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Vaccine Refrigerator Regulator with Data Logger & Back-up Power Supply

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Abstract

Introduction: Many vaccines require a storage temperature between 2-8 °C throughout thesupply cold chain. Multiple studies conducted at healthcare facilities worldwide document an endemicfailure to properly store vaccines, risking the efficacy of local vaccination programs.This "weak link" at the end of the cold chainis largely due to both the widespread use of inadequate domestic refrigerators for vaccine storage, and electrical power interruptions. The required specialized refrigeration equipment and backup power systemareboth prohibitively expensive for smaller facilities. Prompted by this finding, the authors sought an affordable solution for small-scale vaccine storage applications.

Methods: The solution presented is an aftermarketappliance designed toaccompany a wide range of domestic refrigerators.After undergoing an initial calibration step, the device effectively overridesthe refrigerator's native thermostat(s) and assumes thermoregulatory control. All interfaces between the device and the refrigerator are strictly external, allowing for installation by a layperson. Wireless temperature sensor measurements are frequently logged to a removable USB thumb drive to provide vaccine temperature traceability. The device is further equipped to charge an external battery while grid power is available, and upon grid failure automatically source refrigeration power froman attached external inverter.

Results: The regulator device successfullymaintained a 2-8 °C environment for all properly stored vaccine vials. Furthermore, it successfully adapted to and compensated for the individual operational characteristics of various refrigerators, and flagged those unsuitable for vaccine storage. Back-up power outage resiliency is recorded at16-25 hours for 18-28ft^3sized household refrigerators using a 160Ah battery.The cost of manufacturing the device is estimated at $250 per unit.

Discussion: The Baylor/Rice regulator device provides an affordable refrigeration control and temperature monitoring system suitable for converting household refrigerators into effective vaccine refrigerators. The device will also be useful in areas subject to electrical grid failure.

Selection and peer-review under responsibility of the 7th Vaccine Conference Organizing Committee.

*Keywords:*Refrigeration; Cold Chain; Vaccine; Thermoregulation

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1. Introduction

Many vaccines require a storage temperature between 2-8°C throughout the supply cold chain. Multiple studies conducted at healthcare facilities worldwide document an endemic failure to properly store vaccines, risking the efficacy of local vaccination programs. Between 25 to 76% of the observed sites recorded significant departures from the required storage environment, while often still fully compliant with local guidelines.[1,2,3]

The “weak link” at the end of the cold chain is primarily due to the widespread use of older, domestic refrigerators. When used in vaccine storage, they require frequent manual recalibrations of the thermostat control dial in order to combat large drifts in the temperature set point.

Discontinuities in the availability of local electrical grid power further complicate vaccine storage. In many regions rolling blackouts and brownouts are frequent and expected. When these events occur, immediate protective measures must be taken to safeguard vaccine inventories.[4,5]

In a majority of the cases, domestic refrigerators are capable of providing a proper vaccine storage environment. The issue lies with thenative thermostats within these units—they are not designed to maintain strict degrees Celsius temperature windows.

Prompted by these findings, the authors sought to develop a refrigerator regulator that could be utilized by the Centers for Disease Control (CDC) Vaccines for Children (VFC) program. Our objective is to produce an after-market refrigerator control unit that can:

- Maintain vaccine solution temperatures between 2-8°C
- Provide back-up AC power for greater than 30 hours
- Log temperatures from a thermally buffered sensor with hot/cold alerts
- Work with a wide variety of domestic refrigerators and chest freezers
- Require no tools or technical skills to install
- Have a shipping weight under 10 Kg
- Identify inadequate refrigerators
- Cost under $500

2. Materials and Methods

Our prototype consists of three components: a temperature sensing unit installed in the refrigerator cabinet, a display module magnetically mounted on the side of the refrigerator, and the central regulator located at the base of the refrigerator. A novel adaptive software program runs on the central regulator’s microcontroller.

