University of Minnesota - Twin Cities, College of Science & Engineering

A Low Cost Autoclave Temperature and Pressure Monitor

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Problem Definition:

Autoclaves are devices that sterilize medical equipment using heated steam held at high pressure over a certain period of time. Sterility of medical equipment, especially tools used during surgery, is critical to limiting the amount of bacteria transferred to the patient and the prevalence of surgical infections. Inadequate sterilization procedures increase the risk of infection, this increase can be seen in low-income countries[1]. Evaluating the effectiveness of steam sterilization processes is one way of reducing this risk; in order for the sterilization to be considered successful, the autoclave must reach a minimum threshold temperature, and hold the contents of the autoclave at that threshold for a defined length of time. Diversity of autoclave models in low resource areas means that a method of monitoring temperature and pressure for a variety of different autoclaves is necessary.

To solve this problem, a low-cost, reusable temperature and pressure sensing device will be designed. Our proposed autoclave tester will monitor the temperature and pressure inside of the autoclave in real time using sensors connected to an Arduino microcontroller. The CDC recommends the minimum steam exposure temperatures and times for sterilizing medical equipment as "30 minutes at 121°C (250°F) in a gravity displacement sterilizer or 4 minutes at 132°C (270°F) in a prevacuum sterilizer". As such, our device and its temperature sensor will have to be able to withstand both of these temperature and time constraints. In addition, an LCD and series of indicator lights will be used to communicate the status of the autoclave and alert the user in the event that pressure drops below the threshold pressure or temperature.

Using an Arduino and basic sensors, our device will be much simpler and cost significantly less than the market price of autoclave sensors. Currently autoclave diagnostic tools exceed prices of $500[2]. Because only the sensors will be inside the autoclave, we need not be concerned about the rest of the device withstanding the internal temperatures. an LED light will light up to signify a successful or failed sterilization.

Statement of Impact in Developing World:

The most critical impact our device will have for low resource hospitals is reusability for a variety of autoclaves. Existing methods of testing the effectiveness of autoclaves, such as Bowie-Dick cards, are not reusable, difficult to obtain in low resource areas, and expensive, costing over five dollars per use[3]. Guidelines from the World Health Organization surrounding decontamination of medical devices state that for quality assurance purposes, steam sterilization devices should be evaluated each day before using with contaminated medical devices. Using disposable Bowie-Dick cards for daily tests is costly for hospitals in low resource areas, and is not a sustainable solution. Beyond that, simple thermometer gauges are not sufficient to determine whether the autoclave is functioning properly. This is because the internal temperature must remain above the threshold temperature for extended periods of time and regular thermometers do not record data. These devices also break or become faulty often, with no way to recalibrate them.

Our proposed real-time monitoring system for pressure and temperature will be particularly useful in evaluating temperature and pressure readings for donated or damaged autoclaves. Our device can help to understand the condition that an autoclave is in and double check the gauges already, which may not give correct readings on existing temperature or pressure gauges.

This monitoring system also will only pass the cycle if the temperature remains above the threshold for the entire running period. The final readout will only need to be viewed once and can summarize the entirety of the sterilization cycle much better than any currently available options. The system's applications do not end with steam sterilization. The versatility of the temperature and pressure sensors mean that this can be used for various applications inside of a hospital setting. By setting the threshold values and the amount of time, it can be used to determine validity of other parameter-related cycles.

Required Performance Specifications:

In order to confirm the success of an autoclave sterilization, the autoclave testing device must be able to measure and withstand up to 121°C and 30 psi and display success or failure. If the autoclave fails to reach temperatures and pressures above 121°C or 30 psi, respectively, the steam created will not be hot enough to properly disinfect the equipment in the autoclave. These conditions must be maintained for at least 5 minutes for the sterilization to be considered successful. Thus it was also necessary for the device to monitor the duration that the required conditions were met during each autoclave sterilization cycle and display the success or failure of the cycle.

The device also needs to be openable to clean or perform maintenance on. It must also be low cost with the goal being under $100. This will be achieved by sourcing some parts from other old devices, such as the thermistor and casing, while others are only purchased when necessary, such as the pressure sensor and Arduino.

Implementation of Prototype:

Figure 1: Finished Prototype

Mechanical Components:

A cleared out multimeter case served as the housing of the device. Two holes were drilled into the bottom of the case: a round hole with a diameter of 11.1 mm for the power cord and a square hole with a length of 11.3 mm for the USB-A cord of the Arduino. A hole with a diameter of 2.4 mm was drilled into the right side of the case for the thermistor. High-temperature silicone tubing with an inner diameter of ¼” covers the thermistor to connect to the autoclave. A 16x2 LCD screen, pressure sensor, red LED light, and green LED are located on the front of the case. The pressure transducer used was a generic sensor intended for automotive purposes. Due to time constraints and the risks of a high pressure failure there is no connector for the thermistor and pressure transducer to the autoclave.

