VEIN GUARD: VENIPUNCTURE ASSISTANT

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Abstract

Venipuncture as a procedure draws blood from the vein. Blood sample collection is common protocol for many doctor's appointments and is a standardized procedure as detailed by the World Health Organization [1]. Unfortunately, the sheer amount of blood draws performed means complications still happen. The complications range from full punch-through punctures to unintended veins/arteries pricks to nerve pricks. In a nationwide study of blood donations, a total of 752 moderate and severe complications were recorded among 2,575,264 donations, corresponding to a rate of 29/100,000 donation, and nerve injury (sensory changes) found by a post donation interview was reported in as high as 900/100,000 donations [2]. Our device, Vein Guard, intends to be a blood draw assistant medical device that alerts the practitioner when initial venous access occurs. Previous studies have shown that when first puncturing the vein, there is a distinct force drop on the needle [3]. A force sensor detects the occurrence of the force drop, then alerts the practitioner of successful vein penetration through a visual and audio cue. This can thereby reduce the amount of complications. In addition, this device can be used in trainings, allowing new practitioners to be get an idea of blood draw depth.

Acknowledgments

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1) Description of the problem

Proper blood draw relies on the health practitioner's intuition and skill. Although a common procedure, it can have a host of complications ranging from bruising and internal bleeding to punctures and pricks to and nerve damage and claw-hand. These complications arise due to human error or inexperience to darker skin or obesity making it harder to find the vein. This product will be marketed as a training aid for health practitioners developing their skills. With our product, practitioners will be able to better develop their intuition and skill allowing them to transition into the hospital setting easier while also aiding their performance when performing procedures on people.

2) Project Objective Statement

The problem was addressed by creating a reusable device with a force sensor (to detect force drop on the needle) and an LED/beeper combo for visual and audio cues respectively. This idea doesn't intend to shakeup the market, but rather supplement pre-existing blood draw products on the market by using available needles/vacutainers. This decision also meant practitioners wouldn't feel their jobs were being taken away, rather, their job ability is amplified by the device. The device fits into the hand, with the needle extending out 1 inch over the top. The needle pushes on the force sensor relating the force to resistance as measured by an algorithm to detect the force drop and trigger the beeper and LED to warn the user that the needle has entered the vein. All this is powered by a singular 9V battery and a preprogrammed Arduino Microchip. The specifications of our device include components: Arduino Micro; Force Sensor FSS-SMT; Single Supply Micro power Instrumentation Amplifier; LED; Button; beeper; butterfly needle/ Vacutainer combo; 3D Printed Case.

3) Documentation of the Design

Although conventional blood draw needles such as BD needles are quite cheap, the handler expertise operating the needle varies. This human unpredictability along with the volume of blood draws done worldwide contributes to blood draw issues. But, the advantage of that human contact though is the value of human comfort from practitioner to patient.

On the flip side of things, there exists automated blood draw machines. The human unpredictability is factored out in exchange for little chances that the machine breaks down or malfunctions. This means more consistent blood draw or sensitivity. But that means abnormal blood draw situations without a human eye to filter may hurt the patient. Furthermore, machine breakage would be quite damaging to the patient's trust in the machine. Not to mention the cost of placing these machines into every clinic or hospital would be astronomical at the moment. Practitioners might even feel their jobs being displaced.

Our device intends to take the advantages from both viewpoints to bridge the gap, especially from the human connection (conventional blood draw) and consistency (automation). The costs get brought down by using preexisting needles, intending not to replace, but provide a helpful alternative. We tried to imagine how likely it was to shake up an industry with custom needles, and ended up realizing the easiest way was to use the preexisting suppliers.

The reusability of the device helps as well to drive down costs while still remaining portable. The device size was kept to a minimum to be intuitively held by one hand, fitting a palm, with only the micro board, audio/visual cues, single battery, force sensor, and needle.

