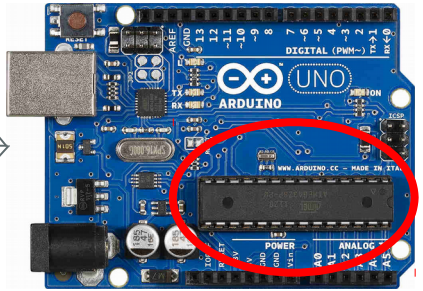
AutoGoni ©

Presented by
BIEN 4280 Class

Course Context

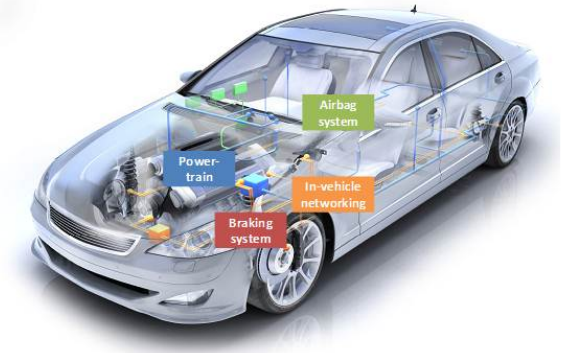
µC/OS-II
The Real-Time Kernel

What is a microcontroller?



What is an embedded system?

What is real-time operating system (RTOS)?



http://www.learnembedded.com/embedded-systems-face-tomorrow/

Product Challenge

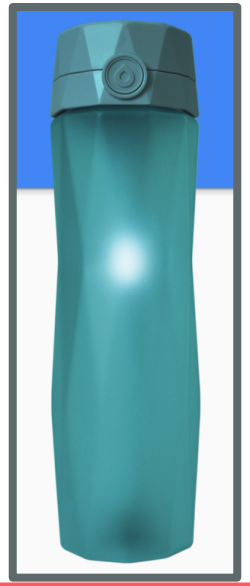
Project Timeline: 16 Weeks

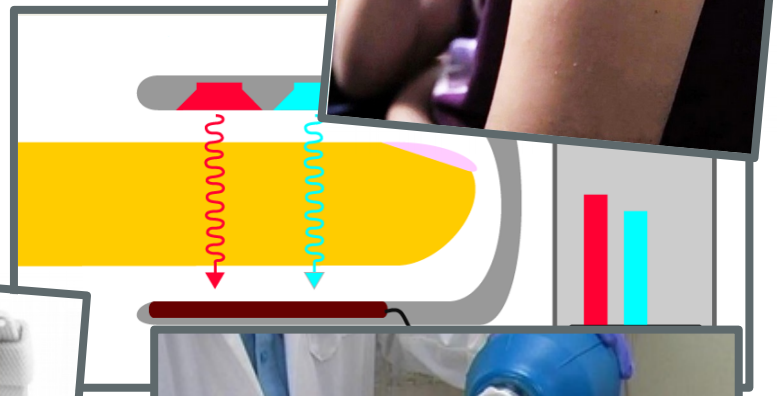
Role	Team Lead
Overall Team Lead	David Vitale
Software Lead	Paul Dang
Server Hardware Lead	Ben Durette
Documentation Lead	Emmali Hanson
Customer/User Discovery Lead	Justin Hauter
Safety Team Lead	JP Rivera
V&V Team Lead	Gleb Sklyr
General Hardware Lead	Jalen Battle
Server Software Lead	Kevin Wright

Product Design Project:

-Potential medical device need?

