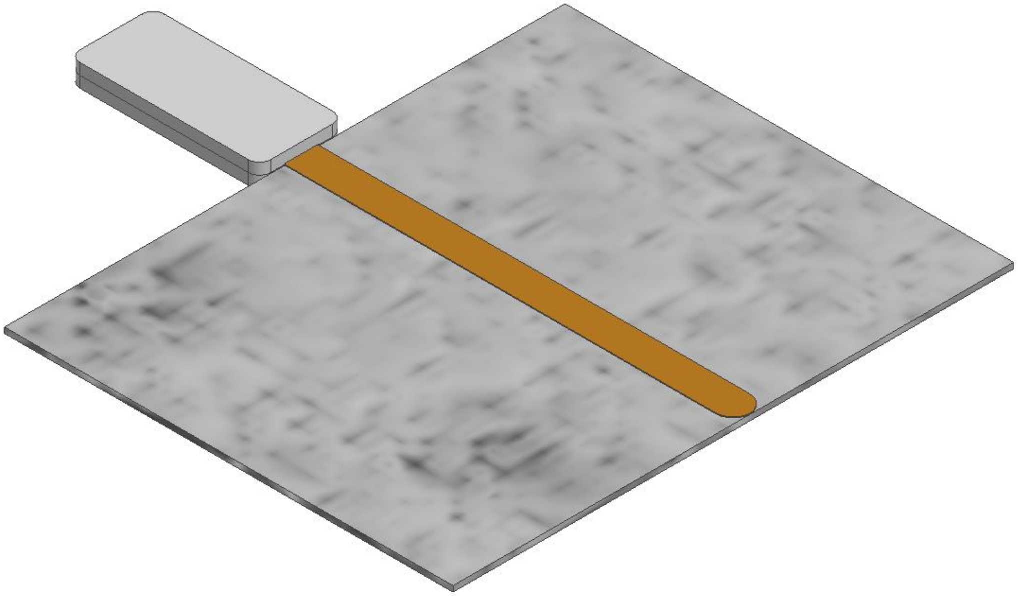
Smart Bandage

Wound Monitoring through a Connected Smart Bandage

Group 1

Michael Blouin, Jenna Hatchard, Jared Cuglietta



ECE 492 Capstone Final Report

ABSTRACT

The Smart Bandage began with the goal of improving the healing process for in-home care of wounds. By allowing medical professionals to monitor a wound remotely, significant cost savings may be achieved over the current method of daily homecare by a health care professional. The project achieved a working Communications Module, Bandage Module, Android Application, and Web Application that were able to successfully relay and display temperature, moisture, and humidity data from the bandage. The bandage device had properly functioning battery management, power regulation, input multiplexing, Bluetooth communication, and low-battery shutdown features. The web application also expanded on its original premise to implement a user and patient management system, with alerts shown to Nurses on login.

TABLE OF CONTENTS

1 Functional Requirements 6
1.1 Backup and Contingency Plans 6
1.1.1 CC2640 Programming/Operation Problems 6
2 Design and Description of Operation 7
2.1 Communication Module 7
2.1.1 Bandage Module 7
2.2 Android Application 7
2.3 Web Application 7
2.4 System Block Diagram 8
2.5 Algorithms 8
2.5.1 Moisture Detection Algorithm 8
2.5.2 Algorithm for Detecting Erroneous Data Points 8
2.5.3 Data Storage Algorithm 8
3 Hardware Requirements 8
3.1 Processor Speed 8
3.2 Battery Duration 9
3.3 Data Storage 9
4 Bill of Materials 9
5 Available Source 10
5.1 Lithium Ion Charge Management and Gas Gauge Circuit Design 10
5.2 TI-RTOS and CC2640 Bluetooth Low Energy Software Stack 10
6 IO Signals 10
7 Background research 11
7.1 Pain Threshold 11
7.2 Ideal Wound Moisture 11
7.3 Other Background Research 11
7.4 PCB Trace Antennas 11
8 Software Design 12
9 Test Plan 15
9.1 Software 15
9.1.1 Communications Module State Machine 15
9.1.2 Android Application 15
9.1.3 Web Server 15
9.2 Hardware 15
9.2.1 Communications Module 15
9.2.2 Bandage Module 15
10 Results of Experiments 16

10.1 Bluetooth Communication Test 16
10.2 Moisture Sensing Grid 16
11 Safety Considerations 16
11.1 Moisture Sensor 16
11.2 Flexible Printed Circuit 16
11.3 Maximum Power 16
12 Regulatory and Society 17
12.1 RF Emissions Certification 17
12.2 Medically Inert Materials 17
12.3 Solder-Free Process 17
12.4 Handling of Medical Data & Class II Medical Device Certification 17
13 Printed Circuit Board Design 18
13.1 Schematic 18
13.2 Communications Module Top and Bottom Boards 19
14 Environmental Impact 20
15 Sustainability 20
16 Future Work 21
16.1 Automatic Notifications 21
16.2 Patient Notifications 21
16.3 Inductive Charging 21
16.4 pH Sensing 21
16.5 Web Application Security and Improvements 21
16.6 BLE Antenna Interference Issues 21
17 References 23
18 Appendix 25
18.1 Appendix α: Hardware Documentation 25
18.2 Appendix β: Source Code 26
18.3 Appendix A: U.S. Government Export Approval for TI BLE Stack 27
18.4 Appendix B: I2C Bus Capacitance Estimation 28
18.5 Appendix C: Moisture Sensing Grid Schematic 29
18.5.1 Appendix C.1: Verification of ADC Parameters 29
18.5.2 Appendix C.2: Selection of Limiting/Sensing Resistor 29
18.5.3 Appendix C.3: Moisture Sensor Diagram 30
18.5.4 Appendix C.4: Algorithm for Determining Region Moisture Content 31
18.6 Appendix D: Smart Bandage Conceptual Models 32
18.6.1 Appendix D.1: Assembled Smart Bandage, Communications Module, and Bandage Module 32
18.6.2 Appendix D.2: Exploded Smart Bandage, Communications Module, and Bandage Module 32
18.6.3 Appendix D.3: Communications Module Dimensions 33

18.7 Appendix E: Battery and Power Management Schematic 33
18.7.1 Appendix E.1: Battery Management Schematic 33
18.7.2 Appendix E.2: Voltage Regulation 34
18.8 Appendix F: Energy Estimation 36
18.9 Appendix G: Storage Capacity Estimation 37

1 FUNCTIONAL REQUIREMENTS

Functional requirements are listed in the table below. The requirements are prioritized in such a way that completing only P1 requirements will result in a complete demo-able result. P2 items are considered ideal to have for project completion, and P3 items are those that add flair and UX.

Note on the Success column: Items marked 'Y' without a note are unequivocally functional. Items with a note may have limited functionality, or may have been adjusted but otherwise implemented. See the note below the table for information.

#	Requirement	Priority	Success
1	The Communication Module can read temperature data.	1	Y
2	The Communication Module can read humidity data.	1	Y
3	The Communication Module can generate a moisture map of the bandage.	3	Y (1)
4	The Communication Module can send real-time data over BLE.	1	Y (2)
5	The Communication Module can keep limited historical data and send it over BLE.	2	Y
6	The Communication Module can detect alert conditions.	2	Y (3)
7	The Communication Module can detect bandage module failures.	2	Y
8	The Android App can communicate with the Communication Module over BLE.	1	Y (2)
9	The Android app can store data in a local persistent cache.	2	Y
10	The Android app can relay data to the web server.	2	Y
11	The web server can store data.	3	Y
12	The web server can graph data.	3	Y

Notes:

1. *While the moisture detection did in general work, no significant testing was performed to determine the accuracy of detection. Furthermore, some difficulties were encountered with achieving good electrical connections with the bandage module.*
2. *Bluetooth communication worked properly most of the time, however it was susceptible to interference in the lab. This problem may be avoided in the future through the use of a higher gain antenna configuration.*
3. *Alert condition checking was implemented; however, the functionality was moved to the web application as the module has no means of alerting users of problems. Alerts are generated in the web application and shown on login.*

1.1 BACKUP AND CONTINGENCY PLANS

1.1.1 CC2640 Programming/Operation Problems

In the event that the on-board CC2640 [4] does not function as expected, or the PCB has significant problems the group has budgeted to purchase a TI Launchpad [5] containing the TI CC2640 which is code-compatible and provides a complete development platform out of the box such that *the entire project can be run on it without custom PCBs* (foregoing the small integrated solution and battery operation).

2 DESIGN AND DESCRIPTION OF OPERATION

The proposed system consists of three main components: the Communication and Bandage Modules, an Android Application, and a Web Application.

2.1 COMMUNICATION MODULE

The communication module attaches to the disposable bandage module, and monitors, stores, and relays data from the sensors on the bandage module to the Android Application.

The module is based on a TI CC2640 MCU with integrated Bluetooth Low Energy (BLE) support [4]. The CC2640 device, Bluetooth antenna, and supporting circuitry are hosted on the LSR SaBLE-x module [6] so as to eliminate the need to create a performant Bluetooth antenna design. Also present on the module will be a 110mAh Li-Ion battery [7], a TI Li-Ion charge management IC [8], a Li-Ion gas gauge IC [9], a buck/boost converter for providing a consistent 3.3V V_{cc} [3] (these circuits detailed in Appendix D), and the detection circuit for the wound moisture sensing grid (described in Appendix C).

The communication module will require a board-to-board adapter for the bandage module, and a micro USB adapter for charging.

2.1.1 Bandage Module

The bandage module is a 10cm long flexible printed circuit (FPC) designed to be sewn into a bandage. It hosts one HDC1050 Humidity and Temperature sensor [10], and three MCP9808 Temperature sensors [11], all communicating over I2C. The module also hosts connectors for the wound moisture detection grid (described in Appendix C).

2.2 ANDROID APPLICATION

The android application will receive data from the communication module via Bluetooth Low Energy (BLE). The application will then relay the information collected by the sensors to the web application.

2.3 WEB APPLICATION

The web application is responsible for long term storage, computation and visualization of bandage sensor data relayed by the android application for Nurses and other medical personnel. Data from the bandage will be stored in an SQL database and visualized with charting web technologies based on HTML, Javascript and CSS.

