

MASTER THESIS

Thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Engineering at the University of Applied Sciences Technikum Wien - Degree Program Biomedical Engineering Sciences

A Gnu Health Monitoring Module

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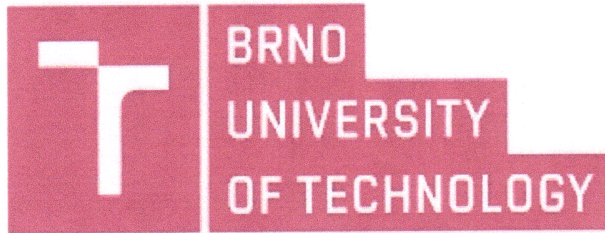
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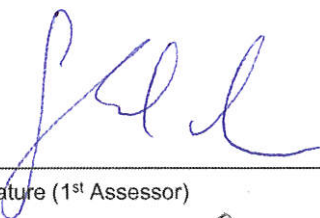
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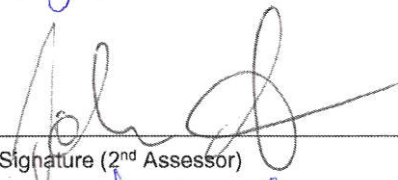
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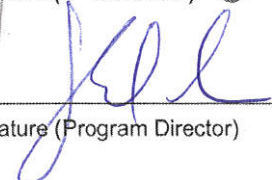
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Abstract

This thesis focuses on the development of a GNU Health Module for electrocardiogram monitoring and the development of an application providing a fundamental electrocardiogram analysis. The theoretical part contains a brief introduction to hospital information systems including electronic patient record and healthcare data standards information, followed by a description of the GNU Health application and the implementation of the electrocardiogram analysis, written in the Python programming language. The practical part deals with the development of the GNU Health Monitoring module and the external application for signal analysis. The results, discussion and the conclusion follow.

Keywords: Hospital Information System, Gnu Health, Tryton, Monitoring Module, Python ECG Analysis

Kurzfassung

Diese Arbeit befasst sich mit der Entwicklung eines GNU-Gesundheitsmoduls zur Elektrokardiogrammberwachung und der Entwicklung einer Anwendung, die eine grundlegende Elektrokardiogrammanalyse bereitstellt. Der theoretische Teil enthält eine kurze Einführung in Krankenhausinformationssysteme, einschließlich Informationen zu Patientenakten und Gesundheitsdatenstandards, gefolgt von einer Beschreibung der GNU Health-Anwendung und der Implementierung der Elektrokardiogramm-Analyse, die in der Programmiersprache Python geschrieben ist. Der praktische Teil befasst sich mit der Entwicklung des GNU Health Monitoring Moduls und der externen Anwendung zur Signalanalyse, gefolgt von Ergebnissen, Diskussion und Schlussfolgerung.

Keywords: Krankenhausinformationssystem, GNU Health, Tryton, Überwachungsmodul, Python-EKG-Analyse

Abstrakt

Tato práce se zaměřuje na tvorbu GNU Health modulu pro monitorování elektrokardiogramu a vývoj aplikace poskytující základní elektrokardiogramovou analýzu. Teoretická část obsahuje stručný úvod do nemocničních informačních systémů včetně elektronických záznamů o pacientech a standardech zdravotnických dat, následuje popis aplikace GNU Health a implementace elektrokardiogramové analýzy napsané v programovacím jazyce Python. Praktická část se zabývá vývojem GNU Health modulu pro monitorování a externí aplikace pro analýzu signálů. Následují výsledky, diskuze a závěr.

Keywords: Nemocniční informační systém, GNU Health, Tryton, Modul pro monitorování, Python EKG Analýza

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1 List of Abbreviations

HIS ... Hospital Information System
GDPR ... General Data Protection Regulation
NIST ... National Institute of Standards and Technology
LIMS ... Laboratory Information System
HMIS ... Hospital Management Information System
EPD ... Electronic Patient Dossier
IZIP ... Electronic Health Book
DSI ... Digital Service Infrastructure
CEF ... Connecting Europe Facility
id ... Identification Number
ICU ... Intensive Care Unit
LAB ... Laboratory
AMB ... Ambulance
PC ... Personal Computer
NB ... Notebook
RTG ... Radiology
PACS ... Picture Archiving and Communications system
DICOM ... Digital Imaging and Communications in Medicine
NCPDP ... National Council for Prescription Drug Programs
ASTMInternational ... American Society for Testing and Materials
HL7 ... Health Level Seven
ICD9 ... International Classification of Diseases, Ninth Revision
WHO ... World Health Organization
ICF ... International Classification of Functioning, Disability and Health
APACHEII ... Acute Physiology and Chronic Health Evaluation II
GCS ... Glasgow Coma Scale
EPR ... Electronic Patient Record
XML ... Extensible Markup Language
JSON ... JavaScript Object Notation

ECG ... Electrocardiogram

CT ... Computerized Tomography

MRI ... Magnetic Resonance Imaging

TFT ... Short-time Fourier Transform

DWT ... Discrete Wavelet Transform

TKEO ... Teager-Kaiser Energy Operator

SD1 ... Standard Deviation of the Poincaré Plot Perpendicular to the Line-of-identity

SD2 ... Standard Deviation of the Poincaré Plot Perpendicular along the Line-of-identity

HRV ... Heart Rate Variability

S ... Sensitivity

P ... Predictivity

2 Introduction: Hospital Information Systems (HIS)

A hospital information system (HIS) is a set of technical and programmatic resources, that provide a paperless computing environment for the needs of the hospital, its departments and other health services. The users with varying degrees of authority are allowed to collect simultaneously, process, store, analyse and display the required information related to the individual patient. [1], [2]

A HIS consists of several information subsystems with many interrelationships, that provide a communication link between departments. The importance of interdisciplinary cooperation increases. [1]

Each subsystem could be designed differently and has a specific function focused on its needs. There could be included modules for finance associated with economic parameters such as costs, reports and purchase, administration dealing with scheduling, admission and discharge patients, medical module for cardiology, pediatrics, genetics, surgery, intensive care unit, urology, gynecology and other departments, laboratory for providing test requests, results, pharmacy and stock management for storing and manipulating medicaments and others. [1]

One of the reasons for using a HIS was the need to bring order to a hospital, medical and patient data associated with trying to obtain more comprehensive patient data and new knowledge, that are relatively independent of the location and time of collection. A HIS increases the effectiveness of public healthcare, streamlines the process of documentation of individual activities, accelerates transmission, retrieval, and display of information, improves the organisation of work and eliminates recurrent unproductive activities. It prevents potential conflicts arising from possible misunderstandings and lack of knowledge. All of this reduces healthcare costs. [1], [2]

A HIS must be able to handle large data with a wide range of many different formats for multiple users with different levels of competence. It can be assumed that more computers are connected to the hospital server. Its operation is associated with high demands on the stability and quality of devices, software, technical and program support, database and security. [2], [1]

2.1 Security

A large number of different healthcare professionals have access to a hospital information system. This fact also increases the risk of abuse. The data must be capped confidential and

secure. The security involves the technical (quality of devices and its adequate maintenance) and data management terms (data loss, misuse, fishing or differentiated data access). [3], [2],

The National Institute of Standards and Technology provides standards, guidelines, tools and technologies to protect information systems against threats to the confidentiality and integrity of information and processes availability of information and services. [4]

The data security has to comply the General Data Protection Regulation (GDPR) valid from May 2018, that protects EU citizen's personal data with no interest of the place, where data were collected, processed, or stored. It defines three types of sensitive personal data requiring special protection (data concerning health, genetic data, and biometric data). The GDPR prohibits any kind of processing of these data for these unless explicit consent is given or very specific conditions are met but are permissible for assessing working capacity for employment, for the management of health or social care systems, and services, or for the public interest. [5]

Adequate attention has to be taken in all phases of managing data in an entry, storage, use, and transfer. [3], [2], [1]

A good firewall is necessary.

Access to HIS is different for users with varying degrees of authority and is subjected to a password, that should be unique, strong enough and changing over time. Sensitive information is encrypted. Each object has an owner with all access rights to it, that could decide the level of rights to other authenticated users, that is written in the access control list and matrix. Even so, the audibility is required. [1]

The integrity and correctness of the information is controlled during the entry process. [2]

To avoid data loss, information must be backed up frequently. The process usually happens at the time of the least system load, at night. Backups are created on an external disk and are kept for a certain period of time. [2], [1]

One part of the security policy is also a disaster planning and solving unexpected difficulties. The personal staff must be adequately instructed. [6], [2]

2.2 Database

The database is an entity designed for managing a large amount of data in different formats, that includes demographics (date of birth, gender, ethnic origin, marital status, emergency information, etc.) and administrative information (eligibility, membership of the health insurance, charges and amounts paid, etc.), health risks and health status(lifestyle, family history, genetic factors, patient medical history, test results, etc.). [7]

The data should be accuracy and completeness. The information is continuously supplemented overtime on a daily bases, and the system should allow correcting errors found at a later time. [8], [7]

The database works with different data formats (character, string, numeric, graphs, dates, etc.), that are managed according to the healthcare data standards and terminologies. See in chapter 2.4.

The database could be connected to the hospital information system in two ways:

- **Centralized database**

A HIS with a centralised database is embedded in a network of unconnected computers that meet different user requirements and needs (See in Figure ??). It provides easier maintenance but must withstand high peak loads. [2]

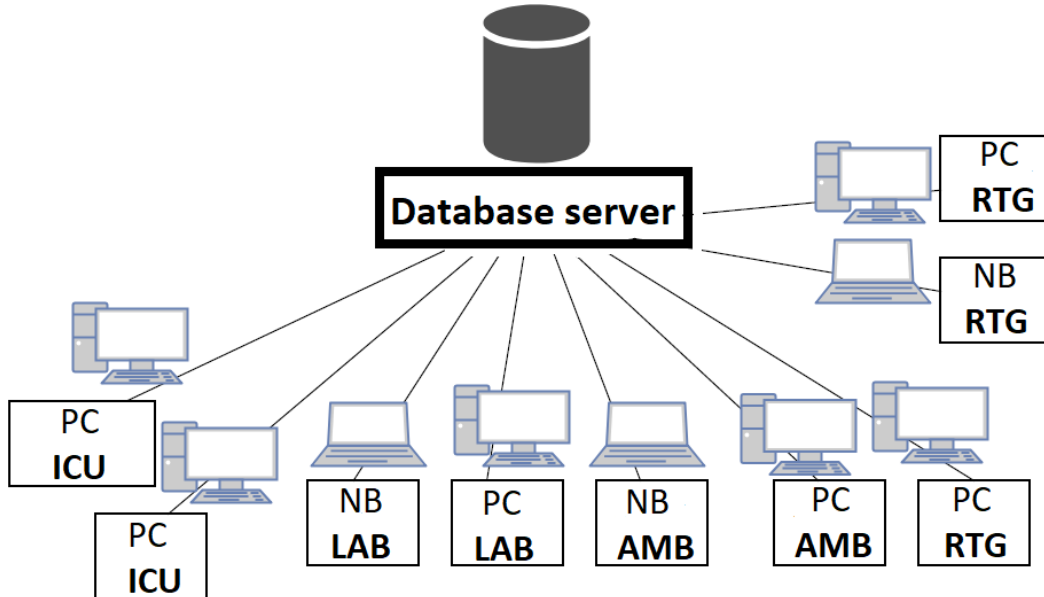


Figure 1: **HIS with centralized database** creates a network of unconnected computers that communicate with a database server. [2]

- **Distributed database**

A HIS with a distributed database is a system of connected subsystems with distributed data (See in Figure 2). Each subsystem can work alone, and data could be made available only to users of this subsystem or to all. A set of data is used in all subsystems. This structure uses an integrated communication server that manages common data and application, exchanges data and provides a Simple Network Management Protocol, that monitors devices and gives information about it to the network manager. [2]