-Idea Pitches

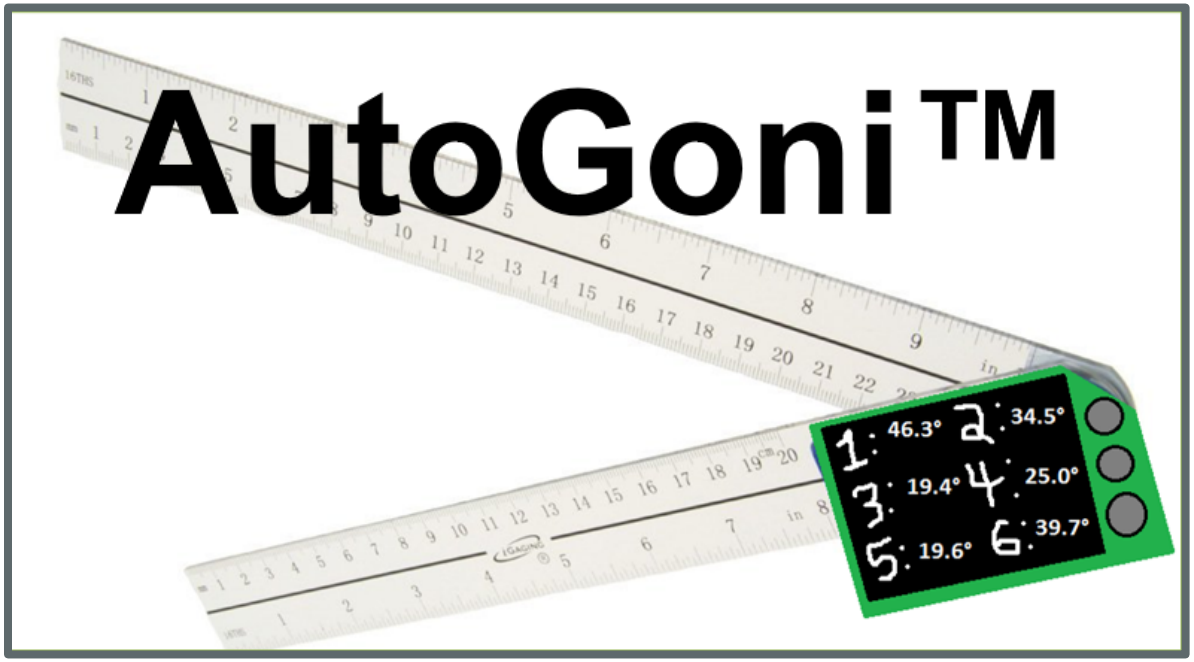




Product Design Project:

-Potential medical device need?

-Idea Pitches



Background and Context

-What is a goniometer?

-What is it used for?

-Who is it used by?

Problem Statement and Hypothesis

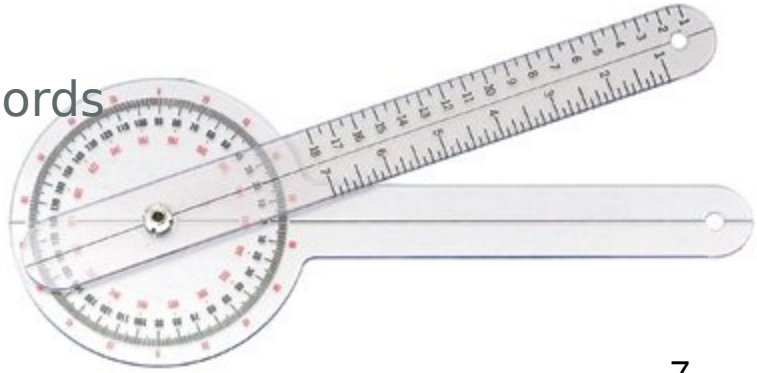
-Manual goniometer can be improved

-There is time to be saved in patient data acquisition for Physical Therapists

-Time to measure angles

-Time to record values

-Time to enter to Electronic Medical Records



Customer Outreach - Interview Phase

- Pre-Planning Customer Discovery
  - Is our original hypothesis supported?
  - What does the customer want vs. need? Is there a need?
- Allowed us to determine the minimum viable product
  - What is a realistic prototype given the parameters, timeline of the project?
- Customer Discovery Interviews
  - Design considerations?
  - Feedback

Customer Outreach Included:

PT Students & Professionals (varying levels of experience)

Customer Voice - Requirement Analysis

Can be tedious…

"there are times when I choose not to measure because I feel it is not that important and I will spend my time doing something else."

[PT interviewee when asked if they always take measurements of the patient]

Can be difficult…

“Sometimes it is difficult to measure because the demarcations are in spaced out intervals”

[PT interviewee when asked about reading measurements]

Different populations can hold different challenges…

“Pediatric patients can be easily distracted and neurological patients (have spasticity based on their injury) may not be cognitively intact. There are a lot of other considerations that need to be addressed while trying to take the goniometric

Customer Pains - Translation to Use Case

Addressing - *Difficult in reading measurements*

-Values are determined and displayed on LCD screen.

Addressing - *Time saved in reading measurement*

-Value does not need to be read. One click replaces reading of values

Values are saved internally and can be displayed / exported to PC in format

*See Appendix for Customer Needs Table with Proposed Solutions

Use Cases

1.Performing goniometric measurements

The physical device should be able to…

2.Device data archival

Once a measurement is displayed on the device …

3.Application of data with software component(s)