2.4 SYSTEM BLOCK DIAGRAM

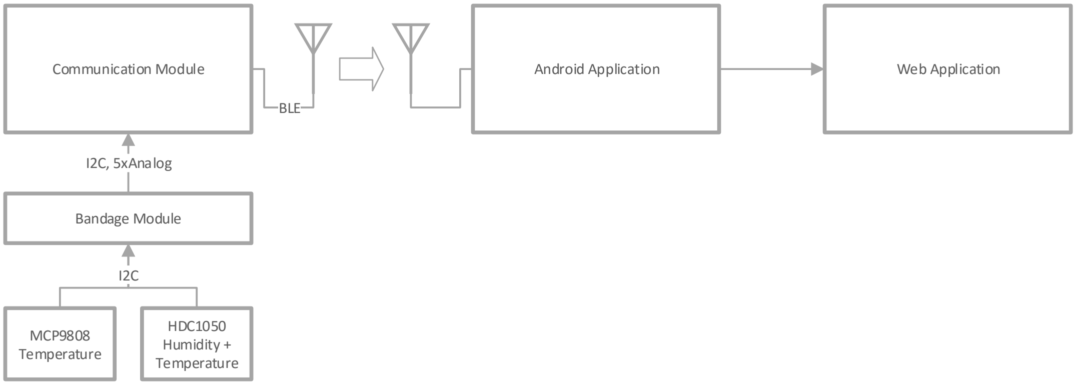


Figure 1: System Block Diagram

2.5 ALGORITHMS

2.5.1 Moisture Detection Algorithm

The moisture detection algorithm is based on the range calculation: $m_L \leq m \leq m_H$, where $m_L \; and \; m_H$ represent the upper and lower bounds of the acceptable level of moisture in the wound. Moisture contents that lie outside of these values will cause an alert to be sent to the android, and subsequently, web applications. For the mechanism and algorithm used to determine moisture content, see Appendix C, specifically Appendix C.4.

2.5.2 Algorithm for Detecting Erroneous Data Points

The detection of erroneous data points is modelled similarly to the moisture detection algorithm. By using reasonable skin temperatures and moisture levels for upper and lower bounds for the algorithm, erroneous temperature readings and moisture content readings will be not be alerted. A differential change in temperature (ΔT) or moisture(Δm) greater than a threshold value $(T_{th} \; and \; m_{th})$ respectively would also not cause an alert.

2.5.3 Data Storage Algorithm

For the intended application of wound monitoring, the optimal time interval for data collect is approximately three to four hours This is due to the fact that no significant changes in a wound occurs in less than the aforementioned time window that would cause need for alert. This reduces the amount of records that are stored on the Bluetooth modules persistent storage. The setup and storage capacity far exceeds the need for an algorithm to handle more data than the device can hold. In the event, that the storage is filled on the device, it was decided upon that records that fall within normal conditions for wound healing will be replaced by newer records.

3 HARDWARE REQUIREMENTS

3.1 PROCESSOR SPEED

Because the MCU will spend the vast majority of its time asleep, as it has very few calculations to perform, processor speed (in MHz) is only a constraining factor for calculating battery life. (See 4.2)

3.2 BATTERY DURATION

Given some estimations for the amount of time the MCU will likely spend awake (per hour) we computed a battery duration of 157 hours, or 6.6 days on the 110mAh battery (See Appendix F for calculations on the Energy estimation).

3.3 DATA STORAGE

The MCU has built in 20Kb SRAM memory and can store up to 465 (See Appendix G for storage capacity estimation calculations) sensor readings containing 4 temperature sensors, 5 moisture sensors, and one humidity sensor while disconnected from the phone. The estimated battery life for the Smart Bandage sensor was calculated to be approximately 157 hours or 6.5 days. Ideally, the sensor would not be disconnected for periods longer than 24 hours. In such a case where the smart bandage module is not paired with the android device, data will be collected at least once every 3 hours, or whenever an interesting data point is found. In the case where an interesting data point is collected, a new data point will be collected every 3 hours from the last interesting data point. Given the data collection interval of one record every 3 hours, this means that there are 8 collection periods per day. Furthermore, with the ability of the SRAM to store 465 records, the smart bandage module can continue to collect data for 58 days without connecting to the android application. With a battery life of 6.5 days, there will be more than enough storage for data collection.

4 BILL OF MATERIALS

The following bill of materials contains parts in sufficient quantity to produce two fully functional copies of each of the bandage module and communication module.

Part	Digikey PN	QTY	Unit Price	Total
TI CC2640	296-41981-1-ND	2	$ 10.95	$ 21.90
Flexible Printed Circuit Board (10 Copies)		1	$ 90.00	$ 90.00
Main board PCB (10 Copies)		1	$ 25.00	$ 25.00
Shipping from China for PCBs		1	$ 18.00	$ 18.00
MCP9808 Temperature Sensor	MCP9808T-E/MSCT-ND	4	$ 1.69	$ 6.76
HDC1050DMBR Humidity + Temperature Sensor	296-42616-1-ND	2	$ 4.46	$ 8.92
Solder Stencils (oshstencils.com)		1	$ 15.00	$ 15.00
BQ24075 Li-Ion Charge/PWR MGMT IC	296-25609-1-ND	2	$ 3.48	$ 6.96
STC3115 IC Gas Gauge	497-15077-1-ND	2	$ 4.02	$ 8.04
TPS63031 Buck/Boost Converter	296-39461-1-ND	2	$ 3.34	$ 6.68
74LV4051BQ 8ch Analog Multiplexer	568-9269-1-ND	2	$ 1.03	$ 2.06
74LVC2G53 2ch Analog Multiplexer	568-5476-1-ND	2	$ 0.88	$ 1.76
TLV71713PDQNR IC Reg LDO 1.3V	296-36773-1-ND	2	$ 0.69	$ 1.38
RES SMD 4.32KOHM 0.1% 1/10W 0603	P4.32KDBCT-ND	10	$ 1.00	$ 10.00

Assorted 0603 Passives		1	$ 20.00	$ 20.00
110mAh E-Textiles Battery (Sparkfun)		1	$ 6.95	$ 6.95
1.5uH 55mOhm Chip Inductor	490-5343-1-ND	2	$ 0.68	$ 1.36
DMC2990UDJ P/N MOSFET Pair	DMC2990UDJ-7DICT-ND	6	$ 0.60	$ 3.60
Ferrite Bead Filter	490-5216-1-ND	2	$ 0.31	$ 0.62
Crystal Oscillator 32.768kHz	535-9543-1-ND	2	$ 1.13	$ 2.26
Crystal Oscillator 24MHz	SER3635CT-ND	2	$ 0.94	$ 1.88
Inductor 2nH 0402	490-6569-1-ND	4	$ 0.15	$ 0.60
Inductor 15nH 0402	490-6559-1-ND	4	$ 0.15	$ 0.60
TCA9554A IO Expander (Testing)	296-43004-1-ND	2	$ 2.54	$ 5.08
Total				**$ 266.99**

5 Available Source

5.1 Lithium Ion Charge Management and Gas Gauge Circuit Design

The project will utilize a tested design and layout for the BQ24075 Charge Management IC and STC3115 Gas Gauge ICs previously developed by Michael Blouin.

5.2 TI-RTOS and CC2640 Bluetooth Low Energy Software Stack

The project will utilize the TI-RTOS [12] and the Bluetooth Low Energy Software Stack [13], both provided by TI under a BSD License specifically for the CC2640 MCU. Note that the Bluetooth Stack has U.S. Government export restrictions, the agreement for which is in Appendix A.

5.3 Android Application

The android application was built on Googles Android API 23 for Android version 5.1.1+.

5.4 Web Server

The web server was built on a web server hosting mysql 5.6 [14]with php [15]database access and ChartJS [16] for data visualization.

6 IO Signals

Signal Name	Location	Voltage	Current	Other
USB Power In (No Data)	Comms. Board	5V	500mA (max)	Used to charge Li-Ion battery.
Comms Vcc	Comms. Board	3.3V	100mA (max)	Regulated volage from TPS63031
I2C Bus (SDA, SCL)	Comms. Board	3.3V	1.1mA (max on V_{OL})	Estimated Bus Capacitance: (Appendix B)

- MCP9808 I2C [11]	Bandage Module	3.3V	5µA Leakage	V_{OL}:0.4V, V_{IH}:2.31V, V_{IL}: 0.99V
- HDC1050 I2C [10]	Bandage Module	3.3V	N/A	V_{OL}:0.4V, V_{IH}:2.31V, V_{IL}: 0.99V
Moisture Sense Lines (5x Analog)	Comms. Board	1.3V/3.3V	0.3mA	See Appendix C: Moisture Sensing Grid Schematic

7 BACKGROUND RESEARCH

7.1 PAIN THRESHOLD

The article "Deleterious Effects of Electric Shock" [17] provided insight into the minimum current perception threshold in men and women. This article stated that the minimum perception current is 1mA for men, and 0.6mA for women. In order to ensure that the current that is passed through the moisture map in the bandage module will be small enough that it will not be perceived by the patient, even though it will be in direct contact with the wound.

The article "Worker Deaths by Electrocution" [18] agreed with the research values for the minimum current that can be detected by a male, suggesting that 1 mA is approximately the minimum current that can be perceived through the human body.

The article “Human Body Impedance and Threshold Currents for Perception and Pain for Contact Hazard Analysis in the VLF-MF Band” [19] provided graphs corresponding to the impedance of the body, and the perception current threshold

7.2 IDEAL WOUND MOISTURE

The article “Treating the chronic wound: A practical approach to the care of non-healing wounds and wound care dressings” [20] discusses the importance of maintaining moisture in a wound to allow for healing to occur, but also discusses the detrimental effects of keeping a wound too moist. The moisture mapping of the bandage module will allow for a way of monitoring the moisture levels, which could increase the speed of healing.

