pIVot Medical Device Market Assessment

Project Name:
pIVot Medical Device, IV Fluid Warmer

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Executive Summary:
In 2018 the U.S. Patient Temperature Management market was valued at $2.64B. $800M was spent on Emergency Medical Services (EMS) patient warming devices. 43% of patients transported via EMS each year have hypothermia (low body temperature) upon arrival to the hospital[1]. Hypothermia is a leading cause of increased mortality rate in trauma patients. Studies show that the earlier you begin managing temperature, the potential for better clinical outcomes increases[1]. After extensive ethnographic research and stakeholder analysis our team chose to explore the area of patient temperature management, specifically tackling the need for a non-invasive way to address heat loss in trauma patients in pre-hospital settings, in order to manage patient body temperature and promote improved clinical outcomes.

Our device, pIVot, achieved this in the form of an IV fluid warmer that incorporates two components: a heated IV bag sleeve for IV fluids and an insulation for the IV drip chamber. There is currently no solution within the EMS market that is universally adopted to manage patient temperature. All available solutions are either too expensive for the limited EMS budget or inefficient in function. In addition, pIVot is applicable in both perioperative and DoD spaces. We believe our device will fill the economic, functional, and clinical gaps in current solutions benefiting patients and the healthcare system at large.

plVot Market Assessment

Technology Overview:

The proposed device will encompass two components: an active warming heated IV bag sleeve and passive warming insulation for the IV drip chamber. The heated sleeve will employ one of the two heating mechanisms: chemical or electrical. For electrical heating, 26 gauge Nichrome wire will be used as the heating element. The nichrome wire generates heat when it is supplied with power, either from a battery or from a wall outlet. For this design, the heating element will initially receive 110 Volts, supplied from a wall outlet. Then, power is supplied to the device using two 9-Volt batteries that are stepped down using resistors to supply 10 Volts to the nichrome wire. The nichrome wire is encased in a thin layer (1-2 mm thick) layer of silicone rubber. The heat is conducted towards the IV fluids. The next layer the heat conducts through is a thin barrier material of conductive nonwoven fabric. Then, the heat conducts into the IV Bag material, and finally into the IV fluids where convection occurs to uniformly heat the IV fluids. On the opposite side of the heating element is a 2 inch thick layer of insulation. The insulation will either be fiberglass or silica aerogel. More experimentation will be done with each material type in the future. This sleeve is secured onto the IV fluid bag to warm fluids while being administered to patients. To prevent heat loss from the fluids in the IV tubing, insulation will be employed to address heat loss from the most critical area, the drip chamber. The drip chamber insulation is made of Polyethylene foam.

Summary of Clinical Need:

Hypothermia is a leading cause of increase in mortality rate of trauma patients. Studies indicate that there is a proportional relationship between decreased temperature and increase in the mortality rate of the patient upon arrival of emergency medical services[3]. Also, studies further demonstrate that the earlier you begin managing temperature the potential for better clinical outcomes increases[3]. 43% of EMS patients are hypothermic upon arrival to a hospital.

Treatment of patients who arrive at hospitals hypothermic cost hospitals an average of $2500-$7000 more than patients who arrive within the normothermic range[2]. Currently there is a lack of an effective EMS temperature management solution that would reduce the potential for hypothermia during treatment and transport to the treatment center. There is a clinical need for a non-invasive technology to address heat loss in trauma patients in the pre-hospital setting.

Product Differentiation:

Our device will encompass two components: an active warming heated IV bag sleeve and passive warming insulation for the IV drip chamber. There is currently no solution within the EMS market that is universally used to manage patient temperature. All available solutions are either too expensive for the limited EMS budget or inefficient in function. We believe our device can fill the economic, functional, and clinical gaps in current solutions benefiting patients and the healthcare system at large. Below is a matrix that illustrates the design needs an effective solution would need and how current devices in the market meet those needs as compared to plVot.

