

The Bifrost  
Final Report  
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## Preface

This technical report will include all information regarding the alpha-prototype of the Bifrost including its purpose, function, and components and planned future directions to move this device closer to market entry.

## Introduction: Rationale for Development

A history of misinformation regarding the addictive nature of opioids by pharmaceutical companies and affiliated academic centers led to large increases in such narcotic prescription in the 1990s.<sup>1</sup> Since then, opioid overdose deaths have increased five-fold with the trend predicted to continue.<sup>2</sup> In fact, the number of Americans that succumb to opioid overdose increased by 30% from July 2016 to September 2017.<sup>3</sup> Up to 12% of Americans who are prescribed opioids develop an opioid use disorder; however, the ability of opioids to very effectively treat pain in both acute and chronic settings has led to their continued prevalence. Together, the addictive nature of opioids and their ability to block sensation has led to misuse deaths accounting for more than 10% of all accidental deaths in the US.<sup>2</sup>

Opioid abuse is especially prevalent in the postoperative patient population. Annually, 14.7% of the more than 51 million Americans who undergo surgery become addicted to opioids, and opioid misuse results in an expenditure of \$78.5B for the US alone.<sup>4</sup> In fact, all four guidelines for postoperative pain management indicated by the American Pain Society recommend the use of analgesics.<sup>5</sup> Even more concerning is that pain management is such a necessity post-operatively that patients who are opioid-tolerant (i.e. history of opioid misuse or overdose) are also onboarded to a pharmaceutical treatment course.

As such, it is pertinent to consider non-addictive mitigators of postoperative pain. Although, this alternative must not forego the beneficial pain blocking effect of the pharmaceutical. These alternatives must provide similar levels of pain inhibition to the current standard of care, not cause addiction, be quantitatively measured/controlled, and be safe for patient use outside of clinic.

This analysis of the current market landscape led to the following problem statement:  
**a non-addictive method for pain management after surgery that does not require additional surgeries would lead to a better quality of life for patients by eliminating side effects of medication and better control of the pain.**

## Verification of Targeted Design Specifications

A battery of verification tests were performed to determine which of the design specifications outlined for the Bifrost stimulator were met. As described by Table 1, a range of 1-5 tests were performed to determine the success of the alpha-prototype in meeting a given specification. Verification tests referenced are described in detail within Appendix section A1.

**Table 1:** A table listing all design specifications, associated verification tests (as listed within Appendix A1), and outcome of the verification tests for the Bifrost stimulator alpha prototype. The color coding for the Outcome column entries are green implies the specification was met or exceeded, red implies the specification was not met, and yellow implies an inability to test the specification. Note, room temperature was defined as between 20 and 25 °C.

Specification Number	Specification	Quantitative Metric	Verification Test(s)	Outcome
1	Operable relative humidity range	0-70%	2	Specification met
2	Usable for people in the following age range	12-80	3, 4, 6, 8, 9	Specification exceeded (12-82 age range)
3	Maximum time achieve pain blocking effect	5 minutes	14	Specification exceeded (12 second on-time)
4	Minimum device durability	28 days	4, 5, 6	Specification not met (drop durability failed)
5	Maximum device dimensions	17.8 cm X 17.8 cm X 10.2 cm (7 in X 7 in X 4 in)	7	Specification exceeded (final dimensions of 15.2 X 15.2 X 10.2 cm)
6	Maximum device weight	1.36 kg (3 lbs)	1	Specification exceeded (.67075 kg)
7	International Protection Marking rating	IP41	4, 5	Specification met (IP41 rating)
8	Maximum temperature of internal circuitry at room temperature	37.8 °C (100 °F)	8	Specification exceeded (maximum temperature of 26.3 °C)
9	Range of operable atmospheric temperature device	12.8-37.8 °C (55-100 °F)	8	Specification exceeded (operable between 4 and 37.8 °C)
10	Battery life	24 hours	9	Specification not met (6.5 hour battery life)
11	Maximum recharge duration	1 hour	10	Specification not met (1.5 hour recharge time)
12	Stimulation frequency	14-26 kHz	11	Specification met
13	Electrical stimulation amplitude (transmission voltage)	0.15-10 V	13	Specification met (0.383 V <sub>pp</sub> )
14	Input carrier frequency	5 MHz	12	Specification met
15	Maximum distance between implant blocker and external power source	4 cm	14	Specification unverified
16	Power Transfer Range	0.5 - 200 mW	13	Specification unmet (7.5 μW power output)
17	Time to completion	5 months	15	Specification met
18	Maximum cost for prototype	\$500	15	Specification exceeded (actual cost of )

Note that verification test 15 was not completed within the performed verification plan due to lack of an available rat. The client informed the design team only 4 days before the *in vivo* verification test was planned and 9 days before the prototype deadline that the murine model intended for use was no longer available. Nonetheless, this verification test is critical to downstream validation of the Bifrost stimulator and is a key next step for proof-of-concept.

Overall, the device complied with the key mechanical and electrical specifications outlined. At face value, 13/17 or approximately 76.5% of the design specifications (that could be tested) were met. Although this is inherently promising as a strong majority of specifications were achieved, it is also critical to consider the relative importance of each specification. Aspects core to device functionality such as usability (specification 2), output signal waveform (specifications 12, 13, and 14) were met or exceeded. In addition, the device remained functional across all environments it is expected to come in contact with during 28-day timeframe of patient use. This includes output signal fidelity (i.e. fulfilling specifications 12, 13, and 14) across the listed temperature and humidity ranges (specifications 1, 7, and 9).

In contrast, a majority of the failed verification tests point to aspects of the prototype that can drastically be improved relatively trivially in later iterations. Namely, specification 4 associated with the durability of the device is bound to increase as a professional manufacturing workflow is leveraged for production of the market-ready version of the device. Custom insulation and support structures designed to fit the internal circuitry exactly will ensure greater durability. Further, conversion from analog to digital signal processing will increase the ability of the components to withstand force.

Failed specifications 10 and 11 are associated with the battery capacity of the system and its power consumption. These are more peripheral design elements that do not speak to the overall device ability to portably generate the intended waveform and are not critical to

proof-of-concept demonstrations. Further, there are known elements of the current prototype that can be augmented or replaced to facilitate increases in battery life and recharge speed. Currently, the entire system is based on analog signal processing. Namely, the 5 MHz and variable stimulating frequency between 14 and 25 kHz are generated as independent analog signals before being sent through another analog component (analog multiplier) for intended output waveform generation. Downstream, the design team plans to convert the circuitry from analog components connected via breadboards to a single PCB chip. This will reduce any inefficiency in power transfer between components. Further, transitioning from analog signal generation (i.e. with an analog multiplier) to digital signal processing will reduce the number of powered components and current draw from the battery to the signal generating components. Paired with pulse width modulation powerering, the battery usage should decrease by at least half. Further, as the space needed for electronic circuitry decreases, a larger battery can be installed. Currently, the installed 2500 mAh battery only takes up 0.78% of the volume of the stimulator. This can drastically increase as the circuitry is compacted, while still allowing the device to retain its portable nature.

Specification 16 is another aspect of the prototype that will assuredly be improved downstream and does not reflect on the proof-of-concept success. Power amplification systems are relatively common electronic components that can be integrated into the output of the current circuit to boost wattage. The reason this was not currently implemented is due to unknown factors such as the type of primary coil that will be used in the patient setting and the impedance between the primary coil and the skin. This is because, in RF power transfer systems, the impedances of the input and output of the coil must be matched to avoid harmful reflection of power back into the electronic system. This reflection of power could have fatal consequences on device functionality such as overheating and possible fire—potentially

harming the user. As such, only when these parameters are well understood can the design team proceed to integrate signal power amplification.

## Validation Results

Validation testing was performed centered on three key criteria: wearability, functionality, and repeatability.

Device wearability was determined by assessing the prototype's ability to conform to the following requirements: (1) the device should be powered with batteries and should not need to be plugged in, (2) the batteries need to be rechargeable, (3) the device must be lightweight (less than 1.36 kg), (4) the device must also be holdable with reasonable dimensions. As demonstrated by Table 1, the final prototype conforms to specifications 2 (usability across the intended age range) and 6 (mass). Further, the device is battery powered and rechargeable albeit not to the expected standards described by specifications 10 and 11, respectively (Table 1). As described above, the shortcomings associated with design specifications 10 and 11 can be remedied in future iterations of the Bifrost. Thus, given that the device fulfills all four criteria outlined to define wearability, the prototype passes this validation requirement.

In terms of functionality, the prototype's ability to fulfill this aspect of the validation was initially planned through a three-tranched strategy. First, initial testing of the direct output signal waveform measured through electronic equipment (multimeter and an oscilloscope) was planned. Next, the design team planned to conduct *ex vivo* testing of signal transmission by analyzing the ability of a signal from the Bifrost stimulator connected to a primary coil to be delivered to a secondary coil through air. Finally, functionality would be assessed by conducting an *in vivo* test wherein the Bifrost would be used to power an implanted nerve stimulator fitted to



a sciatic nerve in an anesthetized murine model. However, 4 days prior to *ex vivo* and *in vivo* testing, the design team was notified by the client that the materials needed for testing would no longer be available. Given the prototype deadline was rapidly approaching (9 days remaining), the design team decided to complete all other planned design verification tests. During the drop durability test, the device failed during a 0.91 meter drop. As such, the team was unable to complete the remaining two tranches of functionality testing. Based on assessment of the prototype through direct waveform measurement, the intended waveform was successfully generated (fulfilled specifications 12, 13, and 14 from Table 1) prior to the drop test.

The last aspect of validation testing involved assessing the fidelity or reproducibility of the system output. It is critical for medical devices to consistently provide the same output to ensure patients can accurately complete the prescribed treatment course. Thus, the prototype was assessed for its ability to produce a repeatable output. Namely, the Bifrost stimulator was connected to an oscilloscope to measure its output signal across three trials separated by 20 minutes. The results of each trial and the percent differences are summarized in Table 2.

**Table 2:** A table listing the output carrier frequency, stimulating frequency, and peak-to-peak voltage across three trials equally spaced across one hour. Note, the carrier frequency was programmed to 5 MHz and the stimulation frequency was programmed to 14 kHz.

Parameter	Trial			Average	Average Percent Variation from Mean
	1	2	3		
Carrier Frequency (MHz)	4.98	5.04	5.07	5.03	0.66
Stimulating Frequency (kHz)	14.05	14.21	14.11	14.12	0.41
$V_{pp}$ (V)	0.376	0.389	0.384	0.383	1.22

Based on the results of Table 2, it is clear that the system confers high fidelity in output signal parameters. Thus, based on the conducted tests, the device fulfills all facets of validation: wearability, functionality, and reproducibility.

# Device Components and Diagrams

## Parts List

The following parts list tabulated in Table 3 includes details for all of the parts used to build the final Bifrost prototype. First pages of the listed the datasheets can be found in Appendix E.

**Table 3:** Part list for components of the Bifrost Prototype. Note lead times refer to order lead time, (time from customer order received to customer order delivered).

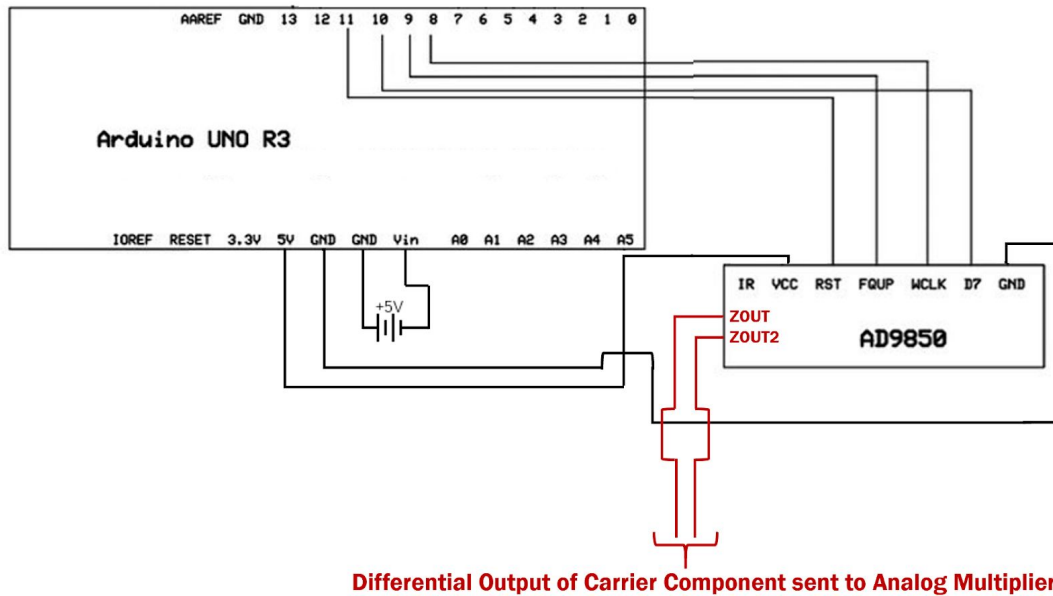
Component (Number)	Price (\$)	Specifications/Data Sheet	Lead Time (Days)	Source
Arduino Uno R3 (2)	44.00	<a href="https://www.farnell.com/datasheets/1682209.pdf">https://www.farnell.com/datasheets/1682209.pdf</a>	2	Arduino Online Store
Hitachi HD 44780 16x2 LCD Display (1)	5.99	<a href="https://www.sparkfun.com/datasheets/LCD/HD44780.pdf">https://www.sparkfun.com/datasheets/LCD/HD44780.pdf</a>	1	Amazon
Rotary Encoder (1)	3.95	<a href="https://www.farnell.com/datasheets/1837001.pdf">https://www.farnell.com/datasheets/1837001.pdf</a>	1	Amazon
2500 mAh Battery (1)	15.99	<a href="https://www.adafruit.com/product/328">https://www.adafruit.com/product/328</a>	2	Adafruit
PowerBoost 1000 Charger (1)	19.95	<a href="https://learn.adafruit.com/adafruit-powerboost-1000c-load-share-usb-charge-boost/downloads">https://learn.adafruit.com/adafruit-powerboost-1000c-load-share-usb-charge-boost/downloads</a>	2	Adafruit
AD834 Analog Multiplier (1)	41.98	<a href="https://www.analog.com/media/en/technical-documentation/data-sheets/AD834.pdf">https://www.analog.com/media/en/technical-documentation/data-sheets/AD834.pdf</a>	7	Digi-Key
SOP8 Board (1)	7.99	<a href="https://www.arieselec.com/products/data/19000-small-outline-prototyping-adapters.pdf">https://www.arieselec.com/products/data/19000-small-outline-prototyping-adapters.pdf</a>	2	Digi-Key
AD9850 DDS Synthesizer (2)	46.80	<a href="https://www.nooelec.com/store/downloads/dl/file/id/24/product/86/ad9850.pdf">https://www.nooelec.com/store/downloads/dl/file/id/24/product/86/ad9850.pdf</a>	1	Amazon
Prototyping Board (2)	3.04	1 x 8 x 5 cm	0	Micro Center
Battery Charger (1)	9.99	5V & 2.5A power supply with Micro USB output, <a href="https://www.amazon.com/Raspberry-Power-Supply-Adapter-Charger/dp/B0719SX3GC">https://www.amazon.com/Raspberry-Power-Supply-Adapter-Charger/dp/B0719SX3GC</a>	6	Amazon
Potentiometer (1)	5.99	<a href="https://components101.com/sites/default/files/component_datasheet/potentiometer%20datasheet.pdf">https://components101.com/sites/default/files/component_datasheet/potentiometer%20datasheet.pdf</a>	1	Amazon
Switch (1)	0.71	<a href="https://www.alliedelec.com/m/d/4b01369cd497d0a29d14c860eb221183.pdf">https://www.alliedelec.com/m/d/4b01369cd497d0a29d14c860eb221183.pdf</a>	2	Allied Electronics
10KOhm Resistor (1)	0.05	<a href="https://www.alliedelec.com/m/d/5c22b21fcadf6efc3f053d50cbf71e24.pdf">https://www.alliedelec.com/m/d/5c22b21fcadf6efc3f053d50cbf71e24.pdf</a>	2	Allied Electronics
Storage Container (1)	12.00	10.2cm x 15.2cm x 15.2cm	0	Target
<b>Total</b>	<b>252.27</b>	<b>N/A</b>	<b>N/A</b>	<b>N/A</b>

In addition to these enumerated resources, unquantified amounts of standard prototyping materials such as solder, single core wire, and heat shrink tubing was used to connect the components. Further, hot glue was used to adhere components such as the LCD screen, power switch, and frequency control knob (rotary encoder) to the device casing and seal any gaps.

