AVIT MEDICAL

Drip Chamber Alarm

Team # **1326**

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B2B BENCH TO BEDSIDE

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1. EXECUTIVE SUMMARY

An estimated 60,000 surgical procedures occur every day nationwide [1]. During these surgical procedures, it is the responsibility of the anesthesiologist or related hospital staff to monitor the total intravenous (IV) anesthesia administered through gravity-assisted drip. However, due to the chaotic nature of the operating room setting, consistent monitoring is not always maintained and leads to a dangerous problem: disruptions during IV anesthesia administration could result in blood occlusions, air embolism, or even sudden anesthesia awareness for the patient if they dip bag runs empty [2]. Our team proposes a new medical device to be implemented into the operating room which utilizes predictive measuring to relieve the burden of the anesthesiologist as well as ensure patient safety with IV. Our team has assembled critical components to such a device, such as a non-contact liquid level sensor and visual/auditory alarm hardware and combined them with innovative techniques to develop codes and printed casings to create a predictive measuring device which notifies approximately 10 minutes prior to the drip bag running empty.

2. IDENTIFY THE PROBLEM

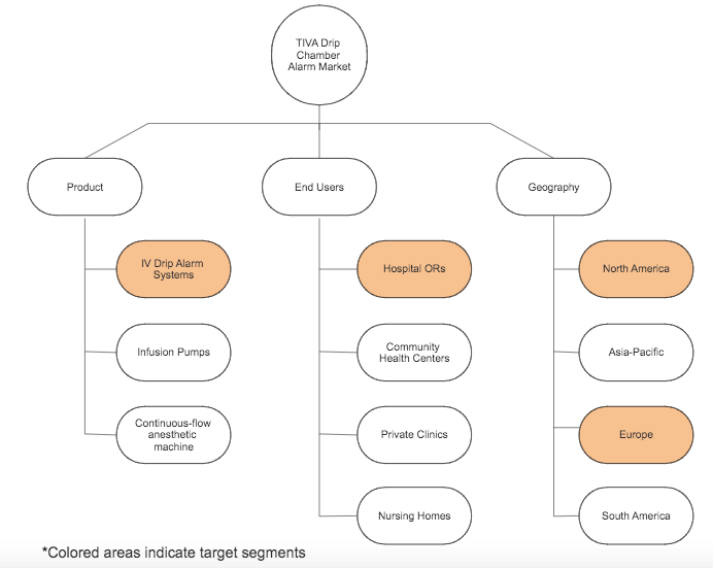
2.1. Clinical Need

The Current drip chamber alarms on the market will only sound at a ±13% flow rate change or once no flow is present. There is no current device design which includes features to be a predictive measuring device and provide alarm notification prior to the drip bag running empty. Our team is confident our device will appeal to anesthesiologists and anesthesiologist techs who often make rotations between different operating rooms. This device will aid in their work to ensure patient safety when it comes to drip bag monitoring. The AVIT device will be intended to raise value for a variety of individuals throughout a hospital, including anesthesiologists, hospital insurers and patients. If anesthesiologists are targeted as the intended market, the likelihood of hospital acceptance is greater. Our team has identified a list of customer/user needs during early development of our device. The user needs are as follows:

- Device needs to estimate a time of IV bag empty and alarm when bag is 10 minutes away from empty
- Device needs to consist of an auditory and visual notification element
- Device must estimate dosage of intravenous (IV) liquid in terms of mL/min
- Device must have a simple interface with less than 5 buttons

These features are documented within our design requirements for the drip chamber alarm device. These user needs are determined with consideration of the anesthesiologist and their work environment. Our team made certain determinations which we are confident will be well accepted by the users of our device. 10 minutes is ample time for a full drip bag to be retrieved and for preparations to be made to replace the drip bag in use. Both auditory and visual elements are implemented and will be easily interpreted as flashing red LED lights and beeping alarm sound for the hospital staff. As to not overburden interpretation of the device, the interface will be simple and read easily understandable measurements.

2.2. Market Opportunity

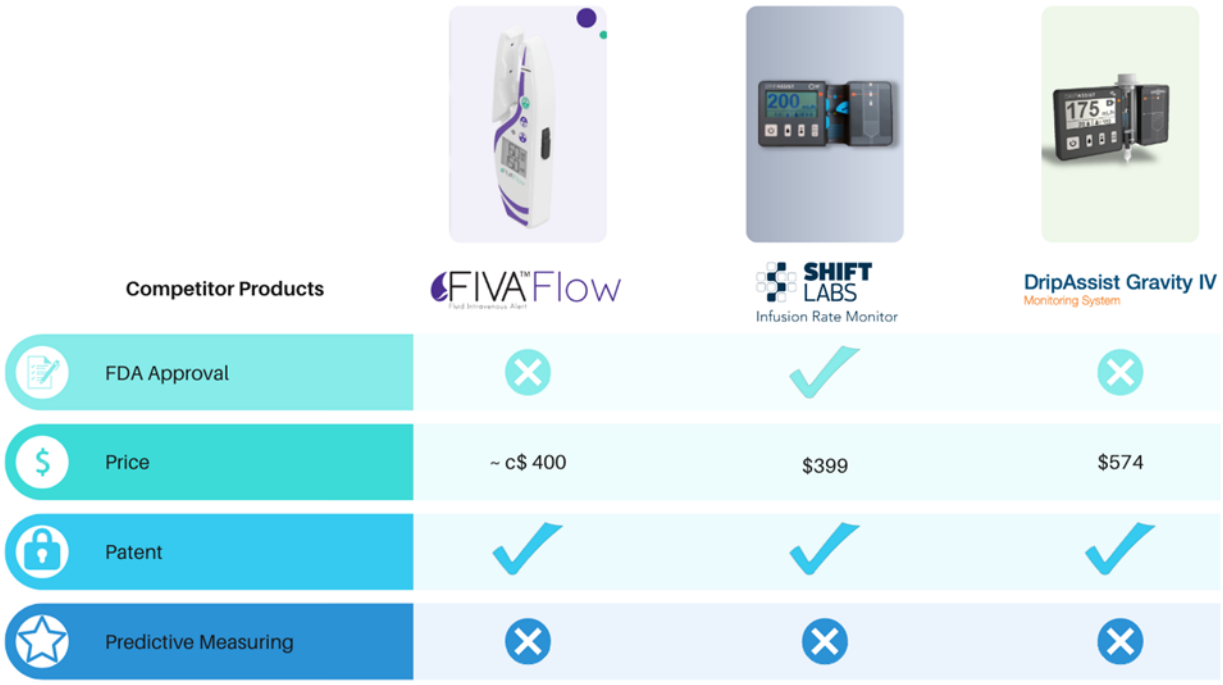


We have broken our market segments into three distinct sections: products, end users, and geography. Under “products”, we have listed product-type markets that could potentially be targeted by our device. We have color-coded IV drip alarm systems, as our device is specific to this market and will not compete against infusion pumps or continuous-flow anesthetic machines. Our end users will consist of solely hospital OR environments as this will help achieve our user needs more effectively. For the geographic locations of our device, we will target only north American and European markets, as those will be easiest to initially gain approval for market release.

Based on medical sensors (pressure sensors, temperature sensors, blood oxygen sensors, Image sensors, flow sensors), the market size is expected to expand at a rate of 10.3% at a compound annual growth rate from the 2021 value of 1.8 billion US dollars. With this in mind, we expect the market size to grow to 1.98 billion in a single year, 2.42 billion in 3 years and approximately 3 billion US dollars in 5 years. It has been determined that drip chamber alarm devices make up 0.6% of the overall medical sensors market.

