# User-driven-development of a compressive, temperature-sensing, and symptom tracking glove for Rheumatoid Arthritis and Secondary Raynaud's

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**Abstract**

Rheumatoid Arthritis (RA) and Raynaud's phenomenon are conditions that cause inflammation, stiffness, and pain and restricted blood flow, respectively. Given the unpredictable onset of symptoms associated with RA and the dependence of the onset of a Raynaud's episode on temperature conditions or stress, it is believed that patients will benefit from having the option to track their symptoms. Additionally, while many current solutions for RA and Raynaud's include compressive gloves, these products are lacking in aesthetic appearance and physical comfort offered to the user. In response to these identified needs, and while working with a need-knower who is also one of this report's authors, a product was researched, conceptualized, designed, and prototyped to address the user's primary needs associated with RA and Secondary Raynaud's. These primary needs were identified as: 1) The AD is temperature aware, 2) The AD is made of materials which facilitate comfort and effective gripping, and 3) The AD is ergonomically designed and is fashionable. The device presented and discussed in this report is a compressive, temperature-sensing, symptom-tracking, and stylish glove intended to address a design space previously not much explored among existing solutions for RA patients. It is made of a stretchy fabric which is sewn to provide compression to the user's hand, and is equipped with sewn-on temperature and pressure measurement sensors to transmit data to the attached Flora microcontroller. An LED onboard the microcontroller provides visual feedback to the user. A proposed study to investigate the function of this device would involve assessing device use for different populations divided according to their medical conditions (a combination of RA and/or Raynaud's). While there are limitations in the final form of the prototype, this initial device could be useful in studies to determine the correlation between ambient temperature and compression on the frequency of pain-reporting. In addition to being useful for both RA and Raynaud's patients, this device can be of use to broader populations of individuals who may have similar symptoms of joint discomfort and temperature sensitivity.

## I. Introduction

Rheumatoid Arthritis (RA) is a long-term autoimmune disease that affects the lining of the joints, primarily in the hands and wrists. Symptoms include inflammation, stiffness, and pain. This can be random or correlated with time of day, temperature, and periods of rest/work. Given the unpredictability of RA symptoms and disease flares, symptom tracking is an invaluable research area for understanding the disease from a patient's perspective, as well as collecting data for their care team. RA is treated with immunosuppressive drugs and therapies such as compressive gloves or localized heat therapies. Compressive gloves are effective and widely used, however there is an unexplored space for designing gloves that are stylish, functional, and incorporate an appreciation of patients' perception of gloves [1] [2]. Raynaud's phenomenon is a condition affecting blood flow in the extremities, primarily the fingers. During a Raynaud's episode, usually triggered by cold temperatures or stress, individuals experience low blood flow, pain, discoloration, and numbness. Raynaud's exists in two forms: idiopathic and secondary. Secondary Raynaud's often presents with other autoimmune conditions such as RA. This paper explores developing a need-sensitive, bespoke assistive device designed by and for one of the authors, a student with RA and Secondary Raynaud's.

### A. Background

Devices to assist with RA symptoms include therapeutic gloves that provide compression and support, and a variety of sensor types exist for wearable sensor-based gloves to monitor hand function and range of motion (ROM).

Current products available for individuals with RA include vibrating arthritis gloves, microwaveable warming mittens, and fingerless compression gloves. However, these solutions, specifically in the case of compressive gloves, are lacking in that the gloves are difficult to wear and take off, visually unappealing and not fashionable, and interfere with daily living activities such as hand-washing. Additionally, gloves meant for winter use are often warm and comfortable, but lead to a loss in dexterity or ROM.

There also exist soft robotic therapeutic gloves for RA [3] which include embedded internal pneumatic actuators which can be used to provide therapeutic compression to the patient's joints. Various gloves with embedded sensors exist for health monitoring for individuals with RA, in varying levels of prototyping and consumer readiness [4].

### *B. Overview*

The remainder of this report will cover 1) Preliminary Results, including a summary of the interview data collected and a justification for the identified needs that were used to guide this project; 2) Methods, including a detailed description of the device function, the guiding hypothesis, and the outline of our proposed study; 3) Intellectual Merit, where the contribution of the work presented in this paper is addressed and any current limitations in the device capabilities are acknowledged and described; and 4) Broader Impact, in which the benefit of this device is discussed as it relates to current patients of RA and Raynaud's, as well as a broader population of individuals who may benefit from compressive, temperature-sensing, and compressive glove features.

## II. Preliminary results

The interview process was planned in detail to ensure that sufficient data and qualitative information about the need-knower's condition, needs, and preference, would be gathered to allow the development of an effective and desirable solution. The interview began with an introduction of the interviewer, a statement of purpose in conducting the interview, and requesting permission to record. The questions were designed to ask about an overview of the effect of RA on the individual's life regarding daily activities, the progression of a typical day, exploring the difference between holding and maneuvering, and the effect RA may have on others' perception of the need-knower or her experience with learning.

The interview responses were comprehensive and provided qualitative information regarding the need-knower's experience with writing and typing; daily activities such as eating, packing belongings, and working in the kitchen; academic impact; the function and description of assistive devices she currently uses to alleviate pain associated with RA; materials and textures that each alleviate and cause discomfort; and actions that alleviate or cause discomfort, such as pushing heavy objects, twisting, and sewing.

Highlights from the interview process included that certain activities are more difficult than others; washing dishes and carrying heavy objects are examples of difficult activities, and there was a special note that pain occurs primarily in the metacarpophalangeal joints. The need-knower also identified that soft, rubbery, and compliant materials are conducive to comfort, while cold surfaces like glass and metal can exacerbate pain. Further, she explained that cold environmental temperature causes lasting stiffness and discomfort, and that she may not be aware of a change in hand temperature until significant time has already passed.

From the preliminary interview results, the following five primary needs were identified for the assistive device (AD):

1) The AD is temperature aware
2) The AD amplifies user-applied forces and torques to facilitate grasping, lifting, and gripping
3) The AD is made of materials which facilitate comfort and effective gripping
4) The AD can be easily worn and manipulated under external conditions
5) The AD is ergonomically designed and is fashionable

Of these five primary needs, three in particular were identified, which our team determined were the most pertinent to the need-knower's preferences and would allow for an achievable solution. Those needs were that: 1) The AD is temperature aware, 2) The AD is made of materials which facilitate comfort and effective gripping, and 3) The AD is ergonomically designed and is fashionable. The second and fourth needs in the original list were omitted to ensure that the needs addressed were specific and related to one another.

