P10044 Fluid Smart LAP-BAND III

Test Plans & Test Results

By: Gabrielle Bartlett
Adam Clark
Jimmy Mounnarat
Oyuna Myagmar
Joseph Sisson
Yonathan Tulu
Albert Sze

Table of contents

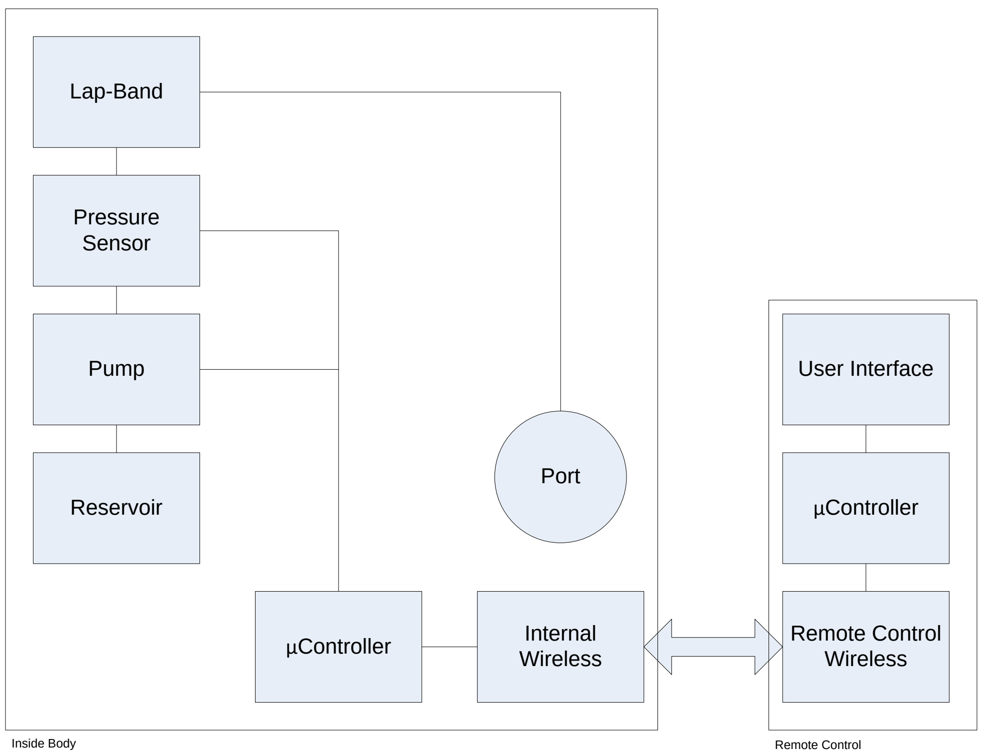
1. MSD I: WKS 8-10 PRELIMINARY TEST PLAN

1.1. Project Overview

1.1.1. The current method of adjusting the LAP-BAND Adjustable Gastric Banding System is an invasive and possibly painful procedure for the patient. This project aims to design a LAP-BAND that will be adjustable via non-invasive means. Some major goals of this project are to design a suitable pumping system, devise a closed loop control scheme, and create fail-safes to insure patient safety.

1.2. Project Sub-Systems

1.2.1. Functional Decomposition



1.2.2. The primary objective of this project is to automate the process by which fluid is added to and removed from the LAP-BAND system. This will be done using a peristaltic pump in order to adjust stomach constriction per doctor requirements. A pressure sensor located on the tubing between the pump and the LAP-BAND will be used to relay information to the doctor for accurate adjustments. The microcontroller works in unison with the other components to monitor the system for leaks. The doctor will make adjustments using a wireless remote interface to communicate with the entire system.

1.3. Approval; Guide; Sponsor

Approved by:

Team Members – Gabrielle Bartlett, Adam Clark, Jimmy Mounnarat, Oyuna Myagmar, Joseph Sisson, Albert Sze, Yonathan Tulu

Guide – Professor George Slack

Sponsor – QUANTUM Technology Associates, Inc.