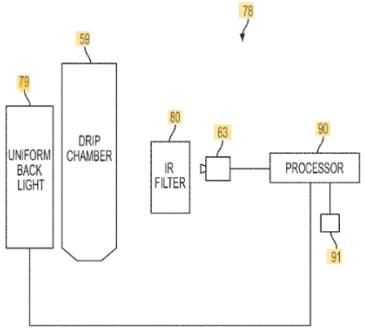
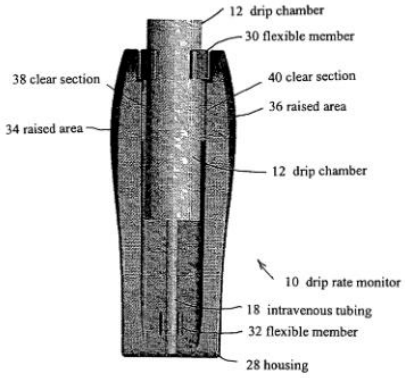
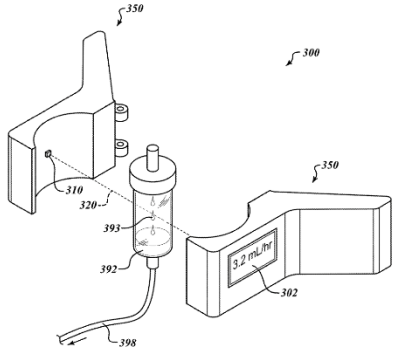
2.3. Competitive Landscape

There are 3 competitor products which target the same intended market as our teams’ drip chamber alarm. As seen in the chart below, there is the FIVAFlow device from FIVAMed, Infusion rate monitor from Shift Labs, and the DripAssist Gravity IV, which has devices intended for both human and veterinary use. The FIVAFlow and Shift Labs device feature a pinching mechanism to prevent further administration of fluid or air embolism if the drip bag is empty. This is certainly a strength these competitor devices have over our team’s device. However, none of these devices offer predictive measuring accuracy, to alert users prior to the drip bag running empty. In addition, our drip chamber alarm is intended to be used in the operating room where a sterile environment must be maintained. After review of the technical specifications of the three devices below, none of the competitor devices are designed to be sanitized and disinfected to meet the requirements of the operating room.



As see in the comparison chart above, the prices of other competing devices average at about $458. Considering the niche and competitive market for this product, taking control via pricing is critical and market studies of other competitor products. After preliminary price analysis, the drip chamber is projected to be sold at approximately $200, which places our device strategically in the market as a cheaper product to be sold.

2.4. Prior Art

Patent Filed By	Title	Patent NO	Description	Image
Deka Products LP	Flow Meter	US9724465B2	Flow meter comprised of a coupler, a support member, an image sensor, and one or more processors.	
Goldberg Barry A, Shu Chung Lai	Drip rate monitor for intravenous infusion set	US7190275B2	An apparatus that is attachable to a drip chamber for monitoring drip rate of an intravenous fluid comprised of a housing, drop sensor, alarm, and processor.	
Shift Labs, INC	Monitoring device including an emitter emitting electromagnetic radiation and a detector positioned to receive the radiation to determine one or more rolling average flow rates	11464905	A monitoring device provided for monitoring delivery of fluids through a drip chamber. The device includes and electromagnetic radiation (EMR) source and an EMR detector. The device includes a tubing set mount for receiving a flange or other portion of a tubing set, such that fluid falling through the drip chamber of the tubing set is detected by the	 FIG.3

			detector. The device is operable to determine one or more rolling averages based on the intervals of drops or time.	

2.5. Needs to Functional Requirements

The design solution will feature several components built-into the drip chamber alarm device to address the user needs as outlined in the design requirements. These components include an ultrasonic sensor, LED alarm lights, tactile push buttons, power source from a replaceable battery, and external stabilizers to the drip chamber and IV pole stand. All of these components will allow for an improved drip chamber alarm system to indicate change in IV drop flow rate and IV drip bag nearing, and reaching empty.

Table: Specifications to Requirements Traceability Matrix

		Specifications	Description of Design Solution	Human Factors and Usability Engineering	Risk/Hazard Analysis Summary	Mechanical Design Details	Material Selection Details	Electrical Design Details	Software Design Details	Cleaning, Disinfection, and/or Sterilization	Shipping/Storage Conditions	Packaging and Labelling
			5.1	5.2	5.3	5.4	5.5	5.6	5.7	5.8	5.9	5.10
Requirements												
Device needs to estimate a time of IV bag empty and alarm when bag is 10 minutes away from empty	5.2 / 5.13.1		X									
Device needs to consist of an auditory and visual notification element	5.2 / 5.13.0		X	X								

Device must estimate dosage of intravenous (IV) liquid in terms of mL/min	5.2 / 5.13.1							X	X			
Device must have a simple interface with less than 5 buttons	5.2 / 5.13.2			X		X						
This device will require a 510(k) submission and proven substantially equivalent to other legally approved devices through the FDA.	5.12.1		X									
Device must be lightweight with precise design in order to achieve secure placement around drip chamber	5.13.2					X						
Device must be long lasting with battery life of 30+ hours of intermittent use	5.13.2			X				X				
Device surface will allow for sanitization	5.13.2						X			X		
Device will feature buttons to control power, volume, drip rate, and other necessary parameters	5.14.1			X		X		X				
Sensor will interface with internal algorithm for variable flow rate	5.14.1								X			
Device will have stabilizing feature extended to IV pole system	5.14.1			X		X						

Device should include only internal electrical components					X							
Device will not emit radiation/interfere with alternate machine radio frequencies within the same room					X							
Device must be easy to remove from packaging	5.15.1											X
Device needs to have the ability to be fastened and removed with normal forces applicable by any trained professional without the need of any additional tools.	5.15.1			X		X	X					
The entire device ensemble must be sterilizable either as a whole or in parts to allow use in a sterilized surgical setting.	5.15.1									X		
The product will the provided with an intuitive yet detailed brochure and guides	5.15.2		X	X								X
Labels on the device and the packaging will confirm to the appropriate parts of Title 21 CFR.	5.15.4											X

3. SOLUTION

3.1. Value Proposition

We believe our product will offer consistent satisfaction to patients, anesthesiologists, and hospitals by allowing them to engage in a simple, attachable, and completely customizable TIVA drip chamber alarm device. We are confident our device will prevent fatal outcomes and complications post procedure, and even increase patient safety by mitigating human error.

We selected this value proposition because we strongly believe our product's features meet our user needs in a way that utilizes its engineering and design to provide the best outcomes for any situation that may arise in the OR.

3.2. Solution Description

3.2.1. Concept Selection

The design solution will feature several components built into the drip chamber alarm device to address the user's needs as outlined in the user's needs. These components include a capacitance-based liquid level sensor, LED alarm lights, tactile push buttons, a power source from replaceable batteries, and external stabilizers to the drip chamber and IV pole stand. These components will allow an improved drip chamber alarm system to detect and indicate changes in the IV drip flow rate and IV drip bag nearing and reaching empty.

3.2.2. Function and Performance Specifications

The most important feature of the drip chamber alarm is reliably notifying all healthcare professionals in the environment that the drip bag is closely approaching empty. This is done by applying the sensor to the drip chamber and monitoring the flow rate. To then specify the design specifications, the focus will be placed on the sensor, the interface of the device, and the alarm. The liquid level sensor will be housed in a 3D-printed casing such that it interfaces in close contact with the drip chamber wall. The casing will hold the following components, the liquid level sensor, the controller board (Arduino Nano Every), LED lights, threaded screws for stabilization to the drip chamber, and the power source. The alarm, coded in with small LED lights, so as not to disturb the patient, will sound from a speaker at around 80 dB for sufficient awareness. The functionality of the device as a whole will be intuitive to use by any healthcare professional, featuring tactile buttons to turn on/off the device, and silence the alarm.

3.2.3. Considerations for Design Solution

3.2.3.1. Public Health, Safety, And Welfare Factors

With regards to an operating room within a hospital, one of the main concerns of the patient's health and safety is to ensure pain management and full sedation of the patient undergoing any form of surgical operation. This allows a controlled environment for the operating surgeon, nurses, technicians, and other personnel. As controlled by gravity, drip bag, chamber, and IV catheter systems are seemingly reliable. Hazardous scenarios arise due to human error and lack of monitoring of the IV fluid volume levels. If not monitored continuously, an empty IV bag is replaced in time, and the patient undergoing the operation could experience not only a lapse in IV fluid administration, but also clotting, and potentially fatal air embolism. The rechargeable battery feature is important to implement, and ensures a reusable factor in the device. Many IV drip bags

are utilized in operating rooms. A single operating procedure could utilize several different IV bags replaced at least twice. Since many IV drip bags and drip chamber systems are utilized per procedure, the TIVA drip chamber alarm will need to be reusable and the power must last long enough to be easily attached and keep up with each system.

