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Final Report

Design Solutions that Mitigate the Possibility of Air Embolism When Administering a Liquid into the Bloodstream

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Executive Summary

If air bubbles enter a person’s bloodstream, it can clog their vessels, preventing blood flow and causing an embolism. Multiple design solutions are analyzed and compared to determine the best method to eliminate the risk of air embolism deaths, with a focus on the impact of human factors. Although some IV pumps have bubble detectors and there are trained steps to prevent air embolisms; there is no specific engineering solution currently available for stopping air from being administered into the catheter line by a staff member. Therefore, the purpose of these design solutions is to ensure that air cannot be inserted into a patient's bloodstream. The goals of the design solutions are balancing the staffing needs, the cost, size, weight and testing requirements of the device. Three design solutions were created including a hydrochromic indicator on syringes, a degassing valve in the tubing and a bubble detector on the tubing. A preliminary assessment was performed on the designs to determine that the bubble detector was the best option. The bubble detector design was implemented into a full prototype design that could be evaluated with engineering and human factors analysis. The design successfully met all the goals outlined. In future work, a full-scale prototype would be built for further analysis and some formative and summative testing would be done.

Glossary

Air Embolism -	A bubble of gas within a bloodstream. This bubble can cause blockages in many organs that require a specific pressure gradient to function.
Catheter -	Tubing of medical grade material, inserted into a patient to treat diseases.
HDPE -	High-Density Polyethylene, a type of thermoplastic polymer.
IV -	An intravenous therapy system uses catheters entering either peripheral or central veins to administer fluids.
IV Bag -	A bag of fluid hanging from a stand, either using gravity or an IV pump to initiate flow.
IV Pump -	The medical device attached around the IV line, regulating specific flow rates based on the fluid and creating a driving flow through motor-induced peristalsis.
Syringe -	A handheld fluid pump for injecting measured quantities of fluid into an IV.

Introduction

If air bubbles enter a person's bloodstream, it can clog their vessels, preventing blood flow and causing an embolism [1]. Only 0.5-1 ml of air in the pulmonary vein can cause cardiac arrest. Therefore, nurses and medical professionals often ensure that syringes are completely full of the desired liquid so that no air bubbles can make their way into the bloodstream. In some cases, a syringe full of clear liquid and a syringe full of air are very difficult to differentiate and unfortunately sometimes air is inserted into the bloodstream by mistake [1]. Different surgeries frequent air embolism between 1 in 47 and 1 in 3000, with the most common associations being with otolaryngology and neurosurgical procedures [2]. Multiple design solutions can be analyzed and compared to determine the best method to eliminate the risk of air embolism deaths, with a focus on the impact of human factors.

The existing solution for eliminating air embolisms is that nurses and doctors are trained to pull back a little bit of blood into a syringe to ensure there is liquid inside the syringe rather than air [3]. Pulling back some blood makes it easy to notice that there is no liquid in the syringe. This solution is not very effective, often nurses are busy and these procedures are missed which can lead to the syringe not being checked. To mitigate the risk of air being introduced at connection points, luer-lock connections and self-sealing valves are used for connections between hoses [4]. There is no specific engineering solution currently available for stopping air from being administered into the catheter line by a staff member.

Objective

The purpose of these design solutions is to ensure that air cannot be inserted into a patient's bloodstream. Three design solutions are analyzed that solve the problem either by identifying an empty syringe, so air is never administered, or by stopping the bubble once inside the tubing. The constraints for this project are that no air bubble can be transmitted to a patient, necessary materials are biocompatible, design solutions must interface with the Baxter Clearlink catheter system [Figure 1] and solution must not negatively impact other health care operations.

Figure 1 - Baxter Clearlink catheter [5]

Goals

The goals of the design solutions are balancing the staffing needs, the cost, size, and testing requirements of the device. The staffing needs cover the increased workload to health care employees, measured in additional steps necessary to implement the solution. This category also covers the value of training time in hours. Costs encompasses the value of each unit, which would ideally be less than $400 as outlined in the Economic Analysis Section, while sizing is measured in the physical proportions of the design solution and has value in both storage capacity and how it interfaces with other devices. The design of the device is made to be smaller than a small woman's arm in length, which was found to be about 19 cm [6]. The device should weigh less than 500 g if it will be resting near or against a person's arm or requires lifting, because 500 g is a manageable weight. Further, the device should be able to stop or warn of bubbles in IV tubing. The testing requirements impact the pre-market time and monetary costs to develop the solution.

Potential Solutions

The first concept is to use containers that change colour or opacity when exposed to a liquid. This would allow a staff member to quickly recognize whether a liquid is present in the device. This concept is based on existing hydrochromic technology, where paints, plastics or fabrics change colour when exposed to water due to a chemical reaction on the surface of the material [7] [8]. For the purposes of this project, a visual change would need to occur in the presence of any liquid, not just water. This hydrochromic indicators would take the form of a regular syringe, where the plastic has been switched to a new kind, or an insert for syringes currently on the market. Either solution would need to be disposable, since they could interface with blood and only be used once.

