Medical Device Concept:

Sleep Apnea Implant Device

Interactiive Systems Engineering II

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***Abstract*—This electronic document presents a medical device concept for the Interactive Systems Engineering II course in which a serious medical condition is targeted. This simple designed medical device is implanted into the patient's body and cures the patient inability to breath properly during sleep. This document starts with an introduction to the medical condition which is Obstructive Sleep Apnea stating the traditional treatments followed by introducing the device concept. Then, through designing the concept, the requirements, diagrams, and models including activity and requirement diagrams are presented with some explanations. Hardware components and user interface are also defined throughout the document, concluding with a discussion and future directions.**

I. Introduction

Obstructive Sleep Apnea (OSA) is a very common and serious condition that affects millions of patients worldwide. It occurs when the muscles in the airway relax during sleep resulting in airway narrowing depriving the reach of oxygen to the brain. This condition can result in high blood pressure, strokes, heart attacks, poor performance, fatigue, and several other dangerous side effects.

The standard treatment for OSA involves wearing a mask during sleep conducting pressurized air through the nose and/or mouth to the throat. This pressure keeps the upper airway open maintaining normal breathing. However, this treatment is not relaxing as the patient faces difficulties to fall asleep in the beginning and might also cause some sort of skin irritation or wounds on the point of contact between the mask and the face.

II. Device Concept

In this document, we introduce the Sleep Apnea Implant Device, this device is designed to provide therapy through the neurostimulation (stimulation of neurons), delivering stimulation to the tongue muscles through the hypoglossal nerve resulting in an open airway during sleep. This means that no masks or any other mouth pieces are connected externally to the patient while asleep.

This device is only used while sleeping, where every time the patient takes a breath, the respiratory sensing lead detects the breathing and therefore sends a stimulation pulse through the sensing lead to the hypoglossal nerve of the tongue.

Patients are not required to always use the device or when they are awake; however, this device is only designed to being used while sleeping.

III. Designing of the Concept

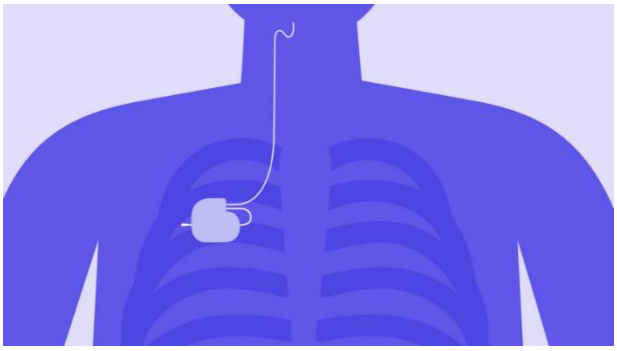

Figure 1: Implant Device Concept [1]

The Sleep Apnea Implant device is easily surgically implanted into the patient's chest with 2 to 3 incisions during an outpatient procedure (same-day surgery) done by an ENT surgeon.

A. Requirements

The device should be able to detect the patient's breathing and trigger response action by sending stimulation pulses to the hypoglossal nerve in the neck. The device should be easy to use, this means that the user should be able to interact with the

implanted device easily through a simple user interface which covers all the functions and specifications of the device.

Since this device is only used when the patient is asleep, or in other words, when the patient turns it on, the device's battery lasts up to 10 years and has a minimum lifespan of 7 years.

Moreover, this device is required to have a small Bluetooth connection stick included in the stimulator, that is responsible for the communication between the stimulator (implanted device), and the external remote control.

B. Use Case

This fully implantable device is designed mainly to treat patients with moderate or severe Obstructive Sleep Apnea who are unable to have a continuous positive airway pressure.

The system is designed to be in use only when the patient is asleep, where it can be turned on and off through a remote control.

C. Main Elements

- Obstructive Sleep Apnea (OSA) patients
- Doctors and ENT surgeons

D. Hardware Components

- Internal (Implanted):
  - a. Stimulator:

    Battery-powered device that is responsible for generating neuro stimulation pulses.

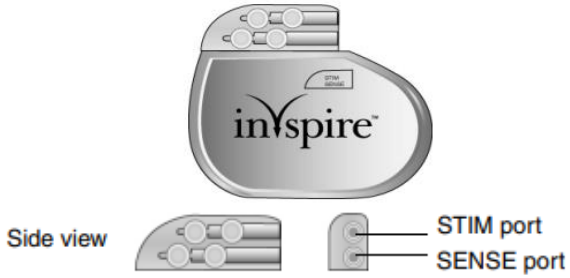

Figure 2: Implant Device (Stimulator) [2]

The stimulator has 2 connector ports which will be connected to the sensing lead and stimulation lead.

b. Stimulation lead:

A flexible lead that delivers those pulses to the hypoglossal nerve in the neck.

