Yes
Defibrillator	Philips	HeartStart MRx	DF-2013-001	7.00	39.000000	8.15	8.15	12.3	Life Saving/Life Support	0.0	in house	Yes
Patient Monitor	GE Healthcare	CARESCAPE B450	PM-2018-003	3.00	15.000000	1.86	8.15	7.0	Diagnostic	0.0	amc	Yes
Ventilator	Medtronic	Puritan Bennett 980	VT-2017-003	5.00	30.000000	8.15	8.15	8.4	Life Saving/Life Support	0.0	amc	Yes
Infusion Pump	Terumo	TE-171	IP-2019-003	3.00	22.500000	5.00	8.15	6.5	Therapeutic	0.0	cmc	Yes
Pulse Oximeter	Masimo	Radical-7	OX-2020-001	3.00	24.000000	5.00	8.15	5.7	Diagnostic	1081.0	in house	Yes
Patient Monitor	Philips	IntelliVue MP50	PM-2021-004	2.20	15.000000	1.86	8.15	4.3	Diagnostic	0.0	cmc	Yes
Ventilator	Drager	Evita V300	VT-2015-004	7.00	39.000000	8.15	8.15	10.1	Life Saving/Life Support	0.0	amc	Yes
Infusion Pump	B.Braun	Infusomat Space	IP-2022-004	1.13	22.500000	5.00	8.15	3.6	Therapeutic	0.0	in house	Yes
CPAP Machine	ResMed	Lumis 150	CP-2022-001	1.15	22.500000	5.00	8.15	3.9	Therapeutic	0.0	amc	Yes
Patient Monitor	Mindray	BeneView T8	PM-2021-005	1.45	15.000000	1.86	8.15	4.1	Diagnostic	0.0	in house	Yes

Figure 10.9: View all Fuzzy obsolescence scores page.

Analysis dashboard: Score Analytics

In this page are displayed:

- Three metrics: Average criticality score, Average mission score, Average Support score.
- Pie chart Criticality distribution(Very Low, Low, Medium, High, Very High) as shown in Figure 10.10.
- Table containing equipment with High and Very High obsolescence score as shown in Figure 10.10. Only 4 parameters are displayed for each device: Description, Serial number, Criticality and Location.

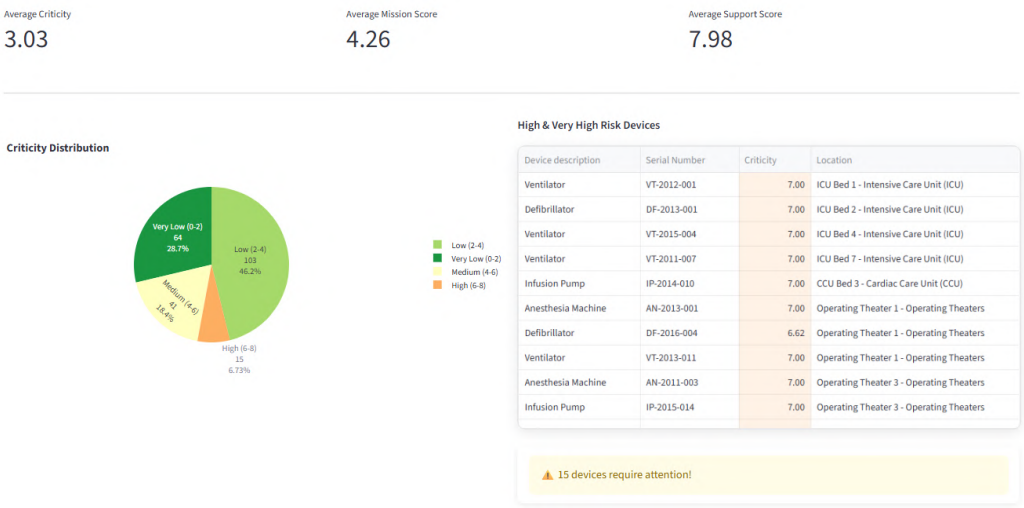


Figure 10.10: Score Analytics page first part.

- Bar chart regarding criticality by device type. As shown in Figure 10.11, the devices are divided in categories(such as X-ray, OT light, ECG, and others) and for each type the bar can have multiple colors corresponding to the level of criticality for each device within the same category. Moreover, a Device category and a range of criticality distribution can be selected to visualize the details with the field chosen.

Figure 10.11: Score Analytics page second part.

Analysis dashboard: Financial Analysis

This page was originally created following the logic of the preliminary algorithm(maintenance cost, cost of the device and maintenance ratio), when sensitive financial data weren't impossible to obtain, this page wasn't utilized anymore. It contains:

- Three metrics: Total asset value, average device value, number of high maintenance ratio devices
- Pie chart of the asset value by ward
- Scatter plot of Maintenance cost ratio vs Asset Value

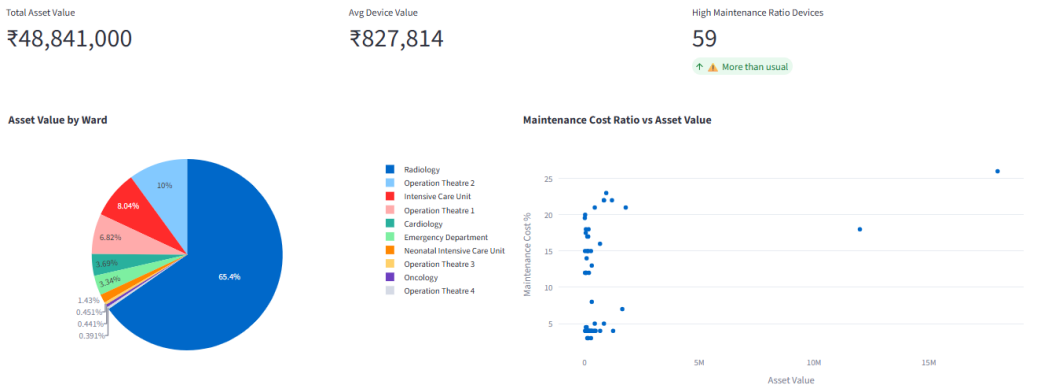


Figure 10.12: Financial Analysis page.