1.4. Specifications

1.4.1. Product Specifications, Block Diagram, and Pass/ Fail Criteria

Revision #: 10

Engr. Spec. #	Importance	Source	Specification (description)	Unit of Measure	Marginal Value
ES1	2	CN9	Battery life	Years	5
ES2	2	CN9	Longevity	Years	5
ES3	1	CN13	Wireless Range - reach outside body	cm	0.5
ES4	3	CN3	Pump fail safe	Kpa	62.05-68.9
ES5	2	CN10	Reservoir volume	cc	4-7
ES6	2	CN15	Time constraint	cc/min	0.25
ES7	2	CN9	Number of adjustments	--	6
ES8	2	CN15	CC's per adjustment	cc	.25-1
ES9	2	CN4	Collapsing of material		feature
ES10	3	CN3	Moisture contamination	g/m^3	
ES11	1	CN8	Leakage fail safe	pascal	

Refer to 1.2.1 for block diagram of system.

The system must be able to meet targets specified above on pressure, fluid volume accuracy, power draw, and fail safe detection.

1.4.2. Functions (hardware) and Features (software, customer needs)

The system consists of the LAP-BAND, peristaltic pump head driven by motor with an encoder to drive the pump and give feedback to controller board on position of motor shaft and a controller board that coordinates all of the parts for easy operation. The motor will be controlled by a remote interface via wireless communication.

Customer requested easy control, small package size, long lifespan, and high precision.

1.4.3. Test Equipment available:

Test stand/Synthetic Stomach from P09042
Takasgo miniature pump and motor
From P09043:
- Prototype Fluid Smart LAP-BAND
- DC Gear motor with integrated encoder
- Peristaltic pump head
- OMEGA Pressure Sensor
- Controller board
- Agilent Logic Analyzer

1.4.4. Test Plan

1.4.4.1. Component/ Subsystem Testing

1.4.4.2. Motor

The motor will be tested by applying voltage in both directions in order to check for proper operation.

1.4.4.3. Pump

The pump will be tested by using the motor supplied by the pump supplier and will be pressure and flow rate tested.

1.4.4.4. Wireless/ Microcontroller

The wireless capabilities will be tested in unison with the microcontroller using a development kit to ensure that it is able to effectively communicate through the simulated skin.

1.4.4.5. Power

The battery/ power to support the system will be tested by applying the theoretical impedance and current draw. In addition, each component will be tested for power consumption.

1.4.4.6. Remote

The remote will be tested using a demo program to determine its usability by multiple users.

1.4.4.7. Reservoir

The reservoir will be pressure tested for leaks and proper operation. The volume will be checked if it is 12 milliliter.

1.4.4.8. Pressure Sensor

The pressure sensor will be used to determine if there is a leak in the system by taking average readings of the analog voltage and comparing it to pervious values.

1.5. Important Terminology

1.5.1. Pump refers to peristaltic type pump with 4 rollers, fixed volume output per revolution.

1.5.2. Controller board refers to collection of semiconductor devices that accepts inputs (pressure sensor), outputs power to pumping system, and displays fluid pressure and volume pumped**.**

1.5.3. Wireless refers to the wireless communication between the microcontroller and the remote.

1.5.4. Remote refers to the remote user interface between the doctor and the system.

1.5.5. Reservoir refers to the enclosure that holds the excess fluid needed to make the adjustments to the LAP-BAND.

2. MSD II WKS 2-4: - FINAL TEST PLAN

2.1. Data Collection Plan; Sampling Plan

2.1.1. Final Test Plan

Component and Subsystem testing will be broken down into several stages to test each component.

2.1.1.1. Control System Test Plan

Purpose:
Pressure, speed and pressure at which the pump head leaks will be tested to ensure components meet specifications.

Items Needed:
Controller board
Pump Head
Gear motor with encoder
-30 in Hg to 20 psi pressure gauge
0-60 psi pressure gauge
Modified water bottle
HP power supplies

Test plan:

1. Power consumption: Monitor pumping system power draw during operation. If power exceeds maximum allowable by driver design, fail driver voltage regulators, replace with higher power devices.

