ECE 445 Spring 2020 Design Document

Electronic Surgical Tray

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1. Introduction

1.1 Objective

Surgical tools are expensive and can usually be sterilized for reuse; however, unused tools are often unnecessarily sterilized and are sometimes even accidentally thrown away or lost, leading to significantly increased costs for hospitals. Currently, the existing solutions aim to prevent unnecessary sterilization of surgical tools and waste of surgical supplies by marking each instrument and tracking them electronically: these solutions include RFID tags, optically detectable polymer coatings, and barcode labels. However, there are still no devices available that help surgeons and nurses conveniently keep track of the use-status (used vs. unused) of surgical tools in the operating theatre during surgery.

To solve this problem, we propose to develop an Electronic Surgical Tray that can hold surgical tools and sense when they are removed from the tray. The tray will have designated spaces (with weight sensors and LED indicators) for each surgical tool to be placed onto. The device's overall function is to allow surgeons and nurses to keep track of which items have been used (red spaces) or unused (green spaces). After the tray has been prepared with surgical tools, a calibration button will be pressed, causing the Electronic Surgical Tray to register all the weights of the tools on the tray. This will generate an electronically stored array of tool weights. After calibration, every space on the tray will light up green, indicating that the tools are unused. When a tool is removed, the tray space will light up yellow. If multiple tools are removed, multiple spots light up yellow. Used items, when placed back onto the tray, will cause the tray to turn red in that space. Importantly, used items do not need to be returned to the same space, as the microprocessor should be able to register their weight and match them to one of the calibrated weights to determine that the tool is one that was previously removed from the tray. Additionally, if a mistake is made lifting up a tool, in order to reset the space in the tray, the nurse can press (and hold down) the reset button while the tool is on the tray. The tray will be easily sterilized so that it can be used for multiple surgeries. Current electronic inventory systems such as barcodes or polymer coating should be used in combination with this tray to help create an overall inventory of the surgical tools on the tray for each surgery, thus allowing the nurses to know exactly which tool was used/unused or missing during the surgery.

1.2 Background

The National Academy of Medicine has estimated that the American healthcare system wastes approximately $765 billion per year, $130 billion of which is due to inefficiently delivered services that include surgery [1]. The main area of waste in surgical operations is the unnecessary disposal, re-sterilization, or loss of surgical tools. In 1994, improperly discarded unused-surgical-tools were estimated to amount to $200 million per year in the U.S., while in 2014, discarded yet recoverable operating room supplies from large U.S. academic medical centers were estimated to be worth $15.4 million per hospital per year [2], [3]. One major avenue for reducing surgical waste is through identification of used and unused tools on surgical trays in the OR. A study of four major surgeries showed that the highest average percent usage of surgical tools on the surgical tray was 21.9%, meaning that at minimum, a shocking 78.1% of surgical tools went unused on average [4]. At UCSF Medical Center, an estimated $2.9 million was wasted in 2015 on unused neurosurgical tools alone [5]. Further, preventing unused surgical tools from being unnecessarily sterilized could save up to $156,461 per year for large non-academic hospitals [4].

Clearly, a method must be devised to keep track of which surgical tools have been used during surgeries. This could help to prevent unused surgical tools from being re-sterilized or being thrown away, both of which are costly outcomes. Our Electronic Surgical Tray would be able to solve this problem because it has weight sensors that would be able to detect when surgical tools are removed from or placed back onto the tray, and a simple LED indicator would signify the whether the tool has been used or not. In contrast, the currently available solutions for tracking surgical tools such as barcodes, RFID tags, and optically detectable polymers all require that the tools be scanned before and after surgery to make sure that no tools have been lost, so they practically exclude the possibility of monitoring surgical tool inventory during surgery due to the inconvenience of manual scanning [6], [7], [8], [9]. Our device, however, would allow nurses and surgeons to easily determine if tools are missing during surgery by looking at the colors of the LED indicators on the surgical tray.

In addition to the aforementioned methods, previous ECE 445 projects by Spring 2015's Teams 21 and 34 (referred to as "Project #21" and "Project #34") also tackled the problem of how to minimize surgical waste and track the use-statuses of tools in the operating room. Project #34 solved the problem by using RFID tags for each tool and using a watch to scan the tag before, during and after surgery. Project #21 solved the problem by using RFID tags on each tool with a stationary RFID reader, and weight module to help weigh the tools after surgery to determine if they are used or unused. Initially, these projects seem to be more advanced than our Electronic Surgical Tray due to their RFID tracking capabilities that can identify specific tools. However, both solutions are still highly impractical, as no nurses or surgeons will want to spend the time to scan surgical tools during surgery and enter the tool's use status into a database. For example, although Project #21 has RFID tags, the tools must be brought close to the RFID reader in order to be scanned, and the user must weigh the tool on the weight module in order to sort the tool into an "opened" or "unused" database. This would cause great delays in processing of the tools and could potentially prolong surgeries, at costs of thousands of dollars an hour. Similarly, although Project #34 increases convenience by using a watch to scan RFID tags, the nurses must still click on the watch to input the use status of the tool for each tool, which is still impractical, as during a surgery, it would be cumbersome to have to scan every tool before handing it to a surgeon, not to mention dangerous if it impedes a surgeon's ability to obtain necessary tools in a timely manner.

Furthermore, the previous projects' solutions cannot determine if items are missing during the surgery, as tools that are lost cannot be scanned, especially because the RFID tag must be held close to the scanners in both projects. Compared to these projects, our Electronic Surgical Tray is much more practical because its function is to simply calibrate to any set of prepared surgical tools, and then indicate whether any of the tools have been removed and are missing from the tray during surgery. In combination with the currently available methods for inventory tracking of surgical supplies, our device would be incredibly useful because nurses could first prepare the trays with tools of known identities (barcodes), and then they could ignore the barcode specifications during the surgery while still monitoring whether tools are missing, thereby allowing them to pay more attention to the actual procedure. During the surgery, if tools are indeed missing and unaccounted for, nurses can instruct staff to search for the tools during surgery and while cleaning up the operating room, instead of waiting until after cleaning up to realize that tools are missing, and then retroactively search for the missing tools, when the likelihood of recovery would be decreased.

1.3 Physical Design

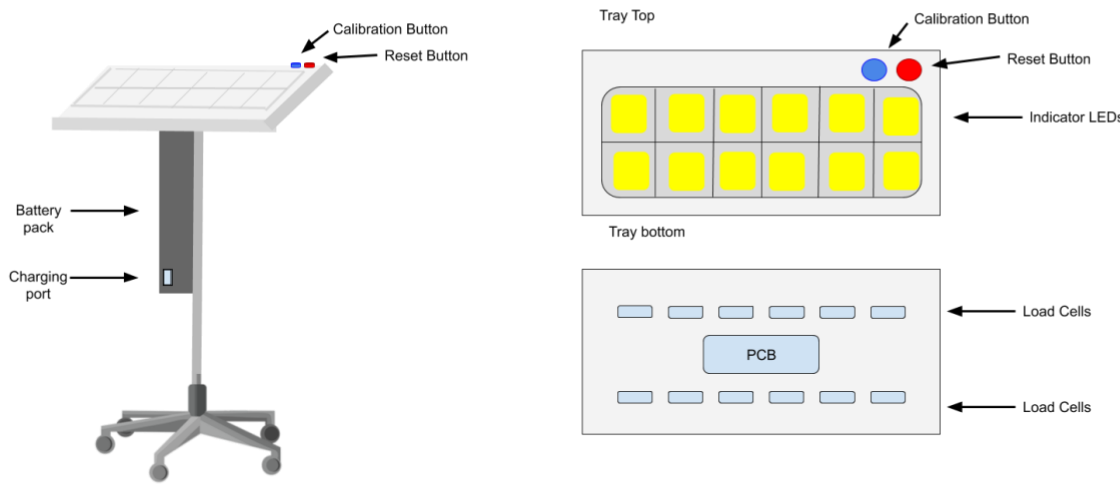

Figure 1. Physical Design Diagram for Electronic Surgical Tray. Surgical tools will be placed into individual spaces that are highlighted in yellow. The number of spaces in the diagram does not represent the actual number of spaces in the device (30 spaces). Indicator LED's colors are not all shown.[1]

The physical design of our device consists of two major parts: the tray housing, and the stand. The tray stand will be a routine stand that has 5 wheels at its base. Attached to the stand will be the battery pack, which contains a charging port. Importantly, the stand can be separated from the tray housing and battery pack, meaning that the battery pack will not have to be sterilized. The tray housing will be a 3D printed box with a height of 5 cm, a width of 0.51 m, and a length of 0.850 m, or dimensions of 0.85 m x 0.51 m x 0.05 m. This is enough to fit all the electronics inside, all of which will have a height of 2 cm at most. The tray spaces will have dimensions of 170 mm x 85 mm, allowing for 10 spaces in length and 3 spaces in width, totaling 30 spaces. They will each be indented by 1 cm and the load cell will be placed under the center of the tray space in a slightly elevated area to receive the full weight of the tool. The tray space dimensions were based on one of the most used surgical tools, known as Mayo scissors[2]; other surgical tools have similar sizes to this one as well. The attachment site of the stand to the tray will also allow the battery to connect to the rest of the circuit inside of the tray.

