Myo

A discreet device to monitor atrial fibrillation for elderly people

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MSc Graduation project
Integrated Product Design

fp.

TU Delft

CARDIOLINE

Graduation Report by Filippo Petrocchi

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Abstract

In collaboration with Cardioline Spa, this graduation project presents the development of a discreet device to monitor atrial fibrillation among elderly people. By means of user research and contest analysis, the project is aims at delivering a new product-system device for the company, for Healthcare institutions and for private patients.
The project is characterized by three main phases: the first one is about the analysis of the holter monitor world ; the second is related to synthesizing the research results into one concept; and the third one focuses on validating and test the concept proposed.

According to the three pillar of Industrial design engineering the research was divided into the three macro areas of: People, Business and Technology.
The people linked with the holter monitor system investigated during several activities including Interviews were 14 elderly patients, one General practitioner, one cardiologist and two nurses. Furthermore, to dive deeper into the experience I underwent a 24 hour holter monitor experience. The magnitude of the cardio healthcare business side was explored by the analysis of the main Healthcare trends. In addition, special attention was given to Cardioline's past innovations and some guidelines for future innovations were outlined.
The technology side was also investigated. The Scope of the technology analysis was to understand the current state of the art of ECG technology and its related evolution over the years.
There was a special focus on the transition from the current situation to the mobile health and to why biosensors are preferred to the standard holter monitor.
To close the technological part, a perceptual map was made in order to compare the Cardioline product with its competitors.
The perceptual map was also used to decide on the transition from the current product to the future product.
All the data collected during the analysis phase was collected in a list of requirements composed of demands (hard requirements) and wishes (soft requirements).
Afterwards a brainstorm session was run taking into account some of the main problem revealed. After several iterations, the brainstorm results were synthesized into three concepts which were presented during the midterm presentation.

Feedback was provided by chair, by mentor and by the Company mentor. Suggestions were used to determined the final user scenario, the final system layout and the final concept. The final concept consisted of a wearable device which records and transmits ECG signal to the smart phone. The smart phone collects and transmits data to the cloud server where the user and Doctor, if authorized, can have access.

With a special focus on the setting up phase, a test was performed. The scope of the test was to check if specific concept features were correctly driving the user towards the hypothesised behaviour. The test revealed good and improvable aspects of the product-system designed. The improvable aspects were used to refine the final concepts.

Finally, together with Cardioline supervision, several engineering recommendations were elaborated. Those recommendations were related to the concept material, to the electronic components

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00

00 **Introduction**

To introduce the reader to the topic dealt with in this thesis, an introductory chapter has been written With an inductive approach, the introduction starts with the central relevance of the Cardiovascular disease then continues with the partner Company and the product involved. Finally it dives deep into the graduation assignment and the approach used for the analysis section.

0.1 Cardiovascular disease and their relevance

According to World Health Organization (WHO) (2016) CVDs are defined as a group of disorders of the heart and blood vessels. CVDs are for instance: coronary heart disease, cerebrovascular disease, peripheral arterial disease, rheumatic heart disease and many others.
With 17.65 million deadly victims every year and 31 % of all global death, CVDs are the leading cause of global death (WHO, 2016) (Fig.1). The same data is also confirmed by Hannah Ritchie and Max Roser (2018). They show in Fig.1 that CVDs are leading the annual number of death by far, followed by Cancers and Respiratory diseases.

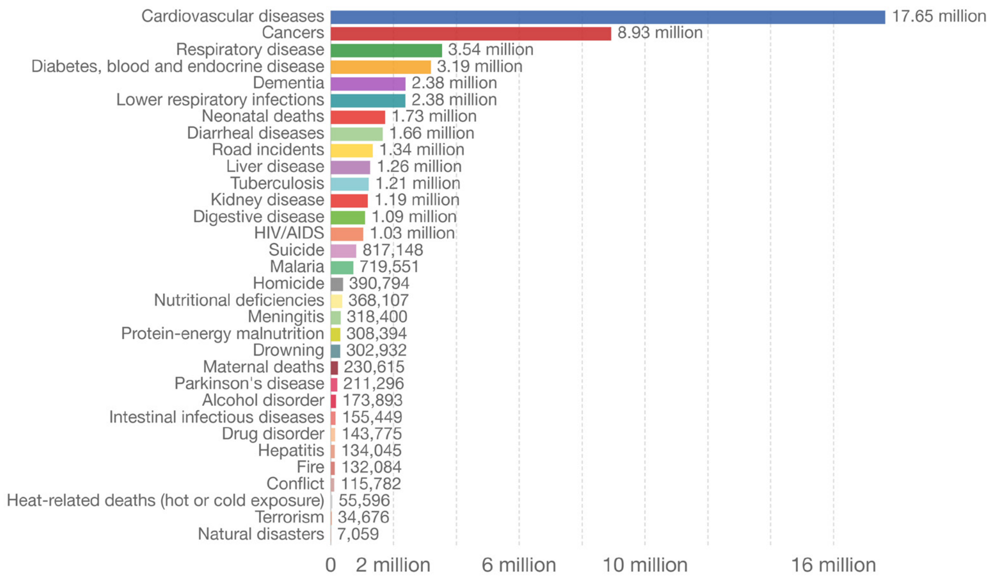


Fig.1 Annual number of deaths by cause 2016

The WHO (2018) is also investigating the risk of factors, which trigger CVDs.
In their research it is shown that having a healthy diet, doing regular physical activity, avoiding the smoke of tobacco and the harmful use of alcohol reduces the risk of cardiovascular diseases. This is also confirmed by Mc Hill (2008) who claims that 90 per cent of those diseases are actually preventable.

Focusing on the personal behaviour and on daily routines is important to prevent CVDs. However, to have scientific data it is important to use a professional, reliable and easy-to-use cardiac device. A device that could discreetly monitor your heartbeat while you are doing your daily routines.

Cardioline, company-partner of this graduation project, is one of the most famous heart-diagnosis Italian device producers since the 60's.

0.2 **Cardioline company**

Cardioline is an Italian-based company specialized in both cardiac devices and in the related software to analyse and process the heart signal.
It is a medium-small company (50-200 employees) and has two main departments: the head-quarter in Cavareno di Trento (Fig.2) and the commercial department in Milano.
Considering the legal framework, the company is an a joint-stock company, with legal personality and perfect autonomy, in which stakeholders' shareholdings are represented by transferable securities: shares.

FIg.2 Cardioline Headquarter - Cavareno di Trento (IT)

Vision of the company is to create an accessible and sustainable healthcare system that is able to provide effective and evidence-based medical procedures by means of devices designed with care and expertise. To realize this vision, Cardioline has developed over the years a strong expert's collaboration (University of Pisa and Glasgow and professional practitioners) which strengthens its own brand value born in Italy during the 60's.

Cardioline's organization structure mainly presents a TOP-DOWN decision-approach which is afterwards verified by a BOTTOM-UP customer survey. Even though each department has its own autonomy the company presents a good interdepartmental communication which helps to reduce general inefficiency (such as unnecessary interdepartmental meetings).
Cardioline's Know-how is mainly internal except for some external collaboration with mostly accademics (University of Glasgow or University of Pisa).

0.3 **Graduation assignment**

Cardioline assignment

Of all the cardiovascular disease it was decided in agreement with Cardioline to focus on paroxysmal atrial fibrillation
Consequently, tthe holter monitor (walk 400h) was selected as a product reference which is also the starting point of this graduation project.

The product reference walk 400h (Fig.3) is a reliable device but it is not very comfortable for the users involved. Scope of the graduation project is to realize a device that combines the miniaturization for the benefit of ergonomics and cognitive understanding with the acceptance of technology by elderly patients

Walk400h description

Walk400h ("Cardioline | walk400h ECG", 2019) is the ECG holter monitor sold by Cardioline which can perform ECG diagnosis with 3, 7 , or 10 wire cables according to the specific need of the exam. The interface is composed by a display TFT 2.2" and a 4-way joystick and the battery supply is a standard AA Battery. the product comes with software to download and analyse the ECG recorded

Fig3. Cardioline Walk400h in contest

0.4 **Project approach**

To design a device which is desirable for the target user, viable for the stakeholders and feasible for the manufacturer the analysis phase has to be structured according to the 3 pillars of Industrial Design Engineering: Business, People, Technology. (Fig.4).

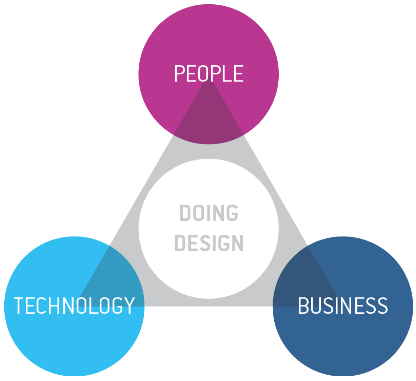


Fig4. The Three pillars of Industrial Design Engineering (Van Boeijen et al. 2014)

Starting from the analysis based on the three pillars of industrial design, the graduation project was then developed in 4 parts : analysis, synthesis, validation and conclusion. (Fig.4a)

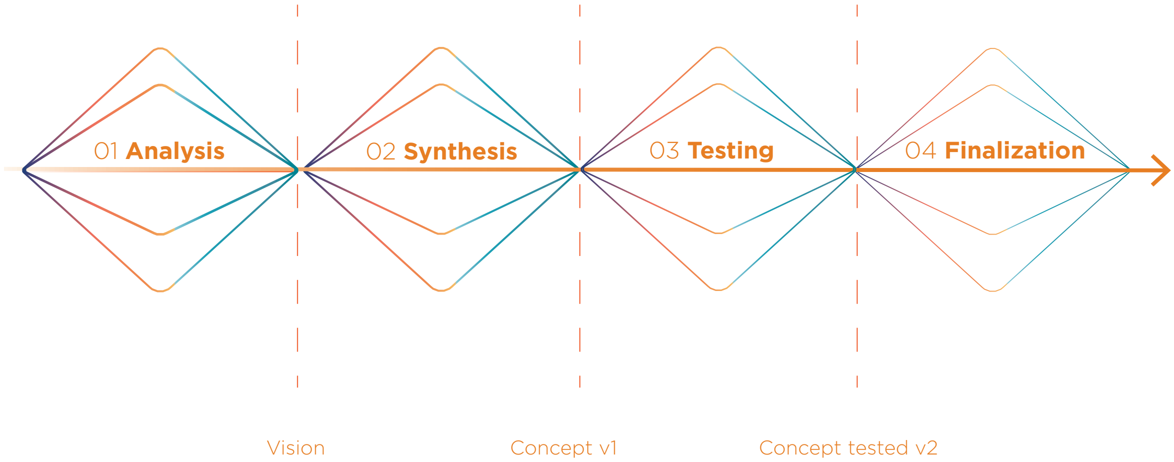


Fig4a. Graduation project overview

PART I **Analysis**

01

01 **People**

To analyse people involved in the holter monitor experience two phases were carried out:
A research phase which consists of interviews with users and stakeholders, 24h holter monitor experience and a video analysis.

Consequence of the research phase was the analysis phase where all the data were collected and synthesized by means of personas and graphic representation such as system layout.

In this section the main project insights are related on one side to understand the main problem and frustrations and to the other to understand relations between context, users and stakeholders.

1.1 **Holter monitor video analysis**

Research

To dive deep into the Cardioline holter monitor procedure (walk400h) an analysis of the related Cardioline walk400h (2018) video has been done.
A systematic approach has been applied throughout the whole video and the final result are several step-series that start with the electrodes application and they end with the medical report upload on the server. All the steps extracted from the video are here reported by means of the Storyboard (Fig.5)

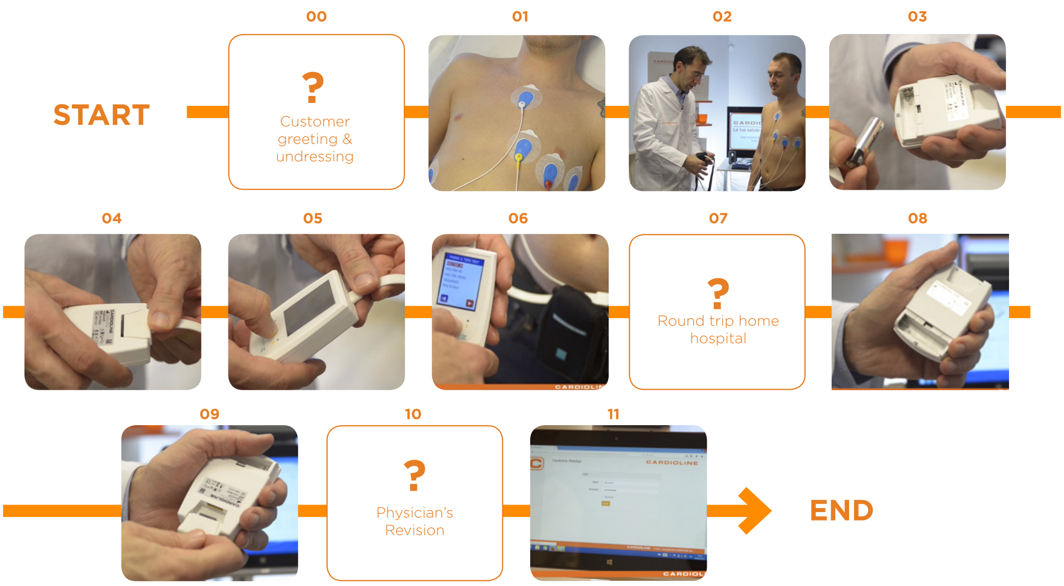


Fig5. Storyboard with all the step-series involved in the procedure

Reflections

Overall the procedure is quite consistent but the cumbersome device aspect negatively impacts on the overall experience
Going deeper into the details of the video an important reflection is about the missing steps in the process. Those missing steps are:

Step 0 when the client gets acquainted to the room and when the electrodes are applied to the body are not included in the process;
Step7 the home-to-hospital travel and back is missing;

Step 10 how data are analysed and a diagnosis is made by the physician.

Since those steps are missing further investigations (interviews or field research) are needed to clarify the overall procedure.

1.2 **Personal Holter monitor experience 24h**

To compare the video of analysis of Cardioline walk400h (2018) with the real experience I personally tested a holter device for the duration of 24 hours.
My experience is here reported by a series of steps and finally some conclusions were outlined

Step 1 **Booking the exam at the booking office centre (CUP)**

After obtaining the prescription from your treating doctor to undergo a holter exam, the patient has to go to the booking office centre. Here the patient has to patiently wait his turn and afterwards he can book and pay the holter monitor examination. Usually the time to get a visit is around 1 month but it also depends on how busy the CUP is.

Step 2 **Waiting at the clinic**

On the day of the appointment a second trip is made to the hospital. Sometimes the patient needs to wait 15-20 minutes. This is usually caused by previous patient's delay.

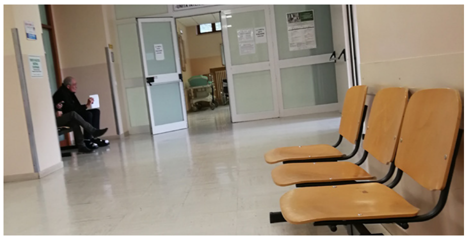
Step 3 **Holter setting up**

After waiting a little while, the setting up is executed by the nurse.
During the process, the nurse has to be focused on different tasks at the same time. Those tasks are: inform the patient about the examination, record the patient-data and check that the device is well set up.
Checking the correct functionality of the holter monitor requires specific attention to the battery to the flash card and to the activation steps.
Extra attention is also put to the adhesive patch electrodes. To avoid possible electrodes detachment a medical tape is applied on them.
Unfortunately, for reasons of privacy I could not take pictures during this phase.

Step 4 **Holter experience within the 24h**

Once the holter monitor setting up phase is completed the patient is free to go back to their routines. Important to remember is to keep the holter monitor distant from other electronic devices because they can interfere with the recordings causing alteration on the ECG track.

Step 5 **Holter experience within the 24h**



Once spent the 24h with the holter monitor a third trip to the hospital is necessary and after waiting a little while, the device is removed by the nurse.

Step 6 **Holter removal**

Once the patient has entered in the nurse's room, the nurse asks if some problems occurred during the last 24 hours. At the same time she fills in the data of the patient on the exam paper.
Once completed she turns off the device, removes the memory flash card and finally removes electrodes and wires. This last step is quite unpleasant since removing patch-electrodes irritates the body skin which is visible on the figure attached.

Step 7 **Exam results**

Exam results are communicated usually 7 days after the exam is performed. A fourth travel is made to collect the results. Shipping is also an option in case the travel demands a lot of time.

REFLECTIONS

After the video analysis and the 24 hours experience it is possible to say that there is a certain discrepancy between what is shown in the Cardioline video and the real holter monitor test.

In the real life experience there are many waiting times involved in the process while in the video there are none. The majority of lost time is due to booking your exam, to waiting for set up and to removing the device.

Another important aspect that is not described in the video is the pain due to the electrodes removal. In my case the pain was tolerable but for patients with hairy breasts, electrodes removal can be extremely painful.

Stay away from electronic devices can limit your daily routines and it can consequently decrease your comfort level since nowadays technology is used for everything.

The device can only be considered discreet when wearing a coat or a pullover. Otherwise, when only wearing a t-shirt it becomes difficult to hide it.

1.3 **Holter monitor video analysis**

After the 24h personal holter monitor experience and walk400h video analysis, several interviews were carried out in the Assisi Hospital.
Interview scope is to understand both users and stakeholders problems and the complexity of the holter monitor system.
All the interviews with Cardiologist, General Practitioner, Patients and Nurses are collected in the respectively appendix D, E, F, G. Here we reported the main insights divided by the aforementioned category.

Cardiologist

The main cardiologist problems are the inability to speak directly with the patient during the ECG analysis and the high amount of time lost to clean the ECG from artefacts (ECG interferences).
Minor issues are linked to the device limits such as limited monitoring-time and no real-time function

Gp

The General practitioner's main issues are linked to the waste of time in understand the patient disease. Be extra cautious is good but better than that there is a first-time correct diagnosis.

