Currently: Lifespan Monitoring for ECG Cables

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THE NEED

- **28.5M+** EMS dispatches/year in US[1], **16%** are due to chest pain[2]
- Defibrillators and electrocardiogram (ECG) cables are used to conduct pre-hospital ECG in emergency medical service (EMS)

Figure 1. a) ECG cable[6], b) Philips MRX saddle bag[7]

- ECG cables endure a variety of stresses during use, including storage in saddle bags

8 Years	2-3 Years	10 min
Defibrillator monitor lifespan[3]	ECG cable lifespan[3]	Time to replace failed cables[3,4]

Receiving a pre-hospital ECG reduces 30-day mortality rates from 8.2% to 7.4%[5]

Table 1. Stakeholders impacted by ECG cable failures

Primary Stakeholders	Secondary Stakeholders
- Biomedical Equipment Technicians - Hospital Risk Department	- Clinical Users - Medical Device Companies - Emergency medical services - Patients

NEED STATEMENT

A way to address ECG cables being used past their lifespan in EMS and hospital settings so that patient care is performed with equipment that operates within manufacturer specifications.

CORE FUNCTIONS

An analysis of current solutions' ability to meet the following core functions is shown in Table 2:

Table 2. Core functions vs. current solutions

Core Functions \ Current Solutions	AED Daily Self Test	Manufacturer Recommended PM	Single-Use Cables	Replace Cables at Failure
Alerts When Replacement is Needed	✗	✗	✓	✓
Detects Premature Cable Degradation	✗	✗	✗	✗
Identify When Cable is Put Into Use	✗	✗	✓	✗

Benchmarking

- No current solutions for lifespan monitoring
- Most common method is replacing at failure
- Masmino Co. has patents to monitor status of SPO2 cables[8,9]
  - Sensor attachment
  - Formulas based on prior number of uses

THE MARKET

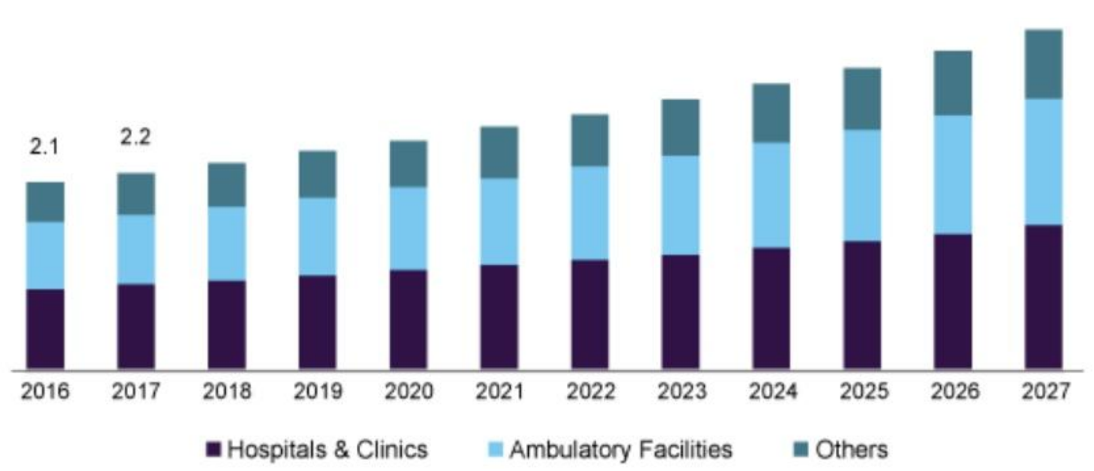

Figure 2. US ECG market size, 2016-2027 (USD Billion)[10]

- ECG **market** share = **$1.6 billion** in 2023[11]
- Primary customer: hospital/EMS purchasing departments

Table 3. Primary customer pains and gains

Pains	Gains
• Unknown equipment status • Risk of procedural failure	• Assured equipment function • Reduced workload

DESIGN AND PROTOTYPE

Design Constraints:

- Monitor wear and tear at cable connector points
  - Majority of cable failures occur at strain reliefs
- Additive design
  - No changes to current cable design or defibrillator software
- Intuitive, simple application method
  - Applied by user in clinical setting

Prototype Iterations:

1. Color degrading material
   - Difficult to engineer material to change color at correct time

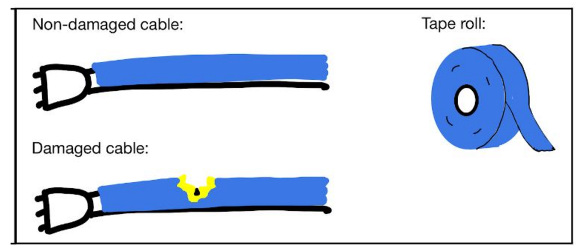

Figure 3. Prototype 1

2. Sacrificial wire coating
   - Application of these materials not suitable for EMS settings

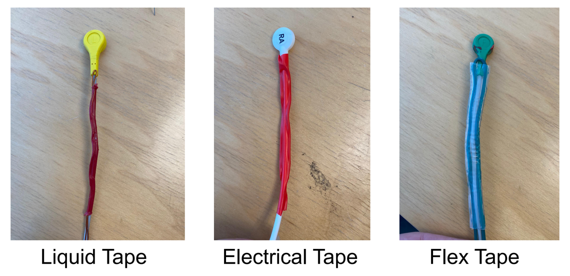

Figure 4. Prototype 2

Final prototype design:

- Sacrificial wire endures stresses put on cables
- Provides audiovisual alert when cable is nearing the end of its lifespan
- Electronic fail-safe on trunk cable connector
- Non-electronic sacrificial wire on lead end