When the tray needs to be sterilized, it will be removed from the stand and the battery entry point will be covered. The tray will also be hermetically sealed using resin. This will prevent steam from the autoclave from entering the tray. Additionally, the datasheets of all components inside of the tray have been checked to ensure that the components are able to withstand the heat of autoclaving at 121°C (Table 13).

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1 Citation for the image of the wheels of a swivel chair: Clipart.email. Swivel Office Chair Clipart. 2020. 1 April 2020. https://www.clipart.email/download/1927379.html.

2 https://en.wikipedia.org/wiki/Mayo_scissors

1.4 Visual Aid

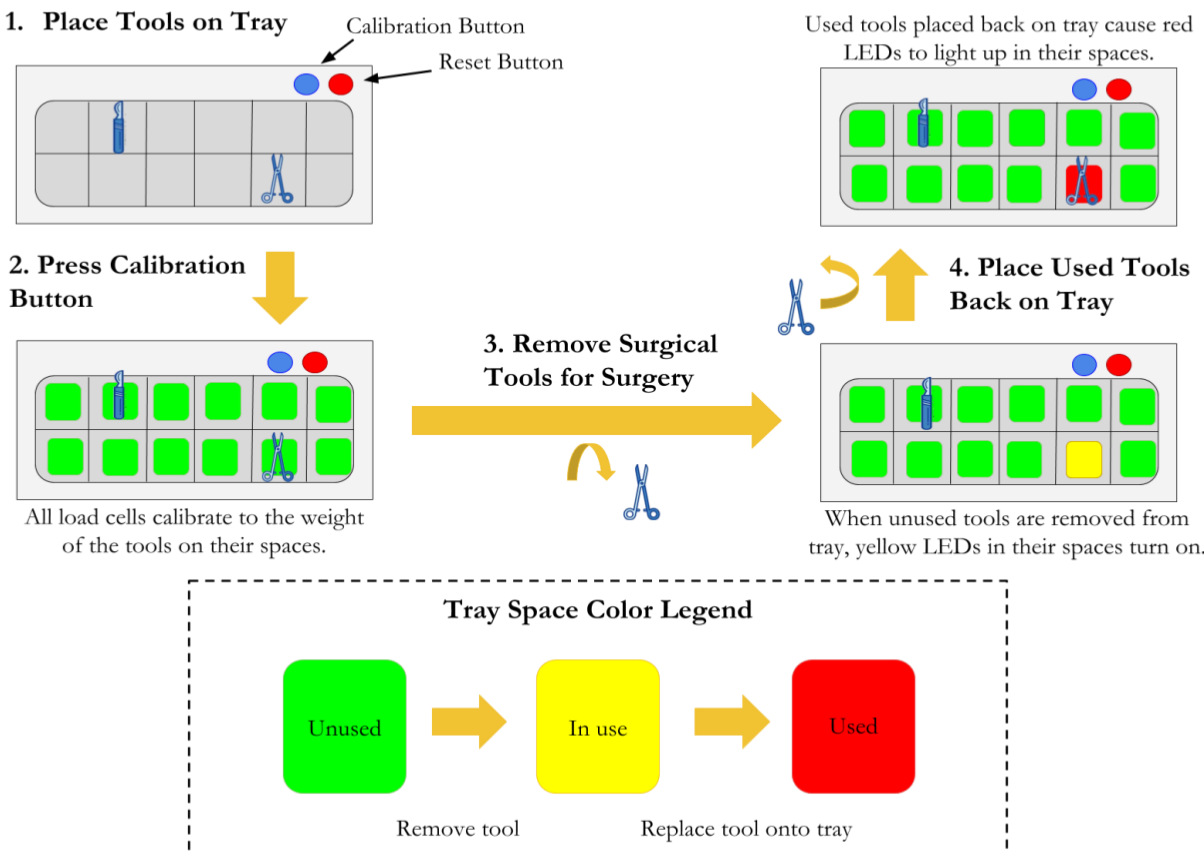

Figure 2. Visual Aid for Electronic Surgical Tray.[3] Note: not all tray spaces are pictured here, and only 2 surgical tools are shown here for clarity of the diagram.

1.5 High-level Requirements List

- Thirty tray spaces can be calibrated to hold 30 surgical tools of any identity that individually weigh between 10 g to 1000 g with an accuracy of ±4 g, and red indicator LED's in the individual spaces on the tray will light up when a tool has been placed back down onto the tray after being used.
- Device can be sterilized in the autoclave at 121°C for at least 30 minutes at 15 psi.
- Electronic tray has enough power to operate for 14 hours without using external power supplies.

[3] Surgical tool clip art: 9e507003fa1dbd92d9b74c3ce50d910f_surgeon-tools-clipart_533-612.jpeg

2. Design

Block Diagram

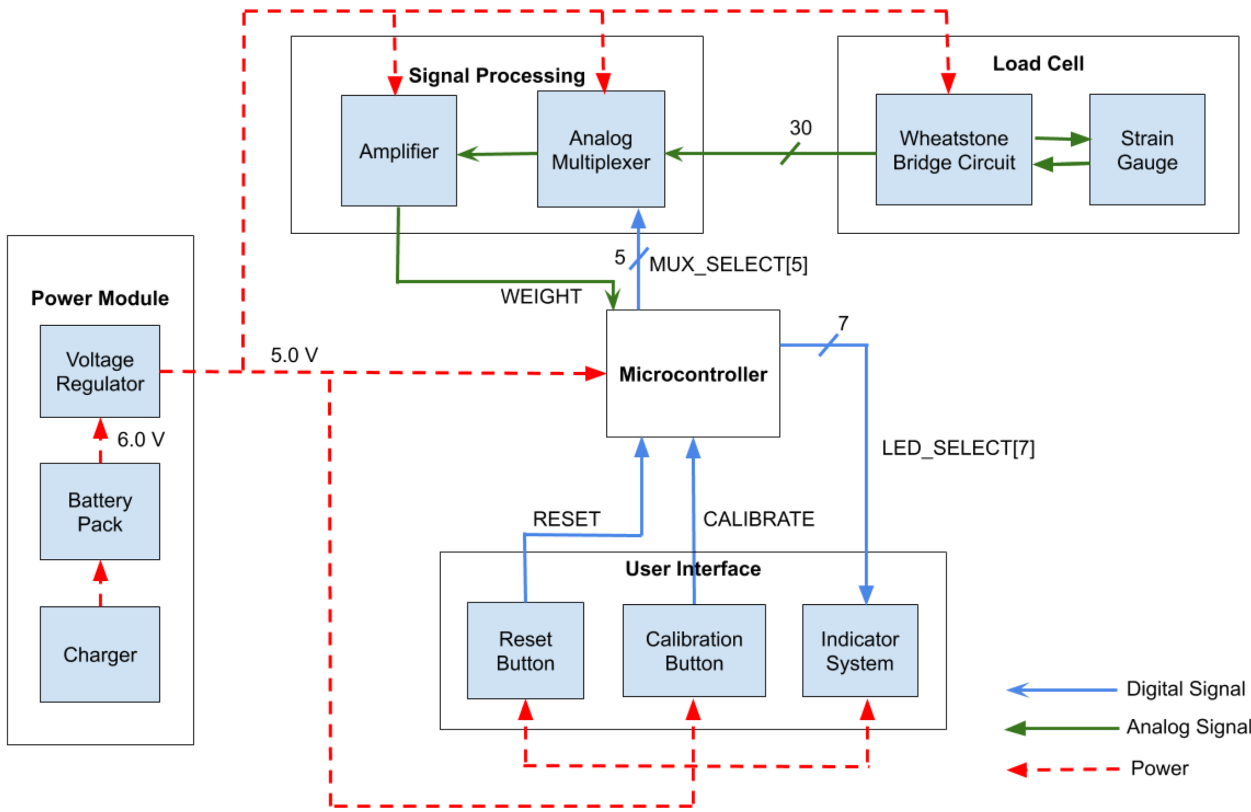

Figure 3. Block Diagram of Electronic Surgical Tray. There are 30 load cells in the Load Cell module corresponding to the 30 spaces for tools in the tray, as well as 2 analog multiplexers in the Analog Multiplexer subsystem, and 2 amplifiers in the Amplifier subsystem. **Note: there are no inter-device protocols necessary** because no peripherals are used here, so there are only pure digital and analog voltages at the input/output ports of the microcontroller.