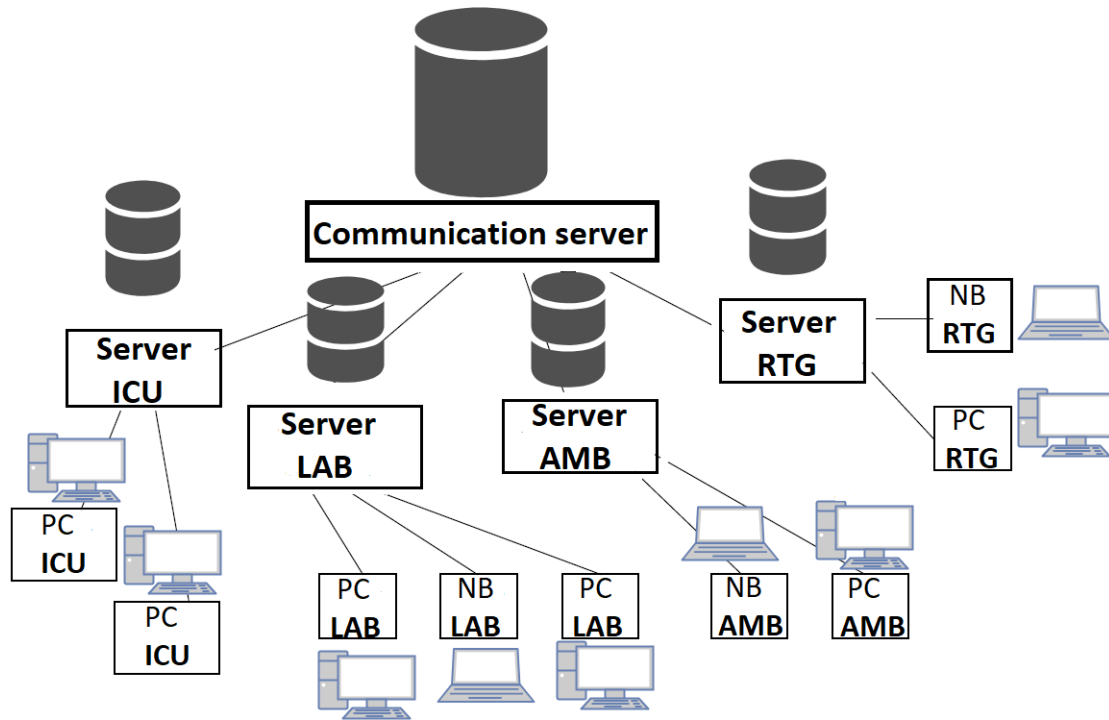


Figure 2: **HIS with distributed database** consists of several subsystems for specific needs with their database servers, that communicate with the central server. [2]

2.3 Electronic Patient Record (EPR)

The healthcare industry is seeking to create a comprehensive record of the individual, called universal electronic patient record (EPR). It is an electronic repository of administrative and clinical patient information in one place identified by an identifier. It is an entity that consists of partial data from a patient and several hospital information systems, where the patient gets care. See in Figure 3 [9], [10], [11]

A EPR places demands on what each system has to meet to contribute and receive data. There are standards and policies for access and control, security, authentication, data storage, archival and retrieval, risk management, data integrity, and system availability. To its creation, universal data standards unifying and gathering information from different information systems are key. [10]

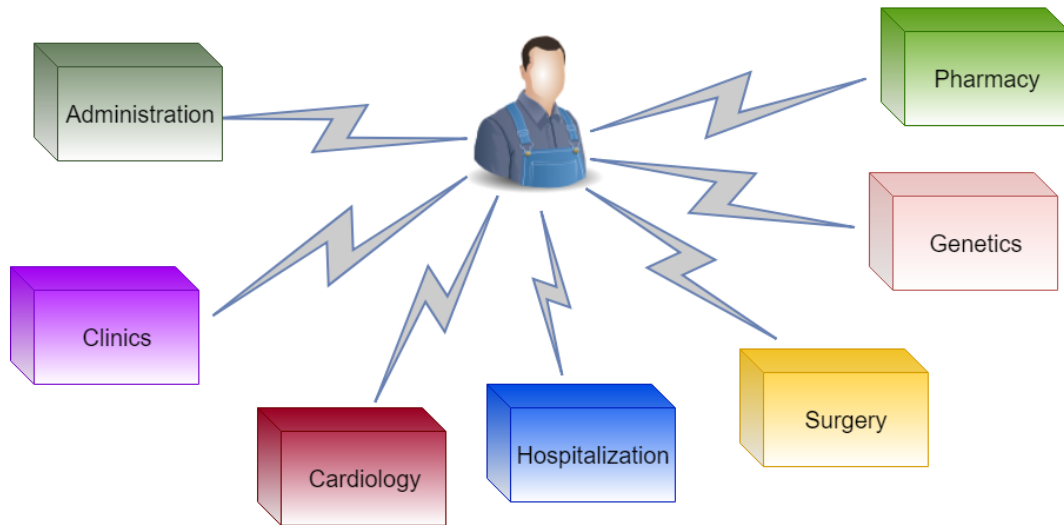


Figure 3: **Electronic Patient Record (EPR)**: serves as an electronic health book of an individual to whom only authorised persons have access. The patient stays in the centre and the hospital wards around him.

2.3.1 National Healthcare Records

A EPR is gradually implemented in the countries of Europe (Czech Republic, Austria, Switzerland, etc.) and some other countries of the world (United States, Australia, Canada, etc.).

In the Czech Republic a EHR is represented by electronic health book (IZIP), that provides relevant information about all contacts of the patient with healthcare services (regular visits to general practitioners, dental treatments, laboratory and imaging tests. The system was developed by a private company IZIP in cooperation with the General Health Insurance Company of the Czech Republic and fully implemented in 2003. [12]

In Austria, a EPR is represented by ELGA. It covers the rights of patients to have quick and convenient access to their own health data. It provides the medical and nursing discharge letters of the public hospitals, laboratory and radiology findings and medication data. The system is gradually implemented from December 2015. [13], [14]

In Switzerland, a EPR is entitled electronic patient dossier (EPD). The patients must grant each provider access to their EPD, at one of three access levels and will could with the approved healthcare providers register the information on patient visits and treatments to EPD. It will be valid up to year 2020 [15], [16]

The eHealth Digital Service Infrastructure (eHealth DSI), program of the European Union, takes care of running information services for cross-border health data exchange under the Connecting Europe Facility (CEF). The program starts deploying the core generic services for patient summary, that allows the health professionals to get to the verified health patient data during an unplanned care encounter while abroad, and ePrescription enabling patients to re-

ceive equivalent medication treatment while abroad to their home treatment. The deploying countries are shown in Figure 4. [13], [17], [18]

eHealth DSI Deploying Countries		
	PS	eP
Austria	♥	♥
Croatia	♥	♥
Cyprus	♥	♥
Czech Republic	♥	
Estonia	♥	♥
Finland		♥
France	♥	
Germany	♥	
Greece	♥	♥
Hungary	♥	♥
Ireland	♥	♥
Italy	♥	♥
Luxembourg	♥	
Malta	♥	
Portugal	♥	♥
Sweden		♥
Switzerland	♥	♥

Figure 4: **eHealth DSI Deploying Countries:** are the countries of European Union, that implement the patient summary or ePrescription to their healthcare. [18]

2.4 Healthcare Data Standards

A data standard is an essential component for the transmission of information between multiple healthcare information systems. It is a unifying component that facilitates the communication of different healthcare providers. It guarantees unity, reusability, greater consistency and complexity of information. [19]

The data standards define the methods, protocols, terminologies, and specifications for the architecture of medical documents, healthcare records, applications, images, devices, and ad-

ministrative processes. [19]

Data exchange standards give message format, document architecture, clinical templates, user interface, and patient data linkage. The widely used ones are [19]:

- **Health Level Seven (HL7)**

Health level seven defines three data standards (V2, CDA and FHIR).

V2 is the primary data interchange standard for clinical messaging. It is independent of the operating systems and programming languages. It designs an abbreviated specification for structures of network communications on the seventh layer of the communication model ISO. It preferably transmits short messages or information with higher priority. [19], [20]

CDA is a document standard defining the structure and semantics of clinical documents for exchange between healthcare providers and patients. [20]

FHIR is an interoperability standard including a content model in the form of resources, and a specification for the exchange of these resources, messaging and documents in the form of real-time RESTful interfaces. The standard facilitates the exchange of information between healthcare organisations. [20]

- **Digital Imaging and Communications in Medicine (DICOM)**

Digital Imaging and Communications in Medicine (DICOM) is a complex standard for processing, storage, printing and transmission of image information in medicine. It is a complete protocol that defines the form and the flow with required elements to convey images and related information with adequate automatic interoperability between biomedical imaging systems from the application layer to bit-stream encoding. It can communicate over the Internet. [21], [2]

DICOM interface could be used in image acquisition equipment such as computed tomography, magnetic resonance imaging, computed radiography, and ultrasonography, in image archives, image processing devices and image display workstations, or hard-copy output devices such as photographic transparency film and paper printers. [21], [22]

DICOM provides a standard template of attributes, that represent entities such as images, procedures or interpretation reports. Their specifications are documented in the information object description. It is an abstract description of a class of entities. Each class is specified differently. The typical classes are for text, code, measurement, image, sound, curve, and waveform. The receiving device is aware of the information structure of the class before receiving it. [21]

DICOM uses a shared understanding between the client and server of the information structure of objects, that allows storage and retrieval of entities by a clinically relevant indexing system based on image attributes. The entity could be searched by an appropriate query key like the patient's name. [21]

- **ISO/IEEE 11073**

ISO/IEEE 11073 is a family of standards, that specifies a communication protocol for a distributed system of point-of-care medical devices and medical IT systems, that need to exchange data, or safely control networked point-of-care medical devices by profiling web service specifications. [23]

- **National Council for Prescription Drug Programs (NCPDP)**

The National Council for Prescription Drug Programs (NCPDP) are used by retail pharmacies. [19]

- **American Society for Testing and Materials (ASTM International)**

The ASTM International provides several clinical EHR standards, data standards, and protocols for security and privacy. [10]

- **Nomenclature of Medical Devices**

The Nomenclature of Medical Devices is a coding system for the identification of medical devices and related health products. Several naming for medical devices is used by a different group of health professionals depending on the needs (maintenance, procurement, accounting, stock keeping, regulatory affairs, and adverse medical device event reporting). [24]

The standard of terminologies provides the rules for the description of the disease in different HIS. It should include semantic interoperability.

- **International Classification of Diseases (ICD)**

The International Classification of Diseases is a standard reporting patient diagnosis and inpatient procedures for billing purpose. It helps to compare the quality of the health-care systems and services. It classifies diagnoses and medical procedures. The code is composed of three to five alphanumeric characters, a letter representing the group of the disease (diseases of the circulatory system, skin, nervous system, etc.) and a digit specifying the diagnose in detail. ICD is simple, but not sufficiently clear. It is inappropriate to clinical practice with the necessary more advanced diagnosis. [10], [25], [2]

- **International Classification of Functioning, Disability and Health (ICF)**

International Classification of Functioning, Disability and Health (ICF) is a standard for the classification of body functions and structures, activities and participation of the people with a disease or disorder. It describes adequate health conditions from the perspective of the body and the individual in society. [26]

- **Systematised Nomenclature of Medicine, Clinical Terms (SNOMED CT)**

The Systematised Nomenclature of Medicine, Clinical Terms (SNOMED CT) is a standard for clinical terminology. It represents a coding system of diagnosis also covering other types of clinical findings such as signs and symptoms. It includes surgical, therapeutic and diagnostic procedures. The unique clinical meaning is referenced using a

unique, numeric and machine-readable SNOMED CT identifier. For example, 44054006 represents diabetes Mellitus type 2. [27]

- **APGAR Score**

APGAR Score is a standard for assessing the health of a newborn. It evaluates the colour, heart rate, reflexes, muscle tone and respiration by giving a score zero, one or two. The higher score means better health prospects. It counts clinical signs of neonatal depression such as bradycardia, hypotonia, apnea or cyanosis. [28]

- **Acute Physiology and Chronic Health Evaluation II (APACHE II)**

Acute Physiology and Chronic Health Evaluation II (APACHE II) is a score, that determines the severity of the disease in patients on an intensive care unit. It is established in the first 24 hours of the patient in ICU. The score gives the probability of hospital death. [29]

- **Glasgow Coma Scale (GCS)**

Glasgow Coma Scale is a standard scale for classifying the consciousness of neurological patients. It assesses the depth and duration of impaired consciousness and coma. The higher number means a higher level of consciousness and better changes to treat. There are limitations in intubated patients. It is the inability to the testing of verbal response, to grade breathing pattern and brainstem reflexes, and to detect a subtle change in the neurological examination. [30], [31]

The coordinated use of established standards for the specific clinical needs (DICOM, HL7) is promoted by an initiative by healthcare professionals and industry, Integrating the Healthcare Enterprise (IHE). [32]

3 Introduction: Gnu Health

Gnu Health is a free open source software that helps digitalizing of the hospital and storing vital patient data. It is used like Health (HIS), Laboratory (LIMS) and Hospital Management (HMIS) Information System. [33]

The GNU Health hospital information system follows healthcare data standards such as HL7, ICD, ICF, etc. (See in chapter 2.4), and can interoperate with viewers to work with DICOM images. [33], [34]

It runs in many countries with different health settings (Haiti, Cameroon, Spain, Jamaica, Brasil, etc.). [35], [36]. It is used in both small medical facilities and large healthcare centres. The application is composed of modules with a specific function, that are composed of models and classes. [33], [36], [37]

3.1 GNU Health Modular Design

At the centre of the application stands the core module GNU Health with models and classes, that are by other modules inherited. There are ten main models (See in Figure 5):

- **Health Institutions**

Health Institution is one of the first things, that is created during the installation. It forms the main part of the core module. The first health institution is the healthcare company, that is designed according to the healthcare facility, for which the information system should be. In this section, it is also determined the organization and capacity of the company - buildings, wards, units, operating rooms and several different types of beds. Gnu Health works for both the entire hospital and individual departments. [33]

- **Domiciliary Units**

For a personal medicine it is important to know a facility environment, where the patient regularly lives. This part cares about the dwelling of the patients. To the domiciliary, units relate illnesses like Dengue fever or Chagas disease. The physical address referenced by latitude and longitude or by an associated address could be a key to determine a disease. [33]

- **Individuals**

A person is taken as a unique individuality, that is part of the family and interacts with the community. It is used as a concept of the party, abstract entity, where attributes differentiate a patient or healthcare workers. A doctor could also at the same time as a

patient be. The person has his Person Unique Identifier Number (PUID) or equivalent issue by a specific country or region. [33]

- **Book of Life**

Every patient has his own Book of Life, that contains demographical, biographical, medical and social information about the patient. Every patient's contact with the healthcare facility (health encounters, procedures, immunizations, prescriptions, surgeries, hospitalization, imaging, family history, social aspects) is there. [33]

- **Families**

This model holds together all individuals from the same family from the legal or genetic point of view. It allows showing the families just two generations. The model determines the roles of the individuals (mother, father, son and more). [33]

- **Health Professionals**

Health Professionals provide physicians, nurses, biochemists, psychologists and other healthcare workers. A Health professional could have more than one specialty and could also be a patient. According to the access rights, he could digitally sign documents and audit their actions. [33]

- **Medicaments**

The model stores information about the medicaments. The information is lately used in other modules.