3.2.3.2 Global, Cultural, Social, And Environmental Factors

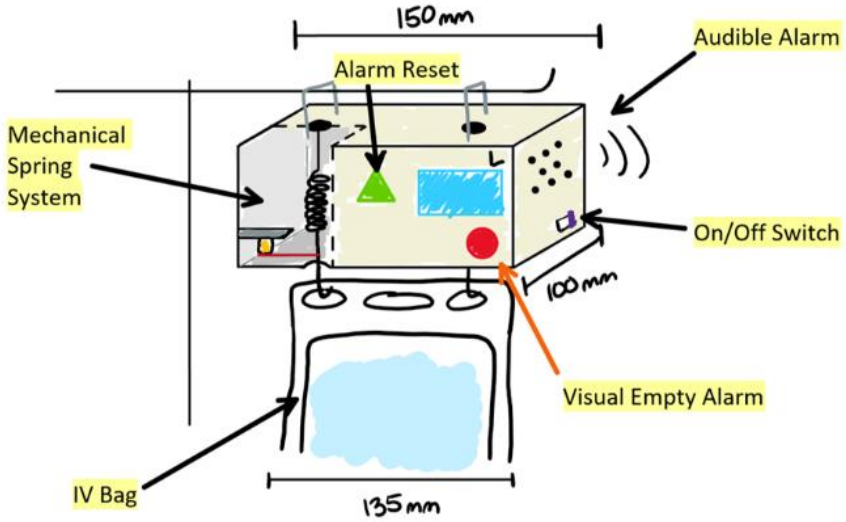
The TIVA drip chamber alarm is designed to eliminate the risk of human error in a chaotic operating room environment. Currently, IV systems operate either with a faulty drip chamber alarm, or a nurse is tasked with constant monitoring of the IV drop system levels for the patient. Our device will monitor the drip rate of the IV bag and sound an alarm prior to the bag emptying to provide enough time for qualified hospital employees to retrieve a new bag. It is possible for this device to develop into similar concepts for applicability to different scenarios; such as at home IV, ICU IV, remote location IV, etc. addressing global needs. The device also addresses cultural and social factors as it is intuitive to interpret the flashing red LED lights as a warning. LED flashing lights in addition to sound alarm systems does well to be inclusive of disabilities which may be encountered in the personnel to interact with the device. Focusing on healthcare professionals, most will have the ability to see and hear and have full motor control to control the device. Even with difficult seeing or hearing, one or the other need is met.

3.2.3.3. Economic Factors

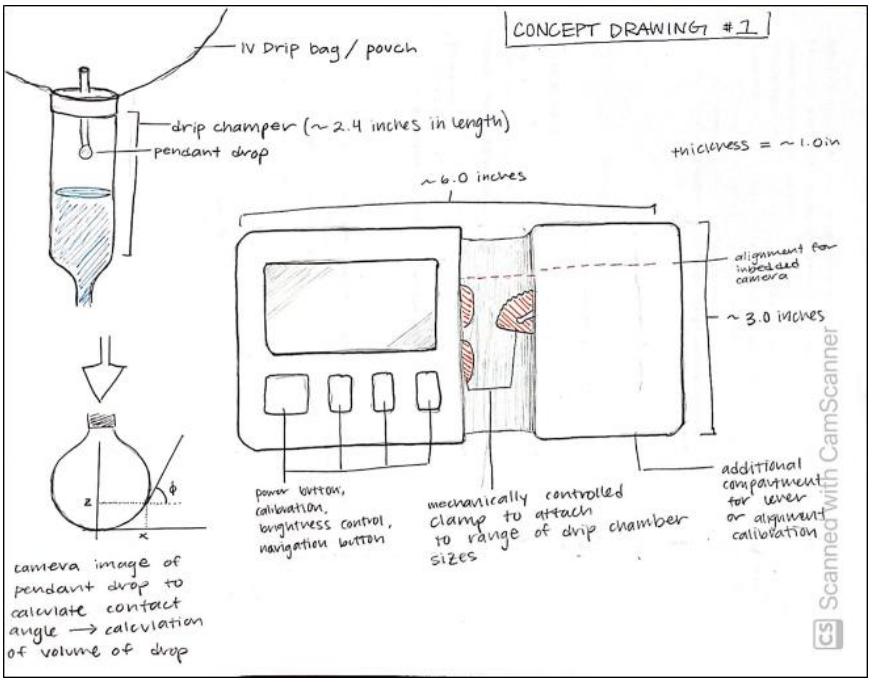
The TIVA drip chamber alarm will reduce costs for the manufacturing company, hospital and can be widely distributed around the globe. This device will be reusable and therefore will not need changed by the hospital staff as frequently. AAA batteries are globally accepted, so this device theoretically can be bought and reused in any country or setting where battery purchases can be made. This TIVA Drip Chamber alarm device will likely be contributing to this increase as the need for automated monitors increase, and hospital staff decreases or plateaus. The cost of the battery, microcontroller and liquid level sensor, which are the most critical components, are reasonable to manufacture and cheap to source or outsource as needed.

3.2.4. Conceptual Representation of Solution

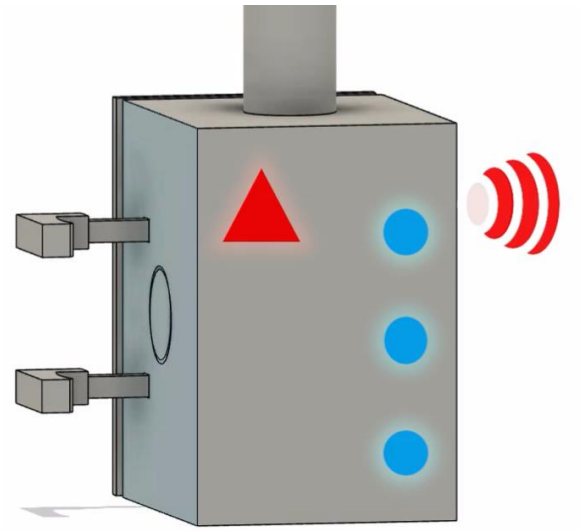
3.2.4.1. Initial Ideation: Concept Drawing 1

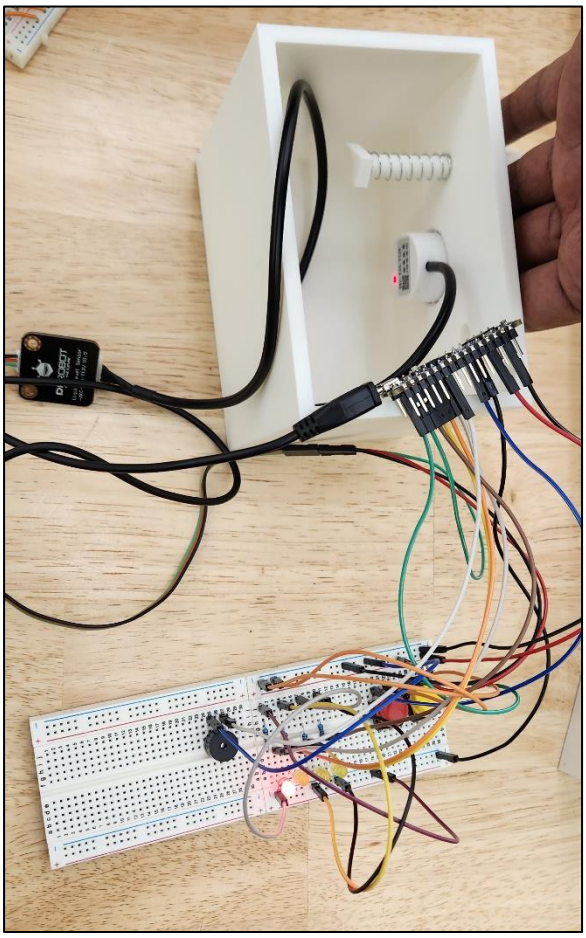


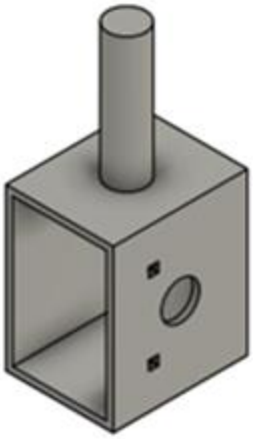
3.2.4.2. Initial Ideation: Concept Drawing 2