The second concept is to install a degassing valve on relevant devices. Degassing valves come in multiples shapes and sizes, with small simple ones being present in coffee machines, and more heavy-duty models present in piping systems. Valve specifics vary depending on application. These valves close when liquid is present in the system, and opens if pockets of air are present in the system. Once the air has left the system, the valve closes again [9]. This concept involves adding small degassing valves to relevant devices in the hospital.

The final concept is a type of sensor that is placed over fluid-filled tubes to detect the presence of bubbles. There are two types of bubble sensors, ultrasound-based and capacitor-based. In both cases, a signal is passed from one node to the other through the tube contents. Based on the signal received, the sensors can detect if the contents of the tube changes and a corresponding signal is tripped [10].

Preliminary Assessment

The designs can be separated into two categories: devices and indicator solutions. For devices, once installed onto the catheter system, the bubble detector and degassing valve both operate passively. Without user input, the devices stop any bubbles that might appear in the system. This advantage is qualitative in nature.
With the hydrochromic indicator, it tackles the specific problem of accidentally administering an empty syringe. It could almost be classified as a type of risk mitigation done on the process itself.

Table 1 - Weighted objectives chart for possible design solutions

Factor	Weight	Concepts					
		Hydrochromic Indicator		Degassing Valve		Bubble Detector	
		Score	%	Score	%	Score	%
Workload	.15	4	.6	3	.45	4	.6
Training	.10	5	.5	2	.2	4	.4
Cost	.15	1	.15	2	.3	3	.45
PMA Req.	.25	4	1	1	.25	3	.75
Blood Contact	.20	2	.4	2	.4	5	1
Size	.05	2	.1	2	.1	5	.25
X-Factors	.1	1	.1	4	.4	5	.5
Total		2.85		2.1		3.95	

To compare and evaluate the quality of each solution, a weighted objectives chart is used [Table 1]. The different categories being scored and their related values, with a focus on human factors, are:

Workload – This group encompasses the additional preparation and steps needed to use the device as intended

Training – Accounts for the necessary hours of instruction for students to become familiar with the material

Cost – Based on the available budget of VIHA and their sales to other companies for similar products [11] [12]

PMA Requirements – The regulatory standards and testing to bring the device to market

Blood Contact – If the device contacts blood, there are additional tests needed to verify biocompatibility

Size – The physical space that the device takes up is important when it comes to shipping and storage capacity

X-Factors – This category accounts for the qualitative properties of each device; these are the characteristics that are advantageous to their development that are not quantifiable through a simple metric

Table 2 - Weighted objectives chart scoring key

Rating	Workload (# of steps)	Training (Learning time)	Cost ($ thousand /year)	PMA Requirements (# of tests)	Blood Contact (# of tests)	Size (cm^3)	X-Factors (# of benefits)
5	1-2	<2 hrs	<550	<10	<3	<300	>2 positive
4	3-4	2-4 hrs	550-700	10-15	3-6	300-400	1-2 positive
3	5-6	4-6 hrs	700-850	15-20	6-9	400-500	0
2	7-8	6-8 hrs	850-1000	20-25	9-12	500-600	1-2 negative
1	>8	>8 hrs	>1000	>25	>12	>600	>2 negative

For the quantifiable values of each objective, the scoring key is used [

Table 2]. The workload score relates the number of additional steps for a health care worker to employ the new solution into the standard operating procedure for administering fluids; fewer steps result in a higher score. Training is the value of time required to fully inform staff on all aspects relating to employing the solution; less training hours to attain a full knowledgebase result in a higher score. For costs, the analysis pertains to the amount of money required to supply the entire VIHA [13]; lower costs per year result in a higher score. PMA requirements are the panel of testing needed for summative testing validation; fewer testing requirement result in a higher score. Since blood contact also results in additional testing, this score relates to the increased burden this may cause; little to no additional testing caused by blood contact results in a higher score. The size of the device can be an advantage for sustained use; a smaller overall size results in a higher score. Finally, the qualitative properties are scored by counting the number of benefits that are in each design, more benefits result in a higher score.