Electrical Components:

An Arduino microcontroller was used to record and track the data received from the sensors. This project consisted of 2 sensors, an analog thermistor and pressure transducer. The device is powered by a 9 volt battery connected by a battery snap power cord. Because this is a prototype, jumpers were used to connect the components within the housing unit. For final production the components would be soldered. An Arduino was selected due to its widespread availability and low price point. An Uno was used for the prototype, but a Nano would be adequate for this project; this would also lower our final cost per unit. This diagnostic tool detected heat and pressure parameters, and utilizes a thermistor and pressure transducer to do so. Both sensors yield a varied voltage output, allowing for the use of the analog read function on the Arduino. The pressure sensor selected is commonly used in the automotive industry, and because of this it comes with a low cost. There are two LEDs on the device, which are used to indicate if both parameters are above their thresholds.

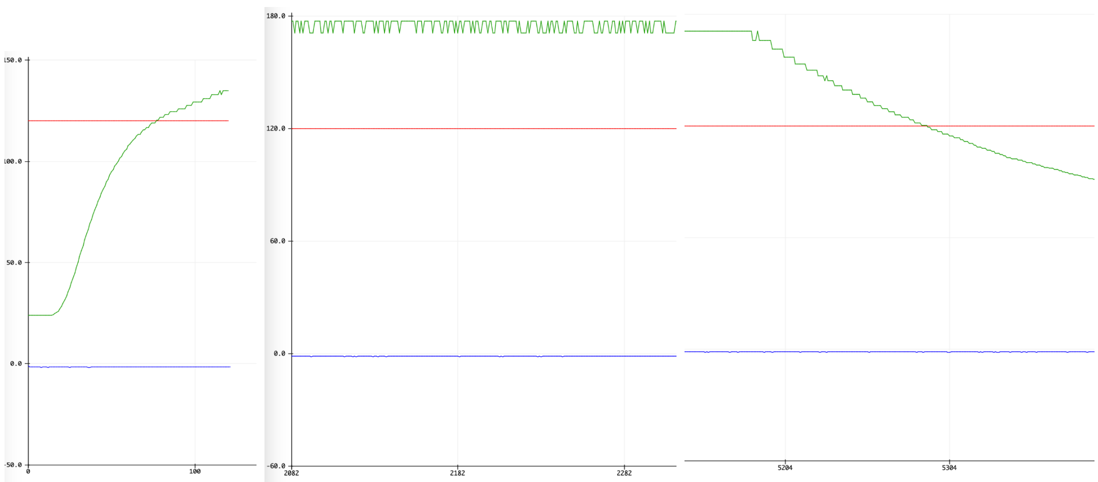
Code:

The first 17 lines of the Arduino code define all critical variables, and identify the library required for serial communication. These variables include the pressure inputs and thresholds, the beta coefficient of the thermistor, and the temperature threshold. Within the setup loop, pins 7 and 8 are clarified as LED output pins, and the serial communication is initialized. Following all component setup, the loop routine begins with defining the analog value to be read as well as several other variables related to the circuit components, such as the resistances and input and output voltages. Next, the analog values from the thermistor are converted into Celsius values, the Fahrenheit values that are compared against the set thresholds. The pressure and converted temperature values are then displayed on the serial monitor and graphed on the serial plotter. An if loop determines which LED is turned on based on the temperature and pressure values. If both temperature and pressure are below their thresholds, the red LED turns on, while the green is on if the temperature and pressure are sufficiently high. Within this loop is a quarter second delay between loop iterations to allow the LED to be seen but also change in almost real time should the temperature drop below the threshold.

Proof of Performance:

The most critical modules for successful operation of our monitor are adequate temperature and pressure sensing. A heat gun was used to perform a long-term heat measurement test, and high-temperature silicone tubing was placed around the thermistor. The heat gun was directed at the free end of the tubing, simulating the effect of having a high temperature in the autoclave, some distance away from the device controls. The Arduino serial plotter was used to record temperature as a function of time for 30 minutes, simulating the CDC minimum duration to sterilized medical devices. A successful temperature test will entail the ability to record a temperature above 121°C for this period of time. A reference temperature was set on a variable-temperature heat gun, and was monitored to verify that temperature did not drop below 121°C for 30 minutes.

