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SafeBladder - Device for the control of the neurogenic bladder

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Integrated Masters in Mechanical Engineering

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"People who think they know everything are a great annoyance to those of us who do."

Isaac Asimov

Abstract

Millions of people see their lives being heavily conditioned daily by suffering from neurogenic bladder. This is the name given to a condition which affects the communication between the brain and spinal cord at the nervous system level, resulting in a lack of control over the bladder. Patients then experience different types of symptoms such as incontinence, urgency and retention. There are some answers to the problem, but all of them are quite backward and desperately hoping for improvement. Currently the most common treatment is clean-intermittent catheterization done periodically. There is no way to monitor the bladder volume, at least in an outpatient environment. It is in this field that this thesis is inserted, representing part of the development of a wearable, comfortable and portable device. The creation of such device will allow people to have much more confidence and freedom in their daily tasks. In this thesis it is possible to learn about the functioning of the urinary system and the physiognomy of the bladder, all this information also supports the choices made for the device concept. This creation uses near infrared spectroscopy technology to take readings of the level of urine in the bladder. The device will also have a system of vibration close to the user's skin and a system of notifications given via mobile phone, so that the user can always be updated on the status of his bladder. In this dissertation it will be possible to read about the advances made on the device being developed, the components used and their role as well as part of the assembly development and programming of the initial prototype.

Keywords: Neurogenic Bladder, Near-Infrared spectroscopy

Resumo

Milhões de pessoas vêem as suas vidas a serem fortemente condicionadas diariamente pelo sofrimento neurogénico bexiga. Este é o nome dado a uma condição que afecta a comunicação entre o cérebro e medula espinal a nível do sistema nervoso, resultando numa falta de controlo sobre a bexiga. Pacientes depois experimentam diferentes tipos de sintomas, tais como incontinência, urgência e retenção. Aí são algumas respostas para o problema, mas todas elas são bastante retrógradas e esperam desesperadamente melhoria. Actualmente, o tratamento mais comum é a cateterização de interferências limpas feita periodicamente. Não há forma de monitorizar o volume da bexiga, pelo menos num ambiente ambulatorial. É neste campo que esta tese é inserida, representando parte do desenvolvimento de um vestível, dispositivo confortável e portátil. A criação de tal dispositivo permitirá que as pessoas tenham muito mais confiança e liberdade nas suas tarefas diárias. Nesta tese, é possível aprender sobre a funcionamento do sistema urinário e a fisionomia da bexiga, toda esta informação também apoia as escolhas feitas para o conceito do dispositivo. Esta criação utiliza espectroscopia de infravermelhos próximos tecnologia para fazer leituras do nível de urina na bexiga. O aparelho terá também um sistema de vibração perto da pele do utilizador e um sistema de notificações dadas através do telemóvel, de modo a que o utilizador pode sempre ser actualizado sobre o estado da sua bexiga. Neste artigo será possível ler sobre os progressos realizados no dispositivo em desenvolvimento, os componentes utilizados e o seu papel como bem como parte do desenvolvimento e programação da montagem do protótipo inicial.

Agradecimentos

Esta tese representa um marco gigantesco para mim, pois é não só o final do trabalho desenvolvido ao longo destes anos na FEUP mas também o final da minha educação e ingresso no mundo do trabalho. Representa ainda que mesmo após todas as batalhas perdidas ganhei finalmente a guerra. Mas tudo isto só foi possível com o apoio de todas as pessoas e grupos de trabalho que tive nesta minha passagem pela FEUP e por isso não poderia deixar de agradecer a todos eles.

Começando pela tese, gostaria de agradecer primeiramente à pessoa que aceitou orientar-me, Engenheira Dulce Oliveira, que me ajudou com os problemas que foram surgindo principalmente os psicológicos. Sem a motivação, o apoio e simplificação dos obstáculos que foram aparecendo não teria sido possível. Devo ainda incluir a ajuda do Engenheiro Eduardo que se mostrou prestável e sempre disponível para rapidamente ajudar a dar os primeiros passos deste caminho. Tenho ainda de mencionar os apoios externos ao mundo do trabalho e é aqui que entram pessoas como a Sofia e o Rui entre outros que sempre me motivaram e sempre se mostraram disponíveis para perder algum do seu tempo comigo, durante este projeto.

Referindo-me agora aos dois Super-Heróis, que mais do que eu, são os responsáveis por este desfecho na minha formação, os meus Pais. Ter um filho é algo que muda muito a vida de uma pessoa, marca o momento em que se deixa de viver apenas para prazer pessoal e passa-se a viver com a constante preocupação de dar educação, formação e amor a um novo ser para que ele se torne uma pessoa capaz de realizar os seus sonhos. Felizmente eu sempre tive acesso a tudo isso pois eles sempre trabalharam diariamente para que eu pudesse sonhar. Estiveram sempre presentes desde o primeiro dia e mesmo eu não sendo o melhor aluno, o mais bem-comportado ou o mais focado, sempre investiram em mim e me convenceram que eu tinha capacidade para terminar um curso universitário, mesmo eu querendo desistir inúmeras vezes, pois nunca acreditei que estudar fosse para mim. Aqui está, estou prestes a ser Mestre em Engenharia Mecânica pela FEUP, esta é para vocês por tudo, espero que pelo menos no final compense as dores de cabeça e discussões.

Aos amigos todos eles desde os mais antigos até aos que conheci neste último ano, dos que faziam asneiras comigo em criança aos que perderam o seu tempo para me ensinar o que não aprendia nas aulas por faltar às mesmas. É também graças a vocês que é possível estar onde estou, só espero conseguir retribuir na mesma moeda tudo o que fazem por mim.

Muito obrigado.

João Chaira

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Chapter 1

Introduction

The bladder is an organ of the human being which belongs to the urinary system. Its main function is to store and release urine coming from the kidneys. The control of bladder function is done by the central and peripheral systems.

Neurogenic bladder is a result of neurological damage which causes in patients lack sensation and control of their bladder. Since it affects millions of people across the globe, it is also a well-documented dysfunction.

Neurogenic bladder, which from now on can be described as NB, is then linked to the nervous system and usually occurs as a side effect of several diseases affecting the comunication between the spinal cord and the brain. These diseases include multiple sclerosis, heart attacks or spinal cord injuries.There are different types of neurogenic bladder and so the patients also have different types of symptoms, which can vary from aggravated retention or overactive bladder to both. This can be due to a combination of overactive detrusor and overactive sphincter. Still on the nature of the symptoms, as mentioned before, the NB appears as a side effect, and so the type of symptoms felt are directly linked to the primary disease that led to NB. As an example, it is noticed that in the case of multiple sclerosis between 50% to 90% of patients who also suffer from NB is due to detrusor overactivity. Furthermore for the example of Parkinson's disease between 57% and 83% of the patients experience a poor force of stream and incomplete emptying. As an additional note it is also necessary to mention that patients suffering from neurogenic bladder, especially the younger ones, tend to have psychological problems, such as stress, due to the fact that they do not have any control over their urination.

The methods used for the treatment of neurogenic bladder aim to give back patients the control over their bladder in order to combat the physical as well as psychological problems they are subjected to. However, the techniques are already a little outdated and need urgent development. There are various methods used to try to do this, the most widely used being periodic catheterisation, which is recommended to be done every 2 to 4 hours. Catheterisation is an invasive process which frequently leads to urinary infections or other complications which aggravate the problem of neurogenic bladder. As the bladder is filled by the kidneys, which do not work continuously, it is very difficult to make predictions or patterns of catheterisation.

The biggest problem reported by patients suffering from NB is the frustration of catheterization not being optimized. This means that often there are unnecessary catheterizations in which practically no urine comes out because the bladder is not full, or in other cases, not arriving in time for the catheterization and ending up urinating prematurely, mainly due to the fact that people lose the feeling of a full bladder. Some patients even prefer to use a permanent catheterization, which is significantly less comfortable and even increases the risk of infections and even bladder cancer. Again, NB affects the psychological field and affects the ability of patients to carry out their daily activities, leading to depression. Although there is still no final solution to this dysfunction, after listening to patients' feedback, the easiest way to subtly improve the lives of these people who suffer daily with NB would be to develop a device that gives them access to information on the volume of their bladder, so that they can firstly do only the necessary catheterisation at the correct time and, as a consequence, have more security and confidence to go about their lives without fear of leaking urine at any time.

There are already some devices to perform this job, but all of them lack in one important thing that is application. All of them present some kind of barrier to a normal user like the size or its portability since these devices main focus was for caregivers or clinics, which definitely does not return patients freedom. This thesis is work in progress that aims the development of a device that should be an answer to the outpatient. So based in the near infrared spectroscopy technology, that is already used in other health areas, the end goal should be a wearable, comfortable and non-invasive device that will be able to communicate with the user through a vibration device in the skin and also mobile application, giving information about their bladder volume in a real-time frame. This will allow to solve some of the NB affected patients nightmares.

During this thesis will be possible to understand the background of the choices made for the device as well as understand in a more detailed way the bladder function and processes. It also shows some of the development made in a concept and the future work that should be done in order to achieve a proper device capable of changing millions of lives.

Chapter 2

State of art

Knowledge about the anatomy of the bladder and abdominal region is essential to understand the nature of the problem surrounding the bladder volume assessment. Moreover an explanation of bladder dysfunction and existent treatments will clarify the need of a volume management, in which non-evasive methods play a central role.

In addition to the explanation, a brief review of the already existent solutions to the problem and other bladder volume management devices existent in the market, a study of the technologies already implemented and respective feedback allows to make better choices in the development of a new device.

2.1 Urinary Bladder

The bladder is located in the lower abdominal area behind the pubic bone. It can be divided into two areas, the upper tract, which is very elastic, expansive and mobile, and the lower tract, which is fixed and it is also where the muscles and organs responsible for the control of urination are located.

The main function of the bladder is to receive, store and then expel urine from the human body. Although the voiding is bladder job it is worth mentioning that it needs the urethra and sphincter support. An important characteristic of the bladder for the present project is that its thickness varies between 2-5 cm. [1, 2, 3]

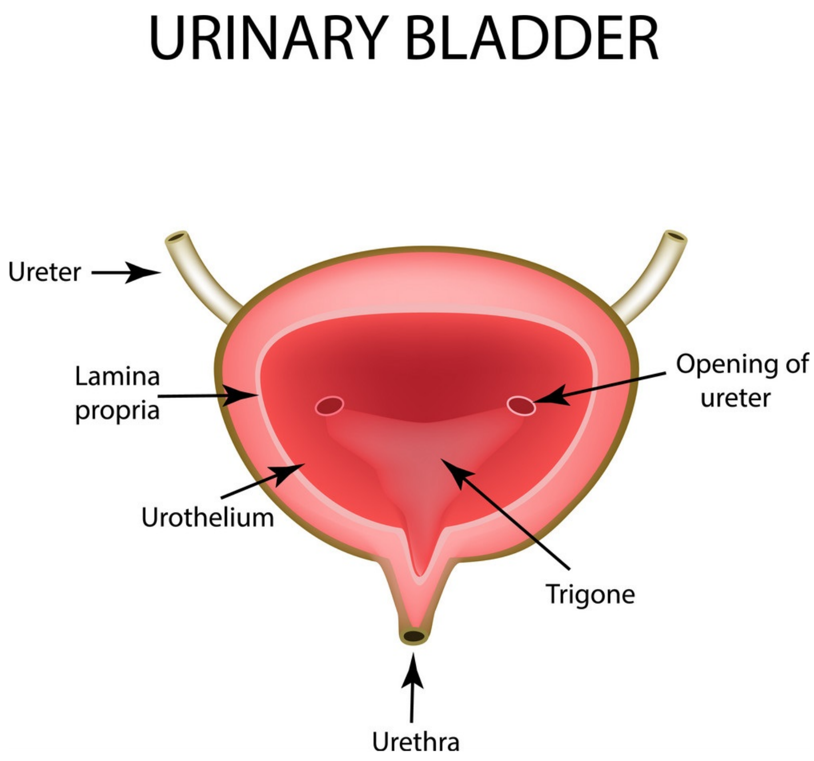


Figure 2.1: Animated image of the bladder and its basic components.