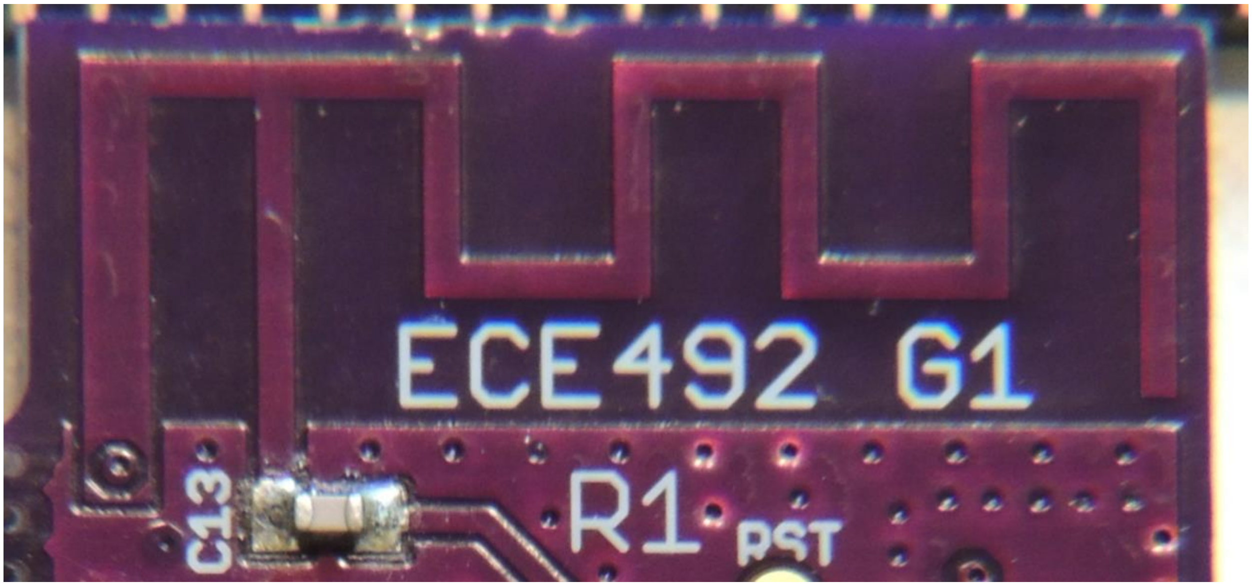
Dr. Burrell will provide critical input in this area as we develop this sensing capability.

7.3 OTHER BACKGROUND RESEARCH

The article “Development of Wearable Sensors for Tailored Patient Wound Care” [21] discussed the concept of wearable sensors for tailored patient care, and discuss various types of sensors that would be beneficial in the process of wound care. While it focusses primarily on sensors outside the scope of this project, it allows for the concept of a smart bandage that extends beyond the temperature and moisture sensors that our current design will be implementing.

7.4 PCB TRACE ANTENNAS

In order to create the PCB trace antenna, a number of application notes and other design documents released by Texas Instruments were consulted including AN043 [1], the CC2640 Datasheet [10], and a reference design [22]. The specific antenna design (shown below) was used to create the positioning, while the datasheet and reference design informed the placement and selection of the other RF components.



8 SOFTWARE DESIGN

The finite state machine displayed below demonstrates how the MCU on the communications module will interact with the sensors on the bandage, as well as with an android application on a smart phone via a Bluetooth connection.

When the communications module is first connected to the bandage module it enters the initialize mode. It then will proceed to the checking mode in order to ensure that the bandage has successfully been detected.

The MCU will spend most of its time in a sleep mode, waking up to check data when the check_data_timer expires, and to transmit data when either the ble_timer expires or when there has been a change in data large enough to generate an alert.

The check mode communicates with the peripherals (the temperature, moisture, and relative humidity sensors) on the bandage module and stores the data. If the data collected is outside of the expected values corresponding to the previous collected data, then an alert is raised.

The alert causes the data to be transmitted via the BLE immediately, instead of waiting until the ble_timer expires. The transmit mode is usually only entered when the ble_timer expires, and the data will then be transmitted regardless of if it has changed.

If the communications module is unable to detect the bandage module, then it enters a temporary error mode. When the communications module has successfully detected the bandage then it proceeds to the initial state.

The permanent error mode is for more significant errors, such as an intermittent connection between the bandage module and the communications module.

The smart bandage web server is built using mysql 5.6.25 for the database backend. PHP 5 is used to interface with the mysql database, as well as ChartJS for the graphical visualization. ChartJS leverages the HTML canvas element to create quality, interactive charts. Bootstrap 3 is a framework developed by Twitter for website design and greatly simplifies the amount of code needed to create functional and visually appealing websites.

mysql database: https://www.mysql.com/

PHP 5: http://www.php.net/

Chart.js: http://www.chartjs.org/

Bootstrap: http://getbootstrap.com/

9 TEST PLAN

9.1 SOFTWARE

9.1.1 Communications Module State Machine

The state machine for the communications module can be easily separated and tested through unit tests. Testing of this core component will ensure that the module is able to correctly move through its state graph, which will control the overall operation of the device.

9.1.2 Android Application

Core components of the android application (web server communication and data storage) will be unit tested using the built-in android unit testing framework. The communication with the device will be tested by a simple handshake protocol between the app and the device that send known edge-case data values to ensure correct operation during each communication.

9.1.3 Web Server

Testing of the web server will be done largely using built in software libraries in android. Using the Android end-to-end test will give a good degree of confidence for the correct functioning of this stretch goal.

9.2 HARDWARE

9.2.1 Communications Module

The communications module is split into two parts: a top and a bottom PCB. These can be tested independently.

The bottom board will be tested first by applying a 5V input from a bench supply, and verifying proper pass-through of the power. Then a battery will be plugged in and the same test performed. Following that a battery charging test will be performed with a partially discharged battery. The low-battery cutoff circuitry will then be tested by simulating a low-battery situation and ensuring that it correctly disables battery operation of the device, while USB-powered operation is still possible. Lastly, the battery gas gauge will be tested by querying battery state over I2C and comparing with known battery state to confirm rough accuracy of charge information.

The top board will be tested first by applying input power and validating that power output from regulators remains stable. Then MCU operation will be verified by connecting and programming test code via the JTAG interface. Operation of the moisture map hardware will then be verified by first applying a known resistance to each output and measuring it with the MCU. Lastly I2C operation will be verified by controlling the I2C IO Expander present on the development attachment board (See Section 13: Printed Circuit Board Design).

9.2.2 Bandage Module

While the bandage module can be tested independently, it is sufficiently simple that correct operation will be verified by directly querying the I2C sensor interface. Temperature and humidity data will then be compared with known/expected values.

10 RESULTS OF EXPERIMENTS

10.1 BLUETOOTH COMMUNICATION TEST

A test was performed using a test framework provided by TI on the CC2650 Launchpad to communicate with an Android application. The simple application was able to detect the device and query the Bluetooth services of the device – acting as a proof of concept for the project.

10.2 MOISTURE SENSING GRID

A test was performed using both a raw pork chop and steak at 33C with a similar sensing circuit to that of the proposed moisture sensing circuit. This test established that the circuit should be able to sense impedance of a wound, however the impedance of non-living tissue (lacking blood) is higher than that of the human body suggested by the background research. For this purpose, the secondary 3.3V source was added to the detection circuit, in the event that the impedance is too high to provide a measureable result using the 1.3V source.

11 SAFETY CONSIDERATIONS

11.1 MOISTURE SENSOR

The moisture sensor applies current directly to the wound, using a 4.32k limiting resistor to limit the max current to 0.3mA (below the 0.6mA DC threshold of sensation). (See Appendix C: Moisture Sensing Grid Schematic).

11.2 FLEXIBLE PRINTED CIRCUIT

These circuits are bendable and for the same reason, have the possibility for the circuit board to fail mechanically. If the circuit board is bent beyond its maximum radius of curvature, the traces on the FPC become unusable for data collection. For this reason, a trace that spans the length of the flexible board is included to make certain that the flexible circuit is still intact and there is no damage to the FPC. Additionally, if the I2C traces fail the error should be detectable either because devices do not respond, or because values are out of the allowable ranges (for example temperature ranges should not exceed -40 – 60C or the host has larger problems than false data collection). By using a write-verify algorithm the device is also able to detect significant failures.

11.3 MAXIMUM POWER

The device is powered by a 110mAh battery with built-in 2C current limiting, as well as under/over-voltage protection, and over-temperature protection. This means that the max discharge rate of the battery is around 240mA, and it automatically stops draw in other unsafe conditions. Additionally the low-voltage operation of the device helps reduce the likelihood of high current draw through a person.

12 REGULATORY AND SOCIETY

12.1 RF EMISSIONS CERTIFICATION

Devices communicating in the 2.4GHz frequency band (Bluetooth) are largely unregulated, but must still comply with RF emissions regulations [23]. This certification is provided by Industry Canada. While not a priority for this project, the communications module would need certification in order to be produced and sold to end-users.

12.2 MEDICALLY INERT MATERIALS

It is a non-goal of the project to use medically inert materials (materials that will not affect the healing process of the subject). However, we recognize that sufficient effort would be required to review all materials and processes used in fabrication to ensure safety.

12.3 SOLDER-FREE PROCESS

The first batch of PCBs will be fabricated using lead-free processes, however assembly will use leaded solder paste. Therefore, only a change in the assembly process would be needed for the board to be completely lead free.

12.4 HANDLING OF MEDICAL DATA & CLASS II MEDICAL DEVICE CERTIFICATION

The project explicitly does not attempt to provide any form of security for the data acquired by the device. However, a commercially viable and responsible product would require significant security measures in order to handle patient data securely and not expose patients to unreasonable risks in the disclosure of their information.

Additionally Canada regulates Class II Medical Devices [24] as:

> *Medical device software that is an adjunct to another medical device and is involved in data manipulation, data analysis, data editing, image generation, determination of measurements, identification of a region of interest in an image, or identification (by an alarm or alert) of results from a monitor that are outside of an established range, is a Class II medical device if it: 1. provides the only means and opportunity to capture or acquire data from a medical device for aiding directly in diagnosis or treatment of a patient; or 2. replaces a diagnostic or treatment decision made by a physician.*

While the device may in actuality be either a Class I or Class II device, both classes require a license to be sold in Canada, with Class II devices being certified pursuant to the regulations in Sections 26 to 43 or the Medical Devices Regulations.

Needless to say it is explicitly *not* a goal of the project to produce a device compatible with these regulations.