Hydrochromic Indicator Analysis

For the workload, the indicator is an interesting solution for scoring. The value of 4 represents that very few additional steps are required, however this number could increase depending on the specific final product and how it's used. For example, if the hydrochromic indicator takes the form of inserted sleeve into a syringe, more steps would be involved to slide them into each syringe in preparation, lowering the score. With a score of 5, the training is not intensive for this solution. This device doesn't change the procedure of administering drugs in any way, only adding the visual indication into the process. A score of 1 for cost was determined from the high number of devices that would need to be purchased, since they are replaced after every use and with every administering procedure. PMA requirements for the hydrochromic indicator would be straightforward, with existing predicates and regulation for standard syringes to follow, resulting in a score of 4. Since the indicator reacts with the water found in solution and blood, it will make secondary contact with the bloodstream, requiring increased testing and a score of 2. The size of each individual unit is small, but there are larger quantities required that result in a score of 2.

The X-factor score of 1 correlates to the limited applicability as it relates to the larger problem and not being a passive solution. The hydrochromic indicator has the qualitative factors of competing against the currently established syringe market and only stopping air from being administered, not stopping air once inside a catheter, limiting its market novelty. These qualitative properties are not beneficial and detract from market viability. The overall score for this solution is 2.85.

Degassing Valve Analysis

The degassing valve needs to be attached and sealed onto the catheter setup, likely adding a few steps into the process, scoring a 3. Since this solution is new and doesn't have a current analogous device, the training time to familiarize workers could require multiple sessions, resulting in a score of 2. This device, like the hydrochromic indicator, is inexpensive as individual units but they need to be disposed after use, resulting in the given score of 2 since they are replaced less often than syringes. The PMA requirements should be extensive, given the lack of predicate design, likely requiring a De Novo classification, resulting in a score of 1. The degassing valve operates on the throughput of fluid, making secondary contact with the bloodstream, also resulting in a score of 2. Size for the degassing valve is small per unit, but needs to be purchased in large quantities since they are disposable, receiving a score of 2.

The degassing valve scores a 4 in X-factor considerations. This solution has the benefit of being passive to operate, possibly catching embolisms created in the absence of workers. This functionality is a completely new safety offering to the health care industry, having little to no competition. Overall, the degassing valve rates a 2.1 on the chart, due to the testing challenges faced.

Bubble Detector Analysis

This device clamps onto the outside of the catheter setup, right before the patient output terminal. The process should take approximately 3-4 steps, scoring a 4 in workload. Attaching this apparatus is like that of an infusion pump, with slight modification, so the process shouldn't take too long for workers to familiarize, resulting in a score of 4. The cost for these devices is more expensive per unit compared to the other solutions, but it is reusable and the components and manufacturing are inexpensive, scoring 3 in cost. For PMA testing, the infusion pump is used as a predicate so the requirements are streamlined slightly. On the other hand, this device involves electronics, increasing testing, representing a balanced score of 3. The bubble detector doesn't make any contact with the bloodstream in any way, so the score in this category is the maximum of 5. The design's slim profile makes each unit quite small, given a size score of 5, since the devices can be reused and cleaned.

The X-factors for the bubble detector are the passive operating functionality, like the degassing valve solution. This puts it in the same niche marketspace, offering ongoing safety for patients. This design can also be integrated into the healthcare intranet to supply warnings at nurses' stations when the device is triggered. Combined with the reusability of the device, the score for X-factors is 5. In total, the weighted value for this design is 3.95, making it the best selection of the three.

Proposed Solution

As the highest scoring potential solution, the bubble detector system is further analyzed with a focus on the human factors involved in its development and use. This device [Figure 2], relies on 2 electrical components that are available currently for low costs. Between these parts, the housing for the power source (AAA battery) and any onboard microprocessor is located. Since the proposed location of this device is in the section of catheter after the branch in the tubing and before the luer-lock, the applications are suited for ambulances, IV bags and both central or peripheral IV's. The selected valve is only opened when powered, increasing the response time and safety when the battery runs out of voltage.