	Blanket (Ex. MediWrap, Mylar, cotton, wool)	Heating Pad (Ex. HAWK Warming Grid)	IV Fluid Warmer (Ex. Thermal Angel, QinFlow)	pIVot
Cost (per unit)	$0.69- $20	$25	~$2,000- ~$5,000	**<$100**
Warm-up Time	N/A	<10mins[1]	4°C to 38°C in <1min[2,3]	**22°C to 42°C <5mins**
Contamination Risk	Nonsterile blanket in contact with open wound	Nonsterile pad in contact with open wound	IV fluid contamination while fluids removed from IV bag	**None** (device does not come in direct contact with patient or IV fluids)
Co-dependencies	Requires source of heat (ex. body heat, active warmer, etc.)	Requires additional blanket on patient to seal in heat	Requires specific flowrate to function correctly	**None** (device warms IV fluids independently)
Feedback Mechanism	None	None	Sensor to regulate temperature	**Sensor to regulate temperature**
Power Source	None	Chemical Heating (<4hrs constant heat when activated[4])	Battery Powered (3-5L of fluid[5])	**Chemical Heating, Electrical, Battery Powered**

1. https://www.rescue-essentials.com/hawk-advanced-hypothermia-management-set/
2. https://qinflow.com/Products
3. https://thermalangel.com/documentation/innovative-technology-whats-so-special/
4. https://www.rescue-essentials.com/hawk-warming-grid/
5. https://www.boundtree.com/IV-Drug-Delivery/IV-Warmers/Thermal-Angel-Ultra-Emergency-Pack/p/TA-UEP#:~:text=A%20fully%20charged%20Ultra%20Battery,patient%20(up%20to%2072%20hrs)

Market Considerations

Market Size:

The total U.S. EMS Market was valued at $8.08B in 2018 with a CAGR of 7.2% through year 2026[4]. An estimated 14.6M patients are transported via EMS each year. EMS products by market size begin with Life support and emergency resuscitation having the largest share followed by patient monitoring systems, wound care consumables, patient handling equipment, and infection control supplies[4]. The total market for patient warming devices specifically within the total EMS product market is about 10% giving a value of $800 M. 42% of hospital bound patients become hypothermic at <34C, 23% at <33C, and 13% at <32C[5]. The mortality rate for each of the temperature thresholds are 40%, 69%, and 100% respectively as a direct correlation with hypothermia[5]. Beyond EMS, the U.S. Patient Temperature Management market was valued at $2.64B in 2018 and is estimated to reach $5B by 2026 at a CAGR of 8.5%[1].

Key Players:

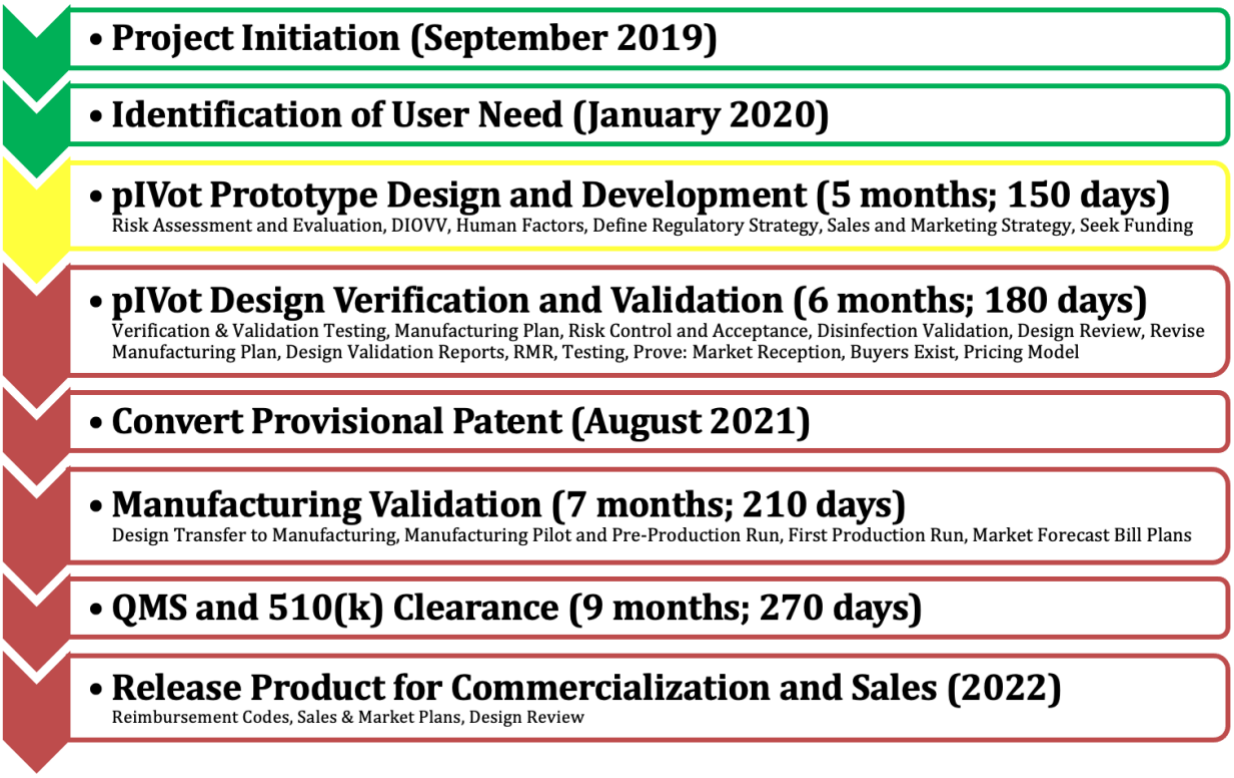
Company	Product
Combat Medical	Hawk Warming Grid
QinFlow	Warrior Blood and Fluid Warmer
Thermal Angel	Thermal Angel Blood and Fluid Warmer
Lifewarmer	Quantum Blood and Fluid Warmer

Other companies within the temperature management market are Becton Dickinson, 3M, Smiths Medical, Zoll Medical, and Medtronic. However neither of these companies have devices in the pre-hospital setting leaving room for innovation and market share. The lack of significant presence by any one product makes it a lucrative market to enter and establish brand loyalty.

IP Landscape

- Currently no technology on the market with similar design
- IP landscape is largely open and ripe for new innovation and will not inhibit our design of our proposed technology
- Majority of relevant patents granted before the 2000's
- Modern IV fluid warmers are expensive and not feasible for use in emergency medical situations that require affordable, portable solutions

Timeline and Key Milestones



Anticipated Budget

Task	Budget
Design Validation (Engineering Bench Testing, Standards Testing, Usability Testing)	$350,000
Quality & Regulatory (GMP, 510(k) submission)	$175,000
Legal Expenses	$150,000
Manufacturing	$200,000
Personnel (3) ($85K/2yrs)	$510,000
Marketing & Sales	$100,000
Commercialization	$150,000
Overhead	$40,000
Total	$2,000,000

Verification and Validation Testing

Testing	Standard
Manufacturing Verification	ISO 17664:2017 ISO 13485
RF/EMC Testing	IEC/EN 61000-4-2 IEC/EN 60601-1-2 ANSI/AAMI ES 60601-1
Packaging Testing	ISTA 2A ISO 14708-1
Human Factors Testing	ISO 13485
Shelf Life Testing	ANSI/AAMI/ISO 11607-1:2006 ASTM F1980-07

Reimbursement Landscape

Our business could benefit from selling our device as a product to a national distributor versus as a service that would require billing codes. Direct sales would be appropriate for companies such as American Medical Response or other large scale EMS providers. If sold as a product and not billed as a service, billing codes will not be needed. However, there are existing CPT and HCPCS codes that reimburse hypothermia related products in the EMS setting. This can serve as a secondary pathway/incentive for hospitals/EMS services to purchase our product. The HCPCS codes are 96360 and 96361 which involve the IV fluid administration set, and the relevant CPT codes are 99.81 which involves treatment of hypothermia and hypothermia related problems.