2.2 Micturition Cycle

The Cycle is defined by two different stages, the filling and after that the voiding of the bladder. The first stage, the filling, starts in the kidneys where the urine is generated and the cleansing done to the blood that floods through the body extracting unwanted impurities mixed with an excessive amount of water (about 91-96%). The urine is then delivered to the bladder filling it. This process allows the bladder not only to expand and change its shape but also to change the thickness of its borders. In addiction to this, the changes to the urethra and sphincter must be contracted through all the filling process to make sure there is no leakage. Usually for an adult the bladder is capable to hold about 400 to 600 ml, but the first request to the leakage should be felt around 350 ml.

The Leakage process starts in the neural systems. Assuming that the automatic and voluntary neural systems as well as the muscle of the urinary tract are in perfect condition, the procedure involves the activation of receptors located in the bladder wall when the bladder is full, then sends a signal to the spinal cord via spinal nerves, more specifically in nodes s2 to s4. Afterwards a stimulus is sent to the sensory cortex, which will interpret as the need to empty the bladder. Even after receiving the information that it is necessary to proceed with the voiding, the sphincter must stay compressed until receives the order to let the urine pass. When the decision is made the motor cortex sends out voluntary signals to start the voiding. The impulses are received by the pontine micturation center, which coordinates simultaneous signals that command the detrusor muscle present throughout the bladder contract (via parasympathetic cholinergic nerve fibers) and in opposite way the sphincter must relax and allow the urine to be expelled (via alpha sympathetic nerve fibers). During the voiding, the bladder must contract and return to the initial shape and size. This cycle must be repeated throughout the persons life.[4, 2, 5, **?**]

2.3 Bladder Controlled

The micturation cycle is an unique procedure to the human and is the only cycle that it is not possible to the humans to control at birth and it is learned autonomously during our childhood.

Control over lower urinary tract (LUT) (urinary bladder and outlet), is possible through a complex nerve system controlled by the brain, spinal cord and peripheral ganglia. A perfect co-ordination between these components is needed to make the LUT work properly, even to do the "basic" jobs of containing and expelling the urine.

When the bladder is full and needs to be emptied a message is sent to the sacral micturation reflex center (SMRC).From the receptors present in the bladder neck, Trigone and Detrusor, and then the SMRC that sends the message that the voiding should happen to muscular structures.

This complicated system turns the bladder very susceptible to diseases and malfunction, because every problem caused to the nervous system will lead to a less controlled urination.[4, 6, 7]

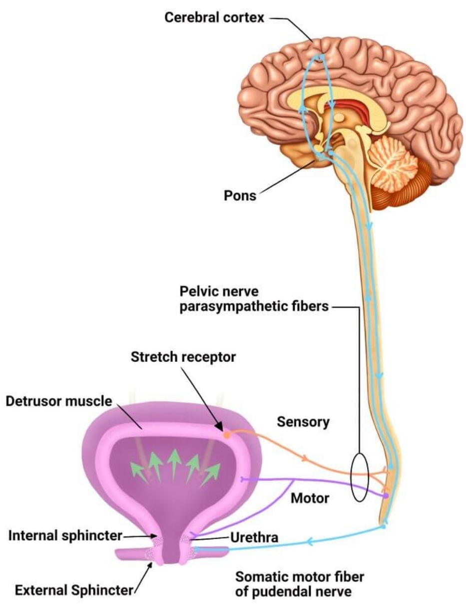


Figure 2.2: Diagram of the nervous system responsible for bladder control

2.4 Neurogenic Bladder

Besides knowing how the micturation cycle works properly and how it is controlled, it is important to understand the problem, the neurogenic bladder, as well as how it can happen.

As described before, the bladder is controlled by a complex nervous system and any kind of disruption in that system will jeopardize its normal operation.

Neurogenic bladder is a condition associated to the loss of control over the urination, meaning that people who suffer from this condition are not able to decide when they should or not void. This inability can be due to different factors such as loss of sensation of a full bladder, loss control over the pressure inside the bladder or even inability of both the urethra and the sphincter to stay dry. These complications lead to incontinence, over-active and under-active bladder dysfunctions.

Neurogenic bladder is related with three different kinds of behavior from the baldder.

- Flaccid - The bladder does not contract and once it overflows the urine stars to drip.
- Spastic Bladder - A spasms is originated in the bladder, when it occurs the muscles squeeze suddenly without any warning, leading the person to rush over emptying it in danger of an unpleasant leakage.
- Both previews conditions- The worst case scenario is to suffer from both types described before, meaning that it is easier for the leakage to happen.

Often the neurogenic bladder appears as a secondary effect of some other injury or disease and it is quite common for people who suffer from conditions such as Parkinson's disease, strokes, spinal cord injury , etc. [8, 9, 2]

2.4.1 Neurogenic Bladder due to Multiple Scleroses

Multiple sclerosis is a disease that is characterized for its attack to the neurons. This causes problems to the nerves affecting the normal communication between the brain and the rest of the body. It also has another characteristic that is to being permanently progressive, so even starting slowly it will eventually affect the whole body.

The urinary tract dysfunction is one of many secondary effects of the disease and one of the most common, being considered that is inevitable for the detrusor and the sphincter to be affected by it. Reports say that the percentage of patients that suffers from NB, ranges between 32 and 96.8% and commonly appears between years 5 to 9.5 of the disease. Studies also show that up to 40% of the persons that have NB end up suffering complications related with it. For example studies show that up to 30% of this patients also suffer from Lower Urinary Tract infections. Morphological damages occur also in 30 % of cases and a fewer reports also refer to bladder cancer being more common on multiple sclerosis patients.[10]

2.4.2 Parkinson Disease

Parkinson's is a neurodegenerative disorder and the main target is the dopamine production. This neurotransmitter is produced in a specific brain area called substantia nigra. At the beginning the symptoms are almost unnoticeable, but this is a progressive disease that gets worse with the past of the time. The most known symptoms of the disease are connected with movement, with patients starting to have movement difficulties. Often people start to become limited and even stop making certain movements such as swinging their arm while walking or blinking. Besides this they also experience uncontrollable shaking and limbs, mostly in the upper members. Other common non-movement related symptoms felt are fatigue, becoming slower, having sleeping problems, cognitive losses and the most important in this case, they usually lose bladder control. Reports say that 37%-70% of Parkinson's disease patients also suffer from neurogenic bladder. This problems appear with the lack of dopamine in the brain.

Fortunately it is already possible to make the fight against this disease easier, with medication and medical monitoring.[11, 12, 13]

2.4.3 Spinal cord injury

Spinal cord injury, further can be referred to as SCI, is the name given to damages in the spinal cord. The most common causes to this type of injury are car accidents followed by falls and, running in third, are motorcycle crashes. Spinal cord injuries can result in different levels of problems, such as small and temporary pain but also permanent and impactful ones. Usually the injury severity is linked with the node affected, the lower the damaged node the worse the consequences, since the spinal cord works just like a series-wired circuit, and once one node is damaged all the following ones will also be affected.

The injuries can be distinguished by two different parameters. The first parameter determines the severity:

- Complete- Happens when all feeling (sensorial) is lost as well as the movement control below the spinal cord damage.
- Incomplete- If even after the damage , the patient is still able to move or feel anything even if it is not complete.

The second one, which is based on the affected areas, characterizes the impact in the human body:

- Tetraplegia - Affects arms, hands, trunk, legs and pelvic organs.
- Paraplegia - Affects trunk,legs and pelvic organs.

The NB appears here as a second effect of the SCI because of the nerve control importance that the spinal cord has. As mentioned before in the chapter, the bladder is controlled by the nervous system, therefore a normal micturation process relies on a perfect coordination between the bladder contraction and sphincter relaxation. This is managed by the lumbosacral neural circuit. A spinal cord injury can heavily affect or even disable the lumbosacral neural circuit and subsequently the patient will loose control over his bladder and normal micturarion process. That's why is so common that people that suffers from SCI also suffers from Neurogenic Bladder. [2, 12, 14, 15]

2.4.4 Strokes

Strokes are not easy to correctly define, but an approximated designation is a life-threatening condition caused by the lack of blood irrigation in part of the brain. The brain, like any other organ, needs oxygen and supplements and the lack of them can lead to a stroke. 85% of the time this happens because of a blood clot preventing blood from reaching the brain. The result damages from strokes are also very difficult to preview, because it can be just an attack that the patient can recover over night and is not really affected by it, but it can also go as far as death. In this wide range of symptoms appears the neurogenic bladder as one of the possible and most common results.

A very common sequel of strokes are the lower urinary tract symptoms. It is estimated that 15% of people who recovered from a stroke suffer from incontinence after one year. There are different stages to the lower urinary tract symptoms (LUTS) observed in post-stroke patients, the numbers say that 35%-40% of patients suffer from incontinence 7-10 days after the stroke. Then exists another three important time frames, three months after the stroke 36% , one year after the stroke 24% and two years after the stroke 13% of the patients still suffer from incontinence. The numbers actually decrease as time goes by, but 13% after 2 years is still a huge number, taking into account the impact on people's normal lives. [2, 16]

2.5 Symptoms of Neurogenic Bladder

- Urinary tract infections
- Kidney stones
- Incontinence
- Loss of feeling and lack of bladder fullness sensation
- Urinary urgency

2.6 Treatments

The best treatment would be the one that could revert all the damage done to the patient and is always with this goal in mid that people work every day, so they can help improve people's quality of life.

In this particularly case it is still not possible to reach that goal and revert the total damages, so the objective is to find ways of controlling incontinence, grant protection to the lower urinary tract and reduce infections.

Every case is a different case so it also requires different approaches, thus in order to achieve the best treatment to everyone different solutions must be found. Next are presented some of the most often used. Some cases even require a combination of treatments.[17]

2.6.1 Catheterization

Catheterization is a very usual procedure that is used for both diagnostic and therapeutic purposes. There are basically two principal techniques that are chosen based in the time expected for the catheterization, so the catheter can either be intermittent (short-term, the catheterization is made in designed times) or indwelling (long-term, the catherization is made permanently this means the bladder is always voiding thought the catheter). The most frequent process is the intermittent catheterization because it helps to maintain a low intra-bladder pressure and achieve urinary continence. It also helps protect the patient of problems that can come up with catheter.

