calmer

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LMIC Calmer Device

Managing Pain in Infants in the Neonatal Intensive Care Unit

Cornell Engineering World Health 2022 Design Competition Submission

Engineering World Health

CALMER

BC WOMEN'S HOSPITAL+ HEALTH CENTRE

An agency of the Provincial Health Services Authority

BC Children's Hospital Research Institute

Cornell Engineering

Cornell Engineering Undergraduate Project Teams

Problem Definition

Worldwide, over 15 million infants are born preterm. A current challenge that the neonatal healthcare community faces today is pain management for preterm infants in Neonatal Intensive Care Units (NICU). It is well established that early exposure to pain in preterm infants is associated with negative effects on neurodevelopmental outcomes.[1,2,3,4] This is especially important in NICUs where preterm infants can undergo multiple painful procedures on a day-to-day basis. However, in lower- and middle-income countries (LMIC), there is a distinct shortage of pain medication available.[5]

There are alternative pain management protocols currently used for preterm infants that involve the use of oral sweeteners like sucrose, but repeated ingestion of sucrose, particularly in infants born very preterm, has a potential negative impact on the developing brain.[6] Another method of pain management is known as the Kangaroo Mother Care (KMC) technique, which involves holding an infant in an upright position on the infant caretaker's bare chest for long periods of time. Specifically, the rising and falling of the caretaker's chest, combined with listening to the caretaker's rhythmic heartbeat and feeling the caretaker's warm skin has been shown to be effective in reducing pain among preterm infants.[7] However, not all parents are available 24 hours every day to provide the KMC technique. Furthermore, countries in sub-Saharan Africa may not employ KMC out of fear of disease transmission from the mother to the infant and of over-exhausting the mother after birth while she is still in pain.[8]

To address this challenge, researchers at the British Columbia Women's Hospital under the leadership of Dr. Liisa Holsti developed the Calmer device, a complex medical instrument that simulates aspects of Kangaroo Mother Care (KMC) to manage premature infants' pain in the NICU.[6] Clinical trials have found that the Calmer device provides the same level of pain management for premature infants as another human touch strategy called facilitated tucking by replicating a heartbeat sound, using a skin-like surface, and mimicking a breathing motion. Patents in Europe and the US have been obtained for this device.[9,10]

Given the disproportionately high rates of preterm births in LMICs, the implementation of Calmer in these areas could make a large impact. Unfortunately, the cost of the current device serves as a barrier to doing so realistically and effectively. Furthermore, the current Calmer device isn't designed for dust protection and easy transport. Thus, the Integrative Design and Electrical sub-teams of our project team worked with Dr. Holsti to redesign the Calmer device for use in these LMICs. Specifically, this LMIC Calmer device needs to simulate the heartbeat and breathing motions of the caretaker (heat will be provided by existing incubators) and the heartbeat and breathing motion must be able to be adjusted individually to match the baby's mother or primary caretaker's heart rate and respiratory rate. We have been working with Dr. Holsti's contacts in Malawi to inform our prototyping process.

Impact in Developing World

The current patented Calmer device costs ~$50,000. While larger hospital systems in developed countries can afford this device, LMICs like Malawi cannot. Thus, the use of an effective and low-cost pain management device can be utilized not only in LMICs like Malawi but in any underprivileged community with access to battery power. Existing technologies have been stated in the problem statement. They either are unsuitable for long term use, use in NICUs, or use in LMICs, or they are much too costly.

Our latest iteration prototype costs $298.69. The detailed bill of materials is listed below in Appendix A. With manufacturing, we can further reduce this cost. Furthermore, we specifically designed our prototype to be able to be easily transported, easily stored, and able to be protected against dust and other factors more prevalent in LMICs. We also sought to modularize our design so if the device is damaged, its parts can be used in other devices or other parts can be easily assembled into this device.

In making this device more affordable and accessible, our team seeks to help break down the technological barriers of healthcare that separate developing and developed countries. With this design, we think that we can greatly improve preterm infant pain management in underprivileged communities to mitigate the negative effects of repeated pain exposure on preterm infant neurodevelopmental outcomes.