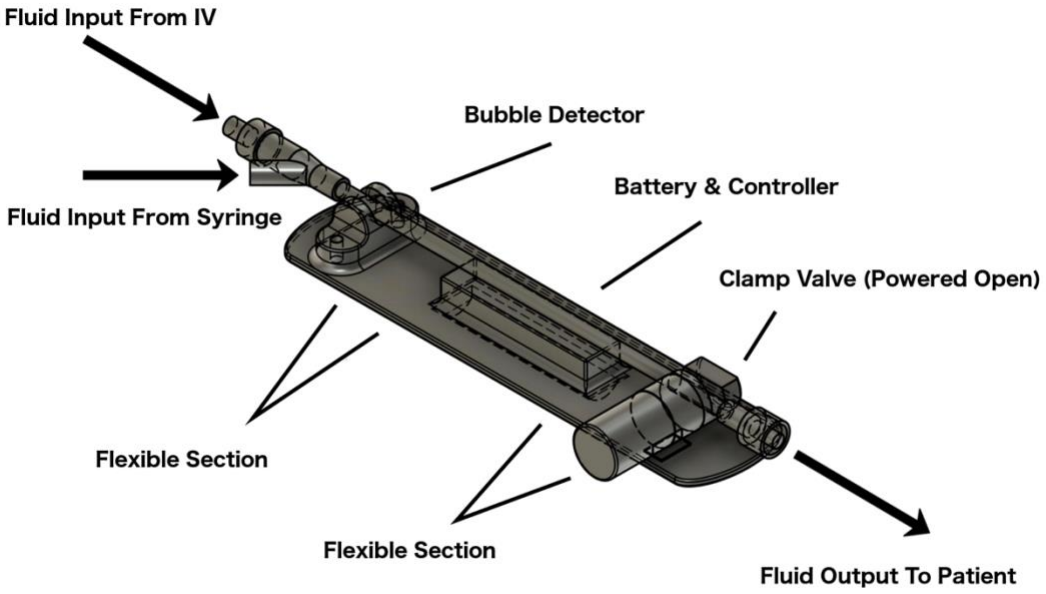

Figure 2 - Prototype design breakdown

All the components for the device are attached to a semi-rigid, base structure. Since this design is only at the prototype stage, the integration of the components onto the base is not as smooth as desired; the clamp valve orientation can be fine-tuned for better maneuverability. The bubble-detector, battery/microprocessor housing and clamp valve are rigid, so conforming to the catheter as it moves needs consideration. The flexible base material is therefore designed to bend in the sections between the rigid electronics. Nothing should limit the functionality of the device by either twisting or flexing the base, if the catheter is secured into the detector and valve. The tubing between these points is free to move.

Proposed Solution Assessment

The bubble detector solution is assessed in two main categories. The engineering analysis measures and quantifies the design specifications to better help future development. The human factors analysis highlights the probable impact that the design could make and receive through rigorous testing and regulations. Together, these validate the design for further research.

Engineering Analysis

Flow Rate

The provided distance on the physical tube for the device to operate is between 100-120 mm. Using the provided flow rates [14] for common procedures, the velocity of a bubble can be determined:

$$Cross-Sectional\ Area\ (min) = \pi(1.05\ mm)^2 = 3.464\ mm^2$$

$$Flow\ Rate\ (max) = 4166.7\ mm^3/sec$$

$$Velocity\ (worst\ case) = \frac{4166.7\ mm^3/sec}{3.464\ mm^2} = 1203\ mm/\sec$$

$$Response\ Time\ (criteria) = \frac{100\ mm}{1203\ mm/sec} = .083\ sec$$

The selected pinch valve in the design has a response time of .025 sec [15], well below the constraint. Additional time will also be needed to transmit and interpret the electronic signals, increasing the response time. The operating pressures for the valve are above those experienced in IV's. This provides good evidence that a bubble can be detected and stopped within the short section of tubing, given this system

Bubble Size

The tubing size conventionally used in IV tubing is 4 mm [16]. Meaning that it has an inner diameter of roughly 2.1 mm. The bubble detector used can detect a bubble size as small as 70% of the inner diameter [17].
Therefore, assuming the bubble is a sphere, using the following equation, the bubble's volume would be found as follows:

$$1.47\ mm\ X\ 0.70 = 1.03$$

$$Vol(sphere) = \frac{4}{3}\pi r^3 = \frac{4}{3}\pi(1.03\ mm)^3 = 4.58\ mm^3 = 0.00458\ mL$$

Furthermore, it was determined that the maximum size of tubing that could be used is 7 mm, which would be too large to fit in the detector anyways which helps mitigate an error of using too large of a tube.

$$7\ mm\ X\ 0.70 = 4.9$$

$$Vol(sphere) = \frac{4}{3}\pi r^3 = \frac{4}{3}\pi(4.9\ mm)^3 = 492.8\ mm^3 = 0.4928\ mL$$

Economic Analysis

Table 3 - Cost of device components

Device Component	**Cost ($ CAD)**
AAA Battery	0.60 [18]
32-bit Microcontroller	0.90 [19]
Plastic Casing for Battery and Controller	0.50 [20]
Base Material: High Density Polyethylene	11.00 [21]
Clamp Valve	142.92 [13]
Bubble Detector	188.65 [22]
Total	**344.57**

The total cost of the device was estimated using the data tabulated [Table 3]. This estimate is used below to determine the overall economic of the device. Note that the cost of the batteries, microcontrollers, and casings are assumed to be purchased in bulk, lowering their individual prices to those found in the table.

To date, the current number of total hospital beds in British Columbia is 11,153 [23]. Making the generous assumption of having one device per bed throughout the province, the total cost of all devices would be $3,842,989. Several notes should be made regarding the accuracy of this number:

- Total hospital bed numbers are currently higher than normal due to the COVID-19 crisis.
- The assumption of one device per bed is likely an overestimate: this device is used in conjunction with IVs, and not every hospital bed in BC uses an IV.
- Again, it should be stressed that the prices above are estimates and may be influenced by the manufacturer or number of devices purchased.
- This number merely represents the cost associated with purchasing the device components. Costs incurred in other parts of the design process are not accounted for here.