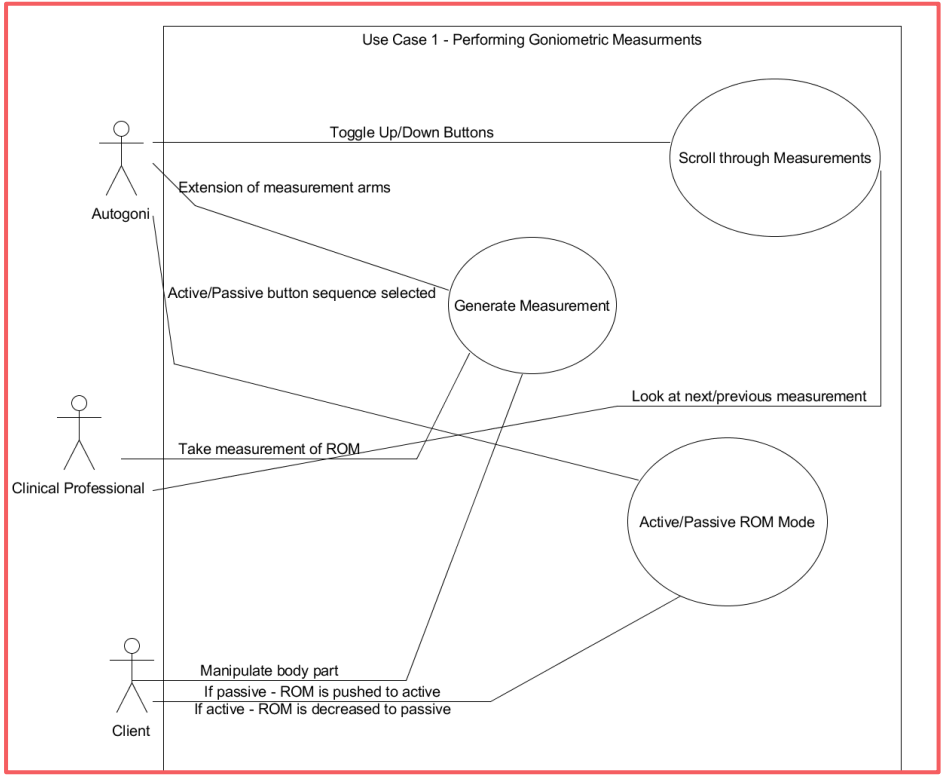
Once the measurements are saved to the device and exported …

Use Case 1 - Performing Goniometric Measurements

*See appendix for use case narrative

Autogoni should be able to:

- Have same basic functionality as a goniometer
- Allow user to scroll through previous measurements
- Allow user to designate passive and active ROM measurements

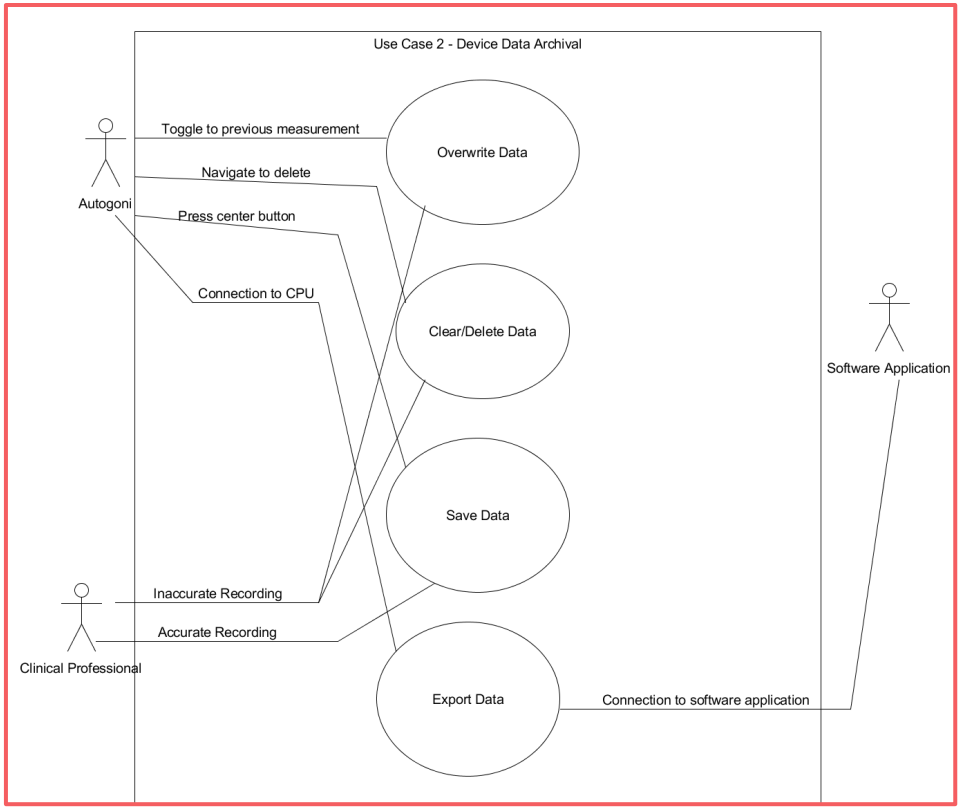


Use Case 2 - Device data archival

*See appendix for use case narrative

Autogoni should be able to:

- Save measurements to device
- Clear/Delete measurement(s)
- Overwrite previously recorded data
- Export measurements to



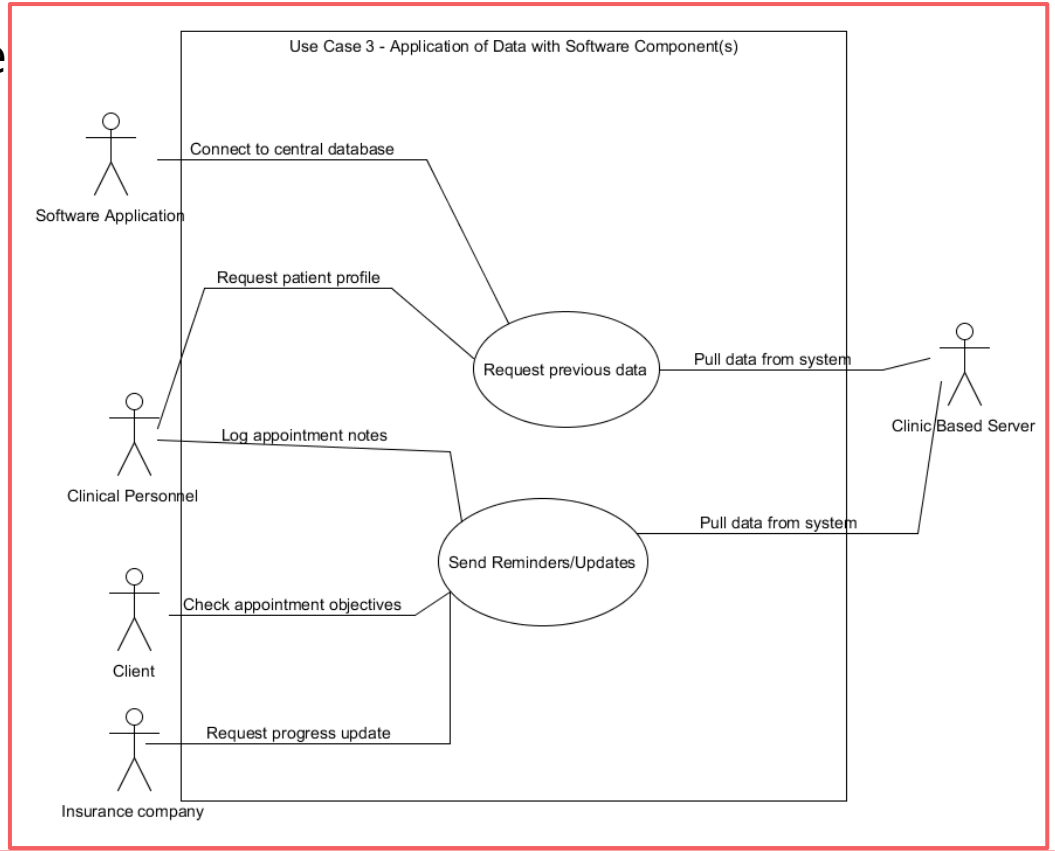
Use Case 3 - Application of data with software component(s)

*See appendix for use case narrative

*Idealized future use case

External software should be able to:

- Store data on accessible location
  - Retrieve previous measurements
  - Show trends in progress
    - Utilize analytics
- Notify clinician/patient
  - Interface with insurance companies?
  - Goals of the week?
  - Appointment times?



Prototype Proposal - with Rationale

Features / Capabilities:

- -Calculates angle automatically
- -Stores up to 64 values in ordered format (Measurement #, Active vs Passive)
- -Exports recorded values via USB to a formatted CSV file

User Interface (Hardware):

- -Rulers used to measure angle
- -Three buttons allow for interaction with the system
- -LCD for easy viewing

User Interface (Software):

- -Up/Down button used to navigate between measurements
- -Center button used to record measurement
- -Press all buttons for export