Design Overview

Our circuit design consists of five major modules: the Power Module, the Signal Processing module, the Load Cell module, the Microcontroller module, and the User Interface module. Firstly, the weight of each tool is measured by the Load Cell module using strain gauges within Wheatstone bridge circuits. Strain gauges are devices whose resistance changes in response to different types of strain. We use a Full-Bridge Type 3 configuration for our Wheatstone bridge circuit, which depends only on axial strain, which is a change in length of a material due to a force parallel to the change. The Wheatstone bridge circuit allows us to measure the change in resistance due to a mass being placed on top of the strain gauges; since the change in resistance is proportional to the mass, we can effectively measure the weight. The 30 voltage outputs of the 30 Wheatstone bridge circuits (corresponding to the 30 tray spaces) is sent to the Signal Processing module, where it is multiplexed to an amplifier that brings the voltage to an acceptable level for reading by the analog input of the Microprocessor module. There are two 16-1 analog multiplexers and one 2-1 analog multiplexer that effectively allow the microprocessor to choose between the 30 weight signals of the 30 Wheatstone bridge circuits in the Load cell module, corresponding to the 30 tray spaces. This means that only one weight measurement is being amplified and recorded at a time.

Once the weight is chosen and sent to the microprocessor's analog input pin 1, it is read and stored in an array of weights within the main program running on the microprocessor. That program controls the specific weight that is chosen to be amplified and recorded via the MUX_Select signal, which are select signals for the two 16-1 analog multiplexers and the 2-1 analog multiplexer; and it also controls the LED colors that light up for each space. The main algorithm is pictured in Figure 5. The microprocessor also polls the digital input pins 2 and 1 for the volatile RESET or CALIBRATE signals (from the User Interface module), which correspond to the user pressing the Reset Button or the Calibrate Button, respectively. These allow the user to reset the use-status of a tool if it was accidentally picked up from the tray, or to recalibrate the tray to all the tools currently on the tray.

The microprocessor also outputs the LED_Select signal, which is a 7-wire or 7-bit signal that controls the specific LED that is to be turned on for each tray. This is accomplished in the Indicator subsystem by using an effective 5:32 decoder and a 2:4 decoder that are logically OR'ed together to produce the negative terminal of each LED. Five select bits are used for the decoder to choose which space should be enabled, and 2 select bits are used to choose the LED color. Interestingly, only 1 LED is turned on at a time by the microcontroller, while all others are off; however, the frequency at which the LEDs are turned on is around 60 Hz, so the LEDs will always appear to be on.

This concludes the functionality of our circuit. As for the powering of the circuit, we are using a lithium ion battery and a voltage regulator to provide a constant voltage to the rest of the circuit.

2.1 Power Module

2.1.1 Battery Pack

The Battery Pack consists of the lithium-ion batteries that are the power source for the system. This subsystem connects directly to the Voltage Regulator subsystem and does not directly deliver power to the other system components. The Battery Pack subsystem is located on the vertical stand of the Electronic Surgical Tray as shown in Figure 1.

Table 1. Requirements and Verifications for the Battery Pack

Requirement	Verification
1. Provides 5-7 V. 2. Provides a max current draw of 750 mA.	1. A) Use a voltmeter to probe the output voltage of the battery. B) Verify that the voltage falls within the tolerance range listed. 2. A) Connect the battery to a set of 15 parallel 100 Ω, 1 Watt-rated resistors grounded at the other terminal. B) Verify that the total current through the set of 15 parallel resistors is around 750 mA by wiring an ammeter or digital multimeter in series with the set of parallel resistors.

2.1.2 Voltage Regulator

The Voltage Regulator subsystem is required to ensure that the power delivered to the rest of the system components is consistent. The voltage regulator will be the LP3985, a linear low-drop out (LDO) voltage regulator. This regulator was chosen in order to achieve a low noise output voltage for the amplifier circuit at a voltage close to the input voltage. It takes a voltage input of 6.0 V from the Battery Pack subsystem and outputs a consistent voltage of 5.0 V. It delivers power to all other system components as shown in Figure 3.

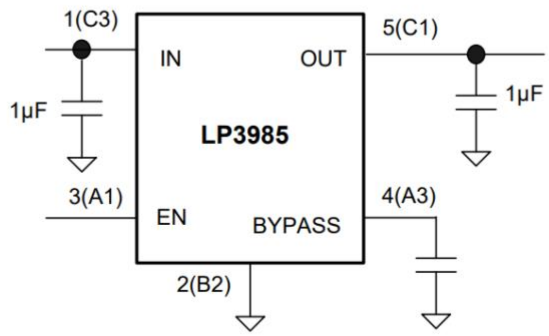

Figure 4. Sample circuit using the LP3985 voltage regulator. Capacitance A3 to the bypass pin should be 0.1 µF.[4]

Table 2. Requirements and Verification for the Voltage Regulator

Requirement	Verification
1. Provides 5.0 - 5.5 V at 750 mA current draw. 2. Has a voltage difference between output and input of below 0.5 V. 3. Has an efficiency of above 75%.	1. A) Set up the circuit shown in Figure 4. B) Connect the charged battery pack to the input of the circuit. C) Attach a set of 15 parallel 100 Ω resistors to circuit to serve as load at the output. D) Use a multimeter to measure the voltage regulator's output voltage. E) Use an ammeter to measure the current through the load resistance. F) Verify that the values fall within the tolerance ranges listed. 2. A) Set up circuit as shown in figure 4. B) Connect the charged battery pack to the input of the circuit. C) Use a voltmeter to measure the voltages at the input and output of the voltage regulator. D) Calculate the voltage drop between input and output to verify that it is below 0.5 V. 3.

[4] http://www.ti.com/lit/ds/symlink/lp3985.pdf

	A) Set up circuit as shown in figure 4. B) Connect the charged battery pack to the input pin. C) Use an ammeter to measure the current across the input. D) Calculate the input power using the measured current and the input voltage. E) Use an ammeter to measure the current across the output. F) Use a voltmeter to measure the output voltage. G) Calculate the output power using the measured current and the output voltage. H) Calculate efficiency to verify that it is above 75%.

2.2 Microcontroller

The Microcontroller module controls the circuit and tracks the use-status of the tools. This module performs calibration by taking weight measurements from the Signal Processing module. It receives only one weight signal from the Signal Processing module, but it controls which signal is multiplexed to its analog input pin 1 by using a 5-bit MUX_Select signal. The bottom 4 bits of this signal are sent to the select signal inputs of the two 16-1 analog multiplexers, while the highest bit is sent to the select signal input of the 2-1 multiplexer. Once calibrated through the Calibration Button, (digital input pin 1) the Microcontroller module then uses an algorithm to poll the weight sensors and check if any of the tools have been removed or placed back onto the tray. Using this information, the Microcontroller module sends a 7-bit LED_Select signal to the Indicator System to display the color corresponding to the appropriate use-status in each tray space. This module takes as inputs the outputs of the Reset Button, the Calibration Button and the analog WEIGHT signal of the Signal Processing module. Its outputs are the 5-bit MUX_Select signal and the 7-bit LED_Select signal.

Table 3. Requirements and Verification for the Microcontroller

Requirement	Verification
1. Has a sampling rate of at least 1500 samples per second. 2. Operates on a 5.0 - 5.5 V power supply.	1. A) Attach oscilloscope cable to microcontroller output. B) Run test script to output HIGH as often as possible for a second. C) Check oscilloscope output to verify output meets rate requirements. 2. A) Attach power supply to microcontroller. B) Turn on power supply and set to 5.0 V and verify that the microcontroller is able to operate. C) Vary the voltage through 5.0 - 5.5 V at 0.1 V intervals and verify that the microcontroller is able to operate throughout the entire range.