2. Accuracy of volume pumped: Inflate LAP-BAND, measure fluid pumped and compare to value controller board gives for fluid pumped. If accuracy is >0.5% average, adjust formula used by controller board to determine the amount of fluid that has been pumped based from the encoder input signal.

3. Accuracy of time the specific volume is pumped: Enter values into the remote control. Verify that system has pumped specified amount of fluid as well as measure the time. If not, revisit test 2, or check control code.

2.1.1.2. Power Consumption Test

Purpose
This test will determine the system life when connected to the selected power supply.

Items Needed
Multimeter
Oscilloscope
Battery
HP Power Supply

Test Plan:
1. The fully functional system will be connected to a power supply and the power consumption of each component and the overall system will be characterized. This will give us a time line of how long the system will be able to run when powered.
2. Then this will be converted to a number of adjustments that the system will be able to make by dividing the total run time of the system by the average time it should take to make an adjustment.
3. For a final verification, the system will be run continuously until it stops due to loss of power.

2.1.1.3. Wireless Communication System Test Plan

Purpose:
The communication scheme will be tested to verify that it is able to provide low latency, low error rate, and high data rate trough the simulated skin. The signal to noise ratio and the bit error rate will be derived to determine they are within specifications.

Items Needed:
CC430 SoC with RF module Developer Kit
Simulated Human Skin
Logic Analyzer

Test plan:
1. A test pattern will be generated using the development kit and it will be transmitted using the transmitter. The unit under testing will be encased with the simulated skin and the data it receives will be compared with the test pattern generated.

2. Error will be introduced to determine the error checking capability of the protocol used by connecting the transmitter and receiver to a logic analyzer, while generating the test pattern with the development kit, along with the error to be inserted. The error correction scheme will also be analyzed to determine if it introduces high latency.

2.1.1.4. Remote Control System Test Plan

Purpose:
The full functionality of the remote control system will be tested to verify functionality, with each individual component tested at first and all together to validate integration.

Items Needed:
Arduino Duemilanove
CC1111EMK868-915 Evaluation Module Kit
LCD and buttons
FTDI chip

Test plan:
1. Power and plug into USB slot of a computer with the proper drivers and software to make sure the communication, programming and software works. Create some simple programs like making the LEDs flash.
2. Plug the CC1111 Evaluation Module Kit as specified by the design (using the specified layout on a breadboard and especially paying attention to pin connections) into the FTDI chip that connects to the Arduino Duemilanove. Use the CC1111 and FTDI chip datasheets and the Simpliciti protocol to program wireless functionality to the hardware.
3. Plug into Arduino board and use serial communication to test functionality. Program Arduino to print simple text. Next program to show last button pressed. Test to see how much current is being drawn.
4. Plug into Arduino board and plug a flash drive formatted in FAT. Use libraries and examples to program Arduino to access and write to the flash drive.
5. Plug everything into the Arduino Duemilanove to see if there is enough pins. Test functionally to see if the battery can power the entire remote. Write a program that simulates the workflow, simulating wireless communication with the LAP-BAND.

2.1.1.5. Electronic Waterproofing Test Plan

Purpose
To determine that a waterproof encapsulation of the electronics is capable.

Items Needed
Piece of cardboard
Water
Container
Liquid Electrical tape
Tissue Paper

Test Plan
1. Cut the piece of cardboard to approximate size of the electronics
2. Cover the cut piece of cardboard with tissue paper
3. Use the liquid electrical tape to encapsulate the cardboard in the same manner the electronics will be encapsulated
4. Let the liquid electrical tape harden
5. Submerge the cardboard in water for a period of 3 days
6. After 3 days, remove the cardboard from water and inspect for any places water penetrated the encapsulation
7. If leaks occurred, repeat steps 1 – 6 to attempt to successful create waterproof encapsulation

2.1.1.6. Reservoir Test Plan

Purpose:
To ensure that under slightly extreme conditions that reservoir will be able to with stand an excessive amount of water with breaking or leaking. As well as ensure that the reservoir will not collapse on itself and cause plugging of the tube.