To assess whether the $3.84M estimate is affordable or not, data into BC's and Vancouver Island's Healthcare spending was done. The graph of Vancouver Island Health Authority (VIHA) spending on vendors in 2018/2019 [Figure 3], with the current estimated cost highlighted in yellow.

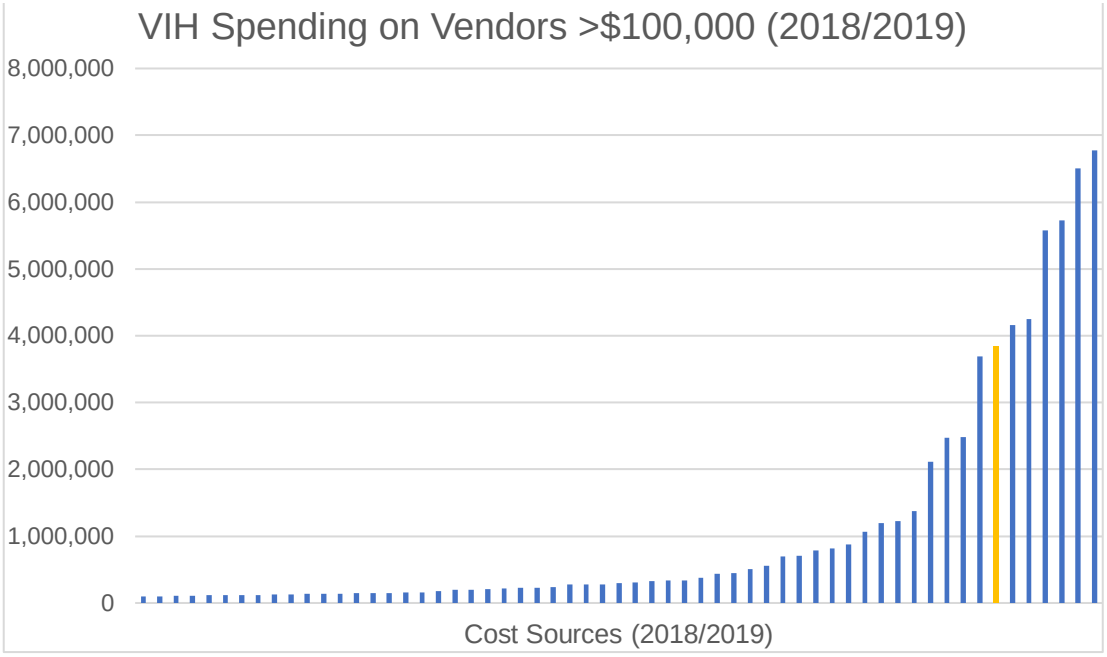

Figure 3 - VIHA spending on vendors in 2018-2019 [24] (total estimated cost highlighted in yellow)

From the graph, VIHA spending over $5 million on a single vendor is not particularly uncommon. In theory, VIHA could purchase devices for the whole of BC. BC healthcare spends $21 billion a year [25], meaning that this project would cost 0.02% of their annual budget. With the listed data in mind, it is concluded that $3.84M would be a reasonably affordable cost.

Human Factors Analysis

Human factors engineering is defined as the study of the interrelationship between humans, the tools and equipment they use in the workplace, and the environment in which they work [26]. For the case of the bubble detector design, usability revolves around how easily the device can be set up and used, how the devices feel to the patient or worker and how many use case errors are found during testing. Device errors or use case errors can lead to risks that need to be mitigated.

Key Opinion Leaders (KOL) are individuals whose expert advice is respected by others in the field [27]. The key opinion leaders of this device include patients, nurses, doctors, hospital cleaning staff, purchasing staff and biomedical engineers. The environment that this device would be used in is hospitals and clinics, or extended care facilities.

Risk Considerations

Table 4 - Risk analysis criteria

Probability Criteria	Severity Criteria
1 - Extremely Unlikely: Unreasonable to expect this failure mode to occur in any system and cause harm. Occurs in less than 1 in 1,000,000 devices	1 - Negligible: Only little damage to the device occurs and/or slight discomfort to the patient or user
2 - Improbable: An event leading to harm whose occurrence cannot be ruled out but is not likely to occur in any system. Occurs in 1 in 1,000,000 to 1 in 100,000 devices	2 - Marginal: Minor damage to the equipment causing temporary inoperability and/or temporary impairment or injury not requiring professional medical attention
3 - Remote: An event leading to harm which is known to occur on rare occasions. May appear in isolated systems. Occurs in 1 in 100,000 to 1 in 10,000 devices	3 - Moderate: Permanent damage to equipment prevents operation and/or impairment/injury requiring professional medical attention
4 - Occasional: An event leading to harm which is known to occur once or several times during the life of an individual system. Occurs in 1 in 10,000 to 1 in 1,000 devices	4 - Critical: Will commonly cause severe or life-threatening injury or major system damage requiring corrective action
5 - Frequent: An event leading to harm expected to occur often during the life of an individual system. Occurs in greater than 1 in 1,000 devices (0.1%)	5 - Catastrophic: Will cause death or major system loss