The stimulation lead is connected from one side to the stimulator device through the connector pin, and from the other side to the hypoglossal nerve through the self-sizing stimulation cuff.

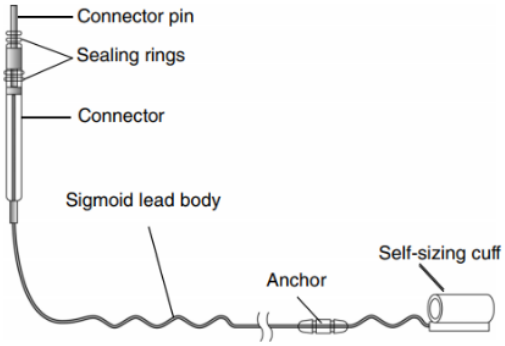

Figure 3: Stimulation Lead [2]

c. Respiratory sensing lead:

A sensor that detects the breathing of the patient.

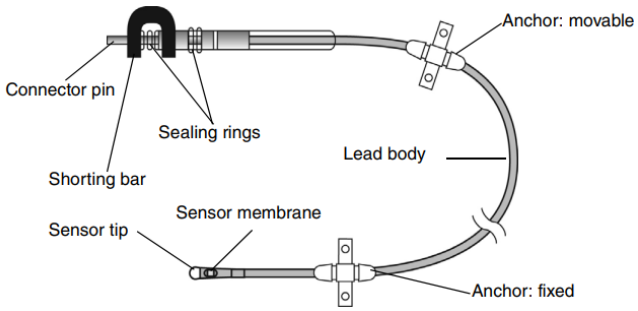

Figure 4: Respiratory Sensing Lead [2]

The lead has a pressure sensitive sensor membrane that converts the mechanical energy of respiration into an electrical signal. It is connected to the stimulator device through the connector pin from one end, and to the lungs from the other end.

d. Microcontroller (PIC18F1Q40):

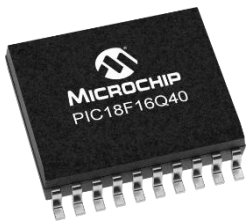

Figure 5: Microcontroller included in the Stimulator [3]

e. Bluetooth communication system:

Included in the stimulator, and inked to the remote control, the Bluetooth system is responsible for the interaction of the patient with the device.

- External:

A remote-control that allows patients to start, stop or pause the therapy (neurostimulation pulses) and increase/decrease stimulation intensity.