Included below is a chart of primary interview findings:


Fig. 1. Summary of interview findings by category

# III. Methods

## A. *Overall Device Design*

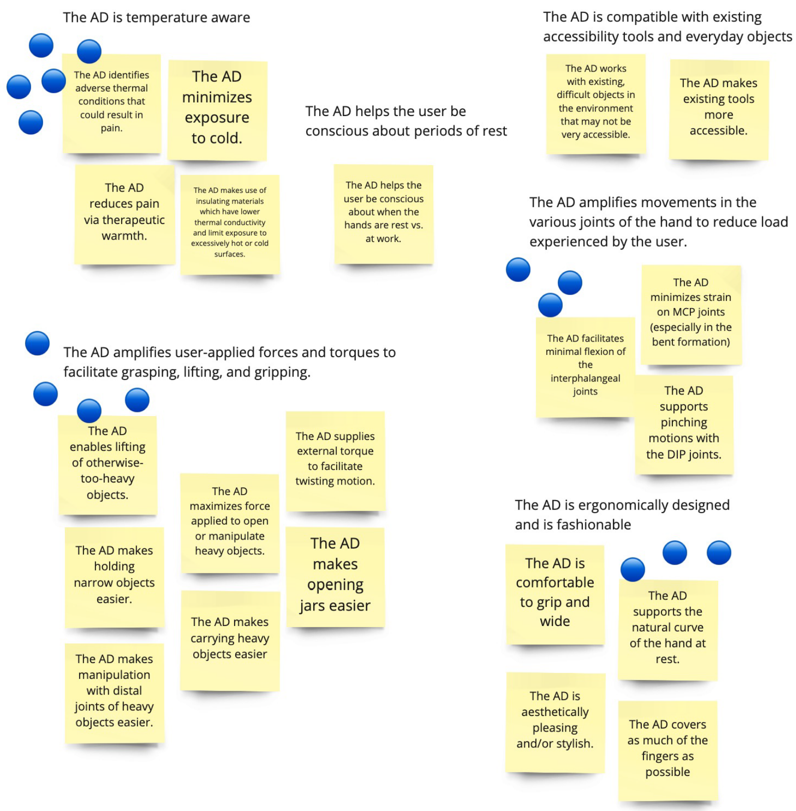


Fig. 2. Visualization of the design down-selection process using dot-voting (part 1 of 2)

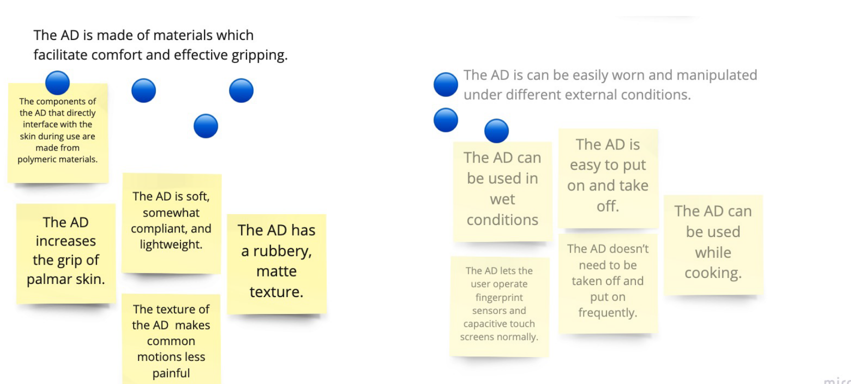


Fig. 3. Visualization of the design down-selection process using dot-voting (part 2 of 2

| Criteria | Criterion Weight | Design Options/Themes: Glove based devices that are made of soft materials that provide padding and extra grip to the skin surface. These mostly do not have any components that are actuated and distribute the load applied to the hands when manipulating objects | Ergonomic and therapeutic devices that provide heat to the hands. This includes an ergonomic mouse, and a heating pad for putting the hands at rest mindfully, as well as temperature aware gloves. | Gloves that increase the force/torque applied to objects based on tendon-like structures or materials for the palmar surface of the glove. | Soft/silicone rings and bands that go over each interphalangeal joint and provide support. |
|---|---|---|---|---|---|
| The AD is temperature aware | 0.2 | 3 | 4 | 1 | 2 |
| The AD amplifies user-applied forces and torques to facilitate grasping, lifting, and gripping. | 0.25 | 3 | 1 | 4 | 2 |
| The AD is made of materials which facilitate comfort and effective gripping. | 0.3 | 4 | 2 | 1 | 3 |
| The AD can be easily worn and manipulated under different external conditions. | 0.15 | 3 | 1 | 2 | 4 |
| The AD is ergonomically designed and is fashionable | 0.1 | 3 | 1 | 2 | 4 |
| **Sums** | **1** | **3.3** | **1.9** | **2** | **2.8** |

Fig. 4. Decision matrix, showing the five criteria, associated weights, and design options being weighed

The design identified as most capable of fulfilling the primary needs was the following: a glove based device that is made of soft materials that provide padding and extra grip to the skin surface. An emphasis was put on soft, pliable materials that would take the form of the object being manipulated and provide compression and support.

The device that was conceptualized and developed has functionality that specifically "enables the study of human dexterity or measure hand/arm mobility/strength/sensitivity" and "improves function or prevents reduction in hand/arm mobility/strength/sensitivity", as enumerated in the project guidelines. Specifically, this is done with the use of temperature and pressure sensors as well as a compressive glove design. This device is a functional prototype of a physical device and incorporates mechatronics components, including a microcontroller and sensors. There is no actuation component of this device, and this device does not assist the user with motion.