- **Prescriptions**

The model includes prescriptions for patients in GNU Health system from the entire medical facility. [33]

- **Vital Records**

Gnu Health creates and signs birth and death certificates, that are official documents used in most countries. The information are taken from the patient or just after born from pediatrics in the hospital. The birth certificate works on a similar principle as a death certificate, that additionally stores information about causes and circumstances of death. It is important for law, administrative, demographics and epidemiology. [33]

- **Immunizations**

The model includes immunization schedules per county and year, the vaccination process, the patient immunization history and status reports. thanks to this review, vaccines can be stored as needed. [33]

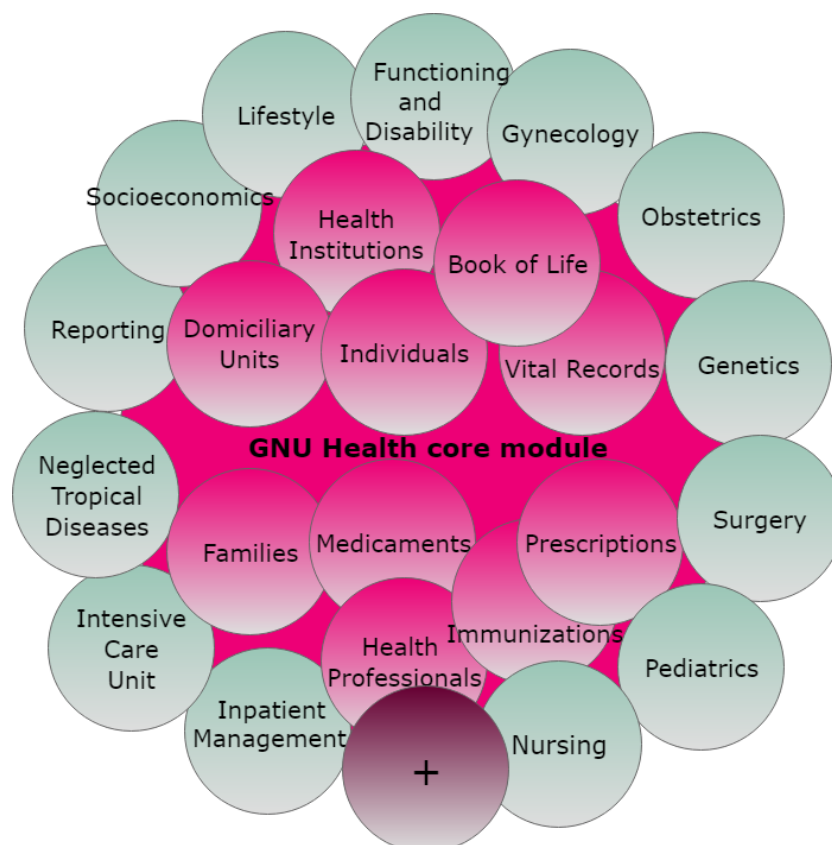


Figure 5: **GNU Health Modular Design:** GNU Health consists of a set of mandatory core (pink), optional modules (green) and other developed modules (purple). The core contains (from the left) Domiciliary Units, Families, Health Institutions, Individuals, Medicaments, Health Professionals, Book of Life, Immunizations, Vital Records and Prescriptions. The other modules are (from top clockwise) Functioning and Disability, Gynecology, Obstetrics, Genetics, Surgery, Pediatrics, Nursing, Inpatient Management, Intensive Care Unit, Neglected Tropical Diseases, Reporting, SOcioeconomics and Lifestyle.

Other modules that extend the core can be selected by individual healthcare facilities according to their requirements. Modules are for (See in Figure 5):

- **Socioeconomics**

The module manages information about housing conditions, educational level, workspace, essential patient services (sanitary sewers, gas supply, telephone, internet) and the family background(functioning, health problems and social support in a family). It also provides information about other issues such as drug addiction, family abuse, domestic violence, working children and others. [33]

- **Lifestyle**

Health is closely related to the lifestyle of the individual. The module gathers information about a diet and exercise (physical exercise, sleep, meals, etc.), sexuality (sexual disease, violence, unwanted pregnancies, discrimination based on sexual behavior, sexual practices, preferences, partners and anti-conceptive methods), safety (awareness and education about risks and dangers in and around the house, accident prevention) and additional information (smoking, alcoholism, recreational drugs). [33]

- **Function and Disability**

Function and Disability is a part of the HIS taking care of the patients with handicaps classified by International Classification of Functioning, Disability and Health (See in chapter 2.4). [33], [26]

- **Gynecology**

The module documents the health of woman reproductive system. It stores information about basic gynecologic conditions such as obstetrics history (number of pregnancies, premature births, abortions and stillbirths), menstrual history with a date of last menstrual period, length, frequency or volume, and screening informations (mammography, PAP Smear or colposcopy history) for a determination of an early stage of disease. [33]

- **Obstetrics**

Obstetrics module deals with information related to pregnancy, childbirth and postnatal period. It also contains a report for puerperium, period six weeks after the birth of a child, when the mother's body, uterus size and hormone levels return to a non-pregnant state. [33]

- **Genetics**

A knowledge of genetic predisposition of a human to disease is inestimable. It is beneficial to know the exact cause of an illness to better treatment and prevention. This module gives details about hereditary risks, family history and individual relevant genetics. [33]

- **Surgery**

The module store information about the surgical procedures of the patient. It uses the ICD-10 Procedure Coding System (See in chapter 2.4) of the World Health Organization (WHO) to determine the type of surgery. [33]

- **Pediatrics**

Pediatrics focus on the health of newborn, children and teenage patients. For newborn, it uses APGAR score (See in chapter 2.4) for assessment of health status, reflexes, congenital diseases, neonatal signs and symptoms. [33]

- **Nursing**

The module provides information about procedures, that are performed by the nurses during ambulatory care. It can store basic parameters (temperature, systolic and diastolic pressure, heart rate, glycemia, respiratory rate, etc.) of the patient overall health. [33]

- **Imaging**

The module Imaging will be described in detail further in chapter 3.2.2.

- **Inpatient Management**

The module deals with hospitalization procedures in the hospital. It manages organizational things. Each patient has to have his bed. In the nutrition there are details about a type of food, that patient can eat according to his health, belief or type of diet (vegetarian, paleo, low-carb and others). In medication, there is a list of medicaments, that patient used during the hospitalization. [33]

- **Intensive Care Unit**

Intensive care unit is one of the main parts of the hospital. The module manages intensive care medicine and stock department. It can create and evaluate data for a patient. The severity of disease of the patients in the Intensive Care Unit is classified by Acute Physiology and Chronic Health Evaluation II (APACHE II - See in chapter 2.4). The higher value means more serious disease and relates to a higher probability to die. The consciousness of neurological patients is determined by the Glasgow Coma Scale. The better chance to recover relates to the higher value of the Glasgow Coma Scale (See in chapter 2.4), that indicates a higher level of consciousness. [33]

- **Neglected Tropical Diseases**

Neglected Tropical Disease is common in tropical and sub-tropical conditions in Asia, Africa and America. They affect more than one billion people. Most are the people living in poverty and lack of hygiene. Gnu Health provides to report the potentially life-threatening Chagas disease and the pandemic-prone viral Dengue fever. [33], [38]

- **Reporting**

The module gathers the summary statistics for demographics, patient evaluations, diseases, specialties by health professionals and injuries from the HIS. It gives a patient census, age pyramid, many cases of a specific disease and more. [33]

The application could be edited in an Administration section, where users, modules, elements of a user interface, languages or data structures such as models or fields could be configured.

3.2 The Technical Information

GNU Health runs in different operating systems such as GNU/Linux distributions, FreeBSD, Windows and macOS. [34]

GNU Health is mostly written in Python and the data for representation on the screen in XML files.

3.2.1 GNU Health Technical Structure

The application uses the robust and scalable open source three-layer computer application Tryton framework, that consists of a client, server and the database management system [34], [39], [33], [36]:

- **Client**

The client is a software component communicating with database management systems. It provides a graphical desktop interface for users. The current version uses GTK2+ and Python2. GNU Health does not provide offline support after the disconnection from the server. [40], [41], [42]

The user interface contains a global menu with the functionalities in a tree structure. The menu is built as button bar and is designed without a specific function. It is used by all modules. It covers the required standard functions such as filtering by text to find the faster-desired item, switching the views, creating the new record and save it, etc. It supports the language translations, print, E-mail or copy URL. [40], [39], [33]

The multiple panel in the top allows to be several active modules at the same time, and the installed items are shown in the left part in a menu. [40], [39], [33]

- **Server**

GNU Health could run on local or two Internet available community servers:

- **health.gnusolidario.org** - provides the previous stable version of HMIS and LIMS servers. [33]
- **federation.gnuhealth.org** - gives the latest stable version of GNU Health. It is a GNU Health Federation community hub. [33]

- **Database Management System**

Gnu Health allows the use of different database management systems such as MySQL or PostgreSQL, that could be implemented in a centralized or distributed environment. The information is stored locally or in a remote database. [33], [36]

The default settings of GNU Health comes with no data, but for better visualization, it is available to download a demo database with fictitious people set into a family and social context, that fills the modules. [33]

Besides, GNU Health also contains Person Master Index and Message Server (Thalamus), plugins and translations. The technical structure of GNU Health is shown in Figure 6.

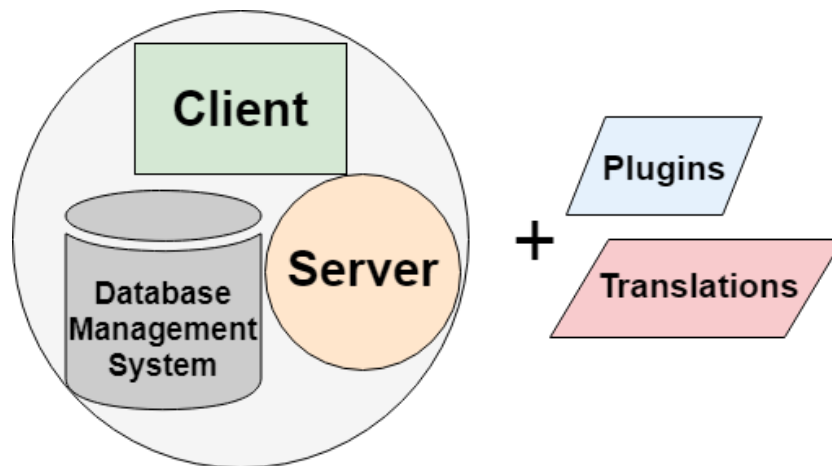


Figure 6: **GNU Health Technical Structure:** The GNU Health contains a client, server and database management system in default. Other tools such as translations and plugins could be added.

Translations

GNU Health provides broad multi-language support. Today it is about 100 different languages such as English, Spanish, German, French, Russian. [33], [36], [37], [35]

Plugins

Plugins represent additional client programs with specialized functionality. GNU Health supports:

- **GNU Health Camera**

GNU Health Camera plugin allows to visualize, transfer and store items from a webcam device such as a camera or microscope directly on the system. It could be used for a person or patient registration, survey of domiciliary units or telemedicine. [33], [42]

- **GNU Health Crypto**

GNU Health Crypto is a plugin for signing, encrypting, hashing, verifying and serialization documents in HIS. It works with the modules, that need it. By default, it is prescriptions, birth and death certificates. The serialization creates information in a certain format (JSON) and encoding (UTF8). The encryption process works on rows and columns. The signing and verifying documents are made via a public free cryptography GNU Privacy Guard. [33]

- **The Federation Record Locator**

The Federation Record Locator Plugin gives a communication link with the thalamus (message and authentication server of the GNU Health Federation) and works with HIS and Person Master Index. [42], [33]

GNU Health also gives a full-server package with its database with a possibility to store information locally, without the need of the network connection to run in Raspberry Pi environment. This setting could be used in developed countries. [33]

3.2.2 Module Technical Structure

Module are basic units of the entire application. The health organization chooses the needed modules for it to meet its requirements. However, some modules are dependent on others. Installation must take into account all dependencies.