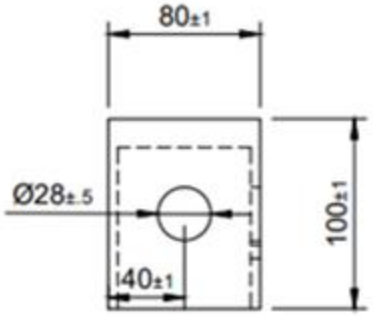
3.2.5 Final Ideation



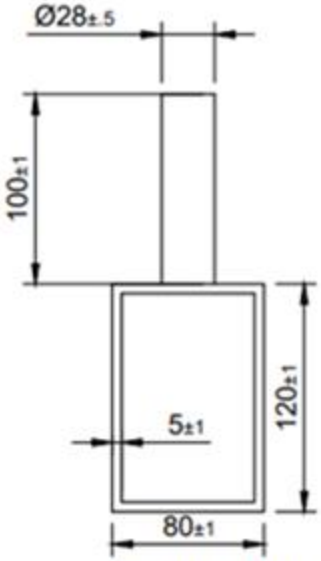




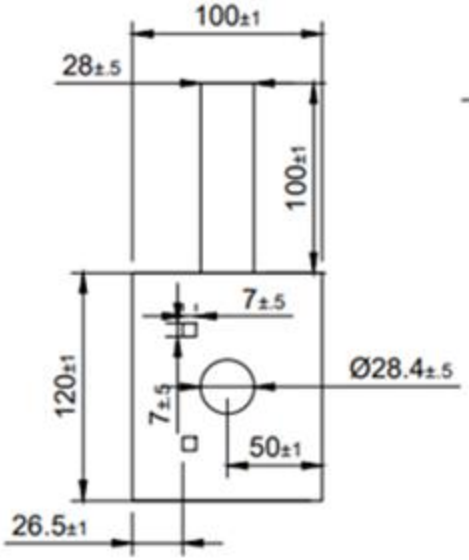
NE Isometric View



Top View



Front View



Side View

Dept. AVIT	Technical reference	Created by Madison Davis 3/19/2023	Approved by
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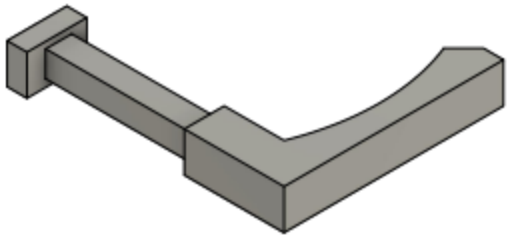

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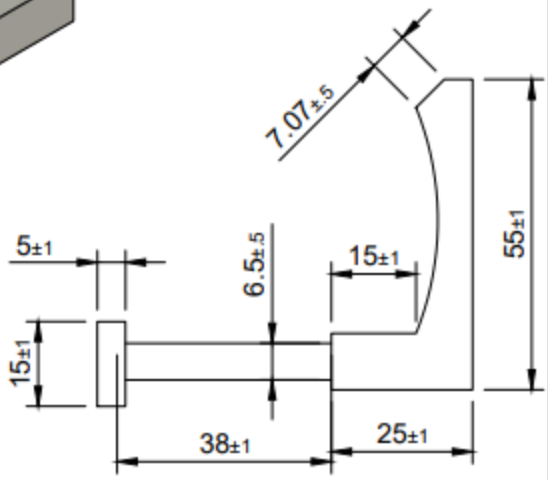
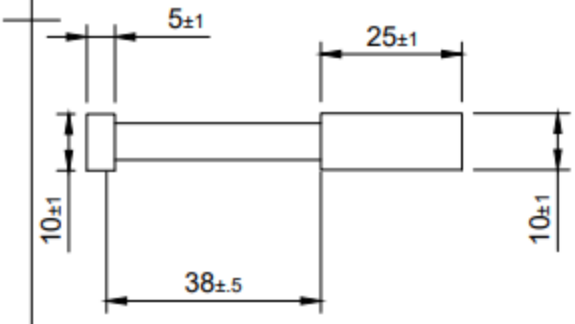
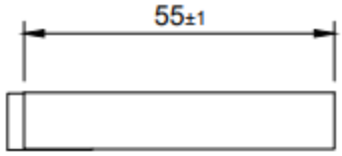


Top View



Front View



Side View

Dept. AVIT	Technical reference	Created by Madison Davis 3/19/2023	Approved by
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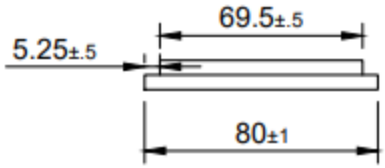
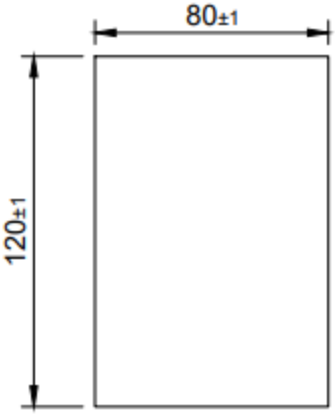
		Title Stabilizing Arms and Spring Caps	DWG No. 2,3,&5
			Rev. / Date of issue / Sheet 1/1

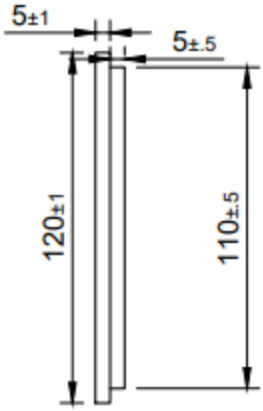
NE Isometric View



Top View



Front View



Side View

Dept. AVIT	Technical reference	Created by Madison Davis 3/19/2023	Approved by
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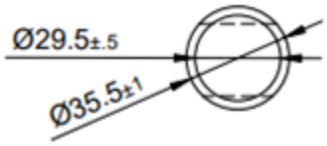
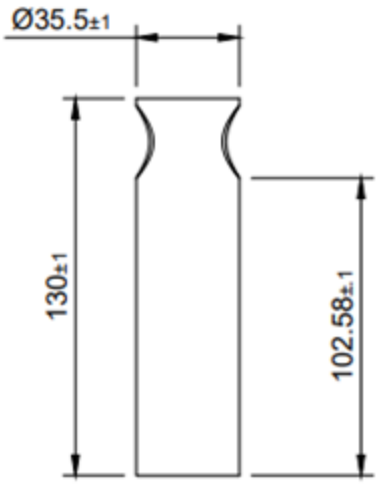
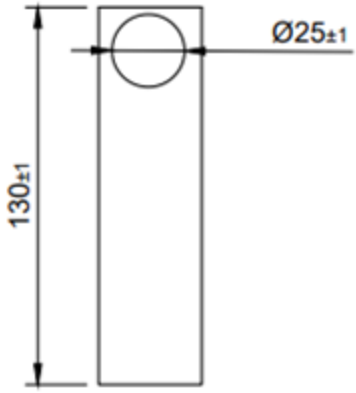
NE Isometric View



Bottom View



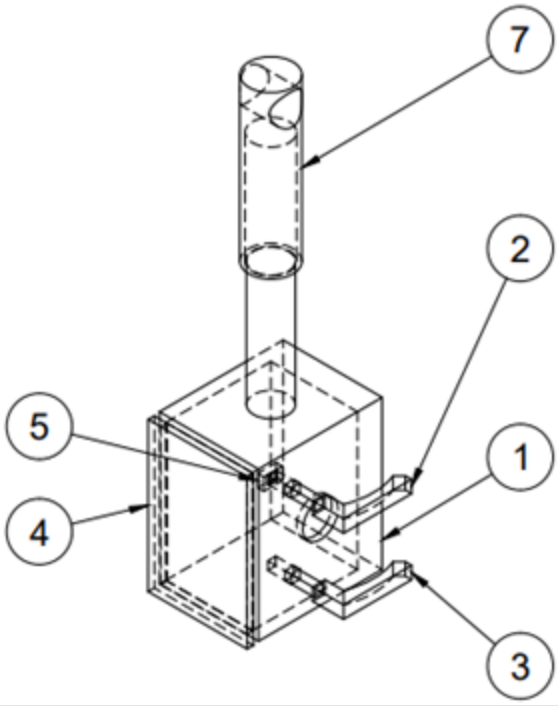
Front View



Side View

Dept.	Technical reference	Created by	Approved by
AVIT		Madison Davis 3/19/2023	
All dimensions and tolerances are in mm		Document type: Engineering Drawing	Document status
Material: PC/ABS		Title: IV Pole Attachment	DWG No.: 7
SCALE- 1:2			Rev. / Date of issue / Sheet: 1/1