Add score parameters

The User can add and edit the parameters of a single device used in the fuzzy logic algorithm. To choose the device, the User can search for it filtering by Ward, Room, and by a keyword research applied to the Brand, Model, Description and Serial number.

Almost all parameters are generally computed automatically, only the number of backups has to be added manually.

Once the parameters of a device are added, the score for that device is computed automatically. Moreover there is a button to compute the score for all the devices, and three metrics: total number of devices, number of devices ready for the computation and number of devices with missing parameters.

Configure parameters

This page allows the user to modify the fuzzy logic membership functions for the Age and Downtime parameters (e.g., defining what constitutes new,

middle-aged, or old equipment). This flexibility enables the algorithm to be customized to the specific needs of each hospital. A configuration can be selected from the database, with the default being the one developed for this thesis. New configurations can be created, saved to the database, and loaded into the system to recompute all obsolescence scores.

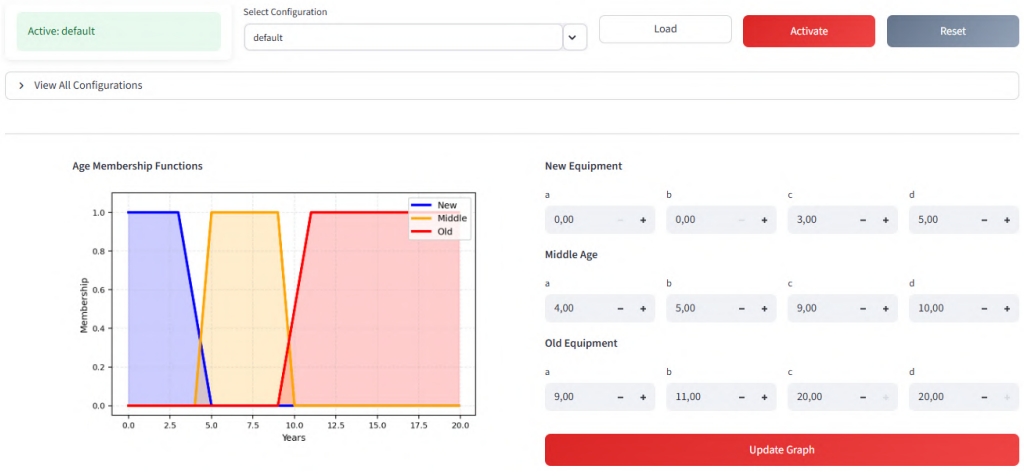


Figure 10.13: Configure parameters page.

10.3 Web-Platform: Cybersecurity module

Dashboard

In this page, as shown in Figure 10.14 the User can visualize:

- Three key metrics: number of devices with vulnerabilities, number of total CVEs, number of critical CVEs, Max CVSS value.
- Table with most critical devices, containing information such as Device Name, Brand, Product, Version, Total number of CVE, Max CVSS,

Number of Critical CVEs, number of High, number of Medium and number of Low.

- Horizontal bar chart showing the distribution of CVEs by severity level. The chart categorizes vulnerabilities into four severity classes (Low, Medium, High, Critical), with bar length proportional to the number of total vulnerabilities identified.

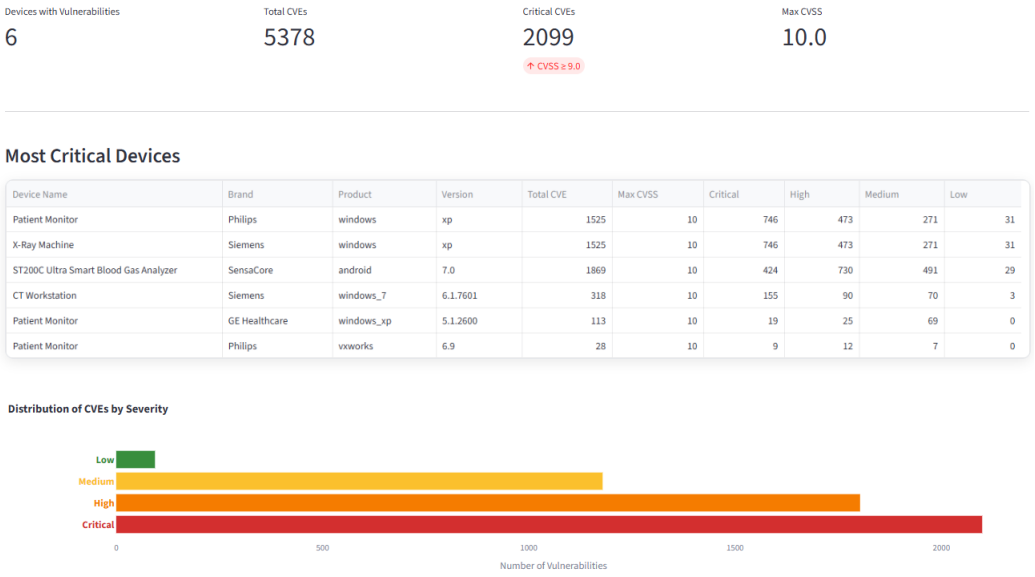


Figure 10.14: Cybersecurity dashboard page.

