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École polytechnique de Louvain

Study of critical medical devices towards an open-source implementation

Reproduction, adaptation and functional validation of a multi-parameter patient monitor

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Abstract

The World Health Organization (WHO), the United Nations' specialized agency for international public health, states in its constitution of 1946 that: "*The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition*". Many aspects must be combined to achieve this optimal state. Among these aspects, Medical Devices (MDs) play an indispensable role. A new way of designing Medical Devices is emerging. This is the creation of open-source devices, i.e. allowing anyone to freely use, copy, modify and redistribute, under defined conditions, the result of development. What could this method bring to the development of classic medical devices? It could help address two major problems in the medical device industry. Firstly, open-source medical devices might turn out to be useful in crisis situations affecting the availability of critical devices. For this, upstream documentation work is essential to tackle such a crisis. Secondly, it could well overcome some of the barriers to access to medical devices worldwide. In this work, these promising ideas will be put into perspective with feedback from the replication of an open-source medical device solution. The solution chosen is a multi-parameter patient monitor, the HealthyPi from Protocentral . This work is in line with Open Medtech's commitment to develop open-source medical devices. The latter is a non-profit organization that emerged following a spontaneous initiative to design an open-source repirator during the covid 19 crisis.

List of Acronyms

BP Blood Pressure

BPMD Blood Pressure Measuring Device

bpm breaths per minute

BT Body Temperature

CDV Cardiovascular disease

ECG Electrocardiogram

EMDN European Medical Device Nomenclature

EMS Emergency Medical Services

EU European Union

FDA Food and Drug Administration

GDP Gross Domestic Product

HR Heart Rate

HRV Heart Rate Variability

IEC International Electrotechnical Commission

ISO International Organization for Standardization

IT Information Technology

LMICs Low-and Middle-Income Countries

MDs Medical Devices

MeDevIS Priority Medical Devices Information System

NCD Non-Communicable Disease

OECD Organisation for Economic Co-operation and Development

PPG Photoplethysmography

QALY Quality-Adjusted Life Year

RR Respiration Rate

WHO World Health Organization

Contents

Chapter 1

Introduction

1.1 Context

The World Health Organization (WHO), the United Nations' specialized agency for international public health, states in its constitution of 1946 that: "*The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition*" [1].

Many aspects must be combined to achieve this optimal state. Among these aspects, Medical Devices (MDs) play an indispensable role. In particular the availability, accessibility, appropriateness and affordability of these are essential. In the context of this work, these four aspects will be taken up under a common denomination: "access to MDs". It is acknowledged in a 2012 WHO report on improving access to MDs , that without these conditions, it will be impossible to address many important public health priorities in Low- or Middle-Income Country (LMIC) [2]. Examples of these hard-to-address priorities are meeting the needs of aging populations, addressing maternal, newborn, and child health needs, and dealing with Non-Communicable Diseases (NCDs).

It does not seem possible to solve the barriers and challenges associated with access to MDs through material donations alone. The reality in the field is more difficult to capture. Indeed, a study conducted by the Canadian Medical and Biological Engineering Society in partnership with the Ghana Biomedical Engineering Association found that despite the benefits of donated medical equipment, many aspects are not sufficiently covered at the moment [3]. Recipients of medical equipment donations in Ghana reported a lack of service training for technical staff, poor communication, and a lack of spare parts to maintain the donated equipment. These difficulties are mentioned as reasons for the high failure rate of donated MDs. Other reasons include severe climatic conditions, unstable power supply, humidity and dust. The WHO general director noted in 2010 that : " *70% of donated complex devices do not work and 70– 90% of all donations never function as intended*" [4, 5]. To address this mismatch between demand and access to

[0]NB: this work relies on AI to improve its form. In practical terms, deepl has been a much-used translation tool. ChatGPT has mainly been used as a rephrasing and proofreading tool for texts I've written.

MDs adapted to the environment, an innovative approach to their development may be relevant.

This approach is none other than the open-source development of the whole hardware, firmware or embedded software but also the process of development. In other words, this would mean allowing everyone to use, copy, modify and redistribute freely, under defined conditions, the output of the development, namely a MD. It is therefore a question of an open-source development approach that does not only concern software but is extended to the hardware aspects. This process is also known as open-hardware development. In the context of this thesis only the term open-source will be used.

An in-depth examination of the reasons why the open-source approach could remedy the current mismatch between offer and demand of MDs is essential. Although, in the field of information technology (IT), the collaborative approach of free and open-source software *"creates a gift economy that encourages rapid innovation"* and is a *"well-documented method of successful technical development"* [6], the following research question remains largely unresolved: **"Is this an adequate and effective development method for the specific case of MDs?"**. Indeed, the reality is that the medical field has very high and strict requirements in terms of quality control, standards and regulations.

Various initiatives are underway around the world to experiment open-source development of MDs. For example, in 2014, Wijnen and al. claim to have created a fully open-source system with features and performance comparable to a commercial syringe pump that would cost about 20 times more [7].

More recently, during the Covid-19 pandemic, shortages of MDs such as ventilators contributed to the difficulty of caring for all those who were ill. At the onset of the crisis, volunteers from different horizons joined forces to design and build open-source ventilators. Among them, people gravitating around the UCLouvain and the Makilab quickly joined by other people, hospitals and companies among which the *Cliniques universitaires Saint-Luc*, the Jolimont Group, the *Clinique Notre-Dame de Grâce*. In the aftermath, in April 2020, the nonprofit organization Open MedTech was created. According to Olivier Lequenne, director of innovation at the Jolimont Group, this ASBL *"aims to perpetuate this spontaneous process of open-source development of medical technologies in crisis situations"* [8].

Today, the goals of this nonprofit organization are to design, prototype and document open-source MDs. The supply chain of the components is also at the heart of their concerns[9].

In this work, there is a study of the general context of the development of MDs and in particular a focus on availability, accessibility, appropriateness and affordability of MDs. This study is put in perspective with an attempt to evaluate the opportunity of an open-source approach to address these aspects. The purpose of this discussion is also to attempt to provide an appreciation of the ability of open-source MDs to provide

valuable rapid response to various crises.

1.2 Objectives

This Master thesis aims to contribute to answer the following question: **Is the open-source approach in medical device development likely to contribute, at least in part, to any of the following considerations?**

- **A means to tackle the global deficit of available, accessible, appropriate and affordable MDs.**
- **A way to respond effectively to divers kinds of crisis in case of MDs shortage.**

In order to better integrate the ins and outs of this topic, a study of essential MDs is provided. Among these, a device is selected, namely a multi-parameter patient monitor which is already available in open-source. The latter is then reproduced as part of this work. **The objectives here are twofold:**

1. **Learn and apprehend through a concrete case what is really necessary to reproduce an open-source system. This could highlight the key points to consider in such projects.**
2. **Reproduce an existing system, in order to carry out a performance assessment compared with the minimum requirements defined by the WHO, as well as a examination of relevant standards.**

In Figure 1.1, a graphical representation illustrates the questions that underlie the investigation of this work.

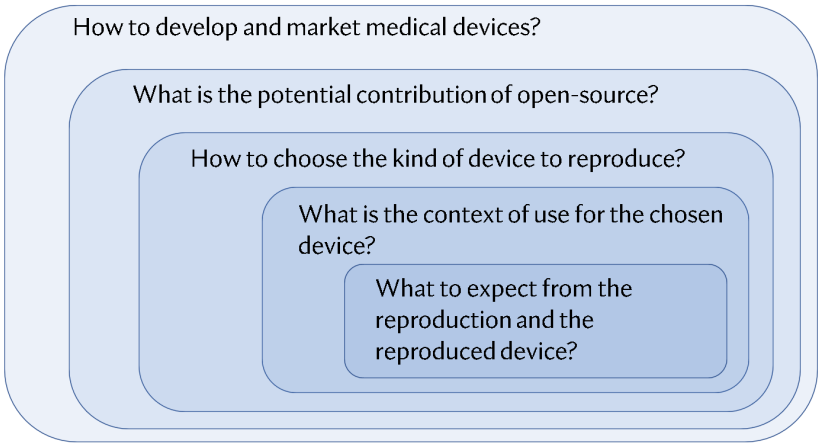


Figure 1.1: Questions underlying the investigation

This work starts with a global approach to MD and ends with the actual reproduction and functional validations of an open-source medical device. Note that assessment performances could not be carried out due to reproduction and functional validations challenges.

1.3 Outline

The second Chapter delves into crucial aspects related to medical devices, encompassing their definition, global access challenges, worldwide regulation, organizations operating in the industry, supply chain aspect, and an economic evaluation of development costs, including case studies.

The third Chapter focuses on open-source medical devices, providing an analysis of their definition and related theoretical notions, including open-hardware. The chapter explores the context surrounding the emergence of open-hardware and quantifies its impact on costs. It also highlights the advantages offered by open-hardware medical devices and discusses the challenges and limitations associated with their implementation. Additionally, the chapter critically evaluates an initiative aimed at addressing shortages in the field.

The fourth Chapter of the work provides a detailed explanation of the methodology used to select the prototype device to focus on. It starts by presenting a database, from the WHO, of all kinds of MDs commonly used in hospitals. This database serves as a baseline for determining which devices are relevant to the research objectives. The core list of MDs is refined to make an informed and strategic choice of a preferred prototype device. This process includes setting filters based on criteria such as the technical complexity of the devices, their criticality, and their potential impact.

The fifth Chapter provides some keys of comprehension on what is a multipara-meter patient monitor. It includes its history, use cases, market description, general requirements. It also discusses the main parameters of this type of MD, underlying physical principles, technologies.

Chapter six focuses on the reproduction, adaptation, and functional validation of an open-source patient monitor solution. It covers the choice of the open-source solution to be reproduced, describing the selection process and criteria used. The chapter provides an overview of the chosen solution, the HealthyPi v4 open-source monitor, including its functionalities and block diagrams. It further details the reproduction process, challenges faced in component ordering, adaptation of the PCB, and assembling of the HealthyPi. The chapter concludes with the functional validation of the HealthyPi UCLouvain version, covering various tests and troubleshooting steps to ensure its proper operation.

Finally, before concluding in Chapter eight, a discussion and prospects are carried out. These are included in Chapter seven.

Chapter 2

Framework for developing and marketing medical devices

This Chapter discusses various aspects of MD development and commercialization. It also presents the counterparts of stringent regulations and high demand for financing, which are barriers to adequate MDs implementation in low- and middle-income countries (LMICs). This last point is studied through the aspects of availability, accessibility, appropriateness and affordability related to MDs. A section is also devoted to shortages caused by various vulnerabilities in the supply chain. Finally, the various aspects surrounding the development of MDs will be synthesized to reflect the complex multidisciplinary dimension of the entire development and marketing process.

The European context will be examined more specifically as OpenMedtech is based in Belgium. Yet, the American context will also be addressed in practice. The reason for this is that the latter have an important influence on the international MD trade. This was notably observed by the 2022 study entitled "*Most influential countries in the international medical device trade: Network-based analysis*"[10]. By examining the structural evolution of global MD trade based on data from 54 different governments, the authors concluded that: *"The United States has a dominant position in the international medical device market [...] The United States has proactive influence and is not overly dependent on other countries. Therefore, to understand the global device industry, countries need to look at the changes in the United States"*. As a probable implication of this last observation, many elements in the scientific literature refer to the US context.

2.1 Definition of Medical Device

In reality, there is no universal definition of MD. Indeed, this denomination is intrinsically linked to the regulation specific to each country responsible for supervising this field. The status of MD for any equipment therefore comes with potential obligations

defined by the local relevant regulation. However, a definition of what is commonly understood can be put forward:

"Medical Device" means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury,*
- *investigation, replacement, modification, or support of the anatomy or of a*
- *physiological process,*
- *supporting or sustaining life,*
- *control of conception,*
- *disinfection of medical devices,*
- *providing information by means of in vitro examination of specimens derived*
- *from the human body;*

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Note: Products which may be considered to be MDs in some jurisdictions but not in others include:

- *disinfection substances,*
- *aids for persons with disabilities,*
- *devices incorporating animal and/or human tissues,*
- *devices for in-vitro fertilization or assisted reproduction technologies.*

This defintion was provided by the Global Harmonization Task Force in 2012 [11]. This is a voluntary international group of representatives from MD regulatory authorities and trade associations from Europe, the United States of America (USA), Canada, Japan and Australia.

2.2 Medical devices context

The utilization of MDs is crucial for various medical procedures. As resume on the WHO website : " *Access to good quality, affordable, and appropriate health products is indispensable to advance universal health coverage, address health emergencies, and promote healthier populations.Without MDs, common medical procedures – from bandaging a sprained ankle, to diagnosing HIV/AIDS, implanting an artificial hip or any surgical intervention – would not be possible*" [12].

This Section provides a brief overview of the position of MDs in the broader health care context. It explores the followings questions:

- How MDs are used in health care?
- How this translates into economic considerations?
- How their health effectiveness is evaluated in Europe?

2.2.1 Position of medical devices in the general context of care

Nowadays, healthcare is regarded as a "merit good". This means that it should be prioritized based on need rather than budget constraints. This viewpoint results from the widely acknowledged benefits of healthcare to society. Since everyone is entitled to access to healthcare, many nations have made it a fundamental right [13, 14].

This focus on health care is mirrored in government budget choices. Figure 2.1 shows the healthcare spending as a percentage of Gross Domestic Product (GDP). In order to focus attention, a worldwide presentation will not be given here. The figure is a graphical representation of government health expenditures of 8 OECD countries.

Over the years, this spending has risen steadily, and now generally represents between 7 and 11% of GDP in the various countries, which is a considerable amount. If are taken into account the non-governmental expenditures, this share increases even more. According to Medtech europe , which is the " *European trade association for the medical technology industry*" [15], an average of about 11% of GDP was spent on healthcare in Europe in total [16]. According to Eurostat, this amount was 11.1% in Belgium in 2020 [17].

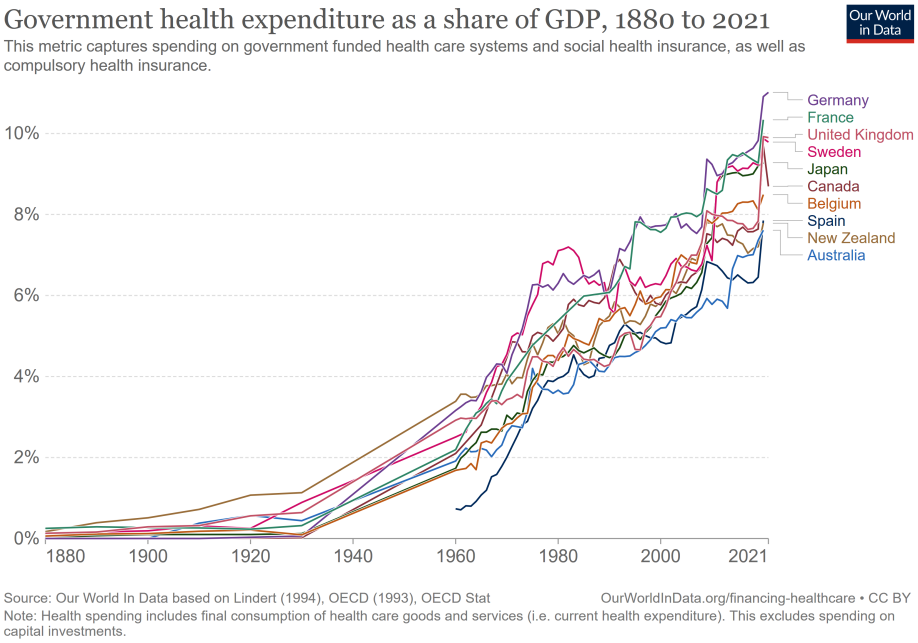


Figure 2.1: Public Health Expenditure as a Share of GDP [13]

As for the share concerning MDs, the total health expenditure on them amounts to 6.7% in 2021 in Europe [16].

2.2.2 Measuring cost-effectiveness of medical devices

Measuring cost-effectiveness is not an easy task. In Europe, this is generally done using the QALY metric [18].

One QALY represents a year of perfect health, therefore a lower value indicates a lower quality of life over a year. This metric is used because "*QALYs enable comparisons of diverse types of consequences on a common scale. [...], QALYs are measures of longevity, in units of years of life, adjusted for the 'quality' of life during those years*" [19].

Thus, according to [18], recommendations for accepting new therapies (i.e. using new MDs) are most frequently based on the proportion of QALYs brought in to costs expended. For example, in England, there is a cost threshold range of £20-40,000 per QALY, determining acceptance or rejection of new therapies. However, the authors deplore that the "thresholds" chosen are most often arbitrary and have little or no economic justification.

2.2.3 World market distribution

The world market distribution is presented in Table 2.1. This Table shows the top 20 countries with total sales of MDs in 2021.

Table 2.1: Top 20 country by MDs total sales, USDmn [20]

Biggest salers in 2021	**Country**	**2021**	**CAGR* 2016-21 [%]**
1	United.States	190831.5	5.3
2	Germany	33441.0	5.9
3	China (Mainland)	33020.8	11.1
4	Japan	27463.7	1.8
5	France	17377.2	4.7
6	United Kingdom	14830.8	7.8
7	Italy	11385.9	4.2
8	Canada	8578.4	6.2
9	Netherlands	8021.3	14.6
10	South Korea	7990.0	8.2
11	Spain	7257.2	6.0
12	Russia	6892.7	11.2
13	Australia	6226.4	4.8
14	Mexico	6084.6	5.1
15	India	4921.5	5.4
16	Switzerland	4775.0	6.0
17	Brazil	3763.7	-3.5
18	Belgium	3681.2	7.7
19	Poland	3373.0	10.0
20	Austria	3249.8	8.0

* CAGR is the compound annual growth rate. It is helpful when comparing the returns on two investments with equal durations [21] $CAGR = \frac{final_{value}}{initial_{value}}^{\frac{1}{n_{years}}} - 1$

Regarding this Table, several elements are noticeable:

1. The United States represented, in 2021, 5.7 times more sales than the 2nd country, namely Germany. In fact, according to [22], it would account for 43.5% of the world total the same year.

2. European countries (including the United Kingdom and Switzerland) account for half of the countries in this list. This represented 27.3% in 2021 [22].

3. The two countries in the top 5 except the US and EU countries are China and Japan. In 2021, they accounted respectively for 7.2 and 5.6% [22].

2.3 Worldwilde overview of the medical device regulation

A regulatory system is by definition a set of rules. The purpose of these rules is to manage risk as best as possible with regard to any negative outcomes resulting from MD use. Generally speaking, a governmental entity is in charge of formulating the regulations, passing them into national law, and ensuring that the legislation is respected. In the end, it is generally the entity that produces the equipment, i.e. the manufacturer, that must comply with the rules [23].

The regulation of MDs varies significantly over the world, from strict control to none at all. Over the past two decades, MDs have become more numerous, diverse, and complicated. From this, greater consistency in regulatory documentation would be beneficial. On the one hand, countries with gaps in their regulations could address them, and on the other hand, it would be easier for manufacturers to introduce their product in more than one market [24].

Nevertheless, it is possible to draw a general picture of a regulation on MDs. Those are explicitly stated by the WHO [23]. These include, at least :

- *The regulatory rules;*
- *a government-approved regulatory authority (to enforce the rules);*
- *one or more "conformity assessment bodies" (which are accredited by a European Union Member State and may issue market approval) to assess whether a manufacturer or a device conforms to regulatory requirements;*
- *a classification scheme that ranks devices by level of potential risk associated with their use (three or four levels, or "classes", are generally used, with most devices in the low and moderate risk classes, and less than 10% in the moderate-to-high risk class);*
- *a quality assurance or management system, managed by the manufacturer, to ensure compliance of a device with quality standards and norms;*
- *a system for evaluating the clinical safety and performance of a device;*
- *a system for granting marketing (market entrance) approval for a device that complies with the regulatory rules;*
- *a surveillance system capable of detecting and investigating adverse events associated with the actual use of a device on the market*

In September 2010, the first global forum on MDs took place. It resulted in the following numbers on the existence of a regulatory framework on these devices:

- 30% of countries had one
- 30% had a partial one
- The rest had none

2.3.1 Focus on European regulation

The European regulation is shown in the form of a summary since, as already mention, the ASBL OpenMedtech is based in Belgium.

The general idea is as follows :

- In order to be sold on the European market, a medical device must bear the CE mark ((CE for Conformité Européenne—European Conformity)) [25].
- *"The CE mark is required to prove both the device safety and that it achieves the performance intended by the manufacturer" [25].*
- It is the manufacturer responsibility to "*demonstrate to the regulatory authority that their products comply with the General Safety and Performance Requirements and have been designed and manufactured to ensure high level of safety and performance*" [26].

The background to the CE certification process is as follows :

- **Regulatory rules -** Formerly regulated by three directives, collectively known as the Medical Devices Directives (MDDs). These have recently been replaced by the Medical Devices Regulation (MDR) and the In Vitro Diagnostic Medical Devices Regulation (IVDR) [25].
- **Government-approved authority -** In Belgium, it is the FAMHP that is *"the Belgian competent authority in charge of ensuring the quality, safety and efficacy of medicines and health products"* [27].
- **Conformity assessment bodies -** Those are called “notified body" and are designated by a Member State [25]. Their role lies in this context: *"Except for class I devices that are not supplied in sterile conditions and/or do not have a measuring function, a third party must ensure that conformity assessment procedures are completed according to the MDD criteria"* [25].
- **Device classification -** In the MDD, there are 4 classes of MDs. In ascending order of potential risk, class I, class IIa,class IIb and class III. *These classifications are based on the intended purpose of the device, as well as the duration of contact with the body, the local versus systemic effect and the degree of invasiveness* [25].
- **Quality assurance system -** This is a requirement, it is outlines in Article 10 of MDR [28].

- **Clinical safety and performance evaluation -** A clinical investigation is mandatory. This is defined by the MDR as "*any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device*". This does not necessarily mean a "clinical trial" ,equivalence with an existing system may be sufficient, although there are strict supervising rules. Indeed, "*manufacturer must gather sufficient evidence about the other device on every feature claimed as equivalent*", wich is not an easy task if documents are not accessible [25].
- **Surveillance system -** *"Clinical investigations are not only required for the CE marking process, but they are also required for post-marketing clinical follow-up (PMCF) . PMCF is needed to confirm existing clinical data on the device and to update the clinical evaluation after the device is launched onto the market"* [25].

2.4 Major organizations active in the medical device industry

In addition to the country-specific role, there are several organizations worth highlighting.

2.4.1 The WHO role in the medical-device field

As stated in the introduction to this work, WHO is a specialized agency of the United Nations responsible for international public health. This organization is composed of 194 member states and its binemium budget (meaning a budget for 2 years) is more than 6.7 billion US $ [29]. The WHO's work on MDs is an integral part of its overall goal of promoting health and well-being. Indeed, this organization is involved in numerous projects related to MD. The key projects are described below.

Firstly, a project such as the "*Global Model Regulatory Framework for MDs including in vitro diagnostic MDs*" is led by the WHO. As reminded by the WHO, any national health plan must include policies, strategies, and action plans for health technologies, especially for MDs. They guarantee that citizens have access to safe, efficient, and high-quality medical equipment. This is done in order to prevent illness and injury, identify and treat it, and help people recover. This WHO project assists Member States in creating and implementing regulations and regional good manufacturing practices to guarantee the effectiveness, quality, and availability of MDs [30].