There are three different catheters based on the application technique, being:

- Urethral Catheter - The catheter is inserted in the urethra until it reaches the base of the bladder. This is the most used.

- Suprapubic Catheter - This is the least used one and is applied through a hole made in the lower belly connecting to the bladder.

- External catheters - This catheter is applied to the genitalia in case of the men and it works like a condom but in the end is connected to a tube, in case of women is attached to the pubic area, and in both cases allows to collect the urine. Good technology to incontinence control.

The choice of the correct way to use the catheter is really important because not everyone can use the same techniques. Some people can not be physically or mentally able of doing an intermittent approach.

Although catheterization is a widely used process, it concerns the specialists because of the problems that can come with its application. It is very common to appear complications such as infections, which is the most frequent one. The probability of this happening scales exponentially with the time the catheter is inside the body and can even lead to bladder cancer. Other less usual complications are low bladder volume/compliance, urethral pain or discomfort and gross hematuria.

The fact that it is an invasive method that forces patients to walk with a urine bag makes it even more uncomfortable and unnatural to the person. In addition, the concern of never knowing when it is the correct time to void, turns this method not a huge life quality improvement besides its effectiveness. [18, 19, 20]

2.6.2 Drugs

Drugs are not a big helper when the problem is neurogenic bladder, however they still represent their role serving mostly as a complement to the treatment.

The most used combination of drugs is antimuscarinics combined with imipramine. A study about the efficiency of this combination was carried out in patients with NB initially on a drug therapy or only on antimuscarinic therapy and then switching to a two or three drug therapy.

The results turned out to be visible and for people who were not on any drug before, the improvement was:

- For the group on two drug therapy: mean bladder pressure reduced by 52% and a mean compliance increased by 5.0-fold
- For the group on three drug therapy: mean bladder pressure reduced by 67% and a mean compliance increased by 9.7-fold. [21, 15]

With this results it is possible to understand the importance of the drug usage in the treatment process even knowing that it can not be the main therapy.

2.6.3 Sacral Neuromodulation

This is an invasive treatment that consists in stimulating the sacral nerves roots by mean of an electrode placed directly over them, this device job is to send pulses that improve patients symptoms. This treatment is used in people that find the combination of intermittent catheterization with oral antimuscarinics intolerable or in-satisfied.

Intra-detrusor injections of onabotulinum toxin-A is the most used procedure in children, for whom the other available methods do not show good results.

This kind of injection results in excellent bladder behavior, but it should be mentioned that poor outcomes were observed on the cases were the patients had low-compliant bladders without detrusor over-activity.[22]

Studied children's ages were 9 +- 3.36 years, and the results were :

- Client success achieved in 64.5% of the patients.
- The max cystometric capacity increased form 172,4 +- 45.6 mL to 236,3+- 67.2mL.
- The mean bladder complience increased from 14.8 +- 8.1 mL/cm H_2O.

2.7 Monitoring the bladder volume

The monitoring of the bladder volume has a huge impact in the quality of life of neurogenic bladder patients, because it allows people to prevent leaking or unwanted voiding. Over the years studies have been carried out continuously with a view to developing new methods and improving existing ones. The devices developed must take into consideration three major points: portability, comfort and being non-invasive so it can prevent further damages to the bladder as well as infections. To achieve that, different approaches have been taken, with different technologies such as: [23, 24, 9]

- Ultrasounds
- Bio-electric impedance
- Near-infrared spectroscopy

2.7.1 Ultrasound

The ultrasound is a form of nonionizing radiation, this technology is already considered mature and it is being used for decades now in different areas of healthcare such as obstetrics, cardiology, gynecology, pediatrics, radiology, neurology, and surgery, but it does not mean that is static. Faster, more precise and improved ways of using ultrasound are constantly being studied. Is one of the imaging techniques that sees the most usage and it is crucial equipment to any hospital or clinic, only surpassed by the x-ray. This method is prioritized in this areas because of its cost-benefit ratio, being non-invasive and its real-time image capability.

In order to obtain the bladder volume through ultrasounds there are different formulas that can be used, all of them are based in measurements made in the ultrasound images . Some examples of the used formulas are: [25, 26]

Haylen's formula

$$vol[mL] = height[cm] * depth[cm] * 5,9 - 14,6 \tag{2.1}$$

Dietz's formula

$$vol[mL] = height[cm] * depth[cm] * 5,6 \tag{2.2}$$

Dicuio's formula

$$vol[mL] = height[cm] * depth[cm] * transverseDiameter \tag{2.3}$$

The different types of ultrasound used to measure bladder are :

- Pelvic Ultrasound Imaging
- Abdominal Ultrasounds
- Transvaginal Ultrasound
- Transrectal Ultrasound

Ultrasound is the standard method used, which is justified because it can grant an accurate measurement in a relatively easy and safe way. It is a non evasive method and the equipment is a must have in any health unit. [26]

2.7.2 Bioimpedance

Bioimpedance is related to the electric properties of our body, this means that this method works with the conductivity of our body. That consists in sending a small electric current through the body using two electrodes and picking it up later with other two. The measurement of the resultant current is the impedance and the smaller the value of the current received, the lower the impedance.Using this information and using some formulas it is possible to obtain information about a lot of things in our body, such as the quantity of water existent, the quantity of fat mass and the volume of the bladder. These results are possible because the body has different types of tissues and all of them have different conductivity.

Bioimpedance, as already mencioned, is used at a wide variety of healthcare areas and its usage can be testified to measure things such as: [26, 27] :

- Body mass index
- Body fluid measurement (total body water, bladder volume)
- Bioimpedance tomography
- Bioimpedance cardiography

This technology offers one of the best solutions to the patients because can be built as a portable non invasive device. This way this device prevents the uncomfortable process of wearing a catheter in the everyday and because of that it also helps prevent infections on the inferior urination tract. As an example of this system there are two studies that can help explaining this product. [28, 27]

2.7.3 Near infrared spectroscopy

Near infrared spectroscopy (NIRS) is a established technology that is already used in some areas of heath care as well as other areas like food industry and agriculture. Infrared (IR) is the region of the electromagnetic spectrum that lies between 780 and 100,000 nano-meters (nm), the near infrared is located inside this waveleghts and corresponds to the range between 780 to 2 500 (nm).

The interaction between the body matter and the electromagnetic radiation is what gives the data necessary for the process to work. A primitive explanation of how the NIRS works can be: an emissor should send NIR radiation and a detector allows to receive the radiation with different wavelenghts.

This technique is based in some parameters from the human body mixed with some characteristics from the spectrum of light used. As described by Fong et al. , the transparent behavior of the tissue before the NIR region of light allows the photons to penetrate inside the body and makes it possible to apply the principle of the NIRS.

After the penetration, the photons move through multiple reflections and can move in different paths. The light that is relevant to the measurement is the part that escapes back to the surface of the tissue in a short distance from the emitter. [3]

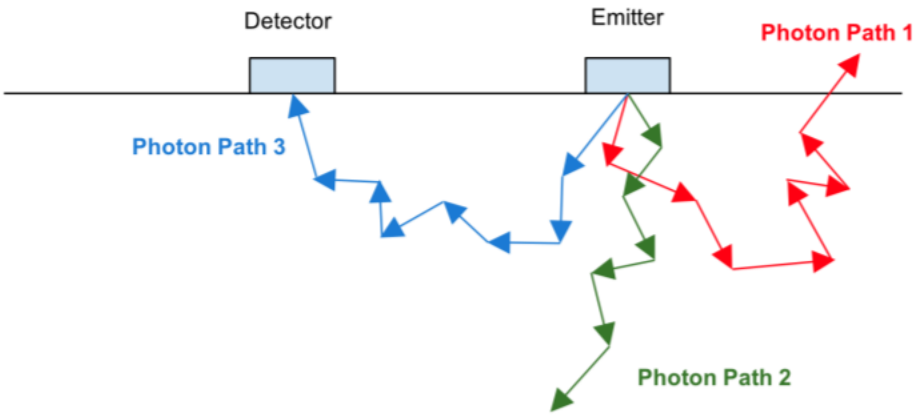


Figure 2.3: 3 different paths that photons can take after the multiple reflections that they suffer.

The image 2.3 can help to understand the previous explanation, it shows the three possible paths that the light can go, being the first one redirected back to the outside of the tissue, but this one is not captured by the receiver. The second path, shows that part of the light is being absorbed by the tissue and finally and the most important one, the third one is redirected back to the outside but in this one the detector is capable of catching and using it to gather the information necessary to the study and control.

To be able to use the information collected by the device, we have to resort to a formula that arises from a small modification of the Beer-Lambert law: the attenuation of light is related with the tissue proprieties that the light needs to cross. [29, 3] The human body tissue predominant components ar:

- Oxyhemoglobin (HbO2)
- Deoxyhemoglobin (HHb)
- Lipids
- Water (H2O)

All these components present different light absorption, which makes it possible to measure the bladder volume. The urine is mostly water so the light detected in the surface when the bladder is filling will be less and less intense. Because of the high absorption that water presents to the 975 nm wavelength, when the light intensity reaches a certain value, it represents that the maximum recommended volume has been reached. Some notes that should be taken into consideration that might affect NIRS success source-detector distance, the angle that [29]

The application of the NIRS in the bladder volume measurement and control due to neurogenic bladder problems has already been studied. The NIRS can be used to develop low-weight, small, comfortable and affordable wireless device that can communicate the volume level of the bladder to patients that suffer from different kinds of neurogenic bladder. A study defends that this approach works because when the bladder is filling it makes it raise out the pelvis below the anterior abdomen wall. When it reaches a certain volume, the light beam detected will suffer an abrupt reduction due to the big water absorption, giving the message that the bladder is full and need to be emptied. [3, 23]

2.8 Commercial products

There are already some products in the market that aim to give people more comfort by measuring the bladder volume and keeping people noted about their status. This devices applies the same principals already studied in this field but using different approaches.
Here we are presented two of them that are already being used.

2.8.0.1 Sens U

The SENS-U is a device designed to be wearable and because it is an everyday use it must be practical, small and comfortable. The device was developed with the purpose of being used in children only.

Utilizing ultrasounds as the way of controlling the bladder volume, the Sens-u is a small device that is attached to the lower abdomen of the human body through a double-sided adhesive. To achieve its purpose the Sens-u makes usage of a combination of four ultrassonic transducers within a field of view of 30º (FOV) that makes possible to keep track of the bladder filling and because the device also utilizes Bluetooth it allows the patient to have a continuous information about his bladder status, making their life much easier and safer.

The tests made to the device obtained excellent results. In 90% of the testsmade, the device was able to measure the bladder fullness with precision. As a note it should be pointed out that the error can grow in an abrupt amount due to miss position of the device and high levels of fat mass in front of the device. [30]

Figure 2.4: Schematic of the application of the Sens-u.

2.8.0.2 Bladderscan

This is another example of an ultrasound based device, a 3D one, used to measure bladder volume. It is mostly used in order to assess urinary retention and post operative recovery without needing urinary catheterization.

The working process has the same base of all the other portable prototypes or devices developed until now. An emitter sends high frequency sound waves to the inside of the body and after some waves reflect and make their way back outside the body, will be detected by the receiver that must pass the info to the machine that will interpret and turn into the volume information expected. [31]

Figure 2.5: BladderScan device

Chapter 3

Concept development

3.1 General requirements

Living with Neurogenic Bladder is a huge burden in a person's life since it is something capable of changing every routine and leading even to problems like lack of confidence and depression. There is a deficit of solutions capable of giving back the life of this patients.

