Project: pIVot

Title: 510(k)

From: [redacted] Biola Ogunfuyi [redacted]

Date: July 19, 2020

INTRODUCTION

Hypothermia is a leading cause of increase in mortality rate of trauma patients. Studies show that there is a proportional relationship between decreased temperature and increase in the mortality rate of the patient upon arrival of emergency medical services. Studies also show that the earlier temperature management begins, the greater the potential for better clinical outcomes increases. 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 and insulated IV tubing. 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. The proposed device will encompass two components: an active warming heated IV bag sleeve and passive warming insulation for the IV drip chamber.

The following is a presentation of the pIVot 510(k) submission.

Medical Device User Fee Cover Sheet *(redacted)*

Table of Contents

SECTION 1: 510(k) COVER LETTER

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center- WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Dear Sir or Madam:

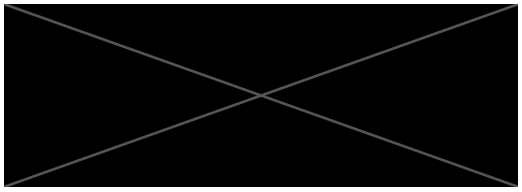
This document contains the information for The Stream Team, pIVot submission for market clearance. In accordance with Section 510(k) of the Federal Food and Drug Cosmetic Act as amended, an in conformance with Title 21 CFR, Part 807, this Pre- market Notification is being submitted at least ninety (90) days prior to the date when The Stream Team proposes to introduce its pIVot device into interstate commerce for commercial distribution. The CD provided with the submission is the official electronic copy of the submission; the eCopy is an exact duplicate of the paper copy. Following contains the regulatory information for the contents of this submission supporting the device's market clearance.

Administration Information

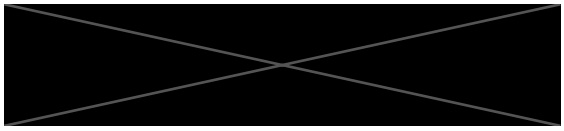
Date of Submission: July 21, 2020

Submission is Completed By: The Stream Team

Application Correspondent:



Submission Sponsor: Stream Team



Device Identification

Type of 510(k) Submission: Traditional

Trade or Proprietary Name: pIVot

Common or Usual Name: IV Fluid Warmer

Regulation Classification:	Warmer, Thermal, Infusion Fluid
Product Code:	LGZ
Class of Device:	Class II
Panel:	General Hospital
Reason for Submission:	New Device
Prior Related Submissions:	No prior submissions for the device

Device and Use of the Device

Table 3A- Principle Factors

Question	Yes	No
Is the device intended for prescription use (21 CFR 801 Subpart D)?		X
Is the device intended for over-the-counter use (21 CFR 807 Subpart C)?	X	
Does the device contain components derived from a tissue or other biologic source?		X
Is the device provided sterile?		X
Is the device a reprocessed single use device?		X
If yes, does this device type require reprocessed validation data?		
Does the device contain a drug?		X
Does the device contain a biologic?		X
Does the device use software?		X
Does the submission include clinical information?	X	
Is the device implanted?		X

All information necessary for a substantial equivalence determination is included herein. Should you require any additional data in order to reach a determination of substantial e uivalence lease do not hesitate to contact me at [redacted] or by email at [redacted]

Sincerely,

[redacted]

SECTION 2: STATEMENT OF INDICATIONS FOR USE

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: July 31, 2021 *See PRA Statement below.*

510(k) Number *(if known)*

Device Name
pIVot

Indications for Use *(Describe)*

pIVot is intended for use for warming intravenous fluids prior and during administration. It is intended to be used by healthcare professionals in hospital, clinics and field environments, to help prevent hypothermia

Type of Use *(Select one or both, as applicable)*
☒ Over-The-Counter (21 CFR 801 Subpart C) ☐ Prescription Use (21 CFR 801 Subpart D)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.
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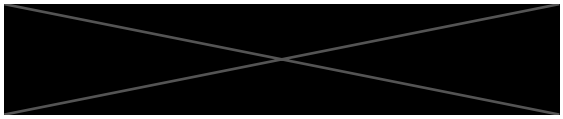
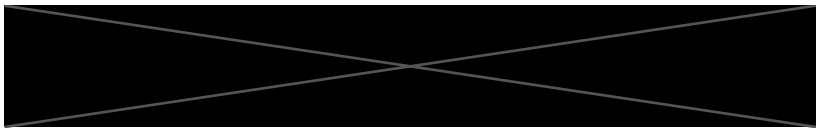
SECTION 3: 510(K) STATEMENT/ SUMMARY

510(k) Summary for pIVot

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92

1. **Submission Sponsor**
   pIVot
   

2. **Submission Corres ondent**
   

3. **Date Prepared**
   July 21, 2020

4. **Device Identification**

Name of Device:	pIVot
Classification Name:	Warmer, Thermal, Infusion Fluid
Regulation:	21 CFR 892.5050
Regulatory Class:	Class II
Product Classification Code:	LGZ
Classification Panel:	General Hospital

5. **Legally Marketed Predicate Device**

Predicate Manufacturer:	Quality in Flow, Ltd.
Predicate Trade Name:	QiF Blood and Fluid Warmer
Classification Name:	Warmer, Thermal, Infusion Fluid
Regulation:	21 CFR 892.5050
Regulatory Class:	Class II
Product Classification Code:	LGZ
Predicate 510(k):	K163708

6. **Device Description**
   The pIVot device is a portable IV fluid warmer, and consists of an IV bag warmer and an insulative coat for the drip chamber.

   Base Unit: The IV bag warmer controls the performance of the system and the outflow fluid temperature. The power source is a rechargeable detachable battery located within the unit along with the electronics.

Disposable Unit: The drip chamber insulator prevents the loss of heat from the fluids within the drip chamber. The window allows for users to visualize intravenous fluids within the drip chamber.

7. **Indication for Use**

pIVot is indicated for use in medical emergencies where warm fluid administration is required to treat the patient. Whenever the introduction of normothermic fluids are desired or indicated.

SECTION 4: DEVICE DESCRIPTION

Purpose of Submission
In accordance with Section 510(k) of the Medical Device Amendments of 1976 and Subpart E of Part 807, Title 21 of the Code of Federal Regulations, The Stream Team Inc. has compiled a traditional 510(k) for pIVot.

The purpose of this submission is to obtain market clearance for pIVot, which is indicated for use in medical emergencies where warm fluid administration is required to treat the patient. Whenever the introduction of normothermic fluid is desired or indicated.

Device Description
The pIVot device is a portable IV fluid warmer and consists of an IV bag warmer and an insulative coat for the drip chamber.

Base Unit: The IV bag warmer controls the performance of the system and the outflow fluid temperature. The power source is a rechargeable detachable battery located within the unit along with the electronics.

Disposable Unit: The disposable unit is a non-sterile single patient use disposable drip chamber insulator. The drip chamber insulator prevents the loss of heat from the fluids within the drip chamber. The disposable unit has an adhesive closure to allow for proper fit around the circumference of the drip chamber and a vertical window apparatus to allow users to visualize intravenous fluids within the drip chamber.

Intended Use:
pIVot is intended for warming intravenous fluids prior and during administration. It is intended to be used by healthcare professionals in hospital, clinics and field environments, to help prevent hypothermia.

Materials

Component Name	Material	Recognized Standard	Exposure
pIVot IV Bag Conductive Layer	Conductive non-woven fabric	ASTM B193 - 19	N/A
pIVot IV Bag Insulation Layer	Fiberglass or silica aerogel	ASTM C1696 - 20	N/A
pIVot Drip Chamber Insulation	Polyethylene	ASTM C1696 - 20	N/A
pIVot Heating Element	Nichrome wire	IEC 80601-2-35:2009(en)	N/A

SECTION 5: SPECIFICATIONS

Design Inputs, Outputs, Verification, and Validation (DIOVV)