Required Performance Specifications

The main performance specifications were provided by Dr. Holsti and were adapted from the original Calmer device. They are listed below in Table 1:

Table 1. Design Requirements

	Design Requirement	Technical Requirement
1	Must fit in a standard incubator of dimensions	Must be smaller than incubator dimensions of 74 cm by 40 cm by 20 cm – must fit small plastic and wire cots.
2	Must be portable	Weigh less than 15 kg
3	Must be waterproof	Keep fluids away from all components
4	Must be able to be easily disinfected since the NICU must be a sanitary environment	Must be wipe-down capable
5	Must provide a rigid surface when not in use for CPR purposes	Capable of withstanding 40 N of force when not in operation

6	Must be able to lift and lower lightweight infants with breathing motion	Must be able to support and lift a minimum of 500 g and a maximum of 4 kg
7	Breathing motion must lift & lower the infant high enough to provide therapeutic effects	Platform must provide an up/down motion range of 10 mm
8	Breathing motion rate must be customized to the RR of the caretaker	Breathing motion rate must be manually adjustable
9	Breathing motion must be vertical only	Breathing motion platform must be constrained to rise and fall vertically only
10	Heart rate sound must be customized to the HR of the caretaker	Rate of heartbeat sound must be manually adjustable and must be no louder than 55 decibels
11	Must be able to operate for long periods of time	Device must be operational for 1000 hours
12	Must be able to protect against dust	Device must be sealed to prevent dust build up
13	Infant must be able to rest comfortably on the device	No pinch points or sharp edges should be exposed and the platform should have sufficient cushioning

Implementation of Prototype

Mechanical Implementation: Our device simulates a breathing motion by lifting an acrylic platform up to 0.5” with a camshaft. Our design restricts the rotational motion of the camshaft to the vertical axis by using linear bearings mounted to the base of the device. Metal rods that are affixed to the mobile platform assure that the platform ascends and descends smoothly into these bearings. This design also incorporates additional features meant to increase the stability of the prototype and breathing motion. These include multiple PLA supports in the middle and the corners of the device to support the platforms, PLA camshaft supports with ball bearings to prevent the camshaft from bending, and a fixed acrylic platform between the moving platform and supports. All of these features are contained in the acrylic outer frame of the device.

The camshaft in our device is powered by a motor utilizing an external power source. The device also contains a speaker that plays the sound of a heartbeat, which can be adjusted for speed and volume by using dials. This component is also electronically powered.

The device also includes a rain poncho and yoga towel placed around the top of the device. The poncho, made out of a flexible, waterproof material, effectively seals the mechanical/electrical components from any outside conditions while still preserving the motion of the device. The towel, which is placed on top of the pool liner, creates a comfortable, somewhat skin-like texture for the baby to rest on. Both of these elements are securely attached to the device using a resistance band. In addition, we have added a piece of foam-like material to create a more padded, comfortable surface for the baby. We designed the device to fit inside a wired cot, with dimensions 75 x 40 cm. The overall device is approximately 61 cm x 30.5 cm x 12.7 cm.