Search Vulnerabilities

The User can search for known vulnerabilities in NVD, OSV and CIRCL databases. It works:

1. selecting a device using a keyword research applied to the Brand, Model, Description and Serial number

2. Filling out the text boxes regarding the Vendor, Product, Version and IP Address, and clicking on "Add software and search CVE"

3. after a device Software/Firmware is added, it will appear in a list at the end of the page, where clicking on "Search CVE" in the last section, the User can search for vulnerabilities again

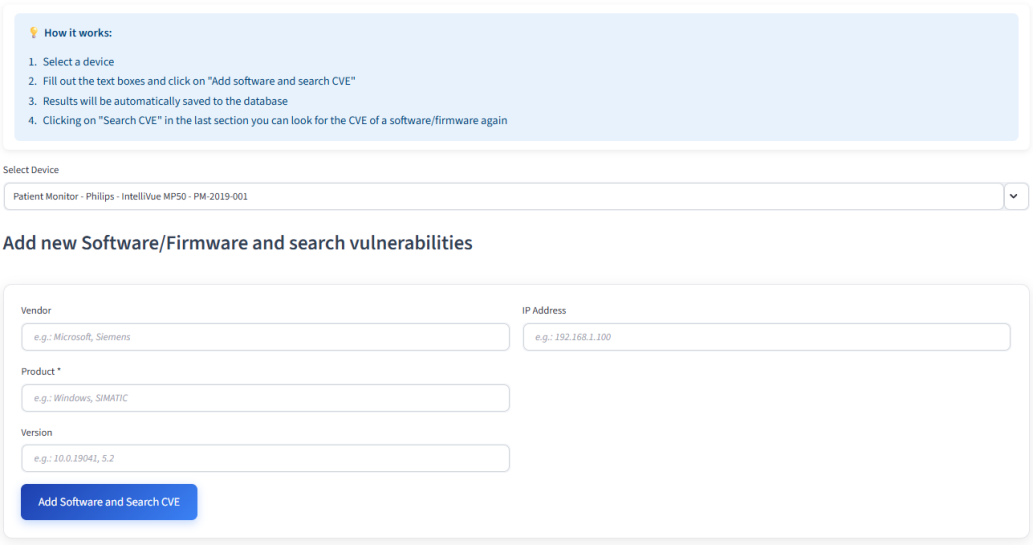


Figure 10.15: Search Vulnerabilities page.

Edit CVE

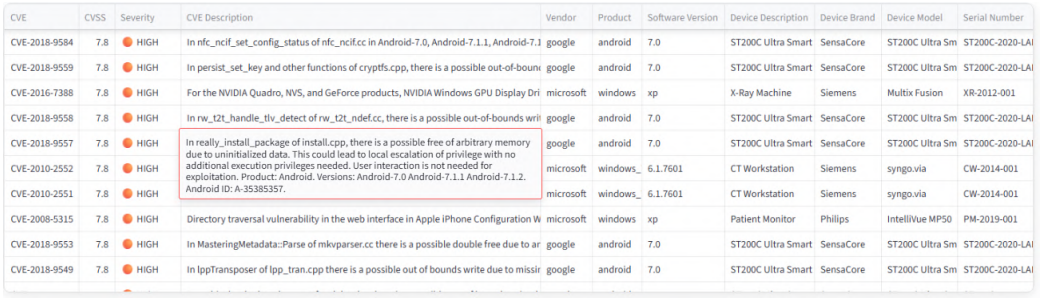
In this page the User can Edit the information of a Software/Firmware. To choose the device and its Software/Firmware, the User can search filtering by Product, Version, and by a keyword research applied to the Brand, Model, Description and Serial number of the device.

Delete Software/Firware/CVE

The user can delete a specific CVE selecting it by its CVE ID. If a CVE exists in more softwares/firmwares, can be deleted from all. Softwares/Firmwares can be select and deleted, filtering by Product, Version, and by a keyword research applied to the Brand, Model, Description and Serial number of the device.

All CVEs

In this page the User can visualize all the CVEs, its CVSS, Severity, CVE description, Vendor, Product, Software/firmware version, device description associated, device brand, device model, device serial number. Moreover the User visualize specific CVE related to CVE-ID, Software/Firmaware and Device using the respective keyword research.