This project aims the creation of a device capable of giving some normality to people that suffer from this condition. The proposal is an everyday portable wearable device capable of a permanent intravesical volume monitoring that also incorporates a notification system. Patients using it should be able to get the status of their bladder volume any time remotely from their mobile phone. Getting access to this technology should improve substantially the comfort and confidence of the users, because it returns some control over their micturation process meaning less sleep interruptions and optimized catherterization/micturation schedule, thus making it possible to reduce stress and prevent overleakage or incontinence.

In a technical view, the device will make possible to get measurements in ambulatory environment, should improve patients life in different areas such as allowing the user to schedule and control his catheterization and with this reducing the number of catheterizations thereby reducing the number of infections. It also allows the doctors to have privileged access to information about the bladder behavior due to continuous data collection made by it, that it would not be possible to obtain otherwise.

There are some requirements that should be taken into account:

- Easy interface.
- Non Invasive.
- Easy to mount/dismount.
- Grant a good time window between the notification and the real max volume.
- Comfortable to wear.

- Long duration battery.

- Ergonomic.

3.2 Chosen method

A comparison between the three technologies referred in the previous chapter (Ultrasound, bio-electric impedance, near-infrared spectroscopy) was made and the chosen option was the NIRS.

Although ultrasound is the most widely used technology for this application, this is primarily due to the fact that it is used in a hospital environment, as it has some shortcomings when the objective is outpatient use. Even though there are some devices developed using them, does not seem to be the best option. Ultrasound requires a powerful computational resource and complex scanning control system. It also demands a permanent gel application in order to work properly. This motive alone is enough to discard the technology because this gel becomes another complication to the person, insofar makes it uncomfortable and unwearable.

Biomimpedance is disappointing since it does not show any advantage over the others, on the contrary, the fact that it uses electrodes can turn it very uncomfortable, plus the measurement process is complex.

The remaining process is NIRS, which turns out to be the method that respects the most requirements. This method allows the device to be wearable, non-invasive and very compact.

3.3 How it works

The proposed device is based in a simple concept which has already been used in other applications such as proximity detectors.

It consists of an optical sensor working in the near infrared range, capable of measuring the bladder volume and then communicating with the patient through a software that sends notifications to his cellphone or a vibration made by the device on the skin. The device must be placed in the lower belly, more specifically 2 cm above the *symphis pubis* centered. The placement is crucial to succeed, so the correct place should be marked allowing the user to apply the device correctly every time.

The device must be always adapted to each user, to set the limits to the bladder filling and warn the user at the correct time. This notification must alert the patient before the bladder reaches its maximum volume, allowing the patient to have time before emptying it, like the normal procedure of a normal person. The patient will need to keep contact with the doctor responsible for the device installation. It should be him in a hospital environment with the assistance of ultrasound to set the correct values as well as keeping the settings correct.

3.4 Project

The development of any product should start with a good planing stage. The first step was already decided, the chosen technology was the NIRS, and with that in mind, the next step should be thinking of a way to test this technology and understand if it really makes sense and works as expected in the theoretical study. So the testing phase was started, beginning with the project and preparation, instead of trying to build a final product that seems a little too ambitious. The chosen path was the development of a concept device, simpler and ignoring some of the must haves already pointed, but that makes possible to put the technology to the test.

For the concept there was different options that could be used and the most important decision was the way to control the system, and that requires a microcontroller.

Also to make the development of the device more efficient and less susceptible to errors it was used a circuit design tool, which in the case was EAGLE. This is a schematic editor that allows to make a project of electric circuit previewing the necessary hardware and connections, this way it is possible to start a circuit built from the zero and understand what is really necessary without having to purchase the components making the budget lower, as well as less susceptible to errors in the assembly or connections. It is possible to observe the full schematic at A.5

3.4.1 Components necessary

Microcontroller

The microcontroller is the brain and operation center of all circuit and device, thus it is essential to the build. This is the place where it will be possible to program and control the information gathered.

Microcontrollers are divided into categories according to their memory, architecture, bits and instruction sets.

The prerequisites for the device are quite simple, as for bits an 8 bit is totally fine for the job, being this device only a concept for doing some tests, it is not necessary an huge precision or speed on the measurements. In terms of memory, it is expected that the microcontroller is connected to an external flash memory device, like an SD Card, and also expected to be possible to overwrite the information. That way it is not necessary an huge built-in memory. The remaining two parameters are not that impactful in the choice, so any of the options are accepted.

With that in mind, there are a lot of different options available to the application, from a more unprofessional/amateur device like Arduino up to more professional ones like Raspberry Pi or Beagle Bone. [32, 33]

Power Supply

The battery life is dependent on the components consumption and requirements, it is necessary to take that in consideration, with dome calculation is easy to preview the amount of energy necessary to keep the device running.

The battery should match some requirements specially because it should be wearable and be in constant contact with the human body. The most important thing is the safety and some batteries can not be used for this application because of radiation or because it is not certain that is safe to use it near human body. There are already batteries studied and tested for medical proposes. Since the objective is to make the life of the user the most normal and comfortable possible, it is necessary to make sure that the battery lasts at least a week without charging, has fast charge option, is easy to mount and dismount and it is as thin as possible so the user must not feel its presence. About the technology used it seems the best option for the application should be a Li-ion battery, which is the most advanced kind of batteries and usually the chosen type for this kind of application.

Source

The sources of light used in NIRS are laser or LED and both have advantages and disadvantages between them. So a comparison needs to be made in order to choose the correct one to the application. Starting for the most important parameter, and bearing in mind that is for human body application, the security is a parameter that both must respect and in fact they are both adequate to human body utilization. Leaving that point behind and focusing now in more technical terms, the next point to be compared is the measurement depth and in this parameter the laser will take the point because, the fact of being an amplified light beam, makes it easier to go further inside the human body, a laser based system can reach until 3 cm of depth compared to a max of 2cm possible to the LED. Wave length is another characteristic that laser wins over the LED. One of the main characteristics of lasers is that they are monochromatic, this means they only have one very defined wavelength in comparison with LED that emits a wavelength with Gaussian-like distribution. Changing a bit the direction now and focusing on the points where LED presents a better option, like portability, the LED appears as a more portable solution. There are already other portable devices for medical purposes based on LED emissions and the laser application is almost if not even impossible to be applied. For now all the devices require a much bigger and complicated electronic construction what makes the laser devices stationary, and for last but not less important the price, the LED price is much cheaper than the laser. It is estimated that a laser device can be ten times more expensive and this should be taken in consideration, because when an health device is being built it must be taken into account that it can be used for the maximum number of patients possible and the price usually is one of the biggest barriers. [34, 35]

Table 3.1: LED vs Laser comparison

Parameters	Laser	LED
Measurement Depth	+	-
Portability	-	+
Price	-	+
Wave Length	+	-
Safety	+	+

Receptor

The detector being used is dependent on the emitter, but taking in consideration that is probable that a LED, the correct receptor must be a photodiode. Photodiodes are used to turn the light signal into electric signal, that is what is expected, and because the conclusion already taken in the previews chapters the emitter and the receptor need to work at a wavelength of 950 nm, due to the separation with the source must have the largest active-area possible, and the angle of action should also be wide, in order to catch the most number of photons possible.

Analog-Digital Converter

The analog-digital converter (ADC) is one of the most important devices in the montage and can not be skipped. In this application it is necessary to read some analog information, the receptors can receive energy from different sources like light, sound, movement temperature and analog information is constantly changing. The ADC job is to receive this information from the receiver and convert to a digital signal that turns possible to the microcontroller to interpreter.

Accelerometer

The accelerometer job is to filter all the measurements, because the information's gathered by the device can be susceptible to errors related with the position of the user. Imagine that at night the user is wakened up by the notification system tell the person to void the bladder, but this only occurs because of the positioning of the people. In the end the accelerometer is used to prevent that problem.

The accelerometer is a device built to read movement. This sensor makes possible to know the position of the device, this means where it is installed. Having this installed in the device, it allows to know if the person is moving, running, lying down or seated, making the measurement accordingly granting that the correct information is given to the person. [36]

Piezoelectric Actuator

In addition to giving notifications via mobile phone, the device should also be able to give a sensory warning to the user. In order to provide this second way of notification, it was used a piezoelectric actuator. This is able to transform electrical impulses received from the source and turn them into small vibrations. These vibrations should be placed close to the user's skin, so that he can also receive the information that the time to empty the bladder has arrived.

3.4.2 Component Assembly

It is essential to use a project prior to assembly, so that it is possible to study the functionality, whether the chosen components fit and function in partnership with each other. In order to do this study, and as it was already said, it was used the program EAGLE, this made possible to look into the correct assembly and certify that all the components will be in their correct place. With this it is also possible to study possible failure points, as well as the necessary components to the normal functionality of the electric circuit, things like resistances and capacitors.

Some essential pieces were added to the circuit granting the correct functioning of the components, it is also showed the organization and correct connections to each one of them.

3.4.3 Chosen Components

The components requirements were presented in the last point. After getting the list of the necessary components the follow-up was choosing the actual elements trying to respect the demands to each one of them. It was considered that this is not a final product but instead a concept, so this led to choose some cheaper and less optimized options in order to make tests to the technique before a full investment in a prototype.

Microcontroller

The microcontroller is one of the components that was picked thinking first in a cheaper version to testing phase, and with that in mind, the chosen component was the Arduino Mega 2560 Rev3. The Arduino appears as the correct choice because of the price quality that it gets, is a relatively cheap device that apparently is able to give us the expected functionality. The fact that all associated hardware (software, libraries, hardware) are open-sourced makes it the perfect choice. Another point in favor is that is a very commonly used platform this makes the existence of information examples and forums plentiful, all this information helps with the development of the device. Nevertheless one of the thing that Arduino can not grant is a long battery life, because it is a device that is not very optimized in terms of energy consumption.