E. Models:

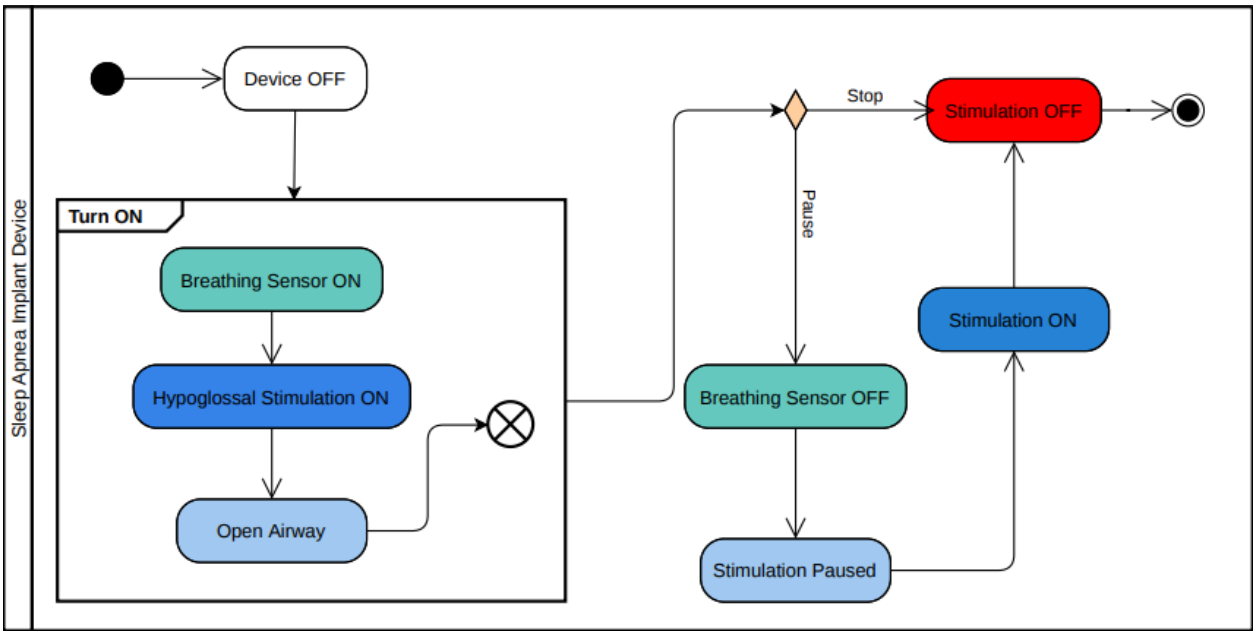

Figure 6: Activity Diagram of the Sleep Apnea Implant Device

The activity diagram shown in Figure 6 shows how the device works after it is turned on. The device keeps on sensing the patient's breath through the breathing sensor and sends stimulation pulses throughout the time the device is turned on. In other words, the device keeps on sending stimulation pulses during the time the patient is sleeping and until the patient wakes up and turns the device off.

The functional requirements part of the requirement diagram shown in Figure 7 defines the requirements of the implant device (stimulator). The device is said to detect the patient's breath through the respiratory lead that is connected to the lungs. After that the device should continuously

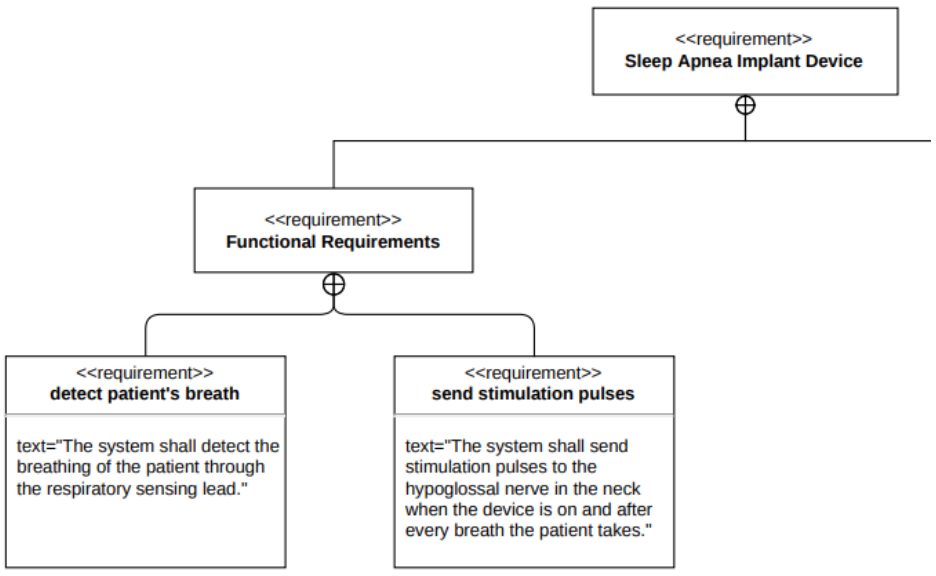

Figure 7: Functional Requirements part of the Requirement Diagram

send stimulaton pulses to the hypoglossal nerve through the stimulation lead which is connected to the device through the stimulation lead connection port.

The non-functional requirements part of the requirement diagram shown in Figure 8 describes that the user should be able to control the stimulator easily and simply. The user should be able to start/stop the therapy without any complications. Moreover the user should be able to modify the intensity of the stimulations to his desire.

preventing the blockage of the airway. This stimulation is delivered throughout the night to prevent obstructive sleep apnea.

Adding to that, there are some equipment and environments that could potentially affect the implanted medical stimulator by generating enough electromagnetic disturbance.