A maximum temperature of 184 C, well above the design requirement, was successfully measured. Furthermore, the indicator LEDs successfully changed from red to green when the temperature threshold was crossed. Appendix D shows images of the experimental setup, and Figures 2A-2C below shows the results of the temperature evaluation:



Figures 2A-2C: Temperature Evaluation at Beginning, Midpoint and End

Pressure monitoring was evaluated by means of a hand-powered bicycle tire pump, with a widened hole drilled into the pump adaptor to accommodate the threaded region of the pressure sensor. The chosen sensor is rated for 150 psi, well above the threshold outlined in the design requirements: detection of pressure spikes will prove sufficient for proof of concept testing. Figure 3 below shows the results of the pressure evaluation, with pressure indicated by the blue line:

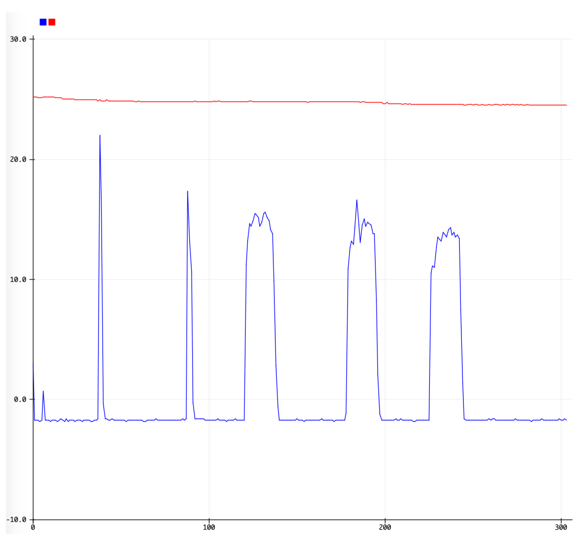


Figure 3: Pressure Evaluation

The main focus for improvement would be developing a connector for the thermistor and pressure transducer to the autoclave. Due to the high pressures that an autoclave experiences, extreme caution would need to be taken to ensure that there are no pressure failures for any added weak points. The connector would also need to be durable to prevent any failures after repeated use. Another area to improve on could be the housing case. Since the case was reused from an old multimeter some of the parts do not fix properly, such as the LCD screen, or have extra unused gaps, such as where the multimeter knob was. If done properly, making a proper case could increase the durability while minimally affecting the cost. Another potential improvement would be a small set of arrow keys with a select button to choose the desired test and units to keep the device as simple and multipurpose as possible.