Secondly, the WHO develops global lists of priority MDs to improve access to appropriate devices [31]. This list is the result of work by the Prioritary Medical Devices (PMD) project. These lists help countries to develop or update their national essential or priority lists to promote availability and support universal health coverage [31]. This will be discuss more in depth in section4.1.

Finally, the WHO also supports member states in assessing national MD needs, particularly in resource-poor regions, by providing guidance tailored to specific country or regional contexts via an online database [30]. will be at the core of the selection method for the device to be reproduced.

2.4.2 The ISO role in the medical-device field

National standards organizations from throughout the world are united under the name ISO (International Organization for Standardization). One standards body is present for each member nation (more than 160) in this non-governmental organization. [32] The latter plays a key role in the global MDs market. Indeed, the standards issued by this entity are a globally adopted source of best practices. These standards provide a solid technical foundation for health, safety and environmental requirements. Among all those related to the field of interest, the most important according to [24] are:

- ISO 13485 Medical devices – Quality management systems – Requirements for regulatory processes
- ISO 14971 Medical devices – Application of risk management to medical devices
- ISO 10993 Biological evaluation of medical devices
- ISO 14155 Clinical investigation of medical devices for human subjects

For the scope of this thesis, only the first two are considered relevant for further explanation.

Firstly, the ISO 13485 certification is an international recognition that demonstrates that a MD manufacturer meets established quality and safety standards [33]. Although ISO 13485 is not specifically mentioned in the EU MDR regulation, it is the only QMS standard that is included in the EU list of harmonized standards, making it indirectly the only practical way to implement a QMS in accordance with the MDR. The complete system provided by ISO 13485 is focused to assisting companies in improving the quality of procedures, thus this is an extra advantage above and beyond complying with MDR [34].

Secondly, concerning the ISO 14971 standard, its purpose is " *the identification, understanding, control and prevention of failures that can result in hazards when people use medical devices*" [35]. In the European context, this translates into those facts: "*the risk management process of EN ISO 14971 represents the generally acknowledged state of the art. Furthermore, it gives a guarantee to medical device manufacturers that this standard can be used to demonstrate compliance with the risk management requirements of MDR and IVDR*" [36].

2.4.3 The IEC role in the medical-device field

The IEC (International Electrotechnical Commission), which was established in 1906, is the leading organization for the preparation and publication of international standards for all electrical, electronic and related technologies [37].

It seems that the contribution of the IEC in the medical world is mainly through the IEC 60601-1 standard and its collateral standards. The first standard is the "*internationally recognized standard that addresses general requirements for medical electrical equipment and devices covering standards for basic safety and essential performance*" [38].

2.5 Obstacles to the access of medical devices in the world

To understand the meaning of this section title, here is the definition of what is intended by "Access to medical devices" according to the WHO in [2].

The term is defined *"as the interaction of different factors that define the degree of access patients have to medical devices and services"*. The six components are the following:

- Availability
- Affordability
- Accessibility
- Appropriateness
- Acceptability
- Quality

"Availability" according to the WHO in [2]

"Refers to when a medical device can be found on the medical device market; it may also mean whether medical devices are physically available at health care facilities and are usable by medical providers to treat patients."

"Affordability" according to the WHO in [2]

Refers to the extent to which the intended clients of a health service or product can pay for its utilization.

"Accessibility" according to the WHO in [2]

"Refers to people's ability to obtain the technology and use it appropriately when needed; it may also refer to whether households or individuals are geographically able to reach health care facilities that offer necessary medical devices for a specific health condition."

"Appropriateness" according to the WHO in [2]

"Refers to medical methods, procedures, techniques and equipment that are scientifically valid, adapted to local needs, acceptable to both patients and health care personnel, and that can be utilized with resources the community or country can afford; appropriateness should include the consideration of available infrastructure and human and financial requirements."

"Acceptability" according to the WHO in [2]

"Refers to households' or individuals' attitudes and expectations towards the use of medical devices, specifically whether those devices are socially and culturally appropriate to meet local demands."

"Quality" according to the WHO in [2]

"Refers to whether the medical devices found in health care facilities and used by medical providers meet regulatory standards for effective and safe use."

2.5.1 WHO Summary Report

Technology transfer to low- and middle-income countries (LMICs) is limited due to several constraining factors. These are described in detail in *Landscape Analysis of barriers to developing or adapting technologies for global health purposes* published by the WHO . Here is a summary from [2]:

1. A lack of information about the health needs of the population, the MDs required and health care infrastructure and equipment. This is due to inefficient or inadequate data and information collection systems.

2. There is a lack of development of business capacity in LMIC, and a lack of change in the model to bring innovation to the market able to answer the unmet needs.

3. The issue of intellectual property is not always adequately protected. This is in many cases more of a constraint to innovators and producers of MDs than a driver of innovation within the country.

4. The safe and effective use and maintenance of MDs is undermined by a lack of a technically trained and qualified human resource.

5. International standards and regulatory frameworks are only partially implemented.

6. Lack of funds, which are required to maintain and operate the equipment continuously during its lifetime.

7. The choice and purchase as well as the safe use of new technologies are difficult because there is a lack of adequate information networks.

8. The creation of product development partnerships between the academic, public, and private sectors is a powerful lever to help inventions reach their target market and maximize their potential.

2.6 Vulnerabilities in the medical device supply chain

It is clear that, for MDs, "shortages affect clinical practice, organisational performance and patient outcomes" [39]. One crisis in particular impacted the availability of MDs, namely covid 19 . It affected the supply of personal protective equipment for medical use, and the supply of respirators was also affected, ...

However, these are not the only cases where the supply chain can be vulnerable. Here is a non-exhaustive list of potential crises leading to MDs unavailability:

- Force-majeure events (such as climate change or natural disasters) [40]
- Macroeconomic and political conditions (including trade-policy or regulatory changes) [40]
- Semiconductor crisis (extremely difficult to purchase chips) [41]

2.6.1 In-house fabrication in healthcare facility

There is one notable way of mitigating these availability problems: in-house fabrication. The latter is an exception to the classic CE marking scheme described in section 2.3.

What this procedure covers is described in a document issued by the Medical Device Coordination Group (MDCG). This group is "an expert group. It was established by Regulation (EU) 2017/745EN • • • on medical devices and Regulation (EU) 2017/746EN • • • on in vitro diagnostic medical devices" [42]. This is how in-house medical devices and their context are described [43]:

- *Medical devices can be manufactured and used within EU health institutions (in-house devices), on a non-industrial scale, to address the specific needs of target patient groups which cannot be met, or cannot be met at the appropriate level of performance, by an equivalent CE-marked device available on the market.*
- *In-house medical devices are exempted from most of the provisions of Regulations (EU) 2017/745 (medical devices Regulation, MDR) and (EU) 2017/746 (in vitro diagnostic medical devices Regulation, IVDR), provided the health institution adheres to the conditions laid out in Article 5(5) of the relevant Regulation.*
- *In order to ensure the highest level of health protection, Article 5(5) sets a number of rules regarding the manufacture and use of such in-house medical devices.*

Covid 19 case

At the hospital and national levels, the availability of some medical devices was under pressure during the Covid-19 crisis. Regarding the situation in wich those medical devices were unavailable in time to treat patients , certain countries expanded the scope of hospital in-house manufacturing [44].

This was the case of Belgium due to a FAMHP circular that " *broadens the scope of hospital in-house manufacturing [...] The circular authorizes hospitals to subcontract the manufacturing of these medical devices to third-party organizations*". This circular is specific to a particular case and a given time: it "*gives a framework for the 3D printing production* " [44].

2.7 Economic evaluation of the development costs

As summarized by [45], *"the medical device industry requires a great deal of time and investment before research results are commercialized. The uncertainties regarding success are also very high"*. However, it is not trivial to quantify this premise. Indeed, the MD market is a very specific field where it is not easy to estimate in advance the costs related to development. One of the drivers of this is noted in the section [46] on strict regulations. Indeed, costs are contingent on strict regulations that result in significant financial burdens.

Nevertheless, in the context of this state of the art, it is still possible to get a more tangible idea of the amounts involved in the development of a MD. To the best of my knowledge, this area is not well documented. Hence, this section is restricted to summarizing the work of Maresova et al. [46]. The objective of this last work was to provide an overview of "the complexity of the actions required in relation to the different phases and the implication of economic methods to evaluate the effectiveness of investments". In addition, the study aims to assist in understanding the cost of the development phases of MDs, thereby minimizing the overall exposure to risk and uncertainty. Finally, it provides a more realistic view of the associated financial expenditures.

The model presented in this article is considered particularly relevant for this master thesis. Indeed, the information on the provisions for a development is not well-known on a general level. The cause of this is illustrated in the discussion part of the article: "*the know-how is often owned by companies and trade secrets*".[46]

The process is divided into critical steps by the authors. An economic value is then assigned to each of these steps. This is achieved by using the available literature as well as by comparing with the actual development states of the devices. The critical steps goes as follows :

1. Initiation
2. Concept proposing
3. Design and development
4. Verification and validation
5. Production
6. Market device deployment

Usually, according to this paper [46], it is possible to evaluate the appropriateness of investments into a MDs project under 3 types. Namely:

- "Strategic and financial valuation of projects"
- "Weighting and scoring of products and product criteria"
- "Human decision-making"

It also happens that some choices are based on a "gut feeling".[46]

Nevertheless, it is important to keep in mind that projects rarely go as planned. It is therefore not necessary to focus too much on numerical precisions, but rather on the quality of the inputs. This is why "the purpose of this study is to propose a comprehensive model of the MD development to subsequently discuss economic evaluation methods as a part of a relevant phase of MD development process. The individual phases are described at a sufficient level of detail so that the idea of time or financial demands of each phase can be outlined".

In the following parts, these various steps are described. Several numerical tables will be presented. These are based on actual information from small companies that engage in the design, development and manufacture of Class I and IIb MDs. Costs may vary depending on the size of the company, but the specific procedures and phases of design, development, production and sales, and their financial requirements, remain largely the same according to the authors. In the context of this thesis, only the outputs of [46] are considered. Their case study is also included.

2.7.1 Step1: Initiation

As with any product development, customer needs are identified through discussions with physicians, end users or patients, and a review of existing systems. The following consideration should be is whether or not the product that meets the customer's needs is an MDs. To go trought this process described in section, it is useful to have a preliminary view of the following points [46] :

- Functionality and intended use
- Advantages over existing solutions
- Analysis of competing products
- Preliminary estimate of development expense, futur income, and financing

The existing intellectual property landscape is reviewed during the initiation phase. The intellectual property landscape refers to existing patents, trademarks, and other intellectual property that may impact the development and commercialization of the product.

It is then necessary to determine the type of DM in question (cfr **??**). Afterwards, it is possible to apply the classification rules established in the MDD regulation, which is risk-based.

2.7.2 Step 2: Concept proposing

A multidisciplinary team produces a design and development plan that includes [46] :

- Product specifications (its functions, size, materials)
- Packaging and production concept
- Feasibility assessment
- Action schedule

The team is composed of key experts from R&D quality assurance, production, marketing/sales, regulatory, clinical and legal entities. Ultimately, the concept proposal is used to convince potential investors to support the proposed idea.

2.7.3 Step 3: Design and development

At this point, "the product is ready for the conversion from concept to development" and "the market opportunity is already identified". During this stage, verification and validation tests are performed before and after the design is finalized. These tests basically ensure that the product meets the required quality and performance requirements. The documentation of these verification and validation studies must be complete and reproducible. Such documentation is at the focal point of the ISO 13485 standard [46].

Product design, design verification and validation, technology protection verification, or even specification of supporting documentation are all design-related processes. Technical solutions to meet customer requirements, specification of all key parameter specifications, production technology design, material design, supplier decision, regulatory (post-market clinical monitoring plan, post-market performance qualification, clinical evaluation plan), risk management (failure mode and effect analysis, advanced failure mode and effect analysis update), and technical specifications are just a few of the development-related activities.

Several tests are performed at this third stage of the MD development process to confirm the safety. For example, the electromagnetic compatibility of the device is evaluated by a laboratory accredited to IEC 606012-1-2.These reviews can extend up to a year if a test is not passed. The device is also biologically evaluated to determine if it is considered safe for patient use.Additionally, a preclinical study must prove (at least theoretically) that the principle is safe. Another clinical study, which may take one to two years if the device is brand new, is required. In case similar devices are already on the market, a similarity can be acted if considered sufficient. Finally, this clinical report is written and included in the conformity assessment. The processing of all documentation without a clinical trial takes approximately 90 days.

Below, the table 2.2 illustrating the needs in time and money of such tets is provided. This table is taken directly from the above mentioned document [46] , except that the prices have been converted from Czech crowns to euros using the rate of 1€=25 CZK.

The rate on December 12, 2019 was 1 EUR ≈ 25.5 CZK [47]. This date corresponds to the date of receipt of the document by the publisher.

Table 2.2: Examples of the time-consuming mandatory tests for class IIb of MD. This table is taken directly from [46]
Note : Average time and money with case study based on the conditions for the Czech Republic (see case study paragraph)

TESTING	**TIME**	**PRICE**
EMC	90 days	EUR 5200
Electrical safety	180 days	EUR 6000 - 12,000
Type test	180 days	EUR 6000
Biological evaluation	90–120 days	EUR 10,000
Preclinical evaluation	40 days	EUR 2000 (worker´s salary per 2 months)
Clinical evaluation	Up to 360 days	EUR 2000-4000 (clinical trial based on the use of its own clinical data) EUR 400,000 (annual clinical trial, 100 patients, device IIa)

2.7.4 Step 4: Verification and validation

In this phase, all of the above steps are being completed. At the same time there is *"the creation of formal design impressions, verification and validation of the final product, and preparation for commercial launch and regulatory approval*". The duration of this stage will depend on the points already addressed in the previous stage (successful electromagnetic testing without failure, full clinical evaluation or equivalence,...). [46]

At this stage, the packaging is finalized. This includes the requirement for the final product to contain certain symbols that are specified in the ISO 15223-1:2021 standard [48].

Finally, there is the conformity procedure assesment. This last one can be divided in 2 parts, namely: the design phase of the product and the manufacturing phase.

Table 2.3: Time and financial demands of the conformity assessment process (expert's estimation of prices and conditions of the Czech Republic) compared to Emergo by UL estimates for the US customers. This table is taken directly from [46]

Conformity Assessment	**Time**	**Price (*CZE Estimate*)**	**Complexity**	**Price (*US estimate*)**
Class I			1	EUR 4500–13500
Class Ir, Is, Im	360 days	EUR 6000	2	EUR 13,500–27,000
Class IIa			3	EUR 27,000–45,000
Class IIb	480 days	EUR 14,000–20,000	4	EUR 45,000+
Class III			5	EUR 45,000+

"It should be noted that both estimations presume that the manufacturer has the quality management system (QMS) already in place and validated and did not take into account cost associated with its maintenance, because it is considered as a fixed cost for a manufacturer".

Concerning this last point, this cost is far from being negligible. Indeed, if we take the example of the ISO 13485 standard specific to quality management in the MDs industry, according to [49] , the implementation cost is at least 3 times the order of magnitude of the price of the standard which is under 100 €.

2.7.5 Step 5: Production

The purpose of this step is to ensure that the following three types of requirements are met: those of the consumer, those of the regulator, those set by the IPR (intellectual property regualtion). At the end of this process, the product will be ready for the commercial release. In order to reach this state, the risks are reviewed. The application of the CE marking is also operated since the request for the mark has been made. The national authority, the national administrative agency that registers definite types of MDs, receives the mark after it has been granted. Additionally, a compliance assessment application is submitted [46] .

2.7.6 Step 6: Market device deployment

As the final step of product deployment, marketing objectives outlined in business plans must be monitored, along with market launches. There will be accessible follow-up research and post-market surveillance. Data is gathered, assessed, and a mechanism for keeping track of unfavorable events is in place in the form of a PMS (post-market surveillance). PMS can potentially allow manufacturers to bypass future clinical studies.

To do so, they have to configure the PMS as best they can to obtain clinically relevant data. These data might then be used to replace clinical trials [46].

2.7.7 Case study

The conditions of the Czech Republic, which is ranked 19th among EU nations in terms of GDP, are used to illustrate the economic assessment of the stages of the development of MDs. The annual wage level in 2017 was EUR 837 per month, with EU average equal to EUR/Month 1520. As a comparison, wages in Belgium were 3558 EUR/Month in 2017 [50] [46].

Based on the examination of each of these phase or activities within them, MDs economic development is assessed in the following table 2.4 [46].

Table 2.4: Type of costs in individual phases per a MD of class IIb. This table is taken directly from [46]

Phase	Type of Costs
Initiation	Wages
Concept proposal	Wages
Design and development	Wages
	Electrical safety (test costs in the accredited testing facility) EUR 6000–12,000
	Biological evaluation EUR 4000-10,000
	Clinical testing EUR 2000-400,000
	Type examination EUR 6000 thousand
Verification and validation	Wages
	Conformity assessment EUR 14,000-20,000 thousand (for Is, Im, Ir EUR 6000, for IIa/IIb EUR 14,000)
Production	Wages
	Material
	Output control (electrical MD production of own tester, for mechanical MD preparation and production of own test system)
Market device deployment	Wage per hour
	Fee for patent filing (patent application in relation to the type of patent protection European, national, worldwide)

2.7.8 Discussion on the described economical evaluation

Criticism is needed for the entire Section 2.7 for several reasons:

- Firstly, no other studies have been found to describe the development cycle of MDs. It is therefore by definition not a synthesis of the present state of the art.

- Describing the devellopement cycle of MDs is a multi-disciplinary task, as it combines legislative and normative aspects, as well as knowledge of this market where industrial secrecy is very strong.

Caution is therefore urged, as this summary is more of a perspective, which is likely to include biases that are difficult to detect.

Chapter 3

Open-source medical device

The aim of this chapter is to see how open-source devices may or may not play a role in :

- Improving access to MDs
- Providing a potential response to DM shortages

To this end, a few definitions are provided. Then, a more general background on open-hardawre (i.e. an open-source approach where hardware plans are freely available) is provided. Next, the advantages of open-hardware will be presented, along with their limitations and the challenges to their development. Finally, an example illustrating how open-hardware initiative could better perform in comparison to other crisis initiatives aimed at addressing shortages is included.

Note that for the present Chapter only, the use of the term "open-hardware" is privileged to "open-source". On the other hand, to simplify reading and because "open-source" covers "open-hardware", the term "open-source" is the only one used in the rest of this work. This is done in order to avoid any confusion.

3.1 Definition of Open-source and Open-hardware

Open-source software

The Debian Free Software Guidelines, developed by Bruce Perens and the Debian developers, are the source of the most commonly used definition of open-source software (see open-source definition v.1.9 at `https://opensource.org/docs/definition.php`). [51] summaries it as :

"*Open-source software is software with accessible source code, hence allowing peer-review and rapid evolution, complying also with criteria such as free distribution, distribution in source and compiled code, allowance of modifications and derived works, lack of discrimination against specific persons or groups, lack of discrimination against fields*

of use, lack of restriction to other software, lack of product specificity, and technological neutrality."

Open-hardware

The Open-Source Hardware Association (OSHWA) defines open-source hardware in its Statement of Principles 1.0 and Definition 1.0 as:

"open-source hardware is hardware whose design is made publicly available so that anyone can study, modify, distribute, make, and sell the design or hardware based on that design. The hardware's source, the design from which it is made, is available in the preferred format for making modifications to it. Ideally, open-source hardware uses readily-available components and materials, standard processes, open infrastructure, unrestricted content, and open-source design tools to maximize the ability of individuals to make and use hardware. open-source hardware gives people the freedom to control their technology while sharing knowledge and encouraging commerce through the open exchange of designs."
The definition is based on the open-source definition for open-source software that was previously described.

By allowing for the unrestricted interchange of designs, open-source hardware promotes knowledge sharing and commerce while allowing users to control their technology. It is crucial to note that these Principles and Definition of OSHW also state that *"persons or companies producing items ("products") under an OSHW license have an obligation to make it clear that such products are not manufactured, sold, warranted, or otherwise sanctioned by the original designer and also not to make use of any trademarks owned by the original designer."* This is significant because hardware differs from software in that it requires the use of physical resources for the creation of physical goods. [51]

Open-hardware medical device

The following article [51] proposes the following defintion :

"An open-source medical device is a medical device whose design and product development information are made publicly available so that anyone can study, modify, distribute, make, and sell the medical devices, and their related software or hardware, based on the initial available design and information. The design of the open-source medical device should be shared in a format conceived for enabling validation, verification and modification. Opensource medical devices rely on widely available materials and components, benefit from being designed according to international safety standards and processes aimed at guaranteeing patients' safety, take advantage of modularity, even being designed as inter-changeable and inter-operable kits, and rely on open e-infrastructures for information dissemination and promotion of collaboration. FAIR (findable, accessible, interoperable, reusable) data principles are proposed for open-source medical devices. Persons or companies producing and commercializing open-source medical devices are

obliged to attribute to the original designers and to make clear that such medical devices are not manufactured, sold, warranted, or otherwise sanctioned by the original designer."

3.2 Context for the emergence of open-hardware

First, a brief history: the free open-source idea first emerged in the software business many years ago. It was a rival to proprietary software. The concept behind free and open-source software is that contributing programmers create and freely release standard codes, platforms, or programs so that other programmers can afterwards alter and use them in other programs (e.g., Linux, Android) [6].

On the other hand, transposing this principle to material (open-hardware) is not necessarily a given. According to Farré et al, there are two quite new technological means that support open-hardware [6]:

1. Easy access to 3D printers (potentially cheap one) that enable, through the sharing of conventional 3D files, the creation of parts made of various materials otherwise expensive to design and produce.

2. Electronic platforms which are simple and standardized , allow the real-time sensor signal processing, motor control, and sensors reading (for example the Arduino electronic prototyping platform).

3.2.1 Quantifying the impact of open-hardware on costs

What are the expected savings from the open-hardware materials?

This is what the paper [52] attempts to answer, at least partially. The latter focuses solely on open source scientific material : 119 projects were evaluated to assign a percentage of savings over owner equivalent costs. This percentage is obtained by the equation:

$$S = \frac{P - O}{P}[\%] \tag{3.1}$$

where:

- S is the percent savings
- P is the proprietary cost of a commercial system
- O is the open-source device cost (includes only the material expenses)

Concretely, the average savings are 87%. It's a simplistic method, but one that shows the considerable impact that open-hardware approach can have.

3.3 Advantages of open-hardware Medical Devices

According to [51], have no less than the potential to reshape the MD industry. Here is why:

- The open-source approach in the " pre-marketing " phase helps to improve design, safety, security and reliability, as many stakeholders can be involved in the design process and transparency is a given [26]. This confirm by [51] : "*open-source medical devices may well lead to safer and more affordable healthcare technologies, thanks to information sharing and peer-reviewed decisions along their development and through the regulatory compliance verification process*" .
- The overall cost can be reduced [51].
- For healthcare maintenance teams in the "post-market" stage, open-source designs may be a priceless asset as they are frequently unable to find suitable alternatives for replacement. Traditional maintenance methods often lack satisfactory solutions for spare parts [26].
- The open-source method can solve issues including the lack of after-sales support for outdated medical devices, the selling of whole kits rather than individual spare parts, and excessive spare part prices [26].

Some points are examined in more detail below to add a degree of nuance to the arguments put forward.

3.3.1 Advantages on cost aspect

If the above point 3.2.1 is taken as a guide , it can be argued that open hardware lowers costs. However, it is not prudent to transpose this methodology without any adjustments to MDs given the cost structure presented in section 2.7. Indeed, the latter Section presents a whole series of heavy costs (among others quality management, clinical testing, conformity assessment).