Design Input Requirements (DIRs)								
User Need ID	ID	Description	Importance	Design Input	Design Output	Verification	Validation	Rationale
UN-01: The solution must not cause any additional harm to the users.	DIR 1-1	The solution must heat IV fluids from room temperature to a clinically relevant temperature	Critical	The solution must heat the intravenous fluids to a clinically safe temperature range.	The temperature of the heated intravenous fluids must be in the range of 38 - 42ºC	BenchtopTesting Heat Transfer Simulations	Human Factors and Usability Study	This is the accepted safe range to heat IV fluids to as supported by clinical literature
	DIR 1-2	The solution must result in IV fluids administered at the clinically relevant temperature without the IV tubing drip chamber insulation	Critical	The solution must deliver the intravenous fluids throughout the IV tubing within the clinically safe temperature range.	The temperature of the intravenous fluids entering the body from the distal end of the IV tubing are between 36-42ºC without the IV tubing drip chamber insulation.	Benchtop Testing IV Tubing Heat Loss Simulations	Human Factors and Usability Study	This is the accepted safe range to heat IV fluids to as supported by clinical literature. The temperature of the IV fluids should not change as they exit the bag and into the tubing more than a yet to be defined tolerance of X.
	DIR 1-3	The solution must result in IV fluids administered at the clinically relevant temperature with the IV tubing drip chamber insulation.	Critical	The temperature of the intravenous fluids entering the body from the distal end of the IV tubing are between 36-42ºC with the IV tubing drip chamber insulation.	The temperature of the intravenous fluids entering the body from the distal end of the IV tubing are between 36-42ºC with the IV tubing drip chamber insulation.	Benchtop Testing IV Tubing Heat Loss Simulations	Human Factors and Usability Study	
	DIR 1-4	The temperature of the IV fluids must be at a statistically significant greater temperature when entering the body with the IV drip chamber insulation than without it.	Critical	The temperature of the intravenous fluids exiting the IV tubing with the drip chamber insulation must be at a statistically significant higher temperature than that of the intravenous fluids exiting the IV tubing without the drip chamber.	The temperature of the fluids with the IV tubing drip chamber insulation have a greater temperature than that without the insulation that is statistically significant	Benchtop Testing IV Tubing Heat Loss Simulations	Human Factors and Usability Study	
	DIR 1-5	The solution must adhere to proper disinfecting practices	Critical	The solution exterior must adhere to ISO 17664:2017	Conformance to ISO 17664:2017 - Processing of healthcare products - Information provided by the medical device manufacturer of the processing of medical devices	Company manufacturing protocols comply with ISO 17664: 2017	Human Factors and Usability Study	The solution should not add to the risk of infection in the EMS space.
	DIR 1-6	The solution must adhere to proper manufacturing practices	Critical	The solution must adhere to the proper standards for manufacturing medical devices.	Conformance to ISO 13485 - Medical Devices - Quality Management Systems - Requirements for regulatory purposes	Device manufacturing practices comply with ISO 13485	Human Factors and Usability Study	
	DIR 1-7	The solution must produce sufficient energy to heat the IV fluids so that they are administered in the clinically safe range	Essential (Electrical or Chemical Heating)	The heating element must produce at least 85 kJ of energy	The heating element produces 89.77 kJ of energy	Benchtop Testing	Human Factors and Usability Study	92.3 kJ is the amount of energy required to heat 1000 mL of water from 22-44˚C
	DIR 1-8	The solution must prodcue sufficient power when plugged into a wall outlet in order to heat the IV fluids to the clinically safe range within 5 minutes.	Essential (Electrical Heating)	The heating element must output at least 283 Watts over for the five minute Start-Up period, while connected to a wall outlet supplying 110V.	The heating element outputs 300 Watts over the five minute Start-Up period while connected to a wall outlet supplying 110V.	Benchtop Testing	Human Factors and Usability Study	Heating pads are rated 50W
	DIR 1-9	The solution must ouput sufficient power to maintain the temperature of the IV fluids within the clinically safe range for one hour without being plugged into a wall outlet.	Essential (Electrical or Chemical Heating)	The heating element must output at least 2.42 Watts over the one hour Temperature Maintenance Period while running off of portable battery power.	The heating element outputs 2.43 Watts of power for the duration of the one hour Temperature Maintenance period while running off of two portable 5 volt batteries.	Benchtop Testing	Human Factors and Usability Study	Based off of energy (known) and how long we are willing to wait for the IV fluids to get up to 44ºC
	DIR 1-10	The solution must not heat the IV fluids outside of the clincally safe range.	Essential (Electrical or Chemical Heating)	The temperature of the heated IV fluids must not exceed 42ºC	The temperature of the fluids is maintained at or below 42ºC via IV bag temperature feedback control (PID controller).	Benchtop Testing Electrical Testing	Human Factors and Usability Study	
	DIR 1-11	The solution must not alter the flow rate of the IV fluids.	Essential	When using the soluton, the infusion rate of the IV fluids must be unaltered from the user-set infusion rate	The solution does not alter the user-set flow rate of the fluids.	Benchtop Testing	Human Factors and Usability Study	The device should have no influence on the IV drip rate that is set by the user
	DIR 1-12	RF/ EMC compliance.	Essential	The electrostatic discharge must be in compliance with IEC/EN 61000-4-2	Electrostatic discharge is lower than the maximum acceptable IEC/EN 61000-4-2 levels tested in a temperature and humidity controlled chamber	Electrostatic discharge testing conducted in a temperature and humidity controlled chamber. The tests were conducted for the humidity range: 15% humidity to 65% humidity. The temperature varied from 18ºC to 24ºC. The controlled temperature and humidity conditions were used because ESD is largely dependent on environmental conditions, and performing the testing in a chamber allowed for the variation of environmental conditions to see the impact on the device's performance and determine the worst case environmental conditions of the device.	Human Factors and Usability Study	
	DIR 1-13	EM Compatibility/ Interference compliance.	Essential	Solution must conform to electromagnetic compatibility standards according to IEC 60601-1-2	Electromagnetic disturbances and EM emissions of device to the environment are less than the maximum acceptable levels according to IEC 60601-1-2	Appropriate testing was conducted using IEC 60601-1-2 in order to establish conformance to electromagnetic compatibility standards. As part of this testing, the device's performance in the presence of electromagnetic disturbances was quantified. The electromagnetic emissions of the device to the environment were also characterized and quantified to ensure safety and functionality. The device fell within the acceptable ranges for all of the criteria according to IEC 60601-1-2.	Human Factors and Usability Study	
	DIR 1-14	Thermal safety compliance	Essential	Solution must conform to thermal safety standards according to ANSI/AAMI ES 60601-1.	Thermal Safety Testing per ANSI/AAMI ES 60601-1	Appropriate thermal testing was conducted again using ANSI/AAMI ES 60601-1. The temperature of the device was found during regular use over the lifecycle of the device. The temperature was also measured and recorded under extreme conditions, at the top range of the device's safe use environments. The device passed all thermal safety tests.	Human Factors and Usability Study	
	DIR 1-15	The exterior of the solution must be safe to the touch by users of the device.	Essential	The exterior of the solution must not heat to a temperature exceeding 44ºC at any time during the labeled one hour use time.	The maximum temperature the exterior of the IV bag reaches after the maximum labeled use time of 1 hour is 23ºC.	Benchtop Testing Heat Transfer Simulations	Human Factors and Usability Study	Temperatures as low as 44ºC can cause burns, therefore our device must have an external temperature less than that.
UN-02: The device should deliver warmed fluids to the patient.	DIR 2-1	The solution must be designed so that the fluids can be heated while they are being administered to the patient	Essential	The solution must allow fluids to be administered as the fluids are heated or maintained at their operating temperature.	The solution must warm up fluids between 38ºC - 42ºC as fluids are being administered.	Benchtop Testing	Human Factors and Usability Study	The solution should heat reliably and uniformly
	DIR 2-2	The solution must be compatible to heat the IV fluids for all standard 1000 mL IV bags and associated IV tubing.	Critical	The solution must not divert the flow of fluids outside of the IV bag and tubing during any time of heating.	No fluid should be located outside of the IV bag and tubing at any time during usage of the device.	Benchtop Testing	Human Factors and Usability Study	The device must heat externally of the IV bag and tube apparatus (no diverting the fluids out of the tubing/ bag)
	DIR 2-3	The solution must indicate to the user when the IV fluids have heated to the operating range.	Essential	The solution must indicate to the user that the IV fluids are at a clinically relevant and safe temperature to begin administering	The solution incorporates an LED that turns on once the IV fluids are within the clinically relevant and safe temperature range	Benchtop Testing Visual Inspection	Human Factors and Usability Study	The user should always be able to see the actual IV bag temperature
	DIR 2-4	The solution must not damage the IV bag or tubing in any manner.	Essential	The solution must not contain sharp edges, and must conform to the shape of a standard 1000 mL IV bag and tubing.	The solution was designed to conform to the shape of a standard 1000 mL IV Bag	Benchtop Testing - Visual Inspection	Human Factors and Usability Study	The solution should not cause mechanical deformation of the IV bag or the IV tubing
	DIR 2-5	The solution must not damage the IV bag or tubing in any manner.	Essential	The solution must not cause the IV bag or tubing to melt.	The solution is designed such that the IV Bag is thermally isolated from the heating element with a thin nonwoven fabric barrier material	Benchtop Testing - Visual Inspection	Human Factors and Usability Study	This the temperature beyond which IV bag material will melt.
	DIR 2-6	The solution must perform an internal check prior to beginning heating	Essential	The solution must perform a continuity check when powered on.	The solution must check all internal electrical connection by driving current through them.	Benchtop Testing - Electrical Testing	Human Factors and Usability Study	The solution should not operate, or should at least alert the user if something is wrong with the device internally
	DIR 2-7	The solution must alert the users if any device error occurs.	Essential	The solution must incorporate an error alarm system to alert users of any device malfunction.	The solution immediately turns off and red LED turns on if an error occurs, including but not limited to: the device overheating, loose or lost connection between device components, battery errors	Benchtop Testing Electrical Testing	Human Factors and Usability Study	The solution should prioritize safety and should not take time away from the EMT's other responsibilities
	DIR 2-8	The solution must heat quickly and efficiently.	Critical	The heating element must reach its maximum operating temperature in less than 90 seconds.	The heating element reaces its maximum operating temperature (80ºC) in 0.5 seconds.	Benchtop Testing Heat Transfer Simulations	Human Factors and Usability Study	
	DIR 2-9	The solution must prevent the heating element from directly being in contact with the IV bag	Essential	The heating element will be placed in a non flammable material that separates the IV bag from directly contacting the heating element.	The material is a non flammable, conductive nonwoven fabric which has a thermal conductivity of 0.86 W/mK	Benchtop Testing Heat Transfer Simulations	Human Factors and Usability Study	The solution should transfer all the heat from the heating element to the IV bag while creating a barrier.
	DIR 2-10	The solution must prevent substantial thermal heat loss to the ambient environment	Essential	The device must allow less than 5 Watts of power per hour to be lost to the external environment.	The device is incased in insulating material that is 2 inch thick silica aerogel. The insulation loses 2.42 Watts of power per hour to the external environment.	Benchtop Testing Heat Transfer Simulations	Human Factors and Usability Study	The solution must prevent the loss of heat from the heating element in order to maximize heating up of the IV fluids
	DIR 2-11	The solution must heat quickly and efficiently.	Critical	The IV fluids must be heated to operating temperature within 5 minutes of the solution being used	The IV fluids heat to operating temperature (42ºC) in 4 minutes and 52 seconds	Benchtop Testing Heat Transfer Simulations	Human Factors and Usability Study	The solution must be very quick and efficient in warming up to the operating temperature. This range is based on customer interviews, KOL opinions, and competitor devices
UN-03: The solution must be compact, portable, and cost-efficient.	DIR 3-1	The solution must be lightweight.	Essential	The weight of the device should be less than 5 pounds (2.27 kg).	The weight of the device is 4 pounds (1.81 kg).	Benchtop Testing	Human Factors and Usability Study	This weight is from competitor devices
	DIR 3-2	The solution must be portable during the Temperature Maintenance period and safe to the users of the device.	Critical	The heating element must be able to supply sufficient power during the Temperature Maintenance period when supplied with voltage from two 5 volt batteries.	The heating element requires a total of 9.988 volts to operate in the Temperature Maintenance Period.	Benchtop Testing	Human Factors and Usability Study	The solution must not generate a dangerous level of voltage that could pose harm to any of the users.
	DIR 3-3	The solution must be space efficient.	Critical	The solution's dimensions should not exceed 40cm in length x 15cm in width x 40cm in height	The solution's dimensions are 20cm by 10cm by 35cm	Benchtop Testing	Human Factors and Usability Study	The solution should be compact.
	DIR 3-4	The solution must be low cost to manufacture in bulk.	Critical	The solution's manufacturing costs must be equal or lower than that of competitor IV fluid warmers	The solution costs $X to manufacture in bulk.	Manufacturing Cost	Human Factors and Usability Study	This number came from a voice of customer study. The selling price should ideally be $20.
	DIR 3-5	The solution must warm IV fluids for the length of an average ambulance ride.	Critical	The solution must warm fluids within the range of 38-42ºC for at least one hour.	The solution operates continuously for 1 hour when supplied by two portable 5 volt batteries	Benchtop Testing	Human Factors and Usability Study	The solution should not have to be changed out mid-shift, but should operate reliably throughout the whole shift
UN-04: The solution must be intuitive and quick to use.	DIR 4-1	The solution must take less than or equal to 5 steps to unpackage and apply on the patient	Essential	The solution must take less than or equal to 5 steps to unpackage and apply on the patient	The solution takes 5 steps to unpackage and apply on the patient.	N/A	Human Factors and Usability Study	Ease of use requirements from customer interviews
	DIR 4-2	The solution must be intuitive and easy to use	Critical	The solution must be setup correctly and within 1 minute by at least 90% of users with no instructions given.	The solution was setup correctly and within 1 minute by X% of users with no instructions given.	N/A	Human Factors and Usability Study	Ease of use requirements from customer interviews, and differentiation from competitors
	DIR 4-3	The solution must be intuitive and easy to use	Critical	The solution must be set up by at least 95% users within 45 seconds with "little" (3-step instruction guide) training.	The solution was set up by 97% users within 45 seconds with "little" (3-step instruction guide) training.	N/A	Human Factors and Usability Study	Ease of use requirements from customer interviews, and differentiation from competitors
	DIR 4-4	The solution must be intuitive and easy to use	Essential	The solution must take no more 30 seconds to setup.	The solution takes an average of 20 seconds to setup.	N/A	Human Factors and Usability Study	Ease of use requirements from customer interviews, and differentiation from competitors
	DIR 4-5	The packaging must protect the device.	Essential	The packaging must be sufficient to protect the device under normal and storage conditions.	The packaging conforms with the ISO 11607-1 standards.	Drop test, compression test, vibration test, climate conditioning test, marking test	Human Factors and Usability Study	Packaging must comply with ISO standards
	DIR 4-6	The solution must be labeled in compliance with regulatory standards.	Essential	The solution must be labeled according to ISO approved standards for labeling.	The labeling conforms with the ISO 15223-1 standards for medical device labeling.	N/A	Human Factors and Usability Study	Labeling must comply with ISO standards