Further, the following prototyping equipment was used in device construction: soldering iron, heat gun, oscilloscope, multimeter, and drill.

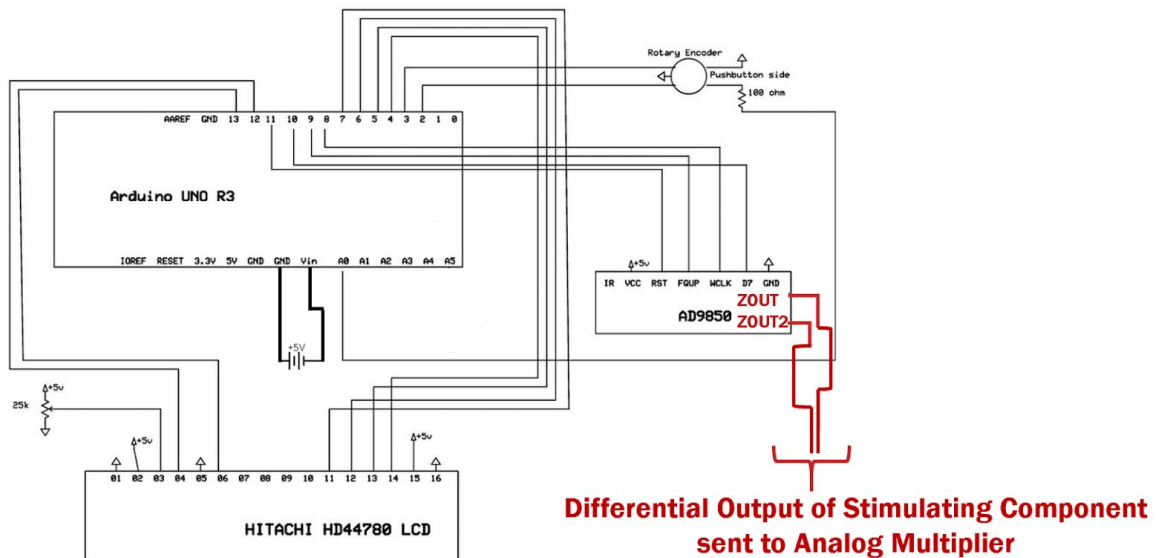
## Circuit Drawings

Circuit diagrams presented represent the carrier frequency (5 MHz) generating component (Figure 1), the variable stimulating frequency generating component (Figure 2), and the composite circuit diagram describing all connections within the Bifrost stimulator and the overall device output (Figure 3). Please note that all perpendicularly crossing wires within the diagrams do not represent connected wires and simply are overlaid due to the 2D nature of these drawings. In the below diagrams, some powered components (such as the AD9850, LCD screen, and potentiometer in Figure 2) are linked to a +5V output and ground in arrow notation and not explicitly a depicted battery. This is simply to ensure readability of the diagram and as there a variety of equally valid configurations that can be employed to successfully complete the circuit. Each of these sources may be powered through the 5V and GND pins voltage out pins on the Arduino Uno R3 or directly from the battery source used to power the Arduino components. The decision between these two options should be made based on the spatial configuration of the devices and length of wire needed to make the different connections within each option.



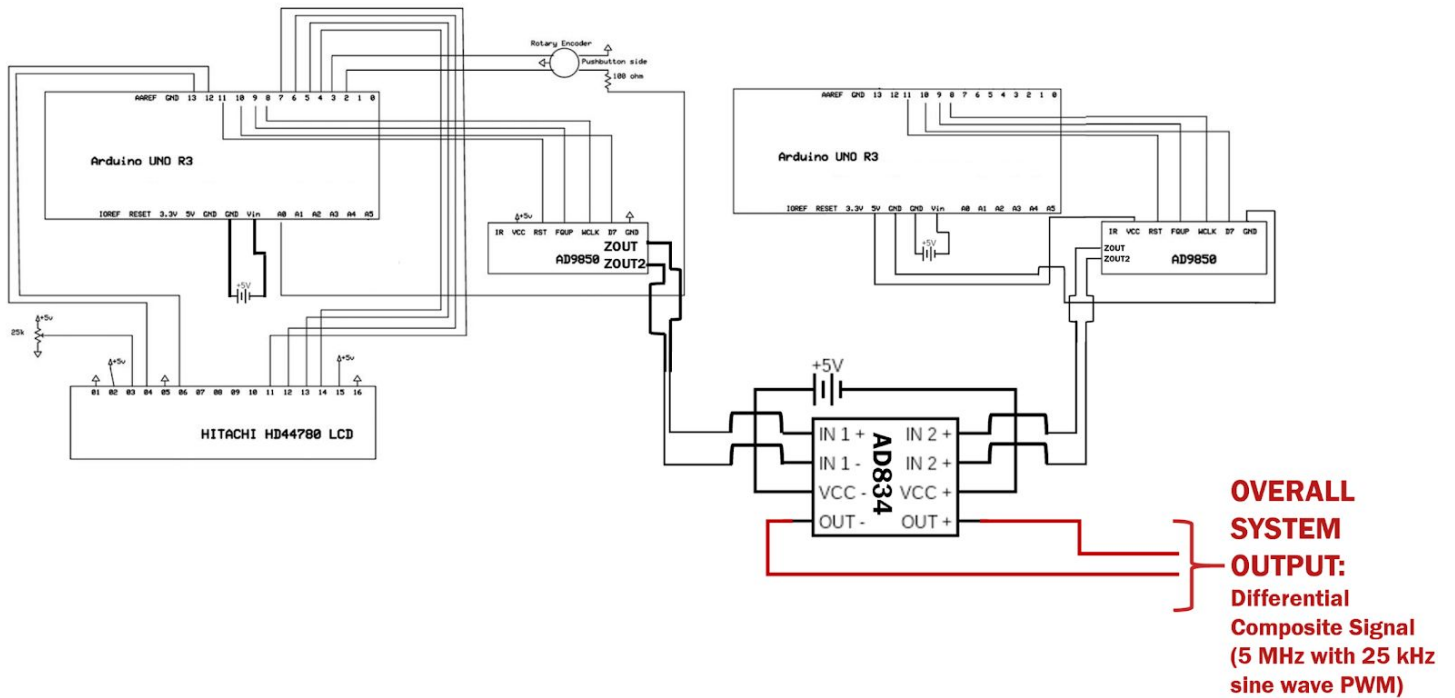
Differential Output of Carrier Component sent to Analog Multiplier

**Figure 1:** Circuit diagram of the Arduino Uno and AD9850 function generator chip used to develop the 5 MHz carrier frequency voltage signal. No user-facing interface is present to alter the output of this component as the carrier frequency is determined by the client’s bioresorbable nerve inhibitor the Bifrost will be paired with and will never need to be changed. Note that the two analog outputs from the AD9850 chip (ZOUT and ZOUT2) are highlighted in red to represent the output of this circuit component within the Bifrost prototype.



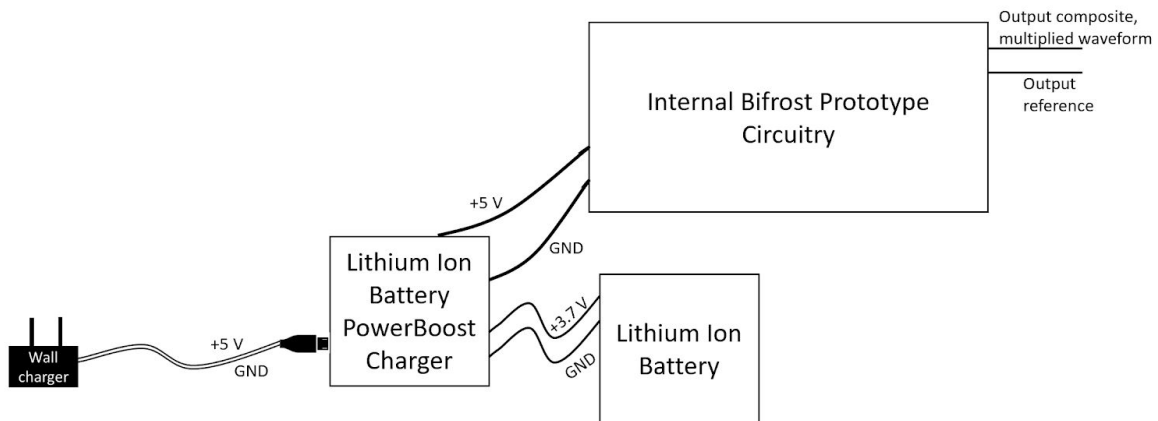
Differential Output of Stimulating Component sent to Analog Multiplier

**Figure 2:** Circuit diagram of the Arduino Uno and AD9850 function generator system used to develop the 14-25 kHz variable stimulating frequency voltage signal. Further, the Arduino logic board was connected to an LCD screen and rotary encoder. The LCD display displays the stimulating frequency output by the AD9850 chip and the rotary encoder allows the user to alter the outputted stimulating frequency. Further, a potentiometer connected to the LCD display is used to control screen contrast.

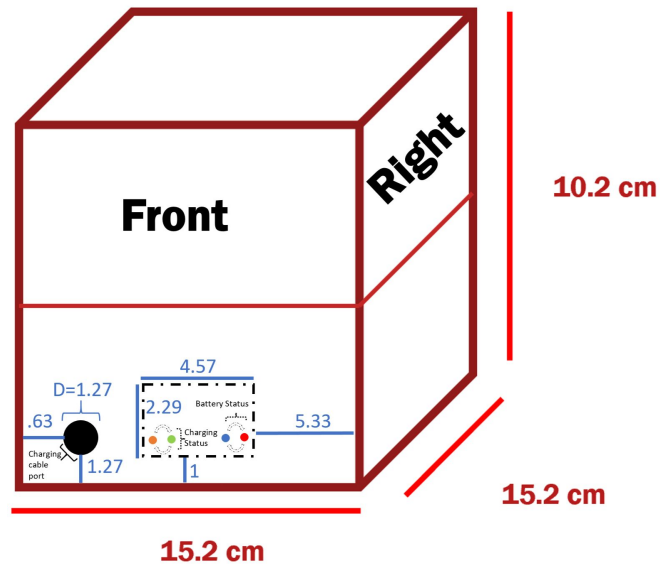


**Figure 3:** Circuit diagram representing complete connection of all electronic components within the Bifrost prototype. Circuits depicted in Figure 2 and Figure 1 are connected to the AD834 high frequency analog multiplier’s differential input pins to generate the composite, overall output waveform (highlighted in red).

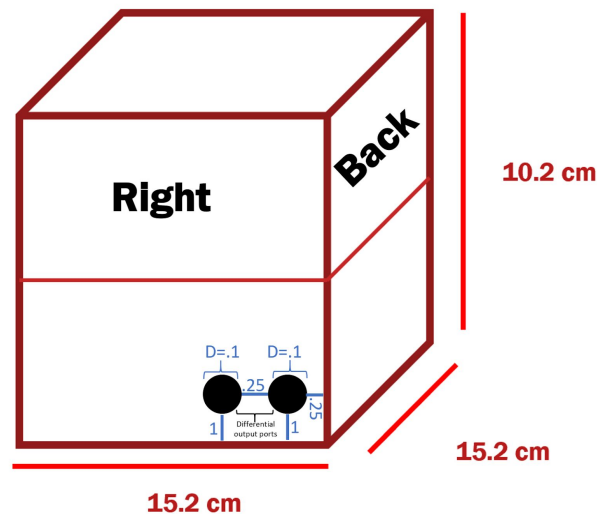
## Wiring Diagrams



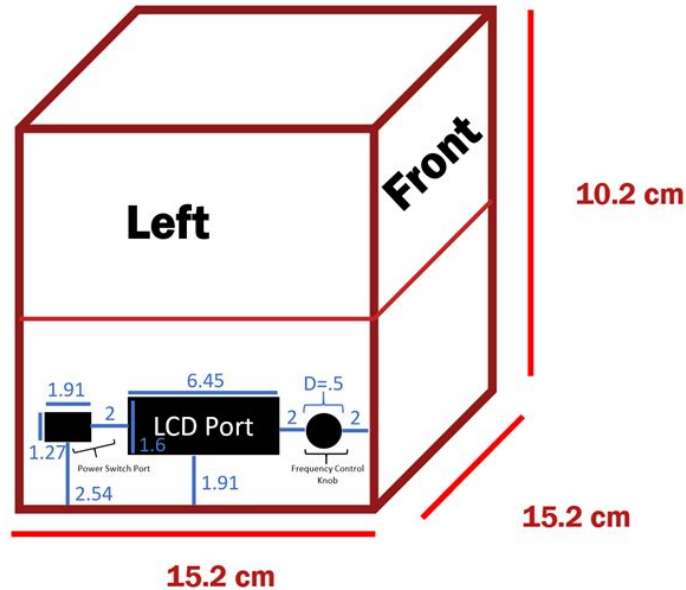
**Figure 4:** Wire diagram demonstrating the overall input and output connections between the Bifrost stimulator and the outside. Note that ground is abbreviated as GND within the drawing. Further, both the PowerBoost and the lithium ion battery used to power the stimulator are located within the prototype but drawn outside in this diagram clarity.



**Figure 5:** Mechanical drawing of the front view of the Bifrost stimulator. The left, black circle represents a hole that needs to be drilled into the casing for the charging cable to pass between the inside and outside of the device. The dashed box represents the battery status chip (PowerBoost 1000 charger) and is placed on the inside of the casing. As it is an electrical component it is insulated by the plastic casing but still visible due to the casing's translucent nature. The charging status switches between orange (charging) and green (fully charged) while the battery status switches between blue (healthy) and red (low battery). Note that the figure is not drawn to scale and all measurements are in centimeters.



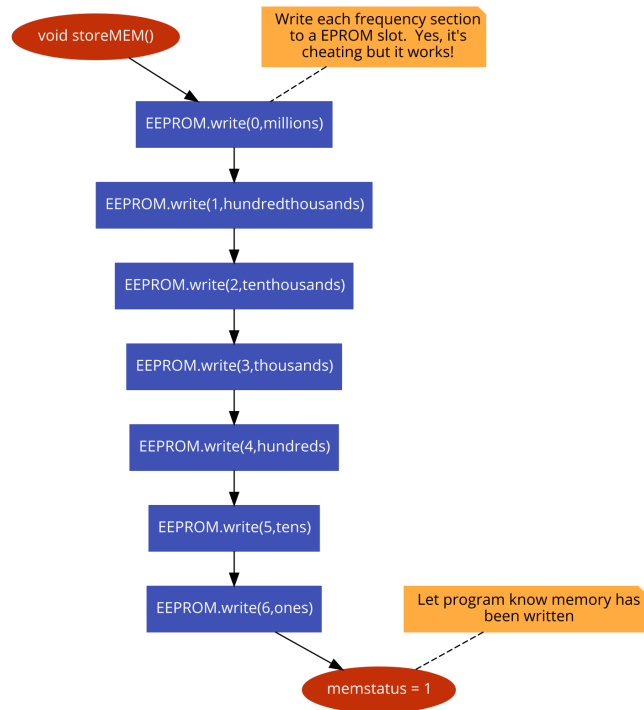
**Figure 6:** Mechanical drawing of the right view of the Bifrost stimulator. The two circles represent 0.1 cm holes to pass the differential output waveform from the inside of the casing to the outside. Note that the figure is not drawn to scale and all measurements are in centimeters.



**Figure 6:** Mechanical drawing of the left view of the Bifrost stimulator. Each port and the knob represent shapes that need to be drilled out of the casing to allow for user access of the power switch, LCD screen, and frequency control knob (from left to right in the diagram). Note that the figure is not drawn to scale and all measurements are in centimeters.