To my knowledge, there is no comparative study that quantifies the impact of open-hardware or open-source on the development and marketing of MDs. Nevertheless, a few studies can be found for specific devices. For example, a 2014 research study demonstrated an Open-Source Syringe Pump. It argues that :*"the cost of the entire system, including the controller and web-based control interface, is on the order of 5% or less than one would expect to pay for a commercial syringe pump having similar features and performance* " [7]. The study does not take into account certification (i.e. CE mark or other) aspects, but only uses performance as an indicator of "equivalence".

3.3.2 Advantages on availability

Firstly, if certification aspects are set aside, it can be argued that accessibility is increased because all kinds of manufacturers are able to legally build the devices. According to [53], it is clear that such a system allows to be more resilient to sustain

the production chain in case of a pandemic or other major disaster. open-hardware, if sufficiently mature, is the best way to allow various manufacturers, anywhere in the world, to legally produce essential products.

Secondly, the leverage of in-house manufacturing could enable healtcare facilities to produce MDs or spare parts that are already documented in the event of a crisis, thus saving precious time.

3.3.3 Easier access to Medical Devices

The possibility of modifying a design could make it possible to adapt the initial design to make it relevant in a new context. Ultimately, this could lead to easier access to MDs by overcoming the barriers outlined in this section 2.5.1.

3.4 Challenges and limitations of open-hardware Medical Devices

The biggest challenge seems to be path certification. At present, European regulations are simply not adapted to open-harware MDs, as each new manufacturer is responsible for showing that the product meets the General Safety and Performance Requirements.

For open-hardware MDs to develop, according to [53], two legislative and regulatory prerequisites should be put in place, namely:

1. Appropriate regulatory processes that are both rapid and secure, allowing these designs to emerge when needed. In other words, this should be the case when it can be demonstrated that any equipment can do more good than harm[53]. In response to the epidemic, the FDA, for instance, changed its enforcement procedures and granted emergency use authorizations (EUA) for a variety of technologies. Within the framework of this authorization, "*FDA may authorize unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when certain criteria are met, including there are no adequate, approved, and available alternatives.*" [54]

2. Laws to protect those involved in the design process. It is heard by the authors that there is a need to find ways to minimize responsibility exposure. Any person who offers reasonable assistance to a person he or she considers to be injured, ill, endangered or otherwise disabled must therefore be protected. It is intended to reduce barriers that prevent a person from offering assistance to another because of the possibility of liability or legal action for unintended negative results.

3.5 Critical evaluation of an initiative to tackle shortage

This section presents an example of an initiative to make MDs design available in case of shortage. Several lessons can be drawn from this initiative.

On March 30 2020, Medtronic, a well-kown MDs manufacturer, released the PB560 mechanical ventilator design in response to the COVID-19 pandemic [55] . In an effort to allow others to use this design to meet the increased demand for ventilators. However, it would appear that crucial details were missing from the reproduction [56], such as:

- Firmware
- Mechanical design
- PCB layout
- Complete BOM, not just of the electronics but of all the components
- Programming, test, and assembly fixtures

This makes Horia Pais, a developer at UTI Defense and Industrial Technologies in Romania, say that "*to start redesigning the equipment, based on the schematics and the PDF is not a very rapid way to obtain the desired result, a working and fully qualified ventilator, ready for the production phase*" [57]. Moreover, according to Yan Wang, an associate professor of computer-aided engineering and design at Georgia Tech, procuring specialist valves produced exclusively by the Swiss business Norgren is a major barrier for manufacturers and academic institutions looking to adapt the PB560 ventilator design [57].

In the end, it can be said that this initiative, with its weaknesses, highlights the areas of concern for which open-source MDs are ideally suited to tackle the crisis. In addition to being ideally ready for production, this solution allow pre-adoption. The latter avoids wasting time on training which constitutes a major barrier [53].

Chapter 4

Selection of the device of interest

This work is in line with Open Medtech's commitment to develop open-source medical devices. Looking at the big picture, the aim could be to cover MDs commonly used in the hospital environment in order to:

1. Prepare the ground for a production of all kind of devices in case of crisis
2. Participate in the research on the emerging field of open-source medical devices

In any case, this is the theoretical starting point chosen for this work, although such a holistic and ambitious approach is not on the agenda.

As defined in the objectives of the work, one of the multiple outputs is the fabrication of a prototype. It is therefore crucial to ask ourselves what hardware it is relevant to realize. This appropriateness must be established on the objective criterions related to the objective of Open MedTech. Nevertheless, in the context of this master thesis, it is important not to put aside more personal criteria, such as my skills, those of the team supervising this thesis, ...

In order to select the prototype device on which to focus, the approach chosen was to document what is covered by medical devices commonly used in hospitals. This provides a baseline for determining which devices are relevant to the objectives of this work.

In addition, this core list needs to be refined to enable an informed and strategic choice of a prototype device to work on. To reduce this list and therefore prevent being overwhelmed by too many options, several filters are defined and then applied. These filters are defined based on a variety of criteria, including the technical complexity of the devices, their criticality and their potential impact. Designing these filters is no easy task, as the outputs are decisive. On the one hand, when considering the technical complexity of a device, it is important to ask whether it is sophisticated enough for a master's thesis or too complex to be feasible. On the other hand, when assessing the importance and potential impact of a device, it is desirable to use as many quantitative criteria as possible.

By following this process and carefully considering these factors, it is possible to ensure that the open-source medical devices developed is revelant in the framework of this work. This strategy is developed further in this Chapter.

4.1 The priority medical devices project

It is chosen to work on the basis of data directly from the WHO. In particular, the choice is made to work on the data that comes from PMD project. As described in the section 2.4.1, the WHO is considered as a reliable and up to date source of information. Moreover, because of its worldwide scope, this organisation cross-references and synthesizes all kinds of situations. Therefore, this is a good reason to base this study on these various works. The aim is to move towards a generalized approach.

At the 2007 World Health Assembly, a resolution was passed (WHA60.29) that directed the World Health Organization (WHO) to create and maintain a database of web-based health technologies. This database, referred to as a "clearinghouse," would provide guidance on the appropriate use of medical devices in various healthcare settings and for various health interventions.Therefore, the WHO's electronic database on medical devices is called MeDevIS (Priority Medical Devices Information System) and is open access [58].

This database is brought by the Priority Medical Device (PMD) project. This one deserves our attention because its scope covers quite well our needs in terms of informative material. Indeed, : "*Under the Priority Medical Device project, WHO is continuously updating this list of priority medical devices needed for the management of high-burden diseases, such as cancer and COVID-19, and for specific populations such as older adults, pregnant women and newborns. Key medical devices are identified in the lists based on their appropriateness and use to prevent, diagnose or treat a disease. The lists are meant to assist countries in developing or updating their national essential or priority lists, to promote their availability to support universal health coverage*" [31].

4.1.1 Description of the approach employed

The process for choosing the priority medical devices is outlined in the WHO publication : "*Medical devices: managing the mismatch: an outcome of the priority medical devices project*". [23] The PMD project team has developed an approach to selecting medical devices that is based, above all, on the need for beneficial health outcomes. This team designed a progressive approach to meet public health concerns [59]. The steps are as follows:

1. Identify the most important public health problems by mapping the high-burden diseases according to the Global Burden of Disease (GBD) and Risk Factors
2. Identify how these health problems are best managed
3. Produce a list of medical devices needed for the management of the identified high-burden diseases based on the first two steps

Moreover, the PMD project team suggests applying an exercise to any researchers or medical device selectors. The point is to take a particular device and ask the following four questions:

1. Is this medical device currently available?
2. Is it currently accessible?
3. Is it currently appropriate to the specific context?
4. Is it affordable?

On this basis : "*It is then possible to formulate a potential research framework for identifying clinical, technological, and/or process and systems knowledge-gaps to best improve access to appropriate medical devices and best address public health needs*" [59].

This process is called the **4A methodology** (for **A**vailable, **A**ccessible, **A**ppropriate, **A**ffordable). This exercise is carried out at the end of this section to validate the choice of device.

4.1.2 Content of the Medevis database

The database contains the output of 6 works up to now. Those are :

1. Interagency List of Priority Medical Devices for Essential Interventions for Reproductive, Maternal, Newborn and Child Health [60]
2. WHO list of priority medical devices for cancer management [61]
3. WHO list of priority medical devices for management of cardiovascular diseases and diabetes [62]
4. Priority medical devices list for the COVID-19 response and associated technical specifications [63]
5. Package of eye care interventions [64]
6. Trauma and Emergency Surgery Kit (TESK) 2019 [65]

To date, the database contains more than 1801 medical devices. Below, a view of the website interface is presented (Figure 4.1).

This site is quite user-friendly. On the left, a drop-down menu allows you to easily apply various filters. Finally, it is also easy to export the results in *.CSV* format. The data processing can thus be done easily in a spreadsheet like Excel.

4.1.3 Limits

The methodology developed by the PMD project has a number of limitations which were identified within the framework of the PMD project [59] :

- *Using global burden of disease estimates as an indication of public health needs for medical devices produces research priorities more relevant to the global rather than to regional or national priorities.*

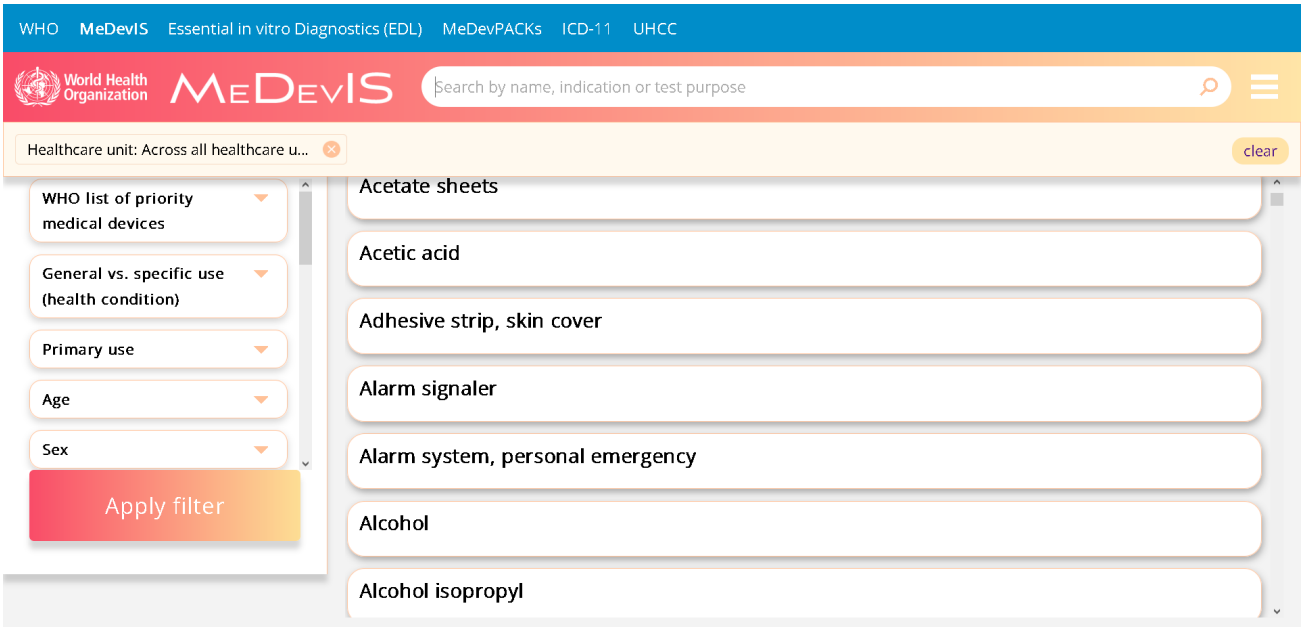


Figure 4.1: MeDevIS website interface [66]

- *As ongoing research is included in the scoping exercise, there is no evidence yet that the results of this research will bring therapeutic benefits.*
- *Using management of specific diseases as a starting point for determining future research needs excludes research needed on medical devices for general use, such as hospital beds, sterilizers, and operating lamps.*
- *The proposed research areas represent the result of a highly selective process and therefore do not cover all possible relevant research areas.*
- *Assessing the need for research in specific areas requires knowledge about current ongoing research. However, in the notoriously competitive environment of medical device development, information about their RD is rarely publicly available.*
- *A constraining factor in the preparation of the suggested research agenda has been the paucity in the clinical guidelines consulted of specific medical devices required for recommended healthcare pathways.*
- *Research on tools for the prevention of ill-health and disability is a vital need but beyond the scope of the suggested research agenda.*

4.2 Proposed strategy for selecting the device

As stated in the opening of this chapter, it is convenient to use different filters in order to obtain a restricted selection. From the latter, it will be t will be easier to select a relevant device that can be the subject of a full research work. Of course, this all depends on the areas of expertise and tastes of the parties in the project.

4.2.1 Filter settings

The proposed approach is designed to be " generic ". As such, it includes devices that apply to a variety of situations. Thus, it will be up to this party to set aside specific instruments for a single disease or condition. By the way, in the first iteration of this list made in June 2022, a "various condition" or "disease specific" criterion existed, but in the last iteration (January 2023), this is no longer the case.

Healthcare unit

For the above reasons, it was determined that only devices from the following care units were considered:

- Accros all units
- Emergency care
- General services
- General surgery
- Inpatient care
- Intensive care

The list is reduced from 1755 to 891 devices.

Knowledge level

This criterion is divided into three levels, namely:

- Basic level
- General clinical level
- Special clinical level

When looking at the content of the "Basic" level, it appears that this content is not adapted in terms of complexity.

There are still 761 elements.

Class

As outlined in the Section2.3.1, the classes of devices are proportional to the risk involved. Thus, the manufacturer is legally bound by various obligations that are more and more restrictive. This is to protect the end user as much as possible. These legal obligations and the level of quality management are becoming such that it does not seem worthwhile to include such devices in the field of possible options.

However, it would be damaging to limit ourselves to the lowest class of devices purely for these risk management considerations. Therefore, in consultation with the team supervising this work, the maximum possible class threshold was set at Class IIb devices.

There are still 628 elements.

Reusable

It was decided to consider only reusable devices in order to have the opportunity to work on systems involving electrical concepts. Thus, this criterion might not be suitable for those in the field of mechanics or materials science, for example.

Depending on the project, the research team or others, it may be necessary to consider both single-use and reusable devices in order to ensure that the best option is chosen.

There are still 493 elements.

Type of medical device

First, it is important to note that this section, as the previous one, is fairly guided by individual motives.

Table 4.1:

Type of medical device	**Number of devices**	**Retained ?**	**Typical example motivating the decision**
Accessories	22	✗	Probe, ultrasound
Assistive products	11	✗	Canes / Sticks
Catheters and related	3	✗	Catheter, suction
Cleaning, disinfection, sterilization equipment	6	✓	Autoclave
Cleaning, disinfection, sterilization solutions	3	✗	Chlorine solution
Collection devices	7	✗	Bag, hydration / nutrition
Consumables for Medical equipment	6	✗	Electrode, loop

Table 4.1 continued from previous page

Type of medical device	Number of devices	Retained ?	Typical example motivating the decision
Dressings, gauzes, bandages, pads	10	✗	Gauze roll
Endoscopes	1	✓	Video-laryngoscope
Imaging	10	✓	Ultrasound scanner, mobile
Infusion devices	5	✓	Drop counter, electronic
Laboratory equipment	4	✗	Burette, intravenous (IV) infusion
Measurement devices	6	✗	Ruler, metal
Medical equipment	122	✓	Infusion pump, precise graduation
Medical furniture	20	✗	Table, instruments
Medical gas equipment	9	✓	Oxygen concentrator
Other	7	✗	Medication cups
Personal protective equipment	16	✗	Face shield
Rehabilitation devices	2	✗	Splint materials
Respiratory accessories	8	✓	Respirator
Solutions and reagents	1	✗	Enzymatic detergent, test strip
Surgical instruments, trays and bowls	195	✗	Forceps
Sutures	1	✗	Surgical plaster roll
Syringes and needles	7	✗	Needle, aspiration
Tubes and cannulae	8	✗	Endotracheal tube introducer
Waste management products	3	✗	Container, disposal, sharps
	Total = 493		

The list obtained after applying these filters now contains 161 items.

4.2.2 Choice of the device

A manual sorting operation removed anything close to chiurgy kits, tubes, electrodes, ... A final list of 71 devices is being drawn up to deal with the options in greater depth. The latter is available in appendix A. The elements that were most considered are the following :

1. Autoclave (sterilizer steam)

2. Bi-Level Positive Airway Pressure Unit (BiPAP)
3. High Flow Nasal Cannula (adult and paediatric)
4. Infusion pump, precise graduation
5. Patient monitor multiparametric (basic, intermediate or advanced)
6. Syringe pump
7. Ultrasound scanner (doppler, portable)
8. Voltage stabilizers

The choice falls on the "Patient monitor multiparametric"[1]. This choice is somewhat arbitrary, except for the fact that it seems to be widely used. This is shown in Chapter 5.

Moreover, its multi-parametric nature is attractive for potential future master theisis work. Indeed, it allows a certain division of effort, with the possibility of carrying out several interconnected projects. For example, by: - entering into the detail of a particular parameter in order to improve its implementation - working on a higher level, i.e. improving the system's form factor, shock resistance, software parts, etc.

Note that the 4A methodology exercise has not been carried out in depth.

[1]Note that in this work, the term "multi-parameter patient monitor" is preferred

Chapter 5

Multi-parameter patient monitor

In the first chapter of *"Monitoring Technologies in Acute Care Environments: A Comprehensive Guide to Patient Monitoring Technology"* [67], James F. Szocik explains the purpose of monitoring, manely "*Monitoring, in the best circumstances, results in an improved diagnosis, allowing for more efficacious therapy*". The renowned neurosurgeon Harvey Cusing recognized this over a century ago. This first American neurosurgeon, H. Cusing (1869–1939), is profiled on the website "Encyclopedia of Cleveland History" [68]. It is mentionned that : *"Through preoperative studies, the use of tourniquets and silver clips to control bleeding, and checks on blood pressure and oxygen levels, he reduced mortality from brain surgery to 10% when most doctors were losing 33 to 50%."*

In "*Make vital signs great again - A call for action*" [69], John Kellett and Frank Sebat (2017) also highlight the importance of monitoring vital signs and taking them into account in patient management. According to those authors, *"vital signs are the simplest, cheapest and probably the most important information gathered on patients in hospital".*

Finally, C.L. Downey adds in [70] that "*Continuous vital signs monitoring outside the critical care setting is feasible and may provide a benefit in terms of improved patient outcomes and cost efficiency. Large, well-controlled studies in high-risk populations are required to evaluate the clinical benefit of continuous monitoring systems*".

The aim of this chapter is to provide an overview of multi-parameter patient monitors (hereinafter referred to as "monitors"). The minimum requirements from WHO [66] for "patient monitor multiparametric" , basic and intermediate (see appendix B) are used as a guide. Note that in this work, the term "multi-parameter patient monitor" is preferred. A brief presentation of the vital parameters involved in those monitors is included.

5.1 Overview of the device

5.1.1 What is a "multi-parameter patient monitor"?

In the document "Priority medical devices list for the COVID-19 response and associated technical specifications" [63] , multi-parameter patient monitors are define as: "

Medical devices that continuously measure, calculate and display physiological parameters designed to monitor patients. They can be basic, measuring one or two vital signs; or advanced, with multiple parameters which are used for critical patients in intensive care units and specialized surgeries. There are portable versions which are battery powered or electrically powered at the bedside. The devices include patient cables, sensors and accessories, depending on the parameters to be measured (e.g. ECG, blood pressure, heart rate, temperature, respiratory rate and respiratory gas concentrations), according to configuration, so that clinicians can be informed of changes in a patient's condition".

The use of patient multi-parameter monitors [58] is wide-ranging, i.e. in emergency services, in general outpatient services and outreach and also in all hospital services. Many health care units monitor vital parameters, among others, emergency care, general and specialized surgery, inpatient care, intensive care, outpatient care, ..., and also for diagnostics.

Finally, it is important to note that "No matter how simple or complicated our monitoring devices or strategies, all rely on basic physical and physiological principles" [67].

5.1.2 General requirements

This table is setting out the general requirements defined by the WHO for basic and intermediate multi-parameter patient monitors. The focus, in this thesis, is not solely on the basic monitor. Actually, as explained in the section on the open-source monitor selection 6.1, none of the monitor projects identified included the blood pressure component with cuff, one of the two mandatory parameters in basic monitor. Based on this situation, the aim is to find a monitor that meets as closely as possible the general requirements of the intermediate monitor.

Table 5.1: General technical requirements of interest in this work. Those can be found in Chapter 3 of [63]

<table>
<tr><th>Type of monitor</th><th>Multi-parameter patient monitor: basic</th><th>Multi-parameter patient monitor: intermediate</th></tr>
<tr><td rowspan="2">Parameters</td><td>Continuous display of:
- non-invasive blood pressure,
- SpO2</td><td rowspan="2">Continuous display on screen of:
- non-invasive blood pressure,
- SpO2
- heart rate,
- respiration rate,
- body temperature,
- ECG</td></tr>
<tr><td>Optional, display of calculated:
- heart rate,
- respiratory rate.</td></tr>
<tr><td>Blood pressure</td><td colspan="2">Blood pressure monitoring range at least 30–270 mmHg, minimum gradation 1 mmHg. Internal pump for cuff inflation for non-invasive blood pressure measurement, with overpressure protection.</td></tr>
<tr><td>SpO2</td><td colspan="2">SpO2 measurement range at least 70–99%, with accuracy better than ± 3% and minimum gradation 1%.</td></tr>
</table>

Table 5.1 continued from previous page

Type of monitor	Multi-parameter patient monitor: basic	Multi-parameter patient monitor: intermediate
Heart rate	Optional: Heart rate measurement range to be at least 30–250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm.	Heart rate measurement range to be at least 30–250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm.
Respiration rate	Optional: No more details	Respiration rate measurement range at least 0–100 bpm, minimum gradation 1 bpm.
Temperature	Not addressed	Temperature probe to be reusable, external skin contact type, but consumable to protect between patients or disinfection method explained. Temperature range at least 30–40 °C, minimum gradation 0.1 °C.
ECG	Not addressed	Minimum 3 leads (and up to 12 leads) ECG measurement and selectable display; an extra option for a simple five-lead connection preferred.
Design	Design must enable use in demanding environments, e.g., shock, vibration, and free fall tests as per tests. Protections of all the functions against defibrillator discharges and electrosurgical units.	
Operating conditions	Capable of operating continuously in an ambient temperature of 10–40 °C and relative humidity of 15–85% (90% preferable). The enclosure should have an ingress protection level IPX1 or better.	

According to this table, the basic monitor has a total of four signals, two mandatory (non-invasive blood pressure and SPO2 measurement) and two optional (heart and respiratory rate measurement). The intermediate monitor, meanwhile, includes those four signals, plus an additional two functions (body temperature and ECG signal measurement).

5.2 Description of market trends

Demand for multiparametric monitors, particularly for the diagnosis and treatment of chronic diseases, is growing all the time. In 2021, the market was estimated to be worth USD 11.0 billion [71]. The total medical device market was estimated in the same year

at USD 532.62 billion [72].