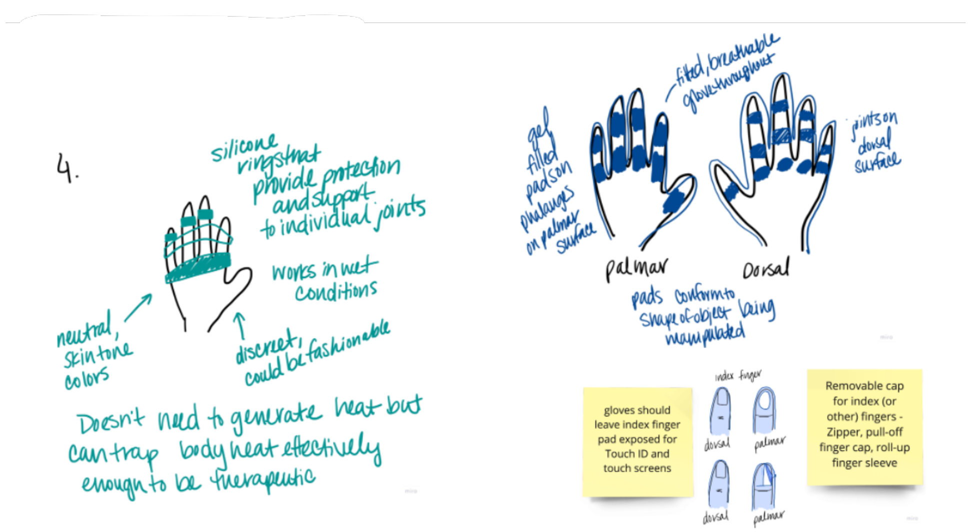


Fig. 5. Preliminary sketches

The final device is a compressive glove made of a single layer of lycra, with portions cut-out from the glove on both the ulnar and radial sides, and with all but two of the phalanges exposed. It is made of a stretchy fabric which is sewn to provide compression to the user's hand, and is equipped with sewn-on temperature and pressure measurement sensors to transmit data to the attached Flora microcontroller. An LED onboard the microcontroller provides visual feedback to the user.

Fig. 6. Final glove prototype

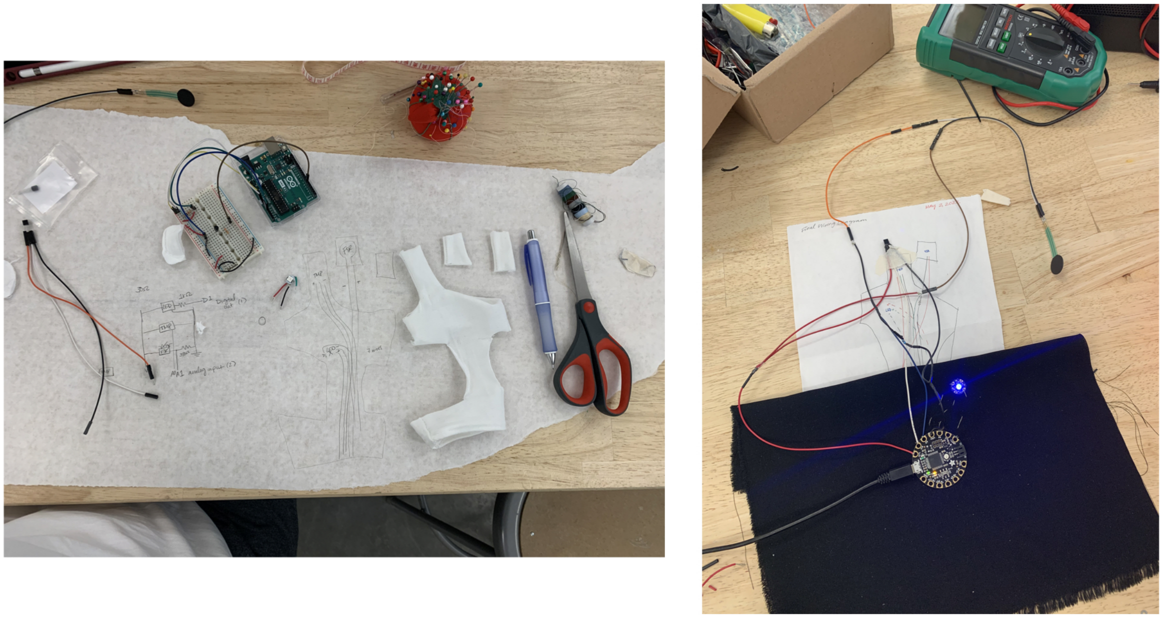

Fig. 7. Early glove prototyping (left) and wiring layout (right).

Fig. 8. Sewing multiple glove patterns.

## *B. Subsystem Description and Proof of Function*

The device consists of mechanical, electrical, and software components.

**Mechanical Features**

The mechanical portion of the device consists of the glove design, placement of components, and material choice. Specifically, the glove is designed to be compressive in nature, which was accomplished both through the specific sewing of the glove outline as well as the placement and size of the fabric cut-outs for the phalanges. Portions of the glove were removed, or cut out, to allow for breathability, to improve the need-knower's range of motion, and to reduce restriction during daily activities such as hand-washing. Specifically, only the third phalange is covered up until the distal MCP while all other phalanges are exposed. The fourth phalange has a separate, disconnected glove portion that interfaces with the sensor that allows for user pain-reporting. The exterior of the glove consists of a lycra fabric which is soft and pliable, but still provides compression. Adding a second, inner fleece layer underneath the lycra was also considered, but eventually not carried out to prevent adding thickness and excessive compression to the design. The temperature sensor and FSR sensors are fixed to the third and fourth phalanges, respectively.

**Electrical Features**

The electrical components consist of the Flora microcontroller, which is compatible with Arduino software and is a suitable option for wearable devices given built-in sewable pins to which conductive wire or thread can be attached. The original design included an Arduino Uno microcontroller which was also compatible with all sensors involved, but was bulky and would have required separate housing to interface with the glove properly. The sensors used include a temperature sensor and FSR pressure sensor. There is additionally an LED on the Flora board itself which changes color according to a gradient based on the measured ambient temperature and the reading from the FSR pressure sensor (for the FSR sensor, the LED has three settings for varying degrees of pressure). For the purposes of the project demo, power was supplied through a wired connection to a computer, but this device may also be battery-powered. In the case of using battery-power, the battery can be held in place against the arm using a compressive wristband which is made of the same material as the compressive glove.

**Software Features**

The software component of this device is written purely in Arduino code and accounts for 1) processing the analog output from the temperature and FSR sensors, and 2) encodes a digital output to the LED pin on the microcontroller according to the respective temperature or pressure readings.

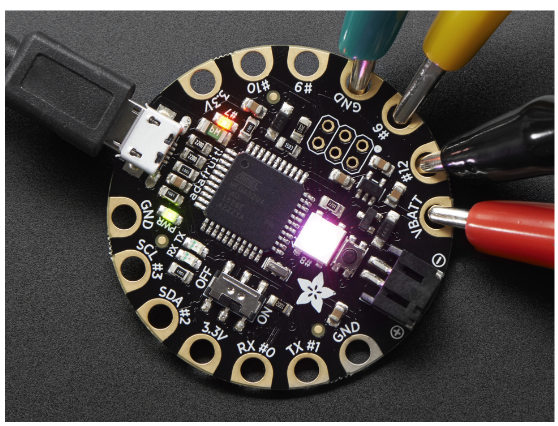


Fig. 9. Adafruit FLORA microcontroller

Fig. 10. Caption

## *C. Proposed Study*

Some questions that we considered during the development of a user study were the following:

1) How often would a user wear the device?
2) When do people with RA experience pain, and does it correlate with the ambient temperature?
3) How might we reduce pain related to RA?
4) How does Raynaud's interact with RA? How does it change with RA?
5) Do compression gloves cause the user to sacrifice range of motion in exchange for the benefit of pain reduction in the MCPs?