4) Prototype of the Final Design

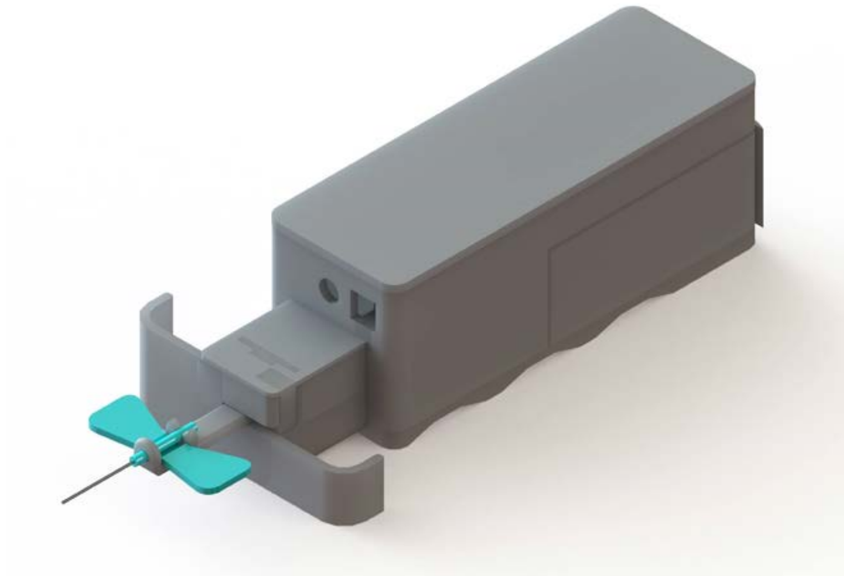

Figure 1: Handle with ergonomic grip/ electronics casing made with SolidWorks design software

A handle with an ergonomic design was created (**Figure 1**). The design incorporates finger grips for a more comfortable grip and finger guards to protect the user from slipping towards the needle. It has removable lids to access the electronics and battery case properly as well.

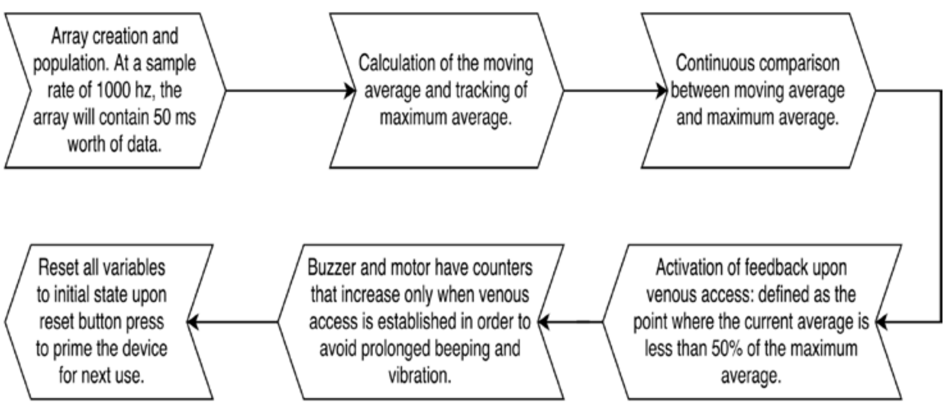

Figure 2: Our algorithm logic flowchart. Figure created in draw.io.

The flowchart above in (**Figure 2**) details how the code logic works. The coding was done with an Arduino Pro Microcontroller in tandem with an Op-amp (INA-122PA). The logic monitors the force sensor for a moving and max average. As the feedback returns, the buzzer and motor is activated if certain thresholds are reached. Afterwards, the reset button is available for the next test.