Each module has a different structure according to a function but has the same spine. At least it has to contain the following main files:

- **Configuration File (.cfg)**

The Configuration file in cfg format provides the information about a module compatible server-version, a list of the XML files and the other modules on that the module depends. [39]

```
1 [tryton]
2 version=3.2.1
3 depends:
4     ir
5 xml:
6     library.xml
```

Code 1: **Configuration File:** specifies a compatible server-version and module dependencies. [39]

- **Initiation File (.py)**

The Initiation file is a python script, that takes the module directory and transforms it into a visible python package and registers the entity classes of the module to the Pool, to an in-memory synchronized image of the database, that synchronize the data loaded in in-memory entities and the persistent data on the database. [39]

```
1 from trytond.pool import Pool
2 from .library import Book
3
4 def register():
5     Pool.register(
6         Book,
7         module='library', type_='model'
8     )
```

Code 2: **Initiation File:** registers the entity of classes of the module to the in memory synchronized image of the databse. [39]

- **Module Python Script (.py)**

The module python script is responsible for the function of the module. It consists of the entity classes, their instances and the features. [39]

```
1 from trytond.model import ModelView, ModelSQL, fields
2
3 # list of all classes in the file
4 __all__ = ['Book']
5
6
7 class Book(ModelSQL, ModelView):
8     # description (mandatory on first declaration)
9     'Book'
10
11     # Internal class name. Always used as a reference inside Tryton
12     # default: '<module_name>.<class_name>' on Tryton
13     # becomes '<module_name>_<class_name>' in the database
14     __name__ = 'library.book'
15
16     title = fields.Char('Title', required=True)
17     isbn = fields.Char('ISBN')
18     subject = fields.Char('Subject')
19     abstract = fields.Text('Abstract')
```

Code 3: **Module Python Script:** cares about the function of the module. [39]

- **Module XML File (.xml)**

There are all static data (actions, views, reports, users, access restriction) put into an XML file. [39]

```
1 <?xml version="1.0"?>
2 <tryton>
3   <data>
4     <!-- All our definitions come here -->
5   </data>
6 </tryton>
```

Code 4: **Module XML File:** describes the views, actions, reports, and access. [39]

- **View File (.xml)**

The view file is defined to be discovered in the desktop client. It is written in a standard XML format. There are two available possibilities to structure it - form and tree. The form creates a new record. The tree represents a list of all records, that were made in a form. [39]

```
1 <?xml version="1.0"?>
2 <!-- This file is part of Tryton. The COPYRIGHT file at the top level of
   this repository contains the full copyright notices and license terms.
   -->
3 <form string="Books" col="6">
4   <label name="title"/>
5   <field name="title" colspan="3"/>
6   <label name="isbn"/>
7   <field name="isbn"/>
8 </form>
```

Code 5: **View File:** describes the interface of the module in desktop client. [39]

Module Imaging

The practical part is inspired by the module Imaging, that provides a workflow with a possibility to attach images. The top of the windows is dedicated to the Tryton menu. The module covers the whole process of medical documentation connected to an imaging test, the requests and results, that divide the module into two parts.

- **The Requests**

The Requests are a part filled by a doctor, who needs a test. It contains of two windows, one with a tree structure and the other with a form structure.

In the first window all requests for the entire duration of module operation are shown. The requests are separated into pages (Draft, Requested, Done and All) according to the

state of a request. Each request is written on a separate line containing: the number of requests, the name of the patient, submission date, the test type and a doctor, who requires the measurement.

The new request is made by clicking a button located in the upper menu, in the second window. The window is separated into two parts (See in Figure 7). The upper part is designed like a form, where all relevant information is set. The tick box indicates an urgency of the request, and the read-only field gives a number of the requests and the field for the patient provides a search tool to open a special window to find or create the patient. The new patient is added to the patient part of the application. The date is entered by selecting the day in the calendar and the time by selecting the possible day hours. From a list there is also a possibility to use a search tool what opens a special window for finding or creating the test type. The new item will be added to the test list. The field doctor is a place for a health professional, who requires the measurement. He could be found in the health professionals part or newly created and saved there. All changes in the application are already present in for the next use. The read-only field of state of the request is also shown. The lower part gives space for comments.

- **The Results**

The Results are filled by a health professional, who performed a test. It offers a similar structure to the Requests. It consists of two windows, one with a tree structure and the other with a form structure.

The first gives all results that were made in the module. Each result is written on a separate line and copies the information given in a result form. The line is specified by the name of the patient, the number, date and time of the result, the type of the test, the doctor requiring measurement and by the health professional, who performed it.

The new result is made by clicking a button in the tryton menu to open the second window. The window is separated into two parts, the first part includes information about the patient, the number, date and time of the result, type of the test and its desired date, the doctor requiring measurement and by the health professional, who performed it. The lower part is divided into two pages, one with a possibility to attach images, that are added into the list and second with a space for comments.

The basic settings of Imaging do not support displaying and working with DICOM images and waveforms. It could be able in cooperation with an Orthanc server and viewers such as Gingko or Aeskulab. [34]

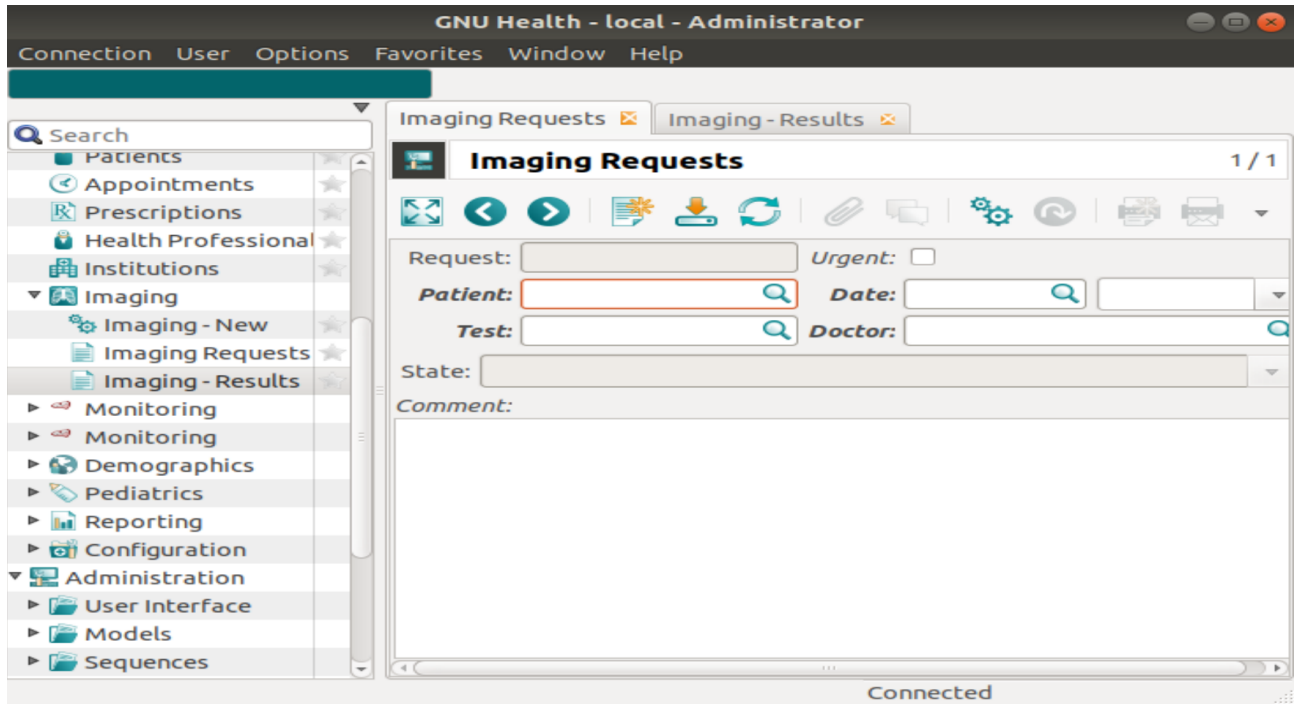


Figure 7: **GNU Health Imaging Module:** contains the Request section, where new requests are created and Results part providing the evaluations of the test.

3.3 Contribution to GNU Health

GNU Health is an free open source project, so contributing to it is possible. The translations in the user's native language, the writing documentation, the reporting of bugs and developing the new modules following the tryton rules are available. [33]

The central concept prohibits to touch the source code and modules. It would be overwritten in the next version and leading to a broken system. The source codes are available online. [33]

The created codes must be written according to the Tryton framework. [39] A new module has to contain a spine of the modules (See in chapter 3.2.2). The given objects and fields could be reused by a new module and inherited from the standard code, the dependencies between the modules are formed. [33]

A new module is installed the same way as standard modules and brings new functionality to the HIS. It allows flexibility of coding according to the requirements and needs of the health institution. [33]

4 Introduction: ECG Analysis

Cardiovascular diseases are responsible for 31 % of all global death. It counts about 17,9 million people each year. Great emphasis should be placed on prevention and early diagnosis. There are a lot of techniques of heart examination (echocardiogram, intravascular ultrasound, cardiac CT or MRI scans) and the analysis of the electrocardiogram (ECG) is one of the widely applied. [43]

4.1 Electrocardiogram (ECG)

Electrocardiogram (ECG) is a record showing the electrical activity of the heart. It is a quasi-periodical signal, that reflects the differences in electrical potentials generated at the interface of depolarized and non-depolarized cells of myocardial segments. [44], [45]

ECG belongs to the standard techniques of heart examination. It helps to diagnose heart diseases such as arrhythmia, heart attack, failure, cardiomyopathy, abnormalities of ST segment, T or P wave, and atrioventricular blocks, or blocks of right and left bundle branch. [44]

The electrical signal can be affected by many factors, both cardiac (the position of the heart in the body, tissue composition, heart disease) and other (the distance of the heart from the electrode, powerline interference, drift, myopotentials, artefacts). [44], [46]

4.1.1 Formation

The sinoatrial node, a special part of the heart, generates an electrical signal spontaneously that is subsequently propagated through special conductive pathways. The depolarization spreads through the atrial muscle fibres to the atrioventricular node, where it comes delayed. Then the depolarization fastly travels to the special conduction tissue, the bundle of Hiss, which is then divided into two left and right bundle brands, each in a different heart half. The depolarization wave goes through it to the Purkinje fibres, where it reaches contractile cells, and they contract. The depolarizing wave is followed by a repolarizing, that relaxes the contractile cells. Electrical signals cause mechanical pumping of the heart. Sufficient frequency and strength of the heart contraction are necessary for sustaining blood flow through the body. [45]

The ECG is sensed by specially placed electrodes on the body surface. The signal must be amplified by several amplifiers and filtered from outside noise and artefacts.

The ECG could be divided into parts with a unique shape. Each part is characteristic of a different phase of the contraction. The P wave represents atrial depolarization, QRS complex

ventricular depolarization and the starting of a contraction and T wave ventricular repolarization. See in Figure 8

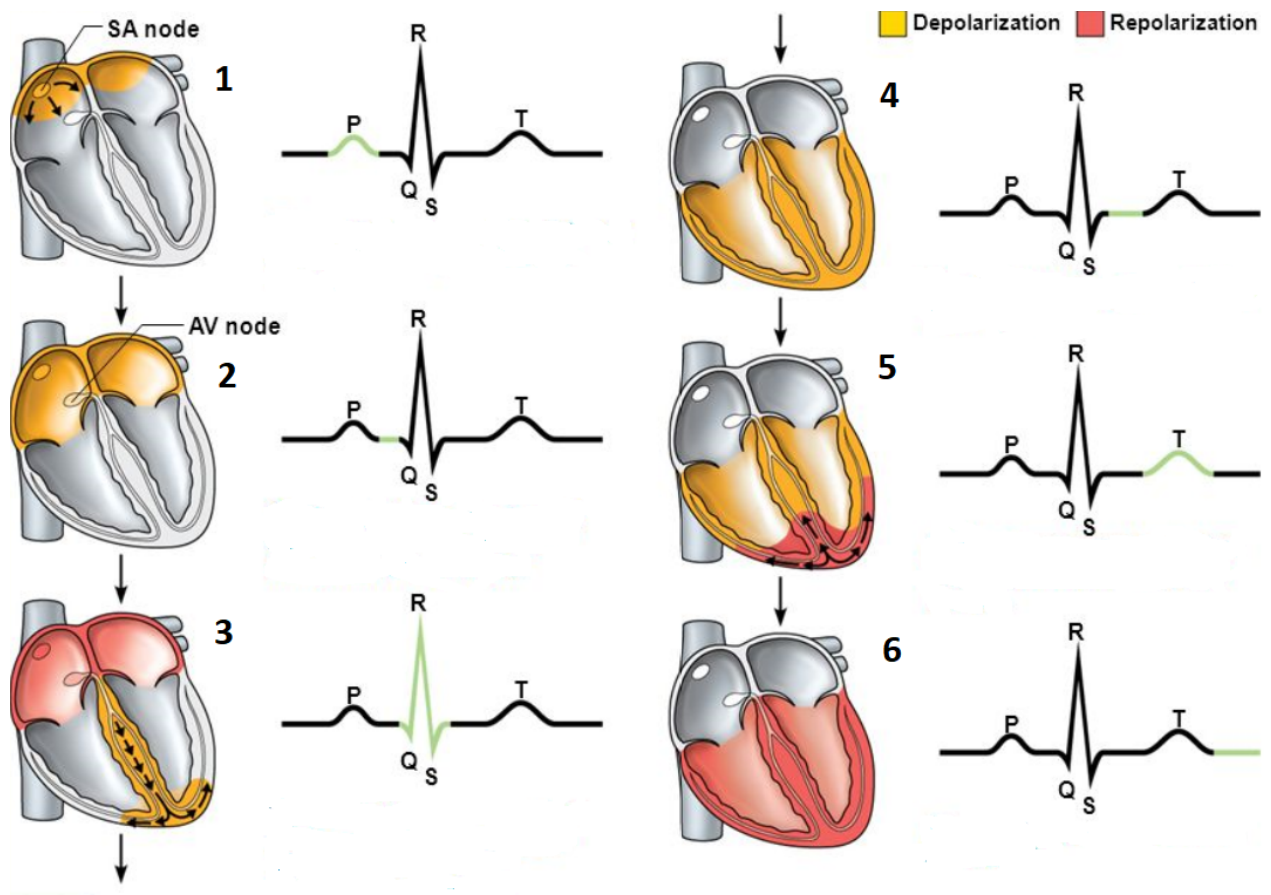


Figure 8: **ECG**: can be divided into six specific parts, that represent different biological situation: 1) Atrial depolarization, initiated by sinoatrial node, causes the P wave. 2) With atrial depolarization complete, the impulse is delayed at the atrioventricular node. 3) Ventricular depolarization begins at apex, causing the QRS complex. Atrial repolarization occurs. 4) Ventricular depolarization is complete. 5) Ventricular repolarization begins at apex, causing the T wave. 6) Ventricular repolarization is complete. [47]

