Requirements Document

The Light Amplifying Signal Sensing Object

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Prepared By:	Dundee iGEM 2014
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1 Introduction

1.1 Project Description

1.1.1 Perspective and Intended Use

Current techniques for determining lung infections in Cystic Fibrosis patients focus on investigating pathogenicbacterial load through laborious lab procedures that take between 72 hours to 2 weeks. The aim of the L.A.S.S.O is to work alongside a synthetically developed strain of *Escherichia coli* which can detect and report the presence of signaling molecules from bacteria in one hour. The *E. coli* will produce bioluminescence in the presence of certain bacteria; the L.A.S.S.O. can read the light level to give a quantitative reading of the bacteria present.

1.1.2 Functionality

The L.A.S.S.O. will be able to give the user a quantitative display of the load of a specific pathogenic bacterium in a sputum sample. This will consist of the user inserting a plate consisting of genetically modified *E.coli* and a sample of sputum**.** The *E.coli* will produce bioluminescence if a molecule produced by the pathogenic bacteria is present in the sputum sample. The L.A.S.S.O. will detect this light using a photodiode, the voltage produced by the diode is then passed through an amplifying circuit. The amplified voltage is then passed to an Arduino Uno™ which is connected to the users computer. The user will have a companion application installed on their computer: the L.A.S.S.O. interface. The application will communicate with the Arduino and be able to record the voltages. Once the L.A.S.S.O. interface has received this value it will compare it to a reference reading taken before the sample was inserted. The difference between these two readings is referenced against voltage ranges for given concentrations of bioluminescent output. Once the reading is complete the user will use a plunger to move the sample from the main compartment to a connected “bin” which will store multiple used samples before it needs to be emptied.

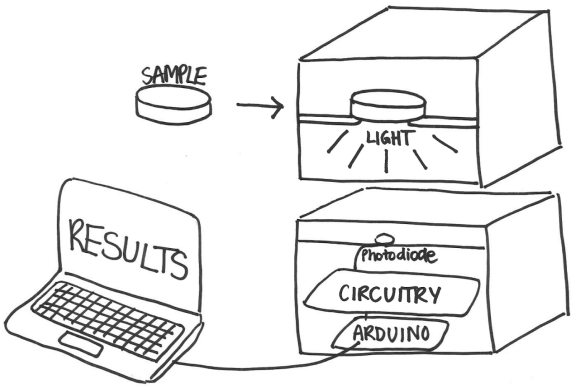

Fig 1: Basic functionality of L.A.S.S.O.

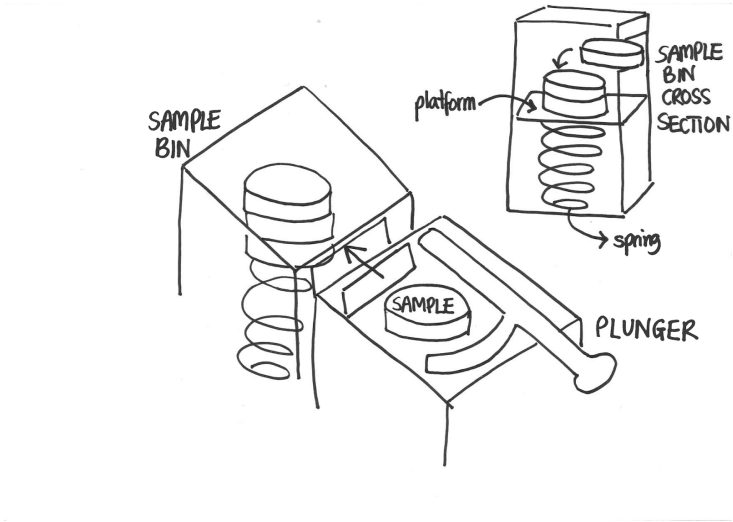

Fig 2: Moving of sample from main compartment to the waste bin

1.1.3 Users

The L.A.S.S.O. will be used by medical staff on home visits to CF patients or medical professionals within CF clinics. It could also be used by patients themselves.