Questions that might be answered with the use of this device include the following:

1) Temperature sensing - correlation of RA pain with temp; relation between RA and Raynaud's
2) Self-reported pain sensing - RA related pain, how to prevent pain related to RA (associated with times of day, location, etc.)

**Hypothesis Development:**

Considering these introductory questions, four distinct hypotheses were developed, all of which may be investigated with the use of this device:

We hypothesize that:

1) Individuals with RA will self-report experiencing pain symptoms at a higher rate than those without RA (when conducting a study with RA patients and a control group without RA)
2) There exists a negative correlation between the sensed environmental temperature and the rate of pain-reporting for individuals with Raynaud's.
3) Individuals with Raynaud's will exhibit a lower average hand temperature than individuals without Raynaud's.
4) Individuals who use gloves with compressive fabric will exhibit a lower rate of negative symptom-reporting as compared to individuals who use gloves without a compressive feature.

**Study Design**

A study that would be useful for better understanding the function of this device would specifically have subjects wear and use the device for a fixed amount of time during the day while carrying out a predefined set of daily activities.

In order to investigate the hypotheses, a study can be designed with four populations of individuals: 1) Patients with RA, 2) Patients with Raynaud's, 3) Patients with both RA and Raynaud's, and 4) Patients with neither condition, and no other underlying health condition involving pain associated with the MCPs or relating to temperature changes (i.e. a control group). To gather a useful body of data and qualitative results, individuals from each population can be observed using two different types of gloves – gloves made from compressive fabric such as lycra, and gloves made of a different, non-compressive material. Experiments can be run for each individual + glove type scenario to gather information on temperature readings, the frequency of pain-reporting for a given amount of time, and the effectiveness of compression upon the user's personal comfort, among other results. These results may then be summarized to draw conclusions about the above-mentioned hypotheses.

## IV. Intellectual Merit

The temperature-sensing, compressive, symptom-tracking, and stylish glove design that was developed over the course of this project provides several useful features that are either not observed in existing products on the market for individuals with RA and/or Raynaud's, or are not found together in such products.

Deliverables that specifically could help other scientists and add to the existing body of knowledge around RA include 1) real-time symptom tracking for RA patients, independent of any features geared towards improving comfort, 2) a comparison between the presence and absence of a compressive glove, and 3) an investigation on the correlation between ambient temperature and the frequency of pain-reporting.

If the data collected from the study described in the previous section suggests that, broadly, there does not exist a correlation between compression or ambient temperature and the frequency of pain-reporting, it could suggest that compressive gloves are not an effective solution for individuals with RA. The study may also reveal whether discomfort or pain due to low temperature is independent from pain experienced in the MCPs (both of which might trigger the user to use the symptom tracking feature of the device).

Finally, there were limitations of the device prototype that was developed which leaves room for future improvement. Some shortcomings include loose wiring and loose attachment of sensors to the body of the glove, which may hinder user movement, as well as the fact that in the current iteration of the device, the Flora microcontroller does not make use of conductive thread and rather relies upon wired connections. In the future, this device may be made more user-friendly by developing a more robust wire management and sensor attachment setup.

## V. Broader Impact

This device has the potential to benefit a broader audience, beyond our need-knower, for both RA and Raynaud's patients alike by providing a neat, modular solution for symptom tracking, temperature-sensing, and compressive comfort. It additionally provides a fashionable and visually-appealing alternative to existing glove designs on the market, which may not have the same sensing capabilities or be bulkier and have less ventilation built into their physical designs.

Additionally, the data collected from symptom tracking and temperature-sensing through initial user studies may be used to answer more questions that impact more general populations, such as what range of temperatures is typically experienced by the hand over the course of a given day, given the individual's location. The compressive and temperature-sensing aspect of the glove device may be of use to individuals with other conditions which have similar symptoms of joint discomfort or temperature sensitivity, respectively.

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# Appendix A
# Discovery Decomposition

*Topic of the interview: rheumatoid arthritis.*

*1) Therapy gloves for patients with rheumatoid arthritis: a review:* [5].

- Background/Hypothesis: Rheumatoid arthritis causes pain, stiffness, and swelling in the hands that can make daily activities difficult. Therapy gloves are recommended as an ”alternative treatment method” for RA. This study reviews literature on the effectiveness of therapy gloves for RA patients as well as the qualities of effective therapy gloves.
- Methods: This article reviewed 8 articles from a database search, including 7 clinical trials and 1 case study. The review grouped measured outcomes into two categories, hand symptoms (including PIP swelling, hand pain, and joint stiffness) and hand function (grip strength, pinch strength, ROM, and dexterity).
- Results: The review aggregated tables where each outcome listed above is compared between each article. The article also compared and rated the quality of the methods by which each article measured pain levels.
- Conclusion: The review concluded that few of the articles examined were quality clinical trials with highly rated methodology. Wearing therapy gloves is beneficial in reducing hand symptoms, but the mechanism by which this is achieved is not clear.
- Test Hypothesis: N/A

*2) Predicting ’normal’ grip strength for rheumatoid arthritis patients:* [6].

- Background/Hypothesis: This study aims to predict ’normal’ grip strength for individuals with RA based on anthropometric measurements of the forearm and overall body.
- Methods: 83 RA patients and 81 patients without arthritis were measured. The study looked at power, pinch, and tripod grip strength as well as forearm measurements. In RA patients, the Ritchie Articular Index and a visual analogue scale for pain severity were also utilized.
- Results: The study found that there was a negative correlation with markers of disease activity and grip strength. The study also found that in individuals without RA, their dominant hand was 8% stronger, but in RA patients, their dominant hand was 20% weaker.
- Conclusion: Anthropometric measurements of the hand and forearm are useful for predicting a baseline for hand strength in RA patients.
- Test Hypothesis: Hand and forearm measurements in RA patients can be used to predict hand grip strength.