13 PRINTED CIRCUIT BOARD DESIGN

The communications module is designed such that two core boards are mounted on each other to provide full functionality. This is because with our manufacturing resources we can only reliably place SMT components on one side of a PCB.

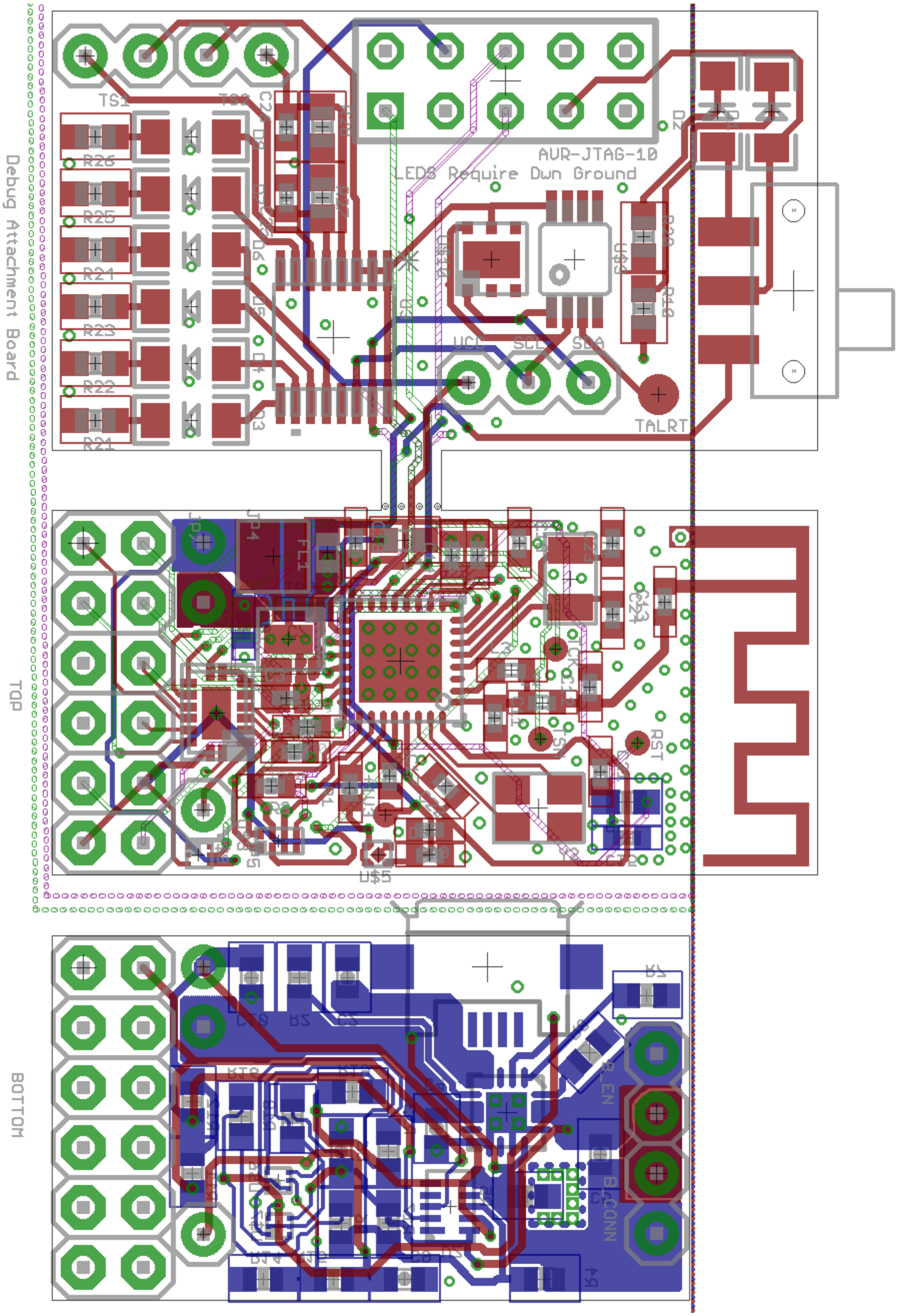
The top board has a detachable programming and debugging interface which provides an easy-to-access JTAG header, 6 LEDs addressed over I2C, 2 buttons addressed over I2C, and temperature and humidity sensors. This interface can be detached from the main module which hosts the MCU, antenna, and 1.3V and 3.3V regulators.

The bottom board hosts the battery management circuitry.

13.1 SCHEMATIC

See Appendix α: Hardware Documentation for a full PCB schematic. The completed circuit board design is shown in Appendix H: Final PCBs.

13.2 COMMUNICATIONS MODULE TOP AND BOTTOM BOARDS



14 ENVIRONMENTAL IMPACT

The first batch of PCBs will be fabricated using lead-free processes, however the assembly will use leaded solder paste.

This is not compliant with the RoHS standard. However, the industry version of this product will be created using lead free solder. Therefore, in order to achieve RoHS compliance, a change in assembly will be the only requirement.

The disposable bandage module and communications module can be disposed of at any Electronic disposal site.

Unlike the disposal bandage module, the communications module can be sterilized and reused throughout patient treatment. This will reduce the waste associated with Smart Bandage.

15 SUSTAINABILITY

The power consumption of the smart bandage is broken down into the sleep mode, broadcast mode, and check mode. The average power consumption of the sleep mode worked out to be 9.6876 mAs. The average power consumption of the broadcast mode worked out to be 84 mAs. The average power consumption of the check mode worked out to be 1564.404 mAs. See Appendix F for calculations.

This gives a total power consumption of 0.69 mAs, or $6.3x10^{-4}$ Wh. Using Edmonton's industry standard 4.521 cents per kilowatt hour, this works out $\$2.53\text{x}10^{-7}$ per year. We estimate that $1.38\text{x}10^{-6}$ lbs of C02 per year would be generated assuming a coal powered plant with Lignite coal fuel at a rate of 2.17 lbs per kilowatt hour.

The maximum current draw of the smart bandage, as shown in Appendix F, was 131 mA, which occurs when the bandage is in the check phase where MCU is checking the sensors for new values. According to our initial energy calculations, the smart bandage could be charged by an off the shelf USB solar charger. The small power consumption of the bandage and the simplicity of charging ensures the smart bandage can be used in remote areas and operate effectively.

The motivation of the Smart Bandage was to reduce the number of homecare visits needed for a patient by remotely monitoring data, and only doing a visit when the bandage actually required attention. By reducing the number of homecare visits needed on a per patient basis, the Smart Bandage will reduce the amount of driving required from the healthcare facility to and from the patients home. Consequently, this will reduce the amount of fossil fuels produced.

16 FUTURE WORK

Potential extensions to the project are:

16.1 AUTOMATIC NOTIFICATIONS

Provide automated notifications to Nurses in the event an alert is raised due to rapid changes in sensor readings or readings indicating problems such as potential infection. This would take the form of another mobile application that would be on the health care professional and only used by health care professionals, allowing them to avoid actively checking back into the web server to see if there are any alerts thrown by the bandage, instead the alerts would be notified to the user with push notifications on their respective device. This would allow for greater mobility of the professional and can check in real time with the patient.

16.2 PATIENT NOTIFICATIONS

Provide an easy to use notification service for the patient application, that informs them that they should contact their home care professional, or that they require a bandage change. The application would provide simple user interface to call their nurse.

16.3 INDUCTIVE CHARGING

Design an inductive charging solution to be placed on the device. Applying the principle of inductive charging to the smart bandage would mitigate the risk associated with having the user tethered to a power charging circuit when the battery needs recharging. This would increase the mobility of the patient and decrease intrusive nature of a physical connection close to the wound site.

16.4 PH SENSING

Additional sensors could be added, such as a PH sensor. PH sensors are relatively large, made of glass and require refractory times between readings in order to maintain their accuracy. Integrating a PH sensor would be a next logical step for the bandage as PH is an important indication of bacterial growth.

16.5 WEB APPLICATION SECURITY AND IMPROVEMENTS

Further integration of the web application system into a health care setting has many challenges in security. Due to time constraints in the project, the web application functionality is based solely for proof of concept. Many optimizations will have to be made in order to have the web app secure enough for production run. Improvements preventing SQL injection attacks, session hijacking and end to end encryption methods such as transport layer security(TLS) will have to be implemented.

16.6 BLE ANTENNA INTERFERENCE ISSUES

The device occasionally experienced difficulty in communicating while in the lab which was due either to other 2.4GHz equipment RF equipment (other projects), RF noise, or from Nancy. It is possible that the PCB Trace Antenna has sufficiently inferior properties to the other equipment in the lab which has gone through more rigorous testing and certification (eg. FCC) before being sold. It is likely that by optimizing the Antenna configuration the quality of Bluetooth communication could be significantly improved. Alternatively, we may also consider investigating other protocols supported by the MCU such as ZigBee, which may provide alternatives when and if BLE is not desirable.

17 REFERENCES

[1] Texas Instruments, "Application Note AN043: Small Size 2.4GHz PCB Antenna," 04 04 2008. [Online]. Available: http://www.ti.com/lit/an/swra117d/swra117d.pdf. [Accessed 1 02 2016].

[2] Texas Instruments, "CC13xx, CC26xx SimpleLink™ Wireless MCU Technical Reference Manual," 09 2015. [Online]. Available: http://www.ti.com/lit/ug/swcu117d/swcu117d.pdf. [Accessed 15 01 2016].

[3] Texas Instruments, "TPS6303x Datasheet," 10 2015. [Online]. Available: http://www.ti.com/lit/ds/symlink/tps63030.pdf. [Accessed 14 01 2016].

[4] Texas Instruments, "CC2640 Datasheet," 10 2015. [Online]. Available: http://www.ti.com/lit/ds/symlink/cc2640.pdf. [Accessed 14 01 2016].

[5] Texas Instruments, "SimpleLink™ CC2650 Wireless MCU LaunchPad™ Kit," [Online]. Available: http://www.ti.com/tool/launchxl-cc2650. [Accessed 15 01 2016].

[6] LSR, "SaBLE-x Module Datasheet," 2015. [Online]. Available: http://www.lsr.com/downloads/products/330-0166.pdf. [Accessed 14 01 2016].