Patients

14 patients were interviewed and the most important problems revealed by them were
the inability to maintain their hygiene level and the itching caused by the removal of the electrodes
Important results from the interviews were also the fact that they are not so keen on smartphones and that they have a very passive behaviour towards the exam.

Nurses

The main problems revealed by the interviewed nurses were related to the patients forgetfulness. In fact patients often forget to compile their daily activity diary and very often to bring the previous holter monitor exam
Important to highlight is also that the main complaints heard from patients by nurses are related to itching and skin irritation.

1.4 Personas

Through interviews, observations and holter experience made during the research phase (APPENDIX D,E,F,G) it was possible to describe users and stakeholders involved in the project by means of “Personas”.

USER **RECURRENT PATIENT**

Gianna
70 years old

Goals
Complete tasks prescribed by the doctor (examinations) and consequently check that all parameters are within the predefined health limits.

Frustrations
It is not possible to perform normal activities such as showering or gardening.

Category description
This patient category frequently uses the holter monitor device and they are aware of all the steps included in the medical exam. Recurrent patients are very passive to the procedure while they are more tolerant towards problems like itching or movement limitations

USER **FIRST-TIME PATIENT**

Antonio
65 years old

Goals
Find a solution for this new disease issue that recently occurred

Frustrations
Antonio’s main frustrations are to reschedule his normal routines as well as to put extra attention to his heart.

Category description
Antonio is the typical patient who recently discover an abnormal behaviour in his heart. Therefore he is very anxious to know the disease reason to make a proper diagnosis and find the best medical treatment

USER **PRUDENT PATIENT**

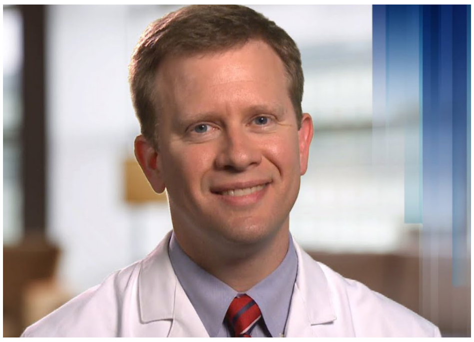
Maria
70 years old

Goals
Maintain a healthy quality of life in the elderly period of her life

Frustrations
Her main frustrations are related to the waiting times: travels from and to the hospital as well as cueing within the clinic.

Category description
The prudent patient is a user that decides to undergo a holter monitor exam for preventive reasons. In the past she/he got a problem and now she/he wants to be sure that his/her heart has no problem at all.

STAKEHOLDER **GP**



Angelo
55 years old

Goal
Goal of the GP is to make an accurate diagnosis and consequently solve the heart problem of the patient

Frustrations
Many difficulties in his job come when he has to extract useful data from the patient symptoms' description. His main frustrations is the disease uncertainty.

STAKEHOLDER **NURSE**

Teresa
30 years old

Goal
Set up the holter monitor and the electrodes in the correct place. Explain to the patient how the holter monitor works and what he can/cannot do with the device.

Frustrations
It is difficult to be sure that the patient understood all the rules linked to the holter monitor. It is a great help if we can explain everything to a caregiver who is usually younger.

STAKEHOLDER **CARDIOLOGIST**

Anna
45 years old

Goal
Analyse patient's ECG trace and check for abnormalities. Make sure if the abnormalities detected by the software are real or just artefacts

Frustrations
The main frustration is to not be able to talk with the patient who can add precious information for a proper diagnosis

1.5 **System Layout**

Description

Once users and stakeholders are individuated the next phase is to integrate them into the System Layout: a graphic visualization of the overall holter monitor process (Fig.6)
Within the system layout it is possible to distinguish the context (HOME, GP CLINIC and HOSPITAL) written in capital letters and the travels indicated with arrows. Numbers and writings (START, END) are added to help the process comprehension.

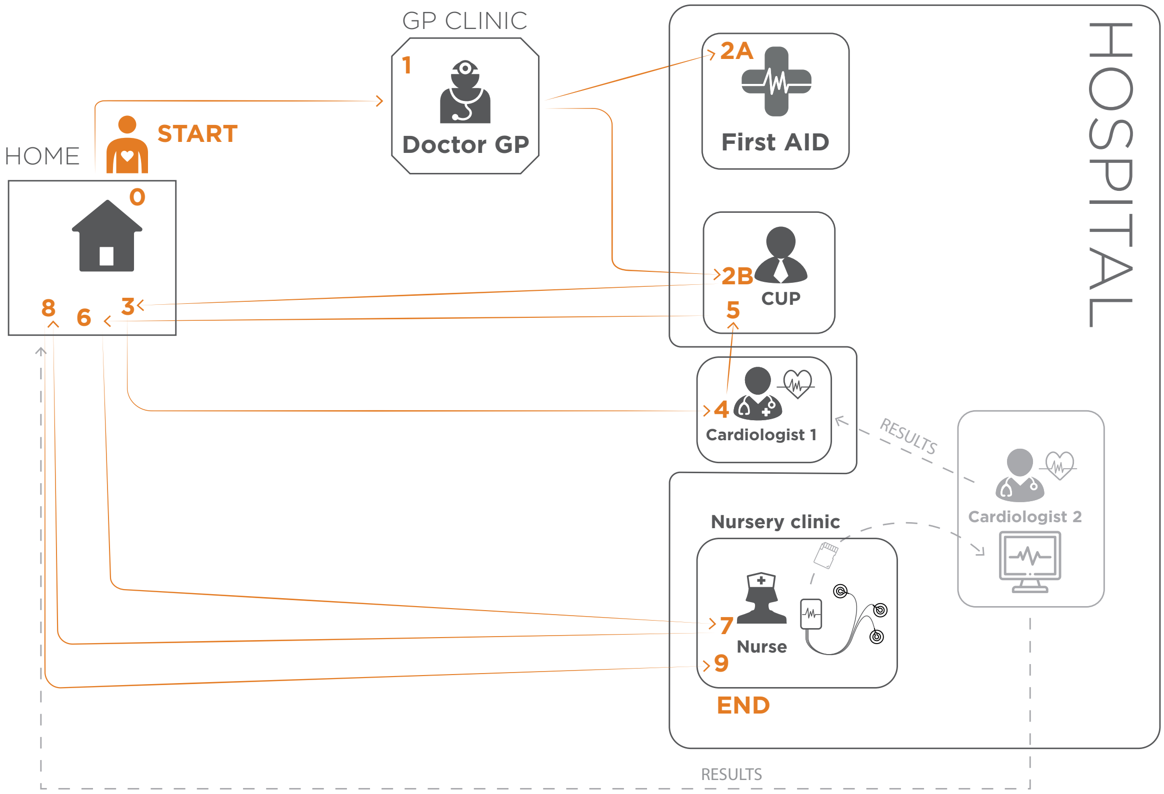


Fig6. System layout of the holter monitor

Reflections & conclusions

Large amount of travels

The first noticeable thing is the high amount of travels (indicated by arrows) from and to the hospital. This large amount involves numerous waiting times which are increased by the queues outside the clinic .From this starting point it is possible to consider several opportunities to improve the overall process:

Booking phase(CUP 2B): With the current technology long queues are not needed, it is possible to book your own spot and arrive on time at that moment. This could save a lot of time for patients as well as for doctors and hospital employee.

Setting up the device (7): With a futuristic view (in 10 years) the process can be done smoothly by watching a video-tutorial where the patient could install the device themselves. But since the elderly are not familiar with current technology in the future in the future caregivers could help those elderly set up the device.

Patient Monitoring (8): Current holter monitors record and store data in their flashcards. This way the results are communicated to the doctor once the exam is finished.
With modern technology in the near future it will be possible to record and immediately upload data to the cloud where also the doctor can have access to them immediately. The real time feature could be very useful especially in the case of paroxysmal atrial fibrillation.

Going digital will open several opportunities such as the collaboration and communication between several doctors, and patients and the possibility to continuously check the electronic patient record.
The electronic patient record is important not only to avoid possible leaks but also because with one's clinical history it is possible to determine the probability of having a heart disease in the future.

1.6 Potential Human improvements

As a conclusion of the people analysis, here is presented a summary of problems found along the research and some guidelines for possible future improvements.

Potential improvements for Elderly Patients

Considering the elderly patient interviews done it is possible to say that the elderly are not keen to use a smartphone. Perhaps over 10 years elderly people will be very confident with smartphones or tablet but for this analogical generation (some of the people interviewed were born in the 30's) a device which refers to their daily routine is needed. A possible solution could also related to the involvement of a younger caregiver which is usually familiar with the modern technologies. If possible it would be better to have a family caregiver than a completely stranger. A problem is also revealed in the communication of symptoms between patient and doctor because symptoms are not always clearly communicated to them. This is due to the different languages and different perspectives of the problem.
Since patients are also very passive to the procedure, more engagement should be considered in the future product.
Strictly related to the product, the main limitations are: to not have a shower, the obtrusive presence of the wires which usually results in itching irritation and the pain felt on the skin caused by the electrodes removal.

Potential service improvements

Perhaps it is not the focus of this project but issues related to the holter monitor service are also useful to consider.
Overall, the holter monitor service involved numerous situations wherea lot of time was wasted. Potential improvements for the holter monitor service could be found in the transition of the current system towards the m-Health.
The hospital transitions towards a digital approach could bring several benefits for the patients as well as for the hospital:
On the patient side, a digital organization could enable a more efficient patient-managing avoiding fastidious queuing and worthless travel from and to the hospital. For instance results could be discussed through Skype calls directly in the patient house without any travel in-between.
On the hospital side the digital transition will facilitate the reduction of the patient under treatment by following the worldly shifting from volume to value.
The sale or the rental of the device is also determined by the frequency with which the patient needs to undergo a holter examination. Probably for first time patients or prudent patients a rental solution is suggested while a sale is more recommended for recurrent patients.

Potential improvements for cardiologist and GP

Regarding Cardiologist and GP possible solutions to improve the holter monitor examination are linked to the communication between doctor and patient
In fact one of the most important issues revealed by the cardiologist is the frustration to not be able to talk to the patient when he/she is analysing his/her

ECG track record.
A similar problem of communication is within the GP and patient's communication where it is difficult to translate the patient's words into medical words. A "translator" interface between them could be useful to solve this problem.

Potential improvements for the nurses

The main problems revealed from the nurses' point of view were: the procedure and device explanation, and the forgetfulness of previous clinical examinations by the elderly patients.
For the forgetfulness problem a solution is already available which is the electronic clinical record. A digital folder where all the previous exams are catalogued and recorded neatly.
The benefit of this electronic clinical record is the patient's possibility to share his/her clinical data with the treating physician at anytime in any place.

PART | **Analysis**

02

02 **Business**

In this section the research dives deep into the business part of the project. An overview of the healthcare business magnitude and the healthcare trends is provided. Finally a special focus is given to Cardioline's past innovations and future guidelines for the holter monitor

2.1 **Magnitude of healthcare and cardio healthcare.**

The economic magnitude of the healthcare industry is underlined by the fact that healthcare spending in major regions of the world will rise from $7 trillion in 2015 to $8.7 trillion in 2020. This is with a current annual growth rate of 1.3 % in the three-year period 2012-2016 and an expected growth rate of 4.1 % in the future three-year period 2017-2021. (The Economist Intelligence Unit. 2016). (Fig.7)

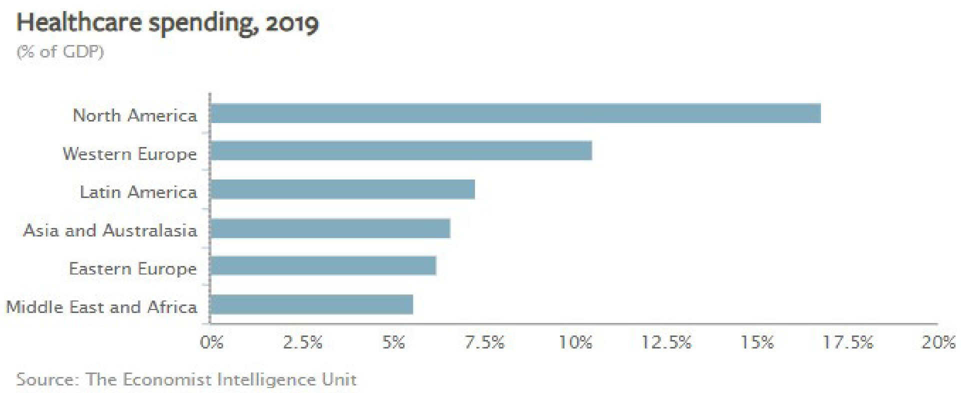


Fig 7.Healthcare Spending 2019

As proof of this growth, companies already present in the sector have had the opportunity to invest to increase their earnings.
One example is Medtronic, the world's leading cardio device company, which earned $9.361 billion in 2014 and is expected by Newmarker, C., & Buntz, B. (2015) to reach $11.588 billion in 2020 (an increase of 3.6%).
The Healthcare growth is so large that it not only involves companies in the medical field but also many economic giants such as Apple and Philips which recently have decided to change their investments focus.
Philips after 123 years of manufacturing, sales and development of light bulbs in 2014 has decided to break its tradition and divide its company into healthcare and lighting. This in order to turn more attention to the growing and more profitable healthcare business. (Derrick, A. 2017).Apple, a historic manufacturer of laptops, smart phones and tablets, has decided to focus on healthcare by implementing it in its apps, services and future strategies (CBInsights. 2018).

2.2 **Healthcare trends**

To be aware of what trends are influencing the healthcare system a DESTEP Analysis has been carried out. The Integral version of the analysis is available in the APPENDIX C while here are reported the main conclusions and reflections drawn from it.
The future increase of senior people mentioned in the demographic trends (The Economist Intelligence Unit 2016) confirms the proper decision of the target group selected for this graduation project : the Elderly people. (Fig.8)

Life expectancy at birth (years)

	2012[a]	2013[A]	2014[a]	2015[a]	2016[a]	2017[b]	2018[b]	2019[b]	2020[b]	2021[b]
North America	78.7	78.8	79.0	79.2	79.3	79.4	79.6	79.7	79.9	80.0
Western Europe	80.8	81.0	81.2	81.4	81.6	81.8	81.9	82.1	82.3	82.5
Transition economies	70.6	71.1	71.5	72.0	72.1	72.2	72.4	72.5	72.6	72.7
Asia & Australasia	71.1	71.4	71.7	72.0	72.2	72.4	72.7	72.9	73.2	73.4
Latin America	74.4	74.7	74.9	75.1	75.3	75.6	75.8	76.0	76.3	76.5
Middle East & Africa	59.0	59.4	59.8	60.3	60.5	60.7	60.9	61.1	61.4	61.6
World[c]	71.9	72.2	72.5	72.8	73.0	73.2	73.4	73.7	73.9	74.1

[a] Economist Intelligence Unit estimates. [b] Economist Intelligence Unit forecasts. [c] Sum of 60 countries covered by the Economist Intelligence Unit's industry service.

Source: The Economist Intelligence Unit.

Fig 8. Life expectancy at birth (years)

The growth of elderly people is followed by an increase in the patients treated and a consequent hospital facilities overcrowding. Hence the hospitals' need to reduce as much as possible the number of internal patients and prefer, if possible, treatment outside the traditional walls. (Digital Deloitte 2017)This new way of treating patients has several consequences for the device used:

- Firstly, devices are not only products but Products-system, interlinked and able to communicate and transfer data between each other.
- Secondly, devices are becoming more and more customer-oriented and with self explanatory interfaces. To enable patients to actively participate in the diagnosis process and to reduce the internal workload of Hospital facilities.
- Finally, this new Healthcare system enhance the community value. A community conceived as a mutual help between users using the same device.

IMPORTANCE OF ICT

This change is also supported by the growing importance of Information communication technology (ICT)

In fact ICT development has reached such a level that it can promote traditional medicine and care to telemedicine and tele-care. (Ekeland, A. G., Bowes, A., & Flottorp, S. 2010). Tele-healthcare and telemedicine could be considered a very promising alternative to traditional hospital methods. This according to:

- The strategic European and global premises towards mobile health (Iakovidis, I., Wilson, P., & Healy, J. C. (Eds.). 2004)

- The tendency of medical procedures to be increasingly carried out in outside hospital facilities. This is mainly due to technological advances and incentives for value-based care rather than volume-based care (Abrams, K., Balan-Cohen, A., & Durbha, P. 2018).

- Telemedicine is proposed as a solution to the shortage of medical staff, especially in the night environment (Sanders, R. B., et al. 2014).Telemedicine is also proposed as a provider of remote home-care health services to prevent and manage the growing chronic diseases caused by the increased stress in our daily lives (Figueredo, M. V. M., & Dias, J. S. 2004,).