Risk Assessment

Probability Scale	Probability Criteria
1	Remote: Not likely to occur ever during useful life
2	Seldom: Not likely to occur during useful life
3	Sometimes: Possible to occur once during useful life
4	Likely: Possible to occur several times during useful life
5	Definite: Will occur during useful life

Prob. of Occurence	Severity				
	1 Nuisance	2 Discomfort	3 Intermediate	4 Major	5 Catastrophic
1 Remote	A	A	A	M	M
2 Seldom	A	A	M	M	M
3 Sometimes	A	M	M	M	U
4 Likely	M	M	M	U	U
5 Definite	M	M	U	U	U

Hazard Identification			Risk Evaluation				Risk Reduction Measures	Residual Risk			Traceability
Hazard #	Hazard	Possible Reason	Possible Cause	Severity	Probability	Risk Category	Risk Reduction Measure(Mitigations)	Mitigated Severity	Mitigated Probability	Residual Risk Category	Traceability
1	**Engineering Requirements**										
1.1	**Electrical**										
1.1.1	Inaccurate or No Temperature Detection	-Sensor Malfunction	-Improper sensor calibration -Improper sensor placement -Loose wiring -Broken components -Short circuit	5	3	U	Benchtop testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV; ISO 60601
1.1.2	Heating Element Malfunction	-Broken Communication	-Loose wiring -Broken components -Short circuit	5	3	U	Benchtop testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV; ISO 60601
		-Broken Heating Element	-Broken components	5	3	U	Benchtop testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV; ISO 60601
1.1.3	Improper Modulation of Temperature of Heating Element	-Potentiometer Malfunction	-Improper calibration of potentiometer -Loose wiring -Short circuit	5	3	U	Benchtop testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV; ISO 60601
		-Heating Element Fails to Turn On or Off	-Loose wiring -Broken components -Short circuit	5	3	U	Benchtop testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV; ISO 60601

1.2	**Material**										
1.2.1	IV Bag Melts	-Heating Element Malfunctions	-Broken Communication -Broken Heating Element	5	2	M	Benchtop testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV
1.2.2	Heating element is not insulated within device	Insulation Fails	-Fiberglass is released -Aluminum breaks -Sharp object/IV needle pierces insulation	4	2	M	Benchtop testing; Quality testing; Verification and validation	3	1	A	Proper maintenance of documentation and testing reports; DIOVV
1.2.3	Heating element is not conducted to IV bag	Conductive layer fails	-Woven coductive material rips -Sharp object/IV needle pierces conductive layer -Conductive layer creates malfunction	3	2	M	Benchtop testing; Quality testing; Verification and validation	2	1	A	Proper maintenance of documentation and testing reports; DIOVV
2	**Physical Embodiment**										
2.1	Device does not maintain integrity	-Material Malfunction	-Heat Decomposes Material	5	3	U	Benchtop testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV
2.2	Device alters flow rate of the fluids	-User Error	-User Places Device Incorrectly	4	3	M	Benchtop testing; Quality testing; Verification and validation	4	1	M	Proper maintenance of documentation and testing reports; DIOVV
2.3	Device pierces IV bag	-Material Malfunction	-Electrical components pierce IV bag	5	2	M	Benchtop testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV
2.4	Device fails to fit the IV bag	-Design Failure -User Error	-Improper fitting of the device by the user	3	3	M	Design verification and validation; Quality testing; Proper IFU; Usability testing; Verification and validation	3	1	A	Proper maintenance of documentation and testing reports; DIOVV
2.5	Device cannot be hung on IV pole	-Design Failure -User Error	-Improper size of hole on device exterior -Device exterior handle or IV bag handle breaks	2	3	M	Usability testing; Quality testing; Verification and validation	2	1	A	Proper maintenance of documentation and testing reports; DIOVV
3	**Environmental Considerations**										
3.1	Device emits excess heat	-Electrical failure	-Heating Source Malfunction -Sensor Malfunction -Potentiometer Malfunction -Faulty Ammeter	5	2	M	Benchtop testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV
3.2	Device emits excess noise	-Mechanical failure	-Components grinding -Noise calibration failure	1	3	A	Benchtop testing; Quality testing; Verification and validation	1	1	A	Proper maintenance of documentation and testing reports; DIOVV
3.3	Device does not maintain functional integrity within temperature/humidity/ altitude of setting	-Material failure -Electrical failure	-Material melts/freezes -Wiring melts/freezes	5	3	U	Benchtop testing; Clinical testing; Animal testing; Situational environment testing; Quality testing; Verification and validation	4	1	M	Proper maintenance of documentation and testing reports; DIOVV
3.4	Device does not maintain mechanical integrity within temperature/humidity/ altitude of setting	-Material failure -Mechanical failure	-Material melts/freezes -Wiring melts/freezes	5	3	U	Benchtop testing; Situational environment testing; Quality testing; Verification and validation	4	1	M	Proper maintenance of documentation and testing reports; DIOVV
3.5	Device is incompatible with existing IV bag in operational setting	-User error	-IV bag placed in device incorrectly	3	2	M	Design verification and validation; Quality testing; Proper IFU; Usability testing; Verification and validation	3	1	A	Proper maintenance of documentation and testing reports; DIOVV
3.7	Device is incompatible with existing electrical connections present in setting	-User error	-Wrong electrical connection used -Device used in setting without proper exectrical connections	3	2	M	Design verification and validation; Quality testing; Proper IFU; Usability testing; Verification and validation	3	1	A	Proper maintenance of documentation and testing reports; DIOVV

4	**Performance/Clinical**										
4.1	The device fails to power off	-Electrical failure	-Wire fails -Sensor fails -Circuit fails -Potentiometer failure	3	3	M	Design verification and validation; Electrical testing; Quality testing; Verification and validation	3	2	A	Proper maintenance of documentation and testing reports; DIOVV
4.2	The device fails to detect change in IV bag fluid temperature	-Electrical failure	-Thermistor failure -Wire failure	5	3	U	Design verification and validation; Electrical testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV
4.3	The device fails to relay IV bag fluid temperature	-Electrical failure	-Thermistor failure -Wire failure	5	3	U	Design verification and validation; Electrical testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV
4.4	Alarm error	-Electrical failure	-Display failure -Communication failure -Alert source failure	5	3	U	Design verification and validation; Electrical testing; Quality testing; Verification and validation	4	1	M	Proper maintenance of documentation and testing reports; DIOVV
4.5	Error is not displayed	-Electrical failure	-Display failure -Communication failure	5	3	U	Design verification and validation; Electrical testing; Quality testing; Verification and validation	3	1	A	Proper maintenance of documentation and testing reports; DIOVV
4.6	LED light does not turn on/off	-Electrical failure	-Communication error -Display error	3	3	M	Design verification and validation; Electrical testing; Quality testing; Verification and validation	3	2	M	Proper maintenance of documentation and testing reports; DIOVV
5	**Safety**										
5.1	Device heats fluid beyond clinically safe range	-Electrical failure -Sensor Failure	-Loose wire -Sensor fails to conncet properly -Wire failure	5	2	M	Benchtop testing; Animal testing; Clinical testing; Electrical testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV
5.2	Device overheats	-Electrical failure -Mechanical failure	-Loose wire -Sensor fails to conncet properly -Wire failure -Electrical cord failure -Battery failure	4	3	M	Benchtop testing; Electrical testing; Quality testing; Verification and validation	3	1	A	Proper maintenance of documentation and testing reports; DIOVV
5.3	Device shocks user	-Electrical failure -Mechanical failure -Design malfunction	-Loose wire -Sensor fails to conncet properly -Wire failure -Electrical cord failure	4	3	M	Benchtop testing; Electrical testing; Voltage testing; Usability testing; Quality testing; Verification and validation	3	1	A	Proper maintenance of documentation and testing reports; DIOVV
5.4	Device burns user	-Electrical failure -Design malfunction	-Loose wire -Sensor fails to conncet properly -Wire failure -Electrical cord failure -Insulation failure -User error	5	2	M	Benchtop testing; Electrical testing; Voltage testing; Usability testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV
5.5	Device alters core temperature beyond clinically safe range	-Electrical failure -Sensor Failure	-Loose wire -Sensor fails to conncet properly -Wire failure -User error	5	2	M	Benchtop testing; Electrical testing; Voltage testing; Usability testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV
6	**Reliability/ Maintenance**										
6.1	The Heating Element Does Not Reach the Same Temperature Every Time	Feedback Control Issue	-Sensor malfunction -Loose wires -Broken Components	4	2	M	Benchtop testing; Electrical testing; Quality testing; Verification and validation	3	1	A	Proper maintenance of documentation and testing reports; DIOVV
		Power Source Malfunction	-Insufficient charge -Loose power connection	3	3	M	Benchtop testing; Electrical testing; Quality testing; Verification and validation	3	1	A	Proper maintenance of documentation and testing reports; DIOVV
6.2	No Detection of Device Overheating	Sensor Malfunction	-Improper sensor calibration -Improper sensor placement -Loose wiring -Broken components -Short circuit	5	3	U	Benchtop testing; Electrical testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV
6.3	No Detection of Low Power	Sensor Malfunction (Specific sensor that reads battery charge)	-Improper sensor calibration -Improper sensor placement -Loose wiring -Broken components -Short circuit	3	3	M	Benchtop testing; Electrical testing; Voltage testing; Quality testing; Verification and validation	3	1	A	Proper maintenance of documentation and testing reports; DIOVV
6.4	No Communication of Device-Related Errors	Communication Error	-Loose wires -Broken components -Short circuit	5	3	U	Benchtop testing; Electrical testing; Circuits testing; Quality testing; Verification and validation	5	1	M	Proper maintenance of documentation and testing reports; DIOVV