[7] SparkFun Electronics Inc, "E-Textiles Battery - 110mAh (2C Discharge)," [Online]. Available: https://www.sparkfun.com/products/13112. [Accessed 15 01 2016].

[8] Texas Instruments, "BQ2407xT Datasheet," 11 2014. [Online]. Available: http://www.ti.com/lit/ds/symlink/bq24075t.pdf. [Accessed 14 01 2016].

[9] ST, "STC3115 Datasheet," 12 2014. [Online]. Available: http://www.st.com/web/en/resource/technical/document/datasheet/DM00066800.pdf. [Accessed 14 01 2016].

[10] Texas Instruments, "HDC1050 Datasheet," 12 2015. [Online]. Available: http://www.ti.com/lit/ds/symlink/hdc1050.pdf. [Accessed 14 01 2016].

[11] Microchip, "MCP9808 Datasheet," 2011. [Online]. Available: http://ww1.microchip.com/downloads/en/DeviceDoc/25095A.pdf. [Accessed 14 01 2016].

[12] Texas Instruments, "TI-RTOS: Real-Time Operating System (RTOS)," 2015. [Online]. Available: http://www.ti.com/tool/ti-rtos. [Accessed 15 01 2016].

[13] Texas Instruments, "Bluetooth Low Energy Software Stack," 30 07 2015. [Online]. Available: http://www.ti.com/tool/ble-stack. [Accessed 15 01 2016].

[14] "mysql," [Online]. Available: https://www.mysql.com/.

[15] "PHP," [Online]. Available: www.php.net.

[16] "Chart JS," [Online]. Available: www.chartjs.org.

[17] C. F. Dalziel, "Deleterious Effects of Electric Shock," in *Meeting of Experts On Electrical Accidents*, Geneva, 1961.

[18] National Institute for Occupational Safety and Health, "Worker Deaths by Electrocution," U.S. Department of Health and Human Services, Cincinnati, OH, 1998.

[19] l. Chatterjeen, D. Wu and O. P. Gandhi, "Human Body Impedance and Threshold Currents for Perception and Pain for Contact Hazard Analysis in the VLF-MF Band," *Biomedical Engineering,* Vols. BME-33, no. 5, 1986.

[20] M. Fonder, G. S. Lazarus, D. A. Cowan, B. Aronson-Cook, A. R. Kohli and A. J. Marnelak, "Treating the chronic wound: a practical approach to the care of nonhealing wounds and wound care dressings," *Continuing Medical Education,* 2008.

[21] S. D. Milne, P. Connolly, H. Al Hamad and J. Seoudi, "Development of Wearable Sensors for Tailored Patient Wound Care," *Engineering in Medicine and Biology Society ,* pp. 618-622, 2014.

[22] Texas Instruments, "SimpleLink CC2650 EVM Kit Design Files," 10 02 2015. [Online]. Available: http://www.ti.com/lit/zip/swrc302. [Accessed 01 02 2016].

[23] Texas Instruments, "How to Certify your Bluetooth product," [Online]. Available: http://processors.wiki.ti.com/index.php/How_to_Certify_your_Bluetooth_product. [Accessed 01 01 2016].

[24] Health Canada, "Software Regulated as a Medical Device - Frequently Asked Questions," 24 01 2011. [Online]. Available: http://www.hc-sc.gc.ca/dhp-mps/md-im/activit/announce-annonce/md_qa_software_im_qr_logicels-eng.php. [Accessed 01 01 2016].

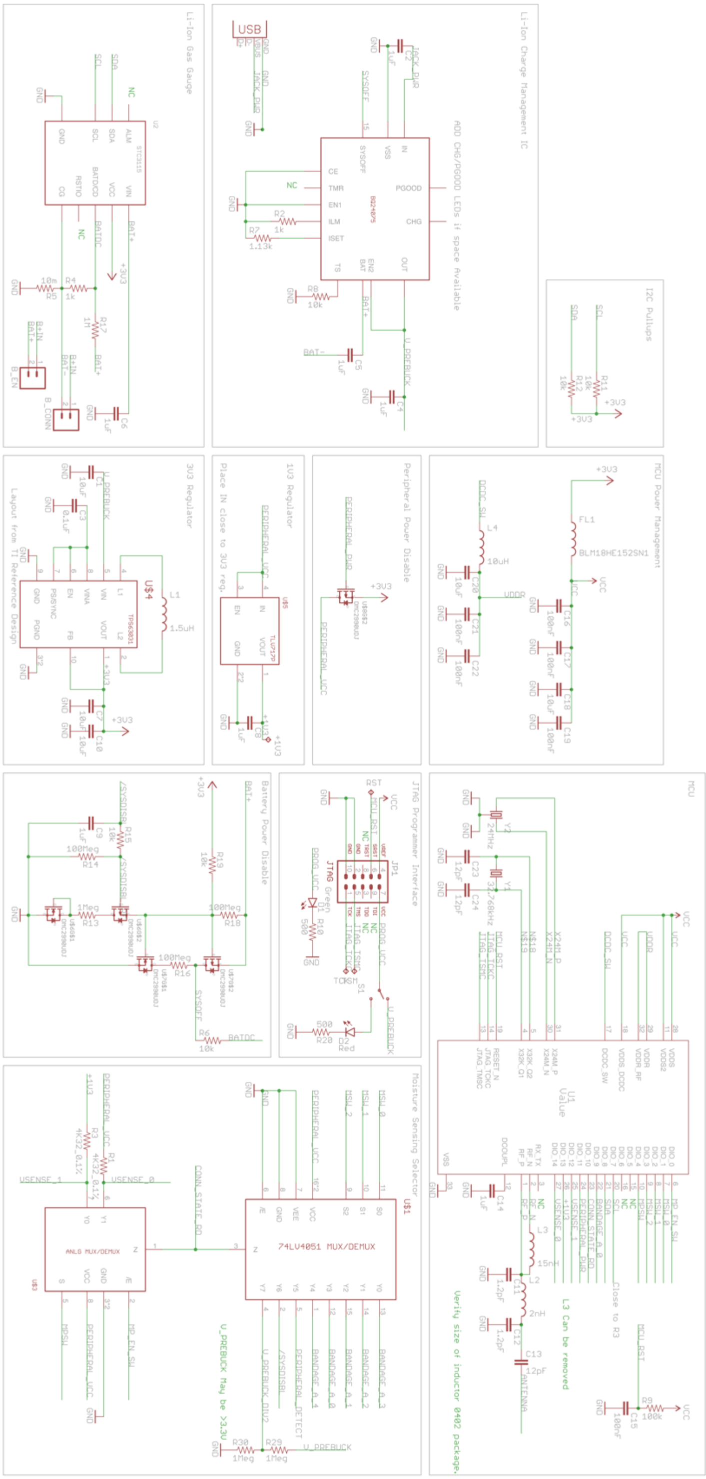
[25] Texas Instruments, "Effect of Parasitic Capacitance in Op Amp Circuits," 09 2000. [Online]. Available: http://www.ti.com/lit/an/sloa013a/sloa013a.pdf. [Accessed 17 01 2016].

[26] L. A. G. C. F. B. Raymond M. Fish, Medical and Bioengineering Aspects of Electrical Injuries, Tucson, Arizona: Lawyers & Judges Publishing Company, 2003.

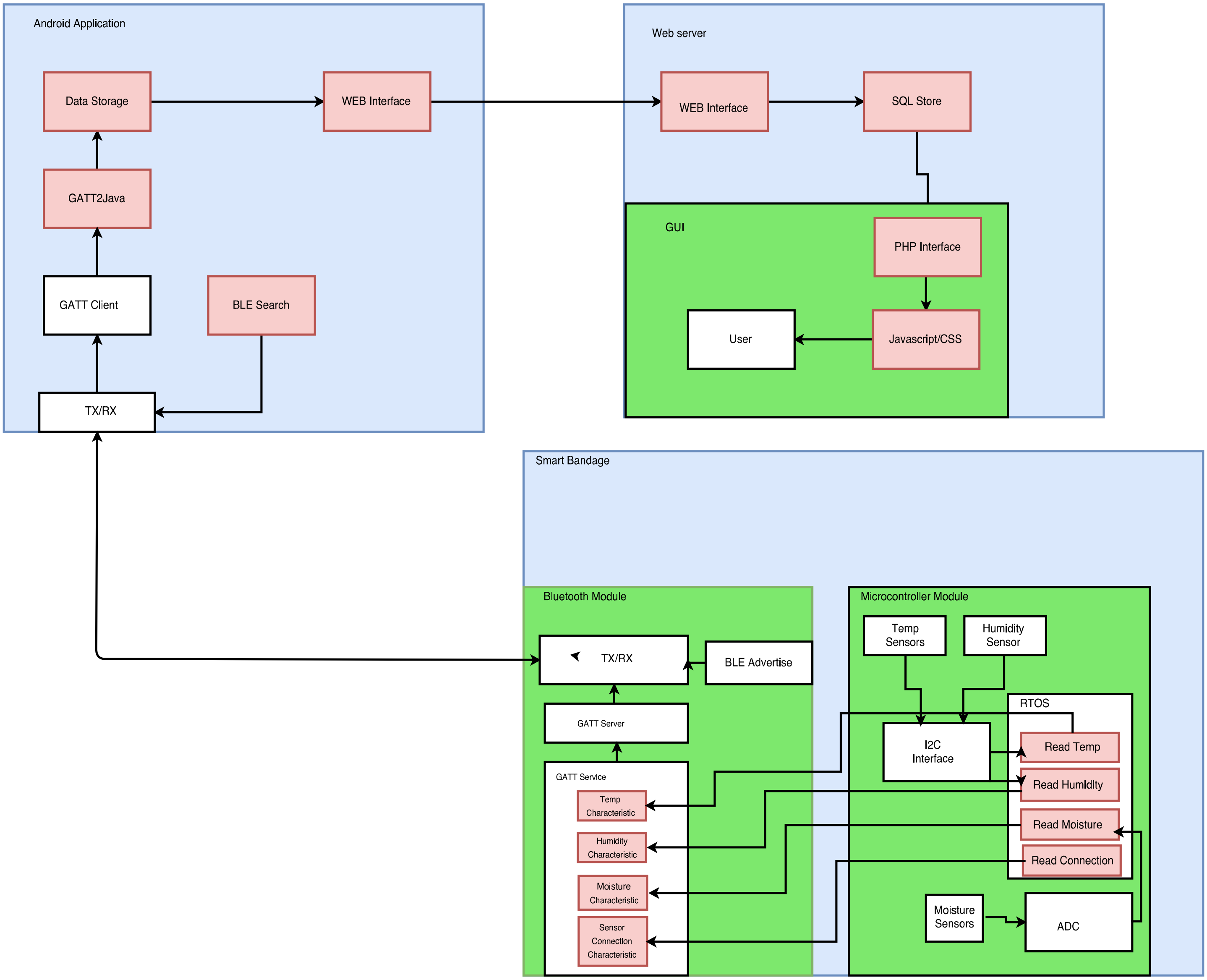
[27] "www.php.net," [Online].