- E-Health is a market with great potential and several infrastructure with smart phones and internet have been already proposed (Ekeland, A. G., Bowes, A., & Flottorp, S. 2010)

2.3 **Cardioline Innovations and future holter monitor guidelines**

Cardioline, even with less investments than Apple and Medtronic, has also taken paths for innovation. Example of this innovation are the holter monitor Touch ECG (Cardioline touch 2018) and the Cardioline Web app (2018) that can be considered the flagship product of the company (Fig.9)

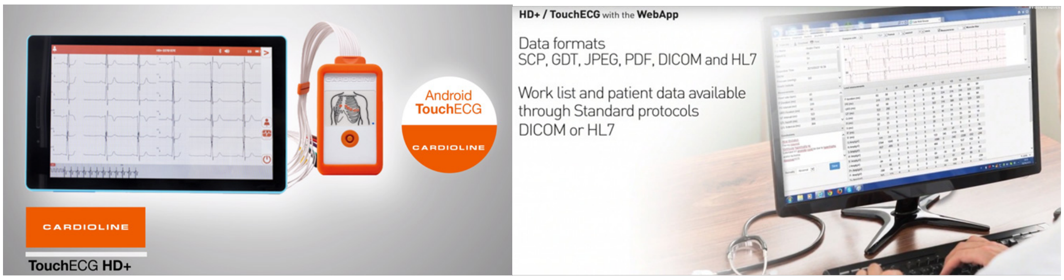


Fig 9. Cardioline touch and Cardioline Web app

Nevertheless, even if those products can be considered innovative steps towards the future, Cardioline still needs to innovate different product-services
With this analysis, it is possible to draw some guidelines for the future Cardioline innovations

- Firstly, the future product will be more a product-service than just a product. A device cloud based, interconnected with the community and with real time diagnosis option. So innovation not only relies on technology but also on the service offered with it.
- Second of all, the product- service should be more user- friendly and in particular ageing-friendly since the main users will be patients over 65 years old.
- Finally, the future product should be a wearable device and as unobtrusive as possible to not limit daily routines of patients

Future holter monitor

From the interview (APPENDIX B) with the marketing and R&D head managers, another specific guideline related to the holter monitor can be added. In fact the company needs a future product that is less expensive on the market but more expensive as far as internal equipment is concerned. This can be translated in Design-words as low cost device with the possibility of a new way of manufacturing.

PART | **Analysis**

03

03 **Technology**

In this section technology related to the holter monitor service is explored.
Starting from the History of Cardiology, the analysis elaborates on all related implications as well as the transition from multichannel to biosensors devices. Furthermore a brief description of mobile health is provided and the current state of art of cardio healthcare services are analyzed
Finally, a perceptual map and some conclusions for Cardioline's future product are outlined.

3.1 **History and evolution of Cardiology**

From the first to the nowadays holter monitor.

An electrocardiogram (ECG) is the recording of the heart electrical activity by means of electrodes placed on skin surface.

The first heart quality measurement was carried out by the Dutch Willem Einthoven by a heavy string-galvanometer (almost 300 kg) at the beginning of 1903 (Fig.10)

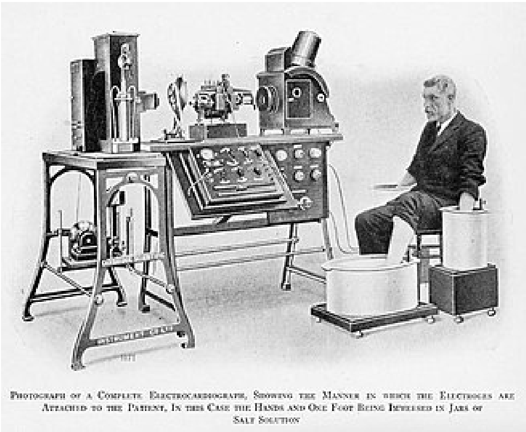


Fig 10. One of the first Electrocardiograph machine

This device invention was so important in for the science field that in 1924 Eintoven was awarded with the Nobel Prize in Physiology or Medicine (2018).
In 1947 Normal Holter made further progress in the world of cardiology by inventing a portable holter monitor (Fig.11)

Fig 11. Norman Jeffris "Jeff" Holter with his invention

The device was considered a big improvement in weight and dimension, even though the size was similar to a bag and the weight was around 38 kg.
Nowadays, several devices are used for medical measurements. From the well-known 12 ECG leads (Fig. 12.left) where the electrodes are connected to 10 different parts of the body (Gailus, C. 2018), to the holter monitor, with 3 to 5 electrodes connected, to a portable device which can continuous measure the heartbeat for several days (Fig. 12.right). (Medium Corporation 2018).

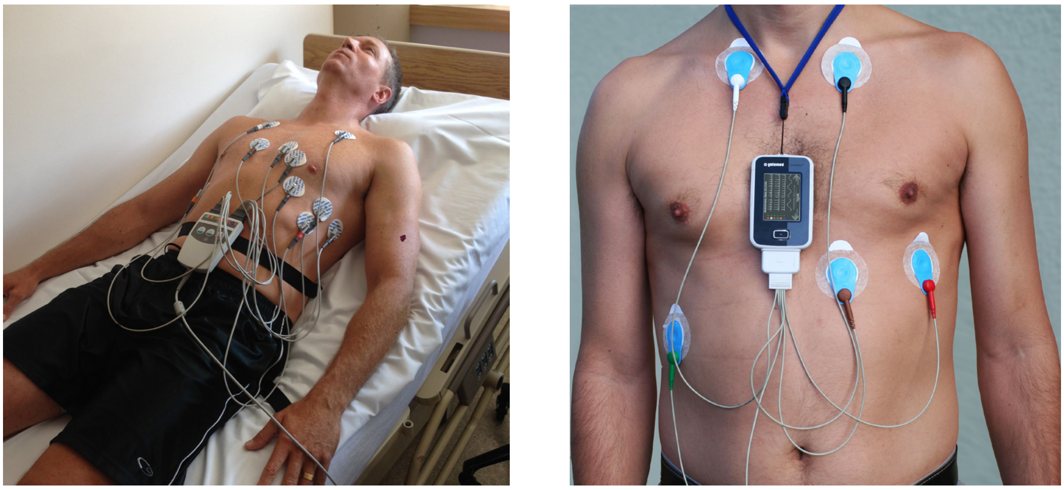


Fig 12. On the left 12 ECG leads; On the right portable holter monitor

Portable holter monitor problems

Nevertheless holter monitor category presents its own problems such as:

Problems with Cables and Electrodes (Trobec R. et al 2018) (Lee, S. P. et al 2018).

Problems due to data analysis which is complex given the large amount of data recorded and to be analysed (Trobec R. et al 2018)

Psychological and physical comfort problems, as reported by an American journalist from the New York Times after a 30-day holter monitor experience

"The wires tickled my torso and puffed out my shirt. The bulk of the recorder on my belt poked my waist, hampering movement. I felt concerned looks whenever the monitor was in plain view. It was hard to forget I was a patient. I felt tethered to, not freed by, technology. These inconveniences were like small physical and psychological co-payments, increasing the cost of the test to me, the patient." Frakt, A. (2018).

Problems due to the limited monitoring time which sometimes it is sometimes insufficient to conduct an appropriate diagnosis (Turakhia, M. P., et al 2013).

Low patient-compliance
"Common areas of non compliance with ambulatory monitoring include the unwillingness to wear a device continuously, intolerance of the electrodes because of rash, failure to activate a monitor in association with symptoms, and inability to transtelephonically download the information." (Lorenz, A., et . al 2007)

Why biosensors are better than traditional holter monitors

Starting from the aforementioned problems, science and technology have developed alternative products to the traditional holter monitor. Of all the options available, the one where the most technological effort is spent is the category of bio sensors (Fig.13).

Fig 13. Example of a Biosensor (ZioXT)

Several reason are here presented explaining why biosensors are currently better than traditional holter monitors

- Turakhia (2013) in his scientific paper explains his results after comparing the traditional holter of 24 - 48 hours with the biosensor Zio patch.

"Extended monitoring with the Zio Patch for 14 days is feasible, with high patient compliance, a high analyzable signal time, and an incremental diagnostic yield beyond 48 hours for all arrhythmia types."

- A similar conclusion is made by Barrett et al. (2014) in his scientific article where he also compares 24 hours of holter monitors with 14 days of ZioPatch. These are the conclusions of his research:

“over the total wear time of both devices, the adhesive patch monitor detected more events than the holter monitor. Prolonged duration monitoring for detection of arrhythmia events using single lead, less obtrusive, adhesive- patch monitoring platforms could replace conventional Holter monitoring in patients referred for ambulatory ECG monitoring”
He therefore states that biosensors are not only less obtrusive but also more effective in detecting cardiac arrhythmias compared to a standard holter monitor

Potential of body sensor

Bio sensors are promising devices for the electrocardiography future. This is because they are not only innovative products but also because they have large margin of improvement.
This is mainly connected to the suddenly growth of the ICT that has enabled the wireless communication data from miniaturized products to cloud by means of smartphone or tablet.
(De Capua, C. Meduri, A. et al 2010).

In addition, potential improvements are also related to the possibility to add multi-functional features to the biosensors. Nowadays, biosensors are limited to only recording and analysing ECG but in the future several functions could be integrated such as:

- analysis of muscle activity
- analysis of ECG-derived respiration
- analysis of patient movements
- Analysis of environmental data around patients such as: temperature, light, etc.

Finally, in the future, different types of data will tend to be merged for more accurate analysis by physicians and professionals. In this scenario, potential improvements are possible in data synchronization, communication and computing complexity and data storage

3.2 **Mobile Health**

Reason and definition of mobile health

Improving cost and efficiency in healthcare, the intentions of a higher life quality, the increasing patient mobility and awareness about their health and the tendency towards a more sustainable healthcare expenditure, are all important factors that explain the progressive involvement of ICT in the healthcare system.

Consequence of the massive ICT involvement in the healthcare system is the creation of an independent sector called "mobile health" which can be regarded as a new way to support clinical healthcare by enabling tele-monitoring, telecare, teleconsultations and other remote services.
Prior to describing potentials and weakness of the mobile health is necessary to dive deep into a brief representation (Fig.14)

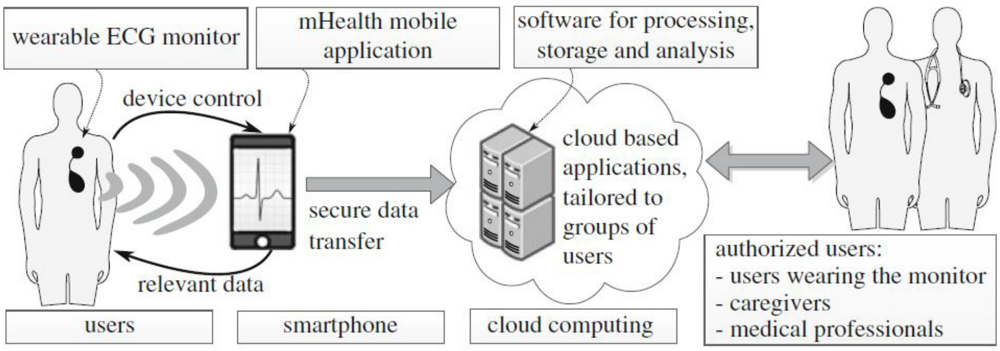


Fig 14. Conceptual scheme of a generic M-health (Trobec R. et al. 2018)

In the mobile health the patient is wearing a wearable ECG monitor which continuously transmits data to the smartphone which are then securely transferred to a cloud-based. Finally, the data can be viewed, analysed by authorized users including physicians, caregivers and patients themselves
Peculiarity of this system is that the user/patient interacts indirectly with the biosensors and directly with the smartphone app.

M-health challenges

Challenges of the mobile Health are the following ones:

Firstly, it is necessary to create a telematic infrastructure that communicates with users in a discreet way. This can be done by biosensors capable of collecting vital signs during normal daily activities.

Secondly, recorded data should be safely transferred to the cloud by means of a personal device (smartphone or tablet).

Finally, Once data are re-transferred to the cloud they can be shared with professional experts that can visualize, analyse and use data to provide proper diagnosis.

Key weakness

The main devices weakness is related to the patient's acceptance. Up to now the problem has been underestimated because companies have solely focused on technology without taking into account the importance of the human factor.

Potential of Mhealth

Mobile health has great potential that can be used to innovate in many areas of medicine such as consulting, monitoring, diagnosis and many others.

The data collected by the sensors could be visualized and analysed in real time through the use of computers. In addition, the computer could generate reports that could be a tool to speed up the diagnosis, as well as cataloguing the patient's medical records.

Possible improvements are related to the device shape and dimensions which can be as discrete as possible. Surely, the reduction in dimension and shape must not affect data-accuracy and the multi-functionality features

3.3 **Commercial ECG**

In this section several Commercial ECG will be analyzed. Scope of this investigation is to look for opportunities and alternatives to the walk400h Cardioline Holter monitor.
Considering all the products on the market, a selection was made taking into account the companies considered by Cardioline as competitors and adding to that selection devices with an innovative approach to the holter experience.
To present results in a structure way all the devices have been divided in 5 categories.

1. **Patch solution**
2. **Hand held solution**
3. **Holter monitor**
4. **Wearable body contact**
5. **Invasive devices**

In order to avoid repetition, only one example per category has been reported in this analysis. The products considered similar have been listed at the end of the description of each category

01 Patch solution **- Savvy**

The first category analyzed is the patch solution and the product reference is Savvy (Fig.15)

Fig 15. A patch solution - Savvy

Savvy is a Slovenian company that provides ECG devices which can be used for long-term heart monitoring, for atrial fibrillation problems and as a prevention tool for cryptogenic stroke. Savvy is more than a product because there is also service included in the offer(Fig.16).

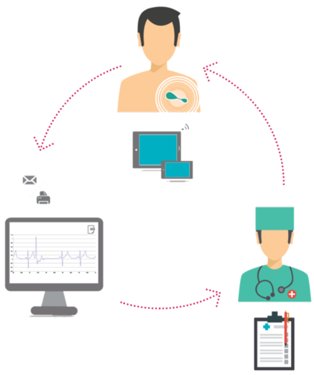


Fig 16. Savvy product-system

Patients who decide to use Savvy are constantly connected with a doctor, who can check the ECG in real time. Furthermore, the patient is able to create a personal ECG report, store it in a dedicated server for further diagnosis and eventually sent it to his/her personal doctor.
The company claims as their potential customers: elderly, athletes and businessmen.

Similar to savvy device there are: Philips vitality (ex Vital connect) Spyder ECG, Zio XT, Bardy DX, Isansys Lifetouch, Cortrium, Epatch by Delta .

02 Hand held solution – **Kardia**

Among the many different companies which produce hand held solutions the most promising one is Alivecor with its product KardiaMobile.

Fig 17. Kardia Mobile

With KardiaMobile it is possible to record ECG anywhere anytime.
The patient has just to gently place their fingers on the device and wait a few seconds. In a few minutes it is possible to get a complete echocardiogram and a diagnosis of the patient's state of health.

Product similar to Kardia are : Neurosky ECG, ECG Check, Wive.

03 Traditional Holter monitor **– Contec**

Countless are the companies that produce holter monitor devices. GE Healthcare, Fukuda Braemer and also Cardioline are included in this category. As most representative of its category the holter monitor Contec is here described.

Fig 18. Traditional holter monitor Contec

This device has been the standard tool of many cardiologists. However, nowadays it is questioned by other types of much more comfortable solutions.
The service related to this product starts with the installation of the device in the hospital by a nurse. Once activated, the device can record up to 48 -72 hours indoors. Only once the data is finished are they downloaded by the doctor and a diagnosis can be made.

Similar product to this are: Cardioline walk400h, Schiller, Bittium Faros

04 Weareable body contact - **Qardiocore**

The body contact category concerns all those products that act as ECG devices without the use of adhesive patches. The example we are examining is Qardio (Fig.19), although there are many similar devices such as Zephyr BioHarness 3 and many others.

Fig 19. Qardiocore body contact ecg device

Once extracted from the package QardioCore is ready to be worn. The set up can be done by the patient itself by following the package insert. The data are collected by the device and stored in a server and, at the patient's request, can be sent to the doctor for a medical diagnosis.

Direct competitor of Qardiocore is Zephyr Bioharness 3.

05 Invasive solution – Reveal **LINQ**

Although this solution is one of the most expensive in some cases, it presents itself as the only one to understand the disease. Some of the most famous companies that are producing this type of solution are: Medtronic with LINQ and REVEAL, and Abbott with SJM. In this analysis as a reference product t is takenthe reveal LINQ of Medtronic (Fig.20)
Medtronic's Reveal LINQ is a service that offers the possibility of implanting under the skin a loop recorder. This device continuously records and erases data.
This is done until it recognizes an abnormal event in the patient's heartbeat. Immediately when this abnormal behaviour occurs the device stores 30 minutes before and 15 minutes after the abnormal heart behaviour. The data is transmitted via a device associated with the doctor who is able to make a real-time diagnosis of what is happening.

Similar services are offered by Medtronic LINQ, SJM Confirm

Fig 20. Reveal LINQ by Medtronics

3.4 Key features for holter monitor device

The state of the art of cardio devices is useful to be aware of what is the current market offer. From this analysis it is possible to extract several insights with which starts the new future product.
Those insights are about the key features for future holter monitor device: Shape and dimensions, IOT integration, Waterproof feature, setting up mode.

Shape & dimension

Driven by technological progress, the old multi-channel holter monitors (ex. CONTEC) are gradually being transformed into wearable smart devices to the point that the device is so small that could be implanted under the skin. (REVEAL LINQ)
Furthermore the shape and the feature of cardio devices are not only related to the pure functionality (HOLTER CONTEC) but more to the lifestyle and the iconic meaning they represent (QARDIO)

IOT integration

The transition from a "traditional" product to a smart product which works by means of Data cloud and IOT infrastructure brings several advantages for healthcare services and infrastructures.
IOT allows to treat patients outside the traditional healthcare boundaries (KARDIA) and it reduces possible inefficiencies due to product malfunction. Real time diagnosis is possible and storage related problems are almost solved due to the possibility to store data on the cloud. Nevertheless battery consumption remains still a significant problem.

Waterproof feature

Waterproof feature could be considered a competitive advantage to stand out from competitors, In fact those devices which are waterproof enable users to execute their main daily routines without any limitation.

Setting up

The phase of setting up the device is also important to consider in a cardio device. The current state of art presents either product with setting up done by users (QARDIOCORE) and products where the setting up is done by nurses or doctors (CONTEC, REVEAL LINQ).

3.5 **Key features for holter monitor device**

Perceptual Map

To define the placement of current and future product a perceptual map Fig.21 has been made.

With this comparison, it is possible to graphically visualize the current product area (A) and the future product area (B) of Cardioline. Aim of the company is to design a new device more unobtrusive and affordable compared to the current walk 400h. Consequently, reference products are those one in the upper left area inside the boundary of the dashed circle B.