Different medical monitors exist, among others :

- The single-box EMS (Emergency Medical Services) devices which present the following characteristics:
    1. Single unit able to monitor, at the same time, a combination of vital parameters, such heart rate, SpO2, blood pressure, temperature, ...
    2. Single power source,
    3. The recording of the all patient data,
    4. Mostly, integration of a defibrillator with ECG display screen.
- The in-hospital monitors witch present more exigences such as :
    1. The wireless transmission to a central monitoring system,
    2. An alert system for the medical team on the vital signs changes of the patient .
- The portable medical devices are particularly useful to monitoring some parameters at home if the medical condition of the patient warrants it.

5.3 Use case for each parameter

5.3.1 Temperature

This section takes as its sole source the work of Wenxi Chen, entitled: "Thermometry and interpretation of body temperature" [73].

In what does the parameter consist?

"The human body is homeothermic, which maintains its temperature at a certain level to coordinate its metabolic activities by its inherent thermoregulatory mechanisms. BT indicates a human body's average thermal energy generated by metabolism within the body."

There are in practice three type of temperature measurement :

1. **Core Body Temperature (CBT) -** The CBT is the closest point to the BT when compared to peripheral tissue temperatures. It is measured via invasive means such as a needle-type or a catheter-type and is used as the gold standard of CBT clinically.
2. **Surface Body Temperature (SBT) -** The SBT is the value measured in sublingual, axilla, groin, neck, ear (tympanum, external auditory canal), thorax, forehead and elsewhere on the body surface. SBT is usually lower than CBT and

when measuring sublingual BT and rectal BT simultaneously on a subject, the former BT is approximately 0.5 °C lower than the latter.

3. **Basal Body Temperature (BBT) -** The BBT takes into account the level of activity while the body is in the most restful state with the lowest metabolic rate. The latter is frequently used to assess the menstrual cycle in women. It is not of interest here.

What indication does the parameter provide?

For correct physiological functions to occur, the normal BT (normothermia) is an essential requirement. Hypothermia (too low) or hyperthermia (too high) are two examples of abnormal body temperatures that may both injure tissue and affect metabolic processes. Significant changes in biological function can result from even minor variations:

- *"An increased BT leads to a large decrease in mental and physical performance."*
- *"A decreased BT can lead to impaired consciousness or in extreme cases to circulatory collapse."*

What is used for patient monitoring?

As described above, CBT is the gold standard in clinical settings. The ideal position for measuring CBT should be harmless and painless, not influenced by local blood flow, and quickly and reliably track small changes in arterial blood temperature. Invasive methods using natural body orifices do not meet the first requirement for prolonged patient monitoring, especially in infants and young children. The surface temperature is much less troublesome for the measurement, but it is not sufficient in terms of accuracy and reliability for real time measurements in the operating room. It can still be useful for real time measurement:

- Fever is diagnosed when SBT (armpit) above 37.2 °C
- Heatstroke precaution and BT monitoring are necessary in the summer season for outdoors activities.A wearable helmet with a built-in noninvasive skin temperature sensor is used to quantify heat strain.

5.3.2 SpO2 or pulse oximetry

In what does the parameter consist?

Measuring oxygen saturation levels is an examination that assesses blood oxygenation. There is two means [74]:

- **By arterial blood sampling -** the Arterial blood oxygen saturation (SaO2) is measured. The latter is the "*fraction of oxygen-saturated hemoglobin relative to total hemoglobin in the arterial blood and as such may indicate a patient's*

oxygenation status. This vital parameter is used in clinical practice for early detection of hypoxemia and is e.g. monitored during anesthesia"[75].

- **By using a pulse oximeter** - Hospitals now routinely use pulse oximetry to get peripheral oxygen saturation (SpO2). This is a method of choice in clinical practice to estimate SaO2. The SpO2 is derived from the cardiac-induced absorption variations of the skin and is considered a good approximation of SaO2 [75].

The pulse oximeter has become an essential medical device in emergency medicine. This easy-to-use, non-invasive technology enables real-time assessment of a patient's oxygenation status. The principle of spectral analysis, in accordance with Beer-Lambert law, is used to quantify the patient's oxygenation status [76].

This law is an empirical one that is commonly applied to chemical analysis measurements. It is use to estimate the concentration of chemical species that absorb light [77].

More concretely, a photoreceptor collects light from two light-emitting diodes. By measuring light absorption of arterial blood at two specific wavelengths, namely 660nm (red) and 940 nm (infrared), oxygen saturation may estimated. Reduced-hemoglobin absorbs 10 times more than oxyhemoglobin at 660nm; on the other hand, oxyhemoglobin absorbs more at 940 nm. The measurement is derived on the basis of the absorbance ratio at these specific wavelengths. Beforehand, a calibration curve must be established to better match actual measurements (Beer-Lambert's need correction because the light is not straight, the blood is not an blood is not a homogeneous red liquid [78]). Calibration is based on this absorbance ratio and actual measurements of arterial blood oxygen saturation (i.e. SaO2). This calibration curve is then use in the pulse oximeter for the arterial saturation to be estimate more accurately [79].

What indication does the parameter provide?

According to [74]:

- Normal SpO2 is, depending on age , between 95% and 100%.
- SpO2 is insufficient below 95%. This is refer as hypoxemia. This term applies to any insufficiency of blood oxygenation.
- SpO2 is below 90% limit is corresponding to an hypoxemia equivalent to a respiratory failure.

5.3.3 ECG

In what does the parameter consist?

ECG, electrocardiogram, records the electrical activity of the heart [80]. "*One cycle of the electrical activity of heart is called an ECG beat*" [81].

In reality, "*The heart is a rhythmic electromechanical pump, the functioning of which depends on action potential generation and propagation, followed by relaxation and a period of refractoriness until the next impulse is generated. Myocardial electrical activity is attributed to the generation of action potentials in individual cardiac cells, and the normal coordinated electrical functioning of the whole heart is readily detected in surface electrocardiograms*"[82].

Thus, ECG measure "*the electrical activity generated by the action potentials in heart muscle at each heartbeat. ECG signal is typically acquired by measuring the voltage difference between two or more points on the body surface over time*" [83].

What indication does the parameter provide?

ECG is the most commonly performed cardiac test [80]. The ECG waveform is used to detect whether the heart's electrical activity is normal or abnormal [81, 84]. Abnormal activities of the heart are called arrhythmias [81, 85]. EGC monitors can be used, among others [84].:

- To detect heart rhythm problems (cardiac fibrillations)
- To detect and monitor heart problems (heart attack)
- To rule out the possibility of heart disease
- To screen for genetic heart diseases

This painless and rapidly done exam is widely used in cardiology consultations, emergency care and intensive care units [84]. It is also important to note that ECG is standard practice among high-risk, critically ill patients [80].

What is used for patient monitoring?

A cardiac lead is the recording of the difference in electrical potential between two points, either between two electrodes for a bipolar lead, or between the exploratory electrode and a virtual electrode for a unipolar lead [84].

Two main categories of ECGs recording exist, i.e. monitoring device and diagnostic device [80]:

- For diagnostic, the 12-lead ECG is used. This conventional ECG is the result of 12 leads requiring 10 electrodes, 6 on the chest et 4 for the limbs [84].

- For rhythm cardiac monitoring, a 3- or 5-lead ECG is sufficient. It seems that "Five-lead electrocardiography (ECG) is commonly used during liver transplantation, while 3-lead ECG is used during most noncardiac operations" [86]. A 3-lead ECG can monitor at the same time the presence of a pulse, the pulse rate, and the basic shape characteristics of the waveform [87].

5.3.4 Respiratory rate

In what does the parameter consist?

"Respiratory rate or the number of breaths per minute is defined as one breath to each movement of air in and out of the lungs" [88]. The normal respiratory rate, i.e. the number of breaths per minute (bpm), varies from 12 to 20 breathing per minute [89, 88].

What indication does the parameter provide?

The purpose of respiration is to provide enough energy to sustain the metabolic needs of the organism ([89]). Two types of respiration exist, namely internal and external Respiration Rate (RR) ([88]) :

- *External respiration is the exchange of gases at alveolar and capillary level*
- *Internal respiration is the metabolism of gases at cellular level, and where the body combines the oxygen with carbohydrates to create energy, producing carbon dioxide as a waste product of the body's metabolic process*

RR is an indicator of physiological deterioration [89], such as hypoxia, low level of oxygen, or hypercapnia, high level of carbon dioxide in the bloodstream [88]. Abnormal respiratory rate is also a signal for serious illness such as cardiac arrest [88].

RR monitoring is used in clinical settings (cardiac arrest, emergency admission), or occupational settings (workers monitoring during their professional activities), or during sport (marker of physical effort).

What is used for patient monitoring?

Two types of respiratory rate monitors exist, i.e. contact-based or contactless [83]. The contact-based monitor techniques could be based, among others, on respiration airflow, on respiration sounds, on the chest wall movements by impedance measurements, on modulation cardiac activity by biopotential measurements (ECG sensors) or by light intensity measurements (PPG sensors) [83] :

- Impedance pneumography technique, using electrodes, is commonly-used; the changes in the electrical impedance of the patient's thorax is monitored. Indeed, there is a correlation between this impedance change and the volume of respirated air [90].

- RR can be extracted from ECG electrodes by injecting high-frequency current [90]. It can also be extracted from the photoplethysmography (PPG), an optical technique used to measure changes in blood volume over time. "*Both ECG and PPG signals are easily and widely acquired by non-invasive sensors in both healthcare and consumer electronics devices, making them suitable candidates for RR measurement in a range of settings, from hospital to outdoor scenarios, two techniques widely used from hospitals to outdoor*" [83].

5.3.5 Heart rate

In what does this parameter consist?

Heart rate, also known as pulse, is the number of heart beats per minute, bmp, [91]. Each person has is propre heart rate, changing from lifetime and depending, among others, on emotions, on body size, on medication use [92]. The range of resting heart rate, RHR, is normally from 60 to 100 bmp [92].

"The pulse is a bulge of an artery from waves of blood that course through the blood vessels each time the heart beats" [91]. The simplest way to measure the pulse rate is to put a finger on a pulse either on the wrist, either on the inside of the elbow, either on the side of the neck or on the top of the foot, and count the number of beats for 60 seconds [92].

What indication does the parameter provide?

"*The heart beat may be too fast, too slow, and may be regular or irregular*" (4). Too high heart rate is an indicator for tachycardias, atrial fibrillations, or ventricular fibrillation [87].

The Heart rate (HR) "*is a nonstationary signal; its variation may contain indicators of current disease, or warnings about impending cardiac diseases. The indicators may be present at all times or may occur at random—during certain intervals of the day*" [93].

Heart rate is controlled into routine clinical exam, giving an instantaneous value [94]. "*Heart rate variability (HRV), the variation over time of the period between consecutive heartbeats, is predominantly dependent on the extrinsic regulation of the heart rate (HR) [...] HRV analysis is the ability to assess overall cardiac health and the state of the autonomic nervous system (ANS) responsible for regulating cardiac activity*"[93].

HRV, is one of the most pertinent indicators to detect cardiovascular problems [95]. Heart rate monitors, tracing instantaneous HR against time axis, are non-invasive and easy perform measurements useful in a large application areas, i.e. for cardiology mental health, sleep health, diabetes, brain and others [96].

What is used for patient monitoring?

The beat-to-beat variations can be measured by two techniques, namely [96] :

- By the electrocardiogram in which the ECG beat corresponds to the time of an heartbeat.
- By photoplethysmography. The latter is a signals that depict blood volume fluctuations in a superficial body location and reflect pulsatile blood pressure changes during each heart cycle. The signals can be measured with low-cost optical sensors placed on the skin of an area with sufficient circulation, e.g., fingertip. Beat-to-beat intervals can be extracted from PPG using software algorithms. Ease of sensor placement, its non-invasive nature, and low-cost render PPG feasible for heart rate measurements. The time duration from one peak of the blood volume curve to the next peak on the PPG signal represents the beat-to-beat interval" [96]. "*Their accuracy at present is similar to that of standard electrocardiography (ECG) monitoring*" [94].

5.3.6 Blood Pressure

"*Lack of access to accurate, affordable Blood Pressure (BP) devices is a significant barrier to proper medical care, particularly in low-resource settings*".[95]

In what does this parameter consist?

"*BP is created by the combination of the force from the heart as blood is pumped into circulation against arterial walls, the blood volume and the elasticity of the muscular arteries*" [95]

Arterial BP, normal value 120/80 mmHg [97], is the "*pressure exerted in the arteries in the systemic circulation*" [97]. The higher number is the "*maximal pressure in the aorta when the heart contracts and ejects blood from the left ventricle*" [95]; this pressure is called systolic BP [98]. The lowest number represents "the pressure in blood vessels when the heart rests between beats" [95]; this pressure is called diastolic BP [97].

Blood pressure (BP), or pulse wave, is a dynamic physiological parameter [95]. BP, changing over time due to different factors such as age, activity, and mental stress, is also affected by the physical environment (e.g. temperature), exogenous substances (e.g. diet, drugs, alcohol) and disease [95].

What indication does the parameter provide?

"*Blood pressure monitoring and management is an essential part of medical care, particularly in the treatment of chronic hypertension, critical care monitoring and trauma care*"[98]. Outpatient BP management reduces significantly stroke or cardiac events through BP control [98]. Finally, BP measurement at home is also use for managing the

hypertension [95].

Screening, diagnosis and treatment of hypertension are done solely with non-invasive devices, whereas invasive monitoring is used in a hospital setting for cardiovascular monitoring to allow quicker assessment of both hyper- and hypotension. Invasive methods should be used only in specialized health care settings [95] .

What is used for patient monitoring?

"*The most commonly used methods for blood pressure (BP) monitoring generally involve either non-invasive inflatable cuff-based oscillometric or invasive arterial line manometric measurement*" [98]. Those techniques are describe just below :

- The oscillometric technique is an automated or electronic BP measurement. This measurement is based on cuff inflation and deflation. Those are "*initiated by the device which detects arterial oscillations, or variations in intracuff pressure caused by changes in pulse volume induced by the heartbeat at different applied pressures. The maximal oscillation during either inflation or deflation (device specific) corresponds to the mean arterial pressure and is used to calculate the systolic and diastolic BP using proprietary algorithms* "
- The auscultatory technique is a "BP measurement technique used with a manual phygmomanometer. Systolic and diastolic BP is detected from Korotkoff sounds using a stethoscope or microphone positioned over a compressed artery during cuff deflation" [95].

Novel cuffless wearable devices and mobile applications for the blood pressure measurement are not yet validated [95]. In reality, "cuffless devices require only one sensor for photoplethysmogram " [95]. The operating principle is as follows : "*an LED emits light with a wavelength of 940 nm, which penetrates the finger and arrives at the photo detector. The photo detector detects changes in blood flow that corresponds to natural pulsation of the blood flow*" [95].

Chapter 6

Reproduction, adaptation and functionnal validation of an open-source patient monitor solution

As established in the objectives of this work, a reproduction of an open-source device is done. This reproduction has two initial objectives:

- The first one is to reproduce a device by evaluating in detail the quality of its open-source components. Evaluation criteria include the completeness of integrated functions, the smooth integration of these functions, and the quality of open-source documentation, including hardware and software aspects. The study of the completeness of functions and documentation is what leads to the choice of device in this section 6.1. Integration is studied in the section describing its operation and functions (section 6.2.1).
- The second objective is to evaluate the system's performance. This is not be done as such, as the work involved in adapting and validating the functionalities has been a consequent challenge. The adaptation and validation are develop in section 6.3 and section respectively 6.4.

6.1 Choice of the open-source solution to be reproduced

The choice of device is made on 2 bases: the extent to which it implements the 6 functions presented in the section, and whether it can be replicated. By replicable, it is expected that the hardware plans are available, that the software is also available, and that it is under open-source license.

The table below shows the information as presented on the official pages of each project.

Table 6.1: Summarize in binary form the key points leading to the choice of device

	Protocentral HealthyPi v4	**Protocentral Pulse Express**	**Vitals E-Medic Plus**	**MediPi**	**Free Pulse**
Non-invasive blood pressure?	✗	✓	✓	✓	✓
SpO2?	✓	✓	✓	✓	✓
Heart rate?	✓	✓	✓	✓	✓
Respiration rate?	✓	✗	✓	✓	✗
Body temperature?	✓	✗	✓	✓	✗
ECG	✓	✗	✓	✓	✓
License open-source?	✓	✓	✓	✓	✓
Software available?	✓	✓	✗	✓	✓
Hardware design available?	✓	✓	✗	✗	✗

Given that there is only two completely open-source software and hardware projects, it's clear that the project for replication will be chosen among them .

Still, it is an interesting discussion to see how the other projects simply didn't fit in. In practical terms, the projects seem more complete and relevant than they actually are.

- The ***Vitals E-Medic Plus*** project seems to integrate each function, with "efficiency, effectiveness, and reliability" [99] in the words of the published paper. However, despite a great deal of research, no other information on this project has been found, i.e. no directory or dedicated site where there would be more than a descriptive paper.

- The ***MediPi*** is a "clinically lead, community based, open platform development ". In reality, the emphasis is on the software part, to make a remote patient care device. Indeed, this platform aims to connect several "commercial devices" within the MediPi platform. So there are no open-source harware parts. Those device connected are :

  1. Omron708BT Upper Arm Blood Pressure Monitor

2. Marsden M430 Scales
3. Nonin 9560 Finger Pulse Oximeter
4. Braun Pro 6000 Tympanic Thermometer

- The ***Free Pulse***, although the software part is documented on github and distributed under the MIT license (an open-source license), it is not intended to be an open-source project. The aim is to patent some part of the project, as indicated in the report "FreePulse: A Low-Cost Patient Monitor" [100].

HealthyPi or Pulse Express?

In the generals requirement of the basic monitor (cfr Table), two functions are mandatory. These same two functions are integrated by the Pulse Express, but not by the HealthyPi, which integrates only one. However, as shown in the description of blood pressure measurement, measurement without a cuff is not a mature technology and therefore not valid. Therefore, it should not be taken into account. In view of the general requirements of the intermediate monitor, however, the HealthyPi is clearly more advantageous, incorporating 5 out of 6 functions.

6.2 Description of the HealthyPi v4 open-source monitor

The *"HealthyPi v4 is a HAT for the Raspberry Pi, as well as a standalone device that can measure human vital signs that are useful in medical diagnosis and treatment"*. It consists of an MCU, the ESP32, various sensors and a dedicated integrated circuit (IC) that allow the HealthyPi v4 to collect biometric signals and data. Biometric simply means "body measurements and calculations related to human characteristics"[101]. The various components of the system are easily accessible :

- **Hardware :** The hardware parts, i.e. the Eagle design files (.brd, .sch), are available on the following github repository : `https://github.com/Protocentral/protocentral_healthypi_v4`.
- **Documentation :** All documentation files can be accessed on : `https://healthypi.protocentral.com/`. Those are also attached in appendix E.
- **Software :** The software files are available in the form of an Arduino library, the "HealthyPi v4 Arduino Library", available on : `https://github.com/Protocentral/protocentral_healthypi4_arduino`.

6.2.1 Functionalities and block diagrams

Here is a block diagram of the main operations and functions of the HealthyPi v4.

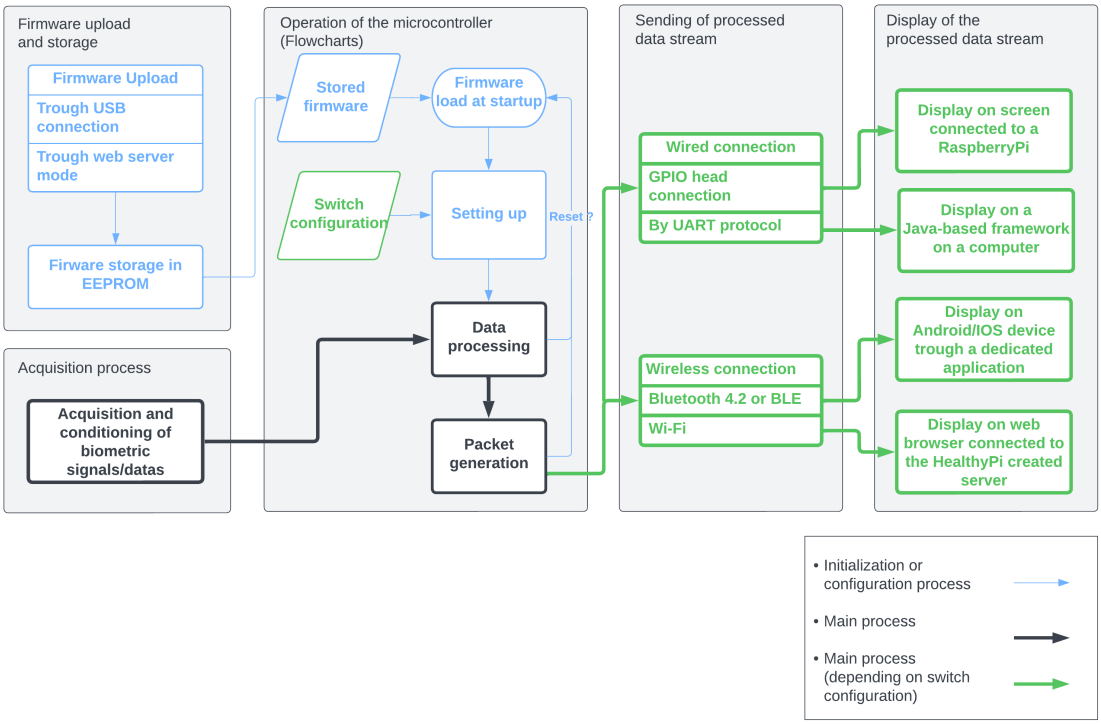


Figure 6.1: HealthyPi operation and function

In a few words, here is some additional information on the block diagram of operations and functions, from top to bottom and from left to right:

- **Firmware upload and storage:** The system embeds a firmware in an Electrically-Erasable Programmable Read-Only Memory (EEPROM), which means that no matter if the system is not powered anymore, the information is not lost. This firmware can be updated according to its operating mode (see appendix E.7). All the code is written in the Arduino programming language (a variant of $C++$ programming language)

- **Acquisition process :** This process is developed in a separate block diagram below (cfr Fig6.2).

- **Operation of the microcontroller (Flowcharts) :** A flowchart is shown here with the stored firmware and the swicth configuration as input. The latter is composed of a "Pi v3 mode" and a wireless mode. The PI v3 mode is defined by the state of a variable $Healthypi\_Mode$. This is determined by the pin status $SLIDE\_SWITCH$. In the wireless mode, the web server mode is the active one by default, if the button is pushed, it will lead to the reboot in BLE mode. Then the information is processed and sent according to the active mode.

- **Sending of processed data stream**: The data stream is sent according to the mode in which the HealthyPi operates.

- **Display of the processed data stream**: It is not useful to detail the different modes as they are quite explicit. All documentation from Protocentral is included in Appendix E. A table naming each mode is included below (Table 6.2).

Table 6.2: This table lists the different operating modes and sub-modes of the HealthyPi.

Mode	**Sub-mode**
Pi v3 mode (wired)	USB connected mode
	Raspberry shield mode
Wireless mode	Wifi mode
	Bluetooth mode

The block diagram of the biometric data acquisition process is shown in Figure 6.2.