18 APPENDIX

18.1 APPENDIX α: HARDWARE DOCUMENTATION



18.2 Appendix β: Source Code



18.3 APPENDIX A: U.S. GOVERNMENT EXPORT APPROVAL FOR TI BLE STACK

The following is the agreement from TI.com permitting access to the BLE software stack:

> *(**a**) I understand that this Software/Tool/Document is subject to export controls under the U.S. Commerce Department's Export Administration Regulations ("EAR").*
>
> *(**b**) I am NOT located in Cuba, Iran, North Korea, Sudan or Syria. I understand these are prohibited destination countries under the EAR or U.S. sanctions regulations.*
>
> *(**c**) I am NOT listed on the Commerce Department's Denied Persons List, the Commerce Department's Entity List, the Commerce Department's General Order No. 3 (in Supp. 1 to EAR Part 736), or the Treasury Department's Lists of Specially Designated Nationals.*
>
> *(**d**) I WILL NOT EXPORT, re-EXPORT or TRANSFER this Software/Tool/Document to any prohibited destination, entity, or individual without the necessary export license(s) or authorization(s) from the U.S. Government.*
>
> *(**e**) I will NOT USE or TRANSFER this Software/Tool/Document for use in any sensitive NUCLEAR, CHEMICAL or BIOLOGICAL WEAPONS, or MISSILE TECHNOLOGY end-uses unless authorized by the U.S. Government by regulation or specific license.*
>
> *(**f**) I understand that countries other than the United States may restrict the import, use, or export of the Subject Product. I agree that we shall be solely responsible for compliance with any such import, use, or export restrictions.*
>
> ***I / We hereby certify that we will adhere to the conditions above.***
>
> ***I / We do not know of any additional facts different from the above.***
>
> ***I / We take responsibility to comply with these terms.***
>
> ***I / We understand we are responsible to abide by the most current. versions of the Export Administration Regulations and other U.S. export and sanctions laws.***

18.4 APPENDIX B: I2C BUS CAPACITANCE ESTIMATION

Part	**Name**	**Address (BINARY)**	**Capacitive Load (F)**
MCP9808 **[11]**	Temperature Sensor	0bxxx 1100	5.00E-12
HDC1050DMBR **[10]**	Humidity Sensor	0b100 0000	5.00E-13
SaBLE-X	CC2640 MCU BLE Board	Master	N/A
STC3115	Li-Ion Gas Gauge	0b000 0111	N/A
Communications Board*	PCB Trace Capacitance	N/A	3.90E-12
Bandage FPC*	PCB Trace Capacitance	N/A	1.30E-11
Total			**2.24E-11**

**Detailed information on the the relative permittivity or other electrical characteristics are not freely available from the proposed PCB manufacturer. With that in mind trace capacitances were estimated at* $3pF/in$ *in accordance with* [25, p. 3]*, with the lengths used being the estimated length of the PCBs multiplied by 1.1 to provide a worst-case estimation.*

While the datasheets for the SaBLE-X device and STC3115 did not detail the pin parasitic capacitance, it was decided that the estimated total bus capacitance (excluding those devices) of $22.4pF$ was sufficiently small as compared to the maximum bus capacitance for an I2C bus of $400pF$ that it would not be an issue to operate at the normal I2C speed of 100kHz.

18.5 APPENDIX C: MOISTURE SENSING GRID SCHEMATIC

The Moisture Sensing Grid Schematic is based off of the medical need for a wound to have the correct moisture level (internally and on the surface) for it to heal properly. Too wet or too dry and it will not. The grid works by interleaving conductive threads through the bandage material. Of the 10 threads in a 10cm wide bandage, every second one is connected to a voltage supply and resistor. The other threads are grounded. By measuring the current through the 5 threads connected to the supply we believe it will be possible to determine the rough moisture content of that patch of the wound.

The (stretch) goal of including this measurement in the project is as a proof of concept. A significant number of medical trials would be required to calibrate the moisture sensing grid.

The CC2640 has an onboard 8 channel 12bit Successive Approximation ADC [2] with a high accuracy mode. By enabling the high accuracy mode, the voltage range is restricted to [0, 1.47V] on the ADC pin. For that reason, a 1.3V linear regulator is used to supply power to the moisture sensing grid ($V_{Supply} = 1.3V$).

18.5.1 Appendix C.1: Verification of ADC Parameters

With 12bits per channel available on the ADC over a range of 1.47 this will provide a resolution of:

$$V_{Resolution} = \frac{1.47V}{2^{12-1}} = 0.718mV$$

Over the limiting/sensing resistor this gives a current resolution of:

$$I_{Resolution} = \frac{0.718mV}{4.32k\Omega} = 0.166\mu A$$

Therefore, sufficient current resolution should be available to detect moisture.

18.5.2 Appendix C.2: Selection of Limiting/Sensing Resistor

The threshold of sensation for a DC current applied to a male and female is approximately 1mA, and 0.6mA, respectively [17, p. 24]. Therefore, it was decided that the maximum current output in the sensing grid be 0.3mA to avoid generating any sensation, with a 0.6mA fallback provided by a secondary voltage source. Resistors in the schematic were then chosen as follows:

$$I = \frac{V_{Supply}}{R_1 + R_H} \leq I_{lim} \leq 0.3 * 10^{-3}A$$

Set $R_H = 0\Omega$ and solve for R_1:*

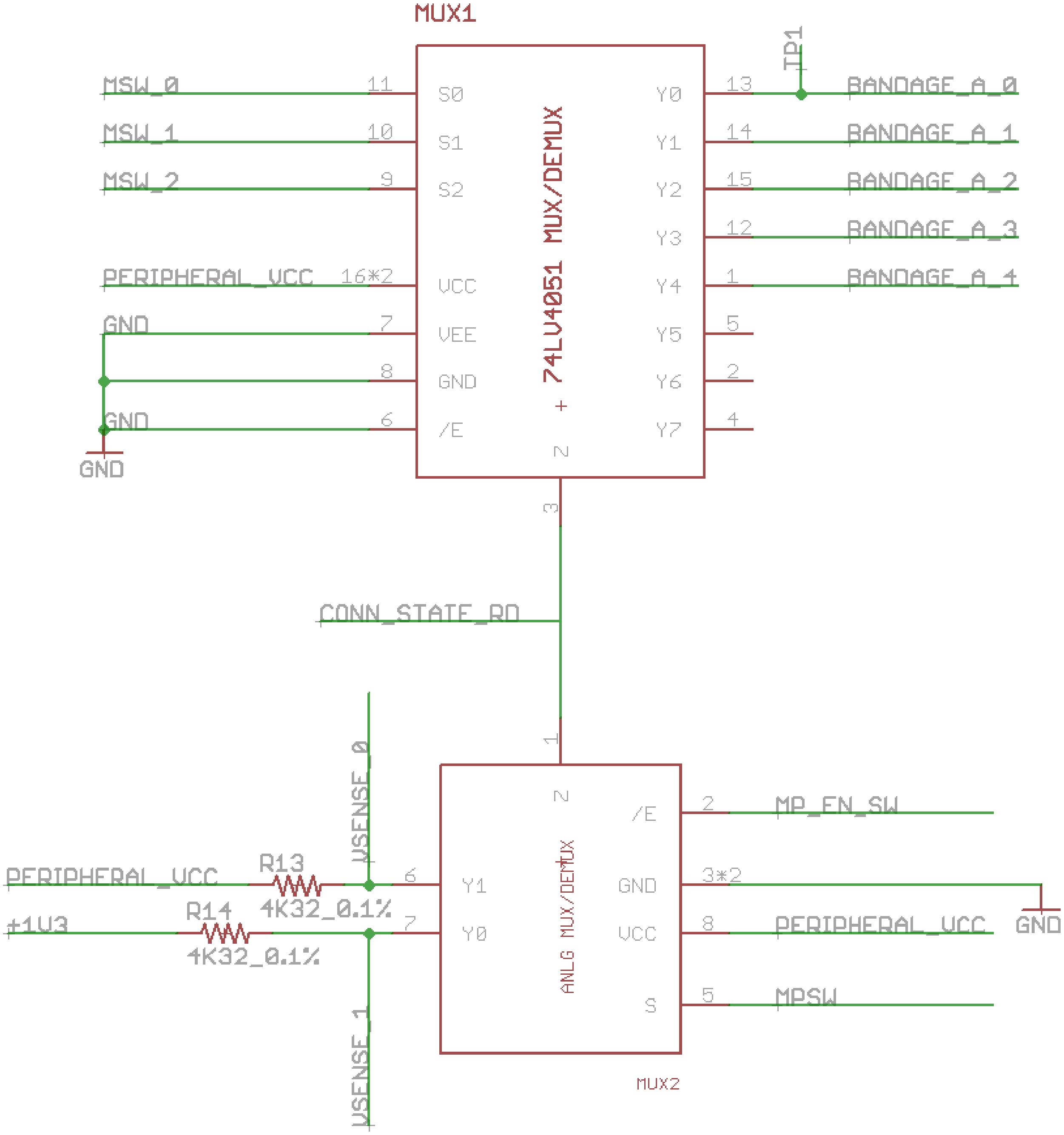
$$R_1 \geq \frac{V_{Supply}}{I_{lim}} \geq \frac{1.3V}{0.3 * 10^{-3}A} \geq 4.33k\Omega \approx 4.32k\Omega$$

**R_H is set to zero to capture the worst case situation of maximum current.*

Therefore a commercially available resistor of $4.32k\Omega$ at 0.1% was chosen for R_1 (Digikey PN: P4.32KDBCT-ND) as this value is able to safely limit current levels.

