Medical Device Tracking System

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BACKGROUND

Stryker Corporation is a medical device technology company that is looking for a system to determine the end of lifetime of one of their partially reusable medical devices.

These medical devices can be simple tools with no moving parts or complex devices that include bearings, bushings, gears, and more. The devices can be exposed to bodily fluids, harsh heat and steam during sterilization, and heavy vibration.

The team has researched different available technologies and has decided to work on developing three systems: mechanical, serialization, and thermal monitoring to determine the end of lifetime.

PROBLEM STATEMENT

"Stryker is looking for a method of tracking a medical device to determine its end of life and when it needs to be replaced. These devices are semi-durable and require certain parts to be replaced after approximately 50-100 uses. This tracking method must be able to withstand the conditions of a surgical environment as well as being run through an autoclave for sanitation.

REQUIRMENTS

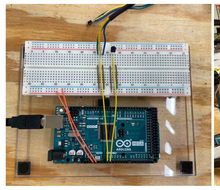
- ❑ Must be able to withstand autoclave conditions.
  - Temperatures up to 230 degrees Fahrenheit.
  - Put the prototype in an autoclave at high temperature and confirm that it still works afterwards
- ❑ The technology must be water resistant.
  - Over the course of an operation, the device could encounter several different types of fluids.
  - Making sure the device can withstand full submersion without failure will identify any issues.
- ❑ The current dimensions and profile of the bur guard or other devices must be maintained.
  - Any applicable technology or other hardware must fit within a 3 mm thickness of device's wall.
  - Changes made to the profile could cause compatibility issues with and cause unforeseen issues.
  - Use CAD software to determine fits and model so that the system fits inside the bur guard.
- ❑ Process should be able to accurately determine the end of life of a bur guard or other devices.
  - Design should be able to alert the users when the device is approaching/has reached end of life accurately to limit the waste.
  - Structured testing plans and life cycle test must be run to insure reliability and consistency.

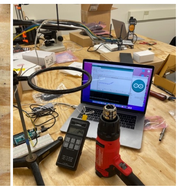
CONCEPTS & EXPERIMENTATION

The deliverable for this project is three different proof of concepts that each give Stryker an in-depth analysis as to what is possible through different methodologies. These three different methodologies are monitoring a device's temperature, serializing devices, and a mechanical counting solution.

THERMAL MONITORING

- The team decided to build a 5X scale bur guard to develop our proposed solution so that parts and equipment are more manageable.
- The team explored various temperature sensor devices and types and settled on using a one-wire temperature sensor, a DS18B20 sensor.
- To read the sensor, an Arduino Mega was used to collect and process the data.
- Once the temperature sensor reads a preset value, signal will be sent to the operators to no longer use that device.



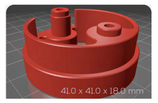


SERIALIZATION

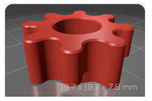
- The team explored 2D barcodes and RFID technology to help track Stryker's surgical equipment
- Laser engraved various QR and PDF417 codes on a stainless-steel rod
- An RFID tag would be placed on the stainless-steel rod
- Database code was created to track the medical equipment after it's been scanned

MECHANICAL

- The team researched different counting mechanisms that were actuated by a manipulator
- Redesigned a ring gear mechanism that is driven by an indexing planetary gear
- 3D printed a design and began working to downsize the dimensions to fit our parameters and desired function
- Calculated the specifications of the gear system using governing equations



Core

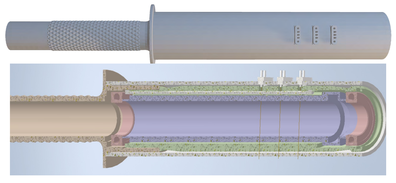


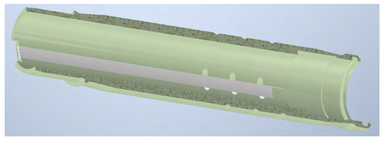
Index Gear

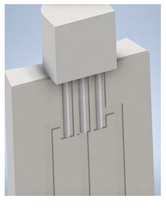
Number Ring

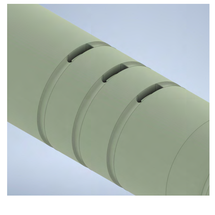
Original Mechanism

FINAL DESIGN



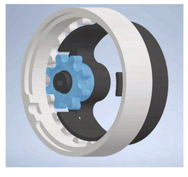


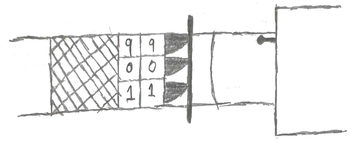




- One Wire DS18B20 Sensor connected to PCB board.
- PCB board assembly slid between the two internal sleeves of the Bur Guard, so temperature sensors are near bearings.
- Copper bands around external of Bur Guard.
- POGO pins on end effector.
- Arduino Mega connected to end effector pins.

- Laser engraved codes juxtaposed with taped on codes from initial prototyping
  - Used CerMark Black Laser Marking Spray to help enhance the image
- RFID Tag Cards melted with a heat gun and shaped into a similar profile to that of the device





- Modified core with fitment piece
- Numbered ring gear
- Modified Index gear
- Manipulator emplaced on end effector

FMEA

Potential Failure Mode and Effect — **Overall Risk Priority Number**

Thermal Monitoring:
- Conductive copper bands corrode causing a loss of electrical connection. (RPN=21)
- Sensors falling off bearings causing an inaccurate temperature reading. (RPN=96) — **277**
- Losing connection between wires and temperature sensor causing an undetectable temperature reading. (RPN=160)

Serialization:
- RFID tag is unable to communicate between the Reader and Excel Spreadsheet due to high frequency in the OR. (RPN=84)
- Epoxy isn't biocompatible or strong enough to last 50-100 Autoclave systems. (RPN=96) — **362**
- QR Code is covered with debris from the patient, making the code unable to be read. (RPN= 128)
- Database adds a step in the scrub tech's workflow. (RPN=54)

Mechanical:
- Gear system or manipulator becomes dislodged or fails to stay intact within the designed system, causing the mechanism to lose count and add additional wear to the bearings. — **225**

Pros & Cons

Thermal Monitoring:

Pros
- Most accurate end of life detection
- No extra steps for scrub nurse
- Very customizable and adjustable
- Very versatile and could be implemented in other bearing devices.

Cons
- Uses electrical components
- Very small temperature sensor size
- Complex manufacturing methods and components

Serialization:

Pros
- Database Reliability
- Creates a Unique Identity for Each Device
- Possibility for Custom Solution
- Historical Data Records build into Solution

Cons
- Marking Solution Durability
- Tag Heat Resistance
- Tag/Code Reading Limitations
- Additional Steps for Workflow

Mechanical:

Pros
- Completely mechanical solution
- No human interference
- Relatively inexpensive
- Less external hardware

Cons
- Size constraints (ergonomics)
- Not able to manually reset count