Risk analysis is a very important consideration of a medical design. The risks of the device were evaluated with respect to probability and severity [Table 4]. The final risk score was found by multiplying the probability score by the severity score. Any risk score that came in at 7 or above had to be mitigated to ensure the safety of the device and user.

Table 5 - FMEA pre-mitigation

Failure Mode	Hazardous Event or Situation	Possible Harm Caused	Severity	Probability	Risk Score
Bubble detector misses a bubble	Bubble (>=0.5mL) makes its way into the bloodstream	Bubble causes cardiac arrest	5	1	5
Bubble detector misses a bubble	Bubble (<0.5mL, >0.005mL) makes its way into the bloodstream	Bubble causes blockage in vessels	3	1	3
Bubble detector misses a bubble	Bubble (<0.005mL) makes its way into the bloodstream	Bubble is usually dissolved into blood, but may cause discomfort	1	4	4
Clamp valve closes unexpectedly	IV fluid cannot go to patient	Loss of IV fluid could result in pain or loss required liquids	3	4	12
Battery runs out	System shuts off	Loss of IV fluid could result in pain or loss required liquids	3	4	12

Table 6 - FMEA post-mitigation

Failure Mode	Hazardous Event or Situation	Possible Harm Caused	Severity	Probability	Risk Score	Mitigation
Bubble detector misses a bubble	Bubble (>=0.5mL) makes it's way into the bloodstream	Bubble causes cardiac arrest	5	1	5	Not required
Bubble detector misses a bubble	Bubble (<0.5mL, >0.005mL) makes it's way into the bloodstream	Bubble causes blockage in vessels	3	1	3	Not required
Bubble detector misses a bubble	Bubble (<0.005mL) makes it's way into the bloodstream	Bubble is usually dissolved into blood, but may cause discomfort	1	4	4	Not required
Clamp valve closes unexpectedly	IV fluid cannot go to patient	Loss of IV fluid could result in pain or loss required liquids	3	2	6	Audible alarm goes off, system is integrated into hospital system, decreasing probability of harm
Battery runs out	System shuts off	Loss of IV fluid could result in pain or loss required liquids	3	2	6	Integrated into greater hospital system, decreasing probability of harm

This results in the initial Failure Mode and Effects Analysis (FMEA) [Table 5] and the mitigated FMEA [Table 6]. Overall, this device is very safe for users and stakeholders, the main risk that needed mitigation is that if the device clamp closes or the device loses power, the IV fluids and drugs will be blocked off which can lead to loss of required liquids or pain for the patient if left unnoticed. To mitigate this problem, the system would be integrated into the hospital system so that the nurses are notified of these issues much like how they are notified when a patient is coding. This change brought the risk score down from a 12 to a 6 by significantly decreasing the probability of harm.

Material Considerations

As listed above in the cost portion of the engineering analysis, the plastic used would likely be HDPE, which is known for its excellent chemical and corrosion resistance [20]. It is reasonable to assume that even with strong cleaning fluids, such as a bleach solution, the device would not show significant wear over various cleanings due to chemicals.

For human factors analysis, the convenience of cleaning may also be considered. Any sharp angles or difficult-to-reach areas, such as the areas between the flexible base and the clamp valve, may be difficult to reach, and accumulate dirt as a result. This design has already factored this in, adding bevels to any right angles.

Regulatory Considerations

When designing a medical device, regulations must be considered and defined. For our device, we've decided we'd like to keep things open and we would like to follow a global regulatory strategy to ensure that our device can be sold in many areas. For ease, we created a plan for selling the device in Canada, the US and the EU noting that many other countries follow guidelines from these regulatory bodies. The following section discusses the regulatory considerations for each of these areas.

Canada

In Canada, the regulatory body for medical devices is Health Canada. Medical devices are classified and regulated based on the complexity and risk and benefits. There are 4 classes in the Canadian system. The bubble detector device would likely be a class III device, meaning that it is a moderate-high risk level. A class III medical device requires a medical device license submission and a Quality Management System certification to ISO 13485: Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes [28].