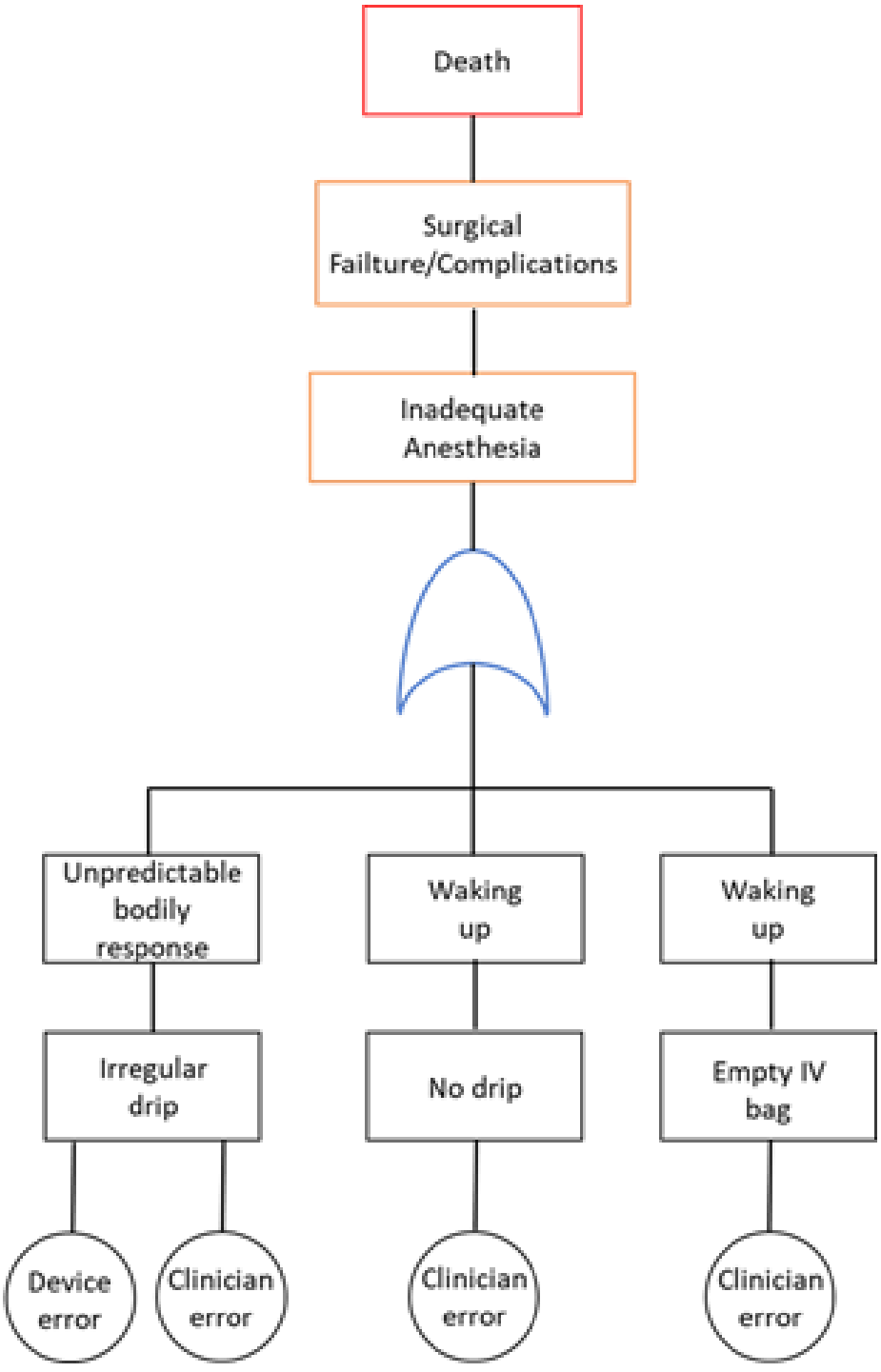
Parts List				
Item	Qty	Part Number	Description	Material
1	1	Main Body Component		PC/ABS Plastic
2	1	Side Stabilizer		PC/ABS Plastic
3	1	Side Stabilizer 2 (1)		PC/ABS Plastic
4	1	Cover Plate		PC/ABS Plastic
5	1	Spring Caps		PC/ABS Plastic
7	1	IV Pole Attachment		PC/ABS Plastic



Dept.	Technical reference	Created by	Approved by
		Madison Davis 3/19/2023	
		Document type	Document status
SCALE: 1:3		Title: TIVA Drip Chamber Alarm	DWG No.
			Rev. / Date of issue / Sheet: 1/1

3.2.6. Risk Analysis

3.2.6.1. Fault Tree Analysis (FTA)



3.2.6.2. Failure Mode and Effects Analysis (FMEA)

LIKELIHOOD OF OCCURRENCE CRITERIA		
Rating	**Likelihood of failure**	**Rate**
10	Very High	>1 in 2
9		>1 in 4
8	High	>1 in 8
7		>1 in 20
6	Moderate	>1 in 80
5		>1 in 400
4		>1 in 2000
3	Low	>1 in 20,000
2	Very Low	>1 in 100,000
1	Remote	<1 in 500,000

Severity Criteria		
Rating	**Effect**	**Criteria**
10	Catastrophic	Potential of multiple deaths
9	Hazardous	Potential of death
8	Serious	Potential of serious injury – Permanent Impairment
7	Extreme	Potential of injury – no permanent impairment
6	Major	Potential of total loss of function/treatment/diagnosis
5	Significant	Partial loss of function/treatment/diagnosis
4	Moderate	Unscheduled downtime or repair
3	Minor	Minor dissatisfaction with device performance
2	Slight	Slight dissatisfaction or inconvenience
1	Negligible	No noticeable effect by the customer

Risk Acceptance Criteria											
L I K E L I H O O D	**10**	10	20	30	40	50	60	70	80	90	100
	9	9	18	27	36	45	54	63	72	81	90
	8	8	16	24	32	40	48	56	64	72	80
	7	7	14	21	28	35	42	49	56	63	70
	6	6	12	18	24	30	36	42	48	54	60
	5	5	10	15	20	25	30	35	40	45	50
	4	4	8	12	16	20	24	28	32	36	40
	3	3	6	9	12	15	18	21	24	27	30
	2	2	4	6	8	10	12	14	16	18	20
	1	1	2	3	4	5	6	7	8	9	10
		1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
	SEVERITY										

≥50 - Unacceptable range

	Item	Failure Mode	Failure Cause	Failure Effect	Failure Detection	Severity Level	Failure Probability	Risk Priority	Risk Mitigation Action
Internal Systems	Electrical system	Insufficient power supply	Wrong power input	Partial power response	Device does not turn on	8	2	16	User needs to be aware of the right input
			Battery voltage issues	Partial power response	Device does not turn on	8	4	32	User needs to be aware of the right input
		No display or alerts	Wires wrongly connected	rewiring of device components	No reading	7	2	14	Increasing quality assurance
			Display screen failure	Screen replacement needed	No reading	6	3	18	Pre-testing screens before assembly
		Electrical wires tangled	Manufacturing defect	Short circuit	Incorrigible feedback	6	2	12	Increasing quality control
	Non-contact level sensor	Does not measure	Placement not tight against chamber	Repositioning required	Detected through lack of data	8	7	56	Fixing working distance in the casing unit
		Constant value	Reading adherent residual drop	False positive measurement	Constant unchanged data value	8	9	72	Optimize against constant small level changes
	Software	Alarm criteria unfulfilled	Errors in code	Incorrect output data	Wrong indications	8	1	8	Strict code Debugging
		Improper graphs	Errors in data output	Incorrect data representation	Incorrect graphs and logs	8	1	8	Strict code Debugging