Products like the implantable reveal link by Medtronic are excluded from the future vision of the product while products like Bittium Faros or Cortrium could represent a step in between holter monitor and the wearable patch.

Important to consider is also the massive influence that ICT has on medical device and especially on wearable biosensors. Relatively Consequence of that is that new innovation is more related to the service/software than to the product itself.

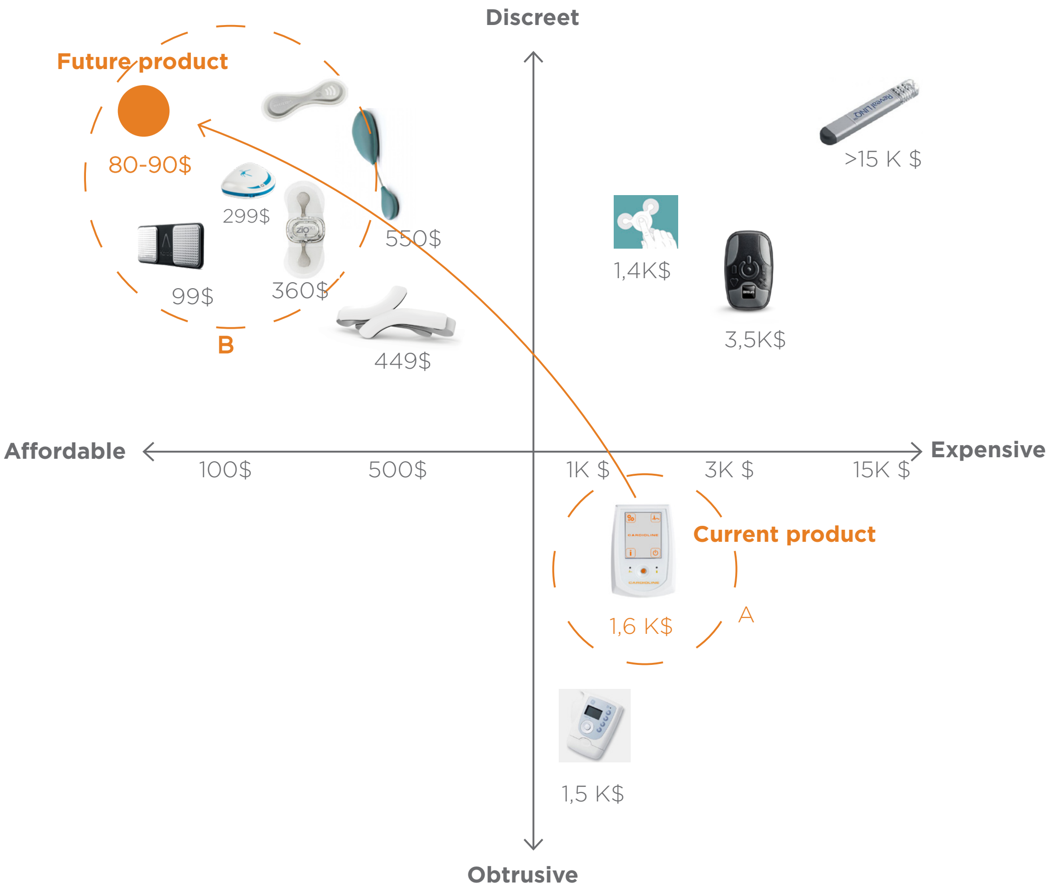


Fig. 21 Perceptual Map

Overall conclusion

The healthcare world is changing from the traditional medicine apparatus to the world of mobile health medicine. A summary of what this shift involves is represented in the following table 01.

Traditional health	M-health
Hospital care (inpatient)	Home care (outpatient)
Product	Product -system
Product for healthcare experts	Product consumer oriented
Internal storage	Data analyzed and cloud transmitted
Passive experience	Active experience

Table 01 . Difference between traditional and mobile health

The increase of elderly people in the world population and the consequential increase in hospital patients brings the healthcare sector to a shift: from hospital care to home care. This means that, when possible, hospital facilities tend to care patient outside the standard hospital walls.

This shift is also reflected onto products which are switching from an only-product towards a product-service . Furthermore the product focus is also different: more and more products will be designed with a more customer-friendly interface. This in order to make the product more understandable for elderly people and offer the holter experience as active as possible.

Consequence of this shift is also in product design. Holter monitors are gradually being replaced by Biosensors because they are more comfortable and they have longer operating time and higher acceptance. Furthermore, while standard holters just record on internal storage, biosensors (like savvy or Philips one) collect and transmit data through a server. Afterwards data can be collected, shared and used for further implications.

Cardioline has already started a process of shifting towards the mobile health with Touch ECG and the Web app dedicated. Aim of this project is to continue in this digital transition towards the mobile health by the creation of a smart biosensor connected, small and obtrusive.

The decision for a biosensor is also in line with the strategy of the future Cardioline product because biosensors meet the objectives of being non-intrusive and affordable. Furthermore they represent an opportunity for Cardioline to enlarge their product offer in an innovative way.

PART | **Analysis**

04

04 **Analysis Conclusion**

From the in-depth DESTEP analysis of healthcare trends, from the Cardioline web analysis, from the interview with R&D and Marketing managers and from the Competitors analysis it is possible to draw up some guidelines for the future product design.

4.1 Guidelines for business strategy

As Fabio Rangoni (Cardioline Marketing Headmanager) explicitly stated in the interview:

"Cardioline wants to bring to market cardiology diagnostic products that are simple to use, effective for diagnosis and affordable."

The future product must be ready to compete in the global market for low-cost products together with GE (USA), Philips (NL) Schiller (CH) . Consequently solutions similar to the implantable Reveal LinQ (costing over $15K) or the walk400h (200 €) are excluded because of their prices.

Closer solutions to Cardioline's strategy are all the other devices delimited by the red B circle in the fig.21 Therefore products to compete with are : Savvy, Philips wearable patch (Ex vital connect),Spyder pro, Kardia,

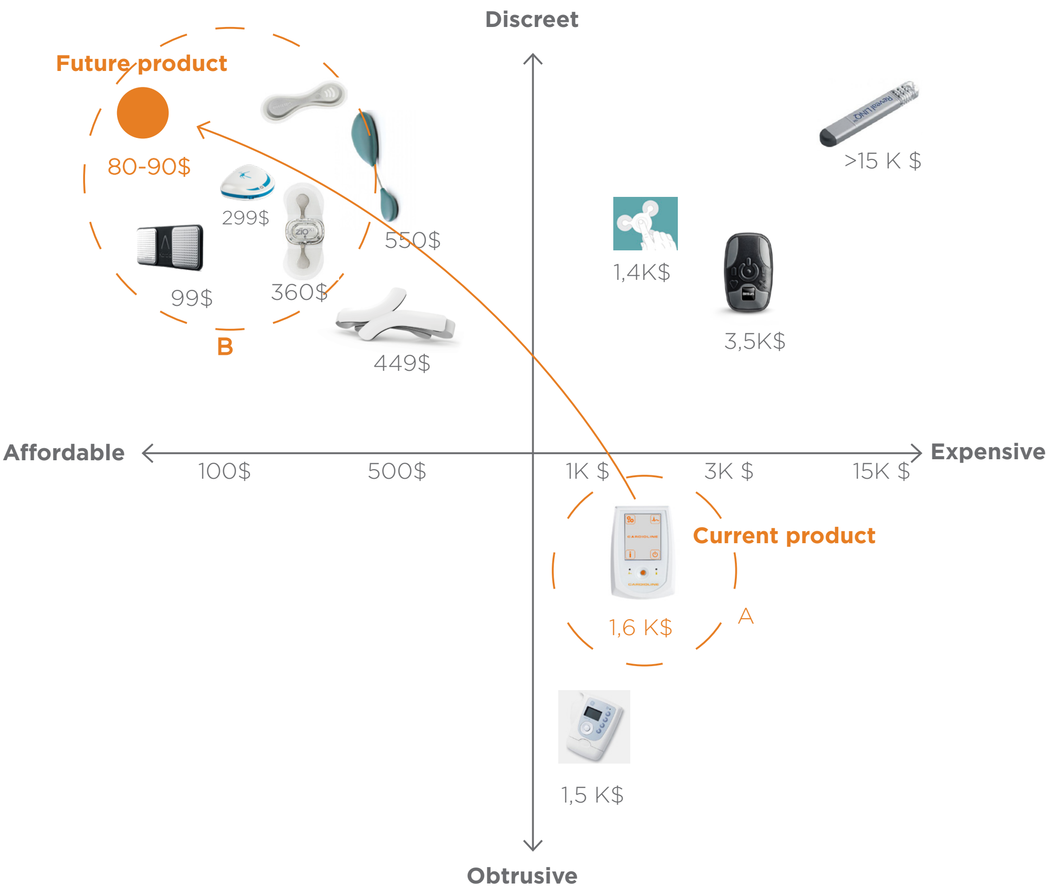


Fig.22 Perceptual Map

4.2 **Guidelines for the new product-system**

Problems of the current system

In the analysis phase several system problems were individuated by means of interviews, holter experience and observations.

Some of the most important ones were:
- One of the most important problem is related to the waiting times cueing during the booking phase, the setting up phase and the dismounting phase
-Lack of interaction between patient and cardiologist in the analysis phase.

Furthermore some minor problems were:
-Nurses' difficulties to explain device instructions to the elderly patient (Possibility of integrating a caregiver to solve the problem)
- Elderly forgetfulness to bring the previous documentation (patient record) as comparison with the new recording exam.

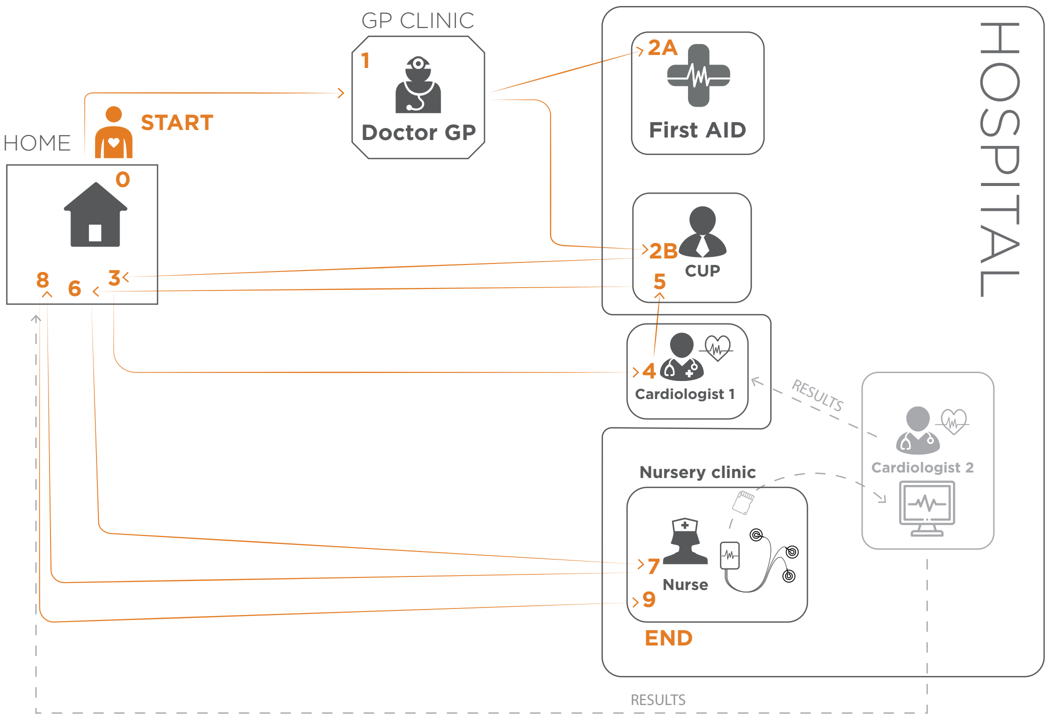


Fig.23 System layout of the holter monitor

Proposal of the new system

Considering all these problems a new product system was layout. following the general scheme of the mobile health (Fig.24)

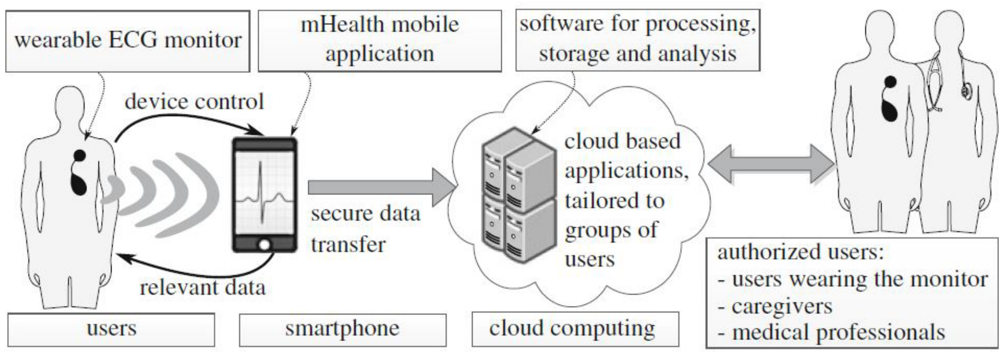


Fig 24. Conceptual scheme of a generic M-health (Trobec R. et al. 2018)

Aim of this new product service is to update Cardioline's perspective from the traditional hospital to the modern infrastructure of the mobile health. A representation of the new product system is given in the following graphic representations (Fig.25)

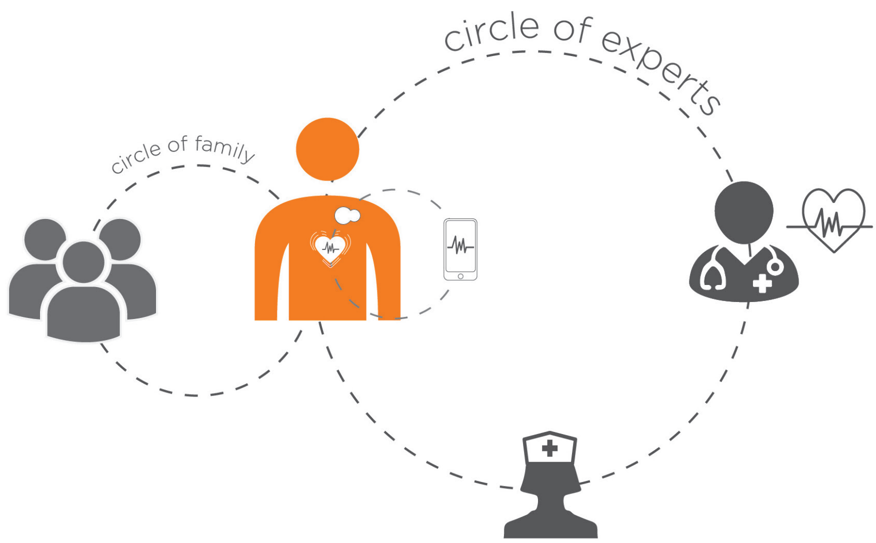


Fig. 25 New System layout

The main innovation in this layout is due to the fact that this system configuration could be done at any location by means of ICT infrastructure.

The patient has a central role in the system and thanks to a personal digital assistant (PDA) the patient is linked simultaneously with the circle of the family (Caregivers) and the circle of experts(Cardiologist and Nurses).

Several improvements are involved in this configuration :
Transition from this new system, can drastically reduce the cueing time by enabling online booking and avoiding unwanted waiting times
The transition towards a more digital system will include a more direct involvement between doctor and patient and through cloud clinical records could solve the problem of Elderly forgetfulness. This is because when you have all your exams online the hard copy is not necessary anymore.

Nevertheless difficulties are also included in the shift from old to the new digital system.
Elderly people are not very keen on changes and they need someone like a caregiver to help them understand new technology. That is the case for the oldest generation of the population, as they were born around the 1930s.

4.3 Guidelines for the new technology

Healthcare sector is one of the most innovative business fields which is constantly innovating in order to improve life day by day. As a result, medical products are constantly updated or replaced by new products and also Holter monitors are included in this perennial and fast innovation.
The image below shows the various improvement levels possible for Cardioline at this moment.

1st stage

The first stage involves a dimension reduction and a wire reduction as well as the overall device performance: longer battery life and larger storage.

2nd stage

In the second stage there is a major change: no more wires and the presence of a cloud to store data. This shift is done by means of a gateway (smartphone) which continuously receives data from the device and securely transfers them to the cloud

3rd stage

The device becomes flexible even in the electronics parts. It is attached to the body through a double-sided tape at the bottom of the device. Totally waterproof by means of the polyurethane top and the hydro colloid gel that makes it hermetic to any water infiltration. No electrodes needed anymore. Possibility to make it disposable.