CVE	CVSS	Severity	CVE Description	Vendor	Product	Software Version	Device Description	Device Brand	Device Model	Serial Number
CVE-2018-9584	7.8	HIGH	In nfc_ncif_set_config_status of nfc_ncif.cc in Android-7.0, Android-7.1.1, Android-7.1	google	android	7.0	ST200C Ultra Smart	SensaCore	ST200C Ultra Sm	ST200C-2020-LAI
CVE-2018-9559	7.8	HIGH	In persist_set_key and other functions of cryptfs.cpp, there is a possible out-of-bound	google	android	7.0	ST200C Ultra Smart	SensaCore	ST200C Ultra Sm	ST200C-2020-LAI
CVE-2016-7388	7.8	HIGH	For the NVIDIA Quadro, NVS, and GeForce products, NVIDIA Windows GPU Display Dri	microsoft	windows	xp	X-Ray Machine	Siemens	Multix Fusion	XR-2012-001
CVE-2018-9558	7.8	HIGH	In rw_t2t_handle_tlv_detect of rw_t2t_ndef.cc, there is a possible out-of-bounds writ	google	android	7.0	ST200C Ultra Smart	SensaCore	ST200C Ultra Sm	ST200C-2020-LAI
CVE-2018-9557	7.8	HIGH	In really_install_package of install.cpp, there is a possible free of arbitrary memory due to uninitialized data. This could lead to local escalation of privilege with no additional execution privileges needed. User interaction is not needed for exploitation. Product: Android. Versions: Android-7.0 Android-7.1.1 Android-7.1.2. Android ID: A-35385357.	google	android	7.0	ST200C Ultra Smart	SensaCore	ST200C Ultra Sm	ST200C-2020-LAI
CVE-2010-2552	7.8	HIGH		microsoft	windows_	6.1.7601	CT Workstation	Siemens	syngo.via	CW-2014-001
CVE-2010-2551	7.8	HIGH		microsoft	windows_	6.1.7601	CT Workstation	Siemens	syngo.via	CW-2014-001
CVE-2008-5315	7.8	HIGH	Directory traversal vulnerability in the web interface in Apple iPhone Configuration W	microsoft	windows	xp	Patient Monitor	Philips	IntelliVue MP50	PM-2019-001
CVE-2018-9553	7.8	HIGH	In MasteringMetadata::Parse of mkvparser.cc there is a possible double free due to ar	google	android	7.0	ST200C Ultra Smart	SensaCore	ST200C Ultra Sm	ST200C-2020-LAI
CVE-2018-9549	7.8	HIGH	In IppTransposer of Ipp_tran.cpp there is a possible out of bounds write due to missir	google	android	7.0	ST200C Ultra Smart	SensaCore	ST200C Ultra Sm	ST200C-2020-LAI

Figure 10.16: All CVEs page.

10.4 Database Schema

The PostgreSQL database consists of nine tables: `medical_device`, `room`, `ward`, `breakdown`, `preventive_maintenance`, `scoring_parameters`, `software_versions`,

`cve`, `authorized_users`, and `fuzzy_config`. Each table is identified by a primary key and linked through foreign key constraints following a hierarchical structure, from ward to room to device, with dependent records for maintenance, breakdowns, scoring, and vulnerability data. The full schema is illustrated in the Entity-Relationship Diagram in Figure 10.17.

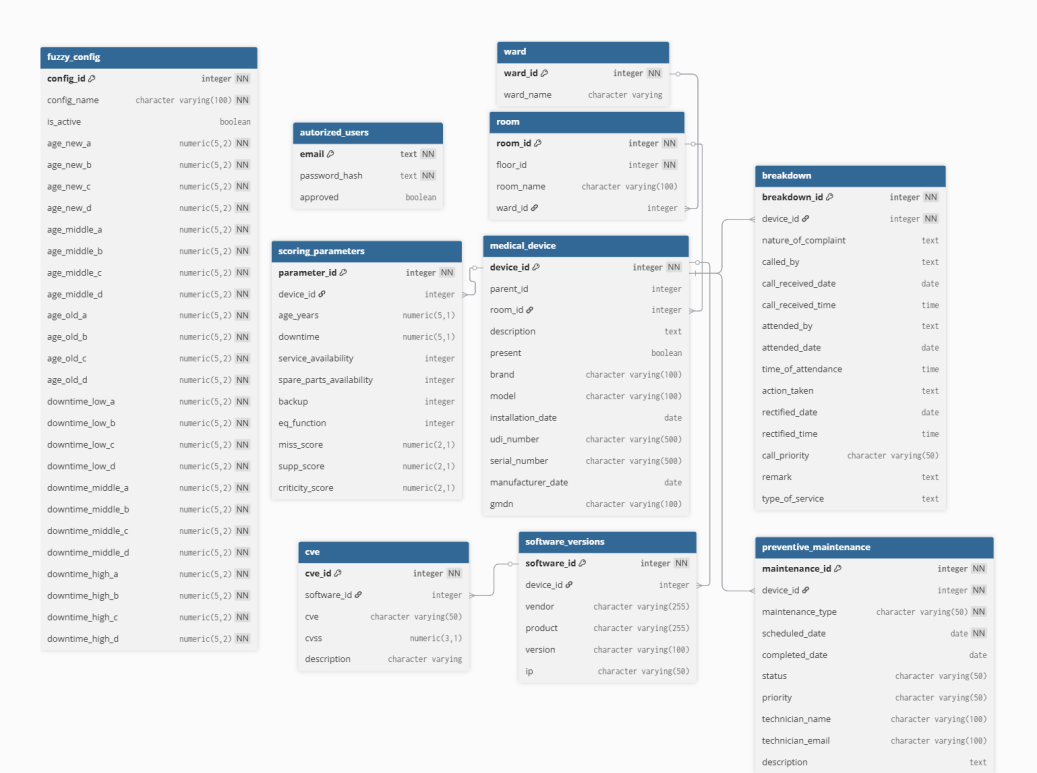


Figure 10.17: Entity-Relationship Diagram of the PostgreSQL database schema.The crow's foot notation indicates one-to-many (1:N) relationships terminating at a foreign key; `NN` denotes a not-null constraint; the key symbol identifies primary keys.

10.5 Iteratively Refined Fuzzy Logic Algorithm and Its Validation

10.5.1 Revised Fuzzy Logic Obsolescence Algorithm

Based on the gap analysis, explained in the methods section, the obsolescence scoring algorithm underwent systematic redesign.