1.2 Points of Contact

1.2.1 Project supervisors - Dr. Fordyce Davidson, Prof. Tracy Palmer, Prof. Frank Sargent

1.2.2 Development team - Dundee iGEM 2014

1.2.3 User - Ninewells Cystic Fibrosis Clinic

2. Requirements Specification

2.1 Functional Requirements

Category	#	Requirement	Comment	Date Reviewed
Reading	**2.1.1.1**	Light level shall be read from various *E. coli* samples.		
Quantifying Bacterial Load	**2.1.2.1**	The L.A.S.S.O. shall test for the presence of *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia* and *Burkholderia cenocepacia*.		
	2.1.2.2	By using methods of averaging with relation to the mean value theorem the device shall obtain stable results.		
	2.1.2.3	Comparing the voltage produced by a *E. coli* sample with known voltages generated by specific bacteria concentrations it shall be possible to quantify the amount of bacteria present in the sample.		
	2.1.2.4	The final voltage from the L.A.S.S.O. shall be mapped to a low, medium and high concentration bacterial loads.		
Power	**2.1.3.1**	The L.A.S.S.O. shall be battery powered.		
	2.1.3.2	The batteries shall be rechargeable.		
	2.1.3.3	Batteries shall be located externally with regards to the device in case of damage (eg. leakage).		

Safety	**2.1.4.1**	The L.A.S.S.O. shall be safe to use within a clinic or patients home.		
	2.1.4.2	The genetically engineered *E. coli* shall never come into direct contact with the user.		
	2.1.4.3	The waste compartment shall provide an additional safety measure in the form of isolated storage for used plates.		
	2.1.4.4	The circuitry of the L.A.S.S.O. shall be in a separate compartment to the *E. coli.*		
Certification	**2.1.5.1**	The L.A.S.S.O. shall pass appropriate medical device certification.		
Ergonometrics	**2.1.6.1**	The L.A.S.S.O. shall be compact and light.		
	2.1.6.2	The L.A.S.S.O. shall be stackable within the trolleys of medical staff.		
	2.1.6.3	The L.A.S.S.O. shall contain the sample, electronics and waste compartment in separate sections to enable technicians easy access to each part for repair and maintenance purposes.		
	2.1.6.4	The L.A.S.S.O. shall be easily assembled from its constitutive parts.		
Aesthetics	**2.1.7.1**	The L.A.S.S.O. exterior shall be light absorbing to cut out light interference with the photodiode.		

Computer Application Graphical User Interface (GUI)	**2.1.8.1**	The application shall display the bacterial load infection results to the user.		
	2.1.8.2	The application shall be user friendly and simple to use.		
	2.1.8.3	The application shall introduce the user to the functionality of the device with step-by-step instructions.		
	2.1.8.4	The application shall run on computers with a Windows operating system.		
Email	**2.1.9.1**	An email shall be sent to the clinic staff with the test results.		
	2.1.9.2	The email will be programmatically written and automatically sent.		

2.2 Non-functional Requirements

Category	#	Requirement	Comment	Date Reviewed
Quantifying	**2.2.1.1**	The mean value of the results shall be within a 20% range of the upper and lower bounds of the data series.		
	2.2.1.2	Output voltages produced by the L.A.S.S.O. shall be mapped to corresponding concentrations of luciferase produced by the *E. coli* in order to create voltage ranges for low, medium and high concentrations of bacterial load.		
Power	**2.2.2.1**	The L.A.S.S.O. shall be supplied with external battery power at 9V.		
Aesthetics	**2.2.3.1**	The coating of the exterior shall reduce ambient light levels by a minimum of 80%.		

Computer Application Graphical User Interface (GUI)	**2.2.4.1**	The language used in the product will be English.		
	2.2.4.2	The user will interact with the application via a graphical user interface		
Safety	**2.2.5.1**	The L.A.S.S.O. shall be serviced every 6 months.		