Clinical and Regulatory Requirements

Our product will involve a Class II 510K submission. This requires multiple steps including preparing our quality team for the FDA's Quality System Inspection. We will prepare an FDA Summary of Safety and Effectiveness Data (SSED) which will comprise data from non-clinical studies (biocompatibility, shelf life, etc.) and clinical studies(if applicable). For any clinical studies, we will adhere to the principles of good clinical practices (GCP) which includes adequate human subject protections (HSP) in order to be compliant with FDA Regulations.

Quality Requirements

Our QMS will follow the ISO 9001 principles in order to document the processes, requirements, and to define roles. Documentation will abide by FDA's 21 CFR 11 Regulations and will indicate the quality policy, procedure, work instructions, and quality manuals. Standard Operating Procedures (SOPs) will be essential to maintain an efficient, effective and safe work environment for employees. Internal audits will be conducted to ensure proper working of the QMS system. If nonconformities occur, corrective actions will take place and results will be reviewed. In addition to this, preventative actions will also be taken by determining possible errors and suggesting measures to prevent them

Operations Requirements

Our operation requirements include a series of actions and capabilities that will improve the results of our product. We will create a process map to depict the workflow required to use the device within an EMS setting.

Accounting Requirements

We will create a balance sheet to track sales as well as the costs involved in production including R&D and manufacturing. We will run an analysis of future expenditures.

Risk Factors

The most significant unanswered question is with the selection of our heating element. We would require additional testing for an electrical heating component. Conducting further experiments to prove the chosen heating element can power the pIVot device to the desired temperature and remain at that temperature for X period of time is crucial to the product's success. Key risks to success are pending approval of our patent- a copy-cat device is not out of reach. Our go-to-market strategy will need to be swift to create and capitalize on brand loyalty.

Exit Strategy

We anticipate exit via outright acquisition by larger players within the patient temperature management market, such as 3M, Becton-Dickinson, Medtronic, Smith & Nephew, etc. Reasoning for acquisition is the threat to gaining substantial market share from these larger companies if our anticipated brand loyalty is achieved. None of these larger players have a product that is considered the "gold standard" within the EMS market. If exit takes place at year 5, we would see an exit valuation of 12.4X annual recurring revenue, according to the EBITDA medical device acquisition multiple for 2019.

Literature Cited

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2. M. Bukur, A. A. Hadjibashi, E. J. Ley, D. Malinoski, M. Singer, G. Barmparas, D. Margulies, and A. Salim, “Impact of prehospital hypothermia on transfusion requirements and outcomes,” The journal of trauma and acute care surgery, Nov-2012. [Online]. Available: https://www.ncbi.nlm.nih.gov/pubmed/23117380. [Accessed: 24-Apr-2020].
3. R. Perlman, J. Callum, C. Laflamme, H. Tien, B. Nascimento, A. Beckett, and A. Alam, “A recommended early goal-directed management guideline for the prevention of hypothermia-related transfusion, morbidity, and mortality in severely injured trauma patients,” Critical care (London, England), 20-Apr-2016. [Online]. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4837515/. [Accessed: 24-Apr-2020].
4. “Patient Temperature Management Market: Industry Report, 2019-2026,” Patient Temperature Management Market | Industry Report, 2019-2026. [Online]. Available: https://www.grandviewresearch.com/industry-analysis/patient-temperature-management-market. [Accessed: 24-Apr-2020].
5. F. J. C. Haverkamp, G. G. Giesbrecht, and E. C. T. H. Tan, “The prehospital management of hypothermia - An up-to-date overview,” Injury, 04-Nov-2017. [Online]. Available: https://www.sciencedirect.com/science/article/abs/pii/S0020138317307775?via=ihub. [Accessed: 24-Apr-2020].