The **Temperature Sensing Unit** consists of two National Institute of Standards and Technology (NIST) traceable thermistor probes attached to a wireless base. Wireless transmission of data removes the need for any penetrating wires, protecting the insulation gasket around the refrigerator door and promoting thermal stability. Two AA batteries power the base. Battery life is maximized using short transmission and long sleep times. Using the newBluetooth low energy standard, theestimated operation between battery replacements is 12-18 months.

The interchangeable thermistor probesused are manufactured with a fixed accuracy of +/-0.1°C (rated from 0-70°C), eliminating the expense of annual recalibrationassociated with thermocouple based sensors. They are suspended in a 0.5ml solution of glycol, modeling the thermal capacity of the smallest vaccine dosage.

The refrigerator cabinet temperatures are stratified vertically with extremes found on the bottom and top shelves.Sensors are initially placed on the top and bottom shelves to capture these poles. Vaccines are only to be stored on a shelf either holding or in between the two sensors. In some instances, the results of the calibration stage will instruct the user to move a sensor up or down a shelf, reducing the area suitable for storage. This step keeps vaccines out of cabinet regions that experience uncontrollable temperature extremes, a problem common with many domestic refrigerators.

The **Display Module** is the native human interface for the device. This module is magnetically mounted to the refrigerator housing, and connected to the central regulator via a USB link.It has a small graphic LCD display, and navigational buttons. Its primary function is to display real time status information on the vial temperatures and refrigeration power source.

Other secondary functions include setting the logging frequency and the date/time. If a vial temperature wandersbeyond 2-8°C range, mains power becomes unavailable, or any other system error occurs, a warning flashes on the display. The display module also plays a critical role in guiding the user through the various steps of the calibration stage.

The **Central Regulator** is the principlecomponent of the regulator device. It is located on the floor behind or adjacent to the refrigerator, and contains the application microcontroller along with various hardware subsystems to control thermal regulation and backup refrigeration power.

On the back face are two standard C13 (IEC-60320) appliance power inputs: one for mains powerand the other for optional inverter power. Two battery input screw terminals provide a connection to an optional 12VDC sealed lead-acid battery. On the front face are three USB ports and a standard AC socket for powering the refrigerator.

The primary job of the central regulator is to override the refrigerator's native thermostat (or thermostats plural in the case of dual freezer/fridge models) and assume thermoregulatory control. To do this, the thermostat(s) must first be set in such a way so that they no longer are active in the 2-8°C range. The initial calibration stage determines what each thermostat should be set to. Afterwards, the central regulator assumes thermoregulation by means of a load switch controlling power to the refrigerator.

For applications utilizing battery and inverter connections, an automatic transfer switch sources refrigeration power from either the default grid input or alternatively the inverter input. When power is available, an integrated 3-stage charger manages the battery. It is capable of bulk charging at up to 10 amperes for rapid battery recovery, and applies a maintenance trickle charge when full. Any power inverter can be paired with the device, however it should have a fairly large peak surge power rating to successfully start a refrigerator compressor (2400+ peak watts). Analogous to the switching of power to the refrigerator, the inverter power switch remains in the on position and the central regulator contains a load switch to control power to the inverter.

The central microcontroller runsan **adaptive refrigerator regulator program** licensed by Baylor College of Medicine. The adaptive portion occurs primarily during the initial calibration stage.During this period, the thermostat algorithm adapts to and compensates for the individual operational characteristics of the refrigerator to ensure successful long-term operation. In particular, this program performs the following functions:

- Flags refrigerators that are unsuited for safe vaccine storage
- Calculates safe min/max compressor cycling frequency and run time
- Prevents early compressor burnout
- Determines override settings for native thermostat(s)
- Minimizes heating effects of defrost cycle interruptions
- Estimates native insulation capacity
- Optimizes battery power run time
- Maintains a 2-8 °C vaccine temperature