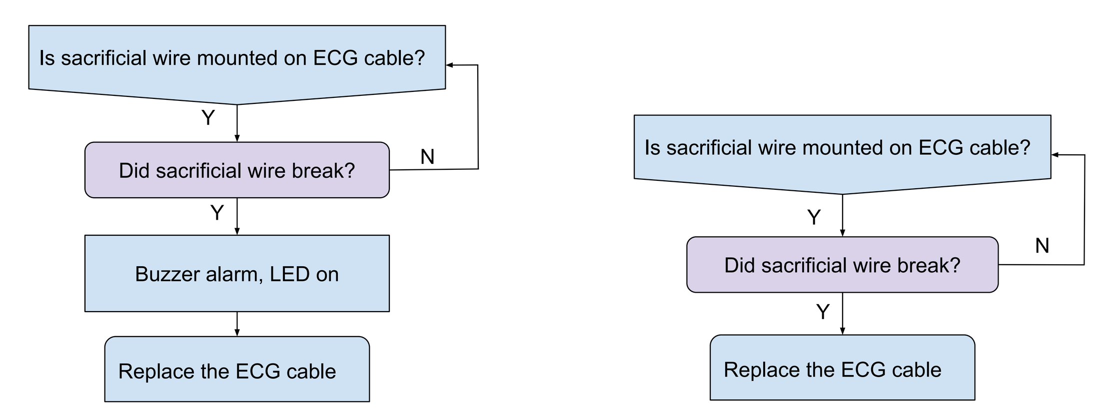

Figure 5. EMS technician maintenance flowchart

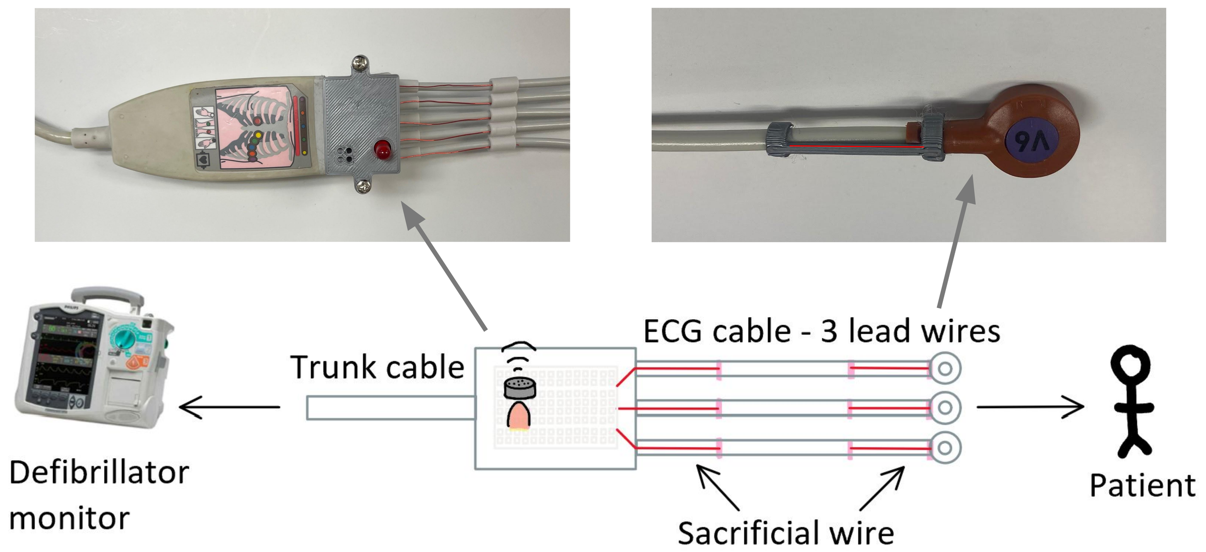

Figure 6. Final prototype features and set-up

DESIGN TESTING

- Designed cable failure test to determine which solid wire gauge will break (24,26,28,30,32)
- Philips testing standard
  - Motor speed: **30 cycles/min**
  - Tension: **1.2lbs**
  - ECG cable guaranteed to survive **5000X** flex at **45 degrees** in each direction

Based on our testing criteria, we selected the 30 gauge as the sacrificial wire.

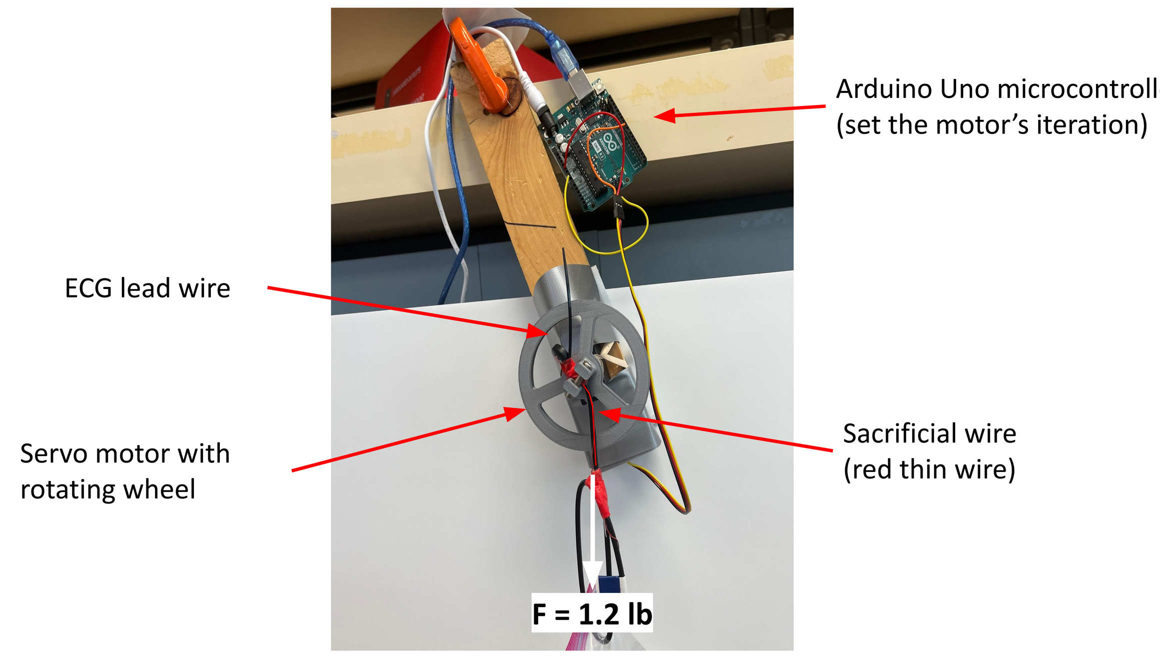

Figure 7. Cable failure test

NEXT STEPS

- Improve resting reproducibility
  - More cable failure tests to determine the average number of cycles until the wire breaks
  - Tension test of 135 N
- Improve portability
  - Streamline electronics module in trunk cable design
- Improve user friendliness and comfort
  - Interview users (EMS technicians)
  - Explore methods of device attachment

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References