Justifying now with a bit more technical information and starting to look in to the aspects required in the components, the Arduino is an 8-bit board and this is sufficient because a lot of the data in not gathered and because the velocity needed can be achieved with only an 8-bit board. About the memory parameter, and due to the low requirements necessary to the application the Arduino offers enough memory, and because it is planed to implant a SD Card reader in the device, so this component can compensate for any lack of flash memory from the Arduino. The remaining parameters are not very important but we can point them out, talking about architecture Arduino utilises Harvard architecture this means that the memory where the program code and data are situated are different, finally the instruction sets is about he Arduino language and that is very specific to the microcontroller, but its totally adequate to the job. [37, 33] Technical information:

Table 3.2: Arduino Tech specs

Microcontroller	ATmega2560
Operating Voltage	5v
Input Voltage (recomended)	7-12V
Input Voltage(limit)	6-20V
Output Voltage	5V or 3.3V
Digital I/O pins	54
Analog Input Pins	16
Flash Memory	256 kb
Length	101.52 mm
Width	53.3 mm
Weight	37g

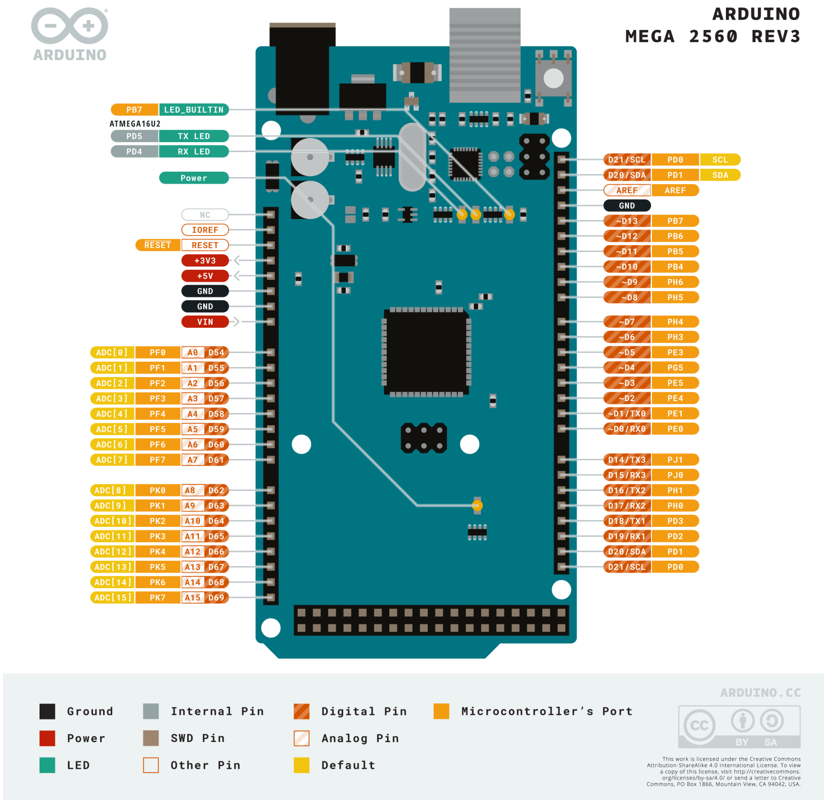


Figure 3.1: Arduino Pin description

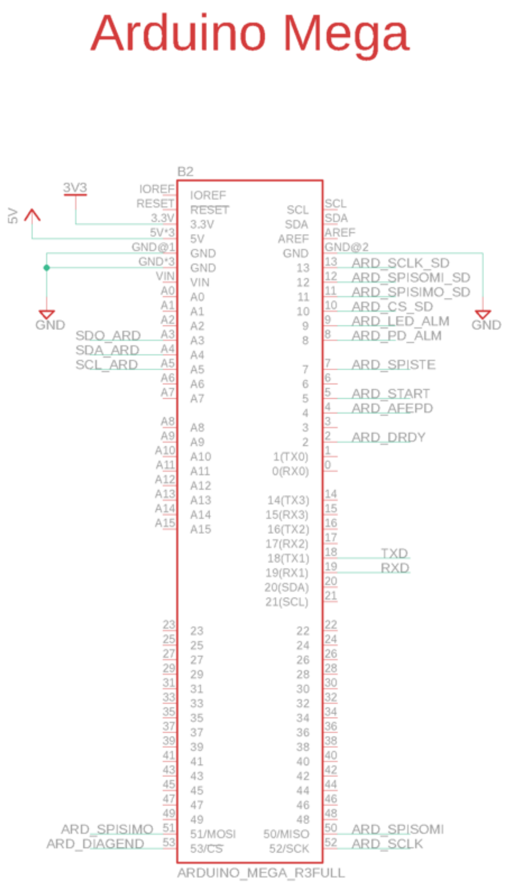


Figure 3.2: Arduino connections Schematic

Power supply

The power supply have a lot to say about, is one of the components that can really impact the comfort and the success of the device, with that being said it also was pointed out that this is a testing stage and that the focus should be in the cheapest and fastest way to put the concept device into testing, so some changes were taken into consideration, instead of looking for a custom made battery that could last for the minimum ideal time of one week, the route taken was to just power the device. Focusing in the Arduino requirements to work that is a 7-12v supply the portable version chosen is a 9V battery, but the ideal one and considering that the test are made in a laboratory environment, using a laboratory power supply unit, being the most versatile and secure, is the perfect selection to the job.

Figure 3.3: Example of a laboratory power supply unit

Source

Their are two main sources of light that can be used to this application, being laser or LED. After the comparison made in the point 3.3.1 the chosen source was the LED.
There are some advantages to both ways but at the end the fact that LED turns the device much more portable and simple even spending less money, makes it the correct answer to the question. The LED is able to deliver the expected results. Since the correct wavelenthg to this fucntion is around 950 nm it should be selected a LED that works in this ranges of light.
The device selected is a very simple LED that operates with a 940nm wavelength, "High Power Infrared Emitting Diode, 940" from Vishay.

Analog-Digital Converter

The NIRS is a technology used in other areas of medicine, and there are other devices already developed that use ADC in combination with NIRS, for example oximetry. The ADC utilized in that application is a fully-integrated front-end analog (AFE) more specifically an AFE4490. With that in mind, it seemed a good idea to try to use this component in the device build.

The reason behind choosing this component is because it is already used in oximetry application and the working principal is similar to the one used here. The device is used to read heart rate as well as SpO2 values. It utilizes a light emitter and a receptor to make the information gathering. The AFE includes a low-noise receiver channel with a 22-bit analog - to - digital converter, a LED transmit section and sensor and LED fault detection. It is a highly customized timing controller.

ProtoCentral AF4490-based Pulse-oximeter shield for Arduino, being a shield allows to mount it on top of the Arduino requiring less ports usage and leaving space for the other components. The AFE package includes also a Standard Nellcor, but this component is for oximetry usage only and is not important to this project. The AFE also comes with a predefined code that makes possible to obtain the SpO2 automatically but it needs to be changed to the project, because the calculations made are not the same to calculate the volume of the bladder.

Table 3.3: AFE4490 specs

AFE4490 pin label	Arduino Connection	Pin Function
GND	GND	GND
DRDY	D2	Data ready
MISO	D12	Slave out
SCK	D13	SPI clock
MOSI	D11	Slave in
CS0	D7	Slave select
START	D5	Conversion start Pin
PWDN	D4	Power Down/Reset
DIAG_END	NC	Diagonostic outout
LED_ALM	NC	Cable fault indicator
PD_ALM	NC	PD sensor fault indicator
VCC	+5V	Supply voltage

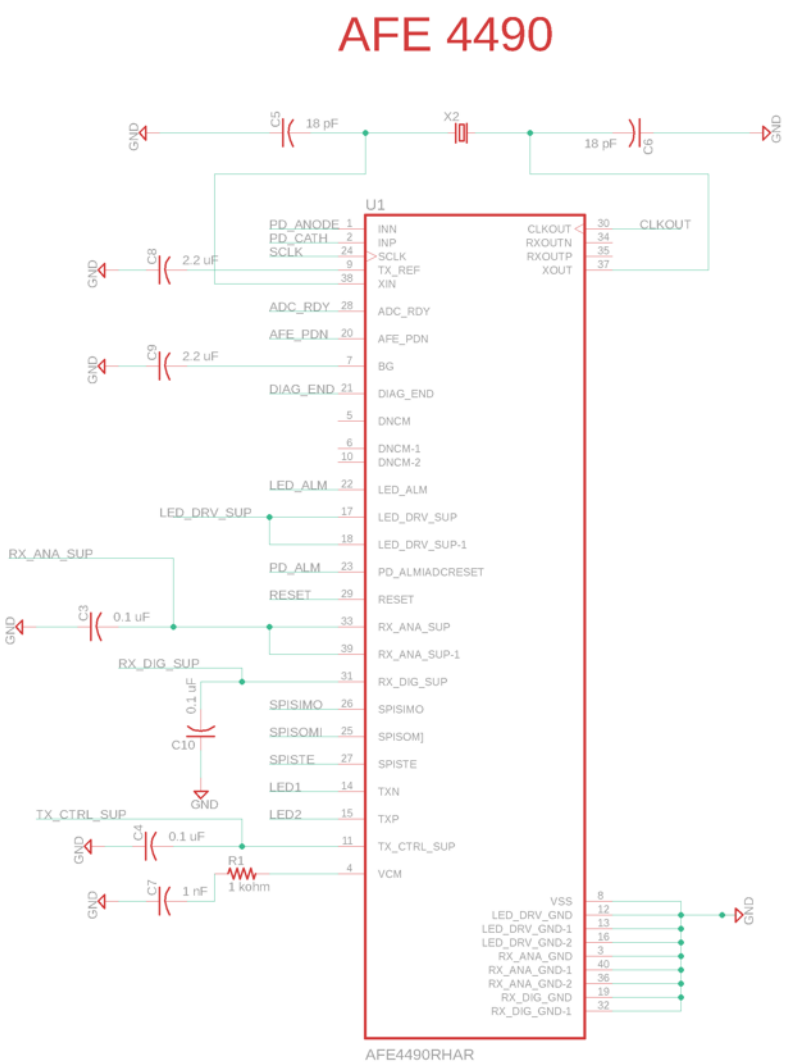


Figure 3.4: AFE 4490 Schematic

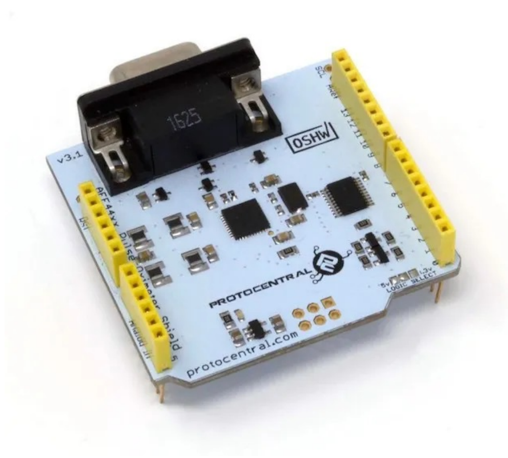


Figure 3.5: ProtoCentral AF4490-based Pulse-oximeter shield for Arduino

Logic Level Converter Bi-Directional

This component is necessary to stepping down voltage from 5V to 3.3V. This is necessary because although Arduino have both type of sources, it is recommended to focus all the power supply on the 5V line and some of the components only works with 3.3V. It also offers other combination, in this case the current from Arduino is not enough to feed all the components with this element is possible to step down a power supply from the laboratory power supply.