Hierarchical structure The Hierarchical structure formula that determine the number of rules is the same as the formula 9.2. The only difference is the number of subsystem and parameters, varying the number of rules necessary for the fuzzy logic algorithm, firstly from $3^7 = 2187$ to 129 with the preliminary one, than from 129 to 67 with the revised one. The subsystems that have been used for the revised algorithm were the following:

1. **Mission Criticality**
2. **Support level**
3. **Age**

The subsystem " **Cost Level**" was eliminated due to his non-accessibility. In the same way as the preliminary algorithm, the revised one, to produce the overall Criticality output, vary from 0 to 10 and is being classified into five linguistic categories: very low, low, medium, high, and very high. Fuzzy rules within each subsystem encode expert knowledge about how parameters interact. For example, within the Mission Criticality subsystem, typical rules include:

- IF backup availability is none AND equipment function is life-support AND downtime is high THEN mission criticality is very high

Each subsystem processes its inputs through such rules to produce an intermediate output. For instance, the Mission Criticality subsystem might output a value of 7.5 on a 0-10 scale, which is then linguistically classified as high. The three subsystem outputs (Mission Criticality, Support Level, Age) are then used as inputs to produce the final Criticality output, for example:

- IF mission criticality is high AND support level is low AND Cost Level is high AND Age is high THEN overall criticality is very high

Input Parameters The parameters for each subsystem were defined as follows:

- **Mission Criticality** assessed the operational importance of the device through:
  - **Backup availability**: no backup (0), adequate backup (1-2 units), or backup (>3 units), same as in the preliminary algorithm.
  - **Equipment function**: classified as analytical/support, diagnostic, therapeutic, or life-saving/life-support, same as in the preliminary algorithm. Category automatically estimated trough keywords matching of medical equipment's description.
  - **Downtime**: low($downtime \leq 1$), medium($1 < downtime \leq 2$), high($downtime \geq 2$), as suggested from the chief biomedical engineer in Apollo hospital. Thresholds can be modified through the user interface according to its own facility's policy.

- **Support Level** evaluated manufacturer support and supply chain factors:
  - **Service availability**: replaced End of life/end of support, automatically estimated based on the presence of a service contract. "Yes" if a contract is established, "No" instead. The value can be edited in a second moment through the UI.
  - **Spare parts availability**: modified in binary outcome, "Yes" or "No". Automatically estimated as "Yes" if a service contract is established and "No" if not. The value can be edited in a second moment through the UI.
- **Age** was represented by a single parameter:
  - **Device age**: categorized as (age<5), medium age(5≤age<10) and old(age≥10), identical to the preliminary algorithm.

As written in the paragraph "Hierarchical Structure", the new number of parameters and subsystems, as shown also in the table 9.2, reduced the number of linguistic rules adopted from 2187 to 129 and then to 67:

$$N_{rules} = (3 \times 3 \times 4) + (2 \times 2) + (3 \times 3 \times 3) = 36 + 4 + 27 = 67 \text{ rules} \quad (10.1)$$

Subsystem	Preliminary Algorithm	Revised Algorithm
Mission Criticality	- Backup availability(3m) - Equipment function(4m) - Uptime(3m)	- Backup availability(3m) - Equipment function(4m) - Downtime(3m)
Support Level	-End-of-life/End-of-support(3m) - Spare parts (4m)	- Service availability(2m) - Spare parts (2m)
Cost Level	- Maintenance cost ratio(3m)	*Eliminated*
Age	- Device age (3m)	- Device age (3m)
Total Parameters	**7**	**6**
Subsystems	**4**	**3**
Number of total rules	**129**	**67**

Table 10.1: Comparison between preliminary and revised algorithm structure. "m" stands for memberships and the number can be used is the formula 9.2 to compute the total number of rules, as shown in the formula 10.1.

10.5.2 Validation of the Fuzzy Obsolescence Algorithm

As already mentioned in the Methods part, three hospitals gave the permission to use their data to validate the algorithm:

- **Homi Bhabha Cancer Hospital**: main collaboration, the data are being used for the validation stage. The hospital provided anonymized equipment inventory, incident logs, maintenance logs and, furthermore, an extended collaboration with the chief biomedical was established.

- **Indus Hospital**: provided anonymized equipment inventory, incident logs and maintenance logs, but some information were missing that didn't allowed to compute the score and execute the validation.
- **Blood Bank (AMTZ campus)**: data collection was not possible, few operational history due to recent opening.

The validation of the fuzzy logic-based obsolescence algorithm was conducted through a systematic comparison with the RPV1 model used in Galliera hospital [3], derived from the original approach proposed by Fennigkoh [45]. The statistical analysis was performed on a dataset of **129 medical devices** within Homi Bhabha Cancer Hospital, applying four complementary validation metrics: Pearson correlation, Bland-Altman analysis, categorical agreement with Cohen's Kappa, and confusion matrix analysis.

The two systems operate on different numerical scales, to enable a direct comparison, RPV1 scores were normalised by dividing by 10, yielding a common scale $[0, 10]$. Categorical classification thresholds were defined in accordance with the literature.