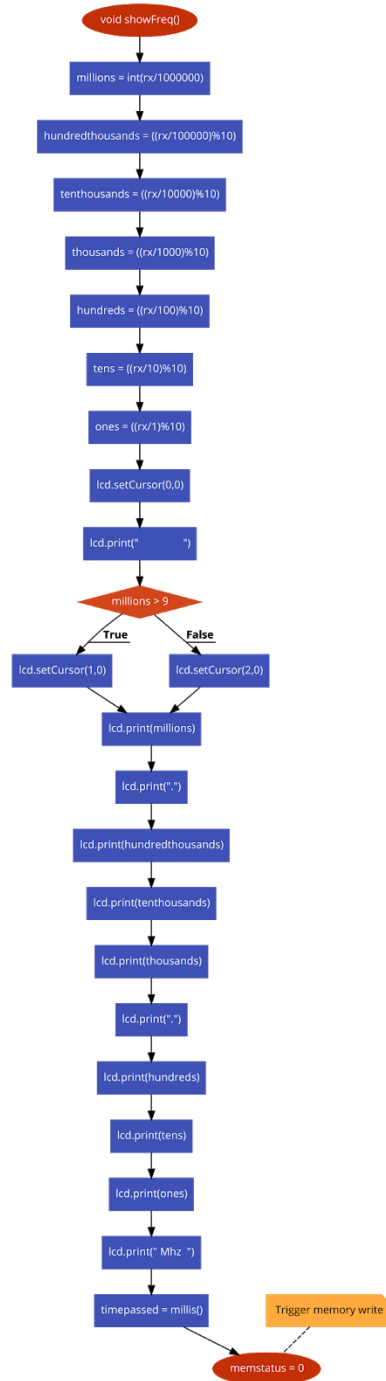
## Software Code Flow Diagrams

Coding diagrams presented demonstrate logic flow for each of the methods the Arduino Uno R3 logical processor is equipped with in the Bifrost device. The actual code employed can be found in Appendices C1 through C3 and the visualization presented in this section was facilitated through the use of the code2flow ([code2flow.com](http://code2flow.com)) platform.



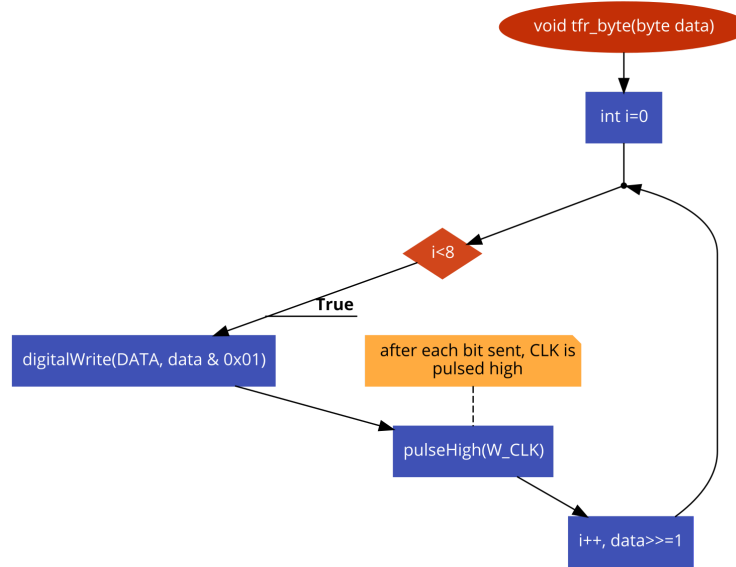
**Figure 7:** Software flow diagram depicting a method that assigns numbers as shorthand for different increments in base-10 to be used by other methods for frequency changes.



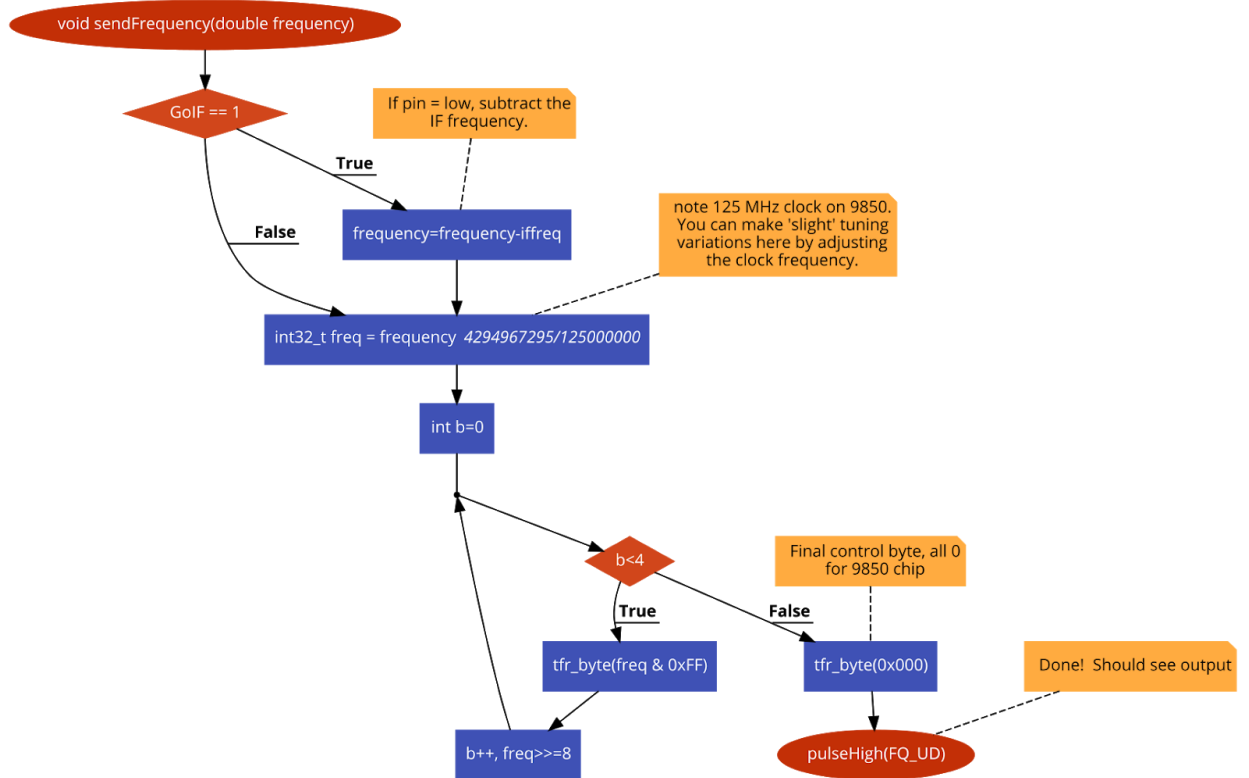


**Figure 8:** Software flow diagram demonstrating how the current set frequency (variable rx) is passed to the LCD display for representation to the user.

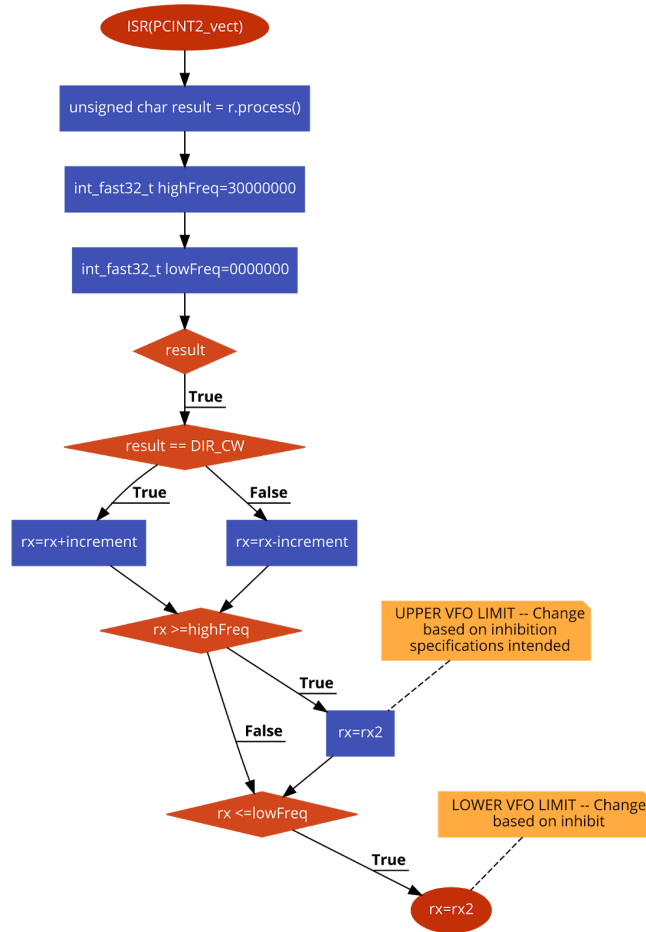




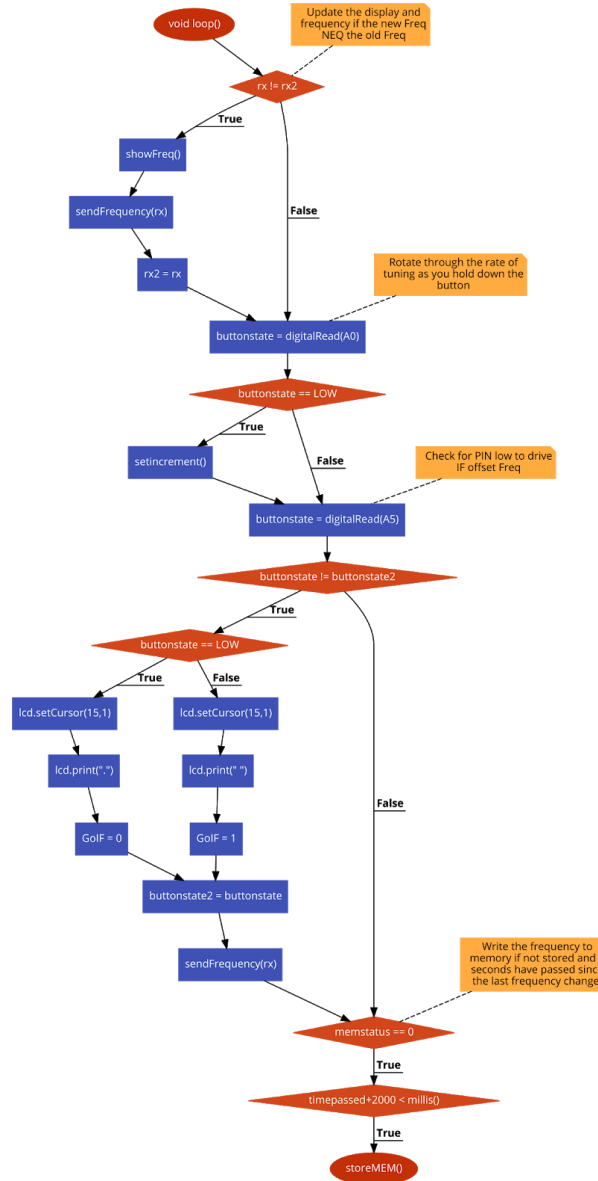
**Figure 10:** Software flow diagram depicting the tfr\_byte method that splits the input variable, data, into bits to send to the AD9850 chip one at a time.



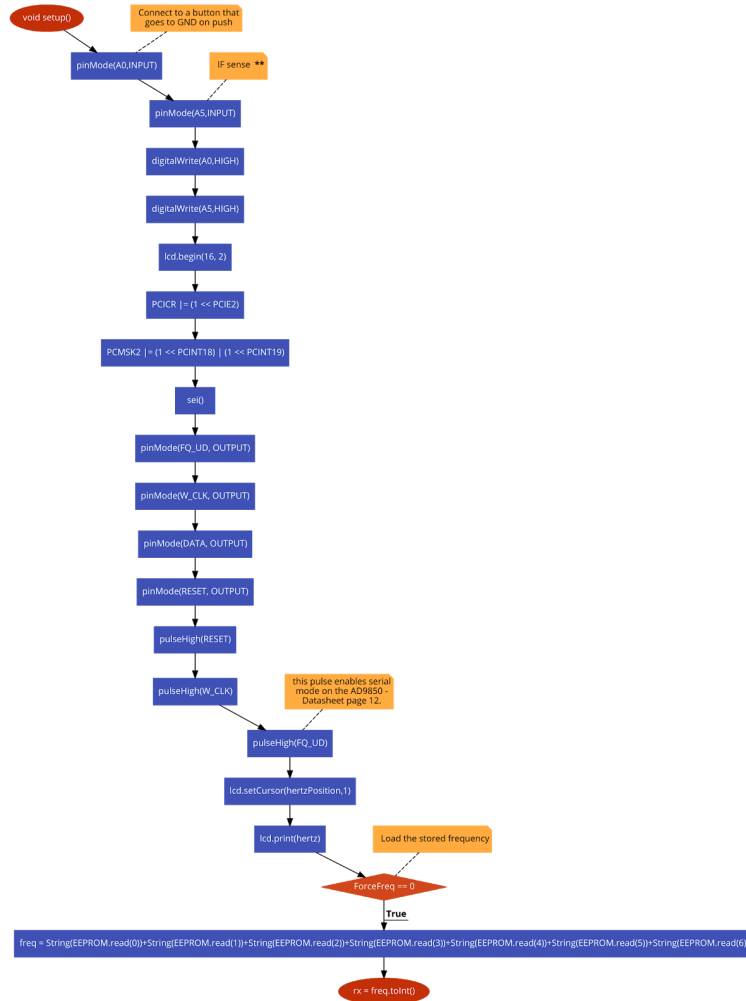
**Figure 11:** Software flow diagram representing the sendFrequency method that takes in a double representing the desired frequency signal and sends the appropriate message to the AD9850 chip to cause a change in that frequency.



**Figure 12:** Software flow diagram depicting the method that ensures turns of the rotary encoder do not cause the frequency request sent to the AD9850 chip to go above or below the set frequency output limits represented by double-type variables highFreq and lowFreq, respectively.



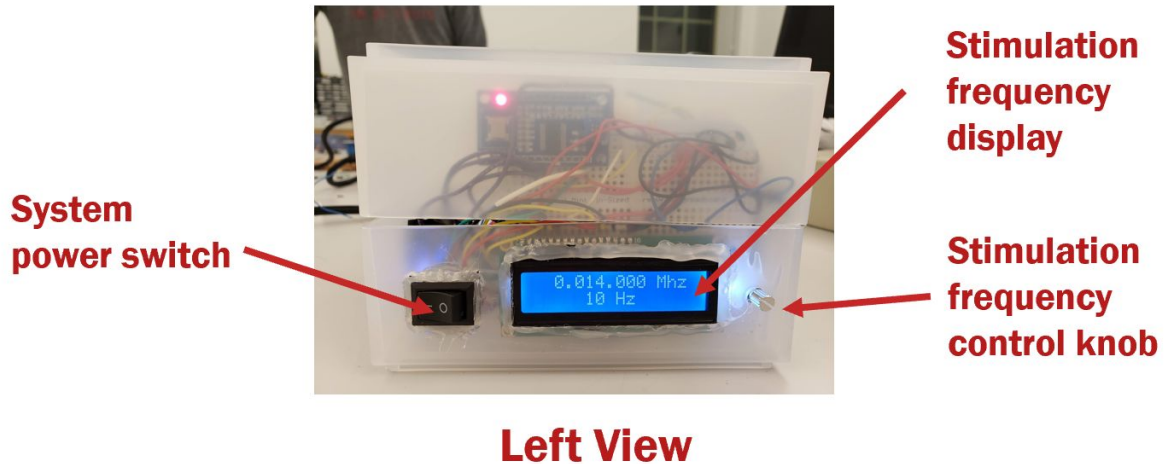
**Figure 13:** Software flow diagram depicting the continuous check between the currently set frequency and that reported by changes in the rotary encoder to ensure the AD9850 chip is outputting the desired frequency in real time.