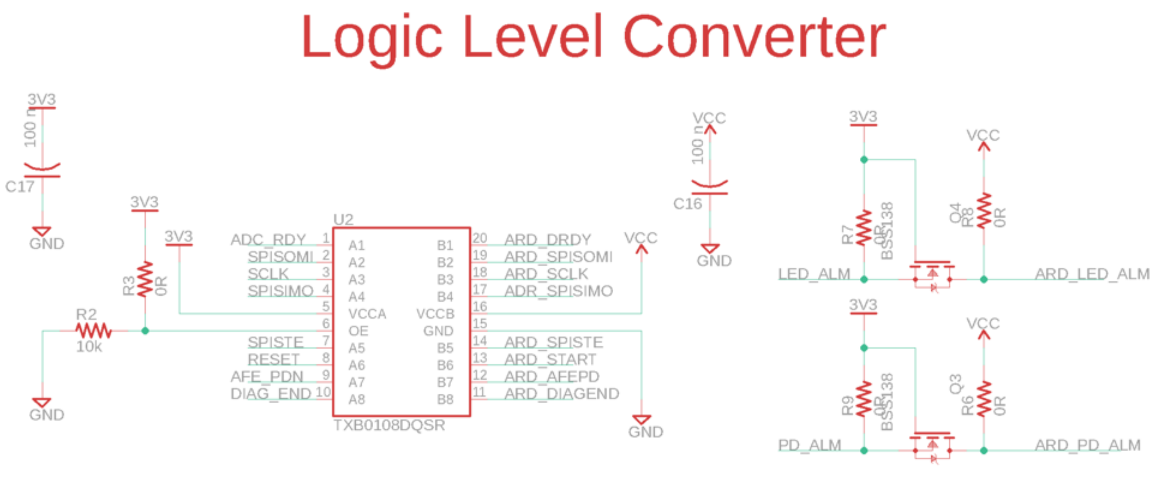


Figure 3.6: Logic Level converter Schematic

SD Card Reader

Previously it was referred that an external flash memory from the Arduino should be used, and for that purpose it was picked the SparkFun Level Shifting microSD Breakout component, its job is just to offer more storage to the device. It was picked this one because it offers a level shifting that allows to use it in the Arduino line as full speed and at 5V.

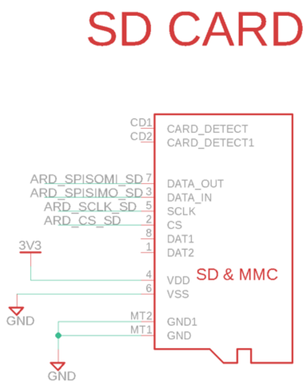


Figure 3.7: SD CARD Schematic

Bluetooth

The device should connect to a mobile phone with the purpose to alert and keep the user always informed about the status of his bladder. To be able to do this connection, and again taking into consideration the low cost concept and the microcontroller in usage, the Bluetooth component chosen was Bluetooth Module HC-05. This is the standard component used for this application. It is used in multiple different applications and always giving the correct response, so it makes sense to use it in this build.

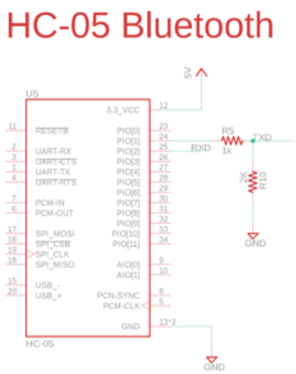


Figure 3.8: AFE 4490 Schematic

Accelerometer

The selected accelerometer to the project was the SparkFun Triple Axis Accelerometer Breakout - ADXL345, there is not much to say about this component, it is a basic accelerometer that measures the 3 axis, and it is assumed that will do the given job.

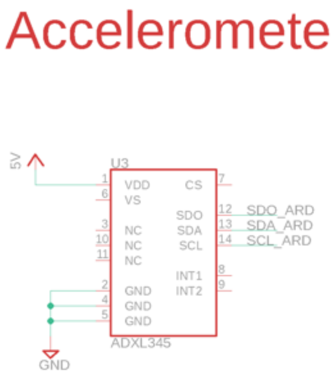


Figure 3.9: Accelerometer Schematic

Dc-Dc Converter

The DC-DC converter prevents to exceed the Arduino current limit, this way is possible to have the power supply nourishing the Arduino and in parallel with the other components. The power supply can be at 7V-12V, that is the recommended voltage for the Arduino and passing through the DC-DC converter having the rest of the components working with 5V.
The chosen DC-DC converter is XL4005 (Módulo Conversor DC-DC Ajustável Step-Down 4-38Vin 1.25-32Vout 5A), this component is the ideal to this application, because it can take a wide range of voltage from the power supply being able to give the expected 5V to the circuit.

Chapter 4

Device Development

The development of the device is quite challenging since several problems have aroused, making the project still incomplete and it is not yet possible to proceed with the final tests. Nevertheless, the development can be divided in three phases: initial assembly, individual component tests and final assembly and tests.

4.1 First Stage - Assembly

The assembly turns out be quite simple because of the previous work done in the software EAGLE is an huge help and guideline. Even though some setbacks that appeared are worth being mentioned like the fact that not all the components were prepared to be assembled, it was required to weld connection points.

All the components are ready to be assembled, but some other components are necessary to bring together the circuit like a breadboard, capacitors and resistances, also step-up converters from 3.3V to 5V. This small components have a very important job in keeping the whole circuit balanced and safe for the components.

For the circuit to work properly and without jeopardising the safety of the components some concerns must be taken into account like if there is enough current to feed all the components, to be sure that the current is adequate instead of being the Arduino alone it was also incorporated a current step-down DC-DC converter able of turning the 9V current (used to feed the Arduino) into 5V. Another concern is if all the components and connections are correctly linked to the ground in order to, once again, protect all the circuit and make sure all the excess electric charge has a place to go.

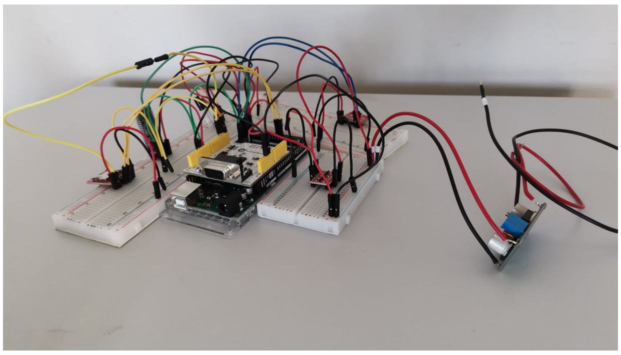


Figure 4.1: Total assembly

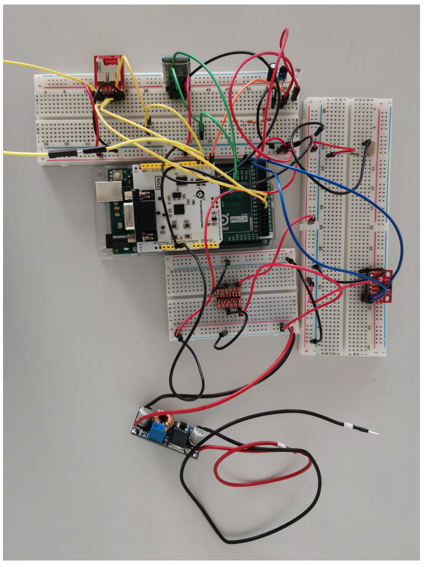


Figure 4.2: Total assembly top view

All this components turn the area necessary to the build huge when compared with the final purpose and one of the mentioned priorities to the end result, but as referred before this is only a concept with the objective of testing the functionality of the idea.

4.2 Second Stage - Programming and Individual Testing

This stage of the project is where most of the practical work has to be done and is also the most demanding phase. Almost everything needs to be developed here. At this point the work was organized in different steps, all the components will be treated individually, it is necessary to assembly each one of them and test if it is working, with that in mind a different program were developed as a way to test them and also understand how they work alone.

The programming done has not always been for final application but for simpler projects, since the aim is to test each component individually and the final programming already requires the combination of all the components. However the jobs chosen for testing are as close as possible to the final application. When it comes to programming, the Arduino is very versatile and is able to interpret different languages like C, C++, but the language used was the Arduino language using an application named Arduino IDE. Arduino is an open-source hardware that has a lot of forums and information about other projects on the internet. All this shared data can help a lot in the moment of writing a new code and that why this language was picked in the project.

4.2.1 Individual components

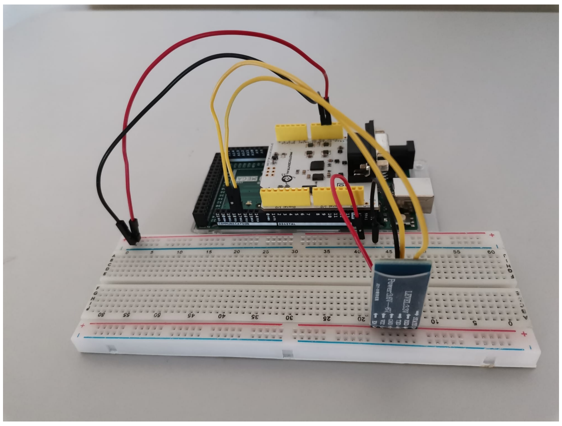
Microcontroller

The microcontroller is the place where the programming must be done in order to the device to work properly. So in this stage of development all the work is directly connected to this component, being the brain responsible for controlling all the other components and organizing the data gathered. Plus it is responsible for how many measurements must be taken in a space of time as well as when should the user be informed. The codes used to tests can be seen on the A .

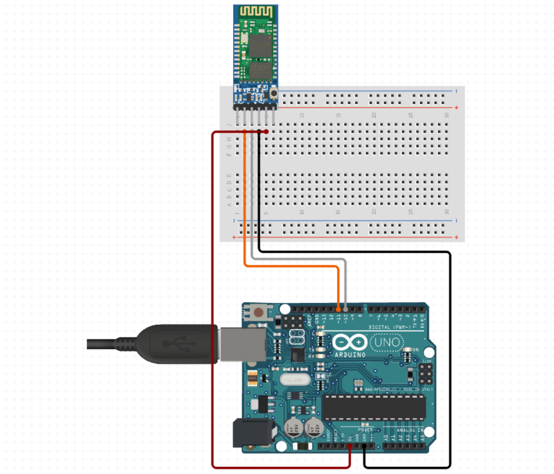
Bluetooth

The Bluetooth module is one of the easiest to be tested and programmed as there is plenty of information on the internet as this is one of the most used components in Arduino applications.

The Bluetooth was tested and the result was the expected being able to easily connect with a cellphone. However it will not be developed a code to connect the device to a cellphone because it is required a cellphone app capable of receiving the information and do all the expected work such as notifications, show the values live, etc. It is therefore impossible to use it at this stage of the project. However, it does not compromise the work since it is not a fundamental part for testing the concept.