*3) Test-retest reliability and convergent validity of a computer based hand function test protocol in people with arthritis:* [7].

- Background/Hypothesis: This group developed a computer-based hand function assessment tool for people with RA or Hand Osteoarthritis (HOA). The study aimed to determine test-retest reliability and convergent validity of the assessment.
- Methods: For the assessment, three objects were fitted with motion sensors and moved with a computer generated visual target. Patients self reported pain and stiffness before and after each task. These tasks were evaluated twice in 40 subjects with RA and HOA. The study also measured grip strength, nine hole peg test, DASH questionnaire, and HAQ score.
- Results: The test protocol had moderate to high test-retest reliability. Also reported was significant reduction in pain and stiffness after performing each task.
- Conclusion: The novel assessment tool offers an objective way to measure task performance and measures pain and stiffness in addition, unlike other assessment methods.

- Test Hypothesis: Performance measures of object manipulation tasks would have high test-retest reliability and moderate correlation with grip strength and additional assessment scores (listed in Methods).

*4) A reappraisal of HAQ disability in rheumatoid arthritis:* [8].

- Background/Hypothesis: This paper aims to investigate the course of self-reported disability in RA using the Health Assessment Questionnaire (HAQ).
- Methods: HAQ disability was assessed in 32,525 observations in 1,843 patients. Linear and nonlinear models were used to model the individual course of patients data.
- Results: 3 key characteristics of HAQ disability in RA patients over time were identified. Linear models fit the data rather poorly, but nonlinear models and the addition of covariates explained a larger portion of the score variations.
- Conclusion: The model that self-reported physical disability as measured by the HAQ as a function of disease over time doesn't fit the data well. The paper supported individual patient models that included more data types might be more effective instead of group-based models.
- Test Hypothesis: RA disease duration is well-modeled by self-reported HAQ scores.

*5) Design and characterization of a soft robotic therapeutic glove for rheumatoid arthritis:* [3].

- Background/Hypothesis: This paper details a pneumatic actuation system for a soft robotic therapeutic glove for RA patients.
- Methods: The prototype glove consists of an outer layer of cotton material and internal inflatable actuators for each finger. The air compressor is controlled via an Arduino processor.
- Results: The novel prototype design was detailed and validated.
- Conclusion: N/A
- Test Hypothesis: N/A

*6) Review of wearable sensor-based health monitoring glove devices for rheumatoid arthritis:* [4].

- Background/Hypothesis: This review examines current sensor technologies that can be used to quantify an individual's RA severity. Specifically, the paper focuses on contact systems.
- Methods: This paper reviews sensors used in smart gloves and identifies measured angles of the joints & movement of the individual fingers as parameters of significance for hand rehabilitation.
- Results: The sensors examined are flex sensors, Hall Effect sensor, and Capacitive Bend Sensors. For hand orientation, the paper compared accelerometers and intertial measurement unit (IMU) sensors. Finally glove materials and use cases are discussed as well.
- Conclusion: The paper stresses that early detection of RA is important but not standardized and easy to execute. Further research on sensors, contact systems, and user personalization and production of gloves for clinical and remote measurement applications is encouraged.
- Test Hypothesis: N/A

*7) Therapeutic gloves for arthritis: development of a design framework:* [1].

- Background/Hypothesis: This paper establishes a classification for therapeutic gloves and their effectiveness.
- Methods: The article utilized an apparel design framework incorporating a Functional Expressive Aesthetic framework.
- Results: A proposed framework for the design and engineering of therapeutic gloves in the form of multi-step flow diagram that feeds back on itself.
- Conclusion: N/A
- Test Hypothesis: N/A

*8) Arthritis patients' experience and perception of therapeutic gloves:* [2].

- Background/Hypothesis: Therapeutic gloves are commonly used in the management of RA. This paper focused on patients' experience of wearing gloves and their perception of glove design.
- Methods: The researchers utilized an online survey of arthritis patients.

- Results: 80% of patients reported wearing their gloves up to 8 hours a day. Most believed they were effective. Patients reported issues with itchy skin and marks on hands after removal. Feedback was reported on style, design, material, color, and perception while wearing.
- Conclusion: Participants reported symptom improvement during glove wear. This review is helpful in identifying key criteria for the design and engineering of gloves that are both functional & comfortable to wear.
- Test Hypothesis: N/A

*9) The immunopathogenesis of seropositive rheumatoid arthritis: from triggering to targeting [9]: .*

- Background/Hypothesis: Patients with RA can be divided into two subsets depending on whether they possess or lack antibodies to citrullinated protein antigens (ACPAs) and of rheumatoid factor (RF). If antibodies are present, it is referred to as seropositive rheumatoid arthritis ( of all cases and more severe disease course).
- Methods: This is a review that summarizes recent progress in understanding of disease development in seropositive patients and discusses implications of this for development of preventive and therapeutic treatments.
- Results: N/A
- Conclusion: N/A
- Test Hypothesis: N/A

*10) A five-year followup of hand function and activities of daily living in rheumatoid arthritis patients [10]: .*

- Background/Hypothesis: Follow hand function and activity of daily living (ADL) capacity during a 5-year period in a group of outpatients with RA.
- Methods: 43 patients (28 women, 15 men) were tested using the Grip Ability Test (GAT), grip strength, Keitel Function Test (KFT), the Health Assessment Questionnaire (HAQ), self-estimated hand function, and pain scales.
- Results: After 5 years, GAT, KFT, and 3 HAQ components were significantly worse in women, but GAT improved in men. 12 patients needed personal ADL assistance.
- Conclusion: Hand function deteriorated in female patients over the five year period. Hand disability (GAT) improved in men while hand impairment remained the same.
- Test Hypothesis: N/A

*11) The structure of an instrument for assessing the effects of assistive devices and altered working methods in women with rheumatoid arthritis [11]: .*

- Background/Hypothesis: Quantify perceived difficulty of daily activities using the Evaluation of Daily Activities Questionnaire (EDAQ), determine whether interventions lead to changes in the difficulty level of certain tasks, and follow changes in the subjects' degree of ability over time with use of assistive devices.
- Methods: 21 women with RA evaluate the perceived difficulty of daily activities with and without the use of assistive devices using the EDAQ.
- Results: 41 items show a significant reduction of difficulty with the use of assistive devices. There was a correlation between easier initial difficulty and the effectiveness of interventions, but difficulty without assistive devices could not predict difficulty with them.
- Conclusion: The EDAQ demonstrated that it's possible to evaluate the effect of using assistive devices on ease of performing daily tasks.
- Test Hypothesis: N/A