For RPV1, the criteria of Maggi et al. [3] are adopted:

$$\text{Category}_{\text{RPV1}} = \begin{cases} \textit{Maintain} & \text{if RPV1} < 40 \\ \textit{Reassess} & \text{if } 40 \leq \text{RPV1} \leq 60 \\ \textit{Replace} & \text{if RPV1} > 60 \end{cases} \tag{10.2}$$

For the fuzzy system, the output thresholds were slightly changed to allow the comparison with the RPV1 score. The output was considered having 3 categories instead of 5; the equivalent thresholds on the $[0, 10]$ scale are:

$$\text{Category}_{\text{Fuzzy}} = \begin{cases} \textit{Maintain} & \text{if } S_f < 4 \\ \textit{Reassess} & \text{if } 4 \leq S_f \leq 7 \\ \textit{Replace} & \text{if } S_f > 7 \end{cases} \tag{10.3}$$

Test	**Results**
Pearson Correlation	$r = 0.779 \;\; (p < 0.001), \;\; R^2 = 0.607$
Bland-Altman Analysis	Bias $\bar{d} = -1.228$ 95% LoA: $[-3.241, \; +0.785]$ Coverage: 93.0% (120/129 devices)
Categorical Agreement	Overall accuracy: 81.4% (105/129) Cohen's $\kappa = 0.497$ *Low*: 82.6% *Reassess*: 75.0%
Dataset	129 devices
False negatives vs. RPV1	0
Devices upgraded by Fuzzy	24 (18.6%)

Furthermore, a confusion matrix was computed as shown in figure 10.18, enabling the analysis of agreements and discrepancies for each pair of categories.

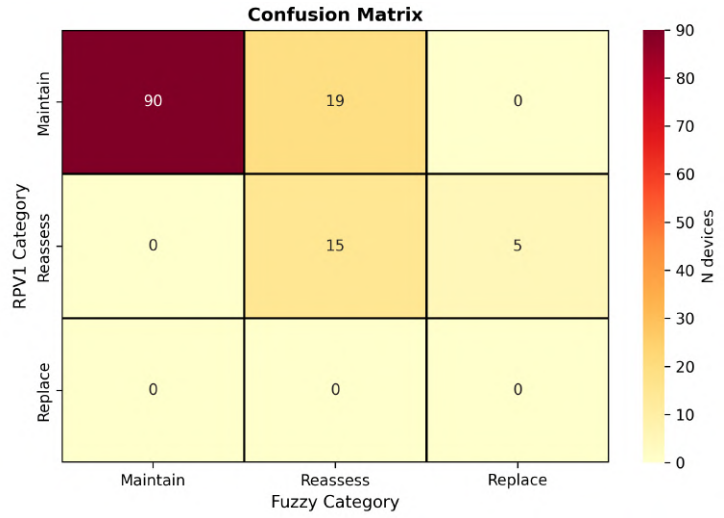


Figure 10.18: Confusion matrix between RPV1 and fuzzy algorithm categories.

All discrepancies are distributed exclusively in the conservative direction: 19 devices classified as *Maintain* by RPV1 are upgraded to *Reassess* by the fuzzy system, and 5 devices classified as *Reassess* are promoted to *Replace*. No case was observed in which the fuzzy system assigned a lower priority than RPV1.

10.6 Outcome of physical connection trials to detect firmware/Software versions

This section reports the outcomes of the physical connection attempts to the two biomedical devices available at the AMTZ campus facilities, **Animal**

Research Center and **Blood Bank**. For each device, all three access methods described in the methodology were executed: serial communication, network communication, and boot sequence monitoring.
The results for each device are presented separately below.

10.6.1 ST-200cc Blood Gas Analyzer (Sensa Core)

Before the connection attempts, the software and firmwares versions of the ST-200cc was partially identified through direct inspection of the device interface. The device operates on **Android 7.0**, with a dedicated application layer identified as **ST-200cc Ultrasmart V3.0.5** (build: 18072023_161345, 18 July 2023). The operating system Android 7.0, reached end-of-support in January 2019 and no longer receives security patches from Google. Searching for known-vulnerabilities on NVD, OSV and CIRCL databases using the web-platform's cybersecurity module, 1,970 vulnerabilities were shown.

Serial Communication

Connection via USB-B port (COM13, Windows) was established at 19200 bps using the PySerial library. Sending the `VER\r\n` ASCII command, the device returned a 64-byte response, confirming physical connectivity. However, the response was not ASCII-encoded: the received data had a binary structure with byte 0x06 (ACK) followed by repeating 0xF8 escape sequences:

```
HEX: 06 F8 06 F8 E6 86 06 F8 00 F8 E6 86 18 F8 66 F8
E6 86 06 F8 78 F8 98 F8 66 F8 1E F8 98 F8 06 F8
80 F8 9E 86 00 F8 00 F8 00 F8 E6 86 00 F8 00 F8
00 F8 9E E0 00 9E E0 00 FF FF FF FF FF FF FF FF
```

Subsequent commands across all tested baud rates using ASTM E1394 commands produced no additional decodable output. The device was found to implement a **proprietary undocumented binary protocol**, incompatible with ASTM E1394 and not publicly documented by Sensa Core. Decoding was not feasible without official protocol documentation, constituting a case of security through obscurity.

Network Communication (LIS)

The device configuration menu indicated LIS connectivity as available, but the **activation procedure was ambiguous** and not documented in publicly available manuals. Contact with the manufacturer's customer support was initiated but no response was received. As a consequence, no HL7 network communication could be established and no version information was extractable via this channel.

Boot Sequence Monitoring

Boot sequence monitoring via RS-232 serial port, using passive listening mode at multiple baud rates, was successful. During device power-on, the initialization sequence transmitted a human-readable message::

```
11-14-25-15:53:17+000-000
ST-200CC
ABG
EM
BLOOD GAS ANALYZER
S/W VERSION:ULTRASMART.3R.013
```

```
Nov-14-25   15:53:19
```

This captured boot message confirmed the internal firmware version designation as **ULTRASMART.3R.013**, which represents the version string embedded in the device firmware, distinct from the application-layer label visible on the user interface (V3.0.5).