4th stage

For the 4th stage the device is directly implanted under the patient's skin, maximum freedom of movement. Important to consider is the cost of the procedure(as it is quite expensive) and that it involves surgery operation with its possible related problems

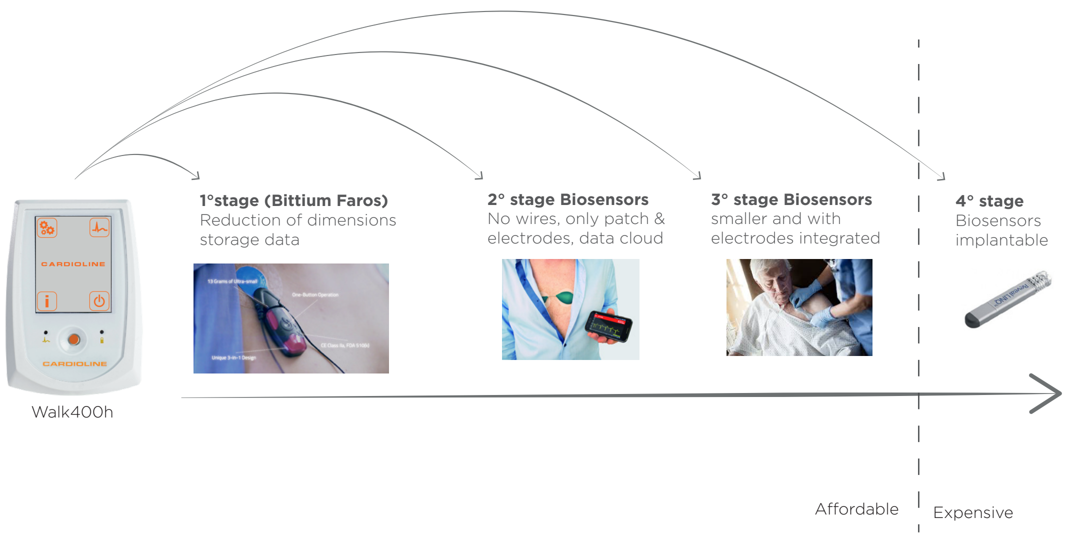


Fig. 26 Improvement stages

4.4 **Vision**

As a result of the business strategy guidelines, the new system product guidelines and those relating to the new technology, a vision has been elaborated

"I want to enhance the holter monitor experience by creating a product- service which results unobtrusive and comfortable for elderly people"

PART II **Synthesis**

05

05 **Conceptualization**

The ideation phase starts with the creation of the List of Requirements that has as expected outcome the Design specifications. Then it follows a brainstorming session and afterwards a conceptualization of 3 concepts proposals. Among the three concept proposals one is selected and further developed .

5.1 **List of requirements**

With interviews, observations, researches done during the entire analysis phase many issues occurred. Purpose of the list of requirements is to synthesize all of them in objectives and goals in order to generate criteria as tool to evaluate the best concept proposal.

Approach

Following the TUDelft (2019) method 4 phases were executed in order to generate criteria.
To begin with the specifications from the analysis were listed. Afterwards a distinction was made between hard and soft requirements (respectively demands and wishes)and similar requirements were deleted. Only then Criteria were extracted and their hierarchy was decided.
Here in order are presented Demands, Wishes and Criteria

Demands

D1) Product Battery should not heat up the patient skin
D2) Product Electronic components must be shielded and protected from water to the standard IPX6
D3) Product should be able to work for a period from 7 to 20 days
D4) Product Dimension should be smaller than 60x60x10 mm
D5) Product should not irritate the skin in a harmful way
D6) Product should be lightweight (30-15gr)
D7) Product cost should be around 50-70 Euro
D8) Product should be feasible in 15 months/worker
D9) Product should be taken into account a batch of less than 3000 pieces
D10) Product should safely store data
D11) Product should be connected with the body safely and reliably
D12) Product should be adaptable to different kinds of elderly bodies
D13) Product should be aesthetically desirable for elderly people
D14) Product should be easy to hold in the hands of elderly people
D15) Product should be comfortable enough to not limit the daily routines of elderly people

Wishes

W1) Product should be easy to clean for elderly at home
W2) Product should be able to connect patient and cardiologist
W3) Product should collect multiple data not only ECG
W4) Product should appear sturdy for nurses
W5) Product should be quick to set up for nurses at the hospital
W6) Product should be easy to clean for nurses at hospital
W7) Product should give information about the origin of the revealed disease
W8) Product should alert local authorities in case of life-danger

Criteria (with hierarchy)

C1.Comfort
C2.Dimension
C3.Flexibility
C4.Reliability
C5.Cost
C6.Manageability
C7.Waterproof
C8.Cleanability
C9.Environment
C10.Set up

5.2 **Brainstorming session**

Together with other 5 designers a brainstorming session was organized. Some images with Cardioline and competitors products were shown as stimuli and five question were used as a tool to generate ideas.
For each question are here reported the main insights related to that. At the end a overall conclusion is made

01 how to inform the patient about the procedure?

The patient could be informed by digital or analogue booklet. By digital tools (app, videos, chatbox, etc.) the patient could be guided into more active holter monitor processing
The control of the experience could be done not only to the patient but also to a caregiver usually more keen to technology. If possible better to select a caregiver within the family since integration could result easier.

02 How to check that the Holter monitor is working properly?

A distinction was made between analogical ideas and digital ideas. Analogical ideas to notify the patient is a system of light or programmed calls between nurse and patient. Digital ideas are more related to smartphone notification. Also here the light colours can be tested.

03 How to communicate problem in the process?

During this part different solutions were discussed: FAQ or chatbox were tools to consider as first tools to solve problems.
Then the idea to add something to not leave the patient alone: a platform or chat where one can discuss about their issues with others.
Communication with doctors is also something to consider when a new service is going to be realized.

04 How to avoid skin irritation ?

Some solutions were presented during the brainstorming.
Dry electrodes instead of Glue electrodes could be a solution to diminish the skin irritation.
Elastic bond is also a solution to consider in order to avoid glue electrodes.
In a situation of multiple days, changing the position of the electrodes could help to diminish the pain.

05 Problem when a patient washing their self

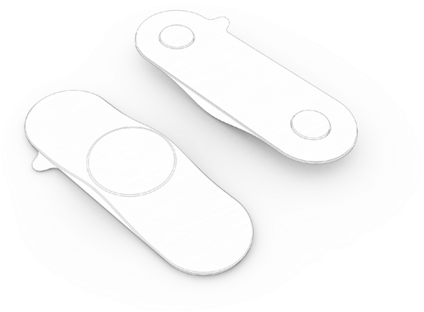
Some solutions come up to solve this problem:
A waterproof cover for the device which works like an umbrella
Dry electrodes can easily removed and replaced. For this particular problem they show their advantage of use.
A protective film upon electrodes could avoid water damaging.
Before putting on electrodes make a cross on the skin in order to replace the electrodes in the same position as the initial ones

Other brainstorming Conclusions

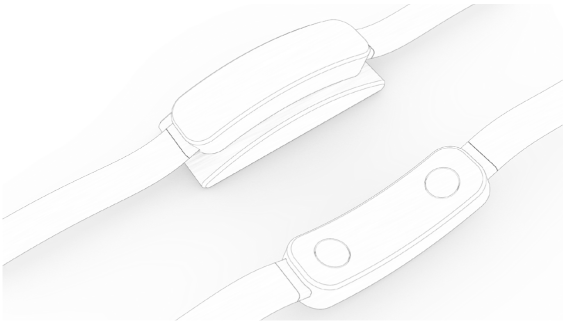
Overall, there is more margin for a new service than for a mere product.
Within the service idea some instructions can be given to the caregiver who can help the patient especially if he/she is not familiar with technology.
A decision needs to be taken between dry electrodes and Glue electrodes because especially for washing activities dry electrodes show their advantages.

5.3 **Concept presentation**

Concept 01 **Flexible patch**
The first concept is a flexible wireless ECG device able to measure the user's heartbeat and transmits that to the cloud by means of a smart phone as a gateway. The unique selling point of this device is the high compliance with the patient's body due to its flexibility feature.



Concept 02 **Holter belt**
Concept 2 is a holter belt monitor able to measure the user's heartbeat by means of dry electrodes. The device periodically transmits data to the cloud by means of smart phone. The unique selling point of this device is the patch absence. That solves most of the issues, such as itching and skin irritation.



Concept 03 **Holter case**
The third concept is a rigid case holter monitor. As the first concept it works with patch electrodes and transmits the ECG signal to the cloud by means of a smart phone.
The unique point of this device is the proximity to the company's production processes and the ease of implementation.

5.4 **Concept evaluation**

With the criteria determined in the list of requirements section the Harris profile (Fig.27) was used to evaluate the three concept proposals. The results of the matrix was that concept 1 was the most promising solution (12+ 1-) followed by Concept 3 (9+ 3-) and Concept 2 (8+ 5-)



	Concept01	**Concept**02	**Concept**03
Comfort	++	+	++
Dimension	+	+	+
Flexibility	++	-	+
Reliability	+	-	+
Cost	+	-	++
Manegeability	+	-	+
Waterproof	+	++	-
Cleanability	+	++	-
Environment	-	++	-
Setting up	++	-	+
Final Score	12+ 1-	8+ 5-	9+ 3-

Fig. 27 Harris profile

5.5 **Final design overview**

Considering the Harris profile results and the Cardioline concept preference, in the embodiment phase the project focus was a combination of concept 1 and concept 3 explained in the previous chapter.
The final solution is a wearable device Patch solution connected with Bluetooth to the smartphone and then connected to a cloud where patients have their own account.
Figure 28 gives a graphic visualization of the final IOT infrastructure for the product service.

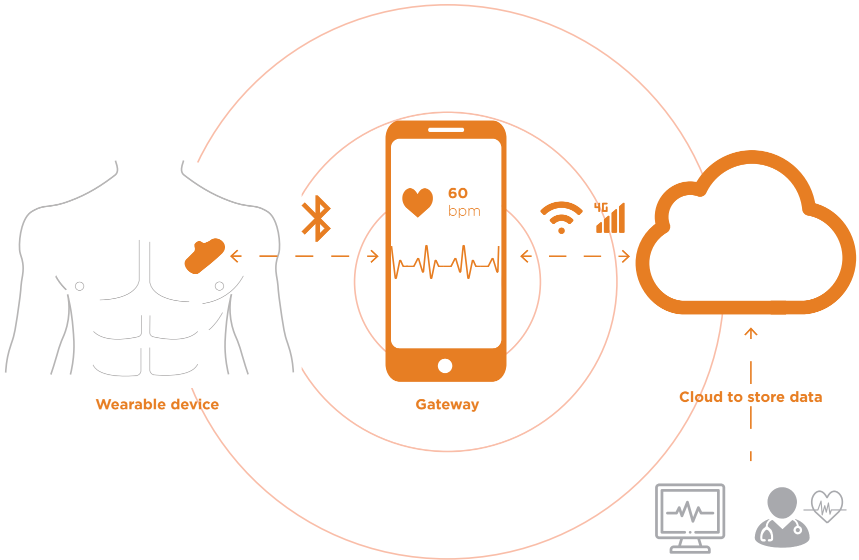


Fig.28 Overall visualization of the system

Target users of the final proposal are elderly recurrent patients. The reason why recurrent patients are selected as central project focus is related to the frequency with which they undergo a holter examination. In fact while recurrent patients need to undergo to the exam once every two months, prudent and first-time patients probably need to undergo a holter monitor examination once a year or even more.

The holter monitor frequency determines also the decision between renting a device from the hospital or having your own personal device. This is also a driver to target recurrent patients more than first-time or prudent patients.
There are several benefits related to this new proposal: less travel needed to and from the hospital, the higher compliance in your daily routines, including washing yourself without compromising the device and consequently the exam results.

Potential improvements are linked to the current elderly people inexperience with the smartphone application. With an educated forecast, within 10 years, elderly people will be completely confident with smart phones but for the current elderly generation it is necessary to provide them extra help for the right device use. An integrated caregiver could be an option in the service, even better if the caregiver is a family member or is already close to the family.

5.6 **Final user scenario**

To summarize the user scenario a storyboard has been drawn. Each step is illustrated from when the device is extracted until the device is placed back into the docking station.

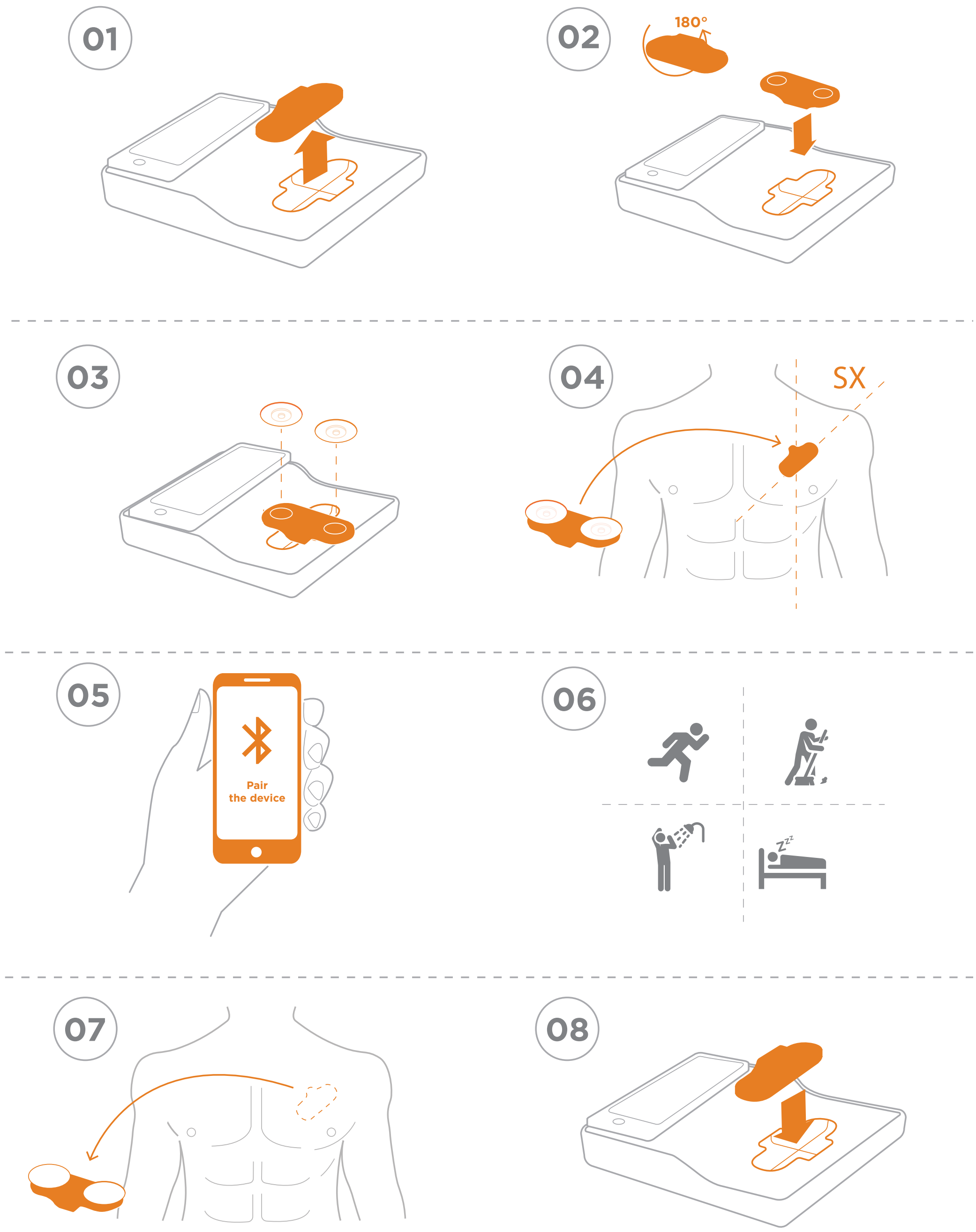


Fig.29 User scenario Step- series

PART III **Validation**

06

06 **Concept testing**

In this chapter presumptions about the final concept are verified through a usability test. Prior to the final test, a pilot test was performed to verify the structure and to prevent possible issues in the final test. The final test was performed with 5 elderly people in their own homes. The test revealed several issues which were address by redesign features, steps and shapes of the final concept.

6.1 **Preparing the user test**

Reason and test objective

To verify the usability of the concept a user test has been set up. Considering the whole process, it was decided to focus on the setting up phase since it is the phase where the main interaction occurs.

Research question

Within the frame of the setting up phase, the user test was the focus to determine negative and positive aspects of the device usability and in particular:

*Which aspects of the **product** and which one of the **user** influence the setting up phase?*

Test structure

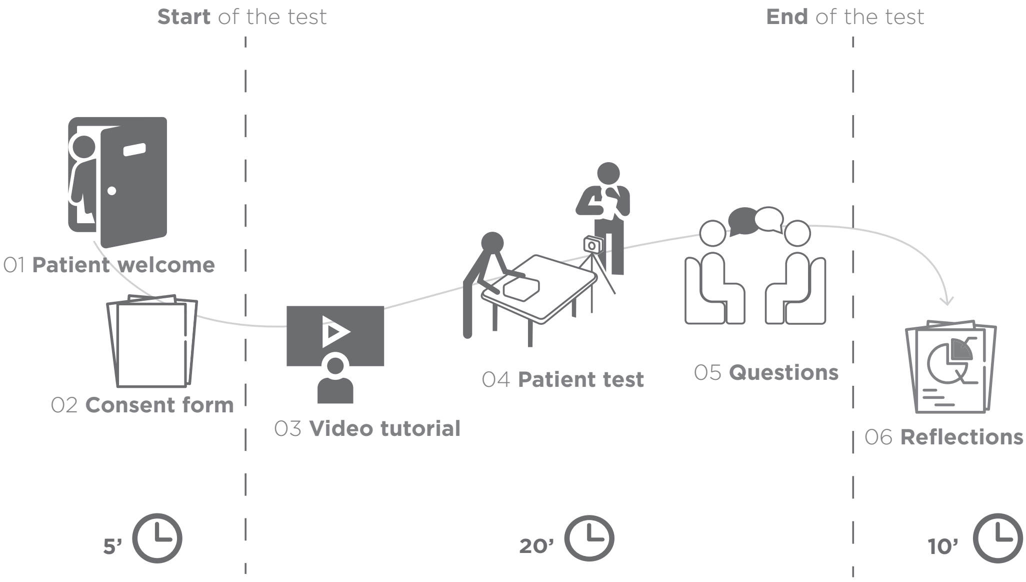


Fig.30 Test Structure

As shown in figure 30 the test begins with welcoming the participant and filling out the consent form. It continues with watching the video tutorial and it will continue with the practical experience to set up the device.
While the patient will be setting up, problems/ issues/ hesitations will be recorded and considered as a starting point of the next phase: the question phase.
The question time begins with the problem investigation examining the causes. Afterwards the patient is questioned on their overall experience.

Presumptions for the user test

Environment presumptions

The environment for the test is the home of the elderly people. The place for the test is a room of their preference with the only condition that there is enough light to see the device, the docking station and the patient’s body.