7	**Human Factors/Usability**											
7.1	User misuses device	-Unclear Instructions	-Device instructions are not written at an educational level in which user can understand -Device training is insufficient	4	2	M	Usability study; Device training programs; Meets ISO 13485; Verification and validation of training documents	3	1	A	Proper maintenance of documentation and testing reports; DIOVV; ISO 13485
7.2	User cannot place device correctly	-Non Intuitive Design	-Design is not intuitive -Insufficient usability studies perfomed	4	2	M	Usability study; Device training programs; Meets ISO 13485; Verification and validation of training documents	4	1	M	Proper maintenance of documentation and testing reports; DIOVV; ISO 13485
7.3	User fails to charge device	-User error -Insulation fails	-Instructions are not clear -User fails training -Insulation pierced	3	4	M	Usability study; Device training programs; Meets ISO 13485; Verification and validation of training documents	2	4	M	Proper maintenance of documentation and testing reports; DIOVV; ISO 13485
7.4	User fails to power on device	-User error -Circuit failure -Insufficient Charge	-Instructions are not clear -User fails training -Sensor malfunction -Loose wire -Component malfunction	3	3	M	Usability study; Device training programs; Meets ISO 13485; Verification and validation of training documents	3	1	A	Proper maintenance of documentation and testing reports; DIOVV; ISO 13485
7.5	User fails to power off device	-User error -Circuit failure -Insufficient Charge	-Instructions are not clear -User fails training -Sensor malfunction -Loose wire -Component malfunction	1	4	M	Usability study; Device training programs; Meets ISO 13485; Verification and validation of training documents	1	3	A	Proper maintenance of documentation and testing reports; DIOVV; ISO 13485
8	**Packaging and Labeling**											
8.1	Packaging does not maintain device integrity	-Packaging malfunction -Manufacturing malfunction -Shipping malfunction	-Unable to use device -Device loses integrity	5	3	U	Simulate shipping process several times on each lot to prevent hazards; Verification and validation to better understand the characteristics of packaging	4	1	M	Proper maintenance of documentation and testing reports; DIOVV; 21 CFR 801
8.2	Broken/damaged package	-Manufacturing malfunction -Shipping malfunction	-Device misuse -Instructions are not easily understood by user	4	3	M	Simulate shipping process several times on each lot to prevent hazards; Verification and validation to better understand the characteristics of packaging	3	1	A	Proper maintenance of documentation and testing reports; DIOVV; 21 CFR 801
8.3	Misuse	-Intenal issue -Manufacturing malfuntion -Mislabeling	-Instructions illegible -Instructions are not easily understood by user	4	2	M	Usability study; Verification and validation	3	1	A	Proper maintenance of documentation and testing reports; DIOVV; 21 CFR 801
8.4	Broken/damaged labeling	-Packaging malfunction -Manufacturing malfunction -Shipping malfunction	-Device used incorrectly -Instructions are not easily understood by user	3	3	M	Simulate shipping process several times on each lot to prevent hazards; Verification and validation to better understand the characteristics of packaging and labeling	2	1	A	Proper maintenance of documentation and testing reports; DIOVV; 21 CFR 801
8.5	Mislabeling	-Manufacturing malfunction -Shipping malfunction	-Incorrect labeling placed on device -Correct labeling not placed on device	4	1	M	Clear instructions and quality checks for manufacturing; Verification and validation	3	1	A	Proper maintenance of documentation and testing reports; DIOVV; 21 CFR 801
9	**Sterility**											
9.1	Device introduces pathogens to user	-Packaging malfunction -Manufacturing malfunction -Shipping malfunction -User error	-Device and/or packaging contaminated during shipment to facility/user -Proper protocol not maintained -User fails to properly disinfect device	5	2	M	Verification and validation testing; Implement a strong QMS system that recognizes failures before they occur; Disinfection testing on different batches to ensure disinfection; Measure bacterial count after disinfection	3	1	A	Proper maintenance of documentation and testing reports; DIOVV
9.2	Packaging introduces pathogens to the device	-Packaging malfunction -Manufacturing malfunction -Shipping malfunction	-Device and/or packaging contaminated during shipment to facility/user -Proper protocol not maintained	5	1	M	Verification and validation testing; Implement a strong QMS system that recognizes failures before they occur	3	1	A	Proper maintenance of documentation and testing reports; DIOVV
10	**Useful Life**											
10.1	Device is nonfunctional before achieving useful life	-Electrical failure -User error	-Components fail -User plugs device into incorrect power source -Device is pierced or physically damaged	4	2	M	Proper device training; Aging studies; Proper verification and validation of aging studies, training and instructions	3	2	M	Proper maintenance of documentation and testing reports; DIOVV

11	**Shelf Life**											
10.1	Device is nonfunctional before achieving 3year shelf life	-Electrical failure -User error	-Components fail -User plugs device into incorrect power source -Device is pierced or physically damaged	**4**	**2**	**M**	Proper device training; Aging studies; Proper verification and validation of aging studies, training and instructions		**3**	**1**	**A**	Proper maintenance of documentation and testing reports; DIOVV

SECTION 6: SUBSTANTIAL EQUIVALENCE

In accordance with Section 510(k) of the Medical Device Amendments of 1976 and Subpart E of Part 807, Title 21 of the Code of Federal Regulations, 892.5050, Inc. has compiled a traditional 510(k) for the device pIVot

Characteristic	QiF Blood and Fluid Warmer	pIVot	SE Justification
Product Code	LGZ	LGZ	Same
Regulation Name	21 CFR 892.5050	21 CFR 892.5050	Same
FDA Class	Class II	Class II	Same
Indication for Use	Medical emergencies or surgeries where warm fluid administration is required to treat the patient. Whenever parenteral introduction of normothermic fluid are desired or indicated.	Medical emergencies where warm fluid administration is required to treat the patient. Whenever the introduction of normothermic fluid are desired or indicated.	Similar. The only difference is the pIVot is used in the prehospital settings for emergencies.
Intended Use	Intended for warming blood, blood products and intravenous solutions prior to administration. It is intended to be used by healthcare professionals in hospital, clinical and field environments to help prevent hypothermia.	Intended for warming intravenous solutions prior and during the administration. It is intended to be used by healthcare professionals in the prehospital environments to help prevent hypothermia.	Similar. The only difference is the pIVot is used in the prehospital settings for emergencies.
Patient Population	Adult and pediatric population experiencing medical emergencies and surgery.	Adult and pediatric population experiencing medical emergencies.	Similar
Components	Warmer with display and a sterile, disposable heat exchanger.	External warmer with resistive heating elements with LED alerts. Disposable insulative drip chamber element.	Similar
Power Source	Rechargeable Battery	Rechargeable Battery	Same
Heating Method	Resistive Heating	Resistive Heating	Same

Characteristic (cont.)	QiF Blood and Fluid Warmer (cont.)	pIVot (cont.)	SE Justification (cont.)
Infusion Temperature	38±2℃	40±2℃	Similar
Safety Features	System self-test Overheat notification Overheat cut-off Battery undervoltage protection (cut-off)	Overheat notification Overheat cut-off Battery undervoltage protection (cut-off)	Similar
Shelf Life	3 years	3 years	Same
Single Use or Reusable	Single use	Reusable and disposable	The differences don't raise any concerns of safety and efficacy
Heat Insulation	Expanded Polypropylene (EPP)	Fiberglass and aluminum	The differences don't raise any concerns of safety and efficacy
Storage Conditions	-4°F to 140°F & 93% RH and compliance to -22°F to 158°F	-4°F to 140°F & 93% RH and compliance to -22°F to 158°F	Same
Operating Conditions	41°F &15%RH to 104°F & 93% RH and compliance with 23°F to 104°F	41°F &15%RH to 104°F & 93% RH and compliance with 23°F to 104°F	Same
Altitude	-1312 to 10,499 ft.	-1312 to 10,499 ft.	Same
Warmer type	Inline Warmer	External Warmer	The differences do not raise any additional concerns for safety and efficacy.

Based on the 510(k) flowchart and the review of performance data, the pIVot device is substantially equivalent to the predicate device. In making this statement, it is obvious that the technological characteristics are substantially equivalent in terms of safety and effectiveness, and that the performance data raise no new questions of safety or effectiveness.