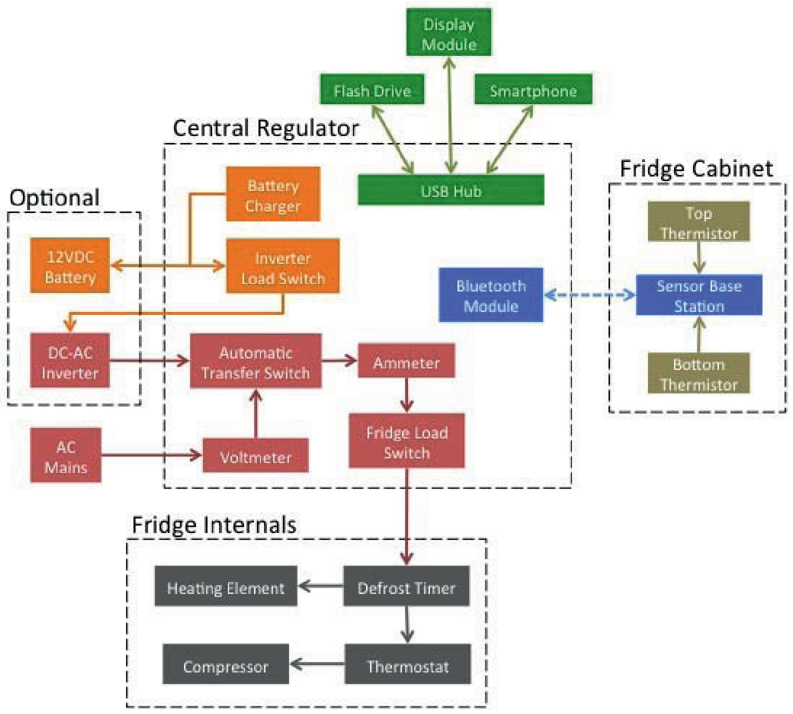

Figure 1. Hardware Subsystems Block Diagram

3. Results

The regulator was tested with one 220 VAC and twelve 120VAC kitchen refrigerators. The device successfully paired with ten refrigerators.During the calibration stage, the device flagged three refrigerators as unsuitable for vaccine storage. Two had lengthy defrost mechanisms which even with compensation still resulted in a vaccine temperature rise beyond 8°C.One refrigerator required an unsustainable compressor cycling frequency to maintain proper temperature. The other tenunits maintained appropriate storage temperatures under acceptable operating conditions.

Backup power tests yielded the following runtimes without water ballasts:

- 16 hours for 28ft^3dual refrigerator/freezers
- 25 hours for 18ft^3dual refrigerator/freezers
- >60 hours for 7ft^3chest freezer (operated as a refrigerator)

Note: If water jugs are used as thermal ballast to fill approximately one third of the refrigerator compartment, the compressor duty cycle decreases and the runtime increases by approximately 25%.

The 160 amp-hour 12VDC battery used for testing is an industrial grade sealed lead-acid gel unit typically used to provide back-up power to cell-phone repeater broadcasting towers. The battery was selected because of the ubiquity of cellphone infrastructure worldwide.

Telecommunications companies can be a resource for obtaining these batteries in remote regions. The estimate lifetime of each battery is 11 to 13 years with a cost of $300 to $450 U.S.

The power inverter used is a Whistler Pro 1600 Watt (3200W peak) power inverter. This inverter is especially suited for starting inductive loads because it provides surge power for up to 10 seconds. This inverter is priced at $110 U.S. for single quantities.

4. Conclusions

The Baylor/Rice regulator provides a low cost vaccine refrigeration control and temperature monitoring system suitable for converting household refrigerators into effective vaccine refrigerators. Currently the design is in revision to improve both manufacturability and compliance with Underwriters Laboratory (UL) standards. Under further development is an Android smart phone application which provides cellular alarms via SMS text messaging.Field-testing is planned after we partnerwith a manufacturer.The device may prove usefulboth domestically and in areas subject to electrical grid failure.

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