4.1.2 Leads

ECG monitoring is used in many different healthcare applications, from intensive coronary care units, postoperative wards, during surgical procedures to treadmill exercise test. A need to specifically modify the placement of the monitoring leads increases. Each test requires different conditions, in an exercise test it is a stability of the baseline and in the avoidance of a surgical procedure of interference from electrosurgical equipment. Therefore, there are more specific electrode connection systems. The main is [48]:

- **The 12-Lead Monitoring**

The 12-lead monitoring gives spatial information of the heart in three orthogonal directions (left-right, superior-inferior, anterior-posterior). It consists of three Einthoven bipolar limb leads (I, II, III), three Goldberger augmented unipolar limb leads in the frontal plane (aVR, aVL, aVF) and six unipolar chest leads in the horizontal plane (V1, V2, V3, V4, V5, V6). See in picture 9. [49], [50], [48], [51]

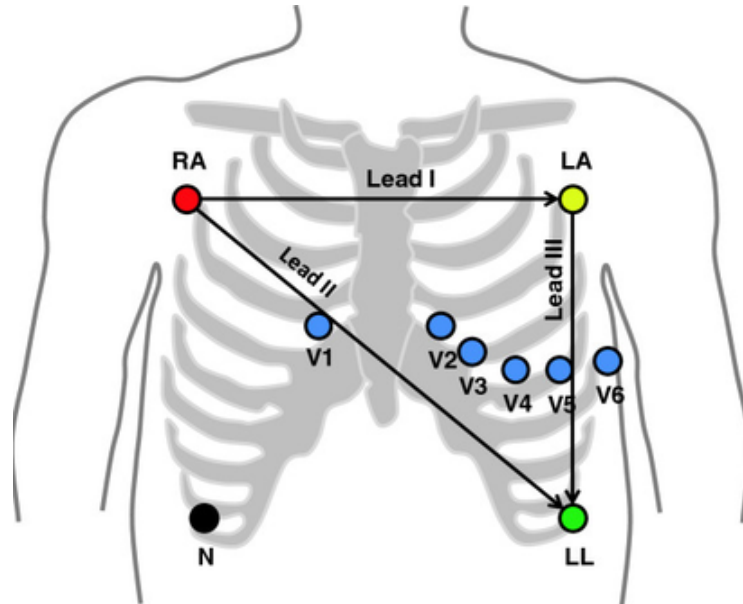


Figure 9: **The 12-Lead Monitoring**: uses three bipolar electrodes: Lead I is from negative RA to positive LA, Lead II from RA (red in the picture) to positive LL (green) and Lead III from negative LA (yellow) to positive LLm; three augmented unipolar limb leads: Lead aVR is from positive RA to [LA & LL], Lead aVL from positive LA to [RA & LL] and Lead aVF from positive LA to [RA & LA]; six unipolar chest leads in horizontal plane: Lead V1, V2, V3, V4, V5, V6 (blue); and grounding N electrode (black). [52], [51]

- **The 5-Lead Monitoring**

The 5-Lead Monitoring is mostly used in current day intensive care monitoring systems. Four electrodes are set on the torso corresponding to the limbs. The right lower limb serving as the ground electrode and the fifth electrode can be placed in any chest lead location depending on the needs, but usually, it is in V1 for better arrhythmia detection. The 5-lead monitoring system can determine the rhythm abnormalities and ST segment deviation. It is often used in two channels monitors, where only two channels are chosen. [48]

- **The 3-Lead Monitoring**

For the 3-lead monitoring two electrodes are needed for active monitoring in any configuration of lead I, II or III, and third is a ground electrode. It was used in telemetry systems. [48]

4.1.3 ECG Types

The ECG is measured in many different applications and conditions. It could be:

- **Resting ECG**

The resting ECG is measured by 12-leads or 3 orthogonal leads while lying still. The interesting band is up to 125 Hz and the usual sampling frequency of 500 Hz. The measured time is about 10 seconds. A signal from one lead is evaluated by a morfologic analysis from a cycle. [53]

- **Exercise ECG**

The exercise ECG is a record during the specific physical activity, that solves an adequate biological response to the stress. It is a clinical tool to detect coronary artery disease or to determine exercise capacity and safe levels of exercise following a heart attack or heart surgery. The physical activity is usually done on bicycle ergometer or treadmill. Thanks to the movement there are more myopotential artefacts in the signal. The test is usually done in athletes and patients with heart problems. [54], [55], [53]

- **Holter ECG**

Holter ECG is a long-duration record of heart function. It is measured 24 hours by default, but it is now switching to monitoring for periods from a few days to several months to detect rare arrhythmias. Holter monitors usually contain three leads and continuously measure ECG. It helps in the examination of suspected cardiac rhythm diseases, and it is also used in patients in the intensive care unit. [56], [53], [46], [55]

The signal is different in fetus, children and adults. ECG is measured when the patient is at rest even under exercise. Therefore, it is necessary to be able to analyze and evaluate it correctly. [44]

The ECG analysis is composed of preprocessing, include filtration, that prepares the signal for following analysis steps, the processing, specific to the objectives of the analysis, and the evaluation, that judges the quality of the analysis by reliability, stability, efficiency, predictivity, specificity.

4.2 Filtration

The raw signal is disturbed. It needs to be filtered and prepared for processing. The noise components are additive often with a low frequency. It could be drift, powerline noise, breathing muscle artefacts and electromagnetic interferences.

The filters have to remove the noise elements, that are not related to the cardiac electrical activity but preserve the shape and the amplitude of the original signal. [57]

4.2.1 Drift

Drift belongs to one of the most solved signal processing problems. It is a fluctuation of a baseline of ECG. The noise is predominant in a frequency range to 2 Hz. It is caused by slow electrochemical processes at the skin-electrode interface, by the effect of breathing (about 0,8 Hz), by loss of the connection between electrodes, or by slow movements of the patient during the recording (up to 2 Hz). [53], [58], [53]

The main drift removing filters are:

- **Linear High Pass Filter**

The linear high pass filter is a basic standard filter, that gives the frequency limit from which the signal passes. The useful signal spectrum starts from 0,7 Hz, so the recommended limit is at 0,67 Hz. The all frequency components of the signal after the filter pass must be delayed by the same time interval to avoid the distortion of the original signal, the most ST segment, caused by non-linearity of the phase characteristics at the very low frequencies. The distortion could be misinterpreted as cardiac ischemia or myocardial infarction. The phase characteristics must be linear and go through zero. The impulse characteristics have to be symmetric. [53], [58]

- **Short-time Fourier Transform (TFT)**

The short-time Fourier transform is widely used to convert signals from the time domain to time-frequency, where the drift could be removed by resetting the spectral lines and then the signal is again converted to time-domain. The STFT uses a constant length window, that must be properly chosen. [59], [57]

- **Discrete Wavelet Transform (DWT)**

The discrete wavelet transform is based on summation, that allows getting the frequency-domain interpretation of the signal. The baseline drift is removed by zeroing the scaling coefficients, and then the ECG is again converted to time-domain. The size of the window is adapted to the signal by changing the number of levels in the decomposition. The wavelet is appropriate for analyzing transient non-stationary signals with high-frequency components. [57]

4.2.2 Powerline Interference

Powerline interference is characterized by chronic sinusoidal elements. It is a narrowband residual noise about 50 Hz, that degrades the quality of the signal and overcomes small features in it. It is caused by the differences between the impedances in the electrode and stray currents through the patient and the cables. It is a complicated problem, that can be solved by [60], [61]:

- **Band-stop Filter**

The Band-stop filter is a basic tool to remove the noise elements. It suppresses components near powerline frequency, but the method is ineffective in larger noise deviation because of the narrow filter spectrum. [60], [61]

- **Adaptive Filters**

Adaptive filters are an efficient tool for removing the powerline noise from the non-stationary biomedical signals. They operate with the interference signal, that serves as a reference, the noisy and error signal, that is calculated like the difference between the estimated and the interference signal. The error signal represents the minimalized mean-squared error. After convergence, the error is an estimate of the required signal or desired ECG signal. [62], [63]

- **Empirical Mode Decomposition**

The empirical mode decomposition is an adaptive non-linear method for non-stationary signal processing. It decomposes a multi-frequency complex signal to set of simple functions with gradually decreasing frequencies. The main advantage is to not losing the time-domain information. [64]

- **Wavelet Transform**

The wavelet transform is clearly described in chapter 4.2.1.

4.2.3 Myopotentials

The myopotential spectrum overcomes the spectrum of the ECG. It occurs between 20 and 500 Hz. For removing this type of noise is often used:

- **Median Filter**

The Median filter is based on choosing the middle value from the sorted sequence of the signal samples inside a floating window by size as an output. It is efficient for elimination the impulse noise from the signal, and it preserves sharp transitions in the ECG. [65], [53]

- **Adaptive Wavelet Wiener Filter**

The Adaptive Wavelet Wiener Filter is one of the most effective methods for myopotential elimination. The aim is to estimate the true wavelet coefficients calculated by noisy observation. The Wiener filter requires the knowledge of the signal and noise statistics. It tends to concentrate the signal energy into a relatively few large coefficients and decorrelate data. [66], [67]

4.3 Processing

The processing of the signal forms the main part of the biomedical analysis. It is specified by the aim of the research. The ECG analysis is a matter of pattern recognition, the shape and height of the signal are evaluated. It helps to diagnose various heart diseases. The often determined parameters are [68]:

4.3.1 Heart Rate

The heart rate is calculated for the detection of various cardiovascular abnormalities such as tachycardia, bradycardia, or premature ventricular contraction. It is a basic parameter for more complex analysis (detection of arrhythmia, ischemia, heart attack). [69]

The heart rate is measured from the frequency of the arterial pressure pulse, cardiac contraction, or by pulse oximetry, but the determination from ECG is considered to be the "gold standard". [70]

Many algorithms are based on the R-peaks detection, and heart rate is then counted as the number of distances between R-peaks in a minute. [46]

R peaks can be detected using algorithms from the field of artificial neural networks, and wavelet transforms, filter banks or adaptive threshold. [46], [53]

Short-term autocorrelation and ECG spectral analysis belong to the direct methods of heart rate detection. The spectral analysis counts with the signal energy, creating the signal envelope, or by calculating Teager-Kaiser energy operator (TKEO) based on the estimation of the harmonic signal shape-like signal envelope, where are by thresholding detected R-waves. [46], [53]

4.3.2 Heart Rate Variability (HRV)

Heart Rate Variability (HRV) is an indicator of autonomic activity given by fluctuations in the time interval between individual heartbeats. It informs about the sympathetic-parasympathetic autonomic balance and cardiovascular health. It can help to predict the mortality in emergency patients transported via ambulance, the sudden cardiac arrest, and diagnose the overdose. [71], [72]

The HRV analysis is performed by using the R-R interval time series given by the QRS complex detection and normal-to-normal (N-N) interval time series, where only R-R intervals appear. [72]

Time domain analysis uses several statistical parameters such as standard deviation of N-N beats, or the square root of the mean squared differences of the successive N-N interval, and some geometrical methods use the sample density distribution of N-N interval duration, or the sample density distribution of differences between adjacent N-N intervals. [72]

Frequency-domain analysis uses the estimation of the power spectrum of the R–R interval time series, that could be calculated by the parametric (autoregressive model) or non-parametric methods (fast Fourier transform or periodogram). The information about the way of variance distribution as a function of frequency is given by the decomposition of the HR variability power spectrum. The frequency domain analysis also contains the computation of higher order spectrum and wavelet transform. [72]