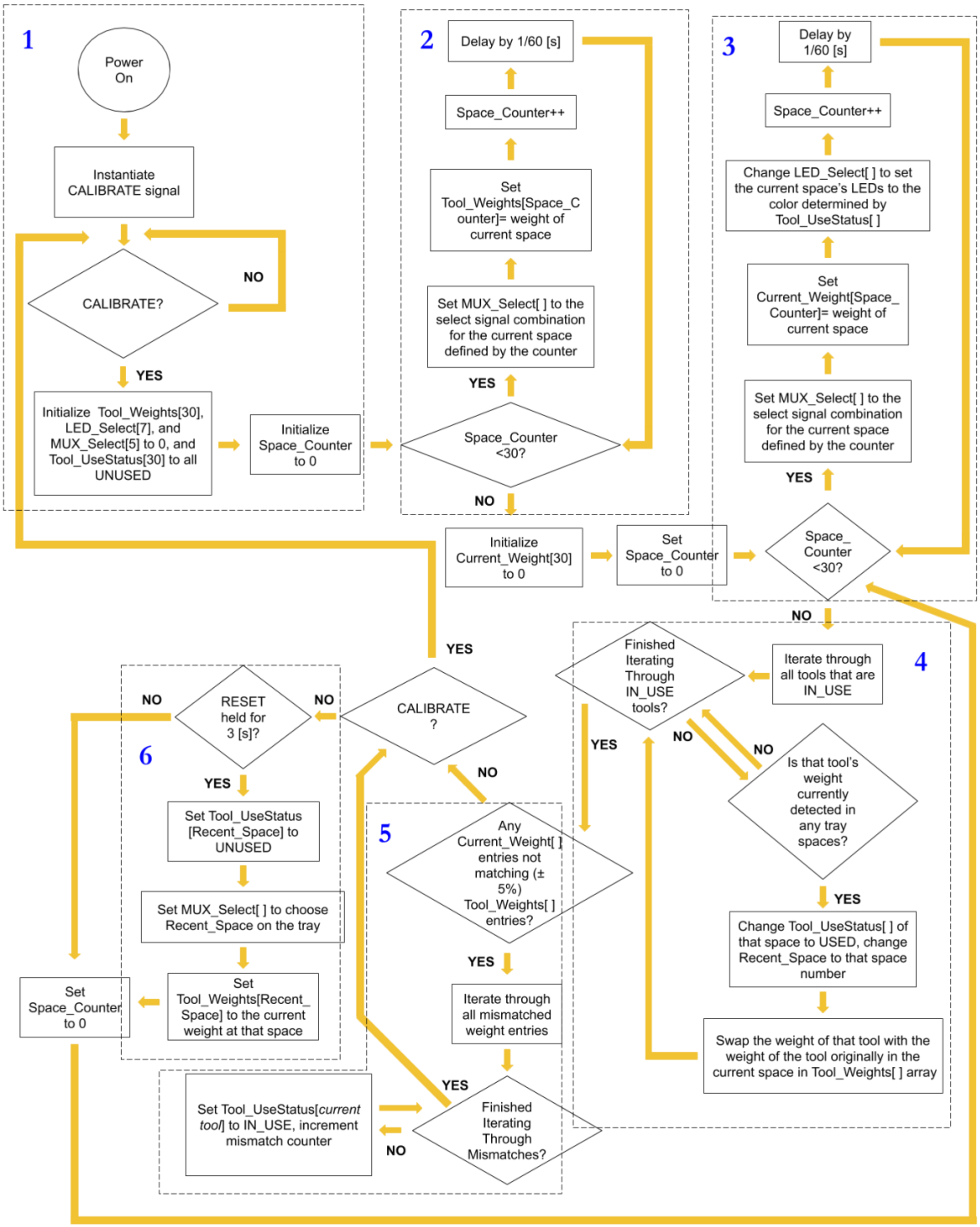

Figure 5. Microcontroller Algorithm Diagram. Variables are described in Table 4. Areas are described in the following section after Table 4. RESET, CALIBRATE, and the WEIGHT (not pictured) variable are volatile variables that come from digital input pin 2, digital input pin 1, and analog input pin 1, respectively. Note: the delay can be adjusted to achieve the correct sampling rate.

Table 4. Description of Variables for Algorithm in Figure 5.

Variable Name	Description
Tool_UseStatus[30]	An array of strings that represent the use-statuses of each tool on the tray. Possible values are "UNUSED", "IN_USE", and "USED". These values are decoded to the LED colors, which are green, yellow, and red, respectively.
Tool_Weights[30]	An array of integers representing the weights of all of the tools that were initially placed onto the tray.
LED_Select[7]	An array of select signals (binary) that chooses the LED color for a specific space on the tray. LED_Select[6:2] are used to choose a space, while LED_Select[1:0] are used to select the color of the LED that turns on in that space.
MUX_Select[5]	An array of select signals (binary) that chooses the weight (the output of the Load cell) from a specific space on the tray.
Current_Weight[30]	An array of integers representing the weight of each tool currently incident on the tray. If no tool is present, the weight will be zero.
Recent_Space	An integer variable that holds the number of the tray space that had a tool lifted from it most recently. This variable only holds values of spaces that have tools "IN_USE".
Space_Counter	Counts the spaces in the tray starting from 0 to 29, or 30 total trays.

Overview of Algorithm in Figure 5:

The algorithm progresses through the areas in the diagram in the following order: 1 => 2 =>3 => 4 =>5 => 6 =>3 =>4... The first two areas are part of the calibration of the tools on the tray. Areas 3-6 are continuously looped through unless the user turns the power off or presses calibrate again. These areas represent the state of the device during active use in the operating room, when tools have already been calibrated and are being picked up from and placed onto the tray. The weights of the tray spaces are monitored so that the program can determine whether a tool has been picked up, in which case the yellow LED for that space is turned on, or whether a tool has been placed back down, in which case the red LED for that space is turned on.

Explanation of the Algorithm in Figure 5, by Area:

Area 1: This area contains a loop waiting for the user to calibrate the spaces on the tray. After calibration is initiated, the necessary variables are initialized before moving into the calibration process.

Area 2: This is the actual calibration process, where each tray space is cycled through, and the output of the load cell (the weight) in each space is read and stored in the Tool_Weights[ ] array.

Area 3: After calibration is complete, the tool weights are constantly polled and stored into the Current_Weight[ ] array. For each space, the LED colors are also set by outputting the relevant select signals through the LED_Select[ ] array values.

Area 4: This loop iterates through the Current_Weight[ ] array specifically at indexes of tool spaces that are IN_USE to see if the tool has been returned to the tray. If it has, then the status is changed to USED. If the tool has been placed in a different tray location, the algorithm is still able to recognize that the tool has been returned, since weights are compared to all original weights in Tool_Weights[ ] array, and the tool is effectively swapped to the new tray position by swapping the weights of the returned tool and another tool that is IN_USE inside of the Tool_Weights[ ] array. This ultimately allows the users to calibrate tools in any position, use them, and place them back down on the tray in any position.

Area 5: This loop interrogates any and all spaces with tool weights that are not matched to any of the weights of the original tools on the tray. For mismatched weights, we assume that any mismatch is due to a tool being removed from the tray. Thus, the use-status of the mismatched tray space is changed to IN_USE, signifying that a tool has been removed from the tray. Mismatches due to the weight exceeding 105% of the original tool weight is assumed to be due to multiple tools placed onto the same tray space, which is purposefully not recognized because the user is instructed not to put multiple tools in the same tray space.

Area 6: This conditional block resets the use-status of the most recent tool that was marked as "USED" to "UNUSED".

2.3 User Interface

2.3.1 Reset Button

The Reset Button allows for the reset of a single tool's use-status. Once pressed, the tool that was most recently picked up from the tray is automatically reset to "unused," resetting the LED indicator for that tool to green. Outputs the RESET signal to the Microcontroller module.

Table 5. Requirements and Verification for the Reset Button

Requirement	Verification
1. When pressed outputs RESET signal and is easily pressed with surgical gloves.	1. A) Create test circuit. B) Attach power supply to input of circuit and oscilloscope to output. C) Put on surgical gloves. D) Set power supply to 5.0 V. E) Press down on button. F) Verify that button press creates an output of 5.0 V by checking the oscilloscope.

2.3.2 Calibration Button

The Calibration Button is used to calibrate the load cells so that the Microcontroller module can determine the proper weights of the tools currently on the surgical tray. When pressed, the use-status of all tools should be reset to "unused," resetting the LED indicators to green. Outputs the CALIBRATE signal to the Microcontroller module.

Table 6. Requirements and Verification for the Calibration Button

Requirement	Verification
1. When pressed outputs CALIBRATE signal and is easily pressed with surgical gloves.	1. A) Create test circuit. B) Attach power supply to input of circuit and oscilloscope to output. C) Put on surgical gloves. D) Set power supply to 5.0 V. E) Press down on button. F) Verify that button press creates an output of 5.0V.

2.3.3 Indicator System

The Indicator System consists of an array of red, green, and yellow LEDs in each of the tray space locations, with 1 red, 1 green, and 1 yellow LED per space on the tray. A 5:32 decoder and a 2:4 decoder are used to control the LED colors through a 7-bit select signal (LED_Select[7]) from the Microcontroller module. The 5:32 decoder is actually created using 4 3:8 decoders and a 2:4 decoder, with the same 3 bits of select signals going to each of the 4 3:8 decoders, and a separate 2 bits of the select signal for the 2:4 decoder. The last 2 bits of LED_Select are used for the 2:4 decoder that chooses between 3 LED colors to turn on the LED's. This subsystem indicates to the user the use-status of the tool in each space. When a tool is unused, the Indicator System should only have the green LED on in that space; when the tool is in use and removed from the tray, only the yellow LED should be on in that space; and when the tool is used and placed back onto the tray, only the red LED should be on in the space that the tool is placed back down onto.

Table 7. Requirements and Verification for the Indicator System

Requirement	Verification
1. Red, green, and yellow LEDs should be distinguishable from each other. 2. Able to take 7 select signals from the Microprocessor unit and choose the LED colors for any of 30 spaces.	1. A) Set up test circuit with sections of red, green, and yellow LEDs. B) Turn on all LEDs at the same time. C) Verify that LED colors are distinguishable. 2. A) Attach power supply inputs in place of LED_SELECT signals. B) Test all the different select combinations. C) Verify that LED_SELECT[6:2] can choose the space that is the decimal equivalent of the binary value of the select signals. (e.g. LED_SELECT[6:2] = 10000 selects space 16) D) Verify that table 8 is correct for LED colors.