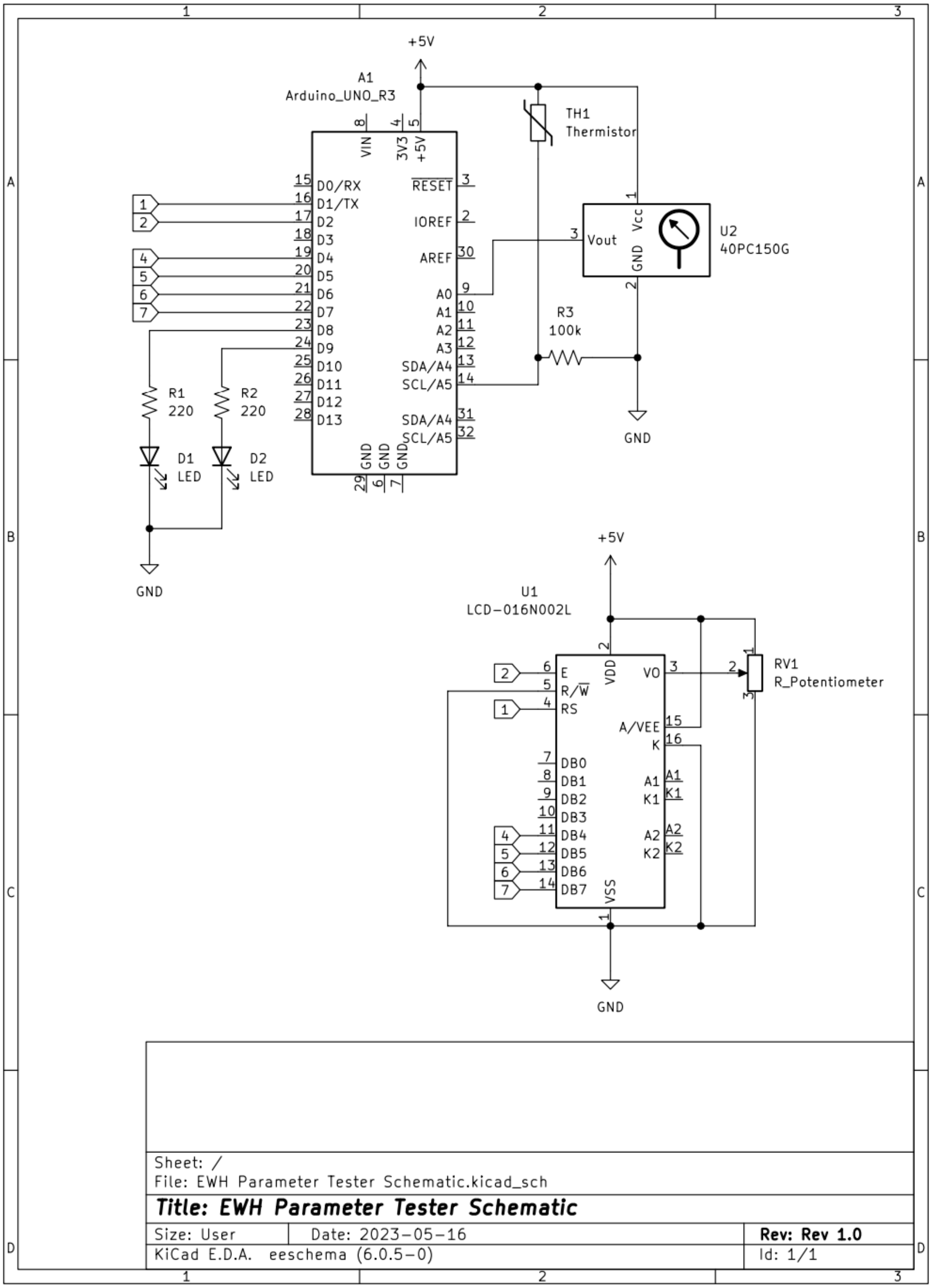
Business Plan and Regulatory Considerations:

Our device was designed to use minimal electrical components, and have easily replaceable or interchangeable mechanical components. Other casing shapes or materials could easily be substituted, for example, in lieu of mass-manufacturing custom-fit cases. Appendix C shows a breakdown of total cost of production for each device - with a current cost per unit of $67.06, our device is a significant improvement over existing autoclave parameter monitors, which typically cost hundreds of dollars, and cannot be repaired with easily replaceable components.[2] Modifications to a future beta-prototype, including replacement of the Arduino Uno with an Arduino Nano, and mass-manufacturing of PCBs, will allow for further cost reductions to our device.

This project was inspired by literature that has been published surrounding autoclave failure in Nepal, emphasizing the need for reusable low-cost autoclave test methods. This device would be manufactured and sold directly to hospitals, as opposed to sale through non-profit organizations. Initial funds would be raised first for construction of a beta-prototype, which would include a redesigned casing, a connector to interface directly with the autoclave, and an Arduino Nano circuit. From there, device circuits and casings can be manufactured in greater quantities.

It will be necessary to abide by any regulatory requirements for medical devices sold in Nepal. According to a 2021 best prospect industry sector for medical devices in Nepal, devices from the United States are becoming increasingly competitive for import, as opposed to import from India. Testing equipment is one of the leading sub-sectors of medical device importation to Nepal: combining this with autoclave failure rates in Nepali hospitals[1] indicates that demand for an exported, low-cost autoclave parameter tester is present.[6]