Demo

Software - Archival Side

Data Storage

Transfers measurements recorded on the Autogoni

Steps

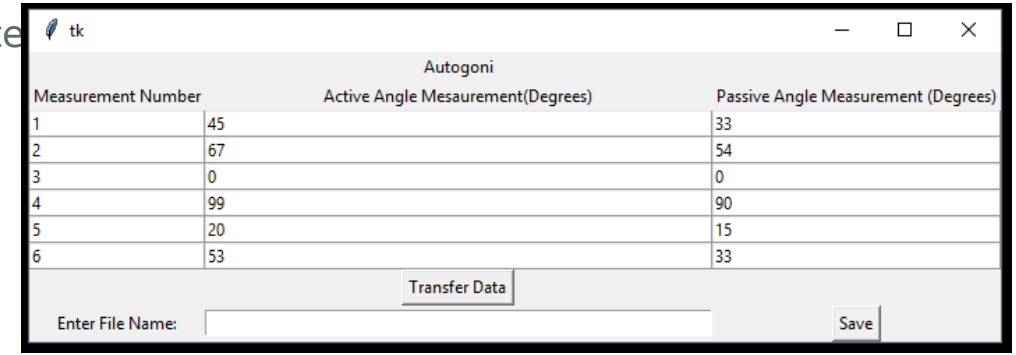
Connect Autogoni to compute

Open Autogoni Application

Verify/Modify measurments

Enter file name

Save data to computer



Software - Embedded Side / Device UI

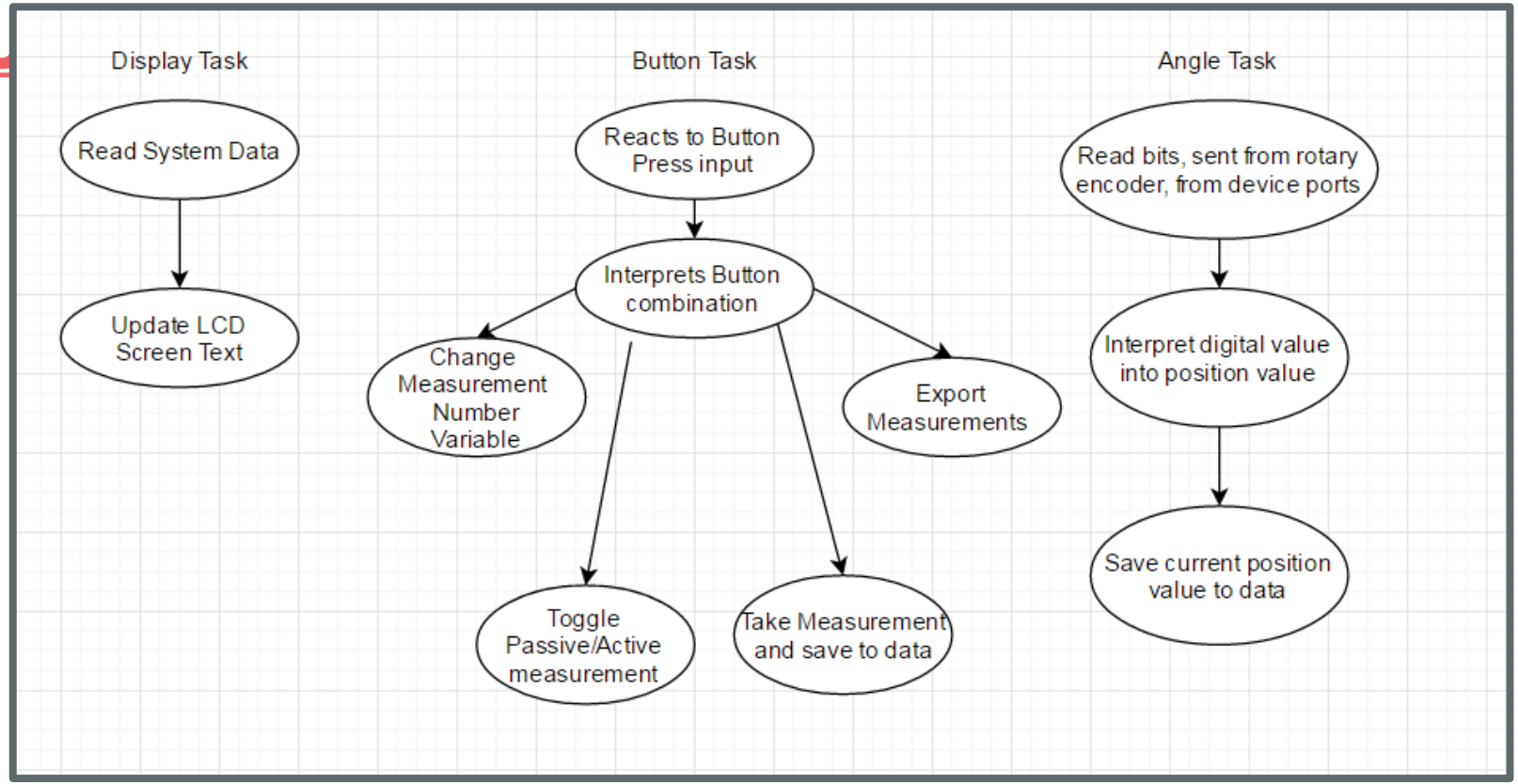
-Developed in C and assembly; running on uC-OS II for real-time event tracking

-Two sets of values are stored on click, for either active or passive measurement