Besides, the HRV could be displayed on the maps such as Poincaré plots. The graphs are geometrical representation of dynamic properties of the system from a time series in a Cartesian plane. See in Figure 10. [73], [72]

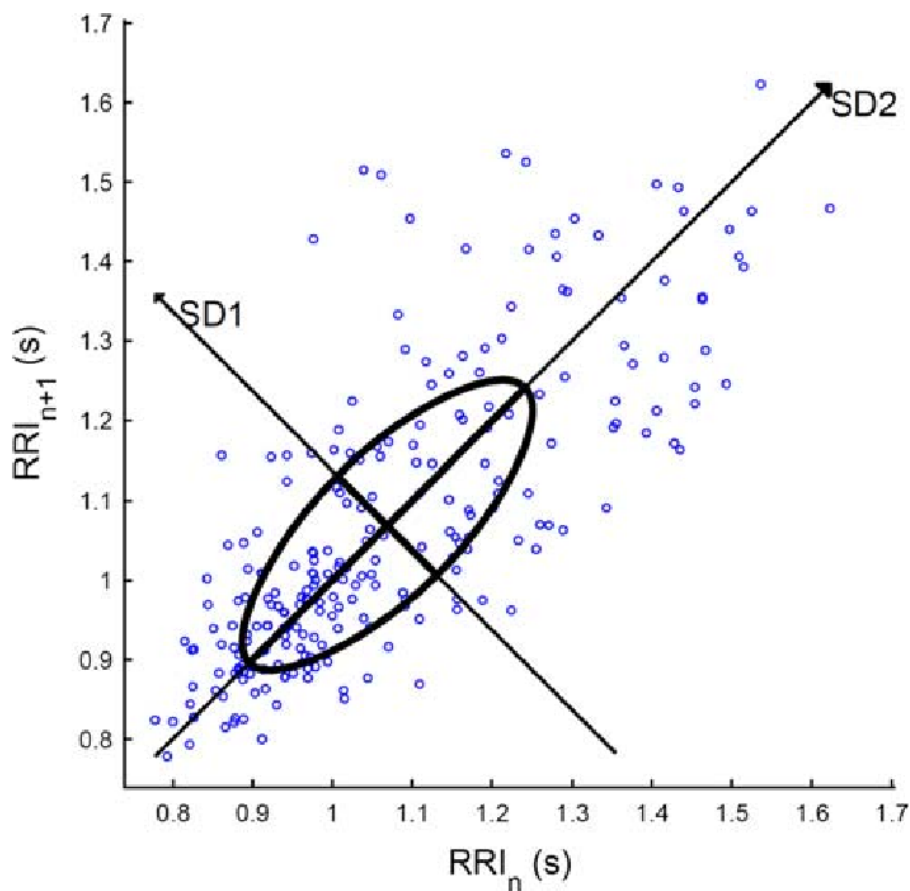


Figure 10: **The Poincaré Plot:** provides the heart rate variability indices SD1, SD2 and complex correlation. SD1 represents a short term variation given by a standard deviation of the Poincaré plot perpendicular to the line-of-identity. SD2 is a long term variation given by the standard deviation of the Poincaré plot along the line-of-identity. The complex correlation determines the temporal dynamics of the system. [74]

4.4 Evaluation

The final part of the biomedical analysis represents an evaluation. It provides information about the quality of the detector by sensitivity and predictivity.

4.4.1 Sensitivity (S)

The sensitivity (S) represents the probability of positive detections. It is the procentage of detect specific features from all these elements in the signal. It is calculated by the equation number 1:

$$S = \frac{SP}{SP + FN}, \quad (1)$$

where SP represents the summary value of the correctly detected elements and FN the value of undetected. Both values give together the total number of all special elements. [53]

4.4.2 Predictivity (P)

The predictivity gives the information about the probability of the special elements presence in positive detection. It is counted by the equation number 2:

$$P = \frac{SP}{SP + FP}, \quad (2)$$

where SP is the summary value of the correctly detected special elements and FP the amont of incorrectly identified. Both values give together the total number of detections. [53]

5 Goals of the Diploma Thesis

The topic A GNU Health Monitoring Module was chosen in AIT, Austrian Institute of Technology.

GNU Health runs in many countries with different health settings (Haiti, Cameroon, Spain, Jamaica, Brasil, etc.). [36], [35] It is a free open source system, so possible to contribute to it. [33]

The main goal was to get familiar with the system and create a module applicable in hospital practice (e.g. Monitoring). The intention was to enrich the system with functional elements such as ECG analysis.

In my Diploma Thesis, I focus on the development of the GNU Health module for electrocardiogram monitoring. The module covers the process of medical documentation from the request to the results and includes a support tool for fundamental electrocardiogram analysis. The module is created for the patient's general practitioner, who enters the request for the measurement and see the results from the cardiologist using the signal analysis.

6 Materials and Methods: Gnu Health Monitoring Module

GNU Health monitoring module represents a part of GNU Health, hospital information system. (See in Figure 11) The module specializes in ECG monitoring from the application form to results. It is designed for the health professionals, and only those with a sufficient level of authority have access to it. The security level corresponds to the security of the entire application.

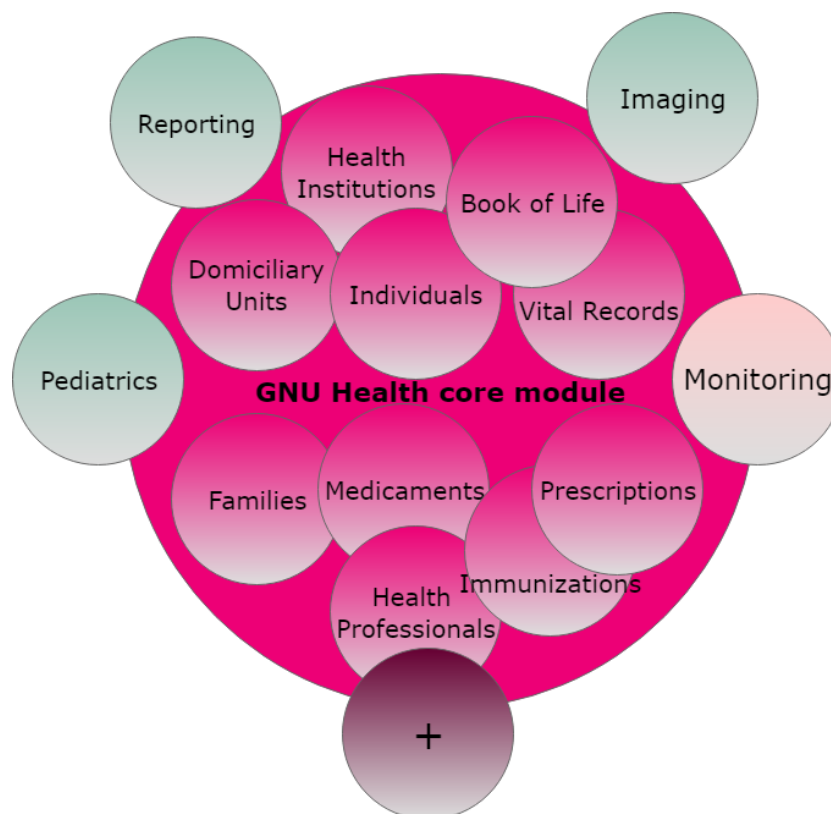


Figure 11: **GNU Health modular design with Monitoring module:** GNU Health contains a core module with models (pink), optional modules (green), developed Monitoring module (beige) and provides a space for other future developed modules (purple).

The module works with other modules and is linked to the electronic health record of the patient, so the user has access to what he needs. He has the option of using a filter to help quickly find a particular patient, doctor, test, etc.

The module runs on the local server and uses the PostgreSQL database, that stores the

information locally in the computer. Data entered in the module are stored to information from other modules. The accuracy of data is already checked when collecting information.

6.1 Materials

To start GNU Health Monitoring Module and the ECG Analysis application, the following requirements have to be fulfilled [33], [42]:

- Operating system: Ubuntu
- RDBMS Database: PostgreSQL
- Python: ≥ 3.5
- Tryton 4.6

The Python works with the following libraries:

- matplotlib - pyplot, FigureCanvasTkAgg, NavigationToolbar2Tk, Figure, font_manager
- pandas
- numpy
- scipy.signal
- tkinter - filedialog, colorchooser,ttk

6.2 Methods

The module is written in the object-oriented programming Python using the XML files for defining the structure. The Monitoring module contains GNU Health workflow based on the Tryton functionality (See in Figure 12) and the external Python written ECG Analysis application using Tkinter graphical support (See in Figure 13).

6.2.1 Module

The module is focused on the need of the patient's general practitioner, who enters a new request for the monitoring, and his cardiologist, that use the fundamental ECG analysis. It is designed practically and simple to use. It inherits the interface and the functions that are allowed in the whole system. It is installed like other modules in configuration, modules section.

After logging into the application, the module is immediately visible with the other modules in the left-hand menu or could be found by entering a keyword in the filter at the top of the list.

For better orientation during the entire ECG measurement process, it is divided into two parts:

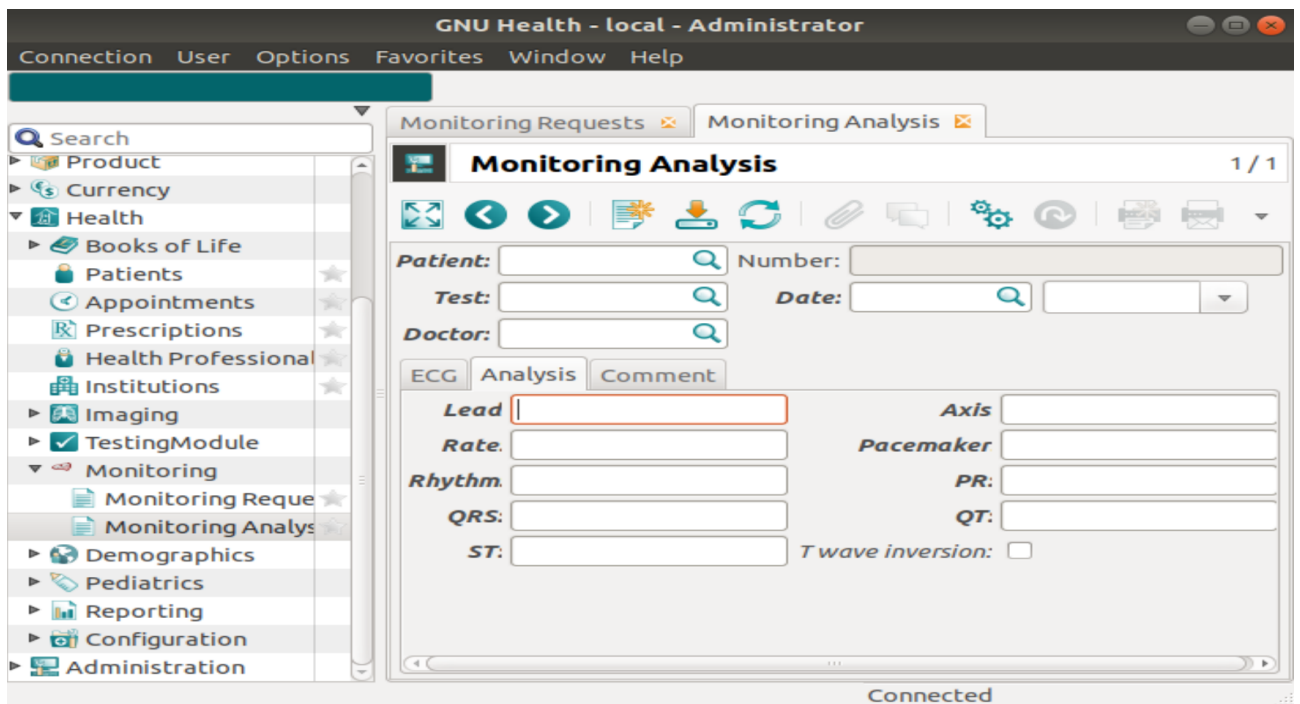


Figure 12: **GNU Health Monitoring Module:** inherits the GNU Health graphical interface.