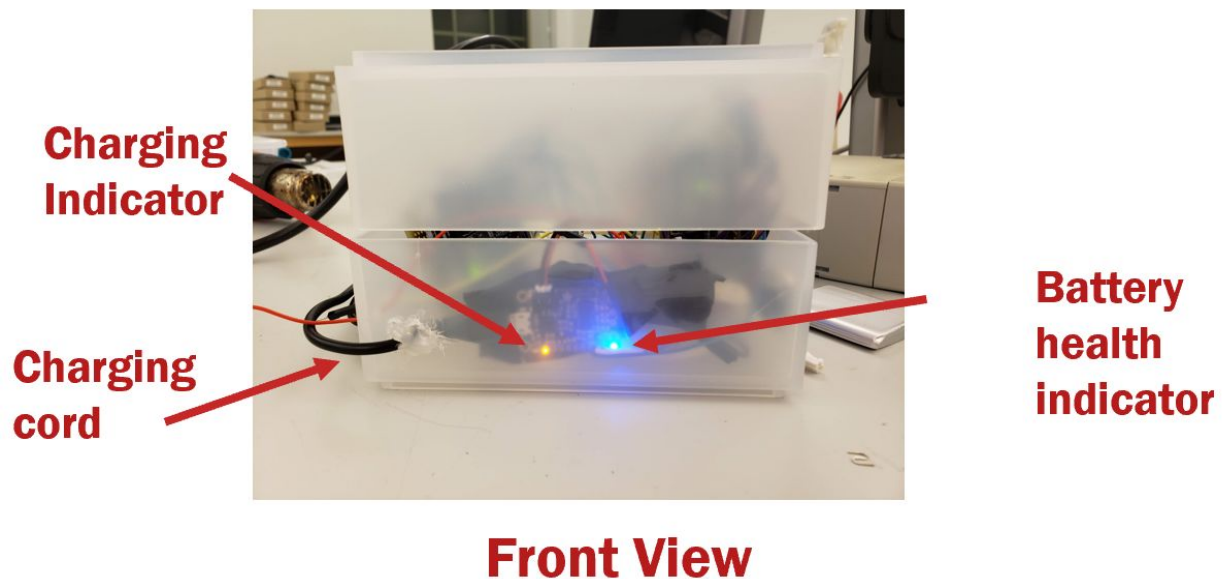
**Figure 14:** Software flow diagram depicting the initialization of the LCD and AD9850 boards upon startup of the Arduino Uno R3 system.

## User Interface and Images of Completed Prototype

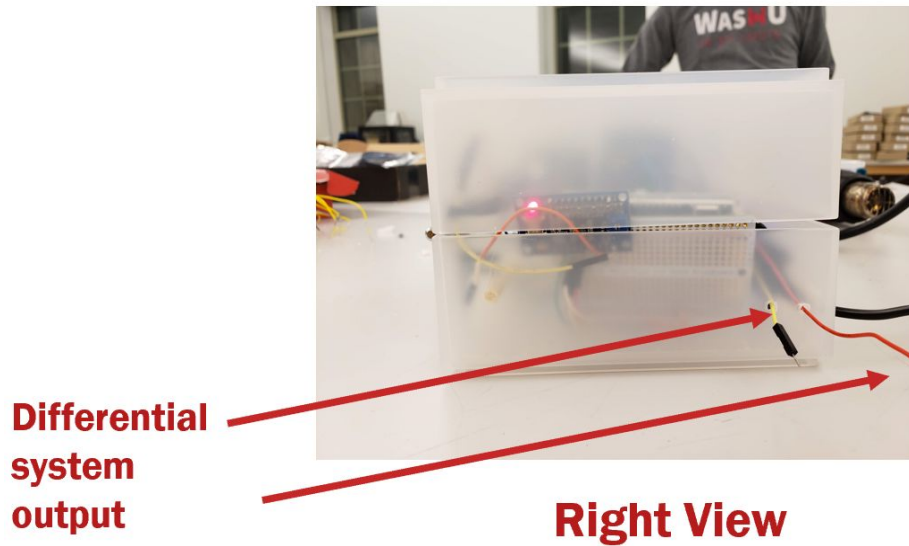
The Bifrost User Interface (UI) is comprised of three key panels: frequency control, device status, and waveform output.



**Figure 15:** Frequency Control panel of the Bifrost Device. This includes a power switch for the whole system, a display of stimulation frequency, and a frequency control knob.



**Figure 16:** Device Status panel of the Bifrost Device (front view). The power status of the device is communicated via a system of LED bulbs on the device status panel. As described in Figure 5, charging status (left LED) switches between orange (charging) and green (fully charged) while the battery status (right LED) switches between blue (healthy) and red (low battery).



**Figure 17:** Output Panel of the Bifrost (Right View). The differential output of the system is transmitted via two wires exiting the lower half of the Bifrost's output panel.

## Ergonomic Optimization

During development of the Bifrost prototype the wide age range of the end-user was considered. To facilitate high usability and accommodate the undoubtedly diverse patient population the device will interface with, the user interface was segmented into three panels (Figures 15, 16, and 17). Each of these panels organized the different aspects of the device. All frequency controlling aspects of the device were sequestered to the Left Panel (Figure 15). The battery status of the device and charging (both associated with device powering) were organized on the Front Panel (Figure 16). Finally, the waveform meant to be sent to the primary coil was placed on the separate, Right Panel (Figure 17). This was because in the planned use-case, the Right Panel would likely be obscured by a primary coil and placed on the location of the patient's body where the inhibitor was implanted. As such, any information presented on this panel would be lost to the user during therapeutic use. Instead, information was contained to the Front and Left Panels of the device that would likely be visible even during use.



Alongside this, universe color language was employed on the battery status indicator as shown in Figures 5 and 16. Green is used to depict fully charged, orange is used to describe charging, and red is used to describe low battery. This ensures that, even with limited instruction, a user would be able to intuitively use the device.

While ergonomic factors were considered in the development of the alpha prototype of Bifrost, this can be further optimized downstream through collaboration with a human factors engineering.

## Safety Analysis and the Regulatory Landscape

### Design Safe Analysis

Overall, hazards of operating the Bifrost device may be broadly categorized as thermal and electrical. The device relies on magnetic induction and associated control systems. If the load (i.e. the body) and source impedances are not properly matched, the energy may be reflected from the load and back to the source (i.e. Bifrost stimulator), which diminishes power transfer efficiency and may damage the source as a result of excess heating<sup>6</sup>. Some of the elements within the Bifrost's circuitry such as the analog multiplier heat up very quickly if connected improperly or shorted. Lithium polymer batteries are designed to operate within a safe voltage range from 3V to 4.2V. However, over-charging above 4.2V could be dangerous and eventually cause fire. As given by DesignSafe, heat risk is categorized as "slight" to "serious" depending on the identity and experience of the operator.

The second major risk posed by the Bifrost is a result of electrical shock. The Bifrost is built from several electrical components powered by a Lithium Ion Polymer Battery (3.7V, 2500mAh). The threat posed by electrical shock may arise from significant exposure to water (i.e. a bathtub) and improper handling of the battery and other circuit components. Risks relating

to electricity are categorized as “slight.” It is important to note that while the alpha prototype is IP41 rated, downstream iterations of the prototype can include more secure plastic casing improving the waterproof nature of the stimulator.

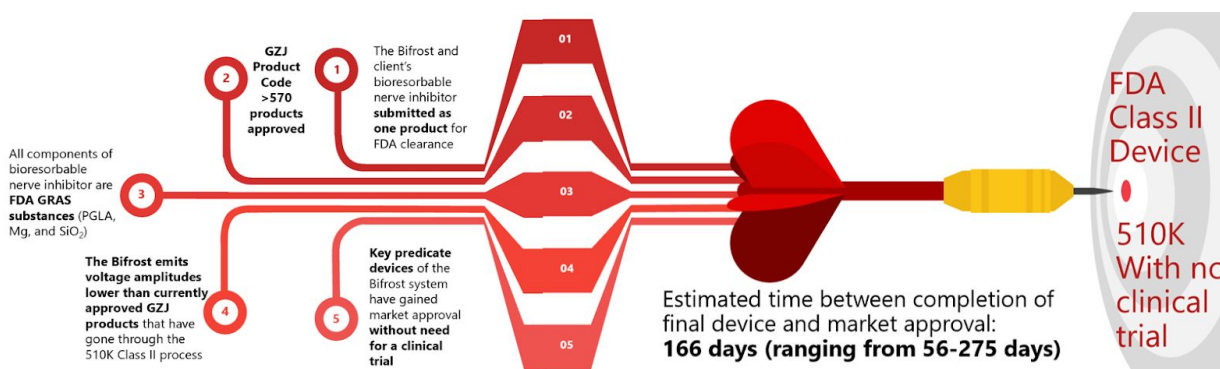
The users of the Bifrost are categorized in three main groups: clinical (doctors and nurses), device technicians, and patients (including family members and caretakers). Each of these users face both the electrical and heat related hazards given above. However, device technicians will be trained extensively to safely handle the device and avoid these hazards. In contrast, patients need not be aware of such risk mitigation strategies, yet they must also be protected from these dangers. Therefore mitigation strategies must not require prior knowledge or training related to electronic hardware. These strategies include warning labels, proper clinician and patient training, and use of thermal and electrical insulators within casing.

Note, the Design Safe Analysis report that led to these conclusions can be located in Appendix D.

## Food and Drug Administration Approval Plan

Within the United States, the Food and Drug Administration (FDA) is the regulatory body that determines whether any new medical technology can enter the market. It is important to recognize that the Bifrost will be submitted to the FDA together with the bioresorbable nerve inhibitor as it is a composite system that together serves to abate pain. This is best characterized by the FDA’s GZJ product code (defined as transcutaneous electrical nerve stimulator for pain relief). This implies a Class II specification - allowing the pain inhibiting system to obtain market approval through the accelerated 510k pathway. In discussions with Graematter, Inc. (an FDA/regulatory consulting agency), a strong history of GZJ devices successfully entering the medical device marketplace through the 510k

mechanism have been discovered. Over 570 neuro-pain management devices have gained market approval. Given that the Bifrost system emits voltage amplitudes lower than other 510k Class II, GZJ devices (882.5275 emits up to 20 V), it is clear that there is a history for FDA endorsement for similar devices.<sup>7</sup> The implantable nerve stimulator is produced with magnesium, silicon dioxide, and PLGA. Magnesium is an essential mineral present in the human body in large amounts, mostly in bones.<sup>8</sup> People obtain most of the magnesium in their bodies through their diet. Silicon dioxide is one of 370 Generally Recognized As Safe (GRAS) substances as classified by the FDA. The Select Committee on GRAS substances said in a written opinion that silicon dioxide and various silicates occur abundantly in the earth's crust, are present in practically all natural waters, animals, and plants, and are part of the normal human diet. PLGA is biocompatible and biodegradable, exhibits a wide range of erosion times, has tunable mechanical properties, and, most importantly, is an FDA approved polymer<sup>2</sup>. Confidence is further bolstered by the fact that the 510K mechanism has also been previously approved for bioresorbable devices (888.3030).<sup>9</sup> Further, key predicate devices for the Bifrost (FDA regulation codes 882.5275 and 882.5890) have gained approval without clinical trials.<sup>7,10</sup> These facts are summarized in Figure 18.



**Figure 18:** A pictorial depiction of the five key aspects of the Bifrost and its associated nerve stimulator that indicate likelihood of FDA market approval through the Class II 510K mechanism. Note, estimation of time between completion of final prototype and market entry is based on analysis of previous GZJ approval time course. This will significantly reduce costs and time to entry to obtain FDA approval compared to a Class III PMA process.

# Manual

## Guide for Clinicians

1. Once the surgical wound has healed properly, instruct the patient to use their Bifrost device for the treatment of pain, as given in the “Guide for Patients and Caretakers” section of this manual below.
2. Power the device on, and place the power coil directly above the implanted receiver.
3. Determine the appropriate stimulation frequency that the patient should apply to fully block pain from the injury site by asking the patient to describe their level of pain for each stimulation frequency (usually between 14-26kHz).
4. Prescribe stimulation how often and how long the patient will need to apply stimulation.
  - a. Transmit information from step 3 to the associated medical technician so that the default, maximum, and minimum stimulating frequencies can be appropriately set in the Bifrost stimulator provided to the patient.
5. Inform the patient that their nerve blocker will dissolve after approximately four weeks, at which point they may take oral pain killers temporarily if pain persists.

## Guide for Technicians

### Setup Guide

1. Plug in the Bifrost device into a wall outlet to charge the internal battery. Use the charging indicator on the left side of the battery status chip on the front face of the device (Figure 5). Once fully charged, the charging status indicator will switch from orange to green.
2. Open the outside, plastic casing of the stimulator and use a USB-A cable to plug in the stimulating frequency generating Arduino Uno R3 chip to your PC.

3. Open your Arduino IDE and ensure that the IDE recognizes the Arduino Uno R3 device
  - a. Note, a guide on setting this up either through a web-based platform or local copy of the IDE can be found here: <https://www.arduino.cc/en/Guide/HomePage>
4. Ensure that the default, maximum, and minimum frequency output by stimulating chip match the physician or other ranking medical worker's recommendation for the patient.
  - a. The default/starting, maximum, and minimum frequencies correspond to the variables rx (of type int\_fast32\_t and located in the initial code definitions), highFreq (of type int\_fast32\_t and located in ISR(PCINT2\_vect) method), and lowFreq (of type int\_fast32\_t and located in ISR(PCINT2\_vect) method), respectively.
5. Turn the device on and see if the information on the LCD screen is clearly readable. If not, adjust the potentiometer until the text is visible.
6. Seal the box and use a multimeter to ensure that less than 5 mA and 0.1 V is measured outside of the electrically insulated casing when the device is on.
7. Provide the device to the end-user and walk them through the User Manual.

## Troubleshooting Guide

1. For proper troubleshooting, use three oscilloscopes. Connect these to the output of the carrier frequency generating component (Figure 1, ZOUT and ZOUT2), to the output of the stimulation frequency generating component (Figure 2, ZOUT and ZOUT2), and to the output of the overall system (Figure 3, analog multiplier differential outputs).
2. See if the red indicator light on each AD9850 board is on when the device is turned on. Lack of light here will indicate either malfunction of the AD9850 chip or a broken wire

connection between the AD9850 chip and its associated Arduino Uno R3 logical processor.

3. If both AD9850 boards LED indicator is showing a red light but the output signal of the chip does not match the intended frequency, reset the associated Arduino Uno R3 board. If this does not resolve the matter, re-transmit the code (Appendices C1 to C3) as described in the Technician Setup Guide.
4. If both AD9850 boards are outputting the correct waveform but the output of the analog multiplier is incorrect, ensure all connections to the multiplier chip are correct. If all connections are correct, the multiplier chip has malfunctioned and needs to be replaced.

Note, all replacement parts can be located through the Parts List above (Table 3).

## Guide for Patients and Caretakers

To operate the Bifrost, the following steps should be followed:

1. Flip the switch on the Frequency Control (Left) Panel to turn the device on.
2. Check the battery status of the device on the power panel. If battery is low, discontinue use, turn the device off, and plug into a power source to recharge.
  - a. If need for pain abatement is urgent, the Bifrost stimulator can be used simultaneously with battery charging. Note, in this case, battery charging will likely take longer than if the device is turned off during recharge.
3. Once fully charged, connect the differential output of the Bifrost to the primary coil. Hover the coil directly over the secondary coil until received power is sufficient.
4. Adjust the stimulation frequency using the knob on the UI panel. Pressing the knob adjusts the incremental step of rotating the knob. Therefore the user may change the stimulation frequency by rotating the knob clockwise or counterclockwise.

5. Leave the device in the above configuration for the prescribed treatment duration.
6. Remove the coil and power down the device. Charge the device in preparation for later use.

## Conclusion

### Reflection from the Design Team

To conclude the project, we were partially successful in meeting Dr. Macewan's goal of building a portable wireless powering device for his dissolvable implantable nerve stimulators. Our device met 13 out of 18 design requirements set forth at the beginning of the project by Dr. MacEwan, Dr. Klaesner, and us. The four tests we didn't complete successfully include the drop test, battery life and recharge time, and power output. Due to damage following the drop test, we were unable to test the maximum distance between the implanted nerve blocker and the external power source, but the literature suggests it should be on the order of 4 cm (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4701313/>). Most importantly, though, we created a portable function generator capable of producing the desired combined waveform composed of a 5MHz carrier frequency and variable stimulation frequency (including the more narrow range of 14-26 kHz). However, future work will be needed to verify that the Bifrost is capable of powering the bioresorbable receiver implanted in both anesthetized and ambulatory murine models.