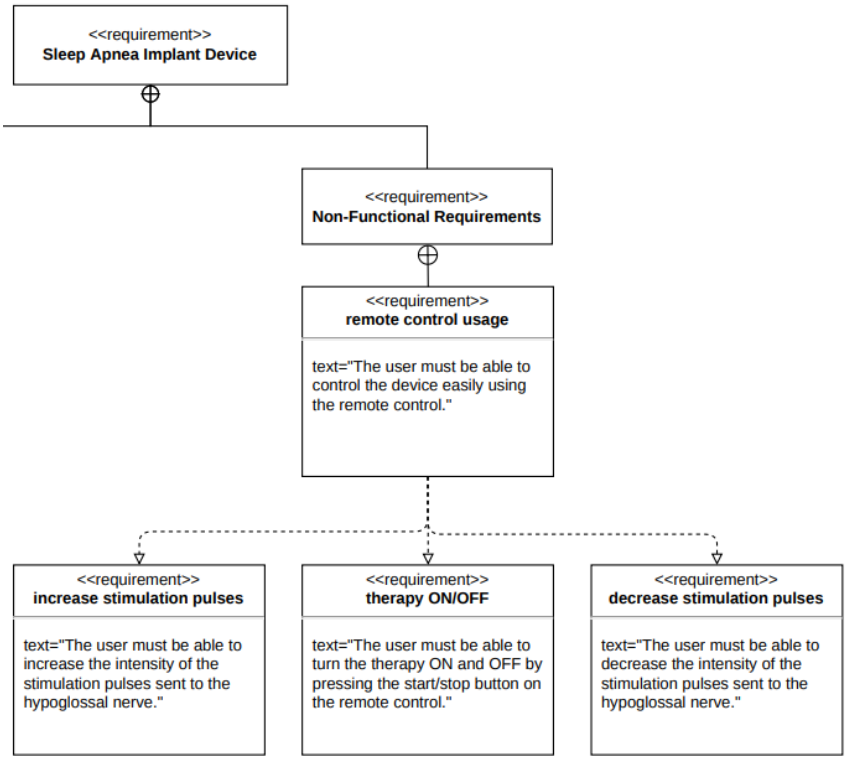

Figure 8: Non-Functional Requirements part of the Requirement Diagram

F. *Critical-based parts of the system*

The device is simply designed and consists of few components helping us achieve the goal of the device easily. As previously stated, this device is only useful when the patient of asleep, therefore it is redundant during the day and while the patient is awake.

After the device is turned on by the patient through the remote control, the patient should receive a mild stimulation confirming that the stimulation therapy has been turned on. Later, stimulation is delayed so the patient has enough time to fall asleep.

After that, the stimulation begins causing the upper airway muscles to strengthen,

It is strongly advised to avoid those environments stated below as much as possible:

- Equipment used for decreasing or eliminating magnetic fields.
- High-voltage areas
- Power amplifiers
- Microwave communication transmitters.
- Power lines or generators
- Radio transmission towers

G. *User Interface*

The patient controls the implanted device using a remote control allowing the user to start, pause and stop the therapy. Moreover, the patient can also increase or decrease the intensity of the stimulation through the plus and minus buttons on the remote. The device monitors the patient's breathing and every time the patient takes a breath, a gentle pulse moves the tongue out of the way ensuring a good night sleep.

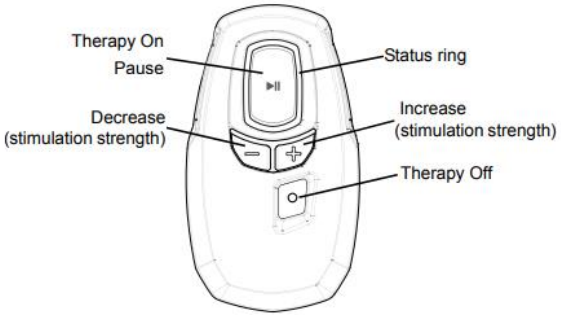

Figure 9: User Interface Remote-Control [4]

Figure 9 shows the user interface of the medical device presented in this electronic document. After turning ON the device, the status ring on the remote-control lights up green and the stimulation starts. The patient can pause the stimulation and increase or decrease the intensity of the stimulation just by the press of a button.

IV. Discussion

The Sleep Apnea Implant Device introduces a solution OSA patients await, where this device provides them a peaceful overnight sleep without the need to connect themselves to an external machine through a mask or a hose.

In the Figure 10, a representation of the mode of action of the implant device is illustrated. In the first picture we can realize that the patient is not able to take a normal breath because of the blocked airway. Then, the respiratory lead senses the patient's breath through the transformation of the mechanical energy (breath) to an electrical signal in which its processed in the stimulator and therefore sending a stimulation pulse through the stimulation lead to the nerve responsible in the neck. Finally, the stimulation of the hypoglossal nerve helps in removing the tongue out of the way thus having an open airway leading to a great sleep.