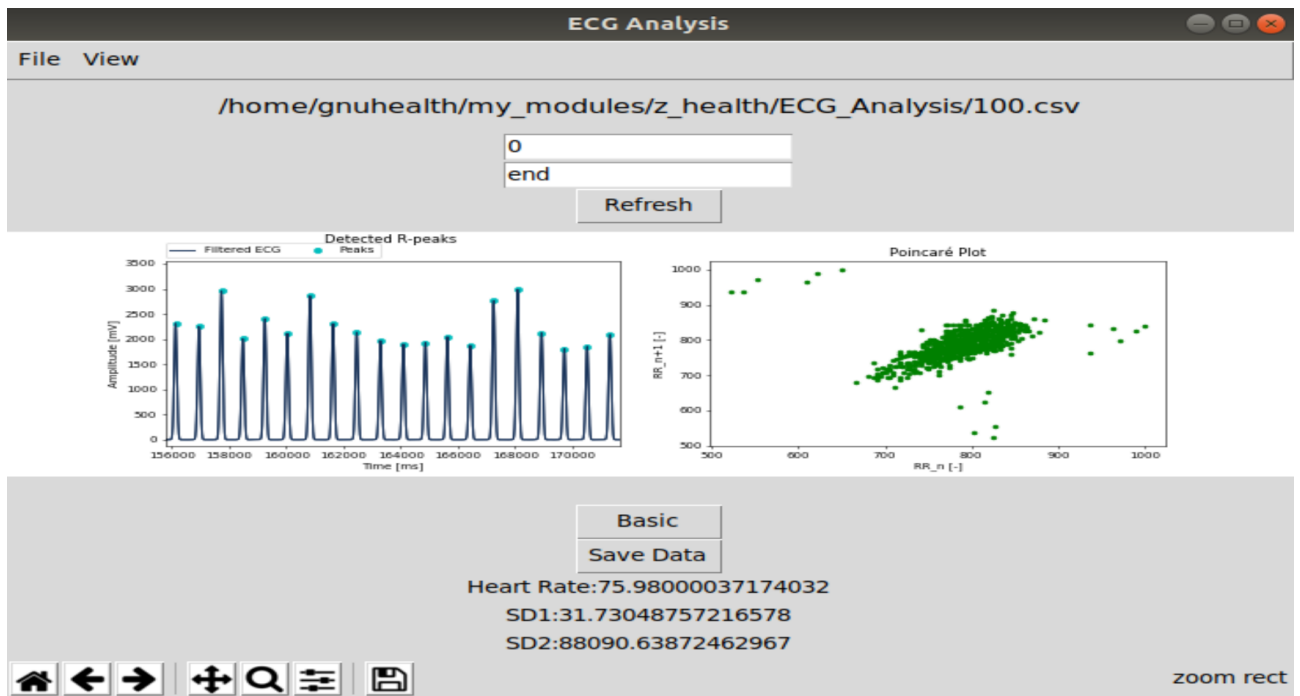


Figure 13: **ECG Analysis Application:** is designed clearly and intuitive to work.

- **Monitoring Requests**

The section Monitoring Requests contains two windows, one with a tree structure and the other with a form structure.

The first window shows all requests entered into the system and their status (Draft, Requested, Done), so the doctor has an overview of the progress of his request. Each request is written on a separate line that contains essential information (doctor's name, patient's name, request number, etc.), that can then be used to trace the specific request easily.

The second window offers to create a new request with a standard form, typical for the modules in the application (See in chapter 3.2.2). The same type of appearance allows for more natural orientation and faster filling. This reduces bureaucracy and adds time to the patient examination.

- **Monitoring Analysis**

The section Monitoring Analysis is accessible by clicking in the left side menu, or the action button at the top menu in the first section. It is filled by a health professional, who performed a test. The part is also divided into two windows with a tree and with a form structure.

The first window provides all done ECG analyses in the system. Each analysis is shown in a separate line with the primary information (patient's name, number of the analysis, doctor's name, date, etc.). These information serves as keywords to find a specific analysis.

The second window is accessible through the button for creating a new analysis at the top. The window composed of two parts, the first part creates a head of the result, with a patient's name, read-only number of the result, test type, date and time and health professional, who evaluated the test. The second part contains three bookmarks (ECG, Analysis, Comment). The first bookmark provides a space to insert images (ECG Signal, Analysis, Poincaré Plot, etc.), that are needed for the entire evaluation. The second bookmark serves like a form, where the necessary information is set and in the third bookmark, the doctor could write the other relevant information determined from the test and comments.

6.2.2 Implementation ECG Analysis of the GNU Health Module

Gnu Health Monitoring Module works with the ECG test information, but Tryton, the base code of the Gnu Health, does not support displaying the graph interface with external inputs, so the module is not able to data display plots of the analysis directly. So with the agreement of both my supervisors, the ECG Analysis is made by external Python written a basic application, that is an elegant solution to this limitation.

Python offers several libraries for graphical design (Tkinter, Qt5) as well as for graph display (Matplotlib) or signals analysis (Neurokit). It provides a lot of functions suitable for biosignal analysis (find_peaks_cwt for peak detection, etc.). ECG Analysis application helps the health professionals determine the result of the measurement. It evaluates the signal in CSV format and provides the necessary information (See more in chapter 6.2.3).

Another option to work with plots is the use of the external DICOM viewers (Aeskulab, Gingko). The signals have to be in DICOM waveform format.

6.2.3 ECG Analysis

The Python Tkinter library creates the graphical interface of the application, that is clear and intuitively usable. The ECG Analysis provides the primary functions to analyse ECG signals.

The application is created as a support tool for the decision of the health professional.

The input data in CSV format are selected by the file button, open file in the top menu. The data are plotted and then analysed by clicking the button.

The analysis offers two plots, one with the processed ECG signal with detected R-peaks for the eye visible control of the correct detection of peaks, and second Poincaré plot, that tells about the heart rate variability in a certain period.

The analysis provides the heart rate based on R-wave detection, the heart rate variability indices, SD1 representing the short term variation, SD2 giving the long term variation and their ratio to determine the temporal dynamics of the system. See below in 6.2.3.

The plots could be saved in image format and inserted to the Gnu Health Monitoring Module, Monitoring Analysis to collect the complete evaluation of the test.

The ECG Analysis application cares about the subjective perception of the user and provides the essential functions affected the interface such as change the colour of the background or the size of the font.

Dataset

For the analysis data obtained from MIH-BIH Arrhythmia Database from PhysioNet Databank were used. The database consists of standard test material for evaluation of arrhythmia detectors and is intended for research of abnormalities in cardiac dynamics. [75]

The ECG recordings are collected from a mixed population of inpatients and outpatients at Bostons Beth Israel Hospital. The recordings contain two channels and are digitalized with a sampling frequency of 360 samples per second per channel with 11-bit resolution over a 10 mV range. The format of the data was converted into text format. [75], [76]

There are 48 recordings of ECG signals available, 22 female and 26 male. Closer information to each record could be found on the webpage. [76] The analysis is made in one channel (MLII) and uses the first ten minutes from the recordings.

Filtering and Preparation

ECG signals are approximately harmonious with the slowly-varying amplitude and frequency. The raw recordings from the dataset are contaminated by powerline interference, myopotential noise and the baseline is shifted (See in Figure 14), so the signals must be filtered.

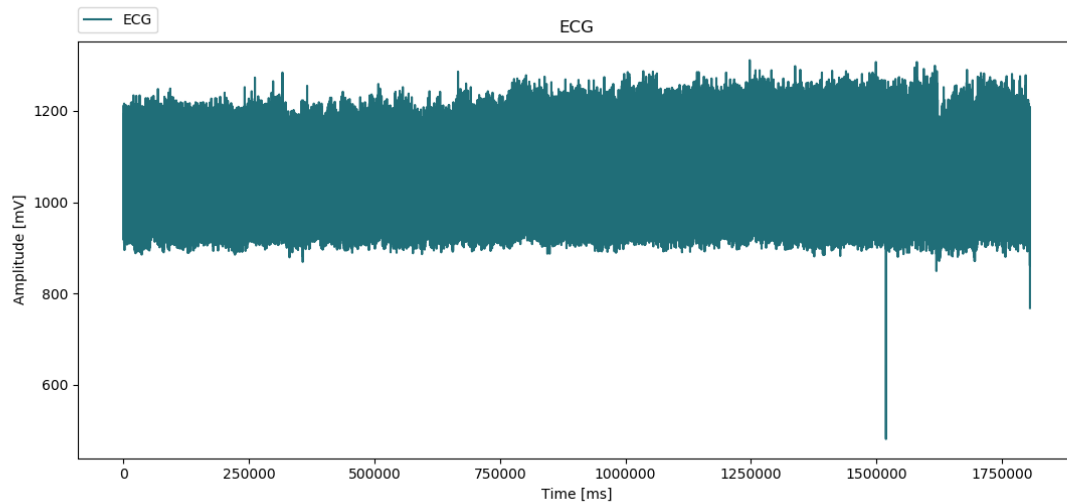


Figure 14: **The raw signal:** of the recording number 100 from the dataset is contaminated by drift, powerline interference and myopotential noise and contains the artefacts. The undesirable elements could be eliminated by the band pass filter.

The Drift is eliminated by a bandpass filter with the frequency band cut off from 11 to 22 Hz. The values were determined based on the frequency spectrum of the signal. The filter counts with the sampling frequency of the recordings, 360 samples per second. The modular frequency characteristics is shown in Figure 15 and the filtered signal in Figure 16. The broadband signal has changed after the filtration to narrowband.

The chosen method of determination of the heart rate and heart rate variability analysis is based on the detection of R-peaks, the peaks with the highest amplitude. The signal is squared and filtered from interference elements by low pass filter with the limit frequency of 2 Hz, selected by the spectrum of the signal to create the rough estimate of the square signal envelope signal, the central part of the analysis, made by a time sequence of instantaneous amplitudes. It is a signal that has only one extreme between adjacent two passes through zero (See in Figure 17). The modular frequency characteristics of the low pass filter is shown in Figure 18 and the filtered signal in Figure 19.

The ECG signal is now prepared for R-peaks detection followed by the determination of the heart rate and heart rate variability indices.

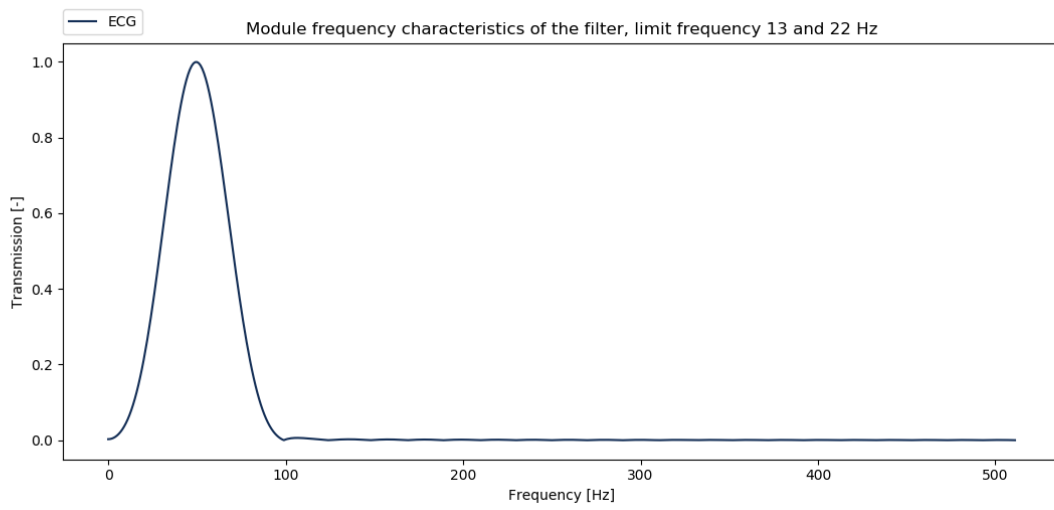


Figure 15: **Modular frequency characteristics of the band pass filter:** with the limit frequencies of 11 and 22 Hz.

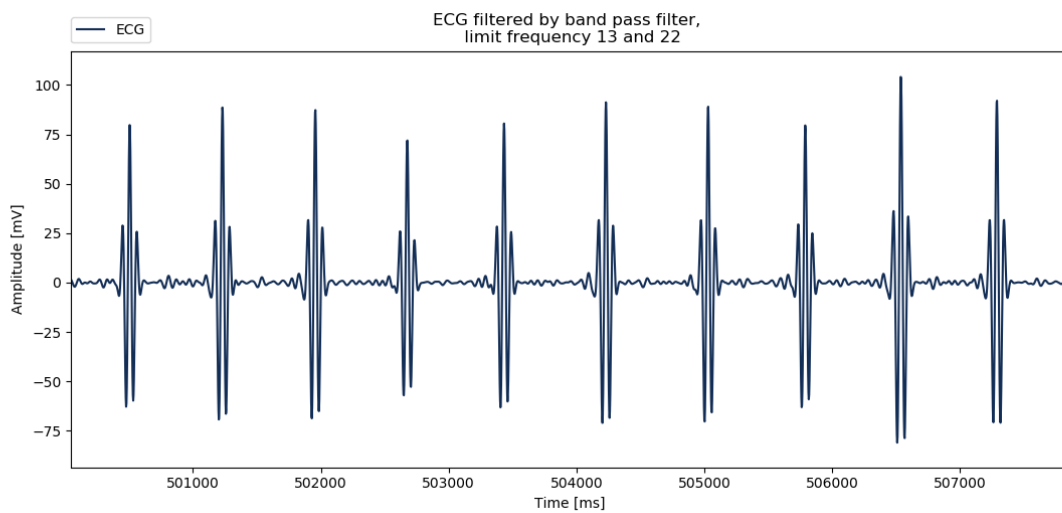


Figure 16: **ECG signal filtered by band pass filter:** with the limit frequencies of 11 and 22 Hz.