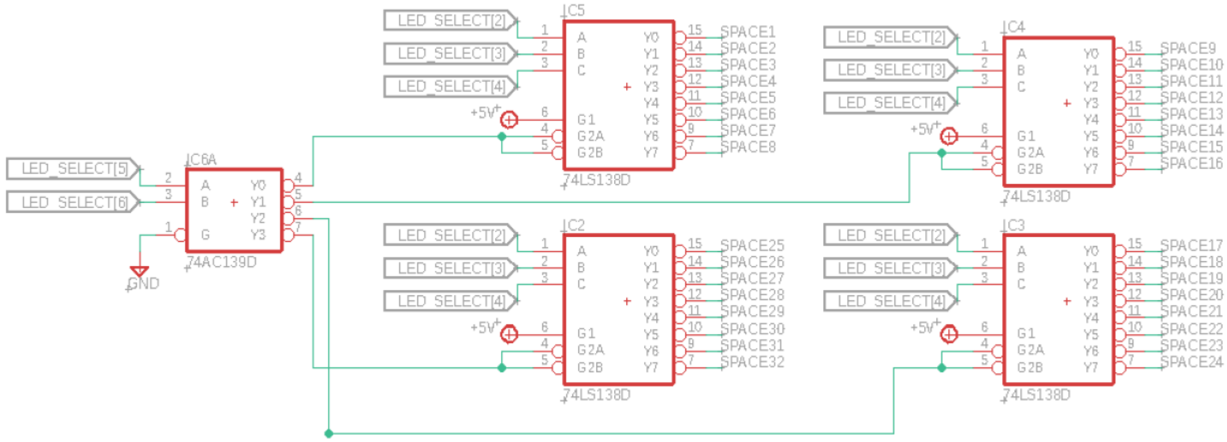

Figure 6. Decoder circuit for Indicator Subsystem. LED_Select[6:2] are used to control 4 3:8 decoders and 1 2:4 decoder as shown above in order to choose between 30 spaces. Outputs SPACE31 and SPACE32 are not connected to any circuit; otherwise, SPACE# outputs will connect to the LED circuits in Figure 7. Based on the datasheets[5], the outputs of both decoders are LOW voltages when selected, or HIGH when not selected. The 2:4 decoder is enabled by a LOW voltage, and the 3:8 decoders are enabled by G1=HIGH and G2A=G2B=LOW.

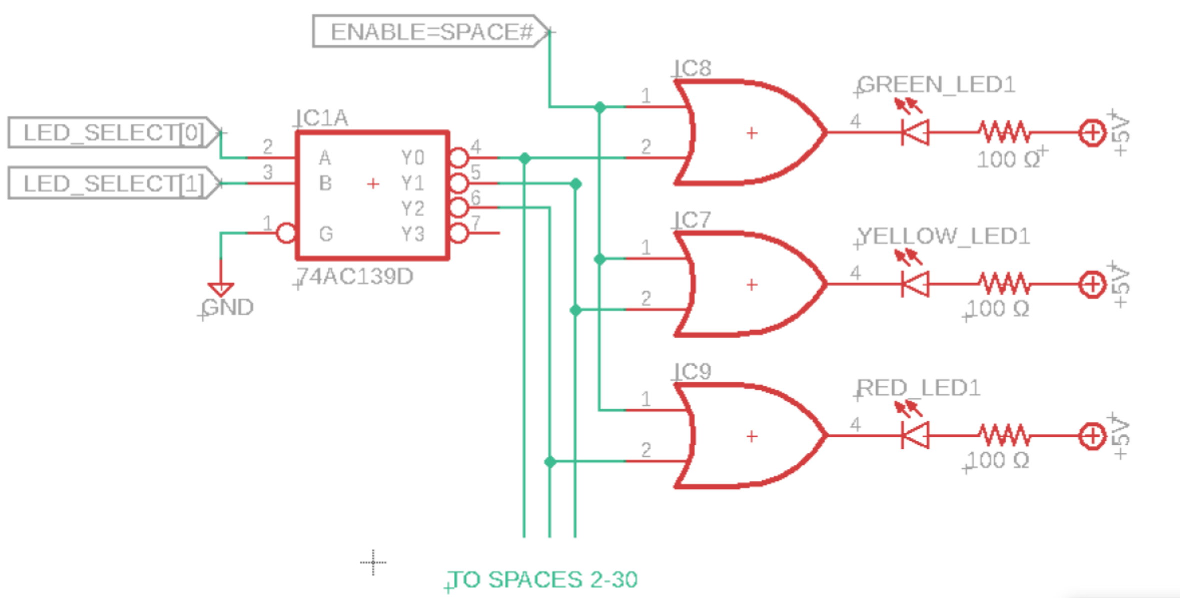

Figure 7. LED driver circuit for Indicator Subsystem. The ENABLE signal is the specific output of the 5:32 decoder that is connected to this particular LED circuit. The ENABLE signal is also designated

5 https://www.mouser.com/datasheet/2/149/74AC139-180829.pdf, https://www.ti.com/lit/ds/symlink/sn54ls138-sp.pdf

SPACE# in the decoder circuit in Figure 6. Since all decoder outputs are LOW voltages when selected, only when the ENABLE is LOW and the 2:4 decoder output for a specific color LED is LOW will the output of the OR gate be LOW, leading to one particular LED turning on. Since the 5:32 decoder only enables 1 out of 32 outputs at a time, and since the 2:4 decoder only enables 1 out of 4 outputs at a time, only one LED in one tray space will be on.

Table 8. LED colors and associated LED_SELECT signals

LED_SELECT[1]	LED_SELECT[0]	Color
0	0	Green
0	1	Yellow
1	0	Red

2.4 Load Cell

2.4.1 Strain Gauge

A configuration of strain gauges will be used to measure the axial force produced by the weight of the tool at the tray location. When these gauges are deformed their resistance changes which can be used to infer the force applied to them if they are biased properly. Multiple strain gauge sensors can be used at different orientations to improve the overall accuracy and compensate for errors that can arise from temperature variations [10]. The strain gauges in the Strain Gauge subsystem are part of the Wheatstone Bridge Circuit, hence the bidirectional analog signals shown in Figure 3 between the Strain Gauge subsystem and the Wheatstone Bridge Circuit. The sensitivity of the strain gauge can be discerned from its gauge factor defined in Equation 1. For this sensor a gauge factor between 2.0-2.2 is needed for accurate weight measurements. The BF350-3AA from ICStation will be used in this design since it has nominal resistance of 350Ω and a gauge factor within our desired range[6].

$$GF = \frac{\Delta R / R}{\Delta L / L}$$

(Equation 1)[7]

Table 9. Requirements and Verification for the Strain Gauge

Requirement	Verification
1. Gauge factor between 2.0-2.2.	1. A) Record original length L and unstrained resistance R of gauge. B) Compress strain gauge by 2mm using a vice and record new resistance value. C). Calculate resistance change. D). Use equation (1) and verify gauge factor is between 2.0-2.2.

[6] https://images-na.ssl-images-amazon.com/images/I/81syDCHm59L.pdf
[7] http://elektron.pol.lublin.pl/elekp/ap_notes/NI_AN078_Strain_Gauge_Meas.pdf

2.4.2 Wheatstone Bridge Circuit

To convert the resistance change in each strain gauge into a usable signal, a Wheatstone Bridge circuit is necessary (1 for each Load Cell). This circuit consists of two parallel voltage dividers where one, two or four of the resistive elements in the voltage divider is a sensing element with a variable resistance. The voltage difference between the two dividers is measured and used interpret the sensor readings. For this application a Full-Bridge Type 3 Wheatstone bridge configuration is used. This type of configuration provides the highest sensitivity of the configurations for measuring axial strain and compensates for variations caused by temperatures [10]. Since this circuit utilizes voltage dividers an external voltage is required. This voltage will be around 5V since the other systems in this design also require that supply voltage. The output of the Wheatstone Bridge Circuit is provided to the Analog Multiplexer subsystem, which will provide one of the signals from the 30 load cells to the Amplifier subsystem to be sampled by the Microcontroller module.