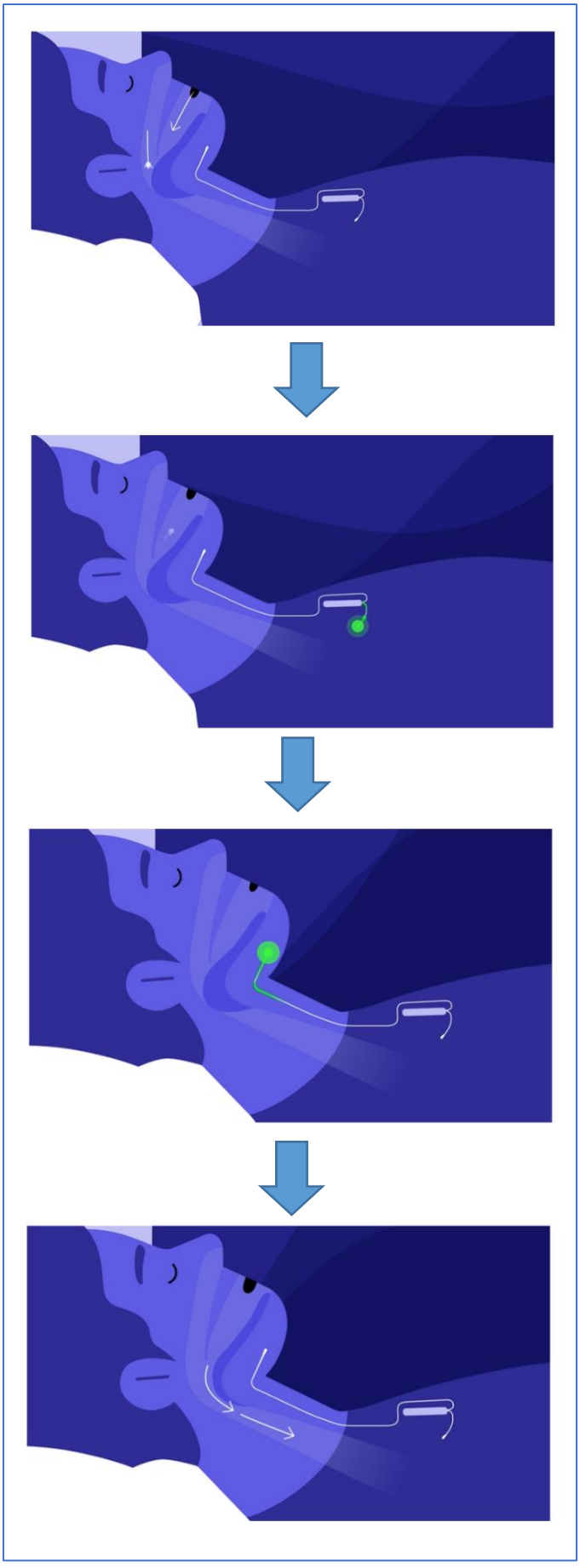

Figure 10: Representation of the Mode of Action of the Medical Device [1]

The idea I first had of this device included having a rechargeable battery, but after presenting my medical device in the exercise class, I took other colleagues' comments into consideration and performed some additional research. I decided to have all stimulator replaced when it reaches low battery. And as I have previously stated, implanting this device in the patient's chest is performed within an outpatient same day procedure, this means that replacing the device will be as easy as possible.

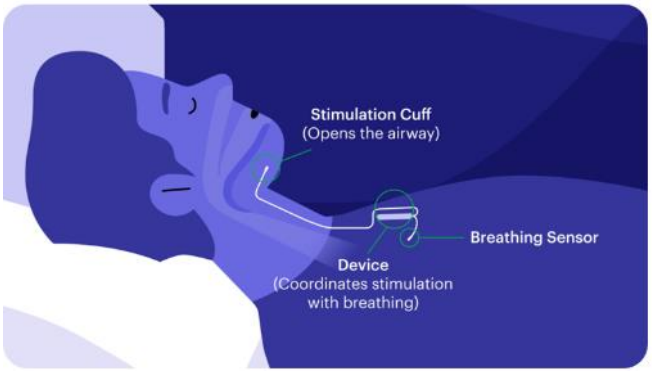

Figure 11: Functioning Components of the Implanted System [5]

V. Conclusion and Future work

A. *Overview and Main Conlclusion*

This medical device system looks and operates much like a cardiac pacemaker but instead of having action on the heart, it sends pulses to the hypoglossal nerve in the neck.

We can call it "Pacemaker for the tongue" with the goal of keeping the airway wide and open during sleep. The concept of creating a medical device that provides therapy for a serious medical condition has been successfully accomplished along with solid requirements, model and the specific hardware components needed for this medical device.

B. *Future Directions:*

The concept device presented above, takes us to another form of discovering and updating our technological advancements in the field of medical therapy.

It is possible to upgrade this implanted device in the future by:

1. Implementing a sleep schedule connected with the patient's health app on the smartphone, into the implanted device in which the neurostimulation therapy will start automatically at the desired patient's bedtime. By doing that we can improve the user experience design with our medical device.
2. Improved design in which the battery can be rechargeable in a way or another.

VI. References

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