In this project we learned how to communicate with a client to satisfy their needs, how important documentation is to the engineering process, the technical advantages and disadvantages of multiple designs, how magnetic induction works and the associated pitfalls, and finally the regulatory path for our device. If we were to do this project again, it would be wise to set a more realistic timeline, speak to experts (i.e. professors in electrical engineering) before

finalizing the prototyping plan, and spend more time understanding exactly how the current experimental apparatus used by the lab works.

## Ethical Considerations

There are two major ethical concerns related to our prototype. If insurance will not cover it as a necessary component of this novel pain management treatment, will our device only be available to affluent people with ample resources? We want the Bifrost to be accessible to any person facing postoperative pain, regardless of their income level. Therefore insurance coverage will be a key consideration for future directions of the Bifrost project. The second ethical consideration is the net effect of this pain inhibiting treatment. Pain is a useful evolutionary adaptation that is often useful for alerting humans to new and sometimes chronic injuries that they sustain. The key consideration here is whether or not the injury was intentional and medically necessary (as is the case with invasive surgery) or unintentional (as is the case with burns, traumatic injuries, etc.). If an injury is a necessary byproduct of surgery, then we believe it is ethical to ease the suffering of patients, and we do not believe that the loss of the sensation of pain will lead to further injury.

## Intellectual Property (IP) Considerations

Based on our understanding of IP law, our device appears to clearly fulfill two categories of the International Preliminary Report on Patentability (IPRP) run by the World Intellectual Property Organization (WIPO)/European Patent Office (EPO) for provisional and non-provisional patent submission. The claims in a patent application for the Bifrost should likely fulfill the "novel" and "industry applicability". There is no other device in market that is portable,



high-frequency function generator built for a bioresorbable nerve inhibitor. Given the large impact of the opioid crisis in America and globally, there is clear industry applicability to a device that is critical to a non-addictive, safer solution to postoperative pain management.

The difficulty will be defending our device in the "inventive step(s)" or "non-obvious" category. The device itself is a relatively trivial combination of basic logic boards and micro-function generator modules. Additionally, several approved filings already use induction for powering many types of implantable medical devices (US8301262B2, US20160331981A1, WO2012056428A1, EP2406655A1, US8827889B2, US20050113888A1, US6345203B1, US8170681B2, US8634928B1, US8847548B2, US9597522B2, US20100280568A1, US20150008761A1, US5954058A). As a result, our device would appear "obvious" or "non-inventive" in the eyes of the patent agent submitting our IPRP Chapter 1 application analysis.

IPRP Chapter 1 documents listing 1 or more claims as fulfilling the three categories strongly increases the likelihood of patentability in any country the stimulator invention is filed in downstream. This process would be far easier would the Bifrost be filed jointly with the bioresorbable nerve inhibitor developed by the MacEwan group. However, they have already filed a patent for this technology (WO2018200723A1). We think this is the best route to file our IP as a continuation of the IP filed by the client on the nerve inhibitor. In this paradigm, the wireless powering mechanism conferred by the Bifrost would be appended as additional claims on the initial patent filed.

## References

1. Block, B. M., Liu, S. S., Rowlingson, A. J., Cowan, A. R., Cowan Jr, J. A., & Wu, C. L. (2003). Efficacy of postoperative epidural analgesia: a meta-analysis. *Jama*, 290(18), 2455-2463.
2. McCormick, P. J. (2019). A Time-Release History of the Opioid Epidemic. *Anesthesia & Analgesia*, 128(2). doi: 10.1213/ane.0000000000003964
3. NIDA. (2019, January 22). Opioid Overdose Crisis. Retrieved from <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis#three>
4. Hah, J. M., Bateman, B. T., Ratliff, J., Curtin, C., & Sun, E. (2017). Chronic Opioid Use After Surgery: Implications for Perioperative Management in the Face of the Opioid Epidemic. *Anesthesia and analgesia*, 125(5), 1733–1740. doi:10.1213/ANE.0000000000002458
5. Chou, R., Gordon, D. B., Leon-Casasola, O. A. D., Rosenberg, J. M., Bickler, S., Brennan, T., ... Wu, C. L. (2016). Management of Postoperative Pain: A Clinical Practice Guideline From the American Pain Society, the American Society of Regional Anesthesia and Pain Medicine, and the American Society of Anesthesiologists Committee on Regional Anesthesia, Executive Committee, and Administrative Council. *The Journal of Pain*, 17(2), 131–157. doi: 10.1016/j.jpain.2015.12.008
6. Frenzel, L. (2018, May 4). Back to Basics: Impedance Matching (Part 1). Retrieved from <https://www.electronicdesign.com/communications/back-basics-impedance-matching-part-1>.
7. 510(k) Premarket Notification. (n.d.). Retrieved November 18, 2019, from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K132660>.
8. FDA, C. for D. E. and R. (n.d.). FDA Recommends Against Prolonged Use of Magnesium Sulfate to Stop... Retrieved from <https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-recommends-against-prolonged-use-magnesium-sulfate-stop-pre-term>.
9. 510(k) Premarket Notification. (n.d.). Retrieved from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K961433>.
10. 510(k) Premarket Notification. (n.d.). Retrieved from <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K151034>.
11. IP Ratings (Ingress Protection). (n.d.). Retrieved November 21, 2019, from <https://www.mpl.ch/info/IPratings.html>.

# Appendix

## Appendix A1: Verification Tests

After device construction is complete using the aforementioned parts list alongside mechanical and electrical diagrams, the below verification tests can be used to determine if the built device conforms to the expected standards.

The Bifrost stimulator verification can be divided into two categories: mechanical (any physical properties of the device including usability and durability) fidelity and electrical (any signal transmission properties associated with the device relevant to signal transmission) fidelity. Note, for all relevant tests, an oscilloscope will be used to verify signal waveform and a multimeter will be used to measure  $V_{pp}$  and power outputted by the Bifrost. Further, the specification numbers listed below correspond to the number assignments in Table 1.

### **Mechanical Verification:**

1) Mass (fulfilling specification number 6):

The Bifrost device will be weighed via a calibrated lab balance to ensure it is below the client specified 1.36 kg.

2) Humidity (fulfilling specification number 1):

The Bifrost will be placed in an incubator with humidity controls and tested for output signal fidelity (i.e. fulfilling specifications 12, 13, and 14). The onboard humidity sensor will be used to report the relative humidity the Bifrost is exposed to during testing to ensure the 0-70% range expected by the client is met.

3) Usability (fulfilling specification 2):

The Bifrost device is intended for use by patients without assistance or input from a medical worker. As such, individuals across a wide age range (12-82) will be allowed to use the device. Each individual will be given instructions about how to use the device and then asked to complete the following tasks 30 minutes later: 1) turning the device on/off 2) tuning the device to the intended stimulation frequency. The user will also be asked if the LCD screen within the Bifrost is readable. Users will not be implanted with a bioresorbable nerve inhibitor and will operate the device in abstraction.

4) Water-resistance (fulfilling specifications 2, 4, and 7):

The Bifrost is expected to come in contact with low amounts of sweat/other physiological fluids. To test the fidelity of the device in this situation, the Bifrost will be placed on a surface sprayed with water as per the International Electrotechnical Commission (IEC) test for IP1 (water).<sup>11</sup> Specifically, the device will be placed upright and rotated at 1 RPM while spraying it with 1 mm of water.<sup>11</sup> It will then be turned on and tested for output signal fidelity (i.e. fulfilling specifications 12, 13, and 14).

5) Solids resistance (fulfilling specifications 2, 4, and 7):

The Bifrost will not only be isolated to clinic use and may come into contact with foreign objects and materials. To ensure it is usable under these conditions, the device will be tested for IP4 (solid particles) classification.<sup>11</sup> The Bifrost will be powered on and small screws, wires, and other objects  $\geq 1$  mm in length will be dropped from 6 inches above the device.<sup>11</sup> It will then be assessed for output signal fidelity (i.e. fulfilling specifications 12, 13, and 14).

6) Drop durability (fulfilling specification 4):

The Bifrost is expected to withstand physical damage due to accidents during its 28-day use cycle. Due to the time constraints of the design project, it will not be possible to observe device function after 28 days of daily use. However, to replicate the potential physical damage

the device would need to withstand, it will be dropped from 1.22 meters (approximate waist height) followed by vigorous manual shaking (with hands) for one minute. Then, the Bifrost will be turned on and tested for output signal fidelity (i.e. fulfilling specifications 12, 13, and 14).

7) Dimensions (fulfilling specification 2 and 5):

The Bifrost is expected to be a portable device a patient can use for pain management throughout the day. So a standard ruler will be used to measure the final length, width, and height and ensure it conforms to the 17.8 cm X 17.8 cm X 10.2 cm requested by the client.

8) Temperature (fulfilling specification 2, 8, and 9):

The Bifrost is expected to function across a range of temperatures it will normally face in a 28-day use cycle in the hands of a patient. As such, the device will be placed in a temperature-controlled incubator and tested for output signal fidelity (i.e. fulfilling specifications 12, 13, and 14) across the 12.8-37.8 °C range requested by the client. The onboard temperature sensor on the Bifrost will also report the temperature range the device was exposed to. It is also important for the Bifrost device to not overheat and potentially harm the patient during use. The device will be left on for a period of one hour at room temperature (20 °C) and the temperature will be recorded through the onboard temperature sensor. This will ensure that the device circuitry does not raise the Bifrost temperature to more than 37.8 °C (i.e. body temperature) at any point during use as per the client requirements.

**Electrical Verification:**

Electrical verification contains an assessment of the battery life of the system, the output signal waveform fidelity, and output signal voltage and power parameters

9) Battery life (fulfilling specifications 2 and 10):

The Bifrost's portability is contingent on successful battery powering. To measure battery life, the device will be plugged in with a fully charged battery source. Then the output signal will

be tested for ability to fulfill specifications 12, 13, and 14. After this, the time until the battery source connected to the Bifrost is fully drained (i.e. Bifrost no longer emits a signal) will be measured to ensure it conforms to the client's specification.

10) Time course from battery fully drained to fully charged (fulfilling specification 11):

Battery recharge ability will be measured by taking a fully drained battery and measuring the time to full charge with a 2 A micro-USB charger to ensure it takes no longer than 1 hour.

11) Stimulation frequency (fulfilling specification 12):

An oscilloscope will be used to record the Bifrost's stimulation frequency outputted by the AD9833 signal generator via an oscilloscope to verify emission of a 14-26 kHz sine wave.

12) Carrier frequency (fulfilling specification 14):

The Bifrost's carrier frequency will be measured by recording the waveform out of the AD9850 signal generator through an oscilloscope to ensure a 5 MHz signal can be produced.

13) Overall voltage amplitude and power transmission (fulfilling specifications 13 and 16):

The Bifrost's output voltage signal's peak-to-peak voltage sent to the primary coil will be tested to ensure it is within the 0.15-10 V range specified by the client. The power transmission of the Bifrost between 0.5 and 200 mW will also be verified with a multimeter.

14) Nerve inhibition parameters (fulfilling specifications 3 and 15):

First, the team will place a set of stimulating electrodes (proximal to the soma and distal to the axon terminal) and a set of recording electrodes (proximal to the axon terminal) on a rat sciatic nerve with the client's bioresorbable stimulator already implanted. The Bifrost will then be powered on and its ability to inhibit the nerve signal sent by the stimulating electrodes (as measured by the recording electrodes) will be observed at varying distances from the nerve inhibitor (as measured by a standard 12-inch ruler). Further, the time between powering the Bifrost and first observation of inhibition will also be measured.

### 15) Cost and Time (fulfilling specifications 17 and 18):

The project is on track to be completed in 5 months (July to December 6, 2019) and the cost of the initial prototype will be tabulated at the end of design completion.

## Coding Appendices

Note, Coding Appendices C1, C2, and C3 were taken directly from

<http://www.mediafire.com/?vn3xfn956k12g> through

<https://www.instructables.com/id/Arduino-30MHZ-DDS-Signal-Generator-In-12/> guide on portable signal generators.

### Appendix C1: 9850.ino code file for programming Arduino Uno R3

```

/*
Main code by Richard Visokey AD7C - www.ad7c.com
Revision 2.0 - November 6th, 2013
Taken from http://www.mediafire.com/?vn3xfn956k12g
*/

// Include the library code
#include <LiquidCrystal.h>
#include "rotary.h"
#include <EEPROM.h>

//Setup some items
#define W_CLK 8 // Pin 8 - connect to AD9850 module word load clock pin (CLK)
#define FQ_UD 9 // Pin 9 - connect to freq update pin (FQ)
#define DATA 10 // Pin 11 - connect to serial data load pin (DATA)
#define RESET 11 // Pin 10 - connect to reset pin (RST)
#define pulseHigh(pin) {digitalWrite(pin, HIGH); digitalWrite(pin, LOW); }
Rotary r = Rotary(2,3); // sets the pins the rotary encoder uses. Must be interrupt pins.
LiquidCrystal lcd(12, 13, 7, 6, 5, 4); // I used an odd pin combination because I need pin 2
and 3 for the interrupts.
int_fast32_t rx=5000000; // Base (starting) frequency of VFO. This only loads once. To force
load again see ForceFreq variable below.
int_fast32_t rx2=1; // variable to hold the updated frequency
int_fast32_t increment = 10; // starting VFO update increment in HZ.
int_fast32_t iffreq = 0000000; // Intermediate Frequency - Amount to subtract (-) from base
frequency. *****
int buttonstate = 0;
int buttonstate2 = 0;
int GoIF = 1;
String hertz = "10 Hz";
int hertzPosition = 5;
byte ones,tens,hundreds,thousands,tenthousands,hundredthousands,millions ; //Placeholders
String freq; // string to hold the frequency
int_fast32_t timepassed = millis(); // int to hold the arduino millis since startup
int memstatus = 1; // value to notify if memory is current or old. 0=old, 1=current.