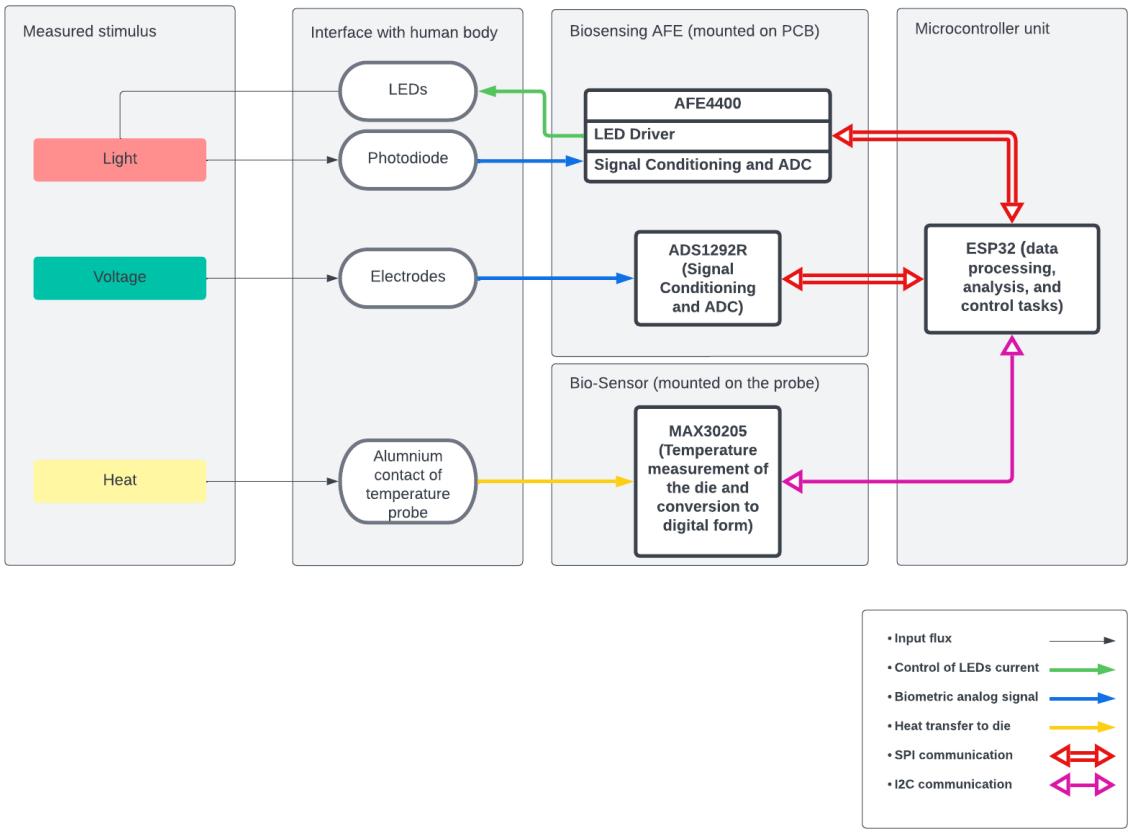


Figure 6.2: Block diagram of the acquisition process of biometric data

This block diagram is divided into five parts, from left to right and top to bottom :

- **Measured Stimulus :** There are three stimulus. Note that the light is, in principle, only that emitted by the two LEDs (red and infrared).
- **Interface with human body :**

1. *LEDs and photodiode* - Both are integrated in a "SpO2" sensor. The two emitted lights are captured by the photodiode. **SpO2 and heart rate acquisition are derived from this measurement.** In the case of the Healthy Pi, the connector (or cable, as both are one-piece units) is a Finger-clip. The connector model was never identified, despite an e-mail sent to the company protocentral, which markets the HealthyPi. The only description of the cable is that it is a "probe with a Nellcor-compatible DB9 connector".
2. *Electrodes* - The heart's electrical potential is captured by these electrodes when they are attached to the skin. In addition, high-frequency current is injected through an electrode. By this manipulation, a change in the electrical impedance of a person's thorax during inhalation and exhalation is captured. **ECG and respiartion rate acquisition are derived from this measurement.** The 3 electrodes used are included in an "ECG cable" which can easily be found on the Protocentral website. In practice, any 3-electrode cable to jack is suitable.
3. *Aluminium contact of the probe* - The aluminum contact is the part of the probe that comes into contact with the skin. The documentation does not specify where to apply this probe. In fact, the probe itself is an open source project named : "ProtoCentral MAX30205 Wearable Body Thermometer Breakout Board – QWIIC compatible". The sensor (the MAX30205) is actually in direct contact with the aluminum layer. **Temperature acquisition is taken directly from the MAX30205.**

- **Biosensing AFE :** *"An Analog Front-End (AFE) is a semiconductor device that is used for signal conditioning that is comprised of analog amplifiers, op amps, filters, and integrated circuits. This configurable functional block is used to interface with a variety of sensors"* [102]. The AFE4490 drives the LEDs as well as conditioning and amplifying the signals received from the photodiode. As for the ADS 1292R, it conditions and amplifies the measurements from the electrodes. It also manages the impedance measurement circuit.

- **Bio-sensor :** As described above, the MAX30205 receives heat from the aluminum interface. Within the sensor, the temperature of the die (the semiconductor material) is measured. The resulting output is converted to a digital form. It is therefore not, strictly speaking, an AFE.

- **Microcontroller unit :** The three ICs - AFE4490, ADS1292R and MAX30205 - communicate with the MCU via serial communication buses. The first two are SPI communications, and the third is I2C communication. Serial communication is simply "*the process of sending data one bit at a time, sequentially, over a communication channel*" [103].

6.2.2 Description of the open-source method used for the development of the equipment

The HealthyPi documentation (Appendix E.11) lists the licenses under which the following points are distributed:

- **Hardware :** All hardware is released under Creative Commons Share-alike 4.0 International.
- **Documentation :** All product documentation is released under Creative Commons Share-alike 4.0 International.
- **Software :** All software is released under the MIT License (`http://opensource.org/licenses/MIT`).

Protocentral, the company that developed the device and markets the HealthyPi v4, describes itself as "the open-source hardware and e-commerce company, well known solution provider in the areas of biomedical instrumentation and sensor electronics".

In general, their product repository is available on github. However, development prior to commercialization seems to be performed in-house and is not publicly accessible. The "HealthyPi v4" project has been financed on a Crowd Supply, which is a crowdfunding platform. It raised 33,165$ [104].

6.3 Reproduction of the HealthyPi

As mentioned earlier, all hardware drawings are available as .brd and .sch files. These files can be used with the free version of EAGLE, a well-known software package for computer-aided PCB design. The bill of materials (BOM) is easily exported to EAGLE, simply click on the "file" section and then on "export".

Theoretically, all one needs to reproduce the HealthyPi is to order parts from one or more suppliers. In our case, these are Farnell and Mouser. The circuit must also be printed (by Multi CB in our case).

Finally, one needs the equipment and the skill to weld very small components on the printed circuit. A dedicated oven is also essential. A stencil can also greatly simplify the application of solder paste.

6.3.1 Component ordering challenges

In practice, ordering is not simply a matter of ordering each component listed, due to 2 factors:

1. The components may be insufficiently named, for example, the name is only partial.
2. More problematic, many components are simply not available when needed.

The Table 6.3 lists the cases encountered that complicated the ordering of components.

Table 6.3: On the left are the original component names, on the right are the final components ordered.

Original component designation	**Complete designation of component ordered**
Incomplete reference or generic name	
ABM3	ABM3-8.000MHZ-D2Y-T
KMR2	KMR241NGLFS
AYZ0202	AYZ0202AGRLC
MICRO-B	USB3076-30-A
PIN20X2	M20-7832046
Original component is out of stock, an equivalent is ordered	
AP2112K-3.3V	AP7347DQ-33W5-7
CIG22L100MNE	MAKK2520H100M
1734354-1	5747844-6
S2B-PH-SM4-TB(LF) (SN)	B2B-PH-SM4-TB_LF___SN_
BAV99W-7-F	BAV99WT-TP
SI2323DS-TI-GE3	PMV48XPA2R
MCP73831	MCP73832T-2ACI / OTSOT-23-5_MC_MCH-M
Original component is out of stock, no equivalent exists	
ADS1292RIPBSR	ADS1296RIZXGT

Finding a complete reference is usually straightforward. On the other hand, looking for an equivalent can be a long and fastidious task involving skimming in details through datasheets.

The case of the ADS1292R is more difficult to manage. Indeed, it is an IC with its own characteristics. To get around this problem, it was decided to integrate the ADS1296R instead. This is a more complete IC of the same game. The main difference is simply that it can hold up to 6 channels instead of 2.

6.3.2 Adaptation of the PCB for the components integration

In practice, the following is done when adapting plans:

- LED resitances values are recalculated so that the LED choose are in a sufficiently bright range when they are supposed to light up. Note that these LEDs are indicator lights on the PCB, nothing to do with LEDs in contact with the finger.
- Equivalent components don't necessarily have the same form factor or the same pin isposition. .sch and .brd files are therefore adapted accordingly.

The case of ADS1292R/1296R is more difficult to handle. Reading the respective datasheets in parallel, it becomes clear that most of the features of the 1296R can be

implemented in a configuration similar to the 1292R configuration.

The form factor, however, is not the same: the 1296R is BGA, meaning that its pins are not on the edges, but underneath the component. The "classic" form factor is not available when ordering.

This component is integrated further to the right than its counterpart in the initial project (cnfr Figures 6.3 and 6.4). This is done, without realizing it, at the expense of the original form factor, which is a Raspberry hat one. In other words, it cannot be inserted above a Raspberry.

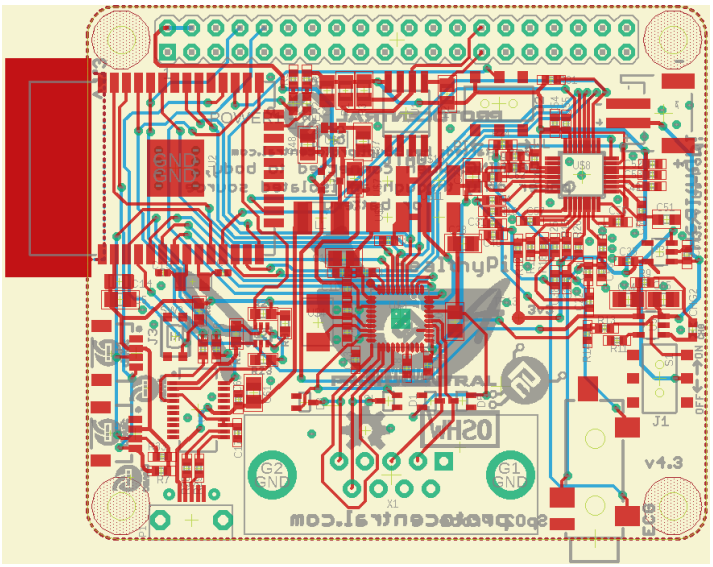


Figure 6.3: View of the original .sch file

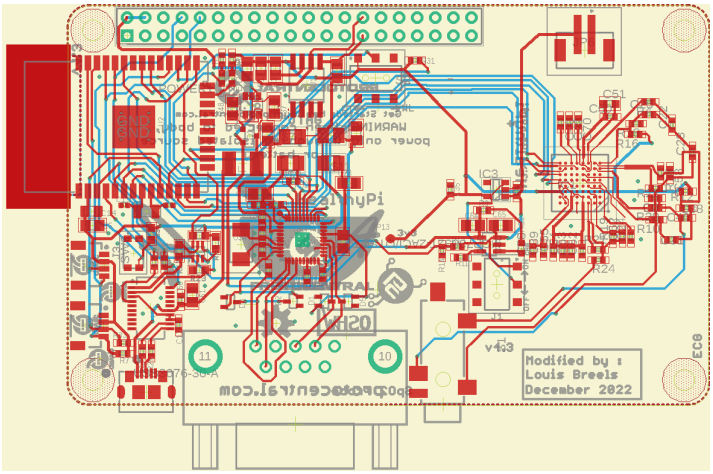


Figure 6.4: View of the modified .sch file

6.3.3 Assembling the HealthyPI

Assembly is completed by the end of December 2022 by an experienced operator my help in slightly less than 4 hours.

The only feedback so far is that the resistors and capacitors used are excessively small. Not only does this complicate installation, but in the event of faulty soldering, it's also less visible.

6.3.4 Reproduction costs

HealthyPi v4 is initially priced at $250 (note that it has just been discontinued in favor of version 5).

The expenses incurred in this project are as follows [1]:

- 117.7 € for 2 printed circuits and a stencil
- 115€ for the components (enough to make one complete system).
- 10€ for the battery
- 30€ for the SpO2 cable, excluding delivery. Please note that, as previously stated, there is no guarantee that the cable purchased is compatible with the device. The only known fact is that it is nellcore compatible : "*Nellcor Sensor means a probe apparatus for use with an optical oximeter as disclosed and claimed in U.S. Patents 4,621,643 and 4,700,708*" [105].
- The cable with electrodes was not purchased

This is to emphasise that it is far more competitive to buy direct. Particularly if the cost of assembly labour is taken into account.

6.4 Functionnal validation of the HealthyPi UCLouvain version

This section presents the experimental tests performed on the HealthyPi PCB reproduced in this work. The objective of this section is to evaluate that the expected functionalities of the HealthyPi PCB are correctly implemented. Indeed, it is about validating the selection of the components and their correct implementation. Through a series of tests are verified:

1. The integrity of the hardware design
2. The power supply implementation
3. The communication interfaces

[1] As state in the acknowledgement, the various costs were supported by a donation from *Louvain Foundation*

4. The signals acquisition capabilities

5. Overall system integration

This chapter provides a detailed account of each test performed, including methodology, procedures, and observations for troubleshooting certain issues. Conducting these comprehensive experimental tests is also an opportunity to better understand the strengths and weaknesses of the HealthyPi. Specifically to identify errors made during the adaptation of the PCB, but also to see the completeness of the documentation expected from an open-source device.

Finally, it is also imperative to ensure that the risks associated with the prototype system are properly taken into account in the test protocol.

6.4.1 Visual Inspection

From a general point of view, it is important to inspect if the components are all well welded. This inspection is essential to reduce the risk of destructive short circuits when the power is turned on for the first time.

Regarding the battery, visual inspection is essential in terms of safety. The reason is their potential risk of thermal runaway, fire or even explosion if mishandled.

The various points of attention are as follows:

- Avoid any structural damage: dropping, drilling or being subjected to physical stress
- Charging system: it is necessary that the charging system is specially designed for this kind of battery. According to [106] "*one cell LiPo battery has a nominal voltage of 3.7 V. When fully charged it has a maximum voltage of 4.2 V*". In our case, this function is mainly provided by the *insert name* which corresponds well to those specifications.
- Stocakge: *"Do not store LiPo batteries in extreme temperatures below 0°C or above 50°C"*[106] ".
- Connection and polarity: "*Never, under ANY circumstances let the positive and negative battery leads touch. This can lead to cell ballooning, cell damage, fire or an explosion*"[106] ". To address this issue, the BJT connector incorporates keying to ensure correct polarity during connection. To verify that there are no design issues, a visual inspection was performed to ensure that the negative terminal (black wire) would connect to system ground in the PCB layouts.

6.4.2 Power Supply Testing

As highlighted in the previous paragraph, precautions should be taken when first turning on the power. Thus, even if the battery is in good condition, the general power

management circuit has not been validated. This is done in 2 parts, one where the power supply is provided, and one where the recharge function is checked.

Setting a current limit

In order to prevent an abnormally high current from flowing through the circuit, use a SMU is use to set a current limit during power supply. This could damage the system. A source measurement unit (SMU) is "*an instrument that combines a sourcing function and a measurement function on the same pin or connector*" [107]. For this work, the N6715B from Keysight, is used.

This test is simply carried out by connecting the SMU with a 3.7 V voltage in place of the battery to check that the current range correspond to normal system operation. A block diagram showing the operations is attached at figure 6.5.

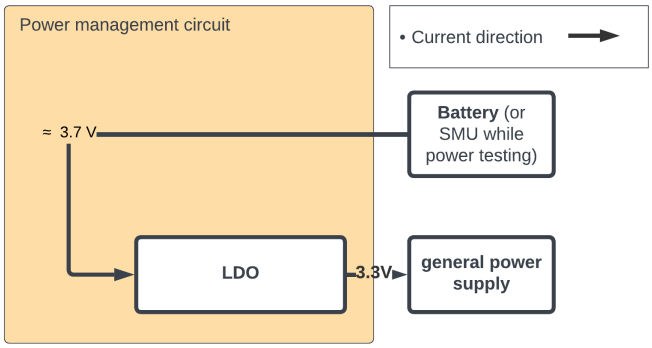


Figure 6.5: The power is supply by the battery or the SMU. A dropout regulator (LDO) is use get the 3.3 V neededto supply the system.

Estimating the current limit

The initial assumption is that the first-order estimate consumption of the system is equal to the sum of the three integrated chips consumptions (MCU, AFE4490, ADS1296R). The power input limit must be sufficient to ensure that the system is supplied with enough power. In this case, with this LDO, the differences between input and output currents can be considered negligible. Thus, it is sufficient to ensure that the input current limit is greater than the current consumed in the theoretical "normal use".

According to the datasheets :

- The MCU uses $240mA$ in the most demanding case.
- The AFE4490 consumes less than $3mW$ without any LED to supply and therefore less than 1mA ($> \frac{3mW}{3.3V}$)

- The ADS1296R consumes less than $6mW$ without any electrode to supply and therefore less than $2mA$ ($> \frac{6mW}{3.3V}$)

Ultimately, only the MCU demand is significant. A current limit of 250mA is selected to provide some margin.

Results

By checking the voltage at the test point, i.e. a point where the PCB is partly exposed, a voltage of 3.3 V is indeed obtained.

Verification of the charge function

To verify this, the voltage and current ranges are checked by the SMU in place of the battery. A usb cable is plugged in and used as a power source. The operation of the complete power management system while charging is shown in the figure 6.6.

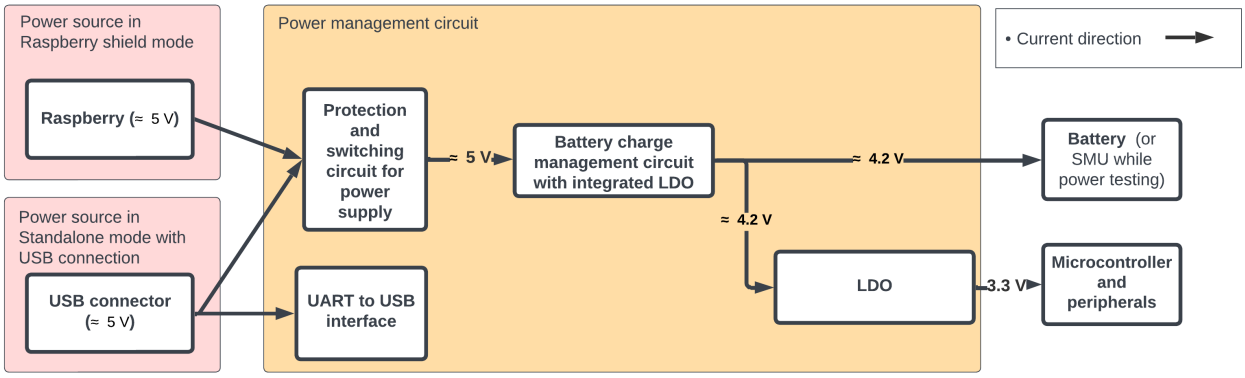


Figure 6.6: This figure illustrates the operation of the complete power management system during charging. The power source is either a usb power supply or a Raspberry PI power supply.

According to the battery datasheet, the charge voltage is 4.2V and the nominal charge current is 525 mA. When the SMU is connected instead of the battery, a current of 500mA and a voltage of 4.06 V is measured. Given that the ranges correspond, the recharging system is considered functional.

6.4.3 Verification of connection functions in different modes

Programming the system is documented on the HealthyPi website as listed in the appendix E.7.

Please note that a usb cable enabling data exchange must be used. Indeed, some cables (like the one used in the first try) offer only a 5 V feed, and no data transfer is

possible. It should also be noted that "ESP32 File system uploader" is not compatible with Arduino IDE version 2.0.

The following points are tested with little difficulty:

- Display "Hello world" using the UART connection via the USB interface
- Connect a PC to the "HealthyPi" Wi-Fi network and point its web browser to the "healthypi.local" website
- Testing Bluetooth with an Android device

Note that the Raspberry shield mode has not been tested, as the form factor no longer corresponds.

As it stands, each test element works as expected, except that no biometric data is received. All parameters (bpm, SpO2 value, ...) remain strictly at 0. This means that communication between the MCU and the respective dedicated IC needs to be studied.

6.4.4 Establishing the ESP32 - ADS1296R communication

As the ADS1292R is replaced by the ADS1296R, SPI communication needs to be revised to enable the MCU and this component to communicate.

Most of these adaptations need to be made to the "Protocentral_ADS1292r.h" and "Protocentral_ADS1292r.cpp" files within the "ProtoCentral_HealthyPi_v4_Library" library. The aim is simply to write a version to accommodate the register assignment and configuration differences since the two components are similar.

The task of adapting these files has been abandoned, as the components have actually been incorrectly integrated on the PCB. This is identified by a test procedure in the datasheet which ensures that the device is fully functional. Very quickly, two signals are identified as improperly linked on the EAGLE plans. Those signal are two essential control signals, namely the *ChipSelect* signal and the *SlaveSelect* Signal. The appendix C documents the various information in greater detail.

In conclusion, it is considered virtually impossible to solve this problem without remanufacturing a PCB. The revised plans will be available in the repository documenting this work.

6.4.5 Troubleshooting ESP32 - AFE4490 communication

The communication between the ESP32 and the AFE4490 is via SPI. This communication channel is partly the same as the one the ADS1296R. This translates schematically on figure 6.7 :

SPI communication is not functional as it is not possible to receive anything other than zeros from the AFE4490. This is noticed by doing the following manipulation: after a reset, a value is written to a register and then an attempt is made to read it. A series of actions is therefore being taken to toubleshoot this problem:

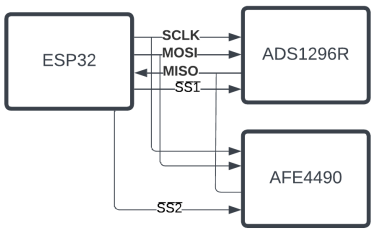


Figure 6.7: SPI link with one master (ESP32) and two slaves (ADS1296R and AFE4490).

The signal are the flowing in SPI communication [108] :

- SCLK: Serial Clock
- MOSI: Master Out Slave In
- MISO: Master In Slave Out
- SS: Slave Select

The first three signals are shared between the different slaves (ADS1296R and AFE4490).

- The ADS1296R is disabled by activating the power down pin with the ESP32. It did not solve the problem.
- The writing of a value by the ESP32 in the AFE4490 and its reading in the other direction are studied on an oscilloscope. These observations enabled trouble shooting. The oscilloscope figures are available in the appendix D. A simplified view of the problematic phenomenon is shown in figure 6.8:

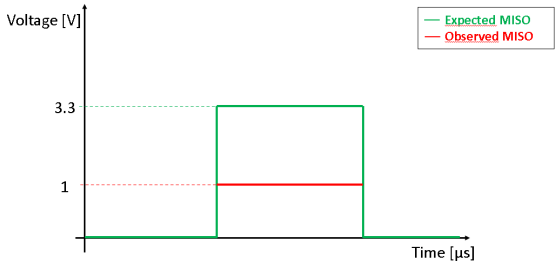


Figure 6.8: This represents the fact that the MISO signal is not behaving as expected. Note that the time scale is deliberately not graduated.