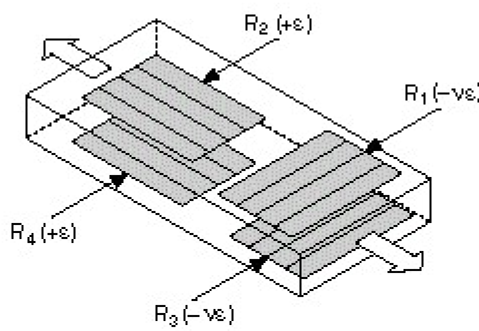

Figure 8. Full-Bridge Type 3 Configuration [10]

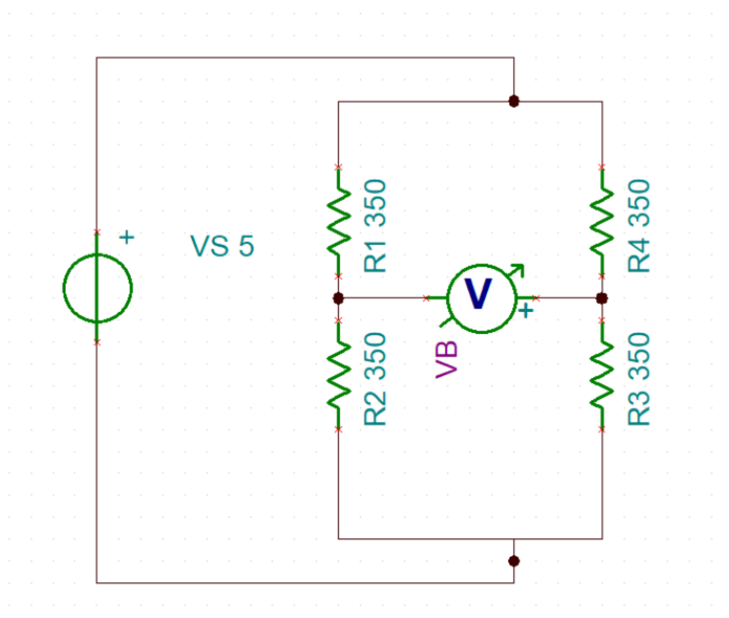

Figure 9. Wheatstone Bridge Circuit Configuration

Table 10. Requirements and Verification for the Wheatstone Bridge Circuit

Requirement	Verification
1. Voltage output of at least 25 mV at max load at a bias of 5 V.	1. A) Create circuit shown in Figure 9 with biasing voltage of 5V with a load of 1000g on the load cell. B) Use a voltmeter to read the output voltage at VB. C) Verify that the output is at least 25 mV.

2.5 Signal Processing

2.5.1 Amplifier

Since the output of the Wheatstone Bridge will be on the order of several mV an amplifier will be necessary to generate a signal that can be read by the microcontroller. Thus, the Amplifier subsystem should output a voltage range that can be read by the analog inputs of the microcontroller in the Microcontroller module. Since the output of the Wheatstone bridge has an input impedance that can change, this must be considered when designing an amplifier or an amplifier configuration that does not depend on the source impedance needs to be used. This problem will be solved by using a three op-amp instrumentation amplifier [12]. The configuration of this amplifier can be seen in figure 4 and has a high input impedance. In this configuration R1=R2 and R3=R4. With R1=10kΩ, R4=50kΩ and RF=8kΩ a Rg value of 410 Ω will yield a voltage gain near 200. The INA827 instrumentation amplifier from Texas Instruments will be used. This package this already includes R1-R4 and Rf so only Rg needs to be connected to set the gain. This configuration is shown in Figure 11. The DC voltage transfer characteristics of this amplifier are shown in Figure 12.

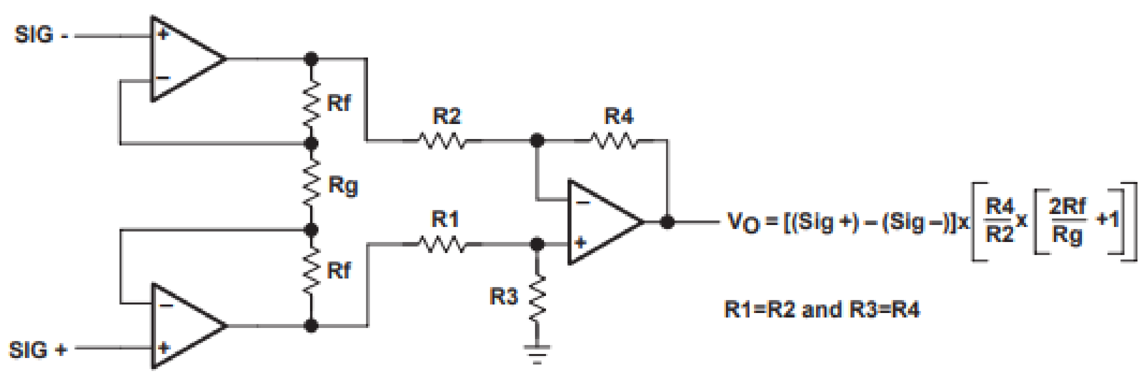

Figure 10. Three Op-Amp Instrumentation Amplifier [12]

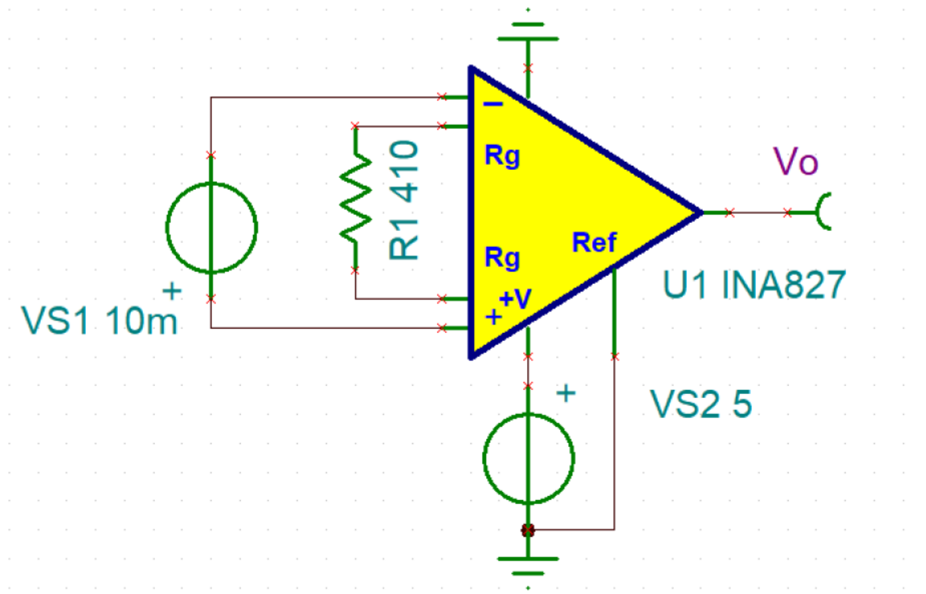

Figure 11. INA827 Configuration

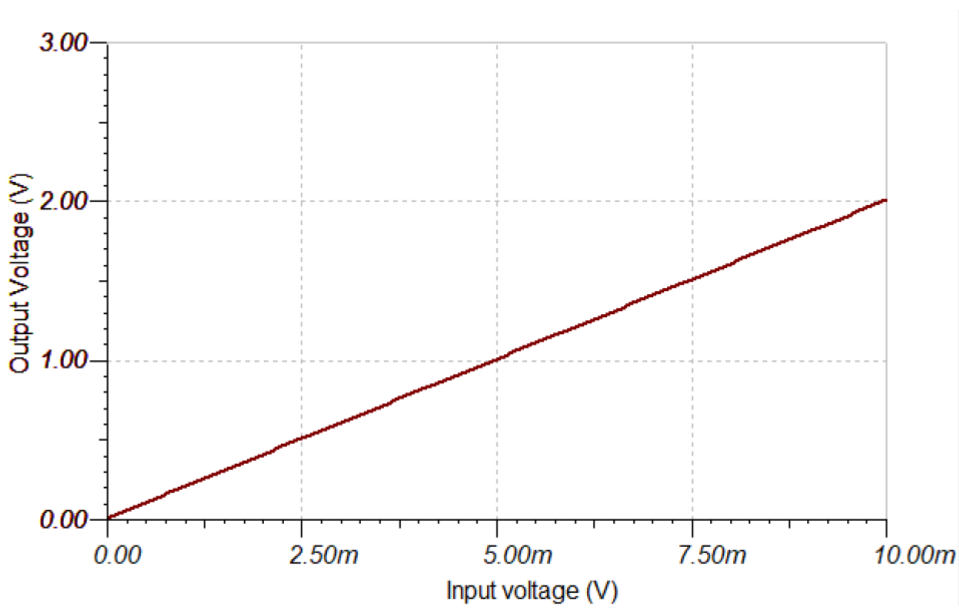

Figure 12. Instrumentation amplifier DC transfer characteristics at 5V bias

Table 11. Requirements and Verification for the Amplifier Circuit

Requirement	Verification
1. Has a voltage gain of 180 – 200.	1. A) Set up circuit shown in Figure 11. B) Attach power supply to inputs of the amplifier circuit. C) Set power input corresponding to VS2 to 5.0 V. D) Set power input corresponding to VS1 to 10 mV.

	E) Use voltmeter to measure output voltage. F) Verify that gain is within the tolerance range.

2.5.2 Analog Multiplexer

Two 16:1 analog multiplexers and a 2:1 analog multiplexer will be used to select between each of the load cell outputs so that the analog inputs on the microcontroller can be conserved. This will also reduce the number of amplifiers needed since each load cell will not require its own amplifier. Thus, the Analog Multiplexer subsystem takes as inputs all 30 outputs of the 30 load cells, and outputs one signals corresponding to only one of the load cells (and thus spaces) on the tray and sends this output to the Amplifier subsystem. The analog multiplexers that will be used for this are the Texas Instruments CD74HC4067M96 and SN74LVC1G3157. These 16:1 and 2:1 analog multiplexers will allow the microcontroller to access all 30 load cells with the need for only 1 analog input and instrumentation amplifier. This will require the analog to digital converter of the microcontroller to sample more often, however, this application does not require high speed data acquisition so the number of times each sensor is polled per second can be low.