SECTION 7: DECLARATIONS OF CONFORMITY AND GUIDANCE DOCUMENTS

IEC 62366-1	Medical Devices-Application of Usability Engineering to Medical Devices
IEC 60601-1	Medical Electrical Equipment-General Requirements for Basic Safety and Essential Performance
IEC 60601-1-6	Medical Electrical Equipment-General Requirements-Collateral Standard:Usability
ISO 13485	Medical devices-quality management systems-requirements for regulatory purposes
ISO 14971	Medical devices-Application of risk management to medical devices
ISO 15223-1	Medical devices-Symbols to be used with medical device labels, labelling, and information to be supplied
ANSI/AAMI/ISO 11607-1:2006 **ASTM F1980-07**	Shelf Life Testing
ASTM F1472 **ASTM F451-99**	Component Standards
ISO 14708-1	Packaging Standards
ASTM F 451-99 **ASTM D 2990-95** **ASTM E 399-97** **ASTM E 647-00** **ISO 5833:1992**	Mechanical Testing

SECTION 8: LABELING

OPERATION MANUAL

General Information

The pIVot Fluid Warmer is a fluid warmer device designed to warm intravenous fluids (IV) safely through regulated electrical heating. pIVot does not provide fluid flow rate control. Intravenous fluids that are normally at room temperature or are taken from a refrigerator can be warmed to temperatures between 36 - 42ºC within only five minutes. pIVot is not recommended for warming blood because it can reach 42ºC.

Intended Use

pIVot is intended for warming intravenous fluids prior and during administration. It is intended to be used by healthcare professionals in hospital, clinics and field environments, to help prevent hypothermia.

Indications For Use

pIVot is indicated for use in medical emergencies where warm fluid administration is required to treat the patient. pIVot is indicated for any use case in which the introduction of normothermic fluid is desired or indicated.

Contraindications

pIVot is contraindicated for any health condition and/or disease process where administering intravenous fluids is contraindicated. pIVot is also contraindicated for any emergency or procedure in which the administration of warmed IV fluids is contraindicated.

Precautions

SAVE THIS MANUAL FOR FUTURE REFERENCE!

- IMPORTANT: Before using the pIVot fluid warming device, please read and understand this IFU. If you have any questions, please contact the Stream Team.
- For IV fluid infusion instructions, refer to your facility/organization protocol
- The disposable infusion tubing set used together with this product should conform to the requirement of ISO 8536.4
- This device uses RF energy for its internal function. The RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. If interference is noticed between another device and this fluid warmer:
    - Ensure the pIVot fluid warmer is plugged into an isolate circuit
    - Increase separation between the pIVot warmer and the interfering device
- Follow all the instructions provided with the IV fluid administration set when infusing IV fluid
- In case of an alert from the LED indicator shut off the system. Do not use the system until it is repaired or replaced
- Charge the rechargeable battery only with the supplied pIVot Battery charger
- pIVot requires a fully charged battery for its operation. The battery does not have a memory effect and may be recharged even though it has not been fully discharged. If the battery has reached its end of life, please contact the manufacturer for purchasing a new battery.

Warnings

Failure to follow the warnings described below could result in the administration of improperly warmed fluids to the patient, which could cause death or serious injury.

- Do not use if the pIVot LED indicator is not functioning. Call the Stream Team to request a new pIVot device.
- The use of pIVot in a non-temperature controlled environment will affect how quickly the fluids heat to operating temperature. In cold environments where the ambient temperature is less than 22ºC, pIVot will take longer than 5 minutes to heat to operating temperature. Always wait for the LED indicator to turn on prior to assuming the fluids have reached the operating temperature of 42ºC.
- Always dispose of pIVot batteries and components according to the disposal instruction in this document. Never dispose of pIVot batteries in the trash.
- Warming IV fluids at flow rates higher than 200 ml/min (for example by using a pressure fluid pump) may result in an output temperature lower than 38 ± 2 °C.
- Do not attempt to reuse the pIVot Drip Chamber insulation. This may lead to contamination. pIVot fluid warmers may only be reused after they are disinfected according to the specifications of the **Disposal and Disinfection Instructions** section of this document.
- Do not use pIVot in MRI, X-ray, and CT environments
- Do not use pIVot to heat blood
- Do not use pIVot to heat heat-sensitive medications
- No modification of this device is allowed
- Use of pIVot not according to its instructions may result in failure of the system or injury to patient

Product Description

Equipment Notices

- pIVot must be unplugged and TURNED OFF when not in use. Failure to turn pIVot off could result in electrical failure, or drained batteries.
- This pIVot warmer is designed to be IV pole mounted, but may also be laid on the stretcher, patient, or rested on any other surface in the ambulance setting.
- The length of the IV line between the patient and the warmer should be limited.
- The pIVot fluid warmer contains an electrical cord, which could pose a risk as a tripping hazard. Always be cautious of the electrical cord.

IV Bag Warmer

The pIVot warmer is a warming sleeve fitted around a 1000mL IV bag. Two clasps are located at the bottom of the IV Bag warmer to allow the IV tubing to come through without obstructing function of the pIVot device or the IV bag setup. Within the pIVot fluid warmer are three primary layers. The outermost layer is insulation, which prevents heat loss to the environment. The middle layer consists of the electrical heating element as well as the electrical controls. The innermost layer is a thin conductive non woven fabric. The IV Bag containing the IV fluids to be warmed rests inside of the device, and interfaces with the thin non woven fabric layer. The heat generated by the electrical heating element warms the IV Bag and the IV fluids.

The pIVot fluid warmer also has both a wall outlet plug-in cord and a battery compartment to supply power to the electrical heating element. Additionally, there is an LED indicator on the exterior of the pIVot fluid warmer that visually indicates when the IV fluids in the bag have been sufficiently warmed up to 42ºC.

IV Drip Chamber Insulation

The pIVot Drip Chamber insulation is a cylindrical polystyrene wrap that fits around the drip chamber. It has a small window to allow for application and removal, and to view the volume and drip rate of IV fluids inside of the drip chamber. This insulation minimizes heat loss, and maintains the temperature of the warmed IV fluids.

Instructions for Use:

1. When a 911 call for a patient who is likely to need IV fluids is dispatched to the ambulance, place the necessary IV fluid bag in the pIVot fluid warmer device. Plug the pIVot fluid warmer into a 110 Volt wall outlet within the ambulance.
2. Close the bottom of the pIVot fluid warmer over the bottom of the IV fluid bag by securing the two snap close buttons closed. The pIVot fluid warmer should not obstruct the view of the IV bag ports or Drip Chamber when closed.
3. Unwrap the pIVot Drip Chamber insulation and wrap it around the IV drip chamber. Secure the pIVot Drip Chamber insulation in place with the adhesive. The pIVot Drip Chamber insulation does not cover the entire surface area of the drip chamber. There is a narrow, open window in the insulation to enable observation of fluid drip rate and volume in the drip chamber.
4. The warmer will start to warm up immediately when it is plugged in. An LED indicator will flash yellow when the device is heating up. The LED indicator will stop flashing and a green LED indicator will turn on, indicating the fluids have heated to 42ºC. The fluids should finish heating within 5 minutes. Once this green LED indicator has turned on, the device has finished the Start-Up period. DO NOT BEGIN ADMINISTERING IV FLUIDS TO THE PATIENT BEFORE THE GREEN LED TURNS ON. If necessary or desired, pIVot may also now be unplugged from the wall outlet. pIVot will maintain the temperature of the IV fluids at 42ºC from battery power for up to one hour.
5. Only once the green LED indicator turns on may the warmed fluids be safely administered to the patient at the proper temperature.
6. Anytime the fluid warmer is turned on (regardless of whether it is plugged in or is running from battery power), the warmer will automatically regulate the temperature of the fluids.

The warmer cycles on and off at controlled intervals based on the current IV fluid temperature to maintain the fluids at 42ºC.

7. When finished using the warmer, follow all disposal and disinfection instructions in the **Disposal and Disinfection Instructions** section of this document.

Effect of Flow Rate of Fluid Temperature

Fluid temperatures exiting the patient line are affected by flow rate. The pIVot Drip Chamber insulation significantly decreases temperature drop in IV fluids. However, quicker flow rates still result in more significant temperature decreases than that of slower flow rates. The design of the pIVot fluid warmer and pIVot Drip Chamber insulation have been rigorously tested across all drip chamber rates. Regardless of drip rate, the temperature of fluids exiting the patient line are within the clinically safe temperature range: 36ºC - 42ºC when using the pIVot fluid warmer and pIVot Drip Chamber insulation.

Symbols

	Manufacturer
	Date of Manufacture
	Lot Number
	Temperature Limitation
	Humidity Limitation
	Class II Equipment
	Caution
	Type BF Applied Part
	Do not dispose of in trash
	Consult Operating Instructions Prior to Use
IPX0	No protection against water

Storage Conditions

This product should be stored in an environment with an ambient temperature range of -10ºC to 55ºC and a relative humidity of less than 80%. The suggested operating temperature environment is 20 - 25ºC. Do not store this close to any corrosive vapor.

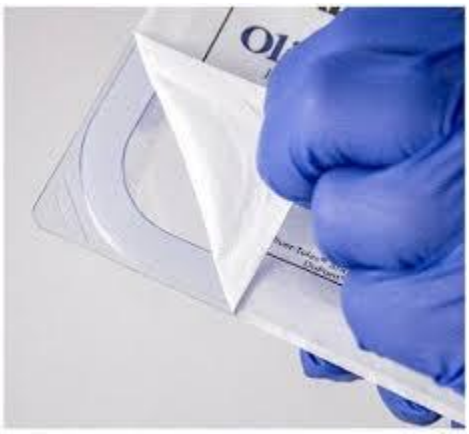
Disposal and Disinfection Instructions

When finished using the pIVot fluids warmer, ensure the device is turned off. Remove the batteries and plug them into a pIVot battery recharger. Clean and disinfect the surface of the pIVot fluids warmer. Use 70-75% solution of isopropyl alcohol and water to clean and disinfect the unit. When finished using the pIVot Drip Chamber insulation, immediately dispose of it in the proper waste location. DO NOT ATTEMPT TO REUSE PIVOT DRIP CHAMBER INSULATION, and this may lead to contamination between patients. Dispose of the pIVot fluid warmer batteries properly. Do not throw them in the trash.

SECTION 9: PACKAGING AND SHELF LIFE

Packaging

pIVot consists of a reusable component which is the bag with the heating element, and a case of insulative material that goes around the drip chamber. The packaging consists of a polyethylene packaging material that fit both parts of the device. The package is 4”x4”x4” in dimensions. The tear open packaging reduces the number of steps taken to use the device. Appropriate labels are placed in the box, which adhere to the labeling standards listed in the document. Additional requirements for packaging follow ISO 14708-1 Section 10 which dictates the packaging requirements of active implantable medical devices. The ISO 14708-1 requirements are summarized below.