*12) Evaluation of Assistive Devices after a Course in Joint Protection [12]: .*

- Background/Hypothesis: This study assessed the costs and effectiveness of assistive devices for women with seropositive rheumatoid arthritis using a Joint Protection education program.
- Methods: 53 women aged 29-65 with seropositive rheumatoid arthritis attended a standardized joint protection course for 13 hours and completed a self-report questionnaire to share which devices they received, which they used and didn't use, and why. Pain during activities while using the devices was visibly measured.
- Results: Participants showed benefits from the joint protection course, assistive devices, and wrist orthosis. 91% of devices were still being used after the study and pain decreased significantly during use.
- Conclusion: 11 of the devices showed potential for increased capacity and ability to work at home, work outside the home, and perform leisure activities with less pain.
- Test Hypothesis: N/A

*13) The immunopathogenesis of seropositive rheumatoid arthritis: from triggering to targeting [9]: .*

- Background/Hypothesis: Therapeutic gloves are commonly used in the management of RA. This paper focused on patients' experience of wearing gloves and their perception of glove design.
- Methods: The researchers utilized an online survey of arthritis patients.
- Results: 80% of patients reported wearing their gloves up to 8 hours a day. Most believed they were effective. Patients reported issues with itchy skin and marks on hands after removal. Feedback was reported on style, design, material, color, and perception while wearing.
- Conclusion: Participants reported symptom improvement during glove wear. This review is helpful in identifying key criteria for the design and engineering of gloves that are both functional & comfortable to wear.
- Test Hypothesis: N/A

*14) Questionnaire to evaluate the effects of assistive devices and altered working methods in women with rheumatoid arthritis [13]: .*

- Background/Hypothesis: The purpose of the study was to detect the reduction in difficulty afforded by the use of assistive devices for individuals with RA.
- Methods: 21 women aged 29-65 answered questions as part of the Evaluation of Daily Activity Questionnaire (EDAQ), which contains 102 items divided into 11 dimensions of daily activities.
- Results: Use of assistive devices led to a reduction of perceived difficulty in 42% of the ratings. Devices such as lever taps, springy scissors, bread knives, and wrist orthosis had the most impact on the dimensions of eating, cooking, and toileting, whereas few effective devices were identified to assist with dressing, washing, cleaning, and mobility outdoors.
- Conclusion: The EDAQ is a useful new approach to determine difficulties in executing daily activities by measuring the areas affected and not affected by interventions.
- Test Hypothesis: N/A

*15) Elastic wrist orthoses: Reduction of pain and increase in grip force for women with rheumatoid arthritis [14]: .*

- Background/Hypothesis: Investigate the effect of wrist orthoses on pain, grip, strength and function.
- Methods: 22 women with seropositive rheumatoid arthritis (mean age 53 years) registered pain experienced using a visual analogue scale for use with and without assistive devices. Grip force at onset pain was measured using an electronic instrument (Grippit) with three types of grips for various ADL situations.
- Results: Pain was decreased by 39%, 42%, and 52%, respectively, for the three ADL situations. Splints provided support and decreased pain in daily activities. Orthoses improved grip force at onset of pain by 26%, 22%, and 29%.

- Conclusion: Application of elastic wrist splints reduces pain during three ADL situations and improves grip force at pain onset.
- Test Hypothesis: N/A

# Appendix B
# Investigational Device Details

You will put the details of your investigational device here.