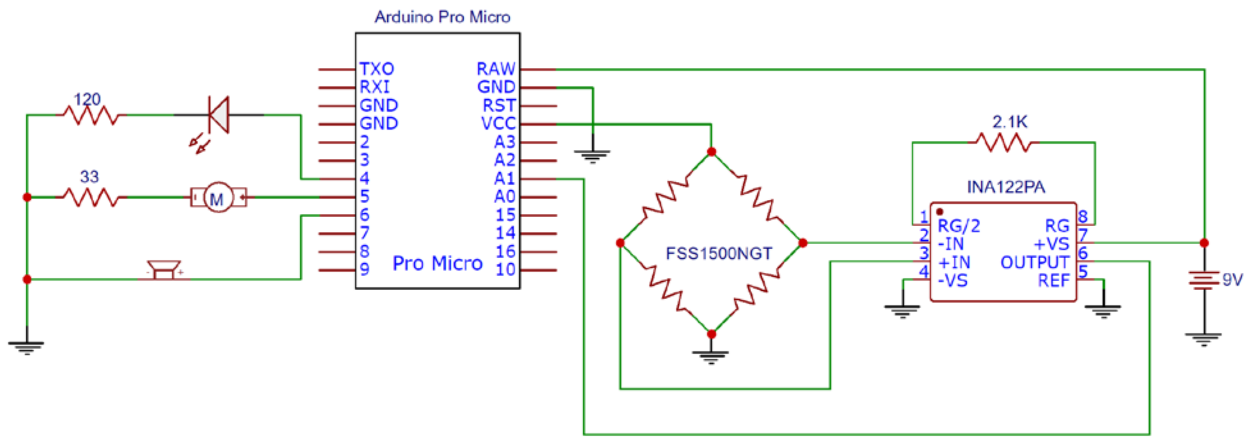

Figure 3: Circuit with INA122PA single-supply instrumentation amplifier and one 9V battery.

The circuit above in (**Figure 3**) uses a single-supply amplifier (meaning only one power source is required, in this case, a 9V battery) for signal acquisition. The force sensor happens to be a Wheatstone bridge, a simple circuit that has 3 known resistances and solves for the fourth resistance to convert voltage to force. There’s also an Arduino Pro micro as the microcontroller or dedicated CPU (computer processing unit). The 2.1k resistor above the amplifier can be changed to different resistors for different ‘amplification gains’.

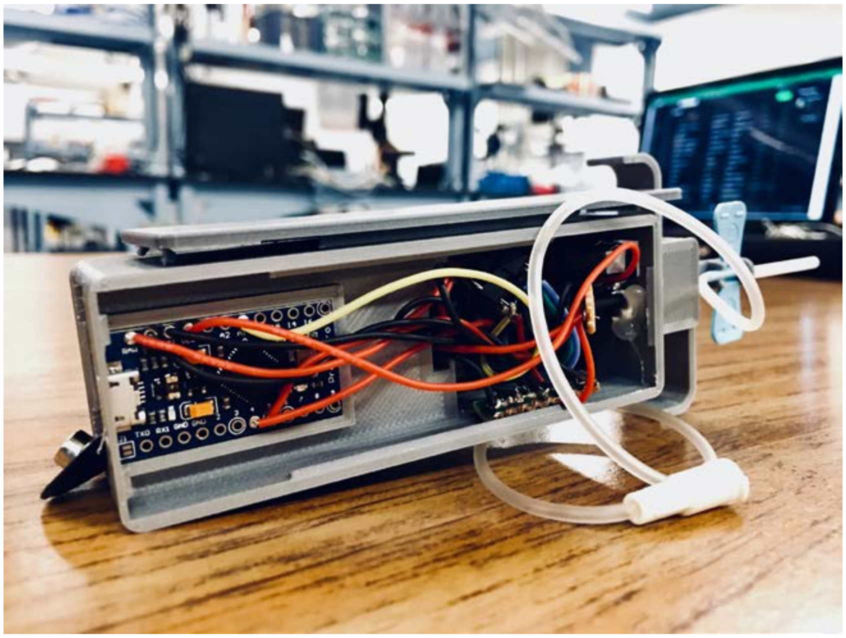

Figure 4: Full design of our prototype with force sensing apparatus, vacutainer holder, and casing.

Our final device printed out can be shown in (**Figure 4**). The circuit fits nicely together, and there's a grounded port along with the needle in place.