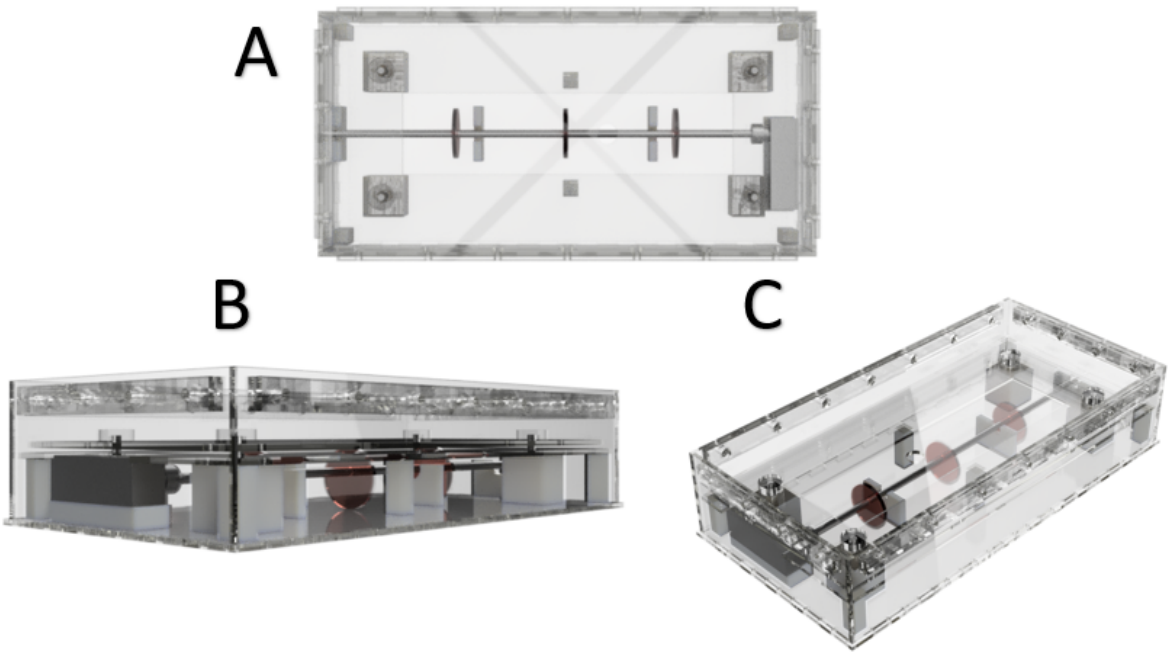

Figure 1. CAD renders of the top view (A), corner view (B), and angled view (C) of the LMIC Calmer device

Figure 2. Images of the latest iteration of the LMIC Calmer device

Electronic Implementation: As stated above, the electronics of this device control the motor, which drives the camshaft, as well as the speaker, which plays the heartbeat sound. The speed of both these components are controlled through turn dials (potentiometers).

More specifically, everything is controlled by an Arduino Nano running code that takes input from the dials/potentiometers. It then takes that potentiometer data and generates a PWM (pulse width modulated) signal to the motor transistor circuit that controls the motors. It also generates a PCM (pulse code modulated) signal to the sound amplification and filtering circuit that controls the speaker. The speaker can be any desktop speaker that has a USB power plug and a 3.5mm headphone jack. All of this is powered by an external power source plugged into the wall outlet. Below is a simplified block diagram of this circuit as well as a more detailed schematic. The code that runs this circuit will also be provided.