The reason why the signal doesn't behave as expected is as follows: although the ADS1296R is power down, the MISO link is still connected to this component. In reality, the AFE4490 is not able to pull the signal up (i.e. 3.3 V).

To solve this problem, all it takes is to unsolder the ADS1296R, which is in any case unusable.

Incorrect acquisition of SpO2 and heart rate.

Although communication has been established, system acquisition is not satisfactory. Normal use, i.e. inserting a fixed finger, produces a zero signal throughout.

In the event of random external stimuli (e.g. rough handling of the sensor), on the other hand, the SpO2 signal reacts. However, no reason could be found for it. The raw values, i.e. the latest samples converted by the ADC corresponding to the 2 channels (IR and red light), were not successfully analyzed.

At present, the observations made do not allow any further description of the problem. This could be due to the cable not being interchangeable with the initial one, to poorly conducted tests or other factors.

6.4.6 Troubleshooting ESP32 - MAX30205 communication

When temperature is to be displayed, the only value extracted is a zero. Since this is the default value, it soon became clear that this value is not updated. It is therefore necessary to examine the communication between the ESP32 (the MCU) and the MAX30205 (the sensor responsible for temperature acquisition), by checking that I2C communication is taking place correctly.

To check whether an I2C device is available, simply use its address with $Wire.beginTransmission()$ and then use the value returned by $Wire.endTransmission()$ to interpret the result according to [109]:

- *0: success.*
- *1: data too long to fit in transmit buffer.*
- *2: received NACK on transmit of address.*
- *3: received NACK on transmit of data.*
- *4: other error.*
- *5: timeout*

NB : Wire is a libary that "allows you to communicate with I2C/TWI devices"[110]; "NACK" stands for Not Acknowledge.

Initially, I2C communication between the ESP32 does not work because the only value obtained by $Wire.endTransmission()$ is 2. The following is a summary of the various hypotheses and tests used to identify and resolve the issue.

Testing on an Arduino

To troubleshoot this issue, a test is being conducted using an example on a breadboard with an Arduino nano. The cable, purchased from Protocentral, comes with a breakout circuit for easy connection to the arduino Nano. The set up is shown on figure 6.9.

This operation did not change the observations; no sign of communication is observed through $Wire.endTransmission()$.

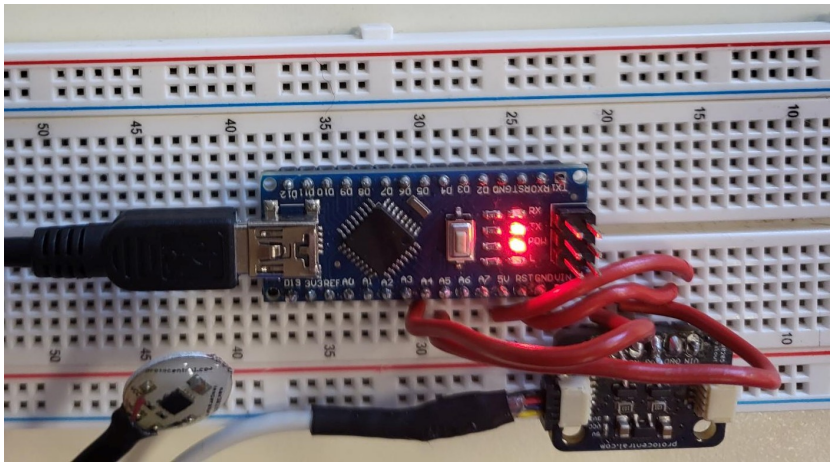


Figure 6.9: Bottom right is the probe integrating the MAX30205, which is connected via the QWIIC connector to the beakout circuit, itself connected to the Arduino Nano.

QWIIC connection defective?

Not finding the problem, it is verified whether the end of the cable, which is slightly loose, is not the source of a false contact.

For this reason, the cable has been stripped in order to solder the cables directly to the HealthyPi. This is done by unsoldering one of the two QWIIC connectors. Once again, it didn't work, and the theory that the cable was defective seemed even more likely.

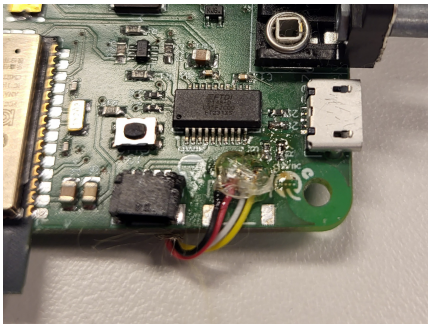


Figure 6.10: Welding wires to the HealthyPI

Closer look at how librarires are used

The Arduino IDE is using the default Wire library instead of the one specific to the ESP32. The problem is that the hardware path specified is not the right one. The hardware path was set to *"C:\Program Files (x86)\Arduino\hardware"* instead of the correct path, which is *"C:\Users\louib\AppData\Local\Arduino15\packages\esp32\hardware"*. A similar problem caused no communication when testing with the Arduino Nano.

To solve this issue, simply change the hardware path in the Arduino IDE configuration parameters so that it points to the correct location. From this point onwards, the acquisition of temperature was no longer an issue.

6.4.7 Overall System Integration

In resume, all aspects of the user experience, with the exception of use with a Raspberry, have been validated.

On the other hand, the biometric data acquisition situation is extremely disappointing:

- The ADS1296 has been poorly implement. This means that no ECG or resiration rate measurement can be performed.
- Although it is possible to communicate with the AFE4490 via ESP32, no clue has been found as to why SpO2 and heart rate are not well acquired (cfr Figure 6.11).

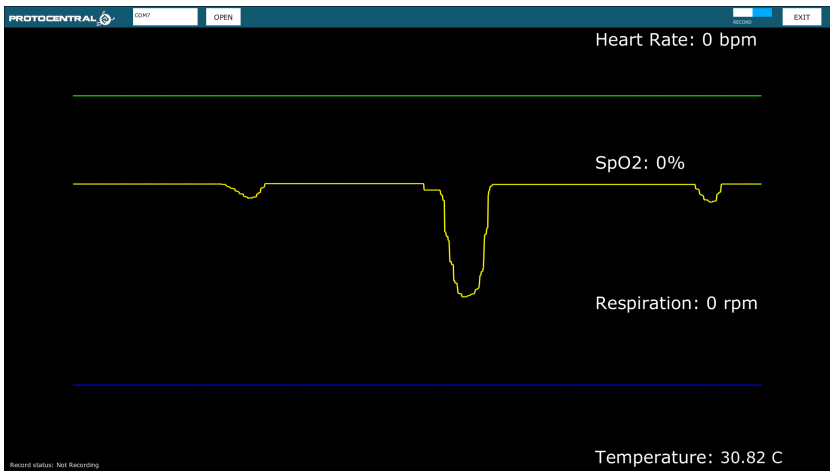


Figure 6.11: This is a screenshot of the signals displayed in USB connection mode. The SpO2 signal results from a manual stimulus by randomly and roughly manipulating the sensor. The temperature measurement are display in real time.

Only the temperature is acquired, the same temperature that can be acquired with the cable and a well-configured arduino nano.

Chapter 7

Discussion and perspectives

7.1 Return of experience on reproduction and adaptation of HealthyPi

The results are disappointing, but the good news is that the problems encountered are not due to the HealthyPi design itself.

The functionalities that make the Healthy Pi a stand-alone or connected device are validated. It also turns out that the individual parameters are each part of a respective smaller Protocentral project. For example, there is a "ProtoCentral AFE4490 Pulse Oximeter Breakout Board Kit". This means that, in the event of an enhancement phase, it is not necessary to reproduce the HealthyPi, but its slimmed-down equivalent.

7.2 Need for a multi-disciplinary approach

The subject of this work involves many aspects that go far beyond the technical domain. Among other things, economic, medical and logistical expertise are involved.

7.2.1 Legislative aspect

The context studied is European-centric, due to the location of the NPO Open MedTech. Studying other contexts would perhaps open up the field of possibilities. Moreover, apart from in-house manufacturing, no other path has been documented as to how an open-source MD could be certified.

7.3 Element not covered by the literature or research premise

As pointed out at the end of Chapter 2, the economic evaluation of the development and marketing of medical devices is not a literature-rich field. This makes it all the more difficult to account for the potential impact of open-source MDs on these costs.

Meanwhile, open-source MD research is still in its early stages. I personally noticed that the same people seemed to power most of this area. It's possible, then, that there are ideas on which people agree, but which are not sufficiently rigorously evaluated. For example, to me, the cost savings that open-source brings to MD as a whole is not a principle already demonstrated only because it's possible to make prototypes cheaper than commercial devices.

7.4 A way to mitigate shortages

If key components are out of stock, open-source may not be able to improve the situation significantly, or even at all. For example, and this is precisely what the HealthyPi reproduction experiment shows, electronic component equivalents are not necessarily available.

7.5 Discussion on the selection device methodology

A database built to mitigate high burden disease was used as a starting point. From this "worldwide" framework, a few devices of interest were selected.

Still, other strategies exist, such as bottom-up strategies for identifying needs.This is addressed in [111].

7.6 What's next

There could be plans to improve HealthyPi (e.g. to include blood pressure). Or a study of the unaddressed requirements of HealthyPi could lead to the development of a monitor made in UCLouvain.

Moving away from MDs strictly speaking, an open-source power supply stabiliser project could be useful. Power supply instability is one of the main causes of the high failure rate of donated MDs.

Finally, perhaps a master's thesis in the CPME option could bring a multidisciplinary vision to a similar project.

Chapter 8

Conclusion

Access to medical devices is a global issue on many levels. Indeed, their availability on the market can be compromised by various crisis and their access is not structurally guaranteed for some LMICs. To make access more resilient, open-source MDs could be a major asset. However, the potential of this kind of open-source material is closely linked to its ability to comply with regulatory requirements.

A global approach presents the framework for developing and marketing MDs, including both the regulatory and economic aspects. This master thesis highlights a point of attention in European regulations that can help guarantee the availability of MDs in the event of accessibility crisis: in-house fabrication. Structural problems of access to MDs, i.e. barriers to technological appropriation, intellectual property or lack of funds, are highlighted.

Putting the global medical context and the advantages of open-source and open-hardware approaches into perspective shows that the cost-reduction potential, supply-chain robustness of open-source MDs, and potential for overcoming barriers to MDs access are precisely what open-source can deliver. The importance of certification path and requirements is the reason why absence of specific regulations makes it difficult to bring open-source MDs to market.

The medical device to be reproduced is selected from an identified database. This database is a list of MDs considered as priorities by the WHO. The developed strategy for dealing with the database enabled an informed choice of MD to be made.

Based on a review of the minimal requirements for the basic and intermediate monitors, some of the selection criteria (biometric information to be included) for the open-source solution to be replicated are established.

Taking into account the other selection criteria, i.e. the availability of the design and software, the HealthyPi is chosen as the material to be reproduced.

Although documentation, plans and software are available, reproducing the HealthyPi proved to be no easy task. There are two reasons for this :

- The design had to be adapted even though the initial design choices are not documented.
- Troubleshooting requires a wide range of specialized skills in electronics. These skills are now partially acquired.

Although the prototype is not yet functional, the work has been a valuable learning experience in technical and non-technical fields.

Appendices

Appendix A

List of List of 72 MDs from Medevis

Table A.1: List extracted from Medevis after the filters used in this work

1	Anaesthesia breathing circuit
2	Anaesthesia set
3	Anaesthesia system
4	Anaesthesia unit
5	Aspirator, electrical, portable
6	Autoclave
7	Autoclave, sterilizer steam
8	Bi-Level Positive Airway Pressure Unit (BiPAP)
9	Detector, End Tidal CO2, colorimetric
10	Electrocautery system generator
11	Electrosurgical unit
12	Electrosurgical dissector, blunt, laparoscopy
13	Electrosurgical pencil
14	Electrosurgical system generator
15	Electrosurgical unit
16	Flow regulator, Intravenous infusion, manual / with dial
17	Flow splitter
18	Flowmeter
19	Flowmeter, oxygen therapy, dialtype
20	Flowmeter, Thorpe tube, dual
21	Fluid warmer
22	Generator system, vessel sealing
23	Haemostasis unit, thermocoagulation
24	High Flow Nasal Cannula, adult and paediatric
25	Humidifier
26	Humidifier, bubble, non-heated
27	Humidifier, heated, servo-controlled
28	Infusion pump, precise graduation
29	Lamp, examination, mobile

Table A.1 continued from previous page

1	Anaesthesia breathing circuit
30	Lamp, flashlight medical
31	Lamp, operating room
32	Lamp, operating room, ceiling
33	Lamp, operating room, mobile
34	Laryngeal mask airways
35	Manometer, Spinal
36	Mask, anaesthesia
37	Mask, manual resuscitator
38	Mask, NIV
39	Mask, Oral/nasal
40	Mask, Oxygen
41	Mask, oxygen, partial-rebreathing
42	Nasal mask, adult and paediatric
43	Needle driver, intraosseous
44	Nitrous oxide supply system
45	Oxygen humidifier
46	Oxygen supply system
47	Patient monitor multiparametric, advanced
48	Patient monitor multiparametric, basic
49	Patient monitor multiparametric, intermediate
50	Pulse oximeter, fingertip
51	Pulse oximeter, table top
52	Pump, Patient Controlled Analgesia (PCA)
53	Pump, suction, electric
54	Rapid Infusion device
55	Pump, suction, manual
56	Sedation equipment, basic
57	Sensor, Flow, ventilator
58	Syringe pump
59	SpO2 sensors
60	Suction and irrigation unit
61	Suction system
62	Suction system, general purpose
63	Suction system, surgery
64	Syringe, aspiration
65	Thermometer, clinical, digital
66	Thermometer, continuous electronic
67	Ultrasonic generator, surgical
68	Ultrasound scanner, doppler, portable
69	Ventilator, Intensive Care Unit
70	Video-laryngoscope
71	Voltage stabilizers

Table A.1 continued from previous page

1	Anaesthesia breathing circuit
72	Venturi Mask

Appendix B

Technical Specification of "Patient monitor multiparametric: basic"

World Health Organization

Patient monitor multiparametric: basic – for non-invasive blood pressure (NIBP) and oxygen saturation (SpO2) (with accessories)

Published on: 19 November 2020 - **Version: 3**
Version 2: 18/06/2014 (modification of the initial version)
Version 1: 13/06/2012 (initial version)

Technical Specification	Minimum requirements
General technical requirements	Continuous display of non-invasive blood pressure and SpO2. Display of calculated heart rate, respiratory rate are optional. Operator can set audio-visual alarm levels for low or high levels of each parameter independently. Operates from mains voltage or from internal rechargeable battery. • Heart rate measurement range to be at least 30–250 bpm, with accuracy better than ± 5 bpm and minimum gradation 1 bpm. • SpO2 measurement range at least 70–99%, with accuracy better than ± 3% and minimum gradation 1%. • Blood pressure monitoring range at least 30–270 mmHg, minimum gradation 1 mmHg. • Internal pump for cuff inflation for non-invasive blood pressure measurement, with over pressure protection. Liquid crystal display (LCD) or thin-film transistor (TFT) screen with: • numerical values visualization; • settable limits for the measured variables; • all parameters can be shown. Design must enable use in demanding environments, e.g. shock, vibration and free fall tests as per tests. Protections of all the functions against defibrillator discharges and electrosurgical units. Pace-maker detection. Capable of operating continuously in ambient temperature of 10–40 °C and relative humidity of 15–85% (90% preferable). Automatic and programmable memory (preferable). Storage of continuous monitoring data (preferable). Trend display of each parameter over a timeframe possible (preferable). Enclosure to have ingress protection level IPX1 or better.
Alarms	Alarm override and temporary silence facility to be included. Audio-visual alarms required: high and low levels for each parameter (operator variable settings), sensor/wire/probe disconnected, low battery, cuff leak, cuff disconnect, hose leak, inflation/deflation errors, failure to take successful reading. Power failure.
Accessories	All the cables, sensors and connectors needed for full monitor functionality are to be included in the bid. Reusable SpO2 probes adult: 2 probes. Reusable SpO2 probes paediatric use: 2 probes. Blood pressure – non-invasive: 3 paediatric reusable cuffs; 3 adult reusable cuffs. Battery: 1 set.
Spare parts	1-year spare parts kit as per preventive maintenance programme, including but not exclusively: sets of spare fuses (if non-resettable fuses used) and battery
Power supply, voltage, frequency and plug vary across the countries	Operated by line electrical power supply with internal replaceable rechargeable battery backup allows operation for at least 1 hour in the event of power failure. Operates from AC power electric line: 100–240 V~/50–60 Hz. Main power cable and plug adapted for various countries. Mains power cable length ≥ 2.5 m. Protections against over-voltage and over-current line conditions. Protection against defibrillator discharges and electrosurgical units. Automatic switch between battery and mains powered modes, when recharging or in mains power failure. The display shall show which power source is in use. Compliance with electrical standards and regulations.
Documentation requirements (English language mandatory)	Set: user and maintenance manuals, hard and soft copies, in English (mandatory) and other languages (preferable). Certificate of calibration and inspection. Troubleshooting, calibration and routine maintenance. List of all spare parts and accessories, with part numbers and contact details for parts supply. Document with contact details of manufacturer, supplier and local service agent.
Primary packaging label	Name and/or trademark of the manufacturer. Electrical power input requirements (voltage, frequency and socket type) and safety use and storage (keep away from oil, grease and petroleum-based or flammable products as well as smoking or open flames). Model or product reference. Information for particular storage conditions (temperature, pressure, light, humidity).
Standards, for the manufacturer	Certified quality management system for medical devices (e.g. ISO 13485). General quality management (e.g. ISO 9001). Application of risk management to medical devices (e.g. ISO 14971).
Regulatory approval/ certification	Free sales certificate (FSC) or certificate for exportation of medical device provided by the authority in manufacturing country. Proof of regulatory compliance, as appropriate, per the product's risk classification (e.g. Food and Drug Administration [FDA] and/or Conformité Européenne [CE]).
Standards, for product performance	Compliance to the following international standards or to regional or national equivalent (including the technical tests for safety and performance from accredited laboratory or third party) for: IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. IEC 60601-1-1 Medical electrical equipment – Part 1-1: General requirements for safety – Collateral standard: Safety requirements for medical electrical systems. IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. IEC 60601-1-8 General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems). IEC 80601-2-49 Medical electrical equipment — Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment. IEC 80601-2-30 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers. ISO 80601-2-61 Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. IEC 62133 – Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells. Part 1: Nickel, Part 2: Lithium. Preferable if tested for: IEC 62366-1 Medical devices – Part 1: Application of usability engineering to medical devices. IEC 60068-1:2013 Environmental testing - Part 1: General and guidance. IEC 60068-2-31 Environmental testing - Part 2-31: Tests: Rough handling shocks, primarily for equipment-type specimens.
Warranty	5 years with regards efficiency and quality of the product (software upgrades included). Availability of accessories and spare parts for at least 5 years.

Appendix C

identifying problems in ADS1296R implementation

C.1 Context

The unavailability of the ADS1292r component has led to the modification of the schematic plans for HealthyPi 4.3, which now integrates the ADS1296r instead. This modification requires creating the "Protocentral_ADS1296r.h" and "Protocentral_ADS1296r.cpp" to adapt the library. However, before proceeding, it is important to verify that the SPI communication is functioning correctly. Therefore, the proper modification of the PCB to allow communication between the MCU and ADS1296r needs to be tested.

To test this, the procedure outlined in section 10.1.1 of the ADS1296r datasheet was followed, which provides a diagram and sample programming codes for basic data capture. This procedure ensures that the device is functioning properly in the system by putting it into a configuration that matches the parameters listed in the specifications section.

Application Information (continued)

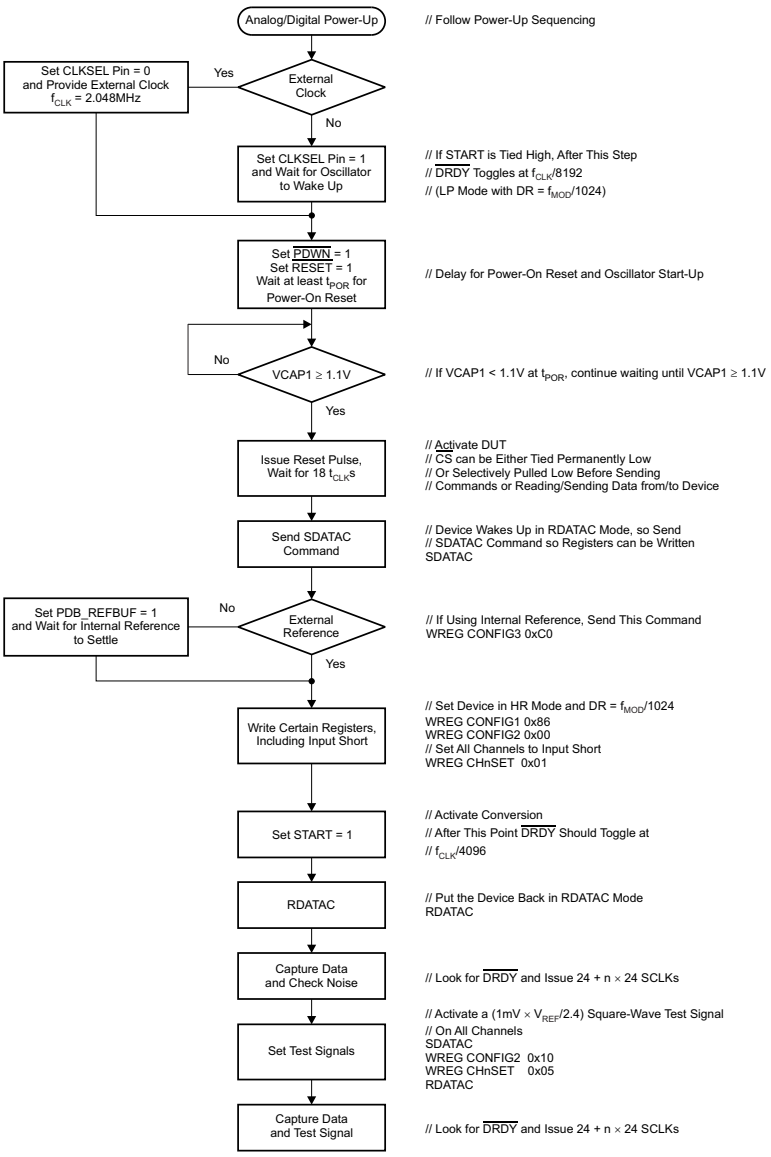


Figure 93. Initial Flow at Power Up

Figure C.1: Setting the Device for Basic Data Capture

C.1.1 CLKSEL problem

The ADS129x offers two clocking options: internal and external. To choose between the two, the CLKSEL pin can be used. Enabling or disabling the oscillator clock to be output in the CLK pin is determined by the CLK_EN bit in the CONFIG1 register. The CLKSEL Pin and CLK_EN Bit are outlined in Table 11 form the ADS1296r datasheet.

Table 11. CLKSEL Pin and CLK_EN Bit

CLKSEL PIN	CONFIG1.CLK_EN BIT	CLOCK SOURCE	CLK PIN STATUS
0	X	External clock	Input: external clock
1	0	Internal clock oscillator	Tri-state
1	1	Internal clock oscillator	Output: internal clock oscillator

Figure C.2: Caption

However, the issue is that the CLKSEL pin is not connected to anything, resulting in its state being undefined. Unfortunately, due to the BGA package, accessing the pin is impossible as shown in Figures C.3 and C.4 (see figure C.3 and C.4).