5) Proof that the Design is Functional and will Solve the Problem

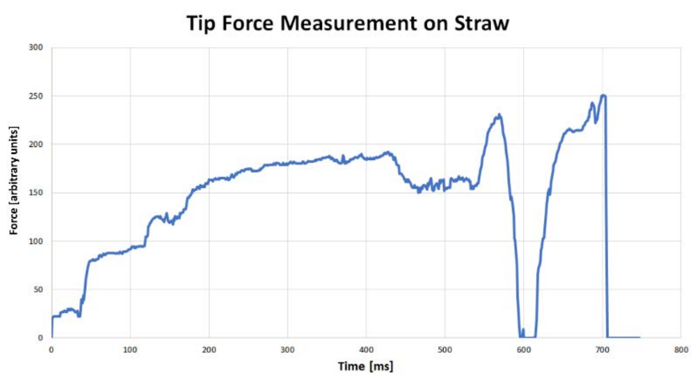

Figure 5: Using our first prototype venipuncture assistant, a force drop at the moment of breaking through a plastic straw (vein) was recorded.

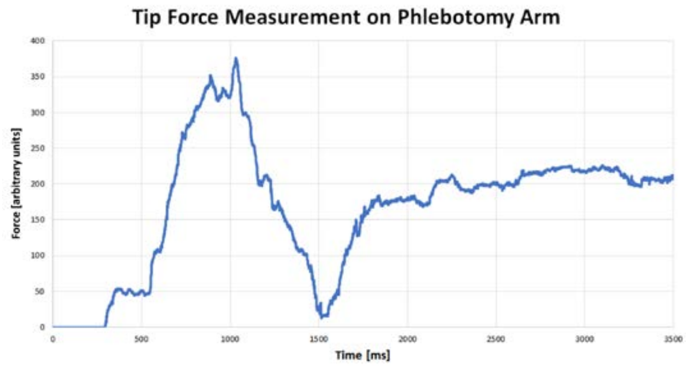

Figure 6: Measurements on a phlebotomy arm were performed. A force drop was observed once venous access was obtained. Tip force on the needle increased during puncture of the venous wall

(**Figure 5)** and (**Figure 6**) show the force drops when the needle punctures through a plastic straw simulation and a phlebotomy arm respectively. The graph differences definitely change through the material properties such as the silicon arm vs. the plastic tube straw. The force increases with time, but drops when the vein is reached at times (500ms and 1100ms on each of the figures).

The reusable device means that only the widely available needles and 9V batteries need to be switched out, making each use fractions of the cost. The only adaptation is practitioners using a device for accuracy and consistency, making learning only a small adjustment. Other than the device, the same blood draw procedure is kept. The size and maneuverability keep this ergonomic device accessible to all sorts of different size hands. No other products combining human contact and machine accuracy are available on the market, making our device unique.

6) Results of a Patent Search and/or Search for Prior Art, Assessment and Patentability

The closest device that our product compares to is the 7th Sense Biosystems TAP Blood Draw Patent(s) which just received FDA approval. The device draws blood through "world's first push-button blood collection device. It makes the process simple, convenient, and virtually painless" [4]. Our device by extension would most likely receive a similar classification at Class II – Most medical devices are considered Class II devices. Examples of Class II devices include powered wheelchairs and some pregnancy test kits. Many of the similar devices are in this class due to being somewhat invasive and withdrawing bodily fluid.

7) Anticipated Regulatory Pathway (510(k) vs. PMA, etc.)

As a medical device, the device must approved by the FDA under the CDRH branch to enter the market. The CDRH is FDA's Center for Devices and Radiological Health. If a device exceeds class I then it becomes necessary to fill out a 501(k) form to approve the device, as shown by our class II. Class IIi devices sometimes require a Premarket Approval Application by extension. A FDA approved medical device related to the topic is the "Butterfly Needle" that incorporated. The Butterfly Needle is classified as a class II medical device with the PMA submitted and approved. Our Vein Guard device builds on top of the Butterfly Needle and vacutainer. As a result, it can be reasonably assume that the regulations and guidelines followed is based on Class II trends.