The dropping and vibration requirements are consistent with the ISTA 2A ship test procedure. The ISTA 2A ship test procedure ensures packages weighing less than 150 lbs are safe to ship using any shipping method. The stacking requirement is based on the weight the bottom box experiences when the boxes are stacked 13.6 ft high. The 13.6 ft is based on legal height restrictions placed on 18 wheel truck trailers.

The stacking test met the stacking requirements shown in the table above. The stacking test performed per the ISTA 2A procedure not only did the system meet the stacking requirement, but the packaging supported 400lbs. The system passed all post-test inspections. All functional components of the system were not damaged as a result of the testing. The system passed the final test requirements after the ship tests.

ISO 14708-1 Section 10 Requirements	Requirement	Result
Dropping Test	Dropped from 28” on manufacturer’s joint, the three edges radiating from the manufacturer’s joint, and all six sides	Pass
Compression Test	Must be able to withstand about 200 lbs of weight on top of it	Pass
Vibration Test	Must be able to withstand vibrations at 1.15 G	Pass
Climate Conditioning	72 hrs at 32°C and 90% Relative Humidity	Pass
Markings	Markings must be legible after water drop or any other spill	Pass
Peel Off Strength Test	Peeling off the paper from the polyethylene should take less than 2 N/cm	Pass

Shelf Life

Accelerated aging shelf life studies were performed for the pIVot packaging. These tests involved mechanical and manufacturing integrity testing over its useful life and the durability of the packaging. In addition to these tests, long-term stability testing will be performed to confirm the shelf life of the device.

The useful life was determined based on the withstandable cyclic and static loading and unloading cycles pIVot could endure, while maintaining its functionality and satisfying all of its design criteria and physical specifications. The physical criteria examined for acceptance in the useful life study included the device’s cyclic and static load bearing capacity over time, the compressive strength over time, and the overall appearance of the device over time. In addition to that, the temperature and humidity storage conditions were examined and how they may affect the device’s safety or performance over its useful life. As part of these tests, the device was tested to failure under simulated use conditions. The results of these tests showed that the pIVot was reliable and functional.

Accelerated aging was done to determine quickly whether time and the storage environment and its packaging and labeling had any adverse effects on the performance. This testing was done based on ANSI/AAMI/ISO 11607-1:2006 and ASTM F1980-07 (2011) standards. The basis of this accelerated aging test was centered around Arrhenius's Law and was done to determine if the packaging was sufficient to protect the device and maintain its functionality and integrity.

Arrhenius Accelerated Test Set-Up	
Test Temperature	55ºC
Ambient Temperature Relative Humidity	22ºC 15%
Q10 (Reaction Rate Factor)	2
Real-time Equivalent	3 years

A sample size of 40 was used in order to achieve 95% confidence level and 90% reliability given a low risk level using the Bayes Success-Run Theorem. At the end of the 90th day, the samples were inspected for any visible damages, and each device was tested for functionality. None of the 40 samples showed any defects, and the accelerated aging study verified a shelf life of three years for the device. Therefore, pIVot was verified to last 3 years through accelerated testing.
Additional testing for long term studies were performed by placing the initial three batches produced to ensure that the results from accelerated testing were consistent with the long term studies results.

SECTION 10: DISINFECTION

For disinfection methods, the pIVot device is classified into the non-critical Spaulding Category. A non-critical medical device only contacts intact skin without penetrating the skin or coming in contact with the mucous membrane. Non-critical devices can be disinfected using low level disinfection.

Disinfection validation requires that the pIVot device be inoculated with bacteria and then exposed to the disinfectant. Any remaining bacteria is extracted from the device and grown on plates in a manner similar to a bioburden test. Low level disinfection requires only a six log reduction of four different vegetative organisms. Disinfectant containing at least 70% ethyl alcohol was used on three separate batches and the device passed each test.

The pIVot device base unit and disposable unit will be provided non-sterile in conformance with ISO 11135. The pIVot device base unit should be cleaned after each patient use.

SECTION 11: MECHANICAL AND THERMAL SAFETY TESTING

Test Name	Applicable DIRs	Test Setup	Test Data and Analysis
Test 1: RF/ EMC Compliance	DIR 1-12 - The electrostatic discharge must be in compliance with IEC/EN 61000-4-2	Electrostatic discharge testing will be conducted on 16 pIVot devices in a temperature and humidity controlled chamber. The tests will be conducted for the humidity range: 15% humidity to 65% humidity. The temperature will be varied from 18ºC to 24ºC. The controlled temperature and humidity conditions are in place because ESD is largely dependent on environmental conditions, and performing the testing in a chamber allowed for the variation of environmental conditions to see the impact on the device's performance and determine the worst case environmental conditions of the device.	The test results from all 16 pIVots tested must comply with IEC/EN 61000-4-2
Test 2: EMC Compatibility /Interference Compliance	DIR 1-13 - Solution must conform to electromagnetic compatibility standards according to IEC 60601-1-2	Testing will be conducted on 16 pIVot devices according to IEC 60601-1-2 testing standards in order to establish conformance to electromagnetic compatibility standards. As part of this testing, the device's performance in the presence of electromagnetic disturbances will be quantified. The electromagnetic emissions of the device to the environment will also be characterized and quantified to ensure safety and functionality.	The test results from all 16 pIVot devices must fall within the acceptable ranges for all of the criteria according to IEC 60601-1-2.
Test 3: Thermal Safety Compliance	DIR 1-14 - Solution must conform to thermal safety standards according to ANSI/AAMI ES 60601-1.	Appropriate thermal testing will be conducted on 16 pIVot devices according to ANSI/AAMI ES 60601-1. The temperature of each device will be found during regular use over the lifecycle of the device. The temperature of the exterior of each device will be measured and recorded under extreme conditions, at the top range of the device's safe use environments.	The test results from all 16 pIVot devices must fall within the acceptable ranges for all of the criteria according to ANSI/AAMI ES 60601-1.

SECTION 12: PERFORMANCE

Verification Testing

Test Name	Applicable DIRs	Test Setup	Test Data and Analysis
Test 1: pIVot IV Fluid Warmer Characterization Test	DIR 1-1 - The solution must heat the intravenous fluids to a clinically safe temperature range. DIR 3-5 - The solution must warm fluids within the range of 38-42ºC for at least one hour. DIR 1-15 - The exterior of the solution must not heat to a temperature exceeding 44ºC at any time during the labeled one hour use time.	Sixteen pIVot IV fluid bag warmers and sixteen IV bags will be used for this test. Eight of the IV bags will have a single port, and the other eight will have two ports. These tests will be performed without any IV tubing, and the entire volume of fluids will be kept in the IV Bag for the duration of the tests. The pIVot devices will be turned on and allowed to heat up for five minutes. Once the warmup period is complete, the pIVot will remain on for one hour. Temperature readings will be taken every 30 seconds in two locations. One thermistor will be placed on the IV bag within the pIVot device. The second thermistor will be placed on the exterior of the pIVot device, on the insulation. The thermistors will be placed in the same location for each pIVot tested.	A total of 240 temperature data points will be taken for each pIVot tested (120 data points taken on IV Bag and 120 data points taken on the pIVot insulation). Across all sixteen pIVots tested, the mean temperature should be between 36 and 42ºC and temperature should not be significantly different between pIVots ($p>0.05$), meaning that each pIVot is equally effective in heating the IV fluids. Every temperature reading taken should be between 36-42ºC. The external temperature registered by the second thermistor located on the exterior of the pIVot devices should never register a temperature greater than 44ºC. If any of these criteria fail to be met, this test will fail.
Test 2: pIVot IV Fluid Delivery Characterization Test	DIR 1-2 - The solution must deliver the intravenous fluids throughout the IV tubing within the clinically safe temperature range. DIR 1-11 - When using the solution, the infusion rate of the IV fluids must be unaltered from the user-set infusion rate DIR 2-1 - The solution must allow fluids to be administered as the fluids are heated or	32 pIVot IV fluid bag warmers, 32 IV bags (eight bags with a single IV port, and eight bags with two IV ports), and 32 IV tubes (eight IV tubes with each of the following drop factors: 10 drop/mil, 15 drop/mil, 20 drop/ mil and 60 drop/mil) will be used for this test. Four different drip rates will also be tested, ranging from slow to rapid: 30 drops/minute, 100 drops/minute, 150 drops/minutel, and 200 drops/minute. The pIVots used in Test 1 may be reused for this testing. However, the batteries	For each test configuration in **Table 1**, temperature data will be sampled every 30 seconds. The temperature of the IV fluids exiting the IV tubing should never be less than 36ºC or higher than 42ºC across any of the configurations tested. Additionally, the actual infusion rate of the IV fluids will be compared to the set infusion rate. The set infusion rate per hour is a function of the IV tubing

Test 2: pIVot IV Fluid Delivery Characterization Test (cont.)	**Applicable DIRs (cont.)**	**Test Setup (cont.)**	**Test Data and Analysis (cont.)**
	maintained at their operating temperature DIR 2-2 - The solution must not divert the flow of fluids outside of the IV bag and tubing during any time of heating. DIR 2-5 - The solution must not cause the IV bag or tubing to melt. DIR 2-4 - The solution must not contain sharp edges, and must conform to the shape of a standard 1000 mL IV bag and tubing..	must be replaced between tests. See **Table 1** of **Appendix A** for the test configurations. The pIVot fluid warmers will be turned on for one hour, or until all of the IV fluids have been delivered. The temperature of IV fluids exiting the distal end of the IV tubing will be measured using a thermistor. The temperature of the exiting fluids will be taken every 30 seconds. The actual infusion rate per hour will be compared to the set infusion rate per hour. Visual inspection will also be performed after each test to check for damage to the IV bag and tubing including: evidence of melting, punctures, etc.	drop factor and the IV drip rate, which is found using **Table 2** of **Appendix A** The actual infusion rate will be found by measuring the volume of fluids that exited the IV tubing in the hour period, or by measuring the time it took for all of the fluids in the IV bag to be administered out of the distal end of the tube. The actual infusion rate should not be statistically different from the set infusion rate for any of the testing configurations tested ($p>0.05$). Finally, there should be no evidence of any kind of damage to the IV bag or tubing for all of the testing configurations. If any of these criteria fail to be met, this test will fail.
Test 3: pIVot with Drip Chamber Insulation Fluid Delivery Characterization Test	DIR 1-3 - The temperature of the intravenous fluids entering the body from the distal end of the IV tubing are between 36-42ºC with the IV tubing drip chamber insulation.	The same experimental setup and testing configurations will be used as in Test 2 above (see **Appendix A**, **Table 1**). All of the pIVot devices used in Test 2 may be reused after replacing/ fully recharging the batteries. The IV tubing may also be reused after Test 2 once the tubing has cooled and returned to room temperature. For each testing configuration, the drip chamber insulation will be used. The temperature of the exiting fluids will be measured using a thermistor and sampled every 30 seconds.	The results of Test 3 will be analyzed compared to the results of Test 2. The temperature of the fluids exiting the IV tubing will be graphed for each testing configuration over time. The results of Test 3 should show a smaller temperature drop over time as compared to Test 2. The results of Test 2 and Test 3 will be statistically analyzed according to the null hypothesis that the mean temperature of each testing configuration in Test 2 is the same as the corresponding mean temperature of each testing