	Item	Failure Mode	Failure Cause	Failure Effect	Failure Detection	Severity Level	Failure Probability	Risk Priority	Risk Mitigation Action
Extermal Systems	Fastening mechanism	Stuck, Loose, Knobs do not turn	Improper manufacturing	Improper drip reading	Slips off IV drip chamber	6	4	24	Increasing quality control
			Improper handling	Inability to fasten properly	Slips off IV drip chamber	7	6	42	Improving packaging
			Damage during transport	Improper drip reading	Slips off IV drip chamber	7	5	35	Improving packaging and labeling
			Fatigue from repeated use	Inability to fasten properly	Slips off IV drip chamber	7	8	56	Better cyclic use testing
		Size does not fit	Improper manufacturing	Cannot fit IV drip chamber	Does not fit IV drip chamber	6	1	6	Increasing quality control
			Damage during transport	Improper drip reading	Does not fit IV drip chamber	8	3	24	Improving packaging and labeling
			Fatigue from repeated use	Cannot fit IV drip chamber	Does not fit IV drip chamber	7	5	35	Better cyclic use testing
	LED	No indications	Fused out	Terminals switched	No visible LED indications	7	2	14	Quality control of electrical components
			Wiring disconnected	Breakage & improper handling	No visible LED indications	7	4	28	Inspection of electrical components
		Faulty indications	Wiring connected to wrong LED	Assembley mishap	Opposite lights upon use	7	2	14	Inspection of electrical components
			Output pins mixed in code	Coding mishap	Opposite lights upon use	7	1	7	Strict code Debugging
	Alarm	No sound	Wiring disconnected	Breakage & improper handling	No indication of level	7	4	28	Inspection of electrical components
		Dysfunctional sound	Insuffient potential	improper part selection	Improper indication of level	7	2	14	Inspection of supply potential

3.2.7. Risk Mitigation

Based on the risk analysis and selection criterion for Risk Priority Criteria of higher than 50 being unacceptable, we determine that fatigue from repeated use and failure of the sensor in calculating the drip level beyond the chamber wall are the main causes of device failure. Mitigation strategies are listed in the table below, which are incorporated into the verification and validation testing plans.

Risk	Mitigation
Fastener mechanism fatigue from repeated use	Device will be tested for its repeated and cyclic use
	Each mechanical component will be independently tested for wear and tear
	Quality control and assurance will be done to certify for a specific use cycle
Sensor does not measure drip level	Range will be determined to the utmost accuracy
	Sensor affixed in the casing unit will be checked for any influence on the range
	Sensor will be moved such that the level lies in the sensor sweet-spot or accurate detection
Sensor measures a constant level regardless of actual level	Sensor will be optimized against the chamber wall
	Type of sensor will be updated to detect levels past the chamber wall
	Sensor will be moved to ensure that the sensing range begins beyond the chamber wall.

3.2.8. Verification Plan

Each element of the device in terms of their hardware, electrical and software components will be tested initially by the team members, followed by external testers using standard testing procedures. The individual elements are listed in the table below.

Component	Test Element
Electronic Hardware Components	Total Weight
	Dimensions
	LED Brightness
	Alarm Audio Loudness
Device Stabilizers and Attachments	Usability
	Force Exertion
	Attachment Load
	Detachment Force
Device enclosure for Electronics and Sensor Mounting	Water Resistance
	Chemical Resistance
	Disinfectant Compatibilty
	Texture and Grip
Sensor Programming and Control Software	Program Coding
	Drop Endurance
	Alarm Sensitivity
	Button Haptic Force

3.2.9. Prototype Cost Structure

The final prototype costs are itemized and listed in the table below to arrive at an estimated minimum cost of manufacturing an factoring margins for sales.

TIVA Drip Chamber Alarm			
Cost per Device (in USD)			1 Unit
Component	**Price**	**Quantity**	**Amount**
Non-Contact liquid level sensor	11.99	1	11.99
BreadBoard	6.69	1	6.69
Jumper Wires	6.99	1	6.99
Arduino Nano Every	15	1	15
Red Buttons - Push	1.5	1	1.5
Blue Buttons - Push	1.95	3	5.85
Red Buttons - Latching	3.95	1	3.95
Resistors Set	11.99	1	11.99
LED set	4.99	1	4.99
PC Filament	29.99	1	29.99
ABS Filament	49.99	1	49.99
Passive Buzzers Set	4.99	1	4.99
		Total	153.92
		Estimated Sales Tax @ 7.19%	11.066848
		Grand TOTAL	164.986848