10.6.2 KB22 Auto Hematology Analyzer (Krish Biomedical)

Device inspection of the KB22 revealed a multi-component software architecture. The device is manufactured under an OEM/ODM arrangement, with the underlying system platform identified as **Genrui KT-6300 V1.5** rather than a Krish Biomedical. All components versions identified on the device screen is summarized in Table 10.2. Cross-referencing the identified components Genrui KT-6300 V1.5 on NVD, CIRCL, and OSV databases returned no known vulnerabilities.

Component	Version
System Software	V01.05.00.1822
Kernel	V01.01.00.004
Guidance Software	V01.00.00.02
Algorithm	V01.04.00.026
Time Sequence	V01.02.00.018
Language	V01.02.00.03
Printer Driver	V01.01.00.02
Printing Template	V01.01.00.02

Table 10.2: Software version components identified on the KB22 Auto Hematology Analyzer

Serial Communication

USB connection was attempted but the device was not recognized, no virtual COM port being assigned. RS-232 connection was partially established, the device was detected, however, all tested command sequences across multiple baud rates returned no response. **No version information was extractable via serial communication**.

Network Communication (LIS)

The device configuration indicated LIS connectivity on port 6661 (IP: 192.168.5.2) with HL7 bidirectional communication enabled. Port 6661, did not appear in the open port scan under normal conditions. To establish communication, a **virtual LIS server** was deployed and an HL7 ORUˆR01 message was transmitted:

```
MSH|^~\&|Genrui|KT-6300|||20251113155142||ORU^R01|26|P|2.3.1
|||||CHA|UTF-8|||
```

This header confirmed the device identity as **Genrui KT-6300**, consistent with the OEM/ODM nature of the KB22 platform.

Boot Sequence Monitoring

Boot sequence monitoring was not found.

Part IV

Discussion and Conclusion

Chapter 11

Discussion

This chapter interprets and contextualises the results presented in Chapter 10, examining the implications of the platform design choices, the performance of the fuzzy logic obsolescence algorithm, the integration of the cybersecurity module and the limitations encountered within the specific constraints of Indian hospital settings.

11.1 Web Platform Architecture and Design Choices

The modular architecture used for the platform reflects the iterative design methodology described in Chapter 9. Rather than building an unique system, creating separate but complementary functional modules (inventory, preventive maintenance, incidents and repairs, obsolescence, and cybersecurity), it brings two practical advantages: first, hospitals at different stages maturity can adopt different modules, second, considering the rapidly evolving regu-

latory landscape in India, individual modules can be updated or replaced in any time without modifying the rest of the system.

11.2 The Revised Fuzzy Logic Algorithm: Design Choices

The iterative redesign of the fuzzy logic obsolescence algorithm from a preliminary seven-parameter, four-subsystem structure to a refined six-parameter, three-subsystem architecture represents the most significant outcome of the field research phase. Each modification was directly motivated by evidence collected during hospital visits and interviews, making the final algorithm not only a purely theoretical instrument. An interesting observation emerged from comparing the revised algorithm with the existing literature: the parameters chosen after the field research process turned out to be almost identical to those adopted in the RPV1 model by Maggi et al. [3], with the sole exception of the backup availability parameter, which is not considered in RPV1. This convergence was not by design, but rather emerged itself from the constraints of the Indian hospital environment. This convergence give additional credibility to the revised parameter set.

The respective web platform module, was built considering the variety of management types among hospitals: it allow to customize the algorithm thresholds based on hospital-specific internal policies. Further work on this project would also include an automatic validation tool and the possibility to choose different algorithms to compute the score.

11.2.1 Interpretation of Validation Results

The Pearson correlation coefficient of $r = 0.779$ ($p < 0.001$, $R^2 = 0.607$) indicates a strong linear relationship between the two scoring systems. This outcome is consistent with what might be expected: a perfect correlation would, in fact, not add independent information relative to the reference model. Categorical agreement of 81.4% (105 out of 129 devices) indicates that, for the large majority of devices, the two systems give the same outcome. The most clinically significant finding of the validation is the directional consistency of all discrepancies. Of the 24 devices (18.6%) where the fuzzy system and RPV1 assigned different categories, every single discrepancy consists of the fuzzy system assigning a higher priority than RPV1. Specifically, 19 devices classified as Maintain by RPV1 were upgraded to Reassess by the fuzzy system, and 5 devices classified as Reassess were promoted to Replace. No case was observed in which the fuzzy system assigned a lower priority than RPV1. The fuzzy system, not having hard threshold as in the RPV1 algorithm, is more likely to give an higher outcome than a lower one. From a patient safety perspective, a false negative is far more severe than a false positive. This property is not a limitation but an added value. The Bland-Altman analysis provides further quantitative support for this interpretation. The mean bias of $\bar{d} = -1.228$ means that the fuzzy system score higher tha RPV1 and the limits of agreement of $[-3.241, +0.785]$ confirms the conservative nature of the discrepancies. In the same way, the study of Maggi et. al. [3] revealed a conservative nature of the fuzzy algorithm respect to the linear one.