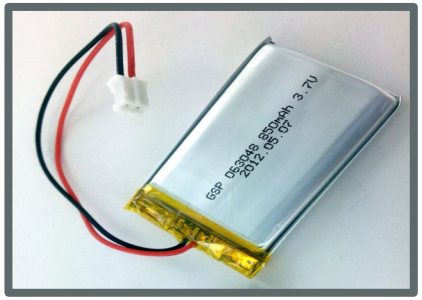
-Using button interface, user is able to scroll through previous measurements

-User is able to overwrite / clear previous values

Software - Embedded Side / Device U

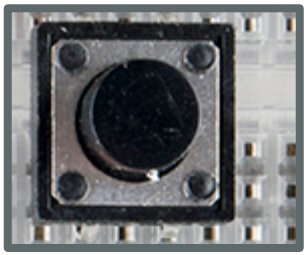


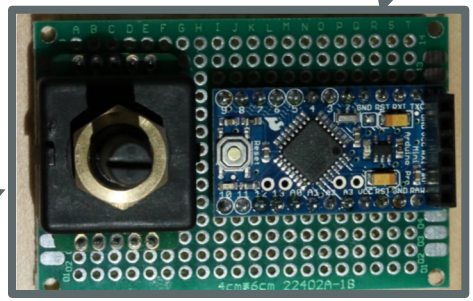
Hardware



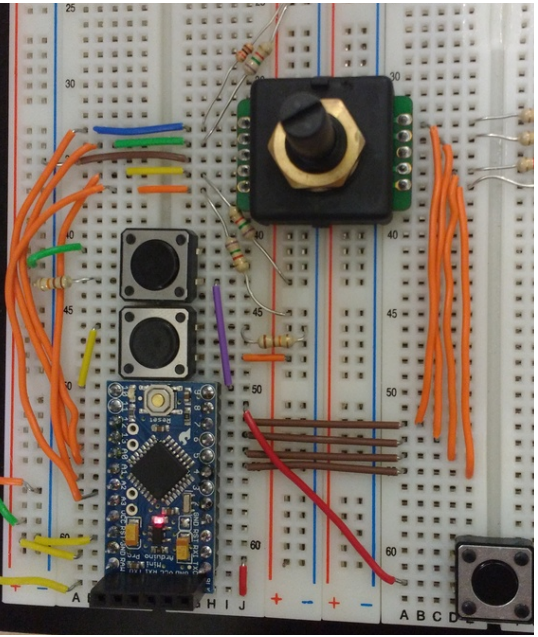
Components:

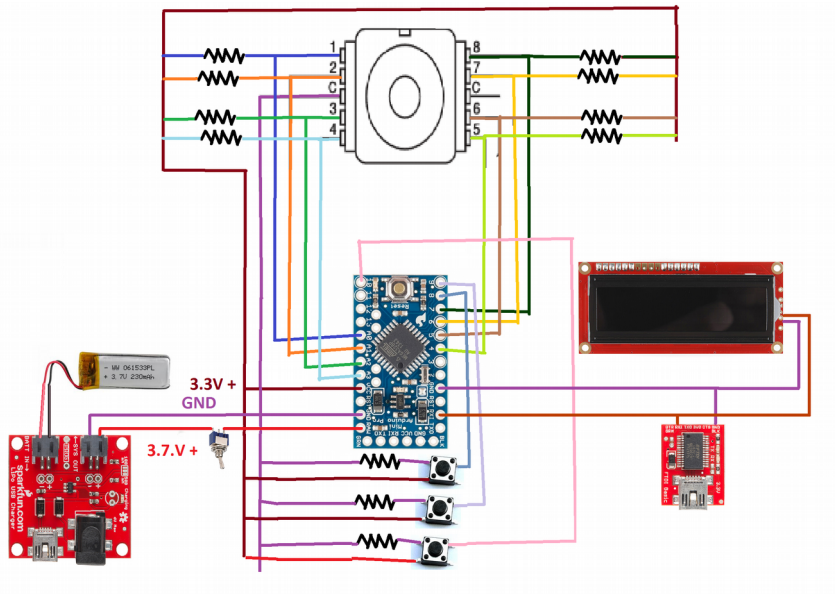
-Arduino Mini	used as microcontroller and for data processing
-6mm tactile buttons	used as user input
-HD44780U LCD II Screen	used for display and for user interaction
-ACE-128 Rotary Encoder	used as hardware interface for angle measurements
-3.3V Battery	used as power source
-2x Rulers	used as goniometer arms for measurement
-Mini-USB adapter	used for interfacing with computer
-USB to mini-USB cable	used for serial transmission and charging