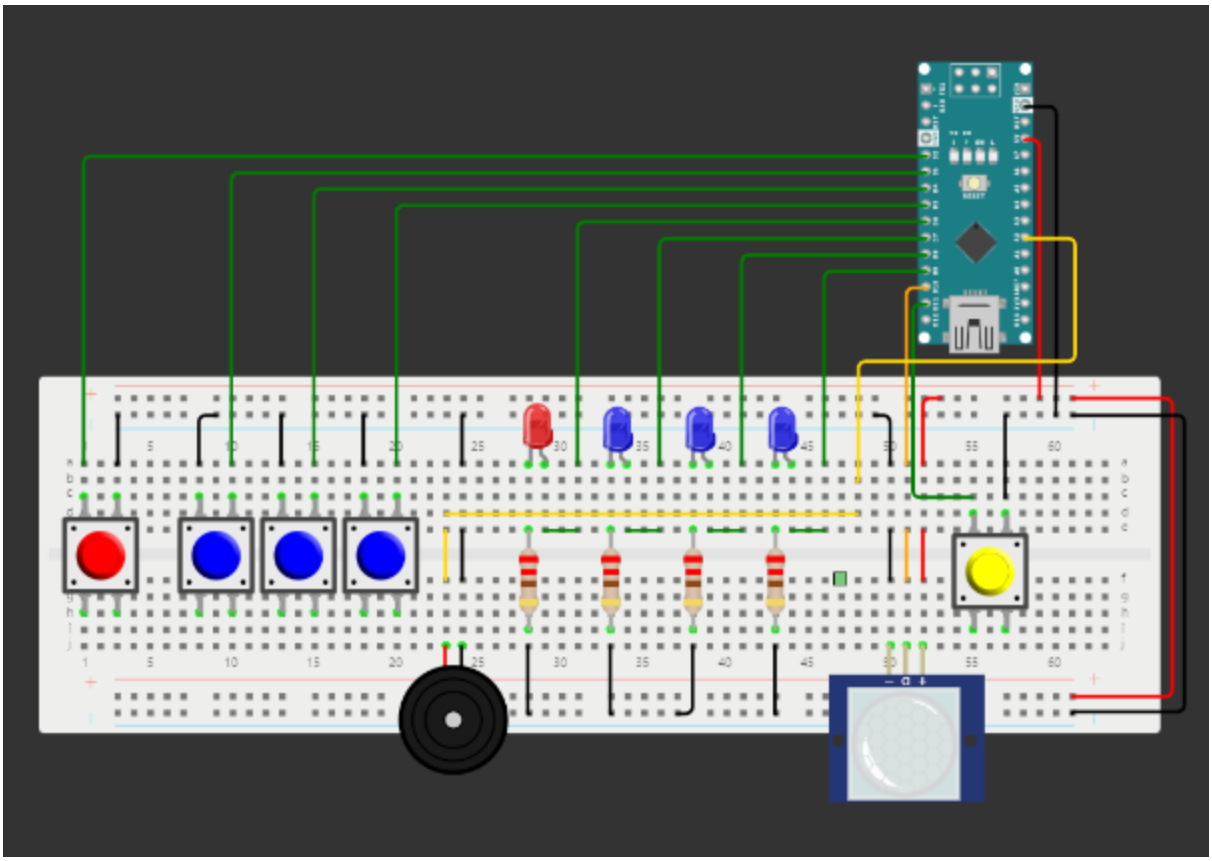
3.3. Freedom to Operate

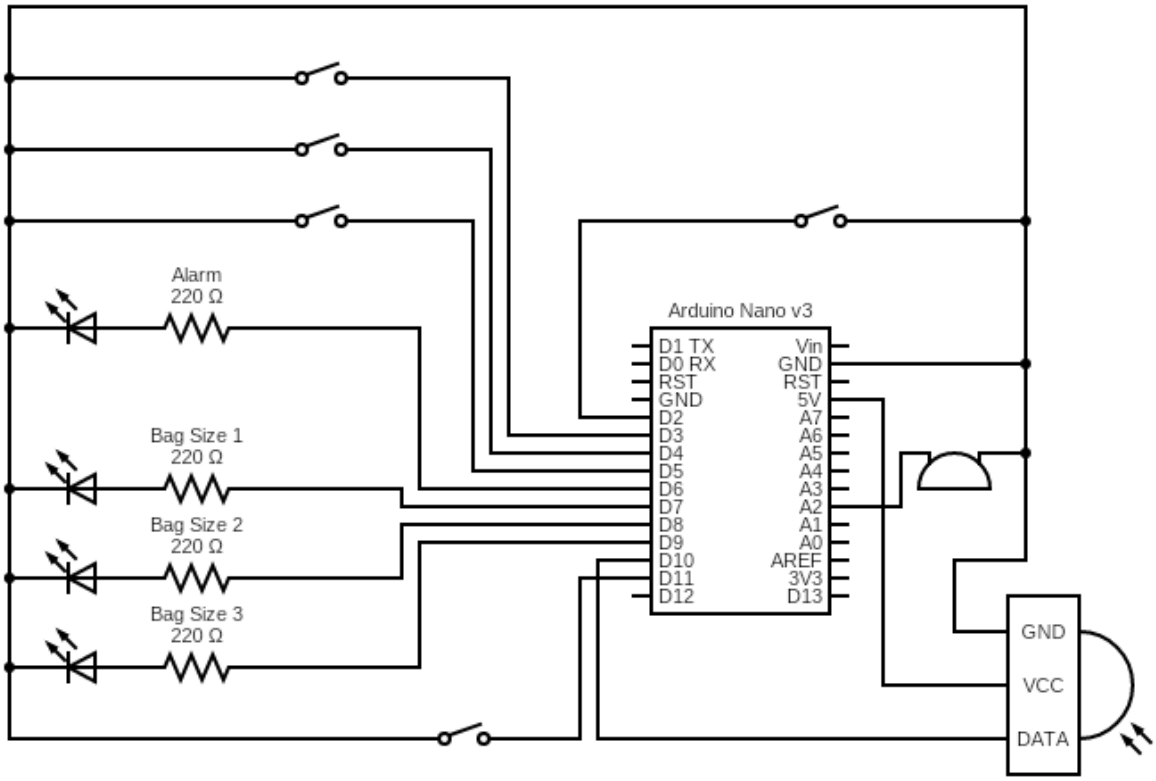
Based upon preliminary prior art research, the device in question does not infringe on existing patents or intellectual property rights. It is likely that the device is free to operate without any legal repercussions. However, it's important to note that prior art research is not a substitute for legal advice. The next steps are to consult with a patent attorney or intellectual property expert and conduct further conversations with the USPTO will be conducted to better understand the market and the freedom to operate within that market. The University of Utah will own a percentage of the intellectual property, the remainder of the intellectual property will be evenly distributed to all four inventors of the device.

3.4. Solution Completeness

3.4.1. Current Prototype

The current prototype is the third iteration of a functional sensor and notification ensemble that demonstrates intended functionality in a simulated drip level change environment. The schematics of final prototype's internal components are shown below.




Alarm
220 Ω
Bag Size 1
220 Ω
Bag Size 2
220 Ω
Bag Size 3
220 Ω
Arduino Nano v3
D1 TX
D0 RX
RST
GND
D2
D3
D4
D5
D6
D7
D8
D9
D10
D11
D12
Vin
GND
RST
5V
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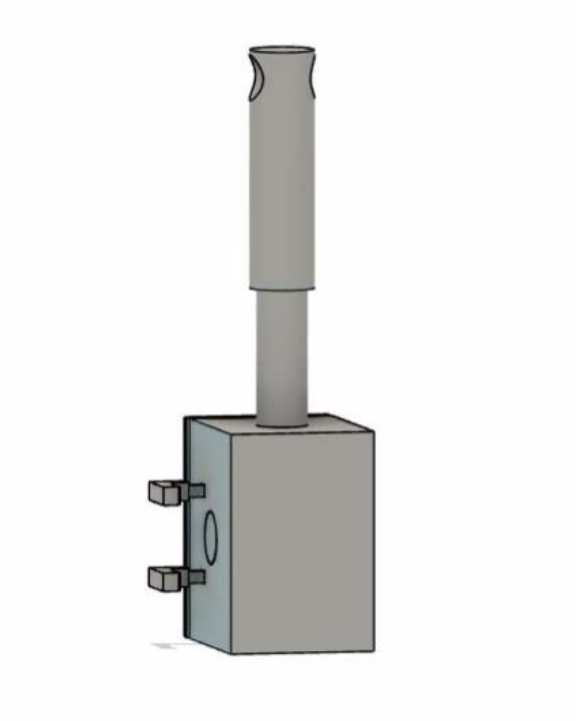
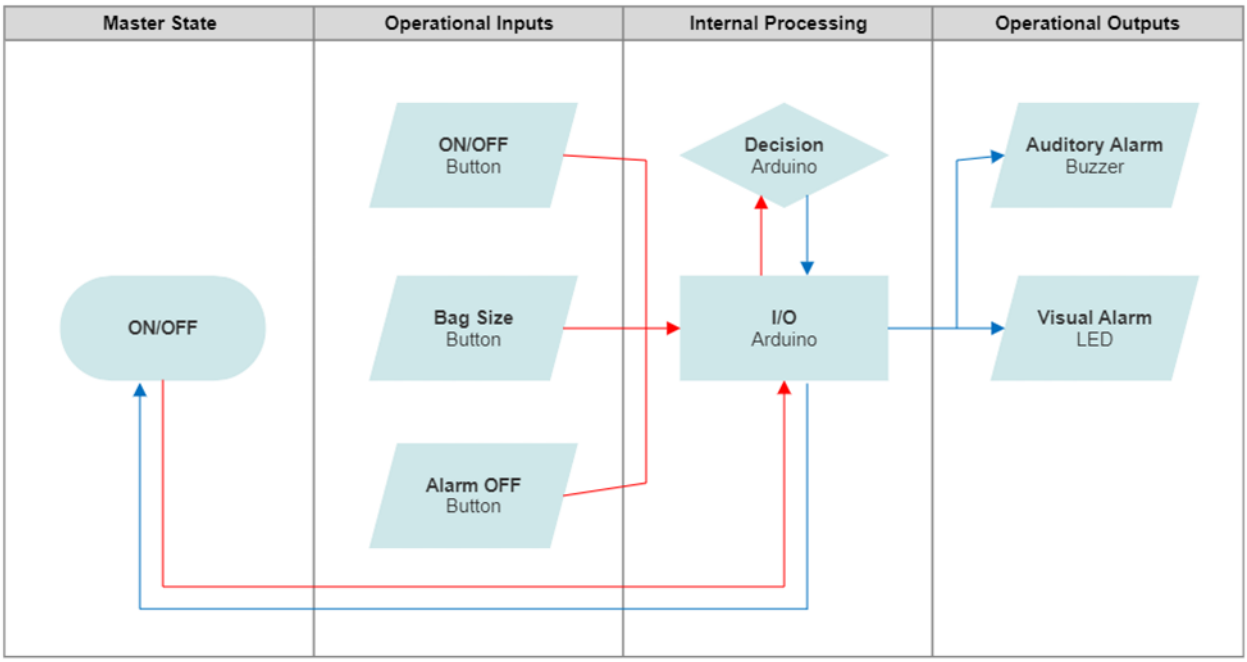
A3
A2
A1
A0
AREF
3V3
D13
GND
VCC
DATA





3.4.2. Technology Readiness Level (TRL) Designation

TRL 6: Technology demonstrated in a relevant environment; The device prototype system and code is verified to work in a simulated environment as expected.

3.4.3. Human Factors and Usability Engineering

When physically interacting with the TIVA drip chamber alarm device, healthcare employees and other users will encounter a variety of simple interfaces designed for easy use. These user interfaces include:

- Device power button
- IV bag volume status light
- Outer fastener - drip chamber positional securing
- Audible alarm
- Alternating bag size options

The design of this device is such that these interfaces are integrated seamlessly to allow for maximum efficiency and minimum time of usage in fast-paced environments such as hospital clinics and operating rooms. All buttons, lights, and audible alarms mentioned above will be located in proximity to each other and can be found on the frontward facing side of the device. All buttons will be raised from the surface to ensure tactile feel for the user. Both fasteners are designed such that when rotated, users will hear simultaneous clicking to ensure that chamber repositioning and resizing is occurring within the device. Safety considerations include recognizing that the bag status light has a possibility of burning out; therefore, the user will be unable to visually see the bag volume from the device if they are not directly looking. Other safety considerations include mechanical fasteners: users should stray from putting fingers inside the device when bolts are being turned.