US

In the US, medical devices are regulated by the Food and Drug Administration (FDA). The FDA's system has 3 class levels. The bubble detector device would likely be a class II (moderate to high risk) device and could likely be done as a 510(k) application with the use of IV pumps with bubble detectors such as the ClearLink IV system. A class II 510(k) application would require Quality System Regulations (QSR) compliance, proof of equivalence and a possibility of clinical data. If the 510(k) application was deemed to not have enough equivalence, a De Novo Application could be done. A De Novo Request would include a pre-market notification, clinical data, more time for review, and would cost a lot more making it less ideal [28].

EU

In the EU, medical devices require a CE mark before they can be placed on the market. The CE mark is a claim that the product meets all general safety and performance requirements of the relevant European Directives. The medical devices are regulated by notified bodies. The EU has 5 classes, the bubble detector would likely fall into the IIb class (low to medium risk). To get a device on the market, you must get a notified body review which includes a technical file review, a design dossier review, which are assessed against the General Safety and Performance Requirements (GSPR) set out by the EU directive as well as ISO 13485 certification from an audit of the Quality Management System. After this, the device will receive its CE mark [28].

Table 7 - Regulatory considerations summary

	Canada	**US**	**EU**
Class	III	II	IIb
Risk Level	moderate-high	moderate-high	low-moderate
Requirements	Medical Device License Submission	510(k) or De Novo Request	Notified Body Review: Technical Review File
	QMS System	Pre-market Notification	Notified Body Review: Design Dossier Review
		Clinical Data	ISO 13485 Certification from QMS Audit

To identify these regulations more easily, they are tabulated [Table 7].

Plan For Formative/Summative Testing

To formatively test the device, the recommended testers would be potential users of the device, with nurses being the primary example, but doctors are recommended as well. The testing environment would simulate hospital room, with a false patient and IV. A bubble would be knowingly injected into the IV system before the test, and the staff member's use of the device would be gauged. Formative testing notes are noted below. The tests would be recorded with video cameras, and ideally, observers would be viewing through a one-way mirror. Some formative tests are:

- Test to see how convenient the device is to pick up and move, see if set size goals are relevant. Notice if device is bulky or awkward – are the staff able to place it in a convenient spot?
- When the device is attached to the IV tube, if left hanging from the tubing, does it disrupt the IV process (e.g. pull the IV out of the patient)?
- Are staff able to clean the device properly? For this test, cleaning staff are recommended to participate.
- If a staff member drops the device, is it damaged?

The following two tests involve critical tasks, and so would be included in formative testing, but would also be the primary focus of summative testing.

- Test to see if user can recognize when a bubble is in the system. Are they able to tell what the problem is? Is it clear what they should do next?
- Test to see if user can recognize when device is out of battery. Are they able to replace it?

Discussion

There is no other device currently on the market that offers the capabilities of the recommended solution. The design meets all constraints and excels in most metrics. With good data provided through the testing process, the design will be refined for better performance within the health-care environment. The materials chosen are easy to clean, with bevels applied to any sharp angles for easy access and with the proper surface characteristics for chemical treatment.

With increased R&D, the design's electronic components can be minimized. Attached to the IV, the device will hang from a patient's arms, so the risk of pulling a line out needs to be mitigated. In current practice, the IV is adhered directly onto the skin [Figure 4]. There could be a way to integrate the device into this application by strapping the base directly to the forearm. In this way, there wouldn't be a need for taping anything to the patient and could be desired for easier removal and comfort.

Figure 4 - Peripheral IV set-up attached to forearm [29]

For production, this device is made from the purchased bubble detector, pinch valve and power supply, requiring only the controller and base-housing to be manufactured. The overall costs for this device are low, allowing significant budgeting towards formative and summative testing.

The risks that are present in the device can be mitigated easily through software solutions and don't add any new hazards into the IV process. Currently the design is constrained to use on a 3-7 mm inner diameter catheter, due to the limitations with the bubble detector. Larger tubing is rarely used in IV's, so it might not be worth the development effort to adapt the design for these applications.

Conclusion

In this report, engineering solutions for air embolism's rare but deadly occurrence are proposed, and through engineering analysis, the best of the proposed devices is selected and further discussed. Initial goals for such a device include a length under 19 cm, a weight of under 500g, and a cost of under $400 CDN. Devices proposed included a colour-changing container, or hydro-chromatic indicator, as well as a degassing valve and bubble detector. Via a weighted objectives table, the bubble detector was determined to be the best choice of the three proposed solutions. The bubble detector device design involves a base plate made of high-density polyethylene, a triple-A battery, a microcontroller, a case for the battery and controller, a pinch-valve, and the bubble detector. The IV tube is intended to pass through the bubble detector and pinch valve so that any bubbles in the IV tube detected by the bubble detector are prevented from entering the patient via the pinch valve. The maximum velocity of fluids through an IV tube and the reaction time of the pinch valve were used in calculations to prove that the device should be able to stop any detected bubbles. IV tubing sizes were then used to find the diameter and volume of any bubbles likely to be encountered by the device. The device's cost was analyzed, component by component, and the cost of a single device was determined to be below the $400 CAD threshold. Supplying BC with these devices was estimated to cost $3.84M CAD, approximately 0.02% of BC Healthcare's annual budget, and so was deemed reasonable. A risk analysis of the device determined it to be safe to use, and regulatory body requirements were estimated based on the device's functions. Specifically, the device was estimated to be Class III in Canada. A brief plan for formative and summative testing was then discussed.