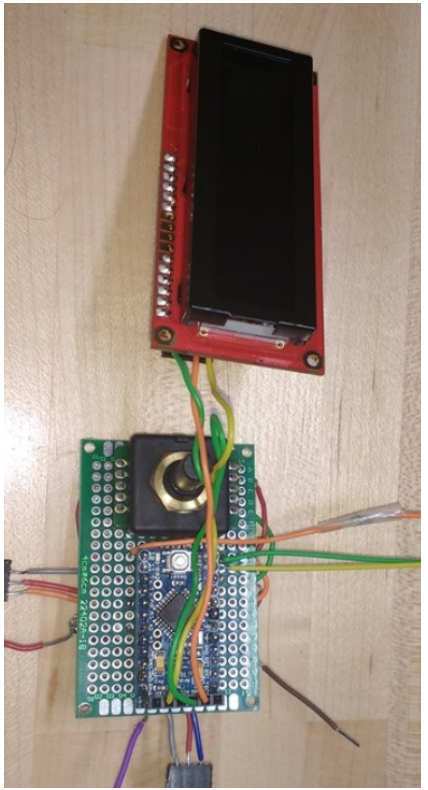




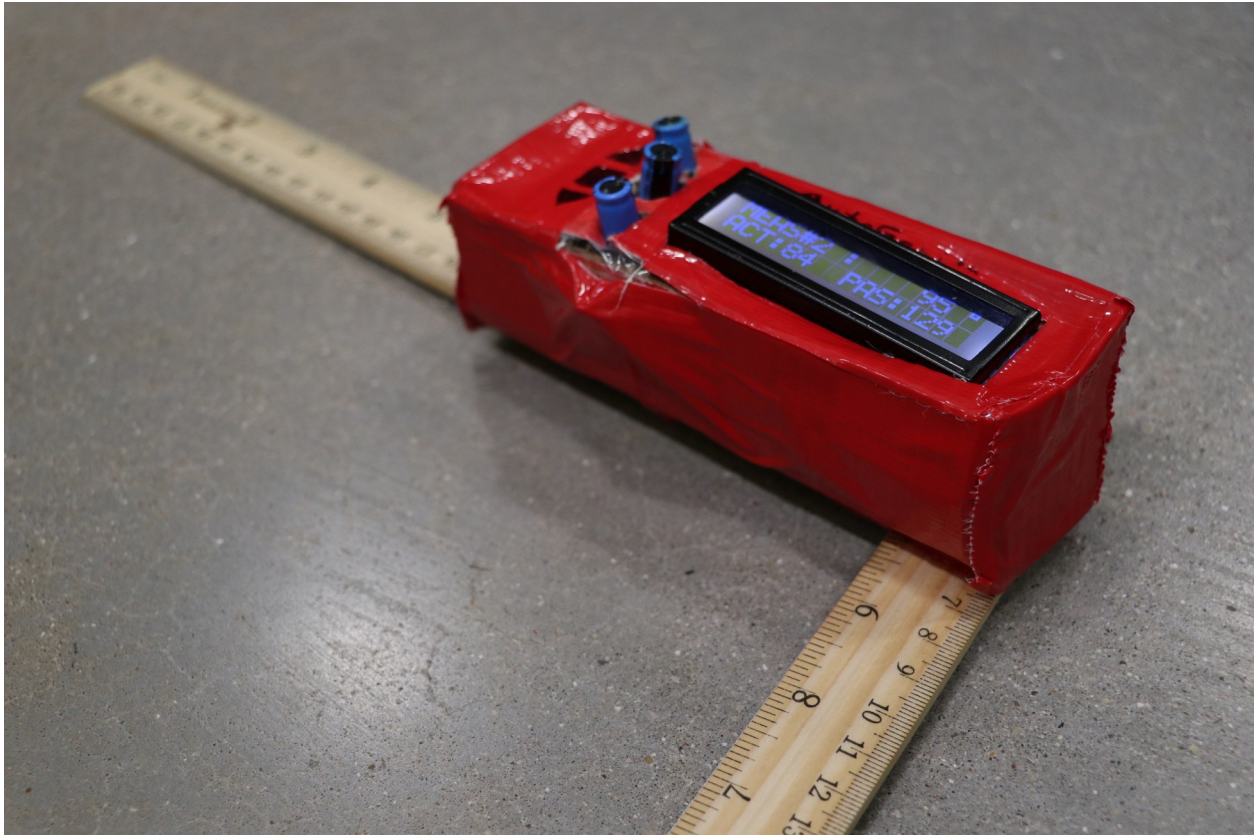
Prototyping Process







Assembled Prototype



Testing

- “Did we build what the customer wanted?”
  - Customer feedback on the prototype
  - Comparison to existing manual goniometer

- “Did we build what we intended to build?”
  - Automated full Range of Motion test bench in Py