```

```
int ForceFreq = 1; // Change this to 0 after you upload and run a working sketch to activate
the EEPROM memory. YOU MUST PUT THIS BACK TO 0 AND UPLOAD THE SKETCH AGAIN AFTER STARTING
FREQUENCY IS SET!
```

```
void setup() {
  pinMode(A0,INPUT); // Connect to a button that goes to GND on push
  pinMode(A5,INPUT); // IF sense *****
  digitalWrite(A0,HIGH);
  digitalWrite(A5,HIGH);
  lcd.begin(16, 2);
  PCICR |= (1 << PCIE2);
  PCMSK2 |= (1 << PCINT18) | (1 << PCINT19);
  sei();
  pinMode(FQ_UD, OUTPUT);
  pinMode(W_CLK, OUTPUT);
  pinMode(DATA, OUTPUT);
  pinMode(RESET, OUTPUT);
  pulseHigh(RESET);
  pulseHigh(W_CLK);
  pulseHigh(FQ_UD); // this pulse enables serial mode on the AD9850 - Datasheet page 12.
  lcd.setCursor(hertzPosition,1);
  lcd.print(hertz);

  // Load the stored frequency
  if (ForceFreq == 0) {
    freq =
String(EEPROM.read(0))+String(EEPROM.read(1))+String(EEPROM.read(2))+String(EEPROM.read(3))+St
ring(EEPROM.read(4))+String(EEPROM.read(5))+String(EEPROM.read(6));
    rx = freq.toInt();
  }
}

void loop() {
  // Update the display and frequency if the new Freq NEQ the old Freq
  if (rx != rx2){
    showFreq();
    sendFrequency(rx);
    rx2 = rx;
  }

  // Rotate through the rate of tuning as you hold down the button
  buttonstate = digitalRead(A0);
  if(buttonstate == LOW) {
    setincrement();
  };

  // Check for PIN low to drive IF offset Freq
  buttonstate = digitalRead(A5);
  if (buttonstate != buttonstate2){
    if(buttonstate == LOW) {
      lcd.setCursor(15,1);
      lcd.print(".");
      GoIF = 0;
      buttonstate2 = buttonstate;
      sendFrequency(rx);
    }
    else{
      lcd.setCursor(15,1);
      lcd.print(" ");
      GoIF = 1;
      buttonstate2 = buttonstate;
      sendFrequency(rx);
    }
  }
}
```



```

    };
};

// Write the frequency to memory if not stored and 2 seconds have passed since the last
frequency change.
if(memstatus == 0){
    if(timepassed+2000 < millis()){
        storeMEM();
    }
}

}

// Interrupt routine to catch the rotary encoder
ISR(PCINT2_vect) {
    unsigned char result = r.process();
    int_fast32_t highFreq=30000000;
    int_fast32_t lowFreq=00000000;
    if (result) {
        if (result == DIR_CW){rx=rx+increment;}
        else {rx=rx-increment;};
        if (rx >=highFreq){rx=rx2;}; // UPPER VFO LIMIT -- Change based on inhibition
specifications intended
        if (rx <=lowFreq){rx=rx2;}; // LOWER VFO LIMIT -- Change based on inhibit
    }
}

// frequency calc from datasheet page 8 = <sys clock> * <frequency tuning word>/2^32
void sendFrequency(double frequency) {
    if (GoIF == 1){frequency=frequency-iffreq;}; //If pin = low, subtract the IF frequency.
    int32_t freq = frequency * 4294967295/125000000; // note 125 MHz clock on 9850. You can
make 'slight' tuning variations here by adjusting the clock frequency.
    for (int b=0; b<4; b++, freq>>=8) {
        tfr_byte(freq & 0xFF);
    }
    tfr_byte(0x000); // Final control byte, all 0 for 9850 chip
    pulseHigh(FQ_UD); // Done! Should see output
}
// transfers a byte, a bit at a time, LSB first to the 9850 via serial DATA line
void tfr_byte(byte data)
{
    for (int i=0; i<8; i++, data>>=1) {
        digitalWrite(DATA, data & 0x01);
        pulseHigh(W_CLK); //after each bit sent, CLK is pulsed high
    }
}

void setincrement(){
    if(increment == 10){increment = 50; hertz = "50 Hz"; hertzPosition=5;}
    else if (increment == 50){increment = 100; hertz = "100 Hz"; hertzPosition=4;}
    else if (increment == 100){increment = 500; hertz="500 Hz"; hertzPosition=4;}
    else if (increment == 500){increment = 1000; hertz="1 Khz"; hertzPosition=6;}
    else if (increment == 1000){increment = 2500; hertz="2.5 Khz"; hertzPosition=4;}
    else if (increment == 2500){increment = 5000; hertz="5 Khz"; hertzPosition=6;}
    else if (increment == 5000){increment = 10000; hertz="10 Khz"; hertzPosition=5;}
    else if (increment == 10000){increment = 100000; hertz="100 Khz"; hertzPosition=4;}
    else if (increment == 100000){increment = 1000000; hertz="1 Mhz"; hertzPosition=6;}
    else{increment = 10; hertz = "10 Hz"; hertzPosition=5;};
    lcd.setCursor(0,1);
    lcd.print(" ");
    lcd.setCursor(hertzPosition,1);
    lcd.print(hertz);
    delay(250); // Adjust this delay to speed up/slow down the button menu scroll speed.
};

```

```

void showFreq(){
  millions = int(rx/1000000);
  hundredthousands = ((rx/100000)%10);
  tenthousands = ((rx/10000)%10);
  thousands = ((rx/1000)%10);
  hundreds = ((rx/100)%10);
  tens = ((rx/10)%10);
  ones = ((rx/1)%10);
  lcd.setCursor(0,0);
  lcd.print("          ");
  if (millions > 9){lcd.setCursor(1,0);}
  else{lcd.setCursor(2,0);}
  lcd.print(millions);
  lcd.print(".");
  lcd.print(hundredthousands);
  lcd.print(tenthousands);
  lcd.print(thousands);
  lcd.print(".");
  lcd.print(hundreds);
  lcd.print(tens);
  lcd.print(ones);
  lcd.print(" Mhz ");
  timepassed = millis();
  memstatus = 0; // Trigger memory write
};

void storeMEM(){
  //Write each frequency section to a EPROM slot.  Yes, it's cheating but it works!
  EEPROM.write(0,millions);
  EEPROM.write(1,hundredthousands);
  EEPROM.write(2,tenthousands);
  EEPROM.write(3,thousands);
  EEPROM.write(4,hundreds);
  EEPROM.write(5,tens);
  EEPROM.write(6,ones);
  memstatus = 1; // Let program know memory has been written
};

```

## Appendix C2: Rotary Encoder Header File

```

/*
 * Rotary encoder library for Arduino.
 */

#ifndef rotary_h
#define rotary_h

#include "Arduino.h"

// Enable this to emit codes twice per step.
// #define HALF_STEP

// Enable weak pullups
#define ENABLE_PULLUPS

// Values returned by 'process'
// No complete step yet.
#define DIR_NONE 0x0
// Clockwise step.
#define DIR_CW 0x10
// Anti-clockwise step.

```

```

#define DIR_CCW 0x20

class Rotary
{
public:
    Rotary(char, char);
    // Process pin(s)
    unsigned char process();
private:
    unsigned char state;
    unsigned char pin1;
    unsigned char pin2;
};

#endif

```

## Appendix C3: Rotary Encoder C File

```

/* Rotary encoder handler for arduino. v1.1
 *
 * Copyright 2011 Ben Buxton. Licenced under the GNU GPL Version 3.
 * Contact: bb@cactii.net
 *
 * A typical mechanical rotary encoder emits a two bit gray code
 * on 3 output pins. Every step in the output (often accompanied
 * by a physical 'click') generates a specific sequence of output
 * codes on the pins.
 *
 * There are 3 pins used for the rotary encoding - one common and
 * two 'bit' pins.
 *
 * The following is the typical sequence of code on the output when
 * moving from one step to the next:
 *
 *   Position   Bit1   Bit2
 *   -----
 *   Step1      0       0
 *   1/4        1       0
 *   1/2        1       1
 *   3/4        0       1
 *   Step2      0       0
 *
 * From this table, we can see that when moving from one 'click' to
 * the next, there are 4 changes in the output code.
 *
 * - From an initial 0 - 0, Bit1 goes high, Bit0 stays low.
 * - Then both bits are high, halfway through the step.
 * - Then Bit1 goes low, but Bit2 stays high.
 * - Finally at the end of the step, both bits return to 0.
 *
 * Detecting the direction is easy - the table simply goes in the other
 * direction (read up instead of down).
 *
 * To decode this, we use a simple state machine. Every time the output
 * code changes, it follows state, until finally a full steps worth of
 * code is received (in the correct order). At the final 0-0, it returns
 * a value indicating a step in one direction or the other.
 *
 * It's also possible to use 'half-step' mode. This just emits an event
 * at both the 0-0 and 1-1 positions. This might be useful for some
 * encoders where you want to detect all positions.

```

```

*
* If an invalid state happens (for example we go from '0-1' straight
* to '1-0'), the state machine resets to the start until 0-0 and the
* next valid codes occur.
*
* The biggest advantage of using a state machine over other algorithms
* is that this has inherent debounce built in. Other algorithms emit spurious
* output with switch bounce, but this one will simply flip between
* sub-states until the bounce settles, then continue along the state
* machine.
* A side effect of debounce is that fast rotations can cause steps to
* be skipped. By not requiring debounce, fast rotations can be accurately
* measured.
* Another advantage is the ability to properly handle bad state, such
* as due to EMI, etc.
* It is also a lot simpler than others - a static state table and less
* than 10 lines of logic.
*/

#include "Arduino.h"
#include "rotary.h"

/*
* The below state table has, for each state (row), the new state
* to set based on the next encoder output. From left to right in,
* the table, the encoder outputs are 00, 01, 10, 11, and the value
* in that position is the new state to set.
*/

#define R_START 0x0

#ifdef HALF_STEP
// Use the half-step state table (emits a code at 00 and 11)
#define R_CCW_BEGIN 0x1
#define R_CW_BEGIN 0x2
#define R_START_M 0x3
#define R_CW_BEGIN_M 0x4
#define R_CCW_BEGIN_M 0x5
const unsigned char ttable[6][4] = {
    // R_START (00)
    {R_START_M,          R_CW_BEGIN,      R_CCW_BEGIN,  R_START},
    // R_CCW_BEGIN
    {R_START_M | DIR_CCW, R_START,        R_CCW_BEGIN,  R_START},
    // R_CW_BEGIN
    {R_START_M | DIR_CW,  R_CW_BEGIN,     R_START,      R_START},
    // R_START_M (11)
    {R_START_M,          R_CCW_BEGIN_M, R_CW_BEGIN_M, R_START},
    // R_CW_BEGIN_M
    {R_START_M,          R_START_M,      R_CW_BEGIN_M, R_START | DIR_CW},
    // R_CCW_BEGIN_M
    {R_START_M,          R_CCW_BEGIN_M, R_START_M,    R_START | DIR_CCW},
};
#else
// Use the full-step state table (emits a code at 00 only)
#define R_CW_FINAL 0x1
#define R_CW_BEGIN 0x2
#define R_CW_NEXT 0x3
#define R_CCW_BEGIN 0x4
#define R_CCW_FINAL 0x5
#define R_CCW_NEXT 0x6

const unsigned char ttable[7][4] = {
    // R_START
    {R_START,          R_CW_BEGIN,  R_CCW_BEGIN, R_START},
    // R_CW_FINAL
    {R_CW_NEXT,       R_START,      R_CW_FINAL, R_START | DIR_CW},

```

```

// R_CW_BEGIN
{R_CW_NEXT, R_CW_BEGIN, R_START, R_START},
// R_CW_NEXT
{R_CW_NEXT, R_CW_BEGIN, R_CW_FINAL, R_START},
// R_CCW_BEGIN
{R_CCW_NEXT, R_START, R_CCW_BEGIN, R_START},
// R_CCW_FINAL
{R_CCW_NEXT, R_CCW_FINAL, R_START, R_START | DIR_CCW},
// R_CCW_NEXT
{R_CCW_NEXT, R_CCW_FINAL, R_CCW_BEGIN, R_START},
};
#endif

/*
 * Constructor. Each arg is the pin number for each encoder contact.
 */
Rotary::Rotary(char _pin1, char _pin2) {
    // Assign variables.
    pin1 = _pin1;
    pin2 = _pin2;
    // Set pins to input.
    pinMode(pin1, INPUT);
    pinMode(pin2, INPUT);
#ifdef ENABLE_PULLUPS
    digitalWrite(pin1, HIGH);
    digitalWrite(pin2, HIGH);
#endif
    // Initialise state.
    state = R_START;
}

unsigned char Rotary::process() {
    // Grab state of input pins.
    unsigned char pinstate = (digitalRead(pin2) << 1) | digitalRead(pin1);
    // Determine new state from the pins and state table.
    state = ttable[state & 0xf][pinstate];
    // Return emit bits, ie the generated event.
    return state & 0x30;
}

```

# Appendix D: Design Safe Analysis Report

12/9/2019

Bifrost

## designsafe Report

Application: Bifrost  
 Description: Analyst Name(s): Joe Beggs  
 Product Identifier: Company:  
 Assessment Type: Detailed Facility Location:  
 Limits:  
 Sources:  
 Risk Scoring System: designsafe Three Factor

Guide sentence: When doing [task], the [user] could be injured by the [hazard] due to the [failure mode].

Item Id	User / Task	Hazard / Failure Mode	Initial Assessment			Final Assessment			Status / Responsible /Comments /Reference
			Severity Exposure Probability	Risk Level	Risk Reduction Methods /Control System	Severity Exposure Probability	Risk Level		
1-1-1	Clinical (Doctor/Nurse) diagnose patients	None / Other : Not a hazard	Minimal	Minimal		Minimal			
1-2-1	Clinical (Doctor/Nurse) calibrate / test / troubleshoot medical monitoring equipment	fire and explosions : hot surfaces	Serious			Serious			
1-2-2	Clinical (Doctor/Nurse) calibrate / test / troubleshoot medical monitoring equipment	heat / temperature : burns / scalds	Serious			Serious			
1-2-3	Clinical (Doctor/Nurse) calibrate / test / troubleshoot medical monitoring equipment	heat / temperature : severe heat	Serious			Serious			
1-3-1	Clinical (Doctor/Nurse) monitor patients	None / Other : Not a hazard	Minimal			Minimal			
2-1-1	Device Technician setup supplies / equipment / instruments for operation	heat / temperature : burns / scalds	Serious			Serious			
2-1-2	Device Technician setup supplies / equipment / instruments for operation	heat / temperature : severe heat	Minimal			Minimal			

12/9/2019

Bifrost

Item Id	User / Task	Hazard / Failure Mode	Initial Assessment		Final Assessment		Status / Responsible /Comments /Reference
			Severity Exposure Probability	Risk Level	Severity Exposure Probability	Risk Level	
2-2-1	Device Technician monitor machines	heat / temperature : burns / scalds	Serious	Serious	Serious		
2-2-2	Device Technician monitor machines	heat / temperature : severe heat	Slight	Slight	Slight		
2-3	Device Technician trouble shooting / problem solving	<None>					
3-1-1	User (Patient/Family/Caretakers) rest/moving	ergonomics / human factors : posture	Slight	Slight	Slight		
3-1-2	User (Patient/Family/Caretakers) rest/moving	ergonomics / human factors : Catastrophic lifting / bending / twisting	Catastrophic	Catastrophic	Catastrophic		
3-1-3	User (Patient/Family/Caretakers) rest/moving	heat / temperature : burns / scalds	Catastrophic	Catastrophic	Catastrophic		
3-1-4	User (Patient/Family/Caretakers) rest/moving	heat / temperature : severe heat	Catastrophic	Catastrophic	Catastrophic		

## Appendix E: Data Sheets



Carbon Film Fixed Resistors



## Type CFR Series

## Key Features

- Low cost, combined with high reliability, make these components suitable for use in most types of circuits, including audio, communications, measurement and computer applications.
- Premium quality carbon film resistors whose ceramic core has a high alumina content offering power to size ratios not normally associated with carbon film product.
- Available in 5 power ratings from 1 ohm to 10 Mohm. The smallest case size (CFR16) has a full 0.25 W power rating.



The resistive element comprises a thin film of carbon, deposited onto a high thermal conductivity ceramic core. Metal end caps are force fitted to the element prior to spiralling to value. Tinned copper lead wires are welded to the end caps and the components are then coated. One coat of phenolic resin is followed by three coats of epoxy resin. All resistors are tested for value and tolerance.

Characteristics -  
Electrical

	CFR16	CFR25	CFR50	CFR100	CFR200
Rated Power @ 70 °C (W)	0.25	0.33	0.5	1	2
Resistance Range (Ohms)	Min 1R0 Max 4M7	1R0 10M	1R0 10M	1R0 10M	1R0 10M
Tolerance (%)			2	5	
Code letter			G	J	
Temp. Coefficient (ppm/°C)	up to 10R 11R - 99K 100K - 1M0 1M1 - 10M	±350 0 to -450 0 to -700 0 to -1500	±350 0 to -450 0 to -700 0 to -1500	±350 0 to -450 0 to -700 0 to -1500	±350 0 to -450 0 to -700 0 to -1500
Selection Series			E24		
Limiting Element Voltage (V)	200	250	350	500	500
Max Overload Voltage <sup>1</sup> (V)	400	500	700	1000	1000
Max Intermittent Overload Voltage <sup>2</sup> (V)	500	700	750	750	750
Operating Temp. Range (°C)			-55 to +155		
Climatic Category (°C)			55/155/56		
Dielectric Strength (V)	400	500	700	1000	1000
Insulation Resistance (Mohms)			1000		

<sup>1</sup>Maximum Overload Voltage is 2.5 times rated voltage up to the specified voltage for 5 seconds.