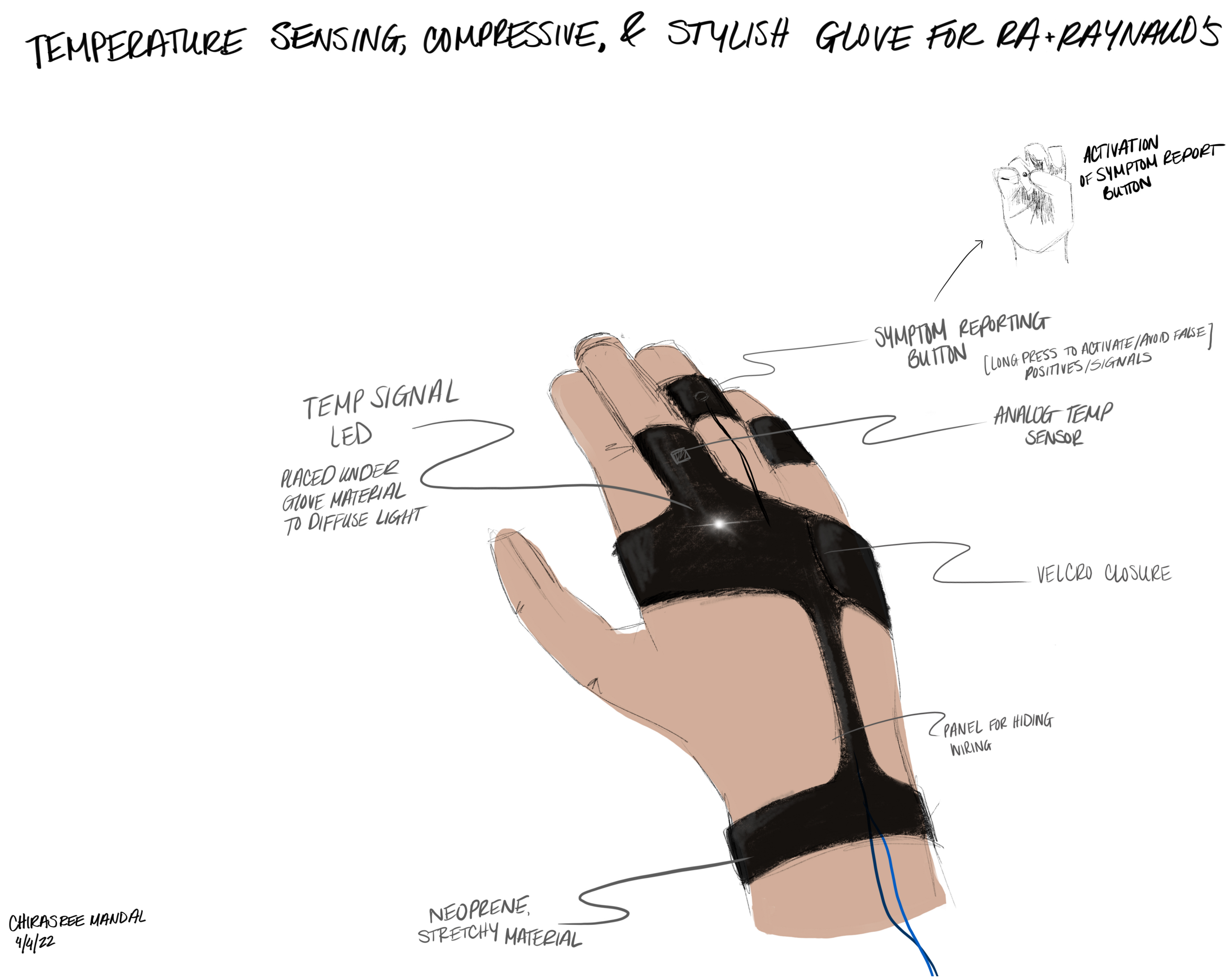


Fig. 11. Physical prototype sketch

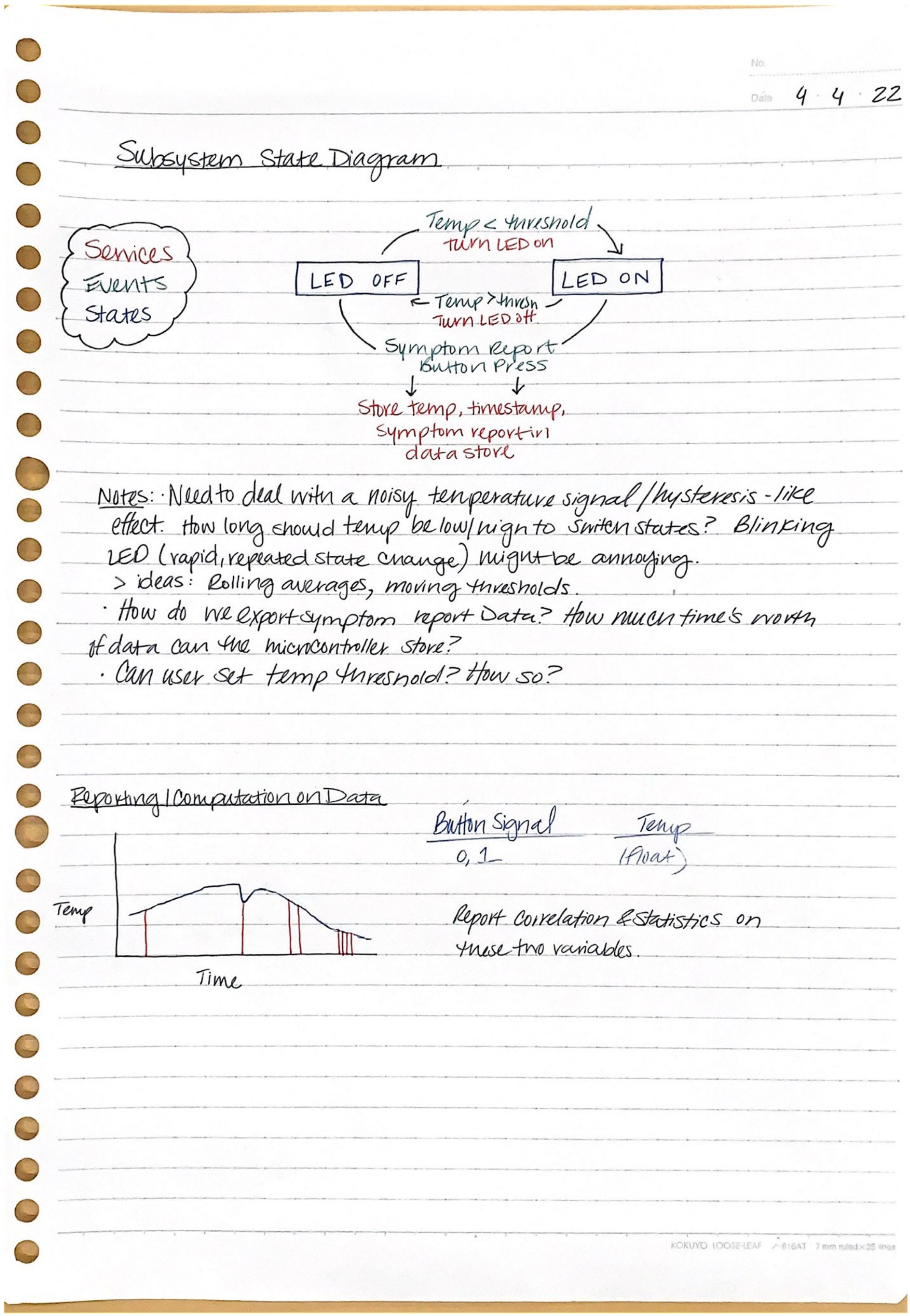


Fig. 12. Subsystem State Diagram

# Appendix C
# Device Arduino Code

```
/*
 * Adapted from:
 *    Professor Hannah Stuart's code for Upper-Limb Prosthesis Design
 *    Temperature sensing code adapted from Adafruit: https://learn.adafruit.com/tmp36-temperature-sensor/using-a-temp-sensor
 *    Adafruit NeoPixel Library
 * Authors:
 * Chirasree Mandal
 * Sneh Jandial
 * April 2022
 */

#include <Adafruit_NeoPixel.h>
#ifdef __AVR__
 #include <avr/power.h> // Required for 16 MHz Adafruit Trinket
#endif

// Which pin on the Arduino is connected to the NeoPixels?
#define NPPIN        8 // On Trinket or Gemma, suggest changing this to 1

// How many NeoPixels are attached to the Arduino?
#define NUMPIXELS 1
#define PIXEL_INDEX 0 //neopixels are 0 indexed

Adafruit_NeoPixel pixels(NUMPIXELS, NPPIN, NEO_GRB + NEO_KHZ800);

#define PIXDELAY 50 // Time (in milliseconds) to pause between pixels

// Define variables ------------------------------------------------------------
//TMP36 Pin Variables
/* the analog pin the TMP36's Vout (sense) pin is connected to
* the resolution is 10 mV / degree centigrade with a
* 500 mV offset to allow for negative temperatures */
#define TMP A10
//Define lower threshold for temperature in Fahrenheit
#define LTMP 69
#define FSR A9
#define DELAY 100



// TEMP RELATED VARS
const int TLEN = 25;
bool lowTempState = 0;
float voltage = 0.0;
float temperatureC = 0.0;
float temperatureF = 0.0;
```

```
float avgTemperatureF = 0.0;
float maxTempRange = 100.0;
//initialize a data queue
int tempData[TLEN];

//data queue index
int tdi = 0;


// FSR related vars
int FSRvalue = 0;
int thresHIGH = 100;
int thresMID = 50;
int thresLOW = 25;
int fsrThresh = thresMID;
int forceSignal = 0;

/*
 * setup() - this function runs once when you turn your Arduino on
 * We initialize the serial connection with the computer
 */
void setup()
{
  Serial.begin(9600);  //Start the serial connection with the computer
                       //to view the result open the serial monitor
  for (int i = 0; i < TLEN; i++) {
    tempData[i] = 75.0;
   }
  pixels.begin(); // INITIALIZE NeoPixel strip object (REQUIRED)
}

/*
 *  fsrEventChecker() - reads FSR pin and sets forceSignal accordingly.
 */
void fsrEventChecker() {
  FSRvalue = analogRead(FSR);
  //Serial.println(FSRvalue);
  switch (forceSignal) {
    case 0 :
      if (FSRvalue > thresMID) {
        forceSignal = 1;
      }
      break;
    case 1 :
      if (FSRvalue > thresHIGH) {
        forceSignal = 2;
```

```
      } else if (FSRvalue < thresLOW) {
        forceSignal = 0;
      }
      break;
    case 2 :
      if (FSRvalue < thresMID) {
        forceSignal = 1;
      }
      break;
  }
}

void updateTDI() {
  tdi++;
  tdi = tdi % TLEN;
}

float averageTempRead() {
  float total = 0.0;
  for (int j = 0; j < TLEN; j++) {
    total += tempData[j];
  }
  return total / TLEN;
}

/*
 * tempEventChecker() - this function reads the temperature sensor via TMP
 * and updates voltage, temperatureC, temperatureF, and lowTempState accordingly
 */
void tempEventChecker() {
  //getting the voltage reading from the temperature sensor
  int tempRead = analogRead(TMP);
  //Serial.println(tempRead);
  // converting that reading to voltage, for 3.3v arduino use 3.3
  voltage = tempRead * 3.3;
  voltage /= 1024.0;
  //Serial.println(voltage);

  // now print out the temperature
  temperatureC = (voltage - 0.5) * 100;  //converting from 10 mv per degree wit 500 mV offset