11.2.2 Validation Dataset Limitations

The validation was conducted on data from a single hospital, Homi Bhabha Cancer Hospital, which is a specialised oncology facility. This specialisation has important implications for the generalisability of the results. Indus Hospital, the second collaborating facility, was unable to provide complete data due to missing parameter values, while the Blood Bank within the AMTZ campus could not participate due to its recent opening. These constraints represents a significant limitation of the study. Future validation studies should include a more diverse sample of facilities, ideally ranging different hospital levels(tertiary, secondary, and primary care) and different models(public, private, and public-private partnership).

11.3 Cybersecurity Module

The integration of a cybersecurity vulnerability assessment module within a biomedical equipment management platform represents a novel contribution. It aligns with the direction being pursued at the European institutional level. The EU-funded SEPTON project (Security Protection Tools for Networked Medical Devices), financed under the Horizon Europe program with a total budget of approximately 4.9 million euros, identifies vulnerability assessment of networked medical devices as one of its four core objectives [71]. The documented cases of cyberattacks on healthcare infrastructures discussed in Chapter 8 illustrate that this risk is not theoretical. In the Indian context specifically, the rapid development and, at the same time, the use of outdated devices, creates a particularly acute vulnerability risk. Cybersecurity

is an open problem in the field, rather than a peripheral concern. No prior system documented in the literature combines fuzzy logic-based obsolescence assessment with automated CVE (Common Vulnerabilities and Exposures) lookup from multiple databases (NVD, CIRCL, and OSV) in a unified hospital management tool. The multi-database search approach (NVD, CIRCL, OSV) adopted in the implementation addresses the limitation of single-source CVE lookups: each database has different coverage and update frequencies, relying on a single source may result in missed vulnerabilities.

11.4 Limitations

The validation dataset was executed from a single, specialised oncology facility and the algorithm was developed not considering the use of the devices over their life-span and the use of refurbished devices.

The physical connection trials highlighted the difficulties to connect to detect the firmware/firmware versions automatically and highlighted the different security protocols and ways to access a device.

Finally, the platform has been developed as a research prototype; a transition to production deployment would require additional work on scalability testing, formal security audit, and regulatory compliance assessment under CDSCO guidelines. Turning to future work, it would regards mainly scalability testing, security protocols, and regulatory compliance under CDSCO guidelines, followed by an expanded validation study covering a more diverse sample of Indian healthcare facilities and a transition to network-based firmware and software version detection, removing the current dependency

on physical device access.

11.5 Reflections on the Field Research Methodology

The iterative, user-centred methodology, moving from prototype development to field validation and back to the algorithm refinement, proved to be essential to create a system that reflects the operational realities of Indian hospitals. Several insights that are being obtained during the field research phase could not have been anticipated in the previous sections. In the Chapter 9 section 9.2.2, the outcome of the formal interviews to the question 3 (When do you decide to dispose a device?) was: "It was told that every device is disposed after the contracts expiring date". Findings revealed that this is frequently not the case in practice, refurbished and post-contract devices remain active across many Indian facilities. India is taking steps to regulate this phenomenon but the gap is still significant. The algorithm that was built in the study does not address this challenge.

Another important consideration in that the divergence between the parameter sets assumed in the preliminary algorithm and the data actually available in hospitals involved in this research, illustrates a challenge in the application of quantitative methods to healthcare settings in low and middle income countries: the gap between the data that obsolescence algorithms require and the data that institutions can provide is frequently wider than the literature suggests, because the literature is largely based on studies conducted in high-income country hospital systems with more mature hospitals. The

international nature of this research, involving interactions with biomedical engineers from India, Ghana, and Italy, gave more value to the design process. This comparative perspective, helped identify which features of the Italian healthcare management approach(e.g. the RPV1 model) were transferable.

Chapter 12

Conclusion

This thesis presented the design and validation of an integrated web-based platform for biomedical equipment management, developed specifically for deployment in Indian hospital settings. The work was carried out over a six-month research period at the Andhra Pradesh MedTech Zone(AMTZ) in Visakhapatnam, in collaboration with Homi Bhabha Cancer Hospital, Apollo Hospital and Indus Hospital.

The obsolescence scoring algorithm for biomedical devices represents the first documented one in the scientific literature, specifically designed for the Indian healthcare context. The principal contributions of this work can be summarised as follows.

A modular biomedical devices management web-platform.

The developed web-platform include a device inventory, ward and room organisation, preventive maintenance scheduling, incident and repair tracking, obsolescence scoring, and cybersecurity vulnerability assessment. The mod-

ular architecture ensures that individual components can be adopted incrementally by hospitals at different stages of maturity, without requiring the entire platform.

An Indian context validated fuzzy logic obsolescence algorithm. The final revised algorithm uses six parameter, three subsystem hierarchical fuzzy inference architecture, reducing the fuzzy rules to 67 (compared to the 2187 rules that would have been required without subsystem and seven parameters). The final algorithm was designed around parameters that Indian hospitals can realistically collect, rather than parameters they should theoretically collect. The validation against the RPV1 on 129 devices from Homi Bhabha Cancer Hospital demonstrated a moderately strong correlation and categorical agreement of 81.4%. The validation revealed a consistent conservative bias: the fuzzy system upgraded 24 devices (18.6%) to higher priority categories relative to RPV1, with zero false negatives. This trend to upgrade the outcome instead of downgrade it, is due to nature of the fuzzy logic, which thresholds are fuzzy as the name says by itself.

An integrated cybersecurity vulnerability assessment module. The platform's cybersecurity module enables the research of vulnerabilities from the NVD, CIRCL, and OSV databases, linked directly to specific devices in the inventory. Not only the cybersecurity assessment module but also the combination of obsolescence scoring and cybersecurity assessment within a single platform is a novel contribution.

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