<sup>2</sup>Maximum Intermittent Overload Voltage is 4 times rated voltage up to the specified voltage for 1 second ON and 25 seconds OFF, >100R ONLY



12/6/2019

Lithium Ion Polymer Battery - 3.7v 2500mAh ID: 328 - \$14.95 : Adafruit Industries, Unique & fun DIY electronics and kits

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## Lithium Ion Polymer Battery - 3.7v 2500mAh **\$14.95**

PRODUCT ID: 328



1

ADD TO CART

4.8 ★★★★★  
Google  
Customer Reviews



# 500 MHz Four-Quadrant Multiplier

Data Sheet

AD834

## FEATURES

DC to >500 MHz operation  
 Differential  $\pm 1$  V full-scale inputs  
 Differential  $\pm 4$  mA full-scale output current  
 Low distortion ( $\pm 0.05\%$  for 0 dBm input)  
 Supply voltages from  $\pm 4$  V to  $\pm 9$  V  
 Low power (280 mW typical at  $V_S = \pm 5$  V)

## APPLICATIONS

High speed real time computation  
 Wideband modulation and gain control  
 Signal correlation and RF power measurement  
 Voltage controlled filters and oscillators  
 Linear keys for high resolution television  
 Wideband true RMS

## GENERAL DESCRIPTION

The AD834 is a monolithic, laser-trimmed four-quadrant analog multiplier. Intended for use in high frequency applications, with a transconductance bandwidth ( $R_L = 50 \Omega$ ) in excess of 500 MHz from either of the differential voltage inputs. In multiplier modes, the typical total full-scale error is 0.5%, dependent on the application mode and the external circuitry. Performance is relatively insensitive to temperature and supply variations due to the use of stable biasing based on a band gap reference generator and other design features.

To preserve the full bandwidth potential of the high speed bipolar process used to fabricate the AD834, the outputs appear as a differential pair of currents at open collectors. To provide a single-ended ground referenced voltage output, some form of external current-to-voltage conversion is needed. This may take the form of a wideband transformer, balun, or active circuitry such as an op amp. In some applications (such as power measurement), the subsequent signal processing may not need to have high bandwidth.

The transfer function is accurately trimmed such that when  $X = Y = \pm 1$  V, the differential output is  $\pm 4$  mA. This absolute calibration allows the outputs of two or more AD834 devices to be summed with precisely equal weighting, independent of the accuracy of the load circuit.

The AD834, available in 8-lead PDIP and plastic SOIC packages, is specified over the commercial temperature range of  $0^\circ\text{C}$  to  $70^\circ\text{C}$ . The AD834A is also available in 8-lead CERDIP and plastic SOIC packages operating over the industrial temperature range of  $-40^\circ\text{C}$  to  $+85^\circ\text{C}$ . The AD834SQ/883B, available in an 8-lead

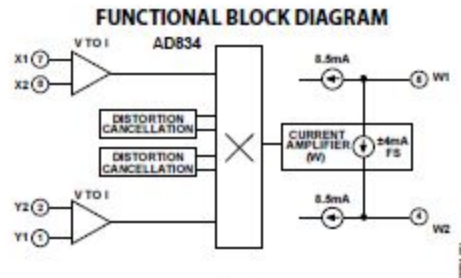


Figure 1.

CERDIP, operates over the military temperature range of  $-55^\circ\text{C}$  to  $+125^\circ\text{C}$ . S-grade chips are also available.

Two application notes featuring the AD834 (AN-212 and AN-216) can be found at [www.analog.com](http://www.analog.com). For additional applications circuits, consult the AD811 data sheet.

## PRODUCT HIGHLIGHTS

1. Combines high static accuracy (low input and output offsets and accurate scale factor) with very high bandwidth. As a four-quadrant multiplier or squarer, the response extends from dc to an upper frequency limited by packaging and external board layout considerations. Obtains a large signal bandwidth of >500 MHz under optimum conditions.
2. Used in many high speed nonlinear operations, such as square rooting, analog division, vector addition, and rms-to-dc conversion. In these modes, the bandwidth is limited by the external active components.
3. Special design techniques result in low distortion levels (better than  $-60$  dB on either input) at high frequencies and low signal feedthrough (typically  $-65$  dB up to 20 MHz).
4. Exhibits low differential phase error over the input range—typically  $0.08^\circ$  at 5 MHz and  $0.8^\circ$  at 50 MHz. The large signal transient response is free from overshoot and has an intrinsic rise time of 500 ps, typically settling to within 1% in under 5 ns.
5. The nonloading, high impedance, differential inputs simplify the application of the AD834.

## Rev. F

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## CMOS, 125 MHz Complete DDS Synthesizer

### AD9850

#### FEATURES

- 125 MHz Clock Rate
- On-Chip High Performance DAC and High Speed Comparator
- DAC SFDR > 50 dB @ 40 MHz  $A_{OUT}$
- 32-Bit Frequency Tuning Word
- Simplified Control Interface: Parallel Byte or Serial Loading Format
- Phase Modulation Capability
- 3.3 V or 5 V Single-Supply Operation
- Low Power: 380 mW @ 125 MHz (5 V)  
155 mW @ 110 MHz (3.3 V)
- Power-Down Function
- Ultra-small 28-Lead SSOP Packaging

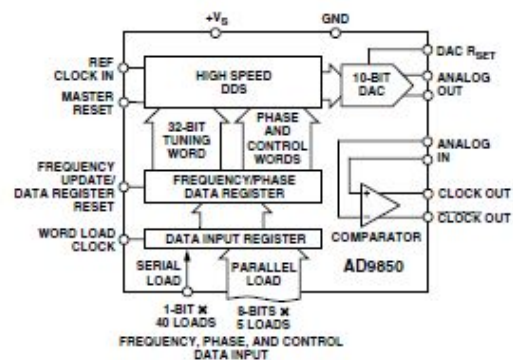
#### APPLICATIONS

- Frequency/Phase—Agile Sine Wave Synthesis
- Clock Recovery and Locking Circuitry for Digital Communications
- Digitally Controlled ADC Encode Generator
- Agile Local Oscillator Applications

#### GENERAL DESCRIPTION

The AD9850 is a highly integrated device that uses advanced DDS technology coupled with an internal high speed, high performance D/A converter and comparator to form a complete, digitally programmable frequency synthesizer and clock generator function. When referenced to an accurate clock source, the AD9850 generates a spectrally pure, frequency/phase programmable, analog output sine wave. This sine wave can be used directly as a frequency source, or it can be converted to a square wave for agile-clock generator applications. The AD9850's innovative high speed DDS core provides a 32-bit frequency tuning word, which results in an output tuning resolution of 0.0291 Hz for a 125 MHz reference clock input. The AD9850's circuit architecture allows the generation of output frequencies of up to one-half the reference clock frequency (or 62.5 MHz), and the output frequency can be digitally changed (asynchronously) at a rate of up to 23 million new frequencies per second. The device also provides five bits of digitally controlled phase modulation, which enables phase shifting of its output in increments of 180°, 90°, 45°, 22.5°,

#### FUNCTIONAL BLOCK DIAGRAM



11.25°, and any combination thereof. The AD9850 also contains a high speed comparator that can be configured to accept the (externally) filtered output of the DAC to generate a low jitter square wave output. This facilitates the device's use as an agile clock generator function.

The frequency tuning, control, and phase modulation words are loaded into the AD9850 via a parallel byte or serial loading format. The parallel load format consists of five iterative loads of an 8-bit control word (byte). The first byte controls phase modulation, power-down enable, and loading format; Bytes 2 to 5 comprise the 32-bit frequency tuning word. Serial loading is accomplished via a 40-bit serial data stream on a single pin. The AD9850 Complete DDS uses advanced CMOS technology to provide this breakthrough level of functionality and performance on just 155 mW of power dissipation (3.3 V supply).

The AD9850 is available in a space-saving 28-lead SSOP, surface-mount package. It is specified to operate over the extended industrial temperature range of -40°C to +85°C.

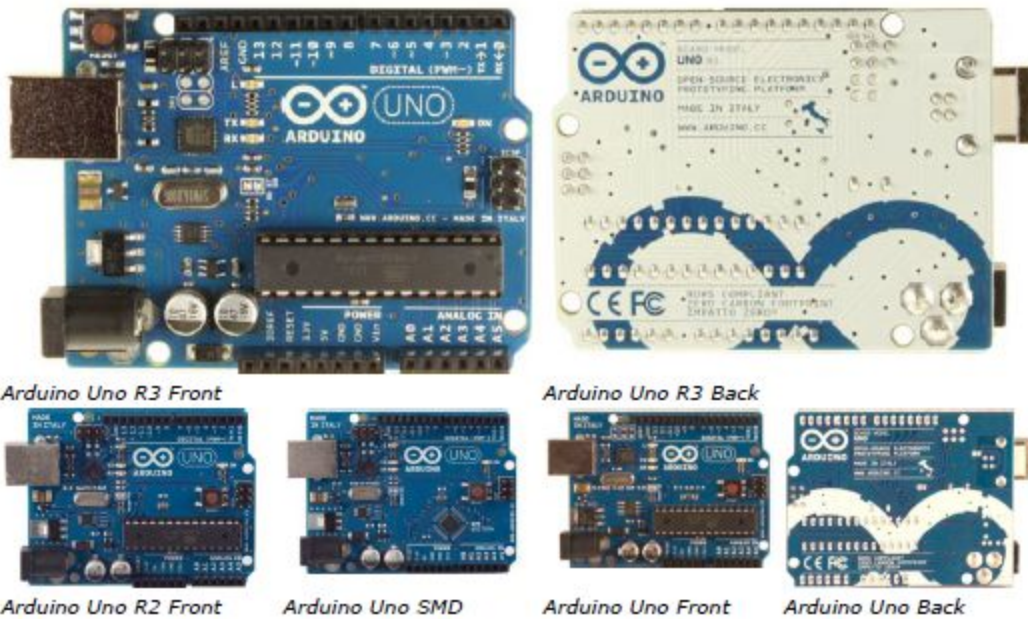
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## Arduino Uno



## Overview

The Arduino Uno is a microcontroller board based on the ATmega328 ([datasheet](#)). It has 14 digital input/output pins (of which 6 can be used as PWM outputs), 6 analog inputs, a 16 MHz ceramic resonator, a USB connection, a power jack, an ICSP header, and a reset button. It contains everything needed to support the microcontroller; simply connect it to a computer with a USB cable or power it with a AC-to-DC adapter or battery to get started.

The Uno differs from all preceding boards in that it does not use the FTDI USB-to-serial driver chip. Instead, it features the Atmega16U2 (Atmega8U2 up to version R2) programmed as a USB-to-serial converter.

[Revision 2](#) of the Uno board has a resistor pulling the 8U2 HWB line to ground, making it easier to put into [DFU mode](#).

[Revision 3](#) of the board has the following new features:

- 1.0 pinout: added SDA and SCL pins that are near to the AREF pin and two other new pins placed near to the RESET pin, the IOREF that allow the shields to adapt to the voltage provided from the board. In future, shields will be compatible both with the board that use the AVR, which operate with 5V and with the Arduino Due that operate with 3.3V. The second one is a not connected pin, that is reserved for future purposes.
- Stronger RESET circuit.
- Atmega 16U2 replace the 8U2.

"Uno" means one in Italian and is named to mark the upcoming release of Arduino 1.0. The Uno and version 1.0 will be the reference versions of Arduino, moving forward. The Uno is the latest in a series of USB Arduino boards, and the reference model for the Arduino platform; for a comparison with previous versions, see the [index of Arduino boards](#).

## Summary

Microcontroller	ATmega328
Operating Voltage	5V
Input Voltage (recommended)	7-12V



# MCP73871

## Stand-Alone System Load Sharing and Li-Ion / Li-Polymer Battery Charge Management Controller

### Features

- Integrated System Load Sharing and Battery Charge Management
  - Simultaneously Power the System and Charge the Li-Ion Battery
  - Voltage Proportional Current Control (VPCC) ensures system load has priority over Li-Ion battery charge current
  - Low-Loss Power-Path Management with Ideal Diode Operation
- Complete Linear Charge Management Controller
  - Integrated Pass Transistors
  - Integrated Current Sense
  - Integrated Reverse Discharge Protection
  - Selectable Input Power Sources: USB Port or AC-DC Wall Adapter
- Preset High Accuracy Charge Voltage Options:
  - 4.10V, 4.20V, 4.35V or 4.40V
  - $\pm 0.5\%$  Regulation Tolerance
- Constant Current / Constant Voltage (CC/CV) Operation with Thermal Regulation
- Maximum 1.8A Total Input Current Control
- Resistor Programmable Fast Charge Current Control: 50 mA to 1A
- Resistor Programmable Termination Set Point
- Selectable USB Input Current Control
  - Absolute Maximum: 100 mA (L) / 500 mA (H)
- Automatic Recharge
- Automatic End-of-Charge Control
- Safety Timer With Timer Enable/Disable Control
- 0.1C Preconditioning for Deeply Depleted Cells
- Battery Cell Temperature Monitor
- Undervoltage Lockout (UVLO)
- Low Battery Status Indicator (LBO)
- Power-Good Status Indicator (PG)
- Charge Status and Fault Condition Indicators
- Numerous Selectable Options Available for a Variety of Applications:
  - Refer to **Section 1.0 "Electrical Characteristics"** for Selectable Options
  - Refer to the **"Product Identification System"** for Standard Options
- Temperature Range: -40°C to +85°C
- Packaging: 20-Lead QFN (4 mm x 4 mm)

### Applications

- GPSs / Navigators
- PDAs and Smart Phones
- Portable Media Players and MP3 Players
- Digital Cameras
- Bluetooth Headsets
- Portable Medical Devices
- Charge Cradles / Docking Stations
- Toys

### Description

The MCP73871 device is a fully integrated linear solution for system load sharing and Li-Ion / Li-Polymer battery charge management with ac-dc wall adapter and USB port power sources selection. It's also capable of autonomous power source selection between input or battery. Along with its small physical size, the low number of required external components makes the device ideally suited for portable applications.

The MCP73871 device automatically obtains power for the system load from a single-cell Li-Ion battery or an input power source (ac-dc wall adapter or USB port). The MCP73871 device specifically adheres to the current drawn limits governed by the USB specification. With an ac-dc wall adapter providing power to the system, an external resistor sets the magnitude of 1A maximum charge current while supports up to 1.8A total current for system load and battery charge current.

The MCP73871 device employs a constant current / constant voltage (CC/CV) charge algorithm with selectable charge termination point. The constant voltage regulation is fixed with four available options: 4.10V, 4.20V, 4.35V, or 4.40V to accommodate new, emerging battery charging requirements. The MCP73871 device also limits the charge current based on die temperature during high power or high ambient conditions. This thermal regulation optimizes the charge cycle time while maintaining device reliability.

The MCP73871 device includes a low battery indicator, a power-good indicator and two charge status indicators that allows for outputs with LEDs or communication with host microcontrollers. The MCP73871 device is fully specified over the ambient temperature range of -40°C to +85°C.



---

# HD44780U (LCD-II)

(Dot Matrix Liquid Crystal Display Controller/Driver)

## HITACHI

ADE-207-272(Z)  
'99.9  
Rev. 0.0

---

### Description

The HD44780U dot-matrix liquid crystal display controller and driver LSI displays alphanumerics, Japanese kana characters, and symbols. It can be configured to drive a dot-matrix liquid crystal display under the control of a 4- or 8-bit microprocessor. Since all the functions such as display RAM, character generator, and liquid crystal driver, required for driving a dot-matrix liquid crystal display are internally provided on one chip, a minimal system can be interfaced with this controller/driver.

A single HD44780U can display up to one 8-character line or two 8-character lines.

The HD44780U has pin function compatibility with the HD44780S which allows the user to easily replace an LCD-II with an HD44780U. The HD44780U character generator ROM is extended to generate 208  $5 \times 8$  dot character fonts and 32  $5 \times 10$  dot character fonts for a total of 240 different character fonts.

The low power supply (2.7V to 5.5V) of the HD44780U is suitable for any portable battery-driven product requiring low power dissipation.