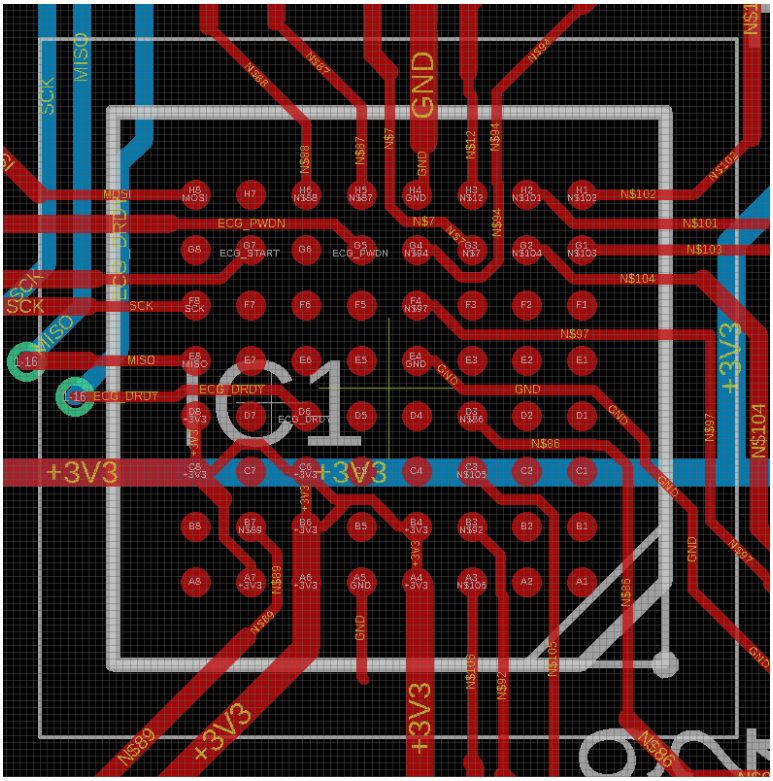


Figure C.3: Pin B8 is not connected to anything

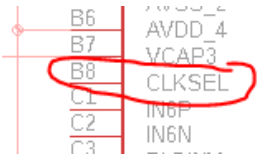


Figure C.4: Pin B8 is not connected to anything

C.1.2 Possible solution for CLKSEL

Since this signal must be connected to 3.3V, it would theoretically be possible to bridge B8 and C8.

C.1.3 ECG_CS

After checking, it turns out that the *ChipSelect* signal is not connected either. In this case, it's not possible to hack the board with u bridge, as the signals are too far apart.

Appendix D

Oscilloscope signals of ESP32-AFE4490

As explained in the main document, communication between the ESP32 and the AFE4490 must be validated in two stages:

1. writing in a register
2. read the previously written value

Here, the aim was to write the value 0x000080 in the "ALARM" register and then read it back.

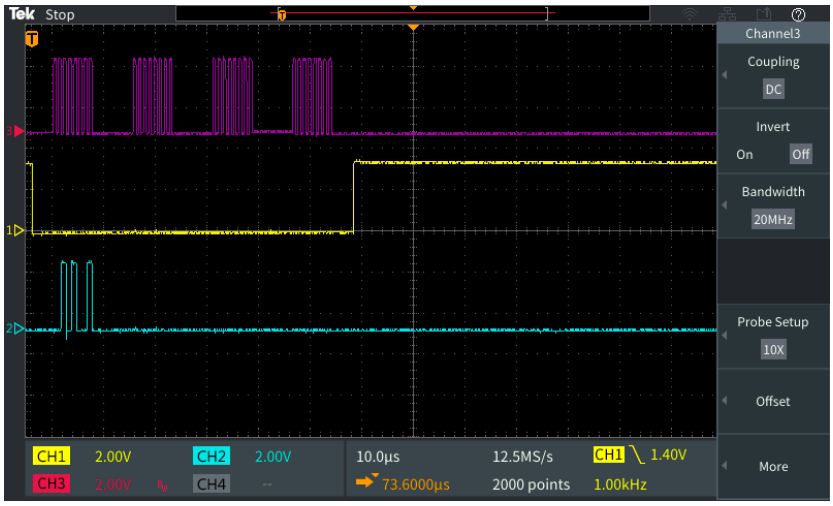


Figure D.1: Reading operation. Purple signal is $SCLK$; Yellow is $SlaveSelect$; Cyan is $MOSI$

When reading, the phenomenon described in section 6 is as follows (D.2)

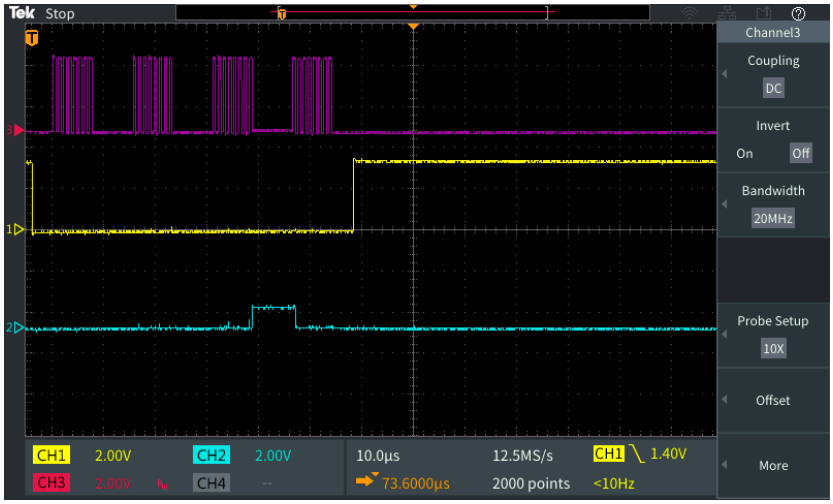


Figure D.2: Reading operation. Purple signal is $SCLK$; Yellow is $SlaveSelect$; Cyan is $MISO$

Appendix E

HealthyPi v4 documentation

E.1 website source

At the time of writing (end of May 2023), all the user documentation is available on : https://healthypi.protocentral.com/

E.2 "Welcome to HealthyPi v4"

Welcome to HealthyPi v4

Welcome to HealthyPi v4

Looking for HealthyPi v3 Documentation?, v3 documentation has moved to healthypi3.protocentral.com

Don't have one? Get yours at ProtoCentral or on Crowd Supply

HealthyPi v4 is a HAT for the Raspberry Pi, as well as a standalone device that can measure human vital signs that are useful in medical diagnosis and treatment. HealthyPi v4 sets a new standard in open source health solutions with mobility, wireless and wearable capabilities. This device presents a snapshot of the user's medical condition within his/her environment and opens up medical research possibilities.

HealthyPi v4 measures the following parameters in real-time and with high accuracy:

- Electrocardiogram (ECG) data, heart rate, and heart-rate variability
- Respiration based on impedance pneumography
- Pulse oximetry (SPO_2)
- Body temperature

HealthyPi v4 is affordable and accessible and the open source aspect means that it's easy to expand on.

You can now purchase a HealthyPi v4 from Crowd Supply

Features

Microcontroller and wireless connectivity: ESP32, in WROOM32 module format, with Dual-core Xtensa 32-bit CPU, 4 MB of on-board flash, Wi-Fi, and support for BLE.

Wireless interface: Wi-Fi and Access Point (AP) modes, a 2.4 GHz radio with an on-board PCB antenna that is compatible with Bluetooth 4.2 and BLE.

Firmware programming: Supports Arduino IDE as well as Espressif ESP-IDF.

Sensors: ECG and respiration front end: Texas Instruments (TI) ADS1292R 24-bit analog front end with signal-to-noise ratio (SNR) of 107 dB Pulse oximetry front end: TI AFE4400 pulse oximetry front end with integrated LED driver and 22-bit ADC.

Temperature sensor: Maxim MAX30205 digital body temperature sensor for monitoring skin temperature.

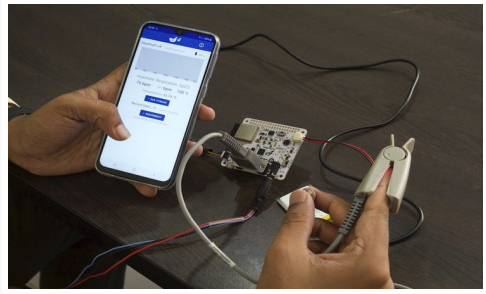
Form factor: Raspberry Pi HAT form factor (65 mm X 56 mm).

Ports and interfaces

- **On / Off Switch :** Powering the HealthyPi v4
- **USB-CDC :** On-board USB-TO-UART converter
- **2x Sparkfun QWIIC:** I2C compatible ports for interfacing any QWIIC based sensors and actuators
- **Sliding switch :** Transition between two different modes(HPi3 mode and Wearable mode).
- **On-board 3 LED :** Power indication and Modes indication
- **Push-button :** Switching between Communication Protocols (BLE and Wi-Fi/Web server)

Multiple operating modes, no programming required

Wearable mode

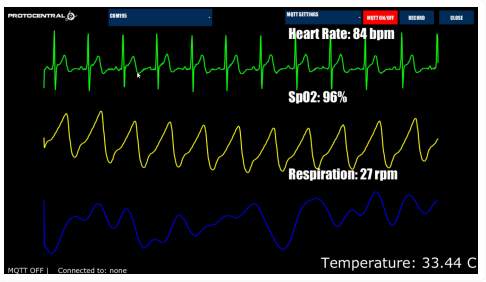


The device communicates to android app via BLE. The real time vital signs (heart rate, respiration rate, spo2 and body temperature, histogram, heart rate variability) along with device battery level can be monitored from the Android mobile application. Additionally, you can also view live streaming of ECG. Added on-board power source (Battery) enhances the device to be used in a complete wearable platform. This mode also contains the HealthyPi Webserver.The HealthyPi v4 webserver page displays live monitoring of physiological data. Additionally with added on OTA updates feature, you can easily update the firmware in minutes.

The HealthyPi Connect mobile App is now available for download from the Google Play Store as well as the Apple App Store

Download on the App Store | GET IT ON Google Play

Raspberry Pi "HAT" mode (HealthyPi v3 compatible)



Using the Raspberry Pi as its computing and display platform, the HealthyPi v4 add-on HAT turns the Raspberry Pi into a vital sign monitoring system, fully compatible with HealthyPi 3.The included GUI displays ECG, respiration and PPG waveforms and their calculated rate values along with temperature can be streamed live through Raspberry Pi display or Computer monitor depending on the user's choice. The user can also record the data for research and analysis.

E.3 Meet HealthyPi v4 !!!

Meet HealthyPi v4 !!!

Reliable health monitoring has traditionally required that we tether ourselves to machines capable of recording our vital signs around the clock. Outside of a clinical setting, however, this is rarely practical. We developed HealthyPi v4 in part to address this challenge. Building upon its predecessor, HealthyPi v4 is a fully open source, standalone vital signs monitor with wireless and wearable capabilities.

Unveiling Healthypi v4 Kit

What's in the box?

1. HealthyPi v4 main board

2. 1000mAH, 3.7V Li-Po Battery with JST

3. Sensor Cable- Electrode pads(3 connectors)

4. Finger-clip SpO2 probe

5. Qwiic based temperature Sensor with Cable

6. Micro USB Cable

7. Disposable ECG electrodes(20 nos)

HealthyPi v4 Complete Kit Contains:

This kit contains everything in HAT Kit, and *additionally* includes:

1. Raspberry Pi 4 Model B computer

2. Official 7" Raspberry Pi touchscreen LCD display

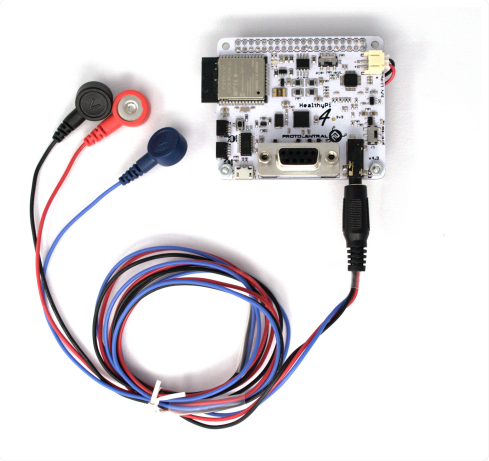
3. SmartiPi Touch-2 Enclosure

4. 16GB microSD Card

5. Medical-grade power supply

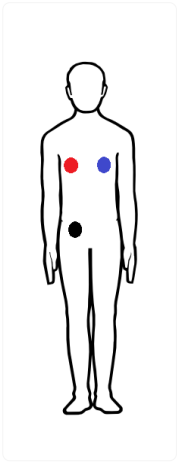
Connecting sensors

Connecting the ECG/Respiration Electrodes



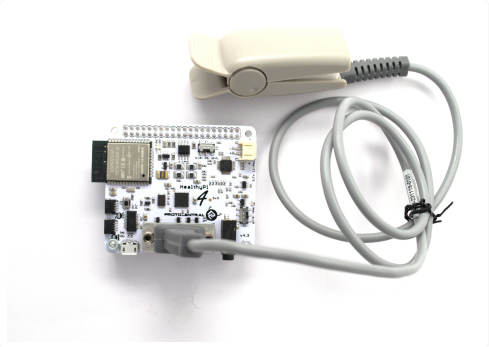
A 3-electrode cable along with a standard stereo jack is provided along with the shield to connect the electrodes to the board. The other side of the electrode connector would connect to Snap-on electrodes attached to the body. For testing purposes, you can use an ECG simulator to provide inputs to the board.

Important Warning: When connecting the electrodes to the body, it is safer to disconnect the mains power source to the Arduino. For example, if you are using the Arduino along with a laptop, disconnecting the battery charger from the laptop would be a safe option.



Place the electrodes on the body in the positions as shown in the image above to get the best signal. However, placing it in other positions on the chest would work as well with differing ECG signal patterns. For getting respiration using the Impedance Pneumography, it's best to wear them on the chest as mentioned in above image.

Connecting the Pulse Oximetry Probe

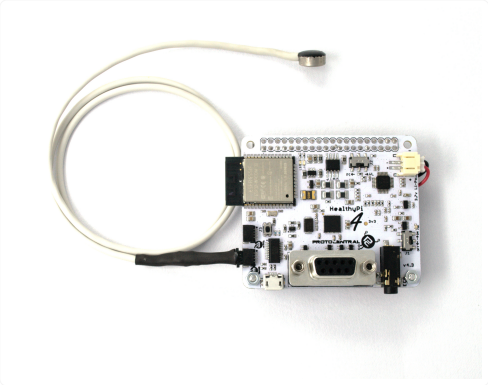


Pulse oximetry is an optical method of non-invasively measuring the oxygen content in the blood. This is achieved with the help of a finger-clip probe that contains some LEDs on one side of the clip and a photo-detector on the other side.

The LEDs emit light in the red and IR wavelengths. Some of these are absorbed by the blood and the rest is transmitted through to the other side of the finger, which is picked up by the photo-detector. The Pulse Oximetry front-end measures this variance in the transmitted light intensity to display the Photoplethysmogram (PPG) signal. SPo2 is a computed value derived from the Red and IR PPG signal.

To start measuring, simply plug-in the provided SPo2 finger-clip probe to the DB9 connector on the HealthyPi v4 board. If the probe is properly plugged in, you should see a Red glow inside the probe.

Connecting the temperature sensor



A digital human body temperature sensor based on the MAX30205 from Maxim Integrated is provided. This sensor provides direct, calibrated temperature values over a digital I2C interface. The sensor comes as qwiic based connectors making the interface even more simpler than before and a cable for maximum flexibility.

No more colour coding confusion, Just Plug the qwiic based temperature sensor directly to read data. Refer the connection shown in the above image.

Selecting modes

Explore with two modes

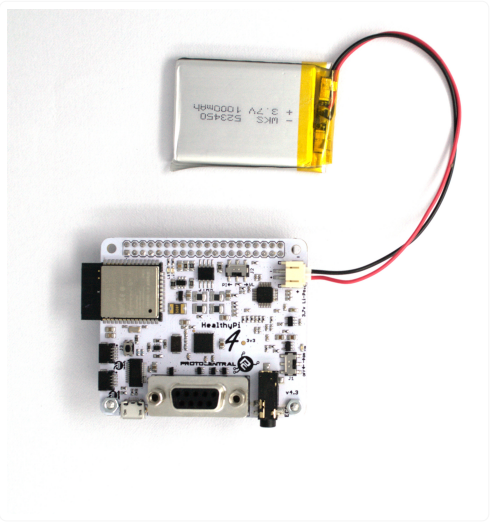
Now switching between two different modes in the HealthyPi v4 is made simple. You have to just slide the mode selection switch to experience the features hidden under the two modes, the default mode will be HPi3 mode and another is the wearable mode.

Choice for connectivity

In the wearable mode the HealthyPi v4 acts as wireless, you can choose the default BLE mode or enter Webserver mode using the on-board push button. Stream live real-time vitals in your smart devices with these communication protocols.

Powering the device

Plugging Battery



Powering the device with a Li-Po rechargeable battery improves its portability. HealthyPi v4 can be used as a standalone device, without external interfaces or power. The battery can be directly

connected to HealthyPi v4 through the onboard 2-pin JST-PH connector. Check out the image above connecting the battery with HealthyPi v4.

Using a USB Port

You can plug cables into a USB port in HealthyPi v4 at any time regardless of whether the device is powered on or off. The USB port can be used for powering the device, uploading the code and charging the battery.

On-board Indication

HealthyPi v4	Indication - LED
Power ON	Yellow LED glows for 2.5sec
HPi3 Mode	Blue LED glows from low to high and high to low
Device Restart	Yellow LED glows for 2.5sec
BLE Mode	Yellow LED blinks until connected
Webserver mode	Yellow LED glows from low to high and high to low
Soft-AP	Blue LED blinks 6 times
OTA Upload Complete Indication	Both(Yellow and Blue) LEDs blinks together
Charge Indication	Red LED glows until battery fully charged

E.4 Setting Up the HealthyPi v4 Complete Kit

Setting Up the HealthyPi v4 Complete Kit

The HealthyPi v4 Complete Kit has all you need to quickly put together a standalone vital monitor. With the latest Raspberry Pi4 added with kit and microSD storage comes up with the HealthyPi v4 software pre-loaded and configured. Just Plug-in to stream live vital signs.

Everything is in the box

The SmartiPi Touch Display that comes included with the HealthyPi v4 Complete kit is already partly assembled. Now it's time for you to take up the task by assembling the display enclosure and the display stand for the provided SmartiPi Touch Case. Check out the below video for instructions on how to assemble the kit.

Using HealthyPi v4 on Raspberry Pi

This section is for those who want to do a manual installation with HealthyPi v4, those who want to modify with the code and generally play with the hardware.

For the simple way to setup HealthyPi v4 on Raspberry Pi, The following are the steps involved to get Raspberry Pi ready for a wireless remote patient monitor. The following video shows you how to connect the HealthyPi v4 as **"HAT"** to a Raspberry Pi.

Step 1 : Install and Update the OS

Install Raspbian Buster with desktop and recommended software from the Raspberry Pi site.The image file can be downloaded from the Raspberry Pi's official website.

Step 2 : Launching the HealthyPi application

Open up a new terminal window (Menu -> Accessories -> Terminal) on Raspbian running on your Raspberry PI:

In the terminal window, type the following commands.


```
curl -sS https://healthypi.protocentral.com/install.sh | sudo bash
```

After the script reboots your Raspberry Pi, you should be able to see the GUI display the sensor outputs in real-time on the screen.

This completes the install!

Getting started with the HealthyPi GUI on Windows, MacOS and Linux

The HealthyPi v4 board now streams the same data on the on-board USB port. This allows you to get the same data that goes to the Raspberry Pi, now on your desktop PC as well.

Java 8 is required on all platforms for running the processing-based GUI application. You can download Java for your platform from the following link.

https://java.com/en/download/

Installing drivers (only for Windows)

HealthyPi v4 uses the same drivers as an ESP32. Once plugged in to the USB port, the device would be recognized as an "Unknown Device". You can locate the device is the Windows Device Manager and manually install the drivers provided in the "drivers" folder in the Windows Executable ZIP archive provided.

MacOS and Linux do not need any drivers to be installed.

Processing GUI Installation

The HealthyPi visualization software has been developed using the Processing. Processing is a Java-based open source framework. The following are the steps to get the visualization software ready for wireless remote patient monitor:

Step 1 : Download Processing IDE for your HOST COMPUTER operating system

a. Latest Version of the Processing IDE can be downloaded from the following link:

Download Processing

Download Processing

b. Unzip the file once downloaded.

c. Click for detailed Installation Instruction

Note:Verified with Processing v3.5.3

Step 2 : Getting the Processing code for the HealthyPi GUI

a. Download the HealthyPi v4 GUI Processing code from Protocentral Healthypi v4 Github repository.

b. Open the Processing and then **File -> Open -> (downloaded path) -> protocentral_healthypi_v4 -> gui-software -> healthypi4_gui -> healthypi4_gui.pde** opens the HealthyPi v4 processing code.

c. Intall its additional libraries from **sketch-> import library-> add library like G4P, ControlP5, mqtt, Graphica.**

Note: On MacOS, if you see an error saying "app is damaged", please follow the steps given in https://support.apple.com/en-us/HT202491 .This is a known issue with Processing on MacOS.

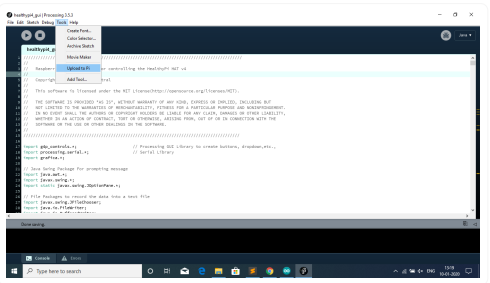
Step 3 : Upload the Processing code from PC to Raspberry Pi

1. In Processing IDE, Select "Tools" from the menu and choose, "Add tools".

2. Select **"Upload To Pi"** tool and click Install button which is present in the button right corner as shown in the below image.

3. Now, connect your raspberry pi to the internet with the same network as your laptop is connected.

4. Select "Tools" menu and choose "Upload to Pi" option from the list.

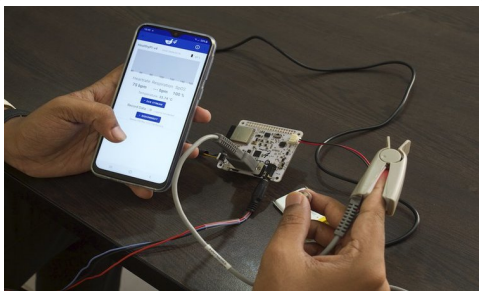


5. If any error occured in uploading the code, check for the internet connection and repeat the process.

E.5 HealthyPi with BLE

HealthyPi with BLE

HealthyPi with BLE



Download on the App Store GET IT ON Google Play

Building upon its predecessor, HealthyPi v4 brings more flexibility to the user. Powered by the popular ESP32, it opens up wireless and wearable capabilities. Now it's portable and standalone with in-built rechargeable battery. It can still be used as a HAT for Raspberry Pi or as a standalone wearable platform.

HealthyPi v4 is powered by the ESP32 SoC module, which supports pairing with smartphones through BLE. BLE is widely used in wearable devices because its low power requirements allow it to function for a long time without charging. HealthyPi v4 also supports pairing with other IoT devices for use in mesh networks. BLE 4.2 adds improved security capabilities.