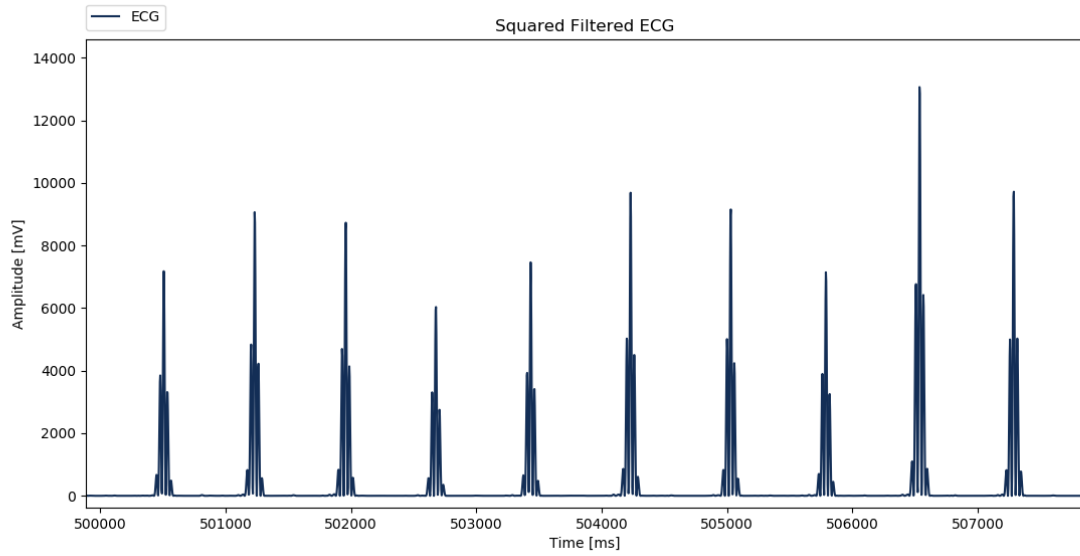


Figure 17: **Rough Estimate of the Signal Envelopes:** creates an important part of the ECG analysis. It is created by squaring the signal elements. The squared signal still contains noise elements, that must be eliminated.

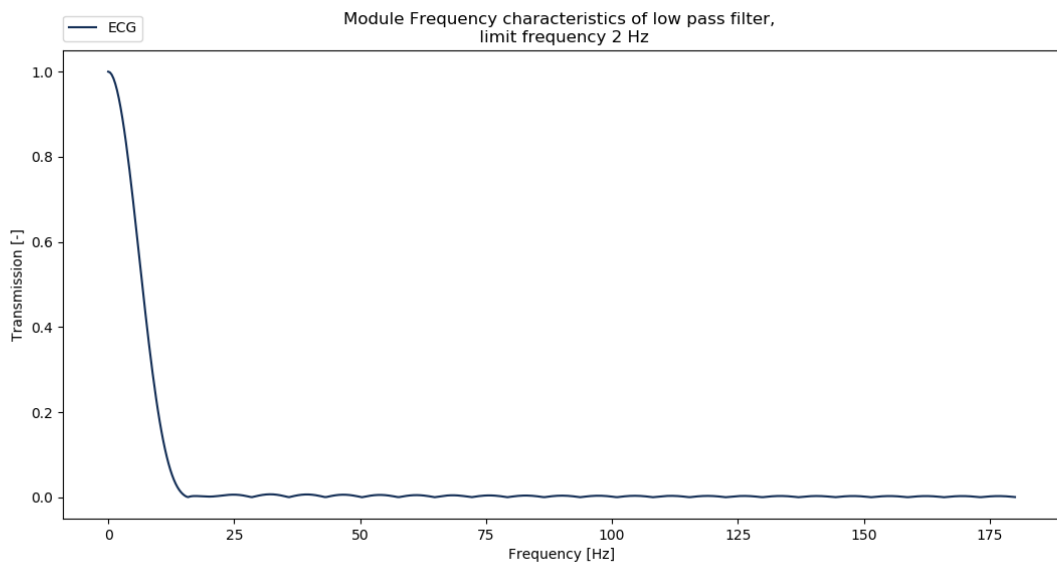


Figure 18: **Modular Frequency Characteristics of the Low Pass filter:** with the limit frequency of the 2 Hz.

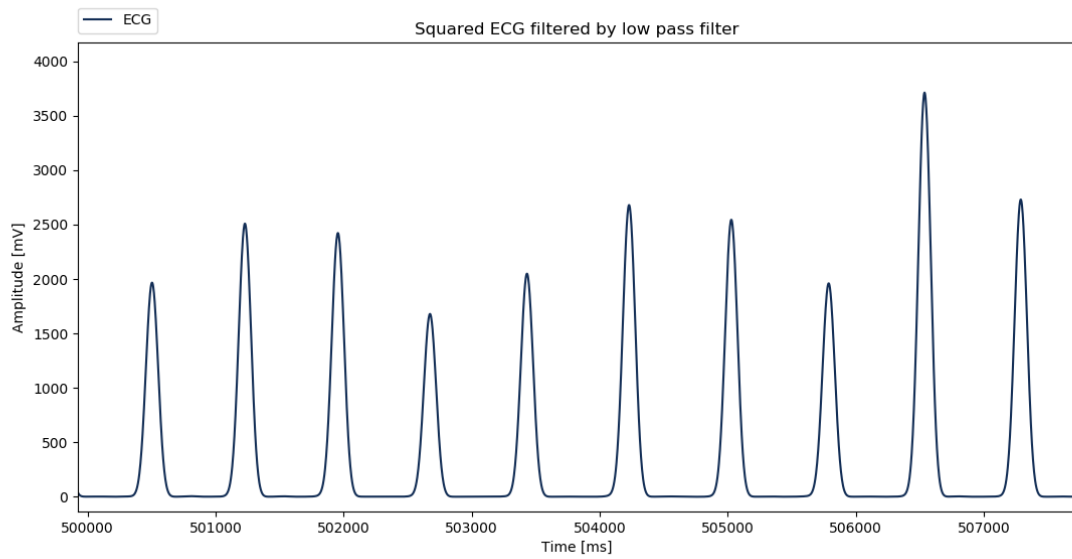


Figure 19: **Filtrated Signal Envelopes:** prepare the signal to the R-peak detection.

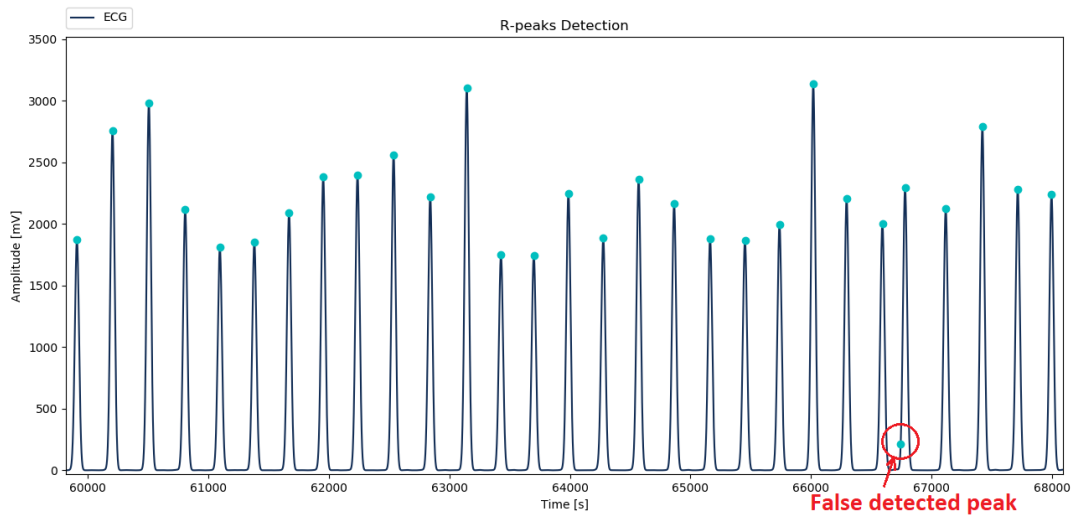


Figure 20: **Detected R-peaks in ECG:** gives the values for the heart rate determination. The peaks are coloured in cyan. The false detected peak is in the red circle.

Processing

The envelope signal is suitable for R-peaks detection. The peaks are found by different decision rules, mostly based on thresholding. I decided to use the python function for peak detection (`find_peakd_cwt`) by convolving it with wavelet (`width`) for each width in `widths`. Relative maxima appeared at enough length scales with sufficiently high SNR are accepted and recorded as R-peaks. The signal with the marked R-peaks is in Figure 20

The heart rate is then counted as the number of distances between R-peaks in a minute. The short term heart rate variation index (SD1) is calculated by the equation 3:

$$SD1 = \sqrt{\frac{1}{2}SDSD^2}, \quad (3)$$

where SDSD is the standard deviation of successive differences. The long term heart term variation index (SD2) is counted by the equation 4:

$$SD2 = \sqrt{2SDNN^2 - \frac{1}{2}SDSD^2}, \quad (4)$$

where SDNN represents the standard deviation of NN series and SDSD standard deviation of successive differences.

7 Results

The effectivity of the peak detector is evaluated by the sensitivity and predictivity, calculated according to the equations number 1 and 2 for four recordings (100, 101, 102 and 103) from the dataset. The identified peaks were compared with the annotations, that were taken as 100%. The mean sensitivity of the detector is more than 90% and the mean of the predictivity is more than 32%. The results are shown in Figure 21

Recording	Sensitivity	Predictivity
100	(99,8 ± 8,9) %	(57,8 ± 25,3) %
101	(90,0 ± 0,9) %	(12,6 ± 19,9) %
102	(93,6 ± 2,7) %	(12,0 ± 20,5) %
103	(99,8 ± 8,9) %	(83,9 ± 51,4) %
106	(82,0 ± 8,9) %	(26,9 ± 5,6) %
107	(80,0 ± 10,9) %	(2,0 ± 30,5) %
Mean	(90,9 ± 6,9) %	(32,5 ± 25,5) %

Figure 21: **Sensitivity and Predictivity:** are the main parameters to evaluate the effectivity of the R-peak detector. The higher numbers determine the better the detector. The mean values of sensitivity and predictivity are shown in the last row of the table.

The Heartbeats of the recordings (100,101,102,103,104,105,106,107,108,109,111) from the dataset are compared with the values of the results given by Heartpy Python library. The documentation to the dataset provides the interval of the normal sinus rhythm rate for each record. See in Figure 22

Recording	ECG Analysis	Heartpy	Documentation
100	75,98	76	70-89
101	64,86	64,5	55-79
102	72,81	72,9	72-78
103	70,36	70,4	62-92
104	70,7	74,5	69-82
105	83,3	83,6	78-102
106	62,7	63,1	49-87
107	70,4	141,6	68-82
108	56,2	103,5	44-78
109	83,9	85,8	77-101
111	69,8	69,6	64-82

Figure 22: **Heart Rate:** belongs to the most studied cardiac parameters. The figure shows the values of the heart rate determined by ECG Analysis application and Heartpy Python library. The interval of normal sinus rhythm rate gives the column Documentation.

8 Discussion

In this work was developed the GNU Health Monitoring Module, that was created for the patient's general practitioner and his cardiologist. It is designed as a part of the hospital information system, so it is linked to the electronic patient record kept in a hospital and other modules according to needs.

It covers the medical documentation process of the ECG measurement from request to results. The module does not fully support the analysis function, which is created externally in the application. The placement of the app brings flexibility to the developing phase, but on the other hand, could be a little uncomfortable for the cardiologist to run two programs simultaneously.

The external application provides a lot of functionality, that would not be allowed in the GNU Health environment (e.g. change the appearance of the interface according to the subjective perception, change font size).

Both software components are intuitive to work with, even though the module and application offer a different graphical environment, Tryton and Tkinter.

The ECG Analysis provides heart rate analysis based on R-peak detection. The level of sensitivity and predictivity correspond to different ECG applications. The mean sensitivity of the detector is more than 90%, and the mean predictivity equals more than 32%. The indicator by eye examination often worked more accurately than the annotations were set. The heart rate calculated from the peak detection is compared with the values given by the Heartpy Python library. The ECG Analysis correctly determined the heart rate in the annotated range of normal sinus rhythm according to the documentation, unlike a library that has set two values differently. It could be caused by strong noise interference in the signal.

The ECG Analysis offers the fundamental ECG Analysis covering the basic needs of the cardiologists such as determination of heart rate and heart rate indices, but in the future, it can be expanded to include additional features (sophisticated analysis of arrhythmia, bradycardia, advanced graph display features or processing multiple formats).

For further development, it would be a good idea to connect the module to DICOM viewers or provide real-time analysis.

9 Conclusion

In conclusion, the structure of the open source system of GNU Health is complicated, and I was struggling with incomplete documentation during my work, but still I got familiar with the GNU Health and a new module for Monitoring was developed.

The module was created for the users with a specific level of the access and covered the medical documentation process from the request to the evaluation of the ECG measurements. The module is connected to the other modules, and the electronic health record of the patient kept in a hospital, so the doctor has the opportunity to look at the information he needs when examining the patient.

The GNU Health functionality does not fully support graph displays, so I decided to create ECG Analysis by external. The ECG Analysis determines the heart rate and heart rate variability indices and serves as a support analysis tool for the health professionals for their test results.

In the future, it would be appropriate to connect the module directly with DICOM viewers and extend the analysis with additional functions.

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