### Features

- $5 \times 8$  and  $5 \times 10$  dot matrix possible
- Low power operation support:
  - 2.7 to 5.5V
- Wide range of liquid crystal display driver power
  - 3.0 to 11V
- Liquid crystal drive waveform
  - A (One line frequency AC waveform)
- Correspond to high speed MPU bus interface
  - 2 MHz (when  $V_{CC} = 5V$ )
- 4-bit or 8-bit MPU interface enabled
- $80 \times 8$ -bit display RAM (80 characters max.)
- 9,920-bit character generator ROM for a total of 240 character fonts
  - 208 character fonts ( $5 \times 8$  dot)
  - 32 character fonts ( $5 \times 10$  dot)

**Model P232/P233**  
**24mm Rotary Potentiometer**  
**Sealed/ Dust Proof**  
**Long Life Element**  
**2 Million Cycle Life**  
**Metal Shaft/ Bushing**  
**RoHS Compliant**



#### MODEL STYLE

Side Adjust, Solder Lugs, Single-Gang	P232
Side Adjust, Solder Lugs, Dual-Gang	P233

#### ELECTRICAL<sup>1</sup>

Resistance Range, Ohms	1K-1M (for "B" taper) 5K-1M (for other tapers)
Standard Resistance Tolerance	± 10%
Residual Resistance	3 ohms max.
Input Voltage, Maximum	200 Vdc max.
Power rating, Watts	0.5W- B taper, 0.3W- others
Dielectric Strength	500Vac, 1 minute
Insulation Resistance, Minimum	100M ohms at 1,000Vdc/ 1 minute
Peak Noise (Contact Resistance Variation) @ 6 rpm	±3% max.
Linearity	±3% max.
Actual Electrical Travel, Nominal	280°
Gang Error	±3dB (-40dB to 0dB)

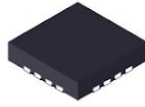
#### MECHANICAL

Total Mechanical Travel	300°± 5°
Static Stop Strength, Minimum	120 oz-in
Rotational Torque, Maximum, Single Gang (P232)	1.5 oz-in
Rotational Torque, Maximum, Dual Gang (P233)	3.0 oz-in

#### ENVIRONMENTAL

Operating Temperature Range	-10°C to +85°C
Rotational Life	2,000,000 cycles

<sup>1</sup> Specifications subject to change without notice.



## SYNCHRONOUS BOOST CONVERTER WITH 2A SWITCH

### FEATURES

- Synchronous (96% Efficient) Boost Converter With 500-mA Output Current From 1.8-V Input
- Available in a 16-Pin QFN 4 x 4 Package
- Device Quiescent Current: 20- $\mu$ A (Typ)
- Input Voltage Range: 1.8-V to 5.5-V
- Adjustable Output Voltage Up to 5.5-V Fixed Output Voltage Options
- Power Save Mode for Improved Efficiency at Low Output Power
- Low Battery Comparator
- Low EMI-Converter (Integrated Antiringing Switch)
- Load Disconnect During Shutdown
- Over-Temperature Protection

### APPLICATIONS

- All Single Cell Li or Dual Cell Battery, or USB Powered Operated Products as MP-3 Player, PDAs, and Other Portable Equipment

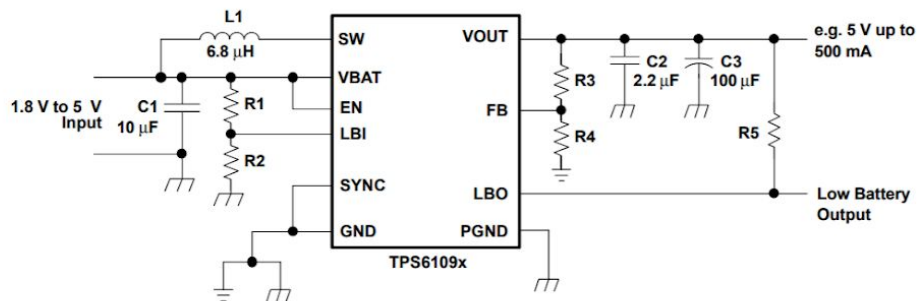
### DESCRIPTION

The TPS6109x devices provide a power supply solution for products powered by either a one-cell Li-Ion or Li-polymer, or a two-cell alkaline, NiCd or NiMH battery and required supply currents up to or higher than 1 A. The converter generates a stable output voltage that is either adjusted by an external resistor divider or fixed internally on the chip. It provides high efficient power conversion and is capable of delivering output currents up to 0.5 A at 5 V at a supply voltage down to 1.8 V. The implemented boost converter is based on a fixed frequency, pulse-width-modulation (PWM) controller using a synchronous rectifier to obtain maximum efficiency. Boost switch and rectifier switch are connected internally to provide the lowest leakage inductance and best EMI behavior possible. The maximum peak current in the boost switch is limited to a value of 2500 mA.

The converter can be disabled to minimize battery drain. During shutdown, the load is completely disconnected from the battery. A low-EMI mode is implemented to reduce ringing and, in effect, lower radiated electromagnetic energy when the converter enters the discontinuous conduction mode.

The output voltage can be programmed by an external resistor divider or is fixed internally on the chip.

The device is packaged in a 16-pin QFN 4 x 4 mm (16 RSA) package.



Please be aware that an important notice concerning availability, standard warranty, and use in critical applications of Texas Instruments semiconductor products and disclaimers thereto appears at the end of this data sheet.

PRODUCTION DATA information is current as of publication date. Products conform to specifications per the terms of the Texas Instruments standard warranty. Production processing does not necessarily include testing of all parameters.

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**EC11** 11mm Size Metal Shaft Type 

Compact and highly reliable type available in many varieties.



**Typical Specifications**

Items	Specifications
Output signal	Two phase of A, B Three phase of A, B and C (EC11EH) Self-return switch (EC111 / EC11E0B)
Rating	10mA 5V DC
Operating life	15,000 cycles 30,000 cycles (EC11EH) 100,000 cycles (EC11K / EC11J)
Operating temperature range	-40°C to +85°C

- Detector
- Slide
- Push
- Rotary
- Encoders**
- Power
- Dual In-Line Package Type
- TACT switch<sup>3)</sup>

**Product Line**

Structure	Shaft configuration	Length of the shaft (L) (mm)	Torque (mN·m)	Number of detent	Number of pulse	Push-on switch	Travel of push-on switch (mm)	Operating life (cycles)	Minimum order unit (pcs.)		Product No.	Drawing No.		
									Japan	Export				
Horizontal			12 ± 7	30	15	Without	—	15,000	700	1,400	EC11B15202AA	1		
						With	0.5				EC11B15242AE	2		
							1.5				EC11B15242AF	3		
Vertical	Flat	20	10 ± 7	18	9	Without	—	15,000	1,200	2,400	EC11E09204A4	4		
				30	15						EC11E15204A3			
				7 ± 2	Without						EC11E1530401			
			10 ± 7	36	18	Without	EC11E1820402							
				7 ± 2	Without		EC11E1830401							
				18	9		EC11E09244BS							
			10 ± 7	30	15	With	0.5				5		EC11E15244G1	
				7 ± 2	Without		EC11E153440D							
				36	18		EC11E18244AU							
				7 ± 2	Without		EC11E183440C							
				18	9		EC11E09244AQ							
				30	15		EC11E15244B2							
				7 ± 2	Without		EC11E153440E							
				36	18		EC11E18244A5							
				7 ± 2	Without		EC11E1834403							
Less shaft wobble	Serrated	25	12 ± 7	30	15	Without	—	100,000	1,000	2,000	EC11G1560414	6		
			8.5 ± 5	Without		1.5	EC11G1574402				7			
				30		EC11G1564411	8							
Vertical	Flat	20	12 ± 5	18	9	Without	—	100,000	1,000	2,000	EC11K0920401	9		
				30	15						EC11K1520401			
				18	9						EC11K0924401			
				30	15	With	0.5				EC11K1524402	10		
											18		9	EC11K0925401
											30		15	EC11K1525401

- Metal Shaft**
- Insulated Shaft
- Hollow Shaft
- Ring Type

**Note**

Other varieties are also available. Please inquire.

Refer to P.167 for product specifications.  
 Refer to P.167 for attached parts.  
 Refer to P.168 for product varieties.  
 Refer to P.193 for soldering conditions.



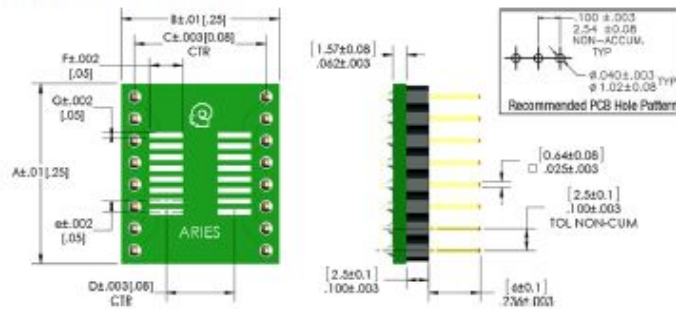
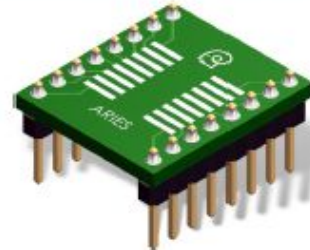
# Aries Low Cost, Quick Turn Small Outline Prototyping Adapters

## FEATURES

- Mates SOT23, SOIC, MSOP, or TSSOP packages to standard breadboard and breakout boards for rapid and easy prototyping
- Panelized adapters available upon request

## GENERAL SPECIFICATIONS

- BOARD MATERIAL: 0.062 [1.58] thick FR-4, UL 94V-0 with 1/2-oz. Cu traces
- PIN INSULATOR: Polyester, UL 94V-0
- PINS: Brass 360 1/2-hard per UNS C36000 ASTM-B16-00
- PIN PLATING: Au Flash
- OPERATING TEMPERATURE: -55°C to +125°C



**ORDERING INFORMATION**  
Indicate desired P/N

Pads	Package	Dim. "A"	Dim. "B"	Dim. "C"	Dim. "D"	Dim. "e"	Dim. "F"	Dim. "G"	P/N
6	SOT23	0.4 [10.16]	0.5 [12.7]	0.3 [7.62]	0.091 [2.30]	0.037 [0.95]	0.035 [0.90]	0.024 [0.60]	LCQT-SOT23
8	SOIC8	0.5 [12.7]	0.5 [12.7]	0.3 [7.62]	0.205 [5.20]	0.050 [1.27]	0.087 [2.20]	0.024 [0.60]	LCQT-SOIC8
10	MSOP10	0.6 [15.24]	0.5 [12.7]	0.3 [7.62]	0.161 [4.10]	0.020 [0.50]	0.039 [1.00]	0.012 [0.30]	LCQT-MSOP10
14	TSSOP14	0.7 [17.78]	0.5 [12.70]	0.3 [7.62]	0.230 [5.48]	0.026 [0.65]	0.039 [1.00]	0.012 [0.30]	LCQT-TSSOP14
14	SOIC14	0.7 [17.78]	0.7 [17.78]	0.6 [15.24]	0.205 [5.20]	0.050 [1.27]	0.087 [2.20]	0.024 [0.60]	LCQT-SOIC14
14	SOIC14W	0.7 [17.78]	0.7 [17.78]	0.6 [15.24]	0.362 [9.20]	0.050 [1.27]	0.087 [2.20]	0.024 [0.60]	LCQT-SOIC14W
16	TSSOP16	0.8 [20.32]	0.7 [17.78]	0.6 [15.24]	0.314 [7.98]	0.026 [0.65]	0.070 [1.78]	0.017 [0.42]	LCQT-TSSOP16
16	SOIC16	0.9 [22.8]	0.8 [20.3]	0.6 [15.24]	0.314 [7.98]	0.050 [1.27]	0.152 [3.86]	0.026 [0.66]	LCQT-SOIC16
16	SOIC16W	0.9 [22.8]	0.8 [20.3]	0.6 [15.24]	0.314 [7.98]	0.050 [1.27]	0.152 [3.86]	0.026 [0.66]	LCQT-SOIC16W
20	TSSOP20	1.0 [25.4]	0.7 [17.78]	0.6 [15.24]	0.222 [5.64]	0.026 [0.65]	0.012 [0.30]	0.039 [0.99]	LCQT-TSSOP20
20	SSOP20	1.0 [25.4]	0.7 [17.78]	0.6 [15.24]	0.285 [7.25]	0.026 [0.65]	0.059 [1.50]	0.016 [0.40]	LCQT-SSOP20
20	SOIC20W	1.0 [25.4]	0.7 [17.78]	0.6 [15.24]	0.396 [10.06]	0.050 [1.27]	0.080 [2.03]	0.026 [0.66]	LCQT-SOIC20W
28	TSSOP28	1.4 [35.56]	0.7 [17.78]	0.6 [15.24]	0.228 [5.80]	0.026 [0.65]	0.047 [1.20]	0.014 [0.35]	LCQT-TSSOP28
28	SOIC28	1.4 [35.56]	0.7 [17.78]	0.6 [15.24]	0.380 [9.65]	0.050 [1.27]	0.079 [2.00]	0.031 [0.80]	LCQT-SOIC28
32	SOIC32	1.6 [40.64]	0.7 [17.78]	0.6 [15.24]	0.362 [9.20]	0.050 [1.27]	0.087 [2.20]	0.024 [0.60]	LCQT-SOIC32
32	SOIC32W	1.6 [40.64]	0.7 [17.78]	0.6 [15.24]	0.425 [10.80]	0.050 [1.27]	0.087 [2.20]	0.024 [0.60]	LCQT-SOIC32W
32	TSOP1	1.6 [40.64]	0.7 [17.78]	0.6 [15.24]	0.598 [15.20]	0.020 [0.50]	0.063 [1.60]	0.012 [0.30]	LCQT-TSOP32-1
32	TSOP1	2.0 [50.8]	0.7 [17.78]	0.6 [15.24]	0.776 [19.70]	0.020 [0.50]	0.047 [1.20]	0.014 [0.36]	LCQT-TSOP32
40	TSOP1	2.0 [50.8]	0.7 [17.78]	0.6 [15.24]	0.598 [15.20]	0.020 [0.50]	0.063 [1.60]	0.012 [0.30]	LCQT-TSOP40
40	TSOP1	2.0 [50.8]	0.7 [17.78]	0.6 [15.24]	0.756 [19.20]	0.020 [0.50]	0.063 [1.60]	0.012 [0.30]	LCQT-TSOP40-1

• ALL DIMENSIONS: INCHES [MILLIMETERS] • ALL TOLERANCES: ±0.005 [0.13] UNLESS OTHERWISE SPECIFIED • CONSULT FACTORY FOR OTHER SIZES AND CONFIGURATIONS

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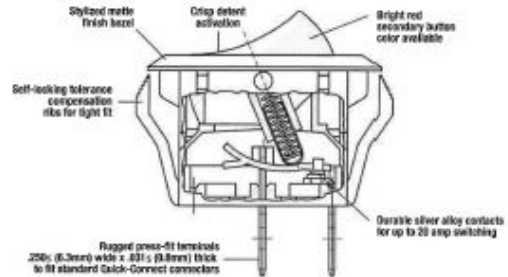


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19000  
Rev. 1.3  
1 of 1

# Single-Pole Rocker Switch CR Series



## Features

- Rugged design to switch up to 20 amps
- 2-color molded button available
- Fits 3 panel cut-out widths
- Splash-proof option available
- Mechanical life: min. 100,000 operations

Electrical Ratings				
Switch Series	EN61058 Rating	UL1054 Rating	Electrical Life at Rated Load	
			According to VDE (Min. Operations)	According to UL (Min. Operations)
CR	16(4)A, 250V~, T125/55	20A 125 VAC; 16A 250VAC; 3/4HP 250VAC	10,000	6,000

Electrical Specifications		Material Specifications	
Ratings:	20A, 125VAC; 16A 250VAC; 3/4HP cULus 16(4)A, 250V~ T125/55 (VDE)	Actuator (non-lighted): (lighted):	Nylon 66 94V-2 Polycarbonate
Dielectric Strength:	1000VAC for 1 minute	Base:	Nylon 66 94V-2
Insulation Resistance:	100M ohms min at 500VDC	Spring:	Steel Wire
Initial Contact Resistance:	0.020 ohms max	Contacts:	Silver Alloy
Temperature Range:	-20°C to + 85°C	Movable Arm:	Silver-Plated Copper Alloy
		Terminals:	Tin-Plated Copper Alloy

RoHS Compliant  
UL File No: E23301



Specifications subject to change without notice.

# Single-Pole Rocker Switch CR Series