User presumptions

Participants of the test are elderly who see the device for the first time. They are elderly with regular eye sight, motor skills, and tactility. Participants are expected to not be very familiar with smart phones.

Device presumptions /use cues

The device presumptions investigated in this usability test are related to the product characteristics (material/shape) that provide the user “tips” on how to use the device. Those characteristics are also called use cues. The following table explains the use cue presumptions of the device, of the docking station and of the application. For each use cue the purpose is explained and a photo it is attached. (Table 02 and Table 03)

App Use cue	Use cue purpose	Photo
Start button animated	Get the attention of the user and consequently guide him to press there	
Arrows and central button	Make the user feel comfortable to navigate further and back or to start all over.	
Bluetooth button (plus written indication)	Activation of the Bluetooth	
Indication of waiting	Feedback of the correct position	
Indication of completed pairing with the smartphone	ECG	

Table 02 . Device App use cues

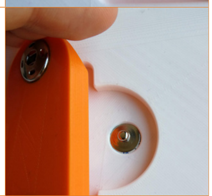
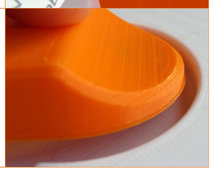
Device Use cue	Use cue purpose	Photo
High contrast in colour (White orange)	To better distinguish device from docking station	
Similar shape between (rounded edges) device and docking station	Correct orientation of the piece	
Similar shape (rectangular) between device and docking station	Correct orientation of the piece	
Metal click sound electrodes-device	Feedback of the correct position	
Metal click sound device docking station	Feedback of the correct position	

Table 03 . Device and docking station use cues

6.2 **Prototyping the user test**

Prototyping the device and the docking station

In order to set up the test several prototypes were realized.
First of all, the physical prototype was 3dmodelled by Fusion 360 software

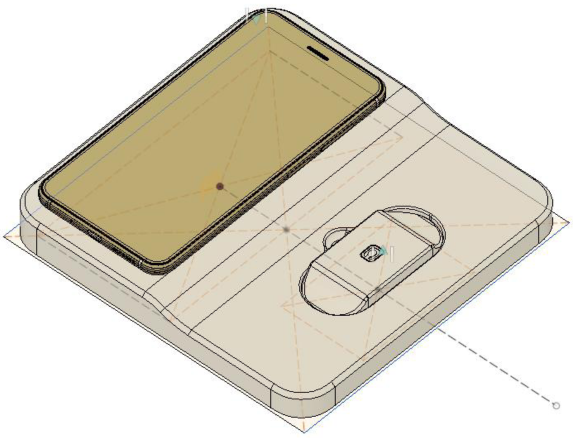


Fig.31. 3d model made with Fusion 360

Afterwards some tolerances were considered in order to make the model feasible

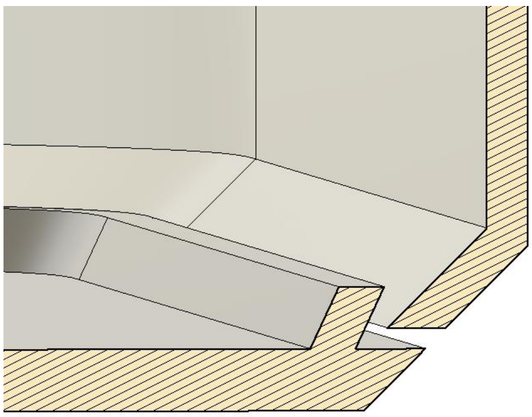


Fig.32 3d Model with tolerances

Then the entire product needs to be exported in Cura where the settings of 3d printing are decided

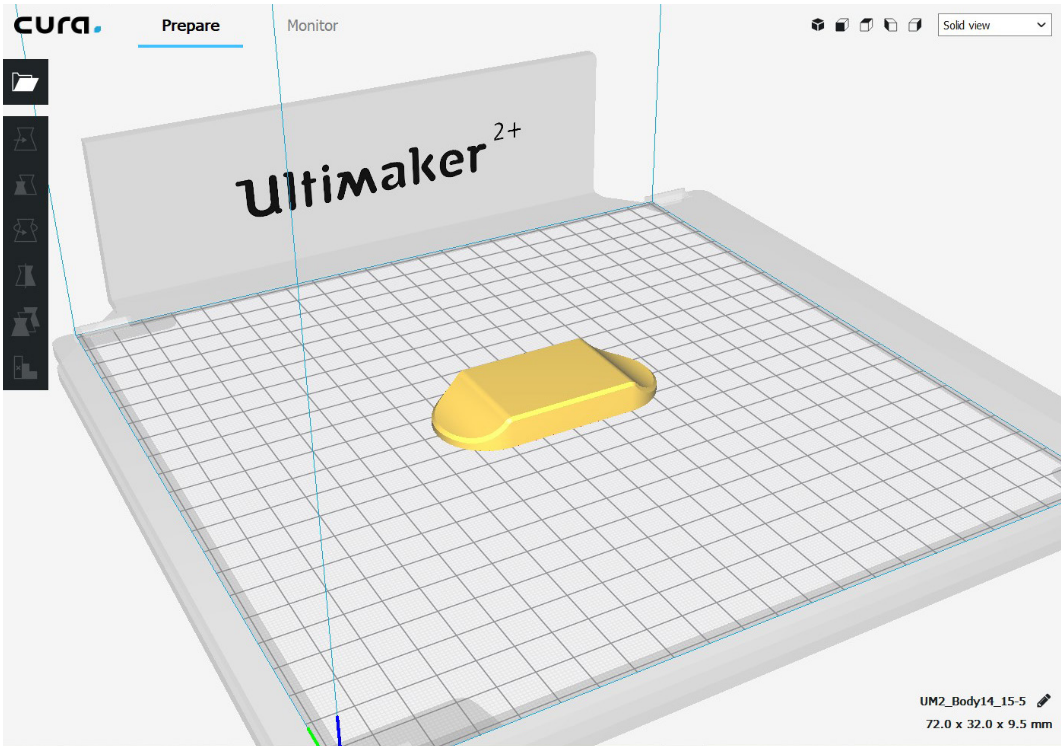


Fig.33 Cura software

Finally the 3d print object is realized, but the result is not always the one expected, as visible in figure 34

Fig.34 First attempt with 3d printer

Several iterations were needed to achieve the final user test prototype (Fig.35).

Fig.35 Final user test prototype.

Prototyping the application

To prototype the application Adobe XD software (Fig 36) was used at first, but after some time spent on building the app it was clear that this was not the right software to use it since it does not support video or GIF animations.

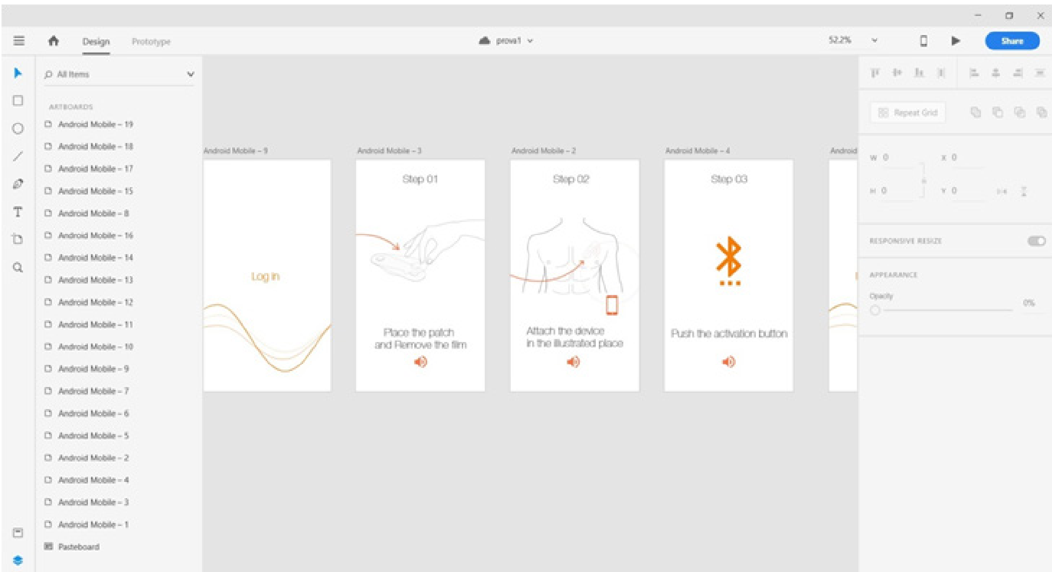


Fig. 36 Adobe XD prototyping

Therefore it was decided to switch to Google slide. The reason for that decision is related to the fact that it supports video and GIF animations and it has the possibility to be edited from a laptop as well as from a smartphone. Figure 37 shows some screen-shots of the first application

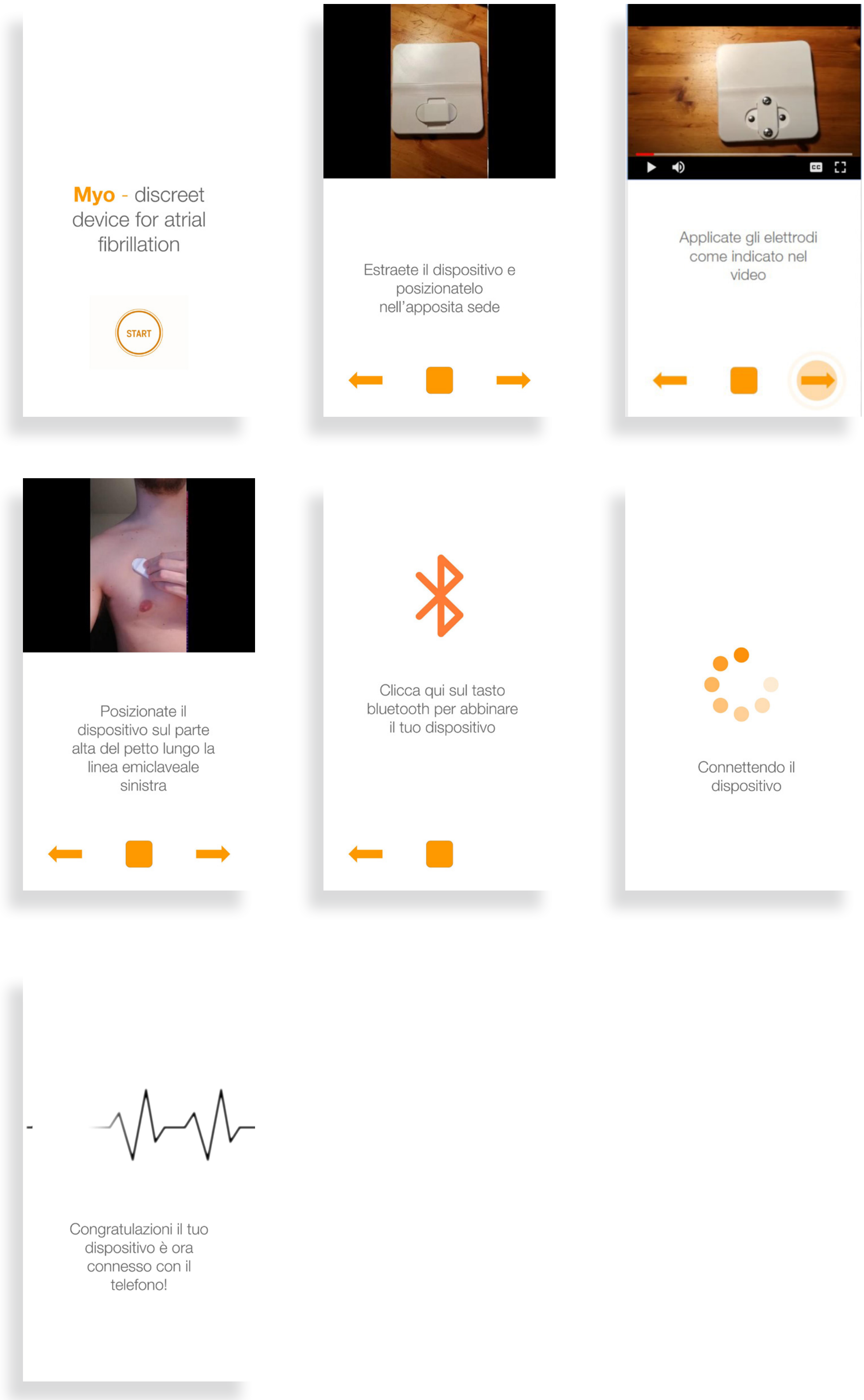


Fig 37. Google slide prototyping

6.3 **Pilot test**

To verify the test structure a pilot test with this configuration (Fig.38) was set up.

Fig.38: Set configuration for Pilot test.

Two participants attend the pilot test separately in a room of the Industrial design engineering faculty of Delft. (Fig.39)

Figure 39: Two IO student during the pilot test

Insights from the pilot test

Overall the procedure was executed quite fluidly and it was perceived as smooth. Nevertheless several problems occurred during the pilot test:

1. It was not clear how to place the device on the body and with which orientation (App and video)

2. The end of the test was not clear (ECG use cue)

3. The Bluetooth button was not clearly indicated (Bluetooth use cue)

4. Applying the electrodes was easy only when you were using two hands, Using only one hand, it was a little challenging because of the not complete fit with the docking station

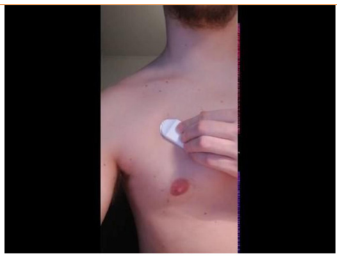
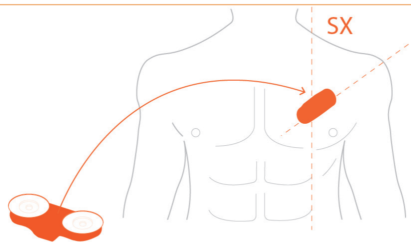
5. Hairy chest can be an issue in attaching the device to the body. Some alternatives need to be considered here, as it can cause pain.

6. Bring a camera for the test because the smartphone one is involved in the test.

Project Improvements after pilot test

After the pilot test some improvements were made to the device and to the smartphone application.

1) It was not clear how to position the device on the body and with which orientation (App and video). "Sx" which is the Italian abbreviation for left has been introduced as well as lines to indicate the right device orientation.

Before the pilot	After the pilot
 Posizionate il dispositivo sul parte alta del petto lungo la linea emiclaveale sinistra	 Posizionate il dispositivo sul parte alta del petto lungo la linea emiclaveale sinistra

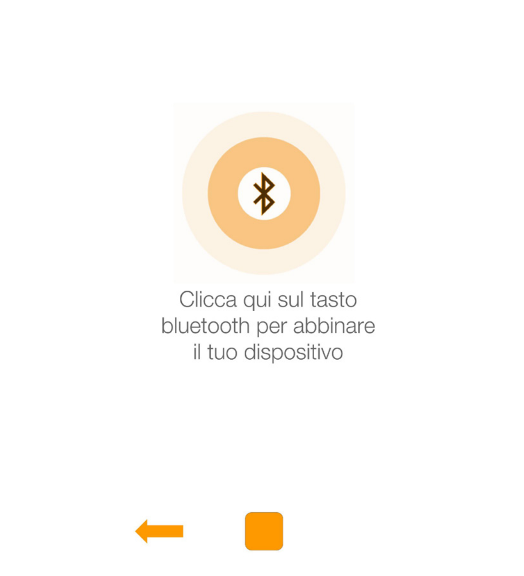
A clearer indication of place and orientation was added.

2) The end of the test was not clear (ECG use cue).

Before the pilot	After the pilot
~~no slide~~	Fine del test

A final slide was used to improve the understanding that the test is finished.

3) The Bluetooth button was not clear indicated (Bluetooth use cue)

Before the pilot	After the pilot
	

A GIF was added to touch the Bluetooth button to guide the user to press the Bluetooth button.

6.4 **Final user test**

Description

With the same structure used in the pilot test, this test was performed by five elderly people: three people of 65 years old and two people of 80 years old. (Fig.40). Two of the five participants agreed to be recorded via video, two only via photos (without the face) and one performed the test but without any recording.

Figure 40: Elderly patients doing the user test

Results

About users

A distinction needs to be made between 65-year-olds and 80-year-olds. The first group is quite acquainted with smart phones and also with the related language while the second one (composed by people born in the '40s) needs some adaptation or repetition. Specifically for 80-year-old participants several problems occur with technical English words such as : app, smartphone, Bluetooth etc. However, once the procedure was understood, even 80-year-old patients had no problems performing all the tasks.

About the device and docking station

In the electrodes placement task , three out of five patients preferred to hold the device instead of place on the docking station.
The docking station slid more than once and especially during the electrodes positioning. Consequence of that also the smartphone slipping

About the app

Overall , the video and app instructions were understood by all the elderly people. three patients did not need to watch the app to start because they already understood the steps from the video tutorial. The app was only used as a task checker and for the final pairing step.
Relevant problems which occurred during the test were:

In the slide illustrated in Fig.41 more than one participant was hesitating about which button to press to move forward.
Even though the participant managed to understand how to move forward, for 5-10 seconds he/she was not sure how to proceed further.

Fig 41 slide with hesitation

Asking the participant why they were hesitating they related the problem to some missing automatic procedure. It was expected that once the video finished the app would automatically move forward.

For one patient it was not clear that the app does not need to be downloaded and the Bluetooth does need to switch off.

In the table below there is a summary of use cues that worked and what did not works as use cue. A colour legend is used : green means the use cues is helpful, orange the use cues is partially helpful, red the use cue is not helpful.

Use cue	Helpful/Not helpful	Photo
		
		
		When you apply the electrodes, they are not stable, as they miss some grip
		The device is not stable, so some patients preferred to hold it firmly by hand
		
		The orientation is not indicated in the device and in the docking station
		
		Easy to understand but becomes less visible with dynamic elements such as videos.
		