(a) Bluetooth circuit



(b) Bluetooth connections

Accelerometer

The accelerometer was tested with an already existent code imported from the internet, making possible to see the rotation position. This code was very simple but efficient and able to give the expected result. Since the final assembly is yet to be maid, this is one of the parts that can always be changed and improved. However the code allows the accelerometer to give information about the position of the patient. Readings of this component fluctuate between 200 and 1000 when the person is strait it should give values near the number 500 that is near the middle point, once the person change is position it also should change the number given. After some small tests the positions given are based in the values obtained, every position should correspond to a gap of results. The component has a measuring range between ±2g and ±16, the one used in this tests was 2G because it gives better accuracy to the tests and the end result of the positions. Then it was possible to have 3 positions:

- 0 - flat
- 200 - 45º rotation
- 400- 90º rotation

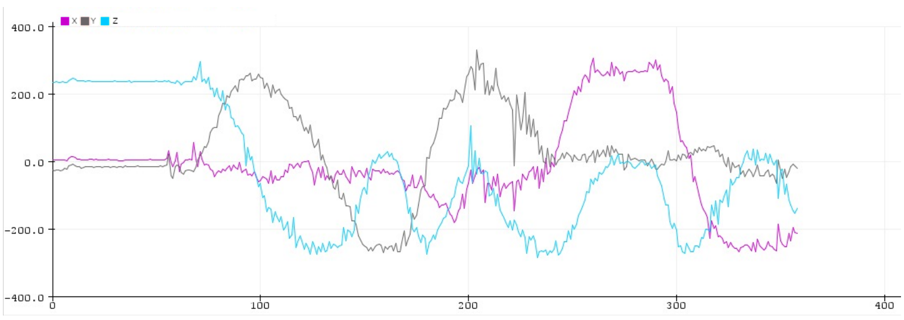
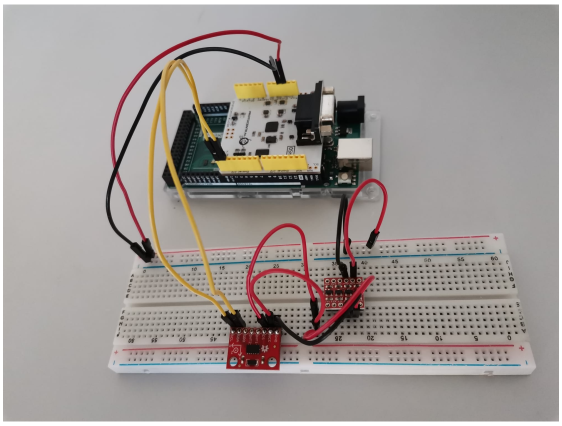
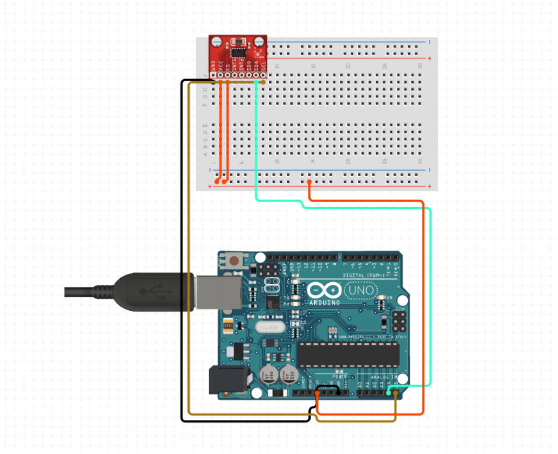


Figure 4.4: Graph showing different positions of the accelerometer



(a) Accelerometer circuit



(b) Accelerometer connections

MicroSD Reader

Another case of basic test code used, to test this part it was also downloaded a code from the internet for a project similar to the device being built here. This was enough to understand that is working properly and it is suitable for the job expected.

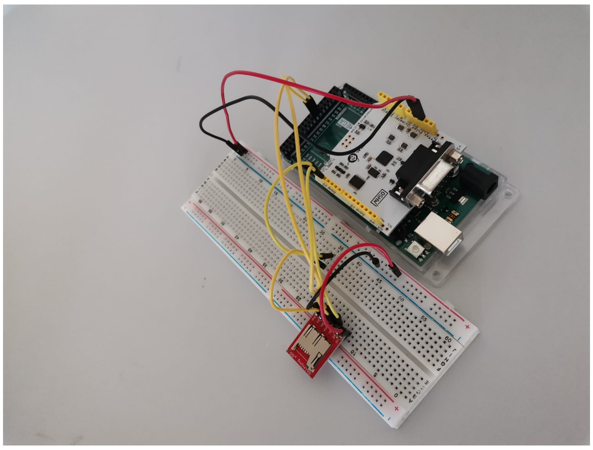


Figure 4.6: SD card assembly

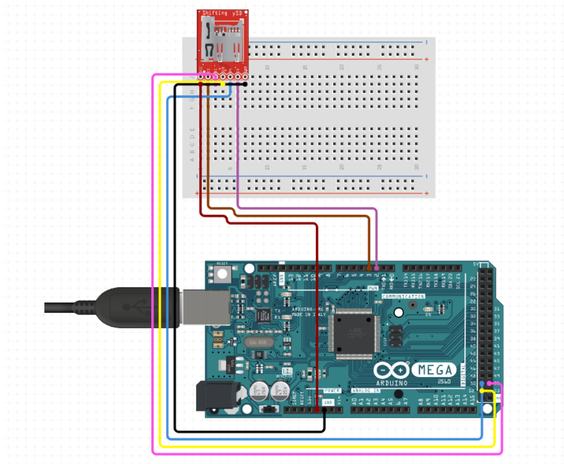


Figure 4.7: SD card connections

AFE4490

For the case of AFE4490 the test was successfully performed using a program that is used in the health area, but differs a little from what is intended here. After some research, a code was found that would allow the measurement of the pulse rate as well as the blood oxygenation using a probe that clips on to a finger. The test with its initial objective of oxymetry was a success and it was possible to make this measurement very quickly and accurately.

Although the testing has been relatively easy, the adaptation of this component to the expected work of this project is being a big challenge and is the main reason why the process is being delayed. The test done has a different purpose, but the process used is similar to the intended, because it also uses the emission of IR light from a LED and then a receiver. With that in mind the adopted strategy is to try to take the initial code and make the necessary changes so that it can be used for the expected purpose. The challenge is also to be able to introduce the collected information to the expected data by passing through Beer-Lambert's law, so it will be possible to collect the correct data. This is because the data read by the AFE goes through a pre-made programming that converts the light intensity reading to the blood oxygen values.

Figure 4.8: AFE4490 Assembly view 2

Side Note

The rest of the components did not require any code, their job is merely to control or adjust the circuit. They were not mentioned in the individual components matrix, although they are showed in the following images.

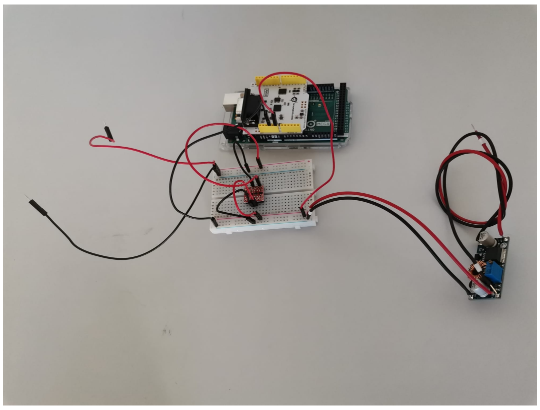


Figure 4.9: Energy converter and Logic Level Converter

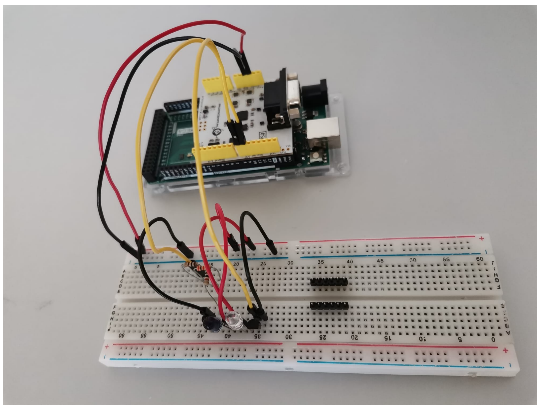


Figure 4.10: Infrared emitter and receiver

4.3 Third Stage - Final assembly and test

This point of the project has not yet been reached and therefore it will not be possible to post the data collected from tests carried out. However the development plan of this stage will be explained, as well as the expected results. Starting then with the final code, as seen in the code examples before, the code is divided in two parts, being the setup and the loop. Every code must have both parts, the setup part is where the preparation of the components is done and also where configurations and preset values are assigned. In the loop part, is where the job that the component must do is written. Writing the code at this stage involves re-copying all the individual component codes and putting them in their place here, taking into account that rule that there can only be two parts per code. Summarising it is necessary to find a way to incorporate every loop in only one loop and the same should happen for the setup.

Some questions that must be taken into consideration because their related to this phase:

- The Beer-Lambert Law should be already present in the reading
- Grant that the position of the user is taken into consideration on the measurement.
- Notifications must be made some time in advance of the bladder limit and at the same time encompass the previous point.

Unfortunately it has not yet been possible to proceed with the tests because of the mention in the text until this point. However it is already possible to make a forecast of expected results. The individual tests turned out positive even though are not close to the final project. As an example, the similarity between the process used in the AFE4490 on the oxymetry job, shows that is possible to obtain readings from the absorption of light sent by a led, and that the Infrared light is capable of go through the different layers of the skin and also capable of transmit the the desired data. Also the test with the accelerometer showed good results and accuracy on the measurements.These are some of the reasons that show possible positive results from the tests done. However, there are other parameters that leave some apprehension such as the precision of the measurement, the errors in the measurement, the bad assembly of the device for testing. The testing environment also plays a huge role, because it shouldn't be done on people at least at the beginning. It is necessary the support of the ultrasound used at the hospital, in order to make a comparison between the results and evaluate the results quality.

Chapter 5

Conclusions and Further Work

5.1 Conclusions

This thesis presents the development of a project which aims to develop a device capable of monitoring bladder volume.
It starts with an intensive research on the functioning of the urinary system as well as on the physiology of the human body. This background allowed us to make decisions about strategies and components necessary for the development of the project. The near infrared spectroscopy technology was chosen, as it is safe for human health and is already used in other areas of health. It is also presented a set of components with the goal of assembling a concept for testing the technology. All the component choices have an explanation of their function and why they were chosen. Although it was not possible to test the studied concept, some advances were made in the programming of the components. Some of the components were tested independently and showed good results and were able to give the expected answers. It is also left an organized and explained work that, allows the continuation of the work so far developed in a simple way.. In short, this thesis allowed to develop a little more of the project initially proposed and that until the moment has great indications about the choices made, and that may culminate in a device capable of improving the lives of many people suffering from NB in the world.

5.2 Further Work

This project is designed to create an innovative and unprecedented product, which makes it ambitious but also very susceptible to improvements and new developments. As such there is a lot of work that can be done in order to improve the final prototype.
This section presents all this work that can be done divided into three parts.

Beginning with the work that is not yet done on the present stage so the more short term. This is mostly ending the job ongoing which consists in compiling all the codes necessary in only one, this will permit to start the first testings of the chosen process. This allows to understand if the chosen idea of using Near-Infrared Spectroscopy is the correct way and is able to give the answer expected to the problem.
Focusing now in the next step that can be called medium term objective. This advancements should only be reached if the previous work is done and the results are positive and the expected. At this point the concept turns out to be the correct choice, now it should be developed a prototype that includes all the components selected. In the final of this phase is expected to have already the Bluetooth component working as well as the mobile phone app , in order to be able to have all the device working and and closer to the final product expected.It is also expected to be completely portable.

The third and final point of the project, and this will be incomplete for sure, the long term. If this point is reached it means that all the results of the previous stages have been achieved, and that the project is ready for the next step which is the construction of a prototype for testing the end product. At this moment it is necessary to rethink all the building in order to do a realistic product, some rules that have been skipped in previous moments need to be taken into consideration now. Rules such as being a small device, the portability, the battery duration and recharge time. Basically now it is necessary to substitute almost every component, it is necessary a new microcontroller, more powerful and smaller, the battery need to last at least one week and contain fast charge technology, etc. Another priority in this stage is the design and wearability of the product, it is strictly necessary to make it comfortable to the user.