Test 3: pIVot with Drip Chamber Insulation Fluid Delivery Characterization Test (cont.)	**Applicable DIRs (cont.)**	**Test Setup (cont.)**	**Test Data and Analysis (cont.)**
	DIR 1-4 - The temperature of the intravenous fluids exiting the IV tubing with the drip chamber insulation must be at a statistically significant higher temp. than that of the intravenous fluids exiting the IV tubing without the drip chamber.		configuration in Test 3. The results of the statistical analysis should result in a p value of <0.05 and the null hypothesis should be rejected, meaning that the temperature of the fluids in Test 3 had a statistically significant higher mean temperature over time than that of Test 2. If any of these criteria fail to be met, this test will fail.
Test 4: pIVot Electrical Characterization Test	DIR - 3-2 - The heating element must be able to supply sufficient power during the Temperature Maintenance period when supplied with voltage from two 5 volt batteries.	A total of 32 pIVots will be operated for one hour. For the first five minutes of testing, each pIVot will be plugged into a wall outlet. After five minutes, the pIVots will operate off of two 5 Volt batteries. To verify the power generated by the heating element, the current and voltage will be measured every 30 seconds during each phase of use (Start-Up period and Temperature Maintenance period). A multimeter will be connected to the device for the duration of time the device is turned on for, and the resistance (Ω) and current (A) will be measured. Power will be calculated as power = $current^2$*resistance. The power in the first 5 minute period (Start-Up period) should be 300 Watts and the power for the rest of the hour should be 2.42 Watts. Energy is power*time(seconds) and will be calculated from the power found above. The temperature of the fluids in the IV Bag will also be sampled every 30 seconds to ensure	The results of Test 4 should show that the resistance of the device is constant, regardless of time, voltage, or current. The resistance across all pIVots tested should not be statistically significantly different (p>0.05) and should have a mean of approximately 41.174 Ω. The current and power should be constant in each phase of the device's operation. In the Start-Up phase, the current should be approximately 2.7 amperes. The Power should be approximately 300 Watts for the entire initial 5 minute period. These current and power values should not be statistically significantly different across all of the pIVots tested (p>0.05). In the Temperature Maintenance phase, the current should be approximately 242 milliamperes. The power
	DIR 1-7 - The heating element must produce at least 85 kJ of energy		
	DIR 1-8 - The heating element must output at least 283 Watts over for the five minute Start-Up period, while connected to a wall outlet supplying 110V.		

Test 4: pIVot Electrical Characterization Test (cont.)	**Applicable DIRs (cont.)**	**Test Setup (cont.)**	**Test Data and Analysis (cont.)**
	DIR 1-9 - The heating element must output at least 2.42 Watts over the one hour Temperature Maintenance Period while running off of portable battery power.	accurate heating of the IV fluids.	should be approximately 2.42 Watts. These current and power values should not be statistically significantly different across all of the pIVots tested. If any of these criteria fail to be met, this test will fail.
	DIR 1-10 - The temperature of the heated IV fluids must not exceed 42ºC		
Test 5: pIVot Warm-Up Characterization Testing	DIR 2-11 - The IV fluids must be heated to operating temperature within 5 minutes of the solution being used	A total of 16 pIVots will be used for this experiment. These pIVots may be reused from previous tests as long as the batteries are new and/or fully recharged. Each pIVot will be connected to a thermistor that will sample the temperature of the IV fluids every 15 seconds. A timer will be started as soon as the pIVots are plugged into a wall outlet and are turned on. The pIVots are designed with an LED indicator that lights to designate the temperature of the IV fluids has reached the clinically safe range (37-42ºC) and the user may begin administering the sufficiently warmed fluids. The time at which this LED indicator turns on will be recorded for each test.	The thermistor measurements for each pIVot should show the temperature of the IV fluids increasing to the clinically safe range within 5 minutes. If any pIVot does not heat the fluids to the clinically safe range within 5 minutes, it will cause the pIVots to fail this test. Additionally, each pIVot should heat the IV fluids at the same rate and within the same amount of time, with a standard deviation of less than 5 seconds for when the fluids have heated to the clinically safe range. The functionality of the LED will be analyzed as well. The LED should turn on within 2 seconds of the thermistor registering the temperature of the IV fluids within the clinically safe range. If any LED does not turn on within two seconds of the temperature criterion being met, or fails to turn on at all, this test will fail.
	DIR 2-3 - The solution must indicate to the user that the IV fluids are at a clinically relevant and safe temperature to begin administering.		

Test 6: Heating Element Warm-Up Characterization Testing	**Applicable DIRs (cont.)**	**Test Setup (cont.)**	**Test Data and Analysis (cont.)**
	DIR 2-8 - The heating element must reach its maximum operating temperature in less than 90 seconds.	The time efficiency of the heating element will also be measured by timing how long it takes each heating element wiring to heat to its maximum operating temperature. The heating element should heat to its maximum operating temperature within 90 seconds of the pIVot being turned on. A thermistor will be attached directly to the heating element. Sixteen pIVots will be used for this test. Temperature measurements will be taken and recorded every 0.5 seconds.	All 16 pIVot heating elements tested should heat to the maximum operating temperature within 90 seconds. Additionally, each heating element should heat at the same rate. The standard deviation for the time each pIVot heating element takes to reach operating temperature should be less than 1 second between all tested pIVots. If either of these conditions are not met, this test will fail.
Test 7: Internal Electrical Checks	DIR 2-6 - The solution must perform a continuity check when powered on.	For this test, a series of malfunctions will be induced and the pIVot will be tested for its ability to detect and alert the user to the malfunctions. See **Appendix B, Table 1** for the testing configuration. For each malfunction tested, data will be recorded for whether the pIVot detected and alerted the user.	If any testing configuration fails to be detected or alerted, this test will fail.
	DIR 2-7 - The solution must incorporate an error alarm system to alert users of any device malfunction.		
Test 8: Manufacturing Verification	DIR 3-3 - The solution must not impede the environment around patient	The physical dimensions (length, width, height) and weight of 32 pIVots will be measured three times for each pIVot. The average of those three measurements will be used for each dimension and the overall device weight. The standard deviation of those measurements across all 32 pIVots will be calculated. Conformance to ISO 17664:2017 disinfecting and ISO 13485 manufacturing standards were adhered to in all manufacturing procedures.	The standard deviation of each measurement (length, width, height, weight) will be calculated. The dimensions and weight of every device measured must be within tolerance. Additionally, the standard deviation of the length, width, and height of the pIVots must be less than 2 mm. The standard deviation in weight must be less than 0.05 pounds. Documents supporting conformance to ISO 17664: 2017 and ISO 13485 were created, demonstrating manufacturing compliance.

Test 8: Manufacturing Verification (cont.)	**Applicable DIRs (cont.)**	**Test Setup (cont.)**	**Test Data and Analysis (cont.)**
	DIR 3-1 - The solution must be lightweight and compatible in weight to competitor devices.		
	DIR 2-9 - The heating element will be placed in a non flammable material that separates the IV bag from directly contacting the heating element.		
	DIR 2-10 - The solution must prevent substantial thermal heat loss to the ambient environment		
	DIR 1-5 - The solution exterior must adhere to ISO 17664:2017		
	DIR 1-6 - The solution must adhere to the proper standards for manufacturing medical devices (ISO 13485).		

Validation Testing

1. PURPOSE

The purpose of this document is to show the steps taken to perform design validation of the pIVot device. The study outlined here ensures that the pIVot device conforms to the defined user needs and intended use. The four high-level user needs being evaluated in this study can be found in the **DIOVV** document and are also listed below:

a. **UN-01:** The solution must not cause any additional harm to the users.
b. **UN-02:** The device should deliver warmed fluids to the patient.
c. **UN-03**: The solution must be compact, portable, and cost-efficient.
d. **UN-04**: The solution must be intuitive and quick to use.

2. STUDY DESIGN

This study was performed over a 2 week period and recruited 30 participants from the Atlanta, GA region, as this device is intended to be marketed primarily in the Atlanta, GA region when it first comes to market.

Participants

Fifteen emergency medical technicians (EMTs) were recruited from Grady Memorial Hospital's EMS Service, and 15 EMTs were recruited from Metro Atlanta's EMS Service. All EMTs had at least 3 years of experience on the job, with their primary current job being EMTs on the ambulance service.

Environment

The study was performed in Grady Ambulance service and Metro Atlanta Service Ambulances with a 'dummy patient' but use scenarios that were pre-defined.

Tests

All EMTs were required to go through each of the tests and were evaluated by two study conductors. All tests were performed on the same day, and each EMT was required to go through the testing process one time. The critical tasks evaluated are outlined in **Table 1**.

Table 1: Description of the various critical tasks, evaluation criteria, and evaluation process in relation to evaluating the 4 high level user needs.