		
		

Table 04. Summary of the helpful/not helpful use cue

6.5 **Project improvements after User test**

Problems revealed during the final user test were:
1. Slippery charger and docking station
2. Hesitations during the electrodes placement
3. Missing orientation for the device
4. Missing some app guide to move forward in the procedure.

Consequently improvements:
In order to improve the critical point revealed by the aforementioned problems the following was done:

1) Slippery charger and docking station
To avoid the docking station slipping and in order to increase friction with the ground four rubber components were integrated in the bottom part of the docking station.
Two rubber stripes were also added on the top part to prevent sliding of the smartphone (Fig.42)

Fig.42 Rubber stripes on the top and bottom part of the docking station

2)Hesitations in the electrodes placement

Since the placement of the electrodes on the docking station and was not comfortable and since three out five patients preferred to use their hands it was decided to change the steps from the docking station to the hand of the patient(Fig. 43). The Consequences of this change are also visible in the shape.(Fig. 44)

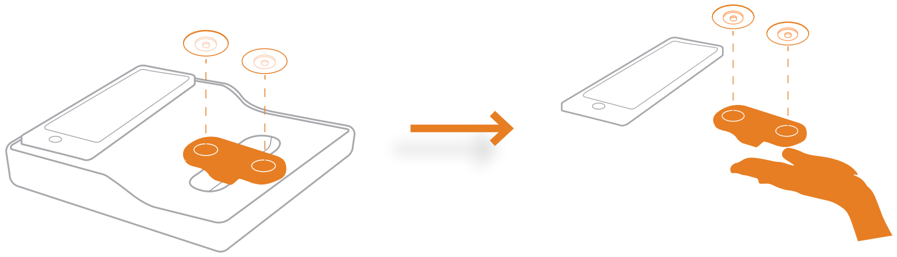


Fig.43 Change in the step

3)Missing orientation for the device

In order to avoid possible bad device positioning for charging on the body, a non symmetrical element was introduced on the device, as well as on the docking station

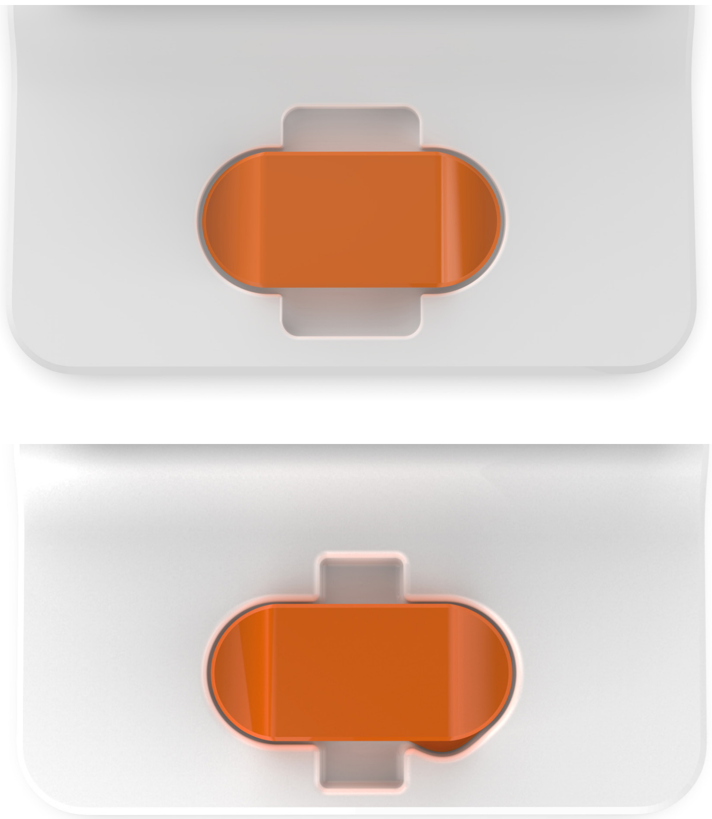


Fig.44. Shape change in the dock station

4)Missing some guide to move forward in the procedure.

To guide the user towards the next step dynamic elements were added on each slide of the app and in particular a pulsing arrow on the right part is added (Fig.45)

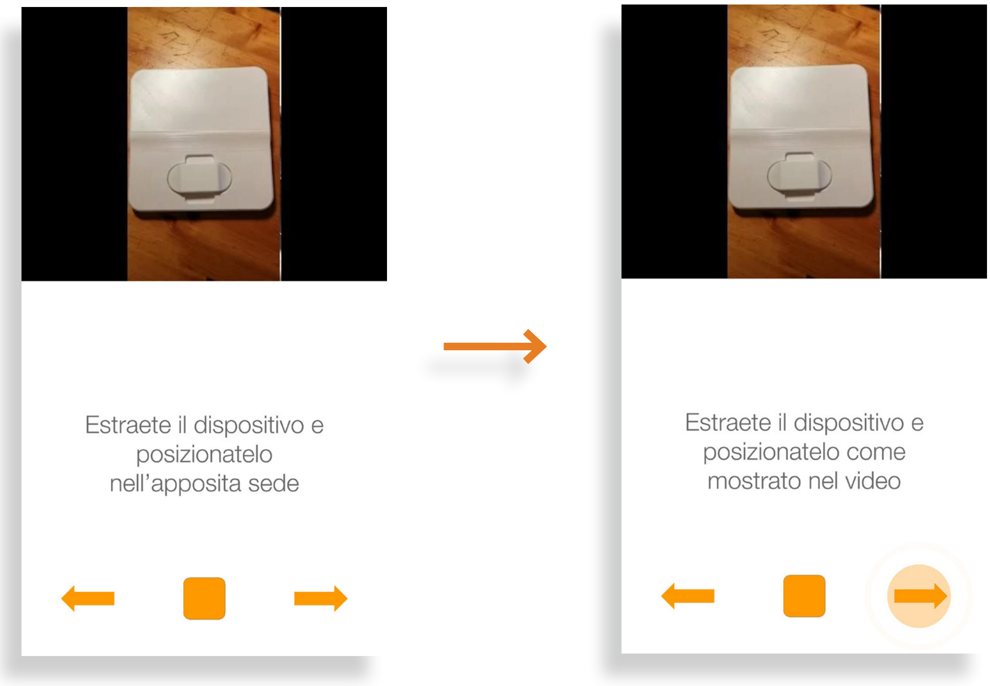


Fig.45. Changing in the App

PART IV **Conclusion**

07

07 **Final Design**

After the testing phase the final concept overview is here presented. This includes: Final System layout, Finale User scenario, Final concept appearance and functions. Together with the final concept also several engineering recommendations were done together with the final working prototype.

7.1 Final concept proposal

Description of the final product system

In collaboration with Cardioline Spa, this graduation project presents the development of a discreet device to monitor atrial fibrillation for elderly people.

What are the components of the new system?

The new product system designed is composed by three elements: the wearable device, the docking station and the smartphone app.
The wearable device is a light and compact biosensor attached to the patient chest by means of patch-electrodes. The device is able to collect the patient's ECG and transmit it to the server cloud by smartphone which works as a gateway.

The device comes with the docking station. The docking station has a double function: on one side it charges the device, on the other, it charges the smartphone through wireless charging.
The wearable device and the docking station are integrated with a smartphone app. The app helps the user to set up the device and to monitor real-time the patient's ECG. Furthermore the app can also be used to notify possible device problem to the user or to the physician.

How it works ?

The patient ECG is collected by the wearable device and then transmitted through Bluetooth to the smartphone which works as gateway. The smartphone continuously receive and send all the data to the cloud where all the data are stored. Data are only accessible to the patient and sharing is possible only through patient's authorization .

Benefits of the new product system

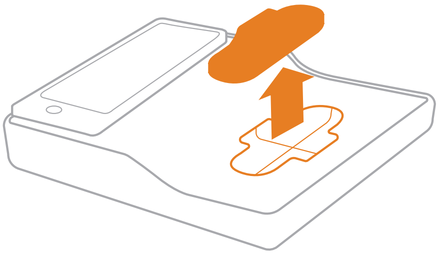
Compared to the current Cardioline holter monitor (Walk 400h) the new device is 70% lighter and 70 % smaller and it is wireless. The device is more comfortable since enables patients to complete all their routines without any movement limitation. (For instance, it is possible to have a shower without removing the device).
Furthermore the new product-system improves the holter monitor experience by removing unwanted travels and waiting times involved in the standard procedure. Additionally, The device presents several margin of improvements as real-time recording, online clinical record and user feedback about the product.

System Layout

User scenario

The user scenario involves 8 steps. The process starts with taking the device in hand and then continues with the application of the electrodes in the lower part of the device. The device is then attached in the upper part of the body according to the orientation shown in the figure. The patient is then free to perform all his/her normal routines until the device is out of battery and it needs to be recharged in its charging cradle.

01



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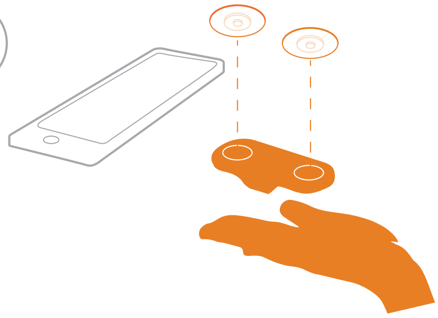

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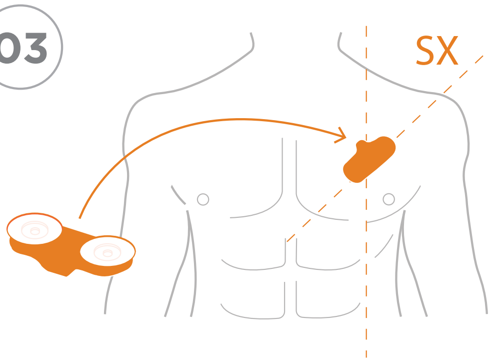

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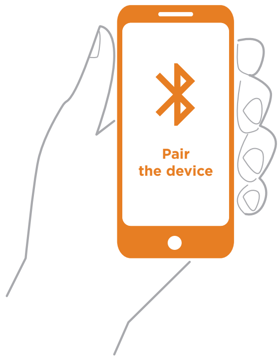

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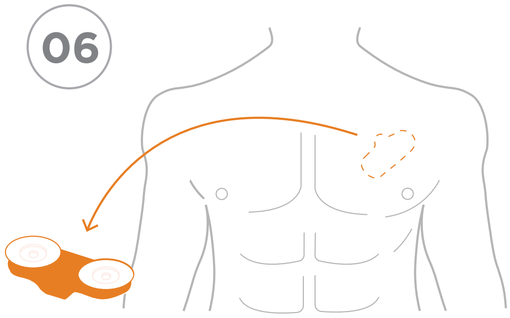
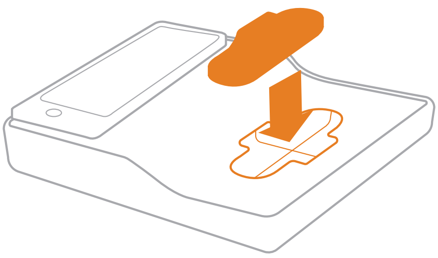
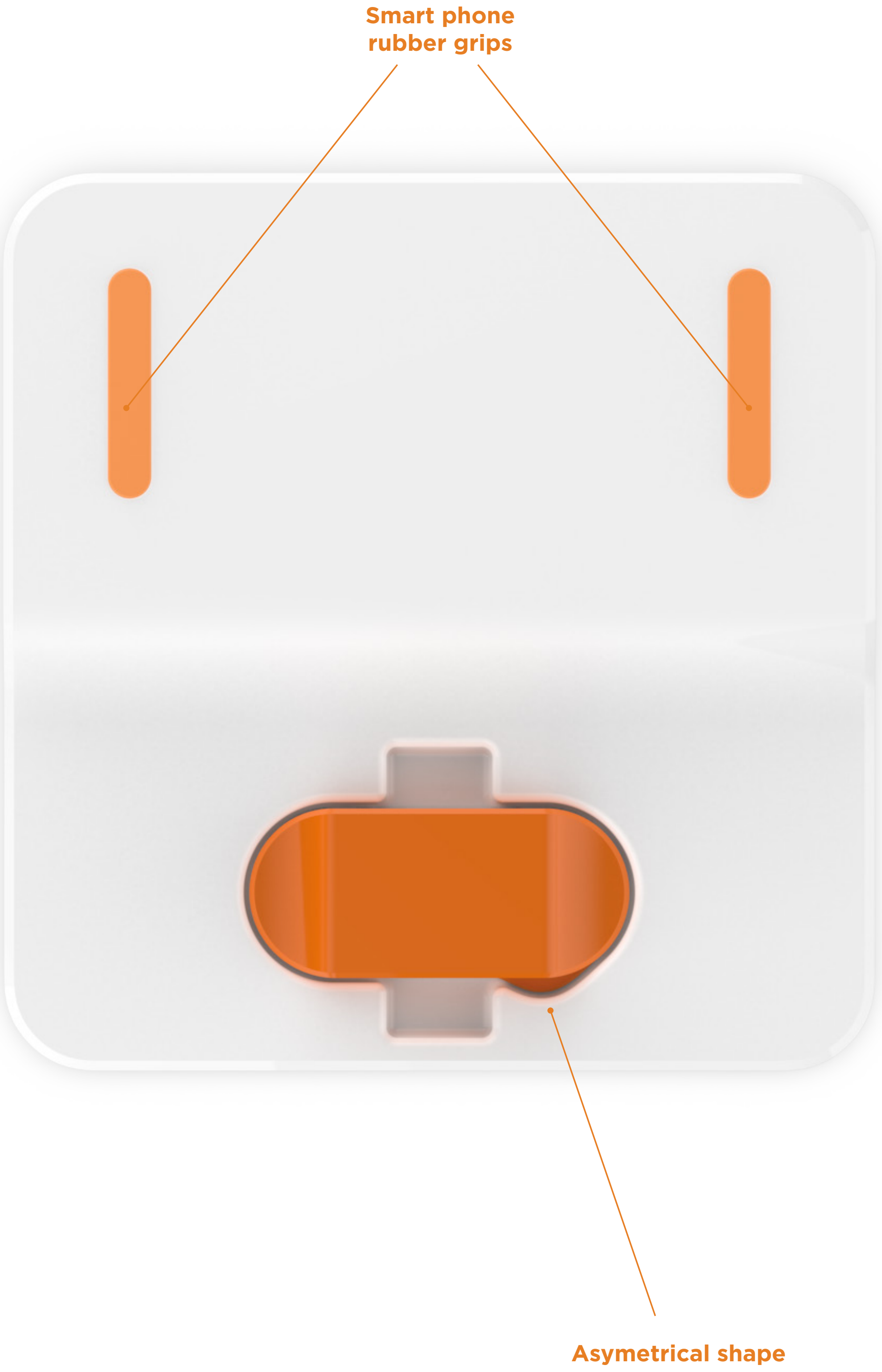


07

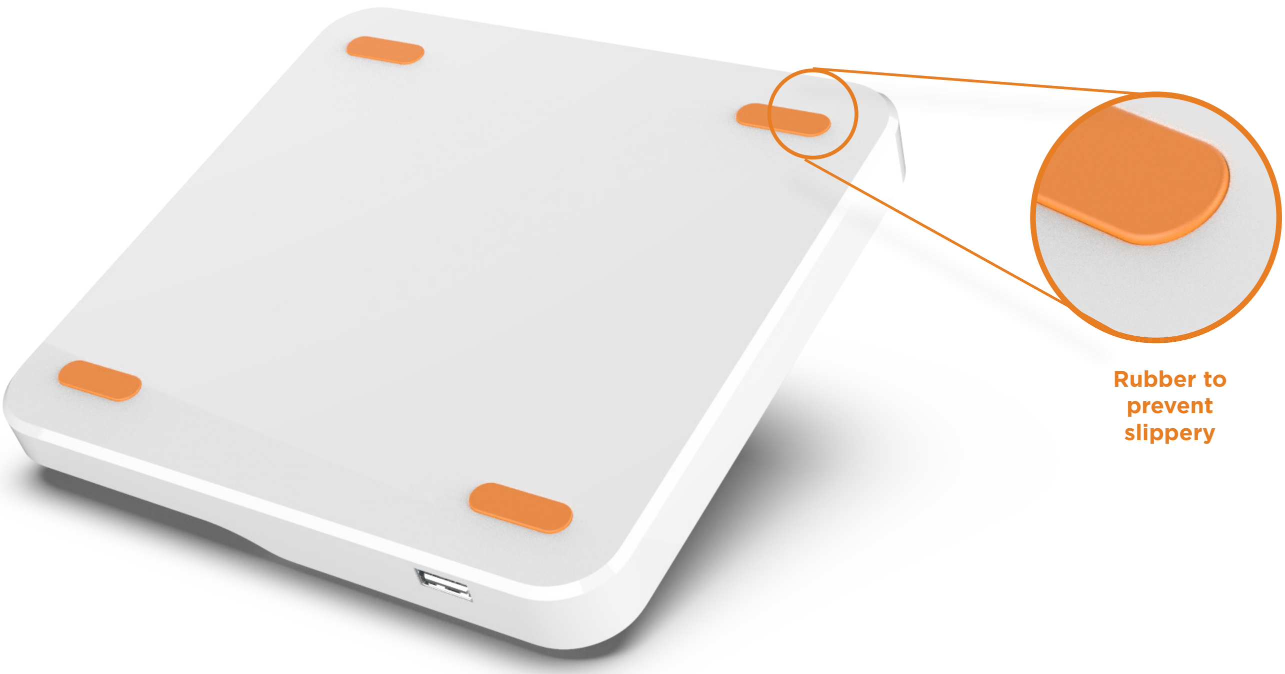


Docking station

The docking station consists mainly of two parts: the first where you can recharge the device and the second where you can recharge your smartphone. To prevent the device and smartphone from slipping, rubber pads have been added to the top and bottom of the docking station. To pick up the device from charger by fingers some room was considered as well a asymmetrical shape to provide the information for the correct device orientation.