Appendix A

Code used for testing

A.1 SD Card Code

```
// Include Libraries
#include "Arduino.h"


// Pin Definitions
#define USD_PIN_CO        2
#define USD_PIN_CS        3



// Global variables and defines

// object initialization


// define vars for testing menu
const int timeout = 10000;       //define timeout of 10 sec
char menuOption = 0;
long time0;

// Setup the essentials for your circuit to work. It runs first every time y
```

```
void setup()
{
    // Setup Serial which is useful for debugging
    // Use the Serial Monitor to view printed messages
    Serial.begin(9600);
    while (!Serial) ; // wait for serial port to connect. Needed for native USB
    Serial.println("start");


    menuOption = menu();

}

// Main logic of your circuit. It defines the interaction between the components
void loop()
{


    if(menuOption == '1')
    {
    // Disclaimer: The SparkFun Level Shifting microSD Breakout is in testing
    }

    if (millis() - time0 > timeout)
    {
        menuOption = menu();
    }

}



char menu()
{

    Serial.println(F("\nWhich component would you like to test?"));
    Serial.println(F("(1) SparkFun Level Shifting microSD Breakout"));
    Serial.println(F("(menu) send anything else or press on board reset button\n
    while (!Serial.available());
```

```
    // Read data from serial monitor if received
    while (Serial.available())
    {
        char c = Serial.read();
        if (isAlphaNumeric(c))
        {

            if(c == '1')
                        Serial.println(F("Now Testing SparkFun Level Shiftin
            else
            {
                Serial.println(F("illegal input!"));
                return 0;
            }
            time0 = millis();
            return c;
        }
    }
}
```

A.2 Accelerometer Code

```
// Include Libraries
#include "Arduino.h"
#include "ADXL345.h"
#include "I2Cdev.h"


// led Definitions
int pd=2;                      //Photodiode to digital pin 2
int buzz=13;                   //piezo buzzer to digital pin 13
int senRead=0;                 //Readings from sensor to analog pin 0
int limit=850;


// Global variables and defines
int16_t adxlAx, adxlAy, adxlAz;
// object initialization
ADXL345 adxl;


// define vars for testing menu
const int timeout = 10000;       //define timeout of 10 sec
char menuOption = 0;
long time0;



// Setup the essentials for your circuit to work. It runs first every time your
void setup()
{
    // Setup Serial which is useful for debugging
    // Use the Serial Monitor to view printed messages
    Serial.begin(9600);
    while (!Serial) ; // wait for serial port to connect. Needed for native USB
    Serial.println("start");

    adxl.init();
    pinMode(pd,OUTPUT);
```

```
    pinMode(buzz,OUTPUT);
    digitalWrite(pd,HIGH);        //supply 5 volts to photodiode
    digitalWrite(buzz,LOW);
}
int RawMin = -400;
int RawMax = 400;
// Main logic of your circuit. It defines the interaction between the compo
void loop()
{



    // SparkFun ADXL345 - Triple Axis Accelerometer Breakout - Test Code
    // read raw accel measurements from device
    adxl.getAcceleration(&adxlAx, &adxlAy, &adxlAz);
    // display tab-separated accel x/y/z values
 //    Serial.print(F("ADXL345 accel-\t"));
    //Serial.print(adxlAx); Serial.print(F("\t"));
    //Serial.print(adxlAy); Serial.print(F("\t"));
    //Serial.println(adxlAz);

 //Read raw values
  int xRaw = adxlAx;
  int yRaw = adxlAy;
  int zRaw = adxlAz;

  // Convert raw values to 'milli-Gs"
  long xScaled = map(xRaw, RawMin, RawMax, -3000, 3000);
  long yScaled = map(yRaw, RawMin, RawMax, -3000, 3000);
  long zScaled = map(zRaw, RawMin, RawMax, -3000, 3000);

  // re-scale to fractional Gs
  float xAccel = xScaled / 1000.0;
  float yAccel = yScaled / 1000.0;
  float zAccel = zScaled / 1000.0;

  Serial.print("X, Y, Z  :: ");
  Serial.print(xRaw);
  Serial.print(", ");
  Serial.print(yRaw);
```

```
  Serial.print(", ");
  Serial.print(zRaw);
  Serial.print(" :: ");
  Serial.print(xAccel,0);
  Serial.print("G, ");
  Serial.print(yAccel,0);
  Serial.print("G, ");
  Serial.print(zAccel,0);
  Serial.println("G");

//led
  int val=analogRead(senRead);  //variable to store values from the photodiode
  val= (val-754)*2;

  Serial.println(val);

  delay(600);

}
```

A.3 Bluetooth Code Test

```
// Include Libraries
#include "Arduino.h"


// Pin Definitions



// Global variables and defines

// object initialization
HardwareSerial& bthc05(Serial1);



// Setup the essentials for circuit to work. It runs first every time circui
void setup()
{
    // Setup Serial which is useful for debugging
    // Use the Serial Monitor to view printed messages
    Serial.begin(9600);
    while (!Serial) ; // wait for serial port to connect. Needed for native
    Serial.println("start");

    bthc05.begin(9600);
    //This example uses HC-05 Bluetooth to communicate with an Android devic


}

// Main logic of circuit. It defines the interaction between the components
void loop()
{


    if(menuOption == '1') {
    // HC - 05 Bluetooth Serial Module - Test Code
    String bthc05Str = "";
```

```
    //Receive String from bluetooth device
    if (bthc05.available())
    {
    //Read a complete line from bluetooth terminal
    bthc05Str = bthc05.readStringUntil('\n');
    // Print raw data to serial monitor
    Serial.print("BT Raw Data: ");
    Serial.println(bthc05Str);
    }
    //Send sensor data to Bluetooth device
    bthc05.println("PUT YOUR SENSOR DATA HERE");
    }

    if (millis() - time0 > timeout)
    {
        menuOption = menu();
    }

}



// Menu function for selecting the components to be tested
// Follow serial monitor for instrcutions
char menu()
{

    Serial.println(F("\nWhich component would you like to test?"));
    Serial.println(F("(1) HC - 05 Bluetooth Serial Module"));
    Serial.println(F("(menu) send anything else or press on board reset button\n
    while (!Serial.available());

    // Read data from serial monitor if received
    while (Serial.available())
    {
        char c = Serial.read();
        if (isAlphaNumeric(c))
        {

            if(c == '1')
```

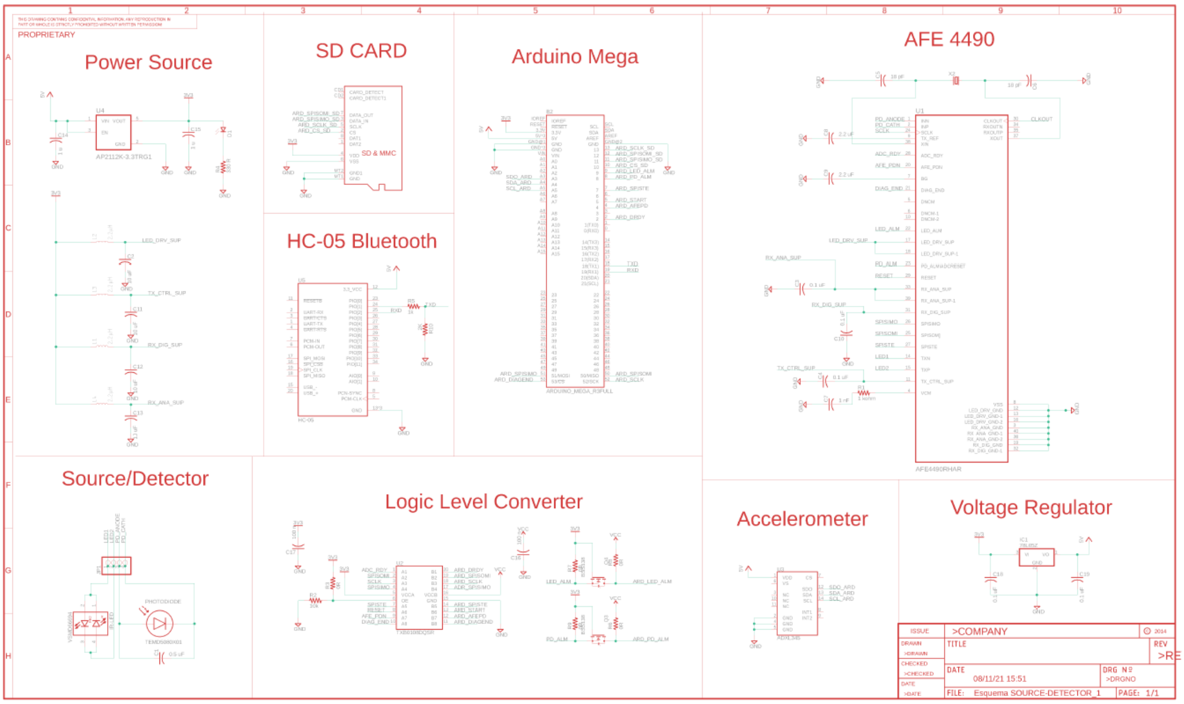
```
                Serial.println(F("Now Testing HC-05 Bluetooth Seri
            else
            {
                Serial.println(F("illegal input!"));
                return 0;
            }
            time0 = millis();
            return c;
        }
    }
}
```

A.4 AFE Code (oximeter)

```
#include <SPI.h>
#include "Protocentral_AFE4490_Oximeter.h"

const int SPISTE = 7; // chip select
const int SPIDRDY = 2; // data ready pin
const int PWDN =4;
const int DRDY_INTNUM =0;   //digital pin2 interrupt num = 0.

AFE4490 afe4490;

int32_t heart_rate_prev=0;
int32_t spo2_prev=0;

void setup()
{
   Serial.begin(57600);
   Serial.println("Intilaziting AFE44xx.. ");

   delay(2000) ;    // pause for a moment

   SPI.begin();
   SPI.setClockDivider (SPI_CLOCK_DIV8); // set Speed as 2MHz , 16MHz/ClockDiv
   SPI.setDataMode (SPI_MODE0);          //Set SPI mode as 0
   SPI.setBitOrder (MSBFIRST);           //MSB first

   afe4490.afe44xxInit (SPISTE, SPIDRDY, DRDY_INTNUM, PWDN);
   Serial.println("intilazition is done");
}

void loop()
{
  afe44xx_output_values afe4490Data;
  boolean sampled_value = afe4490.getDataIfAvailable(&afe4490Data,SPISTE);

  if(sampled_value == true)
  {
    if(afe4490Data.spo2 == -999){
```

```
      Serial.println("Probe error!!!!");
    }else if ((heart_rate_prev != afe4490Data.heart_rate) || (spo2_prev != a

      heart_rate_prev = afe4490Data.heart_rate;
      spo2_prev = afe4490Data.spo2;

      Serial.print("calculating sp02...");
      Serial.print(" Sp02 : ");
      Serial.print(afe4490Data.spo2);
      Serial.print("% ,");
      Serial.print("Pulse rate :");
      Serial.print(afe4490Data.heart_rate);
      Serial.println(" bpm");
    }
  }
}
```

A.5 Full Schematic



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