3.4.4. External interfacing devices

External interfaces to the device include/may include:

- Drip chamber and IV line
- AAA dry cell batteries
- Stabilizer from device to IV pole stand

The device includes a variety of design solutions to integrate external interfaces for efficient use. The top of the device includes a cut-out circular hole designed such that the drip chamber and accompanying IV line can be fed through and adjusted for sensor positioning. Located on the left-hand, back facing side of the device, a square panel can be removed to reveal housing for the batteries. Located in the center, back facing side of the device is hole attachment for the IV pole stabilizer. Safety considerations related to external interfaces include electrical hazards if batteries are not inserted properly and risk of device falling/shattering if back stabilizer is not properly secured to IV pole.

3.4.5. Ergonomics

This device is ideally operated when the user first properly aligns the drip chamber through the top hole and uses both fasteners to secure its position. The device is then to be secured to the IV pole and turned on using the power button. The power button is clicked twice after bag is emptied, once to turn off the device and again to reset the timer. Ways the device can be misused by the user include: exposing it to increased moisture and humidity levels, improper attachment of drip chamber, use of another type of chamber (ie. Infusion pump chamber), device misalignment on

the IV line, and forgetting to turn off the device after bag is emptied so timer is not reset. A user may become confused with the device if they are unaware of the meaning of each color flash or if they are unaware that the power button must be pressed in order to reset.
Ergonomic solutions to the device include a somewhat symmetrical design in which the right side of the device can be gripped to allow the left hand to press the power button. Conversely, the left side of the device can be gripped to allow the right hand to twist the fasteners with adequate stabilization. Safety considerations arise when the device is not used with both hands: if used with just one, a possibility for the drip chamber to come lose from the device and stretch/tear the IV line is presented due to instability.

4. Go-to-Market Strategy

4.1. Intellectual Property Plan

4.1.1. Proposed Patent Filing Timeline

We are currently in conversation with the University of Utah's Partners For Innovation, Ventures, Outreach & Technology Center (hereby 'PIVOT Center') to file a provisional patent for the forthcoming year and in lieu of upcoming public disclosure events. Upon obtaining an initial provision patent, we will move forward along the device optimization and validation pathways with the intent of gearing up to apply for a full utility patent within a year.

4.1.2. Trademark and Branding

We have currently incorporated an image of a drip chamber into the AVIT medical logo to represent the targeted market in both a simple and unique manner. Our company name A-V-I-T is also an easy brand identifier among OR personnel as a very relatable term pertaining to T-I-V-A written backwards.

4.2. Regulatory Pathway

4.2.1. Regulatory Path

Product Classification	CFR 880.2420 - Electric monitor for gravity flow infusion systems
Device Class	Class II Device (Performance Standards)
Product Code	FLN
Pathway	FDA clearance through a traditional 510(K) with substantial equivalence to an existing predicate device
Primary predicate device	DripAssist 510(k) Number: K150687

4.2.2. Reimbursement Strategy

The device is intended to be a safety device adopted by hospitals as best practice. Reimbursement through insurance will not be necessary as the payment for this device will be by the hospital. To ensure that we can be adopted, there will be research documentation and clinical studies to provide sufficient data that the device is a necessary safety measure in operations.

4.2.3. Industry Standards

- ISO 16142: Medical Devices
- ISO 13485: Medical Devices - Quality Management Systems
- ISO 16142: Medical Devices – Safety and Performance Standards
- IEC 60601: Electrical Safety of Medical Equipment

4.3. Manufacturability

4.3.1. Manufacturing

Our product will be manufactured in AVIT Medical's main manufacturing facility located directly in Salt Lake City, UT. Device housing enclosure and attachments will be manufactured in-house through injection molding processes. All other components will be sources from outside partners. Materials include Polycarbonate (PC) and Acrylonitrile Butadiene Styrene (ABS). Listed Partners include:

- Arduino hardware and software
- DFRobot electronics
- University of Utah Biodesign Lab
- Activate Health and The Matchstick Group marketing
- ICU Medical and Baxter International

ABS on average costs $1.50/lb, while PC costs around $2.50. Through the process of injection molding at low temperature combined with the low-cost of our materials and components, we are able to lower manufacturing costs.

4.3.2. COGS (Cost of Goods Sold) Structure

Cost of Goods Sold	
Units of good produced	500
Units of good sold	450
Unit cost for the first three units produ	$70
Unit cost for the last unit produced	$60

	Methods of COGS Accounting		
	First-in-first-out (FIFO)	Last-in-first-out (LIFO)	Weighted Average
COGS	$210	$200	243
Average unit cost	$70	$66.67	81

4.4. Pricing and Distribution

4.4.1. Pricing Strategy

We have implemented skimming as our price strategy, as we have purposely set our prices slightly higher in order to attract serious buyers who are in need of our device, such as hospitals. Our initial offering will be set at $200/unit. This number reflects that our device is complex and will deliver the results needed in order to provide patient safety, yet will still be more affordable than our competitors. Considering one unit is manufactured at $60-$70, this will give us sufficient profit margins when in full production.

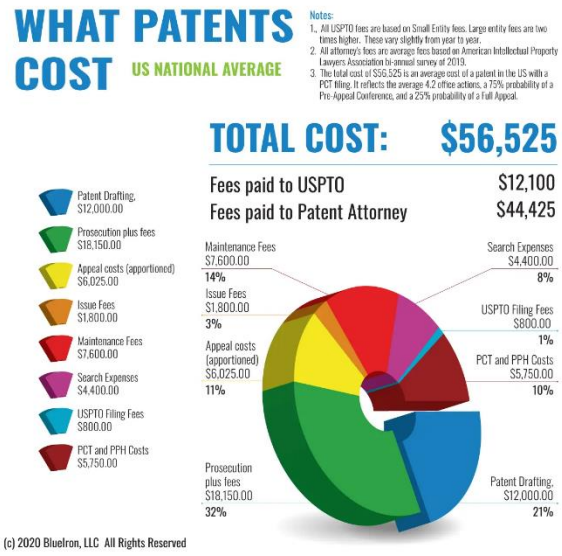
4.4.2. Distribution Strategy

We will engage in indirect distribution since our product is targeted for all hospitals in North America and Europe. To achieve this, we will be using a third-party medical logistics company in order to get our product to target hospitals. In order to market this product for distribution, we will be working alongside two of the top medical device marketing firms, *Activate Health* and *The Matchstick Group* in order to promote the product at launch. Monthly meetings with the respective firms will occur in order to affirm market success and the expansion of the product. We believe our set unit price with accompanying profit margins will allow us to use third-party distribution while still maximizing short and long-term profits.

4.5. Next Steps

4.5.1. Milestone Funding Utilization

The immediate use of the milestone funds will go towards enhancing the design and increasing the compactness of the device. The majority of these funds will go towards filing for and maintaining IP rights in the form of Provisional patent and a full Utility patent after the validation stage.



Stage:	USPTO Fees	Average Patent Attorney Fees
Pre-filing professional patent search	–	$1,500-4,000
Drafting and filing – biotechnology/chemistry	$660	$11,400
Drafting and filing – electrical/computer	$660	$10,923
Drafting and filing – mechanical	$660	$9,500
Amendment/Argument after rejection	$0-660	$2,300-4,000
Examiner interview		$1000-2000
Misc fees (assignments, information disclosure statements, declarations, power of attorney, etc.)		$1500
Issue fee payment	$480	$1500

4.5.2. Launch Timing Strategy

The device launch will be most impactful if it were to coincide with the timing of annual incidence report filings and OR cost audits.

4.5.3. Exit Strategy

We intend to attempt to license our device to larger companies in the medical support device manufacturing space. We believe such a path would be the best way to take the product into the market at the earliest. If no companies are interested in licensing our device, we will pursue setting up a startup to enable independent product sales. Licensing the technology will enable awareness generation for the product, which could also generate interest in an acquisition. Potential acquirers may include BD, Merit Medical, Edwards Lifesciences, Stryker Corporations, and others in the space.

5. REFERENCES

[1] Waking Up to Anesthesia | NIH News in Health; newsinhealth.nih.gov/2011/04/waking-up-anesthesia

[2] IV Monitored Sedation; https://www.asahq.org/madeforthismoment/anesthesia-101/types-of-anesthesia/ivmonitored-sedation/