Items Needed:
Reservoir
Syringe
Water
Pump (Old or New – new would be preferable)
Plug/Stopper for reservoir
Container

Test plan:

Leaking:

1. Place maximum amount of water into the reservoir, which should be 12 cc (12 mL). Than place an additional 2-4 cc (2-4 mL) of water into the reservoir and seal off using the plug.
2. The reservoir will then be left alone for approximately one week in the designated container.
3. After the one week period observations of the reservoir will be made, any tearing or leaks will be noted as well as the locations. If there is water in the container the volume will be measured to see the total of water lost.

Collapsing:

1. The maximum amount of water will be placed in the reservoir which will then be attached to a pump.
2. The water will be drawn out until the reservoir is completely empty and check that the reservoir is still intact and hasn't collapsed.

2.1.1.7. Takasago Motor Flow Characteristics Test Plan

Purpose

To simulate/observe the incremental fluid flow of the pump/motor.

Items Needed

Saline (water)
2 Beakers
Pump/Motor
Timer

Test Plan

1. Measure 20 mL of water and fill into one beaker.
2. Connect the pump/motor to appropriate silicone tubing and insert one end of the tubing into the beaker of water.
3. Position the second beaker (empty of contents) to the side with the other silicone tubing discharging into this beaker.
4. Create an H-bridge to power the pump/motor and connect only positive power supply wire to pump/motor – do not connect ground wire.
5. Make incremental adjustments to the pump/motor by connecting ground wire and disconnecting.
6. Time each incremental adjustment of the pump/motor to correlate which time will be needed to meet the 0.25cc of fluid flow.
7. Document corresponding fluid in the discharging beaker to correspond with each incremental adjustment.

2.1.1.8. Flow rate vs. Pressure Test Plan

Purpose
To create Flow Rate vs. Pressure characteristic curve.

Items Needed
Synthetic Stomach
Saline (water)
Beaker
Funnel
Pressure sensor
Timer
Test Stand

Test Plan
1. Place the LAP-BAND around synthetic stomach using the test stand from Phase I.
2. Connect the pressure sensor to the LAP-BAND and set the pressure constant and record the pressure.
3. Put the funnel on top of the synthetic stomach.
4. Position the funnel underneath the synthetic stomach.
5. Measure 20 mL of water.
6. Pour water through funnel.
7. Start timing as soon as water goes through the synthetic stomach.
8. Stop the timer and record the time.

2.1.2. **Specification Testing**

ES1. Battery Life – See 2.1.1.2 for detailed explanation

ES2. Heat Dissipation – Laser thermometer will be used to measure the surface temperature of the electronics during use.

ES3. Longevity – test for one week.

ES4. Wireless Range – See 2.1.1.3

ES5. Pump Fail Safe -

ES6. Reservoir Volume – See 2.1.1.6

ES7. Time-Constraint – See 2.1.1.1

ES8. Number of Adjustment – feature

ES9. Adjustment Flow Rate – See 2.1.1.1 (2)

ES10. Moisture Contamination - See 2.1.1.5

ES11. Leakage Fail Safe – See 2.1.1.6

2.2. Work Breakdown Structure

2.2.1. Electrical tests:

The two electrical engineers and computer engineer on the team are responsible for checking functionality of the control subsystem, and make sure that the control subsystem and pumping subsystem integrate properly.

2.2.2. Mechanical tests:

The three mechanical engineers and industrial engineer on the team will be responsible for testing all mechanical related tests.

2.3. Assumptions

Fluid Properties: Assume that saline solution used in final system has similar properties to the tap water used in testing (ie: viscosity, density, compressibility, etc.)

3. MSD II – WKS 3-10 DESIGN TEST VERIFICATION

3.1. Logistics and Documentation

Testing is being logged in excel, with results saved onto EDGE in the MSD II section on the main page. Documentation of progress on project design and assembly is recorded in the MSD logbooks.

3.2. Definition of a Successful Test

A successful test is one that meets the minimum requirements stated in the test. If requirements or specifications are not met, the component being tested is considered a failure, and must be revised.