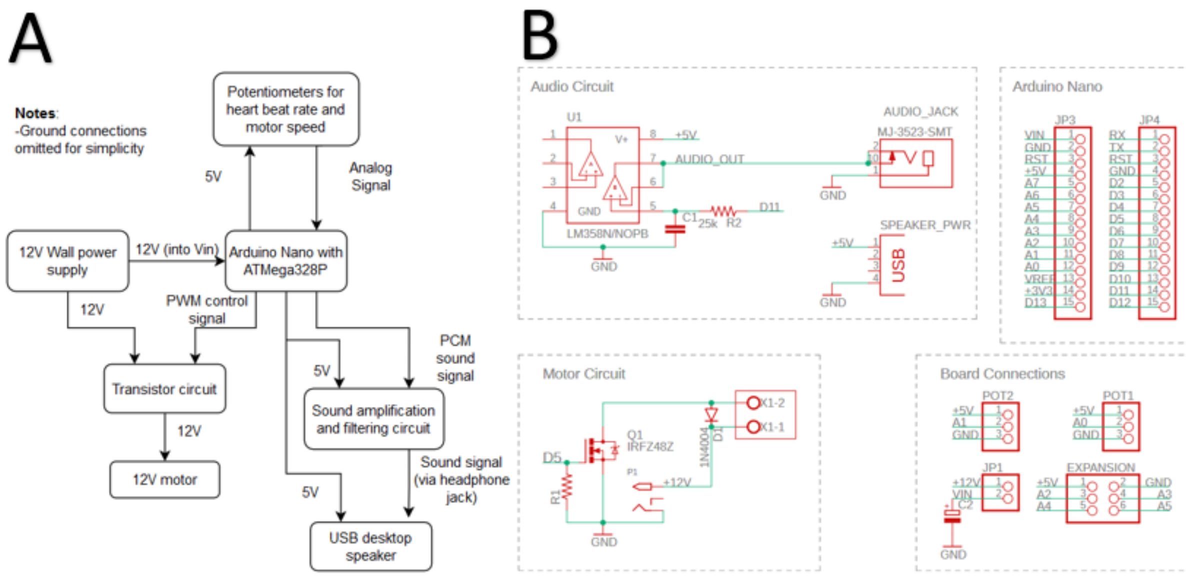

Figure 3: Electronics block diagram (A) and detailed schematics (B)

The electronics can be built on a breadboard based on the detailed schematic above. Additionally, we have designed a PCB (Printed Circuit Board), which we suggest using instead of a breadboard because it is significantly easier to assemble, more compact, and more durable.

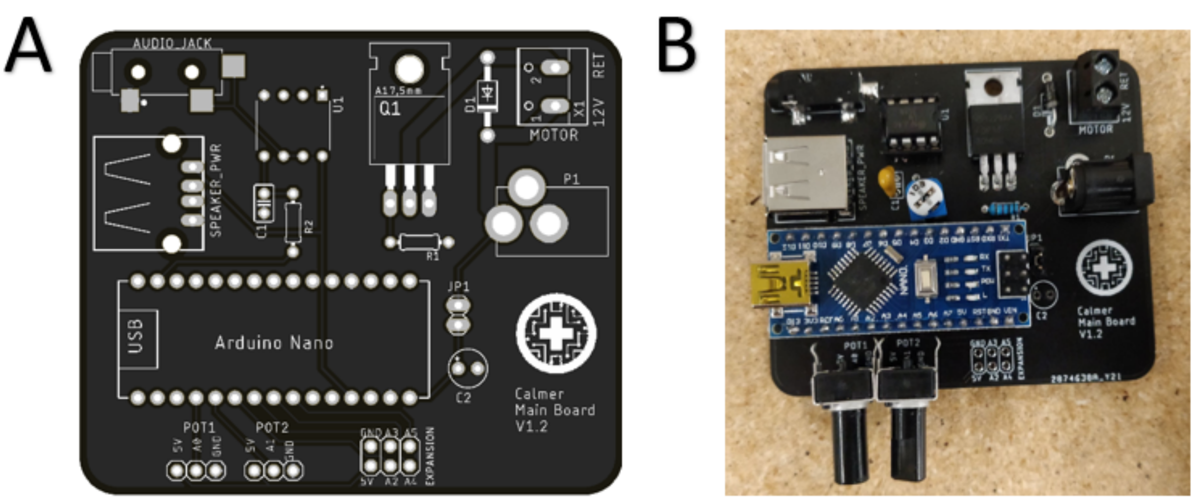

Figure 7: PCB render (A), Assembled PCB (B)

Proof of Performance

While further testing is still yet to be completed to verify the quantitative design requirements, all of the qualitative design requirements have been met. For example, the LMIC Calmer device does prevent fluids from accessing all interior components and it is wipe-down capable. It can withstand 40 N (~4 kg) of force when not in operation and can provide an up/down motion range of more than 10 mm (specifically 0.5 inches). The breathing motion rate as well as the rate of the heartbeat sound are manually adjustable, and the breathing motion is constrained to vertical motion only. The device is sealed to prevent dust from reaching the interior components and there are no pinch points or sharp edges exposed to the infant.

Further durability testing needs to be conducted to satisfy the other quantitative design requirements. Testing in a clinical setting must also be performed to verify that our design does not perform significantly different than the original Calmer device, but it is not feasible for our team to do so ourselves. Thus, a large amount of testing can only be done by our collaborator Dr. Holsti, but there shouldn't be a large difference in performance as the functionality is essentially the same between the two devices just at a much lower cost.