Table 12: Requirements and Verification for the Analog Multiplexer

Requirement	Verification
1. Multiplexer adds less than 0.1 mV of noise. 2. Voltage drop between input and output of multiplexer block is less than 1mV.	1. A) Cascade the 16:1 multiplexers to the 2:1 multiplexer B) Provide 5V to IC supplies C) Turn on power supply and set one input to 1.0 V while grounding all others. D) Select the 1.0 V input using the select bits. E) Use voltmeter to read output voltage. F) Verify that the added noise is below 0.1 mV. 2. A) Cascade the 16:1 multiplexers to the 2:1 multiplexer B) Provide 5V to IC supplies C) Turn on power supply and set one input to 1.0 V while grounding all others. D) Select the 1.0V input using the select bits. E) Use voltmeter to read output voltage. F) Verify that output voltage is within 1mV of the input voltage.

2.6 Tolerance Analysis

Since the surgical tools will only be tracked by their weight it is crucial that these weights are recorded accurately and consistently. In order to transform the gravitational weight of the tool into a signal that can be accurately read by the microcontroller several signal processing steps are required. The basic signal flow for this process is the force due to gravity causes a strain on the load cell strain gauges. This strain causes the resistance of the strain gauges to change, which when configured in a Wheatstone bridge generates a signal on the order of a few millivolts. This signal is then inputted into an analog multiplexer. Whichever signal is then selected from the multiplexer is amplified and sampled by the microcontroller. In each of these steps, errors will be added due to the tolerances of the components. In order to verify the final accuracy of the measurement the signal values at each block will be calculated according to worst case scenario component tolerances to verify the accuracy of the result.

The accuracy of the design will lowest when the range of voltages supplied to the analog input of the microcontroller is the smallest. This occurs when the gain of the instrumentation amplifier is at its minimum tolerable value which in this case is 180V/V. This corresponds to a Rg value of 457Ω. The DC voltage transfer characteristics of this amplifier are shown in figure 13. At this value the max load voltage of the Wheatstone bridge circuit will be amplified to 4.5V.

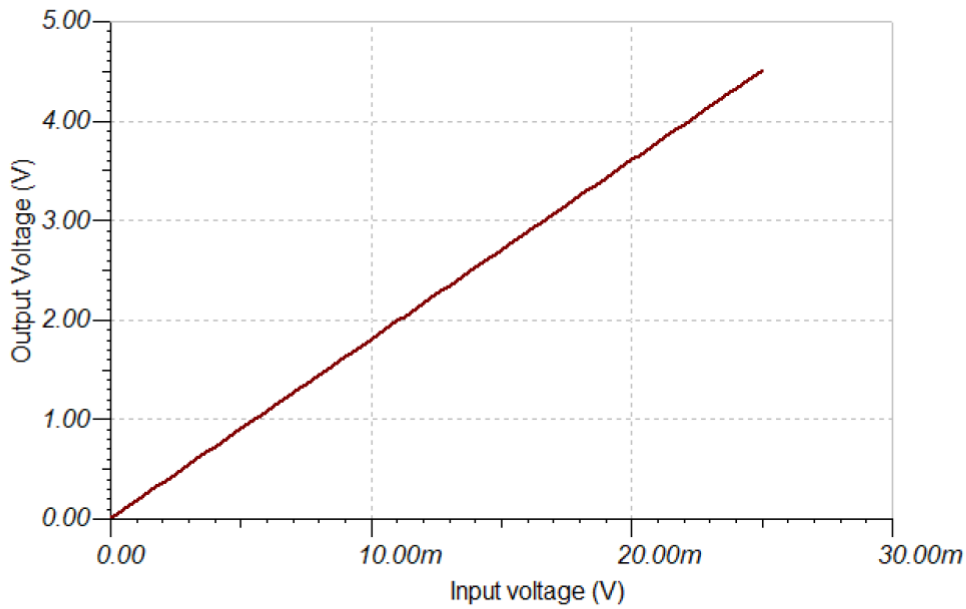

Figure 13. Worst Case Amplifier DC Transfer Characteristics

Next it needs to be determined if the resolution of the analog to digital conversion will be high enough to achieve the accuracy that is required for the successful operation of the device. The resolution of the analog to digital conversion is given by Equation 2. Where M is the number of ADC bits and Vr is the voltage measurement range. The microcontroller used in this device is supplied to at least 5V and has an ADC resolution of 12 bits. This yields a resolution of 1.22mV.

$$Q = \frac{V_r}{2^M}$$

(Equation 2)

When the analog input voltage falls between 0-4.5V this will yield 3686 discrete levels. The range of weights expected to be encoded by these levels falls between 10-1000g. Therefore, each level in this range will correspond to a weight range of .27g which is within the resolution required for this project.

It must also be determined whether any noise added by the signal multiplexing will large enough to alter the accuracy of the measurement. The allowable noise from the multiplexer is ±0.1mV. When this is amplified in the worst case amplification of 180 V/V it yields an output range of ±18mV. This corresponds to 15 quantization levels which is a weight range of ±4g which is an acceptable tolerance for the device's successful operation.

3. Project Differences

3.1 Overview

Two previous ECE 445 projects by Spring 2015 Team #21 and Spring 2015 Team #34 also involved solutions to the problem of how to track surgical tools in the operating room to reduce waste. Project #21 used a stationary RFID module and weight module, along with RFID tags on surgical tool wrappers to track surgical tools as follows: when each surgical tool is unwrapped, the RFID tag can be brought near the scanner to scan the item into the inventory system; at the same time, or after the surgery, the tool can be weighed and the user can select the tool in the inventory using the touchscreen, and then choose whether this tool has been used or not [13]. Limitations of this project's solution include the small scanning range of the RFID scanner (<5 cm), which does not allow for tracking all surgical tools in the operating room, the lengthy amount of time necessary to scan each item and enter the item's information into the system manually, and the impracticality of nurses having to scan, weigh, and manually enter information into the inventory system about surgical tools one by one, at a stationary location, especially when a patient is being operated on [13].

Project #34 uses an RFID scanner watch that can scan items in close proximity to the watch (similar to Project #21's 5 cm limit) and transmit information to a base station within 30 feet; the base station has a software database of the inventory items that have been scanned [14]. Although Project #34 is slightly more practical in that the nurse now can move freely and scan items with a watch, the items can still only be scanned by the RFID reader in close proximity to the scanner, and the design is ultimately quite similar to Project #21 because the information in the database regarding each item can only be manipulated at the stationary graphical user interface. In fact, this design "assume[s] that each product scanned in before the surgery is going to be used" [14], leading to similar limitations as the previous design due to its inability to monitor the status of all surgical tools during surgery, and the impracticality of having to scan items and then walk over to the graphical user interface input information about each individual item.

3.2 Analysis

In contrast to both previous projects, the Electronic Surgical Tray allows nurses to monitor the presence/absence of and the use-status of all surgical tools that are placed down on the tray. Users can place tools onto each of the 30 spaces on the tray, calibrate the tray to recognize the weights of those items, and then freely pick up and place tray items back down onto any available spaces on the tray. The weight sensors and the microprocessor together keep track of which items have been removed or replaced, and LED indicators change colors to allow the nurses to see the use-statuses of each tool on the tray.

Although both previous solutions allow for inventory tracking using RFID tags, this capability proves to be no different than hospital inventory systems such as barcodes that are currently in place (and have been for years): the RFID tags cannot be scanned unless they are within a short range (<5 cm for Project #21, "close enough to the scanner on the watch" for Project #34), and information about the use-status of a tool must be manually entered into a stationary user-interface device such as a computer (Project #34) or a touchscreen weight module (Project #21). On the other hand, our Electronic Surgical Tray does not burden nurses by having to enter information about use-statuses manually into a database to track the statuses of surgical tools during surgery; instead, it frees nurses and surgeons of any complicated inventory tracking beyond simply picking up and placing down surgical tools onto a surgical tray, as would be natural during a surgery. Instead of scanning devices and tracking use statuses individually, all use-statuses can be monitored simultaneously through the simple modality of color vision: red, green, and yellow LED indicators signal that a tool in a particular space has been either used, unused, or is not present on the tray, respectively. The utility of our device is that no barcode information or device specifications are checked, so during surgery nurses and surgeons can focus on the surgery undistracted by such superfluous information, while still using minimal cognitive effort to track the colors on the tray, which indicate what tools are used or unused, or if a tool is missing.

