NeuroPulse: A Device to Preserve Neurological Function During Out-of-Hospital Cardiac Arrest

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Need

User and Problem:

Cardiac arrest is a life-threatening event where the heart stops beating, leading to reduced oxygen circulation, unconsciousness, neurological damage, and potential death. Out-of-Hospital Cardiac Arrest (OHCA) accounts for 350,000 annual incidents with only a 10% survival rate[2]. Remote Ischemic Conditioning (RIC) is a non-invasive technique that involves applying brief, controlled cycles of blood flow restriction and reperfusion to an extremity, triggering protective physiological responses that help preserve cardiac and neurological function. RIC has shown potential in improving neurological outcomes after OHCA. Users include emergency medical service (EMS) personnel, such as paramedics and emergency physicians, who require a simple, portable, and efficient device to administer RIC during OHCA without disrupting their standard workflow.

Limitations in Existing Solutions:

There are no current solutions on the market. Devices such as CellAegis AutoRIC and Life Cuff Technologies were discontinued due to lack of funding and research validation.

Objective:

Design an adjustable, portable, and user-friendly RIC device for EMS to use in real-world settings, enabling researchers to evaluate the efficacy of RIC in improving neurological outcomes post-OHCA.

Design Inputs

Constraints:

- 34 weeks to build solution
- Budget and resources
- Safety standards compliant
- Portable size and lightweight
- Self-contained battery

Requirements:

- Pressure range: 126–146 mmHg
- Ease of Use Setup time: <30 seconds
- Active life: >40 minutes (1 cycle)
- Robustness: Drop resistant
- Adaptability: Accommodate 95th percentile of calf sizes
- Ease of sanitation: withstand multiple cleanings
- Feedback system: 100% cycle accuracy

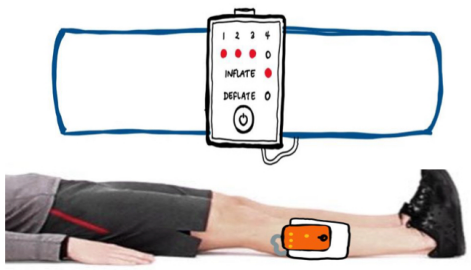
Prototype

Assembled/Intended Use:

The NeuroPulse RIC device inflates and deflates a BP cuff to induce ischemia-reperfusion cycles.

Component Detail:

- Pump: Mini 12V DC Air Pump (3.2 LPM, max 420 mmHg)
- Solenoid Valve: High-flow miniature solenoid
- Pressure Sensor: 0–40 kPa range
- Feedback Display: Indicates RIC cycle stages
- Power: Rechargeable 12V Li-ion battery
- Housing: 3D-printed case with sealant



Regulatory Pathway

Class II Medical Device: 510(k) Premarket Modification

Substantial Equivalence: Pneumatic Compression Devices (Ex: for Lymphedema)

Testing: Biocompatibility, Human factors/usability/risk analysis, Performance, Post-market surveillance*****

Timeline: 12-18 months

Expense Category	Regulation	Cost
FDA Submission Fee	Yearly registration fee	$9,280
QMS Certification*	Manufacturing quality management compliance	~$2,000-$5,000 (Including both stage 1 and 2 audits)
Risk Analysis**	Industry accepted practice for assessing hazards	$1,500
Software Testing***	Software lifecycle management	(Incorporated with QMS audits)
Testing****	Safety of patient use and contact	~$15,000-$25,000
Total		**~$28,500-$38,500**

* ISO 13485:2016 (or QSR, Title 21 CFR Part 820)
** ISO 14971:2019
*** IEC 62304
**** ISO 10993 (Biocompatability), IEC 60601-1/-1-2 (Electrical Safety), IEC 62366 (Usability Testing), ISO 14155 (Clinical Testing)
***** Title 21 CFR Part 803 Medical Device Reporting

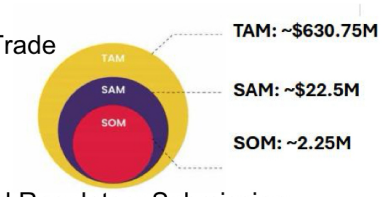
Market & Financial Projections

Market:

- Primary = EMS Agencies, Hospitals, Municipalities
- Secondary = Military, Disaster Units, Training Centers

Market Plan:

- IRB-approved Study and Pilot Programs
- Industry Conferences and Trade Shows
- Regulatory Partnerships



Financial Projections:

- Month 0-18: Prototyping and Regulatory Submission
- Year 2-4: Pilot Programs and Scaling
- Year 5-6: Expanded Market Adoption, B2B and B2G Expansion

Year	Revenue	Devices Sold	Expenses (COGs + R&D + Ops)	Net Profit/Loss
1 (Regulatory + R&D)	$0	0	$48,500	-$48,500
2 (6-month pilot launch)	$100,000	100	$90,000	-$10,000
3 (Pilot expansion)	$630,000	630	$490,000	$140,000
4 (Scaling)	$1.26M	910	$860,000	$400,000
5 (Market Adoption)	$1.8M	1,150	$1,160,000	$640,000

Conclusion and Impact

Accomplishments:

- Developed and verified a portable, user-friendly RIC device.
- Achieved compatibility with existing EMT equipment.

Innovation:

- New RIC delivery for EMS improving patient neurological function

Impact:

- Potential to improve neurological outcomes post-OHCA.
- Supports data collection for further research on RIC efficacy.

Steps forward:

- Rollout device to exemplify efficacy in the greater Philadelphia area
- Seeking additional funding and partners to accelerate development in broadening the market

Acknowledgements:

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References:

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