Business Plan

Because the objective of our team is to create the most meaningful impact in underprivileged communities as we can, we do not plan to implement the Calmer device ourselves. This is because there are much more dedicated and experienced organizations and people like Dr. Holsti who can license, manufacture, and distribute this device much faster with a much higher quality. That way, the people in these underprivileged communities can gain access to better health technology in a much shorter amount of time and our team can make a much larger impact. Thus, Dr. Holsti would be in charge of the business plan, although some things can be mentioned based on previous discussions.

Because this is a collaboration with Dr. Holsti and this is a complete redesign of her original Calmer device, it was mutually agreed that all IP will be owned by the Provincial Services Health Authority in British Columbia, Canada (which also holds the IP for the original Calmer device). Because this is a device that provides therapeutic effects and can pose moderate risk to users if poorly designed, the LMIC Calmer device would likely be classified as a Class II medical device by the FDA. Thus, a 510(k) application would need to be pursued in the US. However, if initial testing is successful, this device can likely be utilized immediately in LMIC countries like Malawi that have much more relaxed regulations.

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Appendix A: Bill of Materials

Item	Quantity	PPU	Total
12 Volt Reversible 35 RPM DC Worm Gear Motor	1	$26.99	$26.99
8mm X 300mm Linear Motion Rod Shaft Guide Diameter 8mm (2 Count)	1	$10.99	$10.99
Linear Ball Bearings, 8mm Bore Dia, 15mm OD, 24mm Length (12 Count)	1	$10.95	$10.95
Bearings 3/8 Inner Dia x 7/8 Outer Dia x 9/32 Width (8 Count)	1	$9.99	$9.99
Ultra-Low-Friction Tape Made with Teflon® PTFE, 3ft Acrylic Adhesive	1	$7.44	$7.44
Heavy Duty Low-Friction Tape Made with Teflon® PTFE, 3ft Acrylic Adhesive	1	$11.03	$11.03
8mm to 10mm Shaft Coupling 30mm Length 25mm Diameter	1	$8.99	$8.99
.222"x18"x24" Clear Acrylic Sheet	2	$31.27	$62.54
JB Weld .85 oz Plastic Bonder	2	$6.88	$13.76
Clearweld Clear Epoxy Adhesive	1	$5.98	$5.98
4mm-0.7 x 16mm Phillips-Drive Machine Screws (12-Count)	1	$1.98	$1.98
Extreme Double-Sided Mounting Tape 1-in x 33.33-ft	1	$19.98	$19.98
3/8-in dia x 3-ft L Coarse Steel Threaded Rod	1	$3.89	$3.89
3/8-in x 16 Zinc-plated Steel Keps Nut (2-Count)	3	$0.76	$2.28
PLA Filament for 3D printers	< 1 spool	~$20	$20.00
Yoga Mat	1	$19.94	$19.94
Poncho	1	$6.69	$6.69
Nano V3.0, 3pcs Nano Board CH340 / ATmega328P with USB Cable	1	$17.86	$17.86
Custom Printed Circuit Board (PCB) Order	1	$3.20	$3.20
Power Supply, Transformers,LED Adapter, 12V, 5A Max, 60 Watt Max	1	$12.99	$12.99
USB Powered Stereo Speaker System	1	$9.99	$9.99
Screw Terminal - 2POS 5MM	2	$1.05	$2.10
USB Jack	1	$0.50	$0.50
Headphone Jack - MJ-3523	1	$0.94	$0.94
CONN HDR 40POS 0.1 GOLD PCB	2	$1.09	$2.18
2.1 x 5.5MM Power Jack	1	$0.99	$0.99
N Channel MOSFET - FQP30N06L	1	$1.62	$1.62
Diode - 1N4001	1	$0.31	$0.31
Potentiometer - 20k Ohm Linear	3	$0.83	$2.49
10k Ohm Resistor	1	$0.10	$0.10

		Total Cost	$298.69