Clearly, Project #34 and #21 are both relatively impractical because they required the nurses to actively scan information, to manually enter the information, and they are not able to track what tools have been used/unused or identify if tools have gone missing during surgery. In direct contrast to this, the Electronic Surgical Tray does not require any active scanning of information, nor does it require any manual entering of numerical or qualitative information, and it tracks the use-status of tools, also allowing for the absence of tools during surgery to be alerted to nurses so they can search for missing tools. While Project #34 and #21 try to improve upon existing inventory-tracking methods, they ultimately do not differ from existing methods where nurses bring tubs full of tools to electronic barcode scanning machines pre/post-surgery to update inventory databases. The Electronic Surgical Tray, however, complements the existing inventory-tracking methods by making the intra-operative surgical tool tracking to be free of barcodes, while still allowing for barcode scanning pre/post-surgery.

4.1 Cost

The labor cost per hour is estimated to be $50 per person at 10 hours per week over a 9-week period. The total cost is calculated as follows:

$$\$50/[hr*person] * 10\ [hr/wk] * 3\ [wk] * 3\ [people] * 2.5 = \$11,250 \quad \text{(Equation 3)}$$

Table 13. Component Costs

Type	Manufacturer	Part #	Quantity	Unit Cost	Total cost	Max Storage Temperature (Celsius)
Voltage Regulator	Texas Instruments	LP3985IM5X-5.0/NOPB	1	$0.53	$0.53	150[8]
Battery	SparkFun Electronics	PRT-11856	1	$15.95	$15.95	N/A
Charger	SparkFun Electronics	PRT-10473	1	$33.75	$33.75	N/A
LED (Red)	OSRAM Opto Semiconductors Inc.	GR PSLR31.13-GTHP-R1R2-1	30	$0.74	$22.20	125[9]
LED (Green)	Cree Inc.	MLEGRN-A1-0000-000X01	30	$0.81	$24.30	125[10]
LED (Yellow)	OSRAM Opto Semiconductors Inc.	LCY G6SP-CBDB-5E-1-140-R18-Z	30	$1.57	$47.10	125[11]
2:1 Analog Multiplexer	Texas Instruments	SN74LVC1G3157	1	$0.43	$0.43	150[12]
16:1 Analog Multiplexer	Texas Instruments	CD74HC4067M96	2	$0.75	$1.50	150[13]
Decoder (4:2)	Texas Instruments	CD74AC139M96	2	$0.64	$1.28	150[14]
Decoder (8:3)	Texas Instruments	SN74LS138N	4	$0.84	$3.36	150[15]
Microcontroller	Microchip Technology	PIC18F2553-I/SP	1	$6.24	$6.24	150[16]
Strain Gauge	ICStation	BF350-3AA	120	$0.90	$108.00	135[17]

8 http://www.ti.com/lit/ds/symlink/lp3985.pdf
9 https://www.digikey.com/product-detail/en/osram-opto-semiconductors-inc/GR-PSLR31.13-GTHP-R1R2-1/475-3227-1-ND/6569597
10 https://www.cree.com/led-components/media/documents/XlampMLE.pdf
11 https://media.digikey.com/pdf/Data%20Sheets/Osram%20PDFs/LCY_G6SP_1-19-11.pdf
12 http://www.ti.com/lit/ds/symlink/sn74lvc1g3157.pdf
13 http://www.ti.com/lit/ds/symlink/cd74hc4067.pdf
14 http://www.ti.com/lit/ds/symlink/cd74ac139.pdff
15 https://www.ti.com/lit/ds/symlink/sn54ls138-sp.pdf
16 http://ww1.microchip.com/downloads/en/DeviceDoc/39887c.pdf
17 https://images-na.ssl-images-amazon.com/images/I/81syDCHm59L.pdf

Amplifier	Texas Instruments	INA827AIDGKR	1	$2.73	$2.73	150[18]
Casing (Estimate)	Illinois Maker Lab		1	$30.00	$30.00	210[19]
OR Gate	Texas Instruments	SN74LVC1G32DCKR	90	$0.29	$26.10	150[20]
				Total cost	$308.55	

Total cost = Labor + Parts = $11,250.00 + $308.55 = $11,558.55 (Equation 4)

4.2 Schedule

Table 14. Schedule

Week	Erik	David	Jane
Week 1: 4/13/2020	Work on the design document. Finish tolerance analysis, Wheatstone bridge design, load cell analysis.	Work on the design document. Finish the Project Differences section, edit the Ethics and Safety section, add requirements and verifications for subsystems, write summary of functionality of design, complete algorithm diagram.	Work on the design document. Determine what components would be needed for the design.
Week 2: 4/20/2020	Work on the circuits for the load cell and signal processing modules.	Create the PowerPoint for the design document review.	Work on the circuit for the power module. Work on PowerPoint and make any corrections to diagrams as needed.
Week 3: 4/27/2020	Work on the final paper.	Work on the final paper.	Work on the final paper.

18 http://www.ti.com/lit/ds/symlink/ina827.pdf
19 https://filaments.ca/pages/temperature-guide
20 http://www.ti.com/lit/ds/symlink/sn74lvc1g32.pdf

5. Ethics and Safety

The Electronic Surgical Tray is designed to be used in the operating room during surgeries and therefore the first point in the IEEE Code of Ethics[21], which discusses the safety and health of the public, is distinctly relevant [15]. Surgeries are medical procedures wherein a human patient is operated on, and their tissues are removed, opened, and or modified. Doctors follow the principle of nonmaleficence, or "Do No Harm," and our device should also do no harm to the patients or the device operators, in keeping with nonmaleficence and the IEEE Code of Ethics point #1. Because patient tissues are being opened/operated on, there is a great risk for infection of the body or blood. Consequently, every surgical tool is sterilized, doctors wear personal protective equipment, and the patient lies within a sterile field, primarily to prevent infection of the patient and biological materials from directly contacting the doctors/nurses. In order to prevent infections of patient tissues due to bacteria or viruses, our surgical tray must be able to be sterilized properly. The standard way to sterilize materials is to use an autoclave, which is essentially an oven with high pressure steam. Autoclaves are effective if used at 121°C for at least 30 minutes at 15 psi [16]. To address this requirement, our second high-level requirement for the device is that it must be able to be autoclaved under the aforementioned conditions, meaning the electrical components must be insulated and sealed within the device so that it can withstand high temperatures, high pressures, and steam.

Additionally, given that this device must be able to track surgical tool use for the entire duration of a surgery, the device's battery must be reliable and safe to use. Our design features rechargeable lithium-ion batteries as a secondary power source. In the case of power failure these batteries must be able to power the device for at minimum 14 hours, which should allow for multiple surgeries to take place. To ensure this, the lithium-ion batteries must be able to hold charge reliably. For our design this means that the batteries must be able to charge up to, at least, 75% of the maximum capacity we have listed. To ensure this we will perform charging tests in which we discharge a battery, charge it to max capacity, and then use a voltmeter to determine whether the batteries meet our guidelines.

There is another ethical concern regarding lithium-ion batteries: due to the chemical makeup of most lithium-ion batteries, there is a chance that the batteries will explode and cause physical and/or electrical damage if overcharged [17]. To prevent damage to the device users and the people around them it is necessary to make the charging process safe. This means that the charging process should not allow batteries to be under or overcharged. To ensure this, our design uses an off-the-shelf battery charger in addition to testing. This testing will occur during the same process as the testing involved in the previous concern. However, the battery's temperature and current will also be measured to ensure that the device is operating safely.

Another ethical issue concerns electromagnetic radiation. First, all devices must be tested for their electromagnetic radiation spectrum to ensure that there is compatibility with other devices and no interference with frequencies used for wireless communication. This will not be a problem since no significant RF frequencies are radiated. Additionally, since this device will be within operating rooms, it is necessary that they do not produce significant radiation which could harm the patients as well as staff. Generally, radio frequency is a type of radiation that is emitted by radios, Wi-Fi, and Bluetooth devices, as well as radars among other devices [18]. Radio frequency can cause damage to human bodies if emitted in large enough quantities. According to the FCC's policy on radio frequency safety, "the NCRP's recommended Maximum Permissible Exposure limits for field strength and power density for the

[21] "To hold paramount the safety, health, and welfare of the public, to strive to comply with ethical design and sustainable development practices, and to disclose promptly factors that might endanger the public or the environment." [13]

transmitters operating at frequencies of 300 kHz to 100 GHz" [19]. However, our device does not utilize RF, Wi-Fi or Bluetooth and is otherwise unlikely to radiate significant amounts of such frequencies, so there is no danger from Joule heating of EM waves emitted from this device.

Finally, with regards to the IEEE code of ethics, #3: " to be honest and realistic in stating claims or estimates based on available data", we will make certain that the requirements and abilities as noted previously in the document or in other supporting documentation are possible [15]. In the case that the device's design changes in any way we will alter the corresponding sections with the correct info, as necessary. We will seek to abide by the IEEE code of ethics, #6: "to maintain and improve our technical competence and to undertake technological tasks for others only if qualified by training or experience, or after full disclosure of pertinent limitations". This means that in the case we are unable to carry out any process of the development we will seek advice if needed. If we determine that training or other knowledge is required, we will endeavor to seek training or undergo further research.

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