Appendix A: Electronics Schematic



Appendix B: Code

```
#include <LiquidCrystal.h>
#include "Wire.h"

const int rs = 1, en = 2, d4 = 4, d5 = 5, d6 = 6, d7 = 7;
LiquidCrystal lcd(rs, en, d4, d5, d6, d7);

const int pressureInput = A0; //select the analog input pin for the pressure transducer
const int pressureZero = 102.4; //analog reading of pressure transducer at 0 psi
const int pressureMax = 921.6; //analog reading of pressure transducer at 100 psi
const int pressuretransducermaxPSI = 100; //psi value of transducer being used
const int baudRate = 9600; //constant integer to set the baud rate for serial monitor
const int sensorreadDelay = 250; //constant integer to set the sensor read delay in milliseconds

const int tempThreshold = 120; //C
const int pressureThreshold = 15; //psi

const float BETA = 4390; // matches the Beta Coefficient of the thermistor

float pressureValue = 0; //variable to store the value coming from the pressure transducer
float counter = 0;

void setup() //setup routine, runs once when system turned on or reset
{
  pinMode(8, OUTPUT); //RED Led
  pinMode(9, OUTPUT); //GREEN Led

  Serial.begin(9600); //initializes serial communication at set baud rate bits per second
  lcd.begin(16, 2);
}

void loop() //loop routine runs over and over again forever
{

  int analogValue = analogRead(A5);
  int raw = 0;
  int Vin = 5;
  float Vout = 0;
  float R1 = 100000;
```

```
  float R2 = 0;
  float buffer = 0;
  float celsius = BETA / (log((1023.0 * 100 / analogValue - 100) / 100) + BETA / 298.0) - 273.0;

  buffer = analogValue * Vin;
  Vout = (buffer) / 1024.0;
  buffer = (Vin / Vout) - 1;
  R2 = R1 * buffer;

  float F = 1.8 * celsius + 32.0;

  //Pressure code
  pressureValue = analogRead(pressureInput); //reads value from input pin and assigns to variable
  pressureValue = ((pressureValue - pressureZero) * pressuretransducermaxPSI) / (pressureMax -
pressureZero); //conversion equation to convert analog reading to psi

  //Serial monitoring code
  Serial.print(pressureValue);
  Serial.print("\t");

  Serial.print(" psi");

  Serial.println("Temperature: ");
  Serial.print(tempThreshold);
  Serial.print("\t");
  Serial.println(celsius);
  Serial.print(" C     ");

  //LCD code
  lcd.setCursor(0, 0);
  lcd.print("T = ");
  lcd.print(celsius);
  lcd.print(" C");
  lcd.setCursor(0, 1);
  lcd.print("P = ");
  lcd.print(pressureValue);
  lcd.print(" psi");

  delay(sensorreadDelay); //delay in milliseconds between read values
```

```
// Determine if green or red LED should be lit:

  if ((celsius < tempThreshold) && (pressureValue < pressureThreshold)) {
    //light red LED
    digitalWrite(9, LOW);
    digitalWrite(8, HIGH);
    delay(100);

    Serial.println(counter);

  }

  else {
    // light green LED
    digitalWrite(9, HIGH);
    digitalWrite(8, LOW);
    delay(100);

    //increment counter by 0.1 seconds for each loop
    //this allows for a running counter of how many seconds both temperature and pressure
    //are above the thresholds:

    counter += 0.1;
    Serial.println(counter);
  }

}
```

Appendix C: Bill of Materials

Component	**Cost**
Arduino Uno	$25.30
9V Battery and Adaptor	$5.00
Jumper Wires	$2.00
LED (x2)	$0.50
16x2 LCD Screen	$7.56
Resistor, 220 Ohm (x2)	$0.15
Resistor, 100k Ohm	$0.05
Potentiometer	$0.50
Thermistor	$1.99
150 PSI Automotive Pressure Transducer	$16.02
Electrical Tape	$2.99
Plastic Multimeter Casing	$5.00
Total:	**$67.06**

Appendix D: Experimental Setup Images

Figure D1: Temperature Test Setup

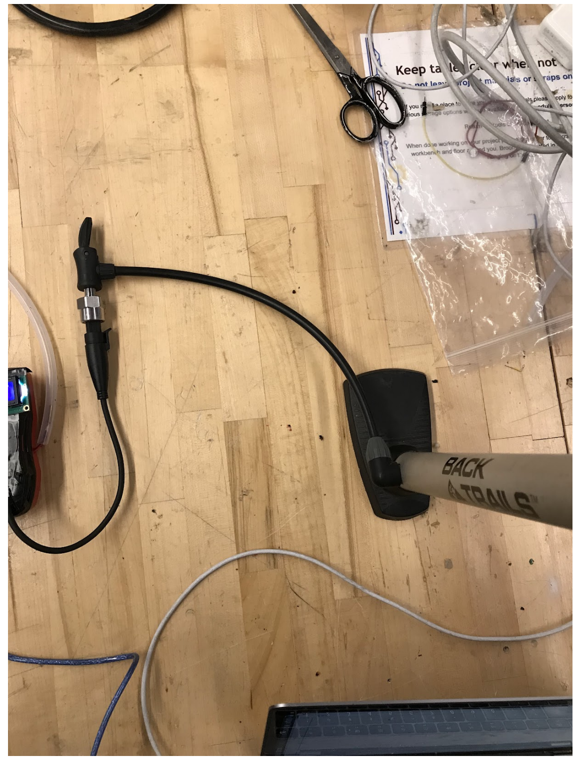


Figure D2: Pressure Test Setup

References:

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