The internal resistivity of the human body is around 500 - 100Ω [18] [26]. Taking this into account the total circuit impedance is $4.82k\Omega$ - $5.82k\Omega$ giving a maximum current of 0.27mA.

18.5.3 Appendix C.3: Moisture Sensor Diagram



In the above diagram MUX1 selects a single bandage line for testing (so as to ensure current draw does not exceed the established limit). Both MUX's are analog and establish a bidirectional connection between 'Z' and the selected 'Y*' input. MUX2 then selects the voltage source to be used for the measurement. The MCU then measures VSENSE_0/VSENSE_1, the selected source (+3V3 or +1V3), CONN_STATE_RD, and if it is in a calibration state, BANDAGE_A_0. Measuring at these locations are done for the following reasons/methods:

Measuring the Source is done internally, in case of +3V3, or directly in the case of +1V3. This allows the MCU to accurately determine the voltage across R13 or R14, establishing the current draw (R13/R14 are 0.1% precision resistors).

CONN_STATE_RD is an analog input that is present due to other required functions. It is utilized for this measure in order to determine the exact voltage drop across MUX2 (expected to be ~80Ω), which can then be used to approximate the impedance of MUX1, as they share the same architecture and performance curves.

TP1/BANDAGE_A_0 is able to be measured in a self-calibration state done before using the bandage. This measurement will be used to generate the specific conversion table used to estimate the impedance of MUX1 from that of MUX2.

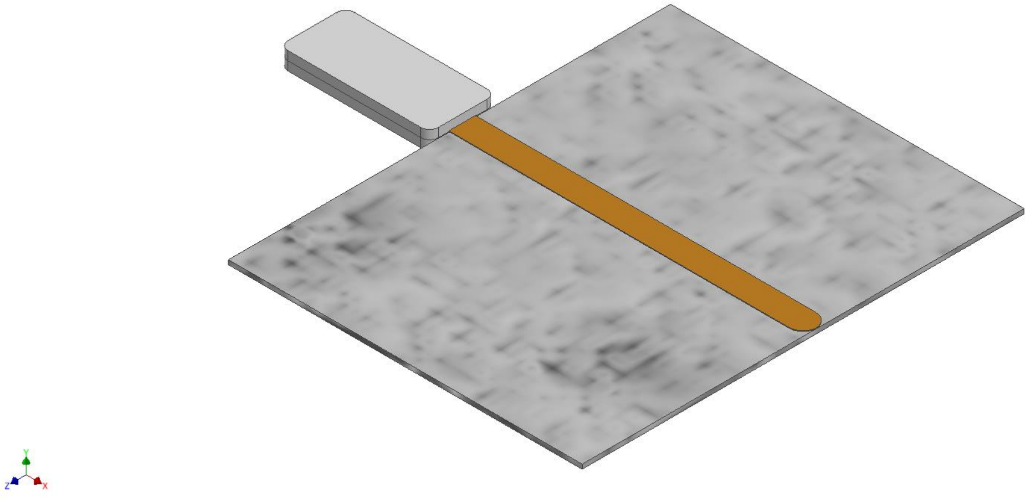
18.5.4 Appendix C.4: Algorithm for Determining Region Moisture Content

The below algorithm is used with the sensor described in Appendix C to determine the moisture content. This algorithm is applied for each line of the grid:

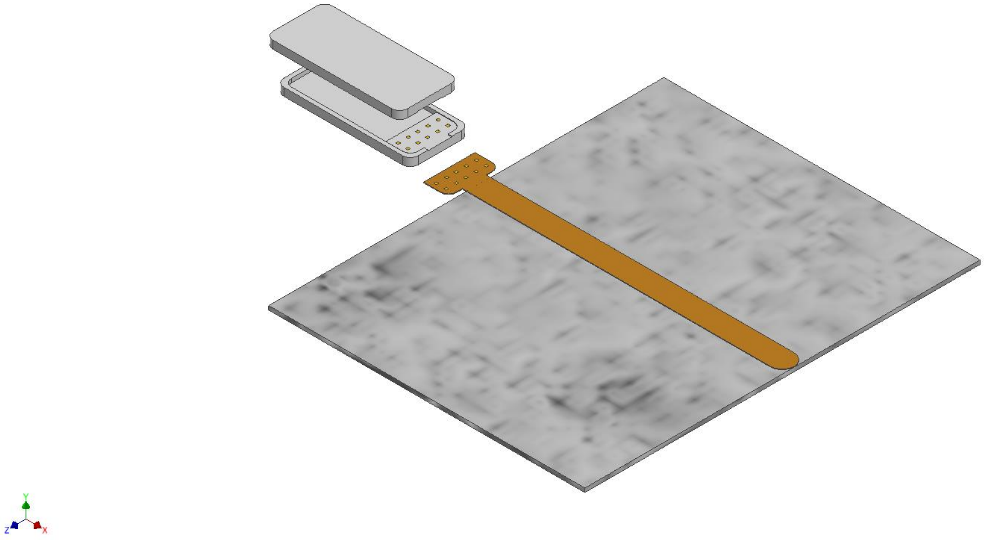
1. Disable MUX2.
2. Disable ADC scaling and select ADC channel.
3. Select +1V3 voltage source using MUX2.
4. Select desired sensor grid line using MUX1.
5. Enable MUX2.
6. Measure source voltage (+1V3), VSENSE_1, CONN_STATE_RD.
7. If measuring line0 measure TP1/BANDAGE_A_0.
8. Using the measurement from 6-7 determine wound impedance.
9. If impedance is too high to be of confidence:
    a. Enable ADC Scaling.
    b. Select +3V3 voltage source using MUX2.
    c. Measure +3V3 source, VSENSE_1, CONN_STATE_RD
    d. If measuring line0 measure TP1/BANDAGE_A_0.
    e. Use values from c-d to determine wound impedance.
10. Map wound impedance to table of moisture values to determine relative moisture %.