8) Reimbursement

Durable medical equipment (DME) unfortunately doesn't cover expenses for our type of device. Normally DME categories are walkers, wheelchairs, or hospital beds orientated towards patient ease and comfortability. Meanwhile, our device can be categorized as an alert system for practitioner or clinic training. Another required qualification for coverage is that it be used in the patient's home contrary to our intended use area in clinics or hospitals. Although some medical alert devices are partly covered by Medicare Part C, a Medicare supplemental plan, ours doesn't qualify due to customers not being the direct patient. Our customers are directed more towards health practitioners instead. Medicaid coverage have four possible programs that potentially can cover some to all medical costs if fitting the right conditions, but still won't cover our device for the same reasons listed above.

9)Estimated Manufacturing Costs

Manufacturing for a medical device commonly requires a number of factors such as: "Create the device master record [DMR] (how to build the device); Set-up the manufacturing area; Validate the process of building the device (validate the DMR); Buy the parts; Ensure the parts meet specification; Store the parts; Receive orders, and translate that into a demand for production; Retrieve the parts (picking); Assemble the device; Ensure the device is good; Pack and ship; Invoice and manage Accounts Receivables (A/R); Set up customer feedback: Service and Warranty, returned goods authorizations (RMA)" [5].

The expenditures then focus on two manufacturing processes: the injection molding to mass produce the casing and the electronics circuit. The 3D printing can be utilized for our first mass production run to make sure that the injection molding would be worth it. For the injection molding process to be worth it on average, 1000 or so components is considered a general rule of thumb. The average pricing for molds tends to be around $12k [6].

The electronics circuit gets much cheaper in bulk. Although the force sensor would probably still make up the bulk of the mass production costs, it would still be able to drop down to 30-40 dollars most likely. Meanwhile the rest of the circuit can be made with less than $10 at a bulk price most likely. The cost breakdown for a single device is in the following chart.

Single Device Cost Breakdown	
Item	**Cost**
9V Battery	$2.00
Force Sensor	$60.00
PLA Filament/3D Printing (70g)	$1.47
Arduino Pro Micro board	$7.00
Beep Tone Alarm Ringer	$0.61
INA 122 Single Supply Op-Amp	$5.00
LED	$0.02
Total	$76.10

10) Potential Market and Impact

Vein Guard intends to provide for blood draw three main blood draw providers: medical schools, hospitals, and voluntary blood draw organizations. The end goal is for the Vein Guard to become an indispensable tool for all phlebotomists in the United States, for both practitioners' and patients' peace of mind.

The main product targets are be medical and other healthcare schools. With about 20,000 first-time medical students and various nursing schools throughout the country, this provides a potential market. It also gives Vein Guard an opportunity to introduce itself to potential doctors and nurses early on to be exposed to the product and potentially utilize the benefits during their actual products. Local smaller nursing colleges like in San Bernardino Valley College or Riverside Community College are potential before larger medical programs like University of California, Los Angeles.

The secondary target for our product are voluntary blood draw organizations like

Lifeblood Inc. and the American Red Cross. First time donors intimidated by visible bruising or horror stories of blood donations may increase if Vein Guard reduces the problems reliably for the device to be adopted in more clinics. The Los Angeles Region of the Red Cross serves over 88 cities as a potential start market.

The final potential markets are hospitals and hospital laboratories like LabCorp and Kaiser Permanente. Established older doctors may feel uneasy around the product, but new students who practiced with the Vein Guard have the best chance at introduction to our product as a standard tool in hospitals over time. Vein Guard's aim is to become a standard for the General Medical industry. With venipuncture procedures done approximately 2.7 million times a day, the market potential is ripe for this supplemental product.

11) Conclusion

Vein Guard is a reusable device compatible with existing needle products. The purpose of this product is to: 1) detect the force drop upon lumen access; 2) alert the practitioner with visual, tactile, and/or audio cues. This was accomplished with an Arduino algorithm that calculates a moving average of force over a set amount of time. By comparing that value to the maximum average force, our device is able to recognize when venous access is acquired and sets off a warning feedback system - red LED, vibrating motor, beeper.

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