User Need	Critical Task Evaluated	Evaluation Criteria	Evaluation Process
UN-01: The solution must not cause any additional harm to the users.	1. Full use life cycle evaluation - are there any adverse events that could lead to potential harm to the user or the patient.	Device-related harmful or adverse events, including but not limited to: -Fluid overheating -Fluid spills -IV bag puncture -IV tubing malfunction -IV port malfunction -Electrical accidents	Reported on a case-by-case basis by the study conductors, based upon the pre-identified, possible adverse events.
UN-02: The device should deliver warmed fluids to the patient.	1. Device application and fluid heating process evaluation - do the fluids heat up to the indicated temperature?	Fluid temperature measured at the exit point of the IV tubing using a fluid temperature sensor, after 1 minute of the device being on the IV Bag.	Fluid temperature is measured using an attachable sensor. Sensor data is collected and imported to a computer after each trial.
UN-03: The solution must be compact, portable, and cost-efficient.	1. The device can be lifted and moved around by the user comfortably. 2. The device can be removed from the wall outlet and converted to portable use when directed by the study conductor 3. The device maintains fluid temperature	1. The user will be asked to remove the device from a storage unit within the ambulance and then remove the device from its packaging. 2. The user will be instructed to convert the device to portable use - the time taken to do so and any other problems	1. Visual inspection and observation by the study conductors to take note of any complications in the device handling process which may be related to the size or weight of the device. 2. Visual inspection and observation

User Need (cont.)	Critical Task Evaluated (cont.)	Evaluation Criteria (cont.)	Evaluation Process (cont.)
UN-03: The solution must be compact, portable, and cost-efficient (cont.)	in the indicated range when put into portability mode.	experienced will be recorded by the study conductors. 3. The device maintains temperature in the range of 38-42C for 30 minutes after it is unplugged and put into portability mode.	by the study conductors to take note of any case-by-case complications in converting the device to portable use. The time required from instruction to full portable functionality is recorded by the study conductors. 3. Fluid temperature is measured using an attachable sensor. Sensor data is collected before and after the device becomes portable, and data imported to a computer after each trial.
UN-04: The solution must be intuitive and quick to use.	1. The device labeling and instructions for use are clear and easy to use. 2. The time required to set up the device and turn it on.	1. The number of questions asked or instances of confusion are recorded. 2. The time required to set up the device is 20 seconds or less.	1. Visual inspection and observation to take note of any questions the EMTs ask, or any instances of confusion in which they fail to operate the

UN-04: The solution must be intuitive and quick to use (cont.)	**Critical Task Evaluated (cont.)**	**Evaluation Criteria (cont.)**	**Evaluation Process (cont.)**
			device or get 'stuck.' 2. A timer is used by the study conductors to measure the time it takes for the EMT to set up the pIVot device and turn it on for use.

Testing Process

Each EMT went through the test, where each of the critical tests highlighted in **Table 1** were evaluated. Two study conductors were inside the ambulance with the EMT during the test, and had access to a computer and sensors to obtain data from the IV fluids at the distal end of the IV tubing. The testing process had the following steps:

1. EMT professionals attended training for the device as a part of an extended learning module, prior to the conduction of the test. The key features of the device, how to use, and when to use were identified during this training period.
2. On the day of the test, the two study conductors entered the emergency vehicle with the EMS professional. A dummy patient was placed onto the stretcher inside the ambulance, and the pIVot device was located in the sliding glass compartment of the ambulance.
3. The EMS professional was giving the following scenario to assume: A gunshot wound trauma patient is the next call, and the ambulance is on the way to the site where the patient is. The patient site is 10 minutes away. At this point, the EMT professional is instructed to begin the pIVot application process.
4. The study conductors fill out the following information into a table (**Table 2)** provided to them for each participant of the study.

Table 2: Template provided to the study conductors for each test

Subject Identifier #:
Date of Test:
Ambulance Service:
Study Conductors:

Evaluation 1: Setup Process

Study Conductor 1 Tasks:
- Start the timer for setup time, stop the timer when setup is complete, record results

Study Conductor 2 Tasks:
- Observe the setup process and record observations
- Record any adverse events

Critical Task	Assigned Conductor	Evaluation Criteria	Results	Observations
The device can be lifted and moved around by the user comfortably.	2	Visual inspection and observation by the study conductors to take note of any complications in the device handling process which may be related to the size or weight of the device.		
The device labeling and instructions for use are clear and easy to use.	2	Visual inspection and observation to take note of any questions the EMTs ask, or any instances of confusion in which they fail to operate the device or get 'stuck.'		
The time required to set up the device and turn it on.	1	The time required to set up the device is 20 seconds or less.		
Full use life cycle evaluation - are there any adverse events that could lead to potential harm to the user or the patient.	2	Device-related harmful or adverse events, including but not limited to: -Fluid overheating -Fluid spills -IV bag puncture -IV tubing malfunction -IV port malfunction -Electrical accidents		

Evaluation 2: Fluids Heating

Study Conductor 1 Tasks:
- Collect Sensor Data after 1 minute of the device being operational

Study Conductor 2 Tasks:
- Record any adverse events

Critical Task	Assigned Conductor	Evaluation Criteria	Results	Observations
Device application and fluid heating process evaluation - do the fluids heat up to the indicated temperature?	1	Fluid temperature measured at the exit point of the IV tubing using a fluid temperature sensor, after 1 minute of the device being on the IV Bag.		
Full use life cycle evaluation - are there any adverse events that could lead to potential harm to the user or the patient.	2	Device-related harmful or adverse events, including but not limited to: -Fluid overheating -Fluid spills -IV bag puncture -IV tubing malfunction -IV port malfunction -Electrical accidents		

Evaluation 3: Device Portability

Study Conductor 1 Tasks:
- Record sensor data when device is converted to portable, and after device has been portable for 30 minutes

Study Conductor 2 Tasks:
- Record any adverse events
- Begin timer, record time it takes to convert use from wall outlet to portable

Critical Task	Assigned Conductor	Evaluation Criteria	Results	Observations
The device maintains fluid temperature in the indicated range when put into portability mode.	1	The device maintains temperature in the range of 38-42C for 30 minutes after it is unplugged and put into portability mode.		

Critical Task (cont.)	**Assigned Conductor (cont.)**	**Evaluation Criteria (cont.)**	**Results (cont.)**	**Observations (cont.)**
The device can be removed from the wall outlet and converted to portable use when directed by the study conductor	2	The user will be instructed to convert the device to portable use - the time taken to do so and any other problems experienced will be recorded by the study conductors.		
Full use life cycle evaluation - are there any adverse events that could lead to potential harm to the user or the patient.	2	Device-related harmful or adverse events, including but not limited to: -Fluid overheating -Fluid spills -IV bag puncture -IV tubing malfunction -IV port malfunction -Electrical accidents		

3. STUDY RESULTS

Table 3: Results of the Validation Study

Criteria	Evaluation Criteria	Results	Observations
The device can be lifted and moved around by the user comfortably.	Visual inspection and observation by the study conductors to take note of any complications in the device handling process which may be related to the size or weight of the device.	-No complications. All users were able to utilize remove and utilize the device without any issues with regards to the size or weight of the device	n/a
The device labeling and instructions for use are clear and easy to use.	Visual inspection and observation to take note of any questions the EMTs ask, or any instances of confusion in which they fail to operate the device or get 'stuck.'	-No reports of unclear instructions -Drip chamber insulation sometimes falls out of the EMTs hand due to the rush/high-pressure situation and can become contaminated. Each device comes with two so this was not a problem.	n/a
The time required to set up the device and turn it on.	The time required to set up the device is 20 seconds or less.	The mean time required for all of the EMTs to set up the device was 17.3 +/- 2 seconds.	-The EMTs have previous knowledge and know how to use the device, so it was as simple as removing the device, plugging into the wall, applying to the bag, applying the drip chamber insulation. There were no complaints about the setup taking too long or the process being an obstacle to the EMS care-delivery process.

Criteria (cont.)	Evaluation Criteria (cont.)	Results (cont.)	Observations (cont.)
Full use life cycle evaluation - are there any adverse events that could lead to potential harm to the user or the patient.	Device-related harmful or adverse events, including but not limited to: -Fluid overheating -Fluid spills -IV bag puncture -IV tubing malfunction -IV port malfunction -Electrical accidents	None reported.	n/a
Device application and fluid heating process evaluation - do the fluids heat up to the indicated temperature?	Fluid temperature measured at the exit point of the IV tubing using a fluid temperature sensor, after 1 minute of the device being on the IV Bag.	The fluid temperature, measured after one minute of device operation, was a mean of 39.4 +/- .3C.	n/a
The device maintains fluid temperature in the indicated range when put into portability mode.	The device maintains temperature in the range of 38-42C for 30 minutes after it is unplugged and put into portability mode.	The fluid temperature difference, measured before conversion to portable mode and after, was 1.2C +/- .3C, with no instances of the IV fluids having a temperature outside of the indicated range.	n/a
The device can be removed from the wall outlet and converted to portable use when directed by the study conductor	The user will be instructed to convert the device to portable use - the time taken to do so and any other problems experienced will be recorded by the study conductors.	The average time taken to convert from wall to portable was less than 10 seconds for all EMTs, with an average of 5.6 seconds +/- 1 second.	-Lots of positive feedback on ease of use to convert from outlet mode to portability mode

4. STUDY CONCLUSIONS

The purpose of this study was to validate the pIVot device against the high level user needs and intended use of the device. Critical tasks were identified for each user need, after evaluating and mitigating potential risks, as indicated in the **Risk v3** document in the DHF. The results of the study led to the following conclusions for each user need **(Table 4)**:

Table 4: Conclusions from the Human Factors/Usability Study

User Need	**Conclusions**
UN-01: The solution must not cause any additional harm to the users.	There were no instances of recorded adverse or harmful events for the users in the study.
UN-02: The device should deliver warmed fluids to the patient.	All data obtained indicated that the fluids were warmed to the indicated range when users applied the device correctly.
UN-03: The solution must be compact, portable, and cost-efficient.	All data indicated that the solution was easily converted to its portable use and maintained fluid temperature in the clinically safe and sufficient range for at least 30 minutes after conversion to portable mode.
UN-04: The solution must be intuitive and quick to use.	Feedback from all users and visual inspection and observations indicated that the device was intuitive and quick to use, with no issues reading instructions or labeling or handling of the device.The application process was smooth and well-supported by the training that was provided to the users prior to the study.

SECTION 13: STATEMENT OF SUBSTANTIAL EQUIVALENCE

Based on the 510(k) flowchart and the review of performance data, the pIVot device is substantially equivalent to the predicate devices. In making this statement, it is obvious that the technological characteristics are substantially equivalent and that the performance data raise no new questions of safety or effectiveness.