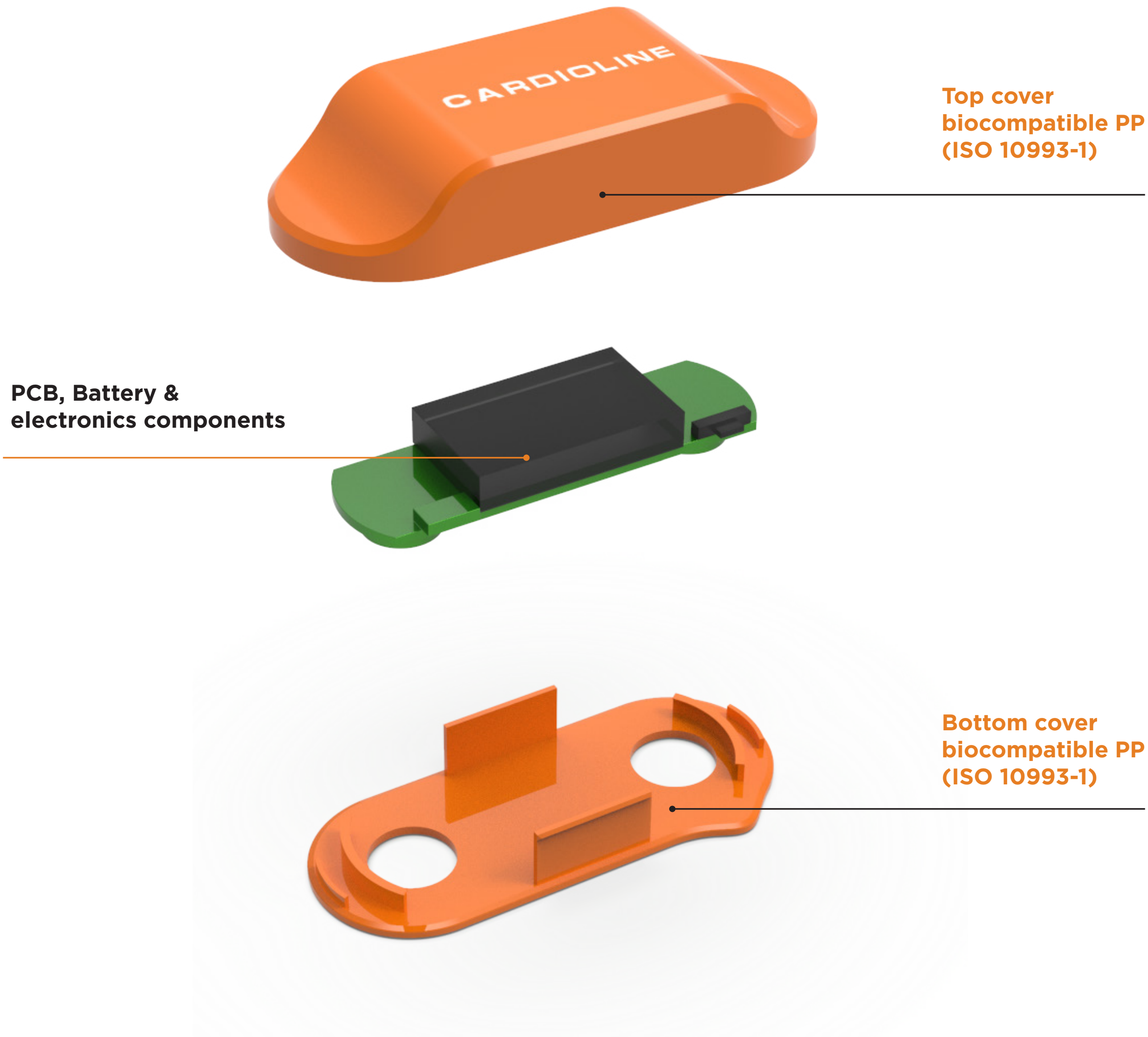



Wireless charger
Area for smartphone
Device charger
via snap-in
connection
USB charger


Rubber to
prevent
slippery

Wearable device

The device is composed by three parts: top shell, bottom shell and the electronics components. Both shells are made by bio-compatible material (ISO 10993-1)



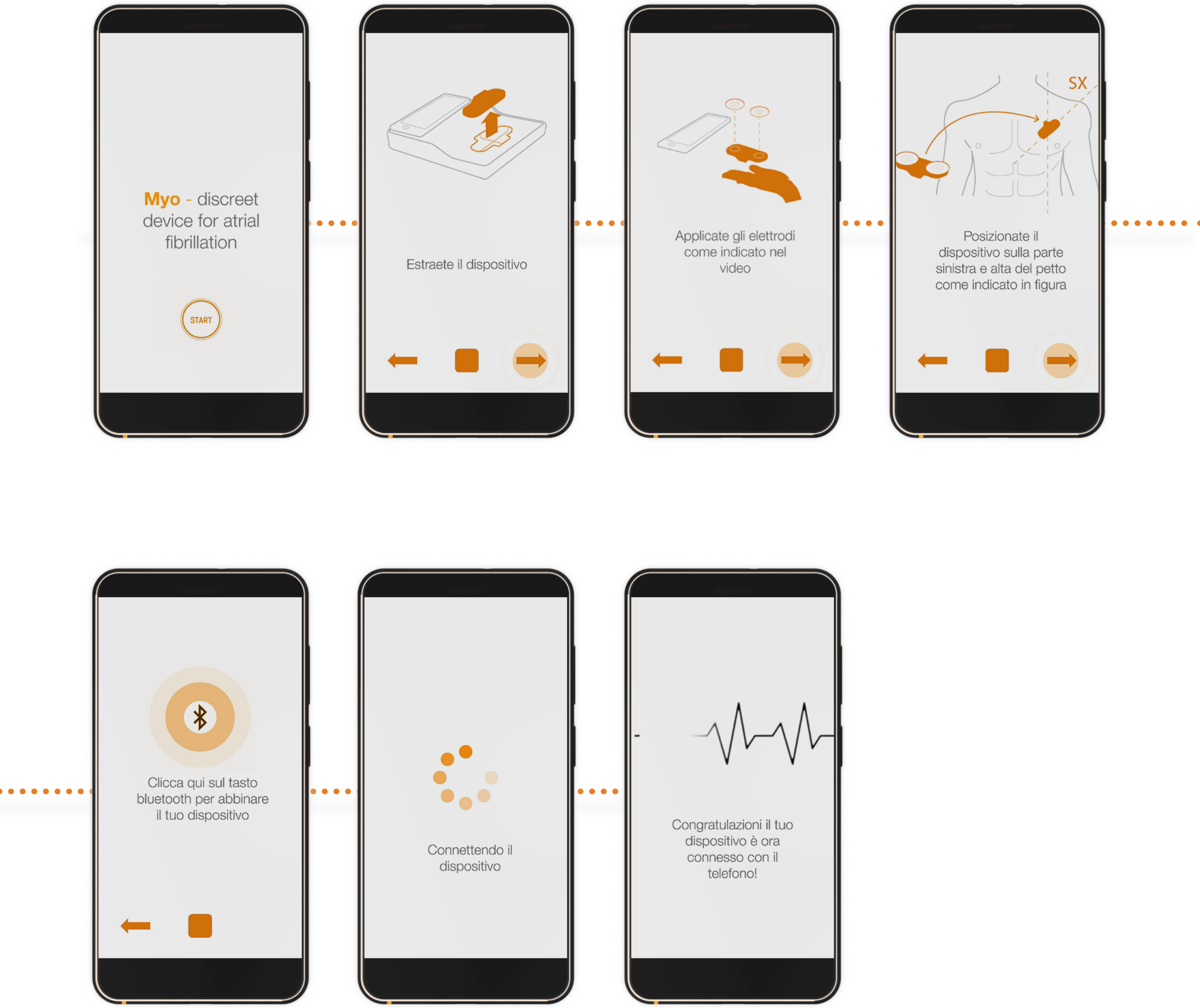
 92


CARDIOLINE


CARDIOLINE

Smart phone application

The smartphone application developed in this project consists of 7 steps which they help user to set up the device .




Myo - discreet device for atrial fibrillation
START

7.2 **Engineering recommendations**

Due to the limited time frame of the graduation project the engineering phase could not be 100% executed within the project. Nevertheless several considerations and recommendations are provided.

00 **Considerations about the approach of engineering**
To engineer the designed device it was agreed to use an inside-outside approach. That means that the process started with the internal component and then finished with the external components.

01 **Determination of the internal component**
Dimension wise, Among all the electronic components needed, the main ones were the battery and the PCB board.

Battery Engineering
For the battery it was determined to take into account a Li-po battery . Several reasons support that decision. Li-po batteries are lightweight, small in size and customizable in shape. Furthermore they have high capacity density and they are rechargeable. Finally, those batteries have very low wattage which is really important considering that the device must not be hot, as it is in contact with the skin.

The final dimension were determined by considering a similar product with an operating time of 7 days . Then , since the target was considered 7-20 days, a similar battery, but with triple capacity, was selected.

The final decision for the battery was the (750 mAh) HW653040 (Howellenergy. 2019 (Fig.46)

Fig.46 An example of Li-po Battery

PCB engineering
Aiming to minimize the space of the internal components, the Selected PCB was one standard PCB with integrated snap-in connectors for electrodes. The final decision for

the PCB was that one provided by Sichiray. (2019). (Fig.47)

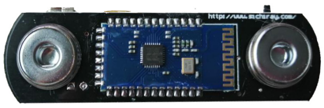


Fig.47 Sichiray an example of PCB with built in snap electrodes connection

Once the internal components were determined, the next step was to decide on the external components:

02 **Top and Bottom shell Engineering**

Material engineering

When determining the material, the healthcare legislation ISO 10993 was taken into account. Then, the compatibility with the injection moulding, the lightweight feature and the good resistance to cleaning and disinfectants were considered.
Next, a decision was made for the PP medical grade - TECAPRO MT by Ensinger. (2019)
To complete the profile of the material the high dimensional stability and the good machinability

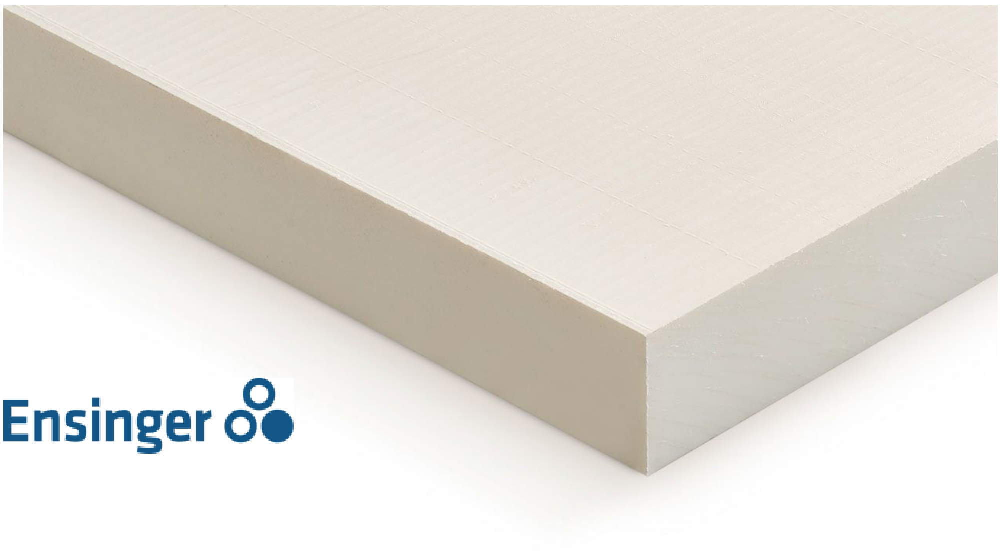


Fig.48 TECAPRO MT material by Ensinger

Shell manufacturing engineering

For the manufacturing process, an injection moulding was selected (Fig.49). The reason for that decision was the high speed of the process and the low unit cost once the tooling is done.

Fig.49 Example of a product finishing by injection moulding

Shell enclosure engineering

For this kind of device and market a certain level of waterproofing is required. Consequently in order to prevent any possible wet electronics a welding process has been chosen.
Out of all the welding processes, the ultrasound welding was selected, because of the high quality finishing, the high speed of the process, the low cost of tooling and unit. An additional benefit is the low environment impact of the process

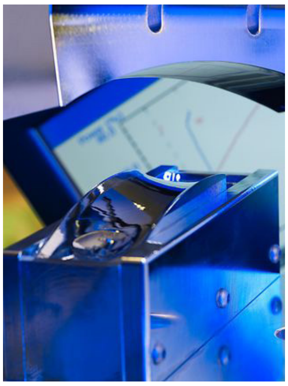


Fig.50.Example of a product finishing by injection moulding

7.3 **First embodiment step**

In order to prove that the concept was valid a first working prototype (Fig.52) of the device was realized.

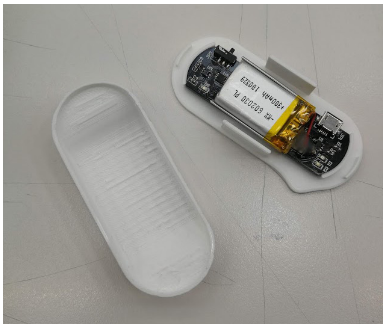


Fig.52.Final prototype

For the electronic components t was used the Sichiray PCB and for the shells it was decided to 3d printed them within the faculties of Industrial design Engineering of TUDelft.
Several attempts were necessary before succeeding to get the shell printed and with the correct snap fit between top and bottom part as shown in figure 53.

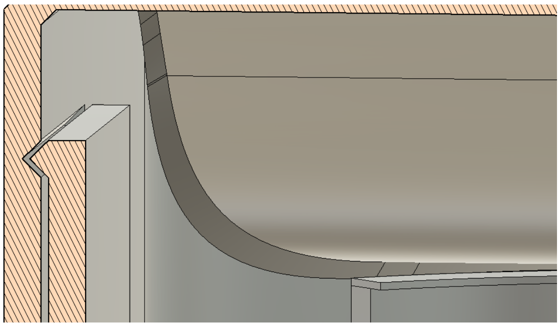


Fig.53.Snap fit connection section

Another issue tha was fixed was how to hold the electronics board by means of the 3d printed bottom shell. In this case, it was decided to design a form-fitting shape as it shown in figure 54.

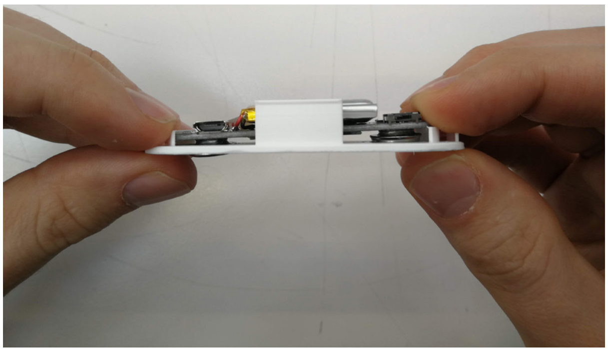


Fig.54 Form fitting with the electronics

PART IV **Conclusion**

08

08 **Conclusion**

With the conclusion chapter the final concept is evaluated by taking into account: how the concept is viable for the company, how it is feasible for the manufacturer and how it is desirable for patients

8.1 Conclusions

Here in the conclusion what has been achieved in terms of viability, feasibility and desirability is presented.

What makes the new product system desirable?

Comparing the current Cardioline holter monitor (Walk400h) the new product-system presents several improments:
The new product is 70 % (45 cm^3) smaller in volume and 73% (25 gr) lighter compared to the walk400h (126 cm^3 and 105 gr). Those reductions are relevant to improving the patient's acceptance.
Although long-term testing needs to be performed, it can be assumed that the new proposal has a triple recording-time (20 days) compared to the Walk400h (6 days)
Furthermore, the new product is wireless, feature which allows the user to have total freedom of movement and more comfort.
Finally, the system designed around the device avoids unnecessary trips to the hospital deleting many waiting times for the user experience.

Is the new product system viable?

Besides all the benefits already mentioned, the new product–system represents for Cardioline an innovative product typology. In fact, the patch is not present in their actual offer.

Is the new product system feasible?

The engineering part is not complete and several iterations are needed to bring the device on the final market. However, to prove that the device dimensions are real and to prove that the device has potential, a first working prototype has been made. The done prototype is able to measure and send the ECG signal from the device to the smartphone by means of bluetooth technology.

8.2 **Further development : looking ahead**

FURTHER DEVELOPMENT looking ahead

Even though the concept is in quite an advanced stage and a working prototype has been created there are several steps that need to be taken before putting the biosensor on the market.
The first step is related to completing the engineering part of the product system. It needs to be produced a prototype, a real App, the docking station charger needs to be defined for the device, and the wireless charger for the smartphone has to be created. Once the engineering is completed then a long-term functionality test is needed. This in order to verify the range of the operating time, the energy consumption as well as long term comfort for patients.

Reflections

What it has offered me.

This graduation project gave me the opportunity to test the industrial Design skills acquired during the two years of my Master's degree studies with a real client. When I look back on the process I think that I have learnt a lot from my mistakes. At the beginning it took me a while to get the right focus. Everything was super interesting to know but recognizing what was really useful it was difficult. What I learnt is that only with great focus can you get the answers you need and that planning what to search for definitely helps in not getting lost.

What I would have done differently

Looking back on the entire process there are few things I would like to have done differently.

First of all my user test comes to my mind. Since there was a limited amount of time and participants (only five) it was not possible to scientifically prove that the new device was more comfortable than the old one. Nevertheless if you consider the number of benefits which the new device brings (wire absence, limited weight, discreet appearance, etc.) it seems very likely to be perceived as more comfortable.

Secondly, I would have liked to worked closely to Cardioline. If I had worked within the structure of Cardioline perhaps I could have learned more on a technical level, even if the results had been less innovative.

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