18.6 Appendix D: Smart Bandage Conceptual Models

18.6.1 Appendix D.1: Assembled Smart Bandage, Communications Module, and Bandage Module



18.6.2 Appendix D.2: Exploded Smart Bandage, Communications Module, and Bandage Module

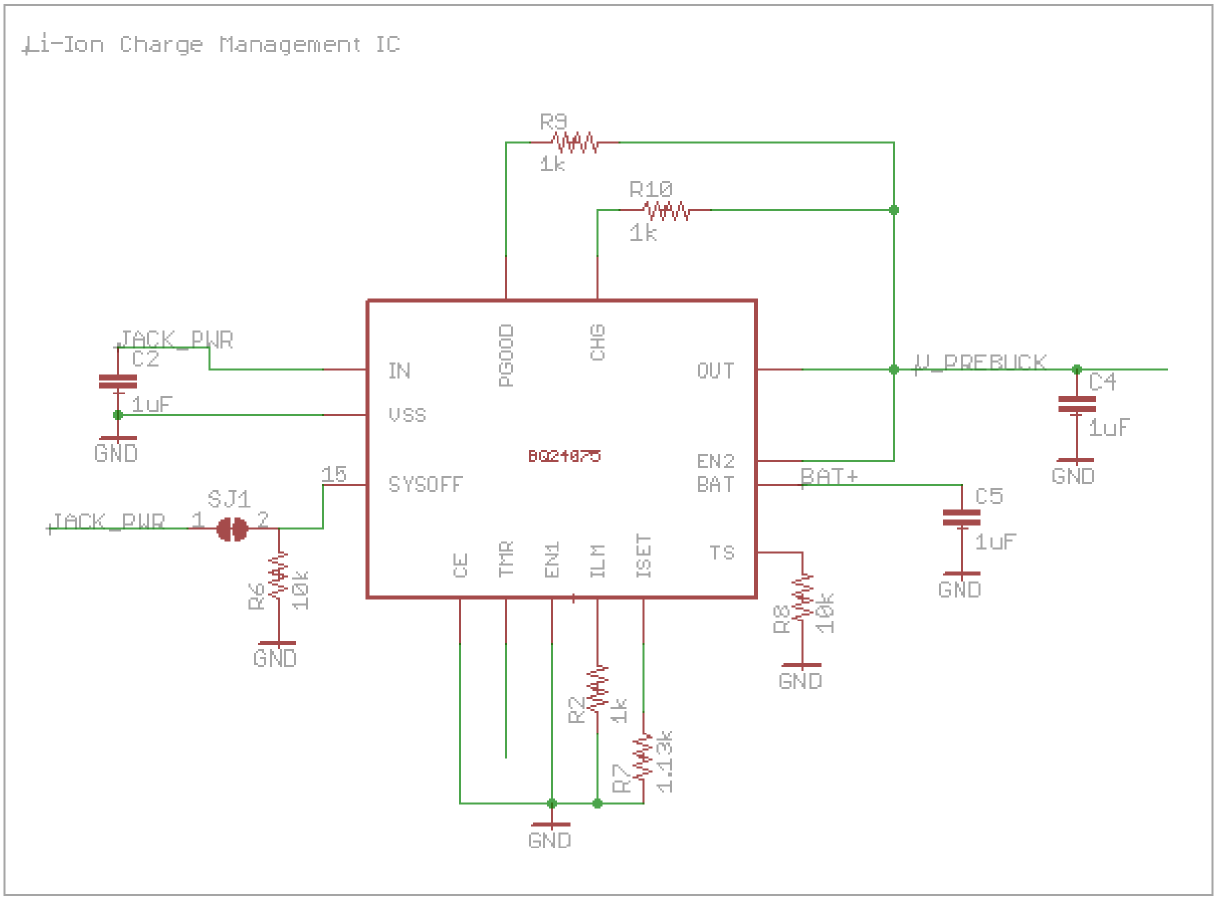


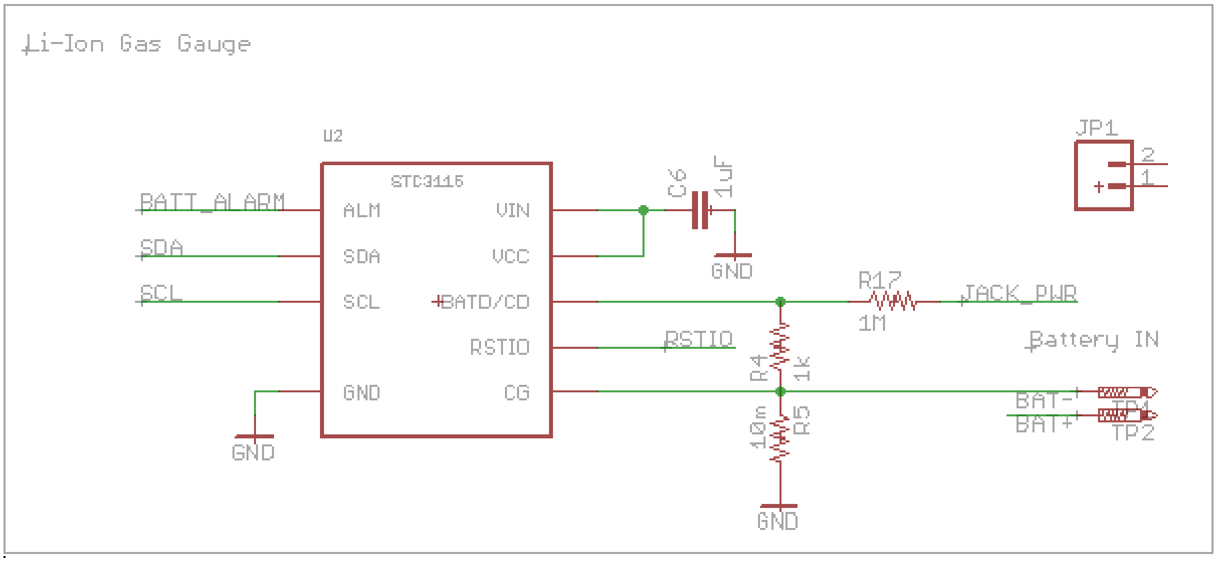
18.6.3 Appendix D.3: Communications Module Dimensions

18.7 APPENDIX E: BATTERY AND POWER MANAGEMENT SCHEMATIC

18.7.1 Appendix E.1: Battery Management Schematic

The TI BQ24075 is an intelligent Li-Ion battery management system that manages charging the battery, and selecting between jack power and the battery. The STC3115 is a gas gauge, and estimates battery capacity using voltage and current monitoring.

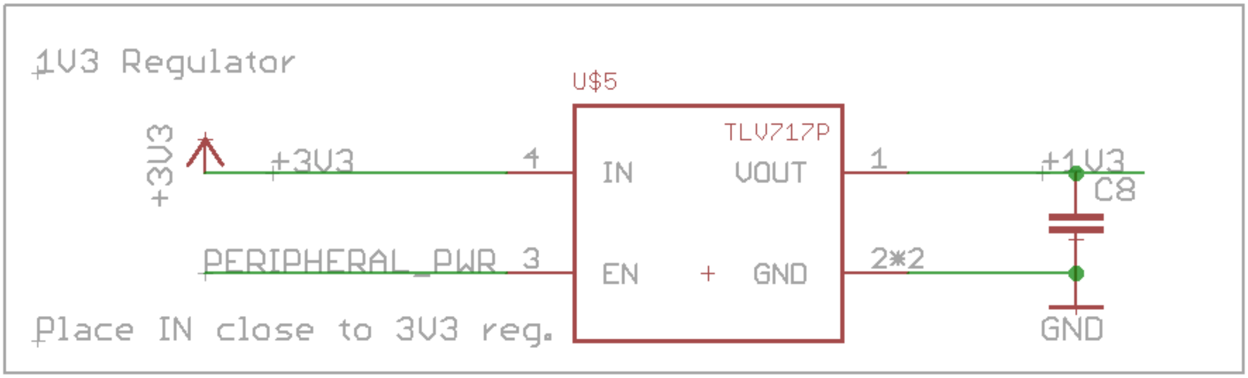


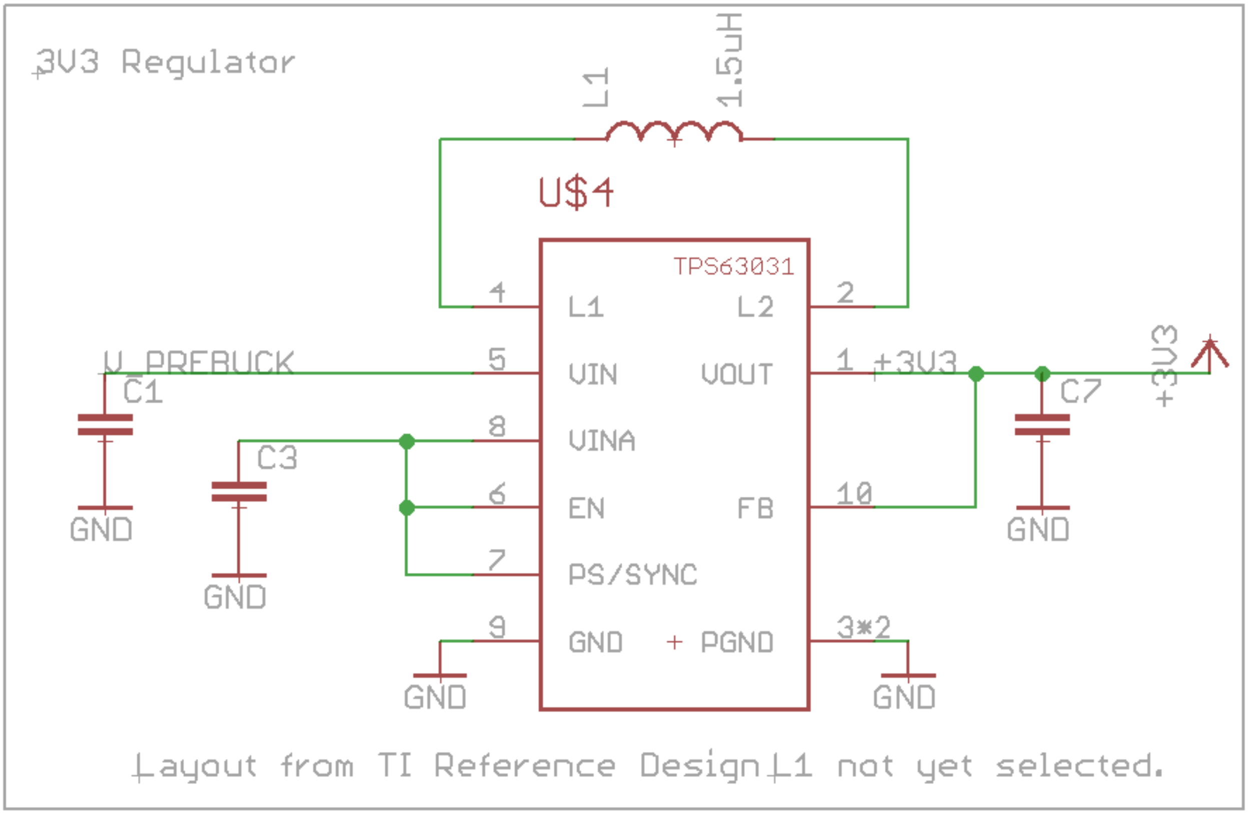


18.7.2 Appendix E.2: Voltage Regulation

The application uses two voltage regulators: 3.3V and 1.3V. The TI TPS63031 3.3V regulator is a Buck/Boost device and is necessary because input from the battery stage may be battery voltage (variably 3-4.2V) or USB power (5V). The buck/boost is designed to automatically step up or down the voltage to 3.3V.

The TLV717P regulator provides the 1.3V source used in the moisture sensing grid, and is connected to the PERIPHERAL_PWR disable output of the MCU to disable all unneeded circuitry for minimal power passive power consumption during sleep.





18.8 APPENDIX F: ENERGY ESTIMATION

We estimated that the check phase would take 100 ms and be done every 30 seconds. This gives a total of 12 seconds spent in the check phase every hour. In addition to 10 seconds every hour spent in the broadcast phase. The remainder of the time which is 3588 seconds is spent in sleep. Summing up the current draw with these estimates gives a 0.69 mAh draw, giving a total of 157 hours or 6.6 days.

Part:	tsleep (µA)	tcheck (µA)	ttotal (µA)	tble
MCU	2.7	129592	133	
Temperature Sensor		200		
Gas Gauge		45		
Battery Chargers			50	
Linear Regulator		500		
Buck/Boost			50	
Multiplexer		30		
Bluetooth tx energy draw				8400
total:	2.7	130367	233	8400

Part:		Power consumption (micro amps)	
MCU	sleep draw	2.7	*tsleep
	check draw	141.58	*tcheck
	peripheral	20	*ttotal
	timer	113	*ttotal
temperature sensor		200	*tcheck
Gas Gauge		45	*tcheck
Battery Charges		50	*ttotal
Linear Regulator		500	*tcheck
Buck/Boost		50	*ttotal
Mux		30	*tcheck
Humidity sensors		61.04	*tcheck

18.9 APPENDIX G: STORAGE CAPACITY ESTIMATION

The microcontroller unit has 20kb of SRAM that will be used to store data while unconnected to the android device.

$$20\ kilobytes * \frac{1024\ bytes}{kilobytes} = 20480\ bytes$$

Using DWORDS of 4 bytes in length

SRAM MEMORY STRUCTURE

0x00	Time 1
0x04	Temp 1
0x08	Temp 2
...	
…	
…	
0x4FFC	

Estimates using offsets of 4 bytes, and a record containing all the temperature, humidity, moisture, and timestamp readings will only occupy 11 DWORDS worth of memory 4 temperatures readings, 1 humidity, 5 moisture, 1 timestamp. This leaves us with 465 record that can be stored.

$$\frac{5120\ DWORDS}{11\ DWORDS} = 465\ Records$$

The SRAM can store 465 records: 19 days at a record per hour, 9.7 days at a record every 30 mins.