Product Verification Summary

#	Document	Section	metric	Acceptable range	Ideal value/range	Actual value/range	pass/fail
1	System Specification	3.3.3	Angle measurement error	3 degrees	0 degrees	2 - 5 degrees	fail
2	System Specification	3.1.1.1.1	Ease of navigating GUI	68 min on SUS	100 SUS	70 SUS	pass
3	System Specification	3.1.1.2	Ergonomic operation	Existing goniometer <=	Existing goniometer <	Existing goniometer ==	pass
4	System Specification	3.1.1.1.2	Time of operation	Existing goniometer >	Existing goniometer >>	Existing goniometer <=	fail
5	System Specification	3.3.4	Precision variation PT-PT	5 degrees' max	0 degrees	N/A	N/A

Documentation

Three main specification documents

- System
- Hardware
- Software

Each document details requirements that the device needs to meet

Requirements are used in testing and final results are detailed in testing document

- All specifics are considered and outlined
- Scales and limits are given for appropriate requirements

Everything is detailed and thought through here so the goals of the

Safety & Failure Mode Effects Analysis (FMEA)

The safety team looked at the potential failure modes, and hazards associated with the hardware and software. Developed a mitigation plan for any hazards that occur in the device.

Occurrence - how often?

Severity - how bad?

Detection - before an error occurs

RPN - Risk Priority number

Future Possibilities

Future capabilities

- Integration with established clinic software
- Stand alone product for smaller applications
- Future market research

Autogoni ©
Medical Record System

Conclusion

- Idea Selection
- Customer outreach
- Prototype proposal
- Software
  - AutoGoni side
  - Archive side
- Hardware
- Verification
- Safety

Acknowledgements

-Dr. Scheidt and Richard Schroeder (Advisors)

-Jeff Wilkens (MUPT Department)

-Elizabeth Zierke (Athletico)

-Albojay Deacon, Corrie Gustin, Casey Houlihan, Jennifer Burke, Abigail Teofanovic, Michelle Naumen and Mrs. Durette (Interviewees)

Questions?

Appendix

Use Case Narrative for use case 1 - Performing Goniometric Measurements

Nominal flow of events:

This use case occurs when a patient would enter a clinic for any type of care (rehabilitative, complaint of pain, etc…). The Autogoni would then be utilized like a goniometer in that the PT would generate and record measurements in order to serve as a baseline value for the insurance company (if they were providing co-payment) or for the PT's use (to provide a targeted improvement plan). During the course of measurement, the PT may want to specify different measurements (active vs. passive), or review measurements from earlier in the measurement process.

Exceptional flow of events:

An exceptional flow of the events may occur if a patient is in the middle of an appointment (after measurements have already been collected) and begins to experience a sudden tightening of a given muscle. The PT would then be called into action to startup the Autogoni and take another set of measurements, possibly utilizing both active and passive measurements. Given the PT had already ported their measurements to an external software application - this interruption in the appointment could be handled gracefully by the Autogoni.

Use Case Narrative for use case 2 - Device data archival

Nominal flow of events:

This use case occurs when a PT has lined up the patient's extremity to the correct ROM and wishes to record the angle value. The PT would simply press the center circle button, saving the value they have displayed on the screen. The PT may also feel the need to delete measurements, overwrite a previous measurement, all of which can be accomplished by selecting the correct sequencing of the buttons. Finally, the patient will wish to export the data to a software application for storage - this will be accomplished by connecting the device via serial port to a CPU.

Exceptional flow of events:

An exceptional flow of the events may occur if for whatever reason, the system reads in garbage values from the Autogoni. In this instance, the PT would need to delete the previously recorded values in the Autogoni, possibly powercycle the device, and quickly retake the measurements running through the same work flow as the nominal flow of events describes. If this situation were to occur, the PT may or may not choose to forgo measurements given, they had already spent valuable time taking measurements in the beginning of the appointment.

Use Case Narrative for use case 3 - Application of data with software component(s)

Nominal flow of events:

This use case occurs when a PT has uploaded the patient data to their system's database and may wish to send it to a central electronic medical record (EMR) system for further application. Although none of the functionality has been created, in theory, the data could be utilized to show trends in patient data, utilize analytics, or provide notifications to any of the groups involved in payment for the patients' treatment (insurance groups included).

Exceptional flow of events:

An exceptional flow of the events may occur if for whatever reason, a patient's place of employment is refuses to assist in payment of a rehabilitation therapy program because they no longer see data to support it. The data analysis that had been performed on the patient's database (stored in a larger EMR system) could be utilized to convince the employer that in fact the patient is still on track in their treatment plan and can save them more money, if they receive appropriate treatment versus if they continue to miss work due to pain from the initial injury.

Customer Needs Table

Customer Needs	Proposed Solution
1. Speed of measurements	Values exported direct to software application
2. Difficulty in reading measurements	Values displayed on LCD screen
3. Simple interface	Select a centrally located button to export data
4. Further application of archived data	Create propeitarity database that can be paired with existing products
5. Flexibility in data recording	Allow user to overwrite incorrect data