                                          //to degrees ((voltage - 500mV) times 100)
   // now convert to Fahrenheit
   temperatureF = (temperatureC * 9.0 / 5.0) + 32.0;
   tempData[tdi] = temperatureF;
   avgTemperatureF = averageTempRead();
```

```
  updateTDI();
   //Serial.println(" degrees F");
  lowTempState = avgTemperatureF < LTMP;
}

/*
 * temp2Color - checks temperatureF and returns a uin32_t (via call to pixels.Color()) accordingly
 */
uint32_t temp2Color() {
  float intensity = temperatureF / maxTempRange;
  int blueVal =  (1 - intensity) * 255;
  int greenVal = 10 * lowTempState;
  return pixels.Color(0, greenVal, blueVal);
}

uint32_t temp2ColorGradient() {
  uint32_t retColor = pixels.Color(0, 100, 100); //default color
  int tempRange = map(avgTemperatureF, 20, 100, 17, 1);
  switch (tempRange) {
    case 1:
      retColor = pixels.Color(112, 191, 30);
      break;
    case 2:
      retColor = pixels.Color(112, 191, 112);
      break;
    case 3:
      retColor = pixels.Color(75, 191, 135);
      break;
    case 4:
      retColor = pixels.Color(75, 191, 150);
      break;
    case 5:
      retColor = pixels.Color(30, 191, 165);
      break;
    case 6:
      retColor = pixels.Color(30, 191, 191);
      break;
    case 7:
      retColor = pixels.Color(30, 172, 191);
      break;
    case 8:
      retColor = pixels.Color(30, 150, 191);
      break;
    case 9:
      retColor = pixels.Color(30, 135, 191);
      break;
```

```
    case 10:
      retColor = pixels.Color(30, 112, 191);
      break;
    case 11:
      retColor = pixels.Color(105, 75, 191);
      break;
    case 12:
      retColor = pixels.Color(135, 75, 191);
      break;
    case 13:
      retColor = pixels.Color(165, 45, 191);
      break;
    case 14:
      retColor = pixels.Color(191, 75, 180);
      break;
    case 15:
      retColor = pixels.Color(191, 30, 172);
      break;
    case 16:
      retColor = pixels.Color(191, 30, 150);
      break;
    case 17:
      retColor = pixels.Color(191, 60, 105);
      break;
    default:
      retColor = pixels.Color(100, 100, 100);
      break;
  }
  return retColor;
}

void loop()
{
  pixels.clear(); // Set all pixel colors to 'off'

  tempEventChecker();
  Serial.print("Temperature:"); Serial.println(avgTemperatureF);
  fsrEventChecker();
  pixels.setPixelColor(PIXEL_INDEX, temp2ColorGradient());

  switch (forceSignal) {
    case 1:
      pixels.setPixelColor(PIXEL_INDEX, pixels.Color(25,19,20));
      break;
    case 2:
      pixels.setPixelColor(PIXEL_INDEX, pixels.Color(20, 0, 0));
```

```
      retColor = pixels.Color(135, 75, 191);
      break;
    case 13:
      retColor = pixels.Color(165, 45, 191);
      break;
    case 14:
      retColor = pixels.Color(191, 75, 180);
      break;
    case 15:
      retColor = pixels.Color(191, 30, 172);
      break;
    case 16:
      retColor = pixels.Color(191, 30, 150);
      break;
    case 17:
      retColor = pixels.Color(191, 60, 105);
      break;
    default:
      retColor = pixels.Color(100, 100, 100);
      break;
  }
  return retColor;
}

void loop()
{
  pixels.clear(); // Set all pixel colors to 'off'

  tempEventChecker();
  Serial.print("Temperature:"); Serial.println(avgTemperatureF);
  fsrEventChecker();
  pixels.setPixelColor(PIXEL_INDEX, temp2ColorGradient());

  switch (forceSignal) {
    case 1:
      pixels.setPixelColor(PIXEL_INDEX, pixels.Color(25,19,20));
      break;
    case 2:
      pixels.setPixelColor(PIXEL_INDEX, pixels.Color(20, 0, 0));
      break;
     default:
      break;
  }

 pixels.show();   // Send the updated pixel colors to the hardware.
 delay(DELAY);
}
```