Future Work

If this device were continually researched and improved upon in the future, a functioning prototype would be built for continued analysis. Potentially, a similar device could be created that allows IV tubing with an inner diameter greater than 7 mm. Additionally, the physical design of the device may be fine-tuned so that minimal plastic is used, sharp corners are rounded off, and areas that would be hard to clean are filled in or otherwise improved. A more in-depth analysis of the cost of the components, manufacturing, and distribution of the device is also recommended. Lastly, the formative and summative testing would need to be carried out with different developed prototypes.

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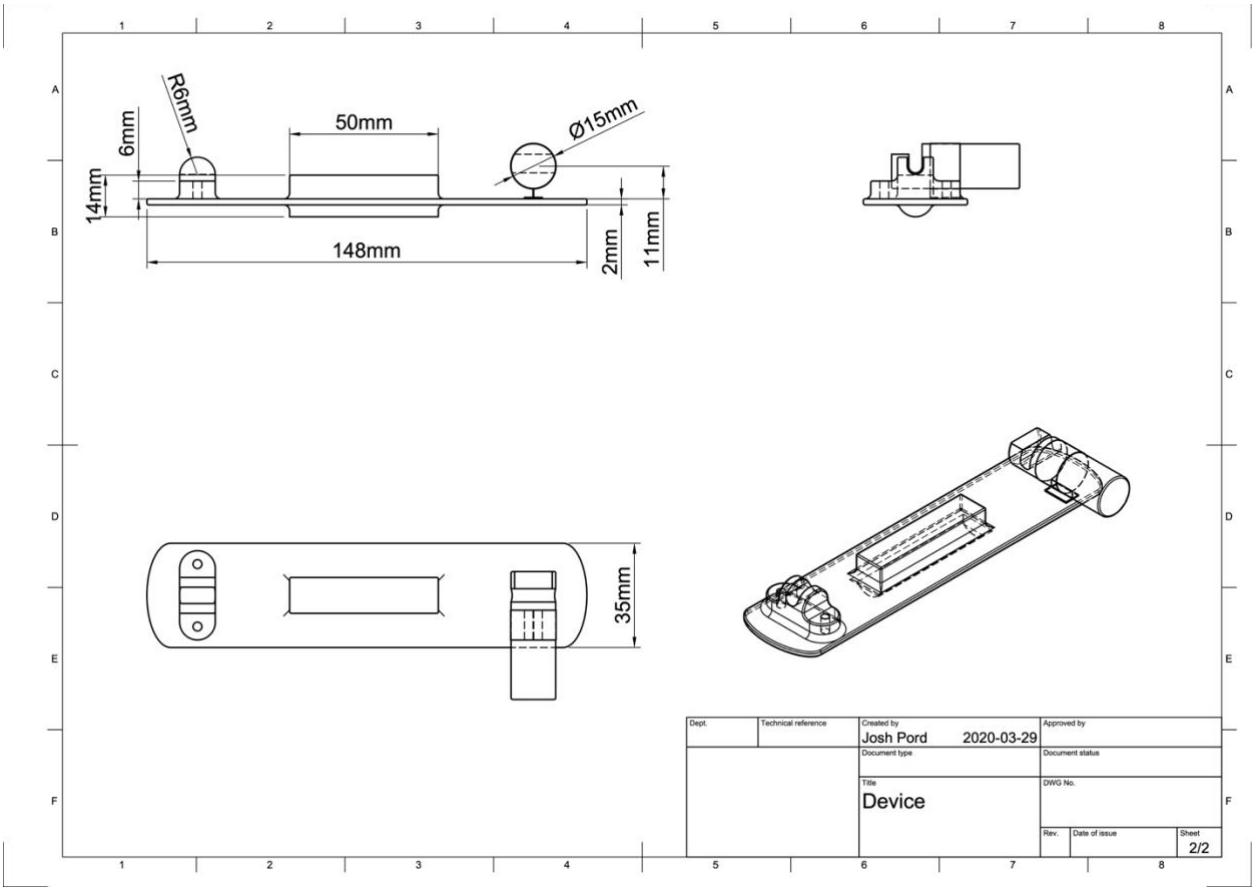
Appendix A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