Data measured by Healthy Pi v4 is accessible through standard BLE services for Heart Rate, Pulse Oximeter, Health Thermometer and Battery Service, as well as custom services for ECG and respiration. Notifications are used to transmit data from HealthyPi to the app.

Change the Slide switch from PI mode to WL mode on the healthypi v4 board to switch from V3 mode to BLE mode. The device restarts with an indication, yellow led stays for 2.5sec and the healthypi v4 enter to ble mode with an indication of yellow led blinks until connected. Once it is connected the led will stops blinking and when disconnected the led will starts blinking until connected.

Service Name	Service UUID	Characteristic UUID
Heart Rate Service	0x180D	0x2A37
Pulse Oximetry Service	0x1822	0x2A5E
Health Thermometer Service	0x1809	0x2a6e
Battery Service	0x180F	0x2a19
ECG Service	0x1122	0x1424
Respiration and Heart Rate variability Service	"cd5c7491-4448-7db8-ae4c-d1da8cba36d0"	"01bfa86f-970f-8d96-d44d-9023c47faddc"
Histogram Service		"01bf1525-970f-8d96-d44d-9023c47faddc"

In the heart rate variability service two Characteristics are included, one for heart rate variability and the other for histogram.

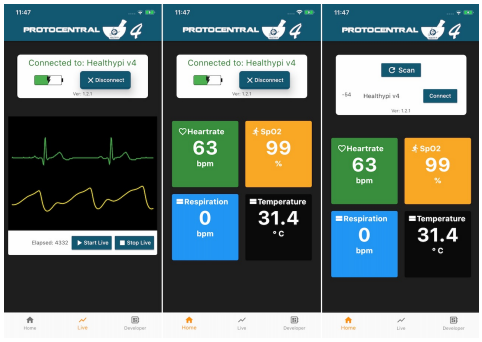
In the ECG service, the default plot is ECG and an option is given to switch from ECG to PPG by writing "spo2" text data.

Introducing the HealthyPi app

Monitoring the human physiological data associated with day-to-day activities becomes much simpler with the HealthyPi app, which is available in app stores, for both Android and iOS devices.

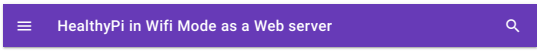
Download on the App Store GET IT ON Google Play

The HealthyPi app is used to communicate directly with HealthyPi v4 hardware, through the same BLE services mentioned above, and can display all vital signs on a single screen.

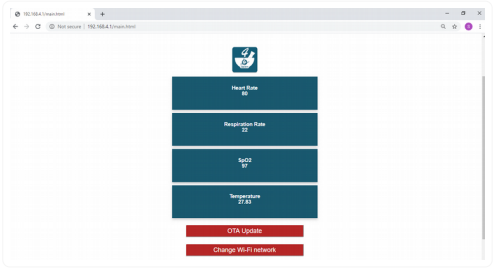


HealthyPi v4 is a powerful tool, and the HealthyPi app opens up new possibilities for using it to monitor vital signs outside of traditional settings. Among other features, it is capable of displaying respiration, Histogram, Heart rate variability and ECG data.

E.6 HealthyPi in Wifi Mode as a Web server



HealthyPi in Wifi Mode as a Web server



In the Wi-Fi/web server mode, HealthyPi can stream live data over the Internet through any available WiFi connection. A push-button boots the device to the web server mode with the default HealthyPi Wi-Fi Access Point (AP). You can connect your from you WIFI-enabled device to the “HealthyPi ” Wi-Fi network and point your web browser to the “healthypi.local” site to access the home page of the application. The HealthyPi web server page displays the live calculated values as well as options to update firmware.

Starting with Web server

1. Push the on-board push button, to switch from BLE mode or V3 mode to Web server mode.

2. The board will restart with WiFi where the yellow LED stays ON for 2.5 seconds and then cycles ON and OFF as an indication for Web server mode and then enters Wi-Fi Access Point (AP) mode where the BLUE LED blinks 6 times. WI-FI Access Point means that you can connect to the ESP32 via any PC or smartphone with Wi-Fi capabilities without having to connect to your router.

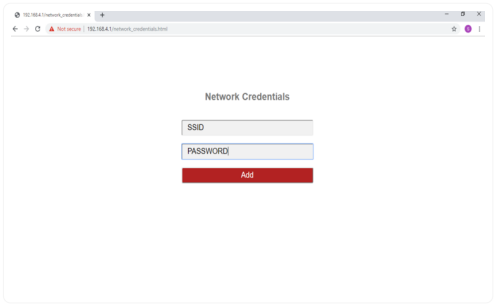
3. Connect your PC or other Wi-Fi enabled smart device to the “HealthyPi” wifi network and type http://healthypi.local in the address bar of your browser, This will re-direct to the Healthypi v4 web-server dashboard where you can view the Heart Rate, SpO2, Respiration and Temperature by

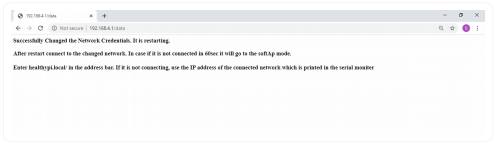
connecting the temperature sensor, the SpO2 probe and the 3 electrode cable to the healthypi v4 board.

4. If the web page is not loaded using http://healthypi.local, use the IP address of Healthypi v4 that will be shown on the serial monitor while using Soft AP mode. Make sure that the Healthypi v4 is in Webserver mode while checking for the IP address on the serial monitor.

5. You can also connect to a private network to view the Heart Rate, spO2, Respiration, Temperature in the webserver mode.

6. To connect to a private network, click the Change Wi-Fi Network button on the dashboard, redirect to the web page to enter the Network Credentials, SSID and Password. Click add, redirect to the “Successfully Modified Network Credentials” web page, and the device restarts and automatically connects to the user’s chosen network and shows the IP address of the private network on the Serial Monitor.





7. In the case that the Healthypi v4 does not connect to the private network, the device will restart and enter the Wi-Fi Access Point (AP) mode with a BLUE LED blinking 6 times.Repeat the 3rd or 4th step

to re-connect.

Updating Firmware

OTA update feature in HealthyPi v4 is a more efficient and effective way to remotely update the software. It is convenient for end users to make changes and upload the software to the board without a USB cable. There is an OTA toolbar in HealthyPi v4 web server page, the user only needs to click the toolbar to update the latest software to the device. Updating the firmware can be done in a matter of seconds.

Flow of OTA in HealthyPi v4

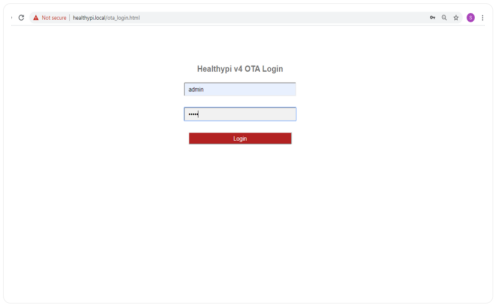
1. Perquisite for OTA update is the binary file of the latest firmware. The binary file is generated by Arduino IDE -> Sketch -> Export Compiled binary. The generated binary file is stored in the same folder as the .ino file.

2. Ensure the Healthypi v4 is in web server mode. The Soft AP mode and STA mode are the two modes in the web server.

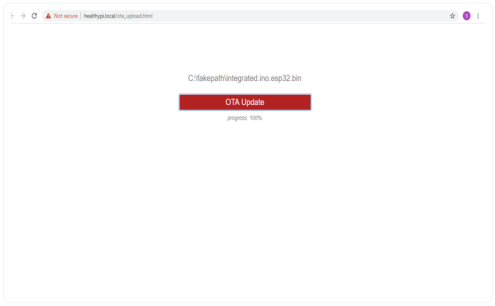
3. On connecting the board via USB to the PC, the IP address of Healthypi v4 will appear on the Serial monitor while using Soft AP mode. Typing the IP address / MDNS (i.e., healthypi.local) in the web browser will direct to the HealthyPi v4 web server dashboard.

4. In order to shift to the STA mode where the user can connect the Healthypi v4 to a private network, repeat the above step and click on the Change WiFi Network button on the dashboard, it redirects to the webpage for entering Network Credentials. The device restarts and automatically connects to the user’s desired network and displays the IP address of the private network in the Serial monitor.

5. On the right hand corner of the web server dashboard, an OTA button is present. On clicking the button, an OTA login page appears for OTA credentials. Enter the username and password as “admin” and “admin” and click on login.



6. Once logged-in, the user will be able to select the available binary files that can be used for software update of the device.



7. Once the binary file has been changed, Healthypi v4 reboots with both Yellow and Blue LEDs will blink and the board will function as per the new binary file / software.

E.7 Programming HealthyPi v4

Programming HealthyPi v4

Programming with Arduino

ARDUINO 1.8.10
The open-source Arduino Software (IDE) makes it easy to write code and upload it to the board. It runs on Windows, Mac OS X, and Linux. The environment is written in Java and based on Processing and other open-source software.
This software can be used with any Arduino board.
Refer to the Getting Started page for Installation instructions.

Step 1: Download and Install the IDE

The Arduino Software (IDE) allows you to write programs and upload them to your HealthyPi v4. You can download the latest version for Windows, Linux and Mac OS using the below link. Download the Arduino IDE

Note: Once you have downloaded, install the IDE and ensure that you enable most (if not all) of the options, including the drivers. Click for installing instructions in windows, linux, Mac OS

Step 2: Get the HealthyPi v4 COM Port Number

Next, you will need to connect the HealthyPi v4 board to a system. This is done via a USB connection. When the HealthyPi v4 is connected, the operating system should recognize the board as a generic USB COM port. The easiest way to do this is to type **Device manager** into Windows Search and select Device Manager when it shows.

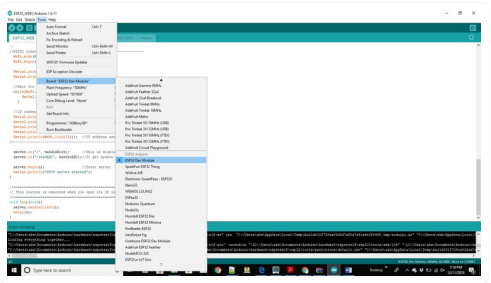
In the Device Manager window, look for a device under Ports (COM & LPT) and chances are the HealthyPi v4 or an Arduino will be the only device on the list.

Step 3: Configure Arduino for ESP32 board support

The Arduino IDE does not come with support for ESP32 out of the box. Please follow the following instructions to add ESP32 boards support to the Arduino IDE.

Installing ESP32 Platform in Boards Manager

You will also need to select the "ESP32 Dev Module" board using the "Board:" option menu as shown in the figure below:



Also, select the following options for the selected board by

- Partition Scheme -> Minimal SPIFFS (1.9MB App with OTA/190Kb SPIFFS)

Next, you must tell the IDE which COM port the HealthyPi v4 is on. To do this, navigate to **Tools > Port > COMXX**. Obviously, if your HealthyPi v4 is on a different port, select that port instead.

Step 4: Install the latest HealthyPi v4 Arduino libraries

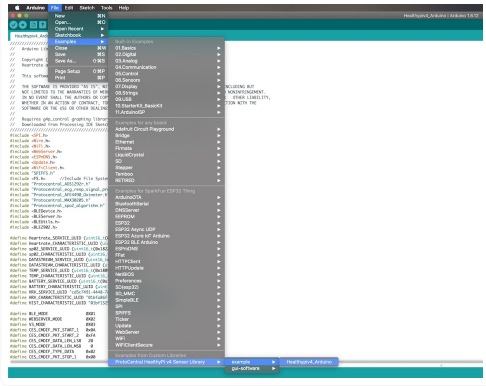
Download the latest Arduino Library for HealthyPi v4 from the link below.

Download HealthyPi v4 Arduino Library

Rename the downloaded file to "healthypiv4.zip" and upload it to the Arduino IDE by going to Sketch -> Include Library -> Add .ZIP library and then select the healthypiv4.zip file. The library should now be installed.

Once installed, restart the Arduino IDE to load these libraries. You can now load the main HealthyPi

Arduino sketch as shown below from File -> Examples -> "ProtoCentral HealthyPi v4 Sensor Library" -> examples -> "Healthypiv4_Arduino"



Step 5: Install the Arduino ESP32 Filesystem(SPIFFS)

The HealthyPi v4 code requires an Arduino tool plugin called the "ESP32 File system uploader" to upload the SPIFFS filesystem. Check this site for direction to download and install the ESP32FS plugin.

Restart the Arduino IDE for the this tool to show in the Tools menu. Once

Navigate to Tools->ESP32 Sketch Data Upload and it will upload the SPIFFS File.

Note: Ensure that the data folder containing all of the SPIFFS file is in the same folder as the location of the sketch file that is currently open.

Step 6: Uploading code to HealthyPi v4

Compile the code and check for compilation without error and upload the code to HealthyPi v4 and see the output in the mode of your choice.

You're now all set to modify and/or write your own code for the HealthyPi v4 !!

Some Example code:

Initializing the functionalities in HealthyPi v4

```
void setup()
{
  Serial.begin(115200);

  if(Healthypi_Mode == WEBSERVER_MODE){
    Serial.println("Starts in webserver mode");
    HealthyPiV4_Webserver_Init();
  }

  else if(Healthypi_Mode == V3_MODE){
  Serial.println("Starts in v3 mode");
  }

  else{
  Serial.println("Starts in BLE mode");
  HealthyPiV4_BLE_Init();
  }

 }
```

In the loop function below we read the vitals data from HealthyPi v4 .

```
void loop()
{

  Heart Rate = (uint8_t) global_HeartRate;
  Respiration Rate = (uint8_t) global_RespirationRate;
  spo2 = (uint8_t)afe44xx_raw_data.spo2;
  temperature =  (uint16_t) tempSensor.getTemperature();

}
```

Programming with ESP IDF

ESP-IDF

Espressif IoT Development Framework. Official development framework for ESP32.

In some cases where you need maximum performance, improved compatibility, and low overhead, you might want to use the native SDK. ESP-IDF is Espressif's official development SDK for the on-board ESP32-WROOM32 module. ESP-IDF also helps you understand what is happening under the hood. Through a simple step-by-step process to illustrate how to use ESP-IDF(Espressif IoT Development Framework).

What You Need?

To develop applications for ESP32 you need:

- PC loaded with either Windows, Linux or Mac operating system
- Toolchain to build the Application for ESP32
- ESP-IDF that essentially contains API for ESP32 and scripts to operate the Toolchain
- A text editor to write programs (Projects) in C

Preparation for development

There are three simple steps in the process of development:

- **Setup of Toolchain**
- **Getting of ESP-IDF from GitHub**
- **Installation and configuration**

Step 1: Setting up the toolchain

Windows don't have a built-in "make" environment, so as well as installing the toolchain you will need a GNU-compatible environment. We can use the MSYS2 environment to provide this environment. The quick setup is to download the Windows all-in-one toolchain & MSYS2 zip file from dl.espressif.com: Toolchain Setup- Windows

The quick setup is to download the linux all-in-one toolchain from Espressif website:Toolchain Setup 64-bit Linux and Toolchain Setup 32-bit Linux

The quick setup is to download the ESP32 toolchain for macOS all-in-one toolchain from Espressif website:Toolchain Setup macOS

Step 2: Getting ESP-IDF

Besides the toolchain (that contains programs to compile and build the application), you also need ESP32 specific API / libraries. They are provided by Espressif in ESP-IDF repository. To get it, open terminal, navigate to the directory you want to put ESP-IDF and clone it from espressif repository in github.

Step 3: Setting up

To set up the software environment and get esp-idf follow the instructions by clicking Windows, Linux, Mac OS.

E.8 Connecting Qwiic Sensors

Qwiic for Quick

The idea behind Qwiic based connectors in HealthyPi v4 is to bring flexibility in interfacing. It makes prototyping easy, less complex and interfacing with I2C has been put up simple. The On-board qwiic compatible connectors has built-in support for popular qwiic sensors.

Simple for interfacing

With On-board 2x Qwiic slots makes sensor plugins much easier, you can keep going by connecting multiple sensors.This would make it more suitable to plug in, detect the sensor, upload the code and read/display data.Many sensors can be interfaced to produce an analog data, temperature, imu, environmental composition, pressure, pH, light intensity etc.

The video below shows how easy it is to connect Sparkfun's Qwiic microOLED display to render HealthyPi v4 output.

Health vs. Environment

Want to track changes in vital signs with respect to changes taking place in the surrounding environment? We connected the SparkFun Environmental Combo Breakout - CCS811/BME280 (Qwiic) sensor to HealthyPi v4 in order to gather a variety of environmental data, including CO_2, barometric pressure, humidity, and temperature. Such data can be used, in combination with vital signs, to help give environmental context to our measurements. Check out the video below:

* Pin mapping and connection instructions:

HealthyPi v4 pin label	Colour Code	Environmental Combo
SDA	BLUE	SDA
SCL	YELLOW	SCL
3V3	RED	VCC
GND	BLACK	GND

Connection Instructions
-> Connect the SparkFun Environmental Combo Breakout Qwiic directly into the HealthyPi v4 Qwiic-1 or Qwiic-2 port

Activity vs. Vital signs

As HealthyPi v4 is a wearable platform, it can be used in conjunction with any IMU based QWIIC sensor to recognize activity. In this experiment, we connected the SparkFun Triple Axis Accelerometer Breakout - MMA8452Q (Qwiic) sensor to HealthyPi v4 and captured accurate activity data alongside the user's vital signs.Check out the video below:

* Pin mapping and connection instructions:

HealthyPi v4 pin label	Colour Code	MMA8452Q Sensor
SDA	BLUE	SDA
SCL	YELLOW	SCL
3V3	RED	VCC
GND	BLACK	GND

Connection Instructions
-> Connect the SparkFun MMA8452Q Sensor Qwiic directly into the HealthyPi v4 Qwiic-1 or Qwiic-2 port

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E.9 Exploring HealthyPi v4

Exploring HealthyPi v4

Remote Monitoring in healthcare

HealthyPi v4 gives patients much greater involvement in the management of their own health, while simultaneously providing peace of mind that vital health information(including ECG and heart-rate, heart-rate variability, histogram, Respiration based on the impedance pneumograph, Pulse oximetry (SPo2), Body temperature) is been monitored in real-time and with high accuracy.

For regions of the world in which professional health care is relatively scarce – and where the cost of conventional patient monitors can be prohibitive – HealthyPi devices can serve as an important stopgap. With support for standalone use and the addition of Bluetooth Low Energy (BLE), HealthyPi v4 is now more accessible than ever.

Open - Always room for Development

Using HealthyPi v4 as open-source mature development platform you can recreate building your own applications. It features On board Espressif ESP32 in WROOM32 module format, ADS1292R 24-bit analog front end,TI AFE4400 22-bit ADC pulse oximetry front end, On board 5V power source, Bluetooth, Wi-Fi, 2x Qwiic compatible connectors and an internal rechargeable battery. Keep making things with HealthyPi v4.

Explore ideas

1.How do you imagine the monitoring system of the future?

Using HealthyPi v4 vital signs monitoring system as source. If you really give it a try - you will make your application live with HealthyPi.

2.Can you respond to the 2019 PhysioNet challenge **and detect Sepsis with your HealthyPi v4?**

One way might be to try Early Prediction of Sepsis using vital signs measured by the HealthyPi v4.

Discovering the best of HealthyPi v4

1. Bringing you the simple healthcare providing the major human physiological data for people who find it really difficult to go to doctors on a daily checkup or for those patients who need continuous monitoring from the doctor.

2. Observing health data and can be used in a variety of clinical research studies.

3. You can customize into your own health monitor by configuring based on your requirements/applications.

4. Add-on human vital signs into your projects related to healthcare.

5. Being a wearable platform, you can explore even more effective.

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E.10 Troubleshooting HealthyPi v4

Troubleshooting

Troubleshooting

As you learn and explore our device, you may encounter some hiccups along the way. We hope to extend our full Technical support and guidance. We have listed out some of the common issues you may come across. Do send in your queries to **sales@protocentral.com**. All your queries will be addressed within 24 hours.

Note: This section will be updated constantly.

</table>

Issue	Solution
* Is the COM PORT of the device is not detected ?	- You can unplug the USB cable from PC and plug it again.
	- Try changing the USB cable.
	- Check whether RED LED is glowing which is for power indication.
	- Try installing the USB Drivers required.
* If there are difficulties while uploading the firmware to the board ?	- Check whether the power switch on-oard is turned ON.
	- Select the correct COM port and Board selection in Arduino IDE -> tools.
	- Check for the latest version of Arduino IDE and ESP-IDF with all drivers installed.
	- Download and upload the latest firmware from Github.
* What if you don't find the BLE device?	- Check if your mobile device supports BLE.
	- Check whether the device is within the prescribed BLE range.
	- Allow the application to turn BLE ON in your device.
	- Check whether the device is advertising or not.
	- Look for Yellow LED blinking for BLE advertising indication.
* Is the Web page not loading?	- Check whether spiffs is uploaded.
	- Ensure that the data folder contains all the required files.
	- Ensure that the data folder is in the same folder as the .ino file.
	- Check whether the system is connected to Healthypi_v4, if the board is in SoftAP mode.
	- Check whether the system is connected to the same WiFi network as the one that was added using 'Network Credentials' webpage.
* Want to switch from Webserver mode to V3 mode or BLE mode but slide switch is already in the respective position?	- Restart the device, it begins to function in the default mode based on slide switch position.
* What if SPIFFS is not uploading?	- Check whether serial monitor is opened, if opened close it and upload spiffs.
	- Try uploading once again.
* What if webpage is not loaded while using MDNS (healthypi.local)?	- Try connecting using MDNS once again or else use the IP address http://192.168.4.1.
* What need to be done incase of a brownout reset?	- Check if the power supply is in fault condition.
	- Make sure that the power supply is sufficient during chip operation, connect the battery to the board. </tr>
* Getting error, "No such file or directory".	- Check in the Tools option, that the board is selected as Esp32 Dev Module.
	- Make sure that the library files are included.
* Getting the error, "Sketch too big. Error compiling for board ESP32 Dev Module".	- Check Partition Scheme option in Tools. Select Minimal SPIFFS(1.9MB APP with OTA/190KB SPIFFS).
* What if OTA update freezes?	- Click on the OTA Update button again it continues updating from where it stops.
	- Check the network connection.
* What if on opening the GUI, the screen is blank and no waveform is plotted?	- Check the HealthyPi board connection. If the firmware is outdated or corrupted, reload it.
	- Healthy Pi board communicates with Raspberry Pi OSM serial interface, ensure the serial lines are free.
* What if the signal quality is bad or the vitals are incorrect?	- Remove the AC adapter from the laptop, as it adds to the noise.
	- Check the Sensor connections.
	- The sensors need to be securely attached to the body.
* Getting the error, "WebServer.h: No such file or directory error".	-Install the latest Arduino IDE version from Official Arduino website
* Getting the error, "Failed to connect to ESP32: Timed out waiting for packet header".	- Check whether the power switch is turned on.
	- Ensure the correct COM port and board is selected.
	- Try uploading the firmware once again.
* Not able to find ESP32 board package in board manager?	- Make sure to add Additional board manager urls in File->preferences. Then Restart Arduino IDE.
	- Check for the latest version of Arduino IDE.
* Is the board restarting regularly?	- It may be due to power insufficient, check whether the battery is connected.
* Is the file updation aborted, when updating file in webserver?	- Check the network connection.
	- Upload the firmware again and make sure the connection